ASME NQA-1–2024

(Revision of ASME NQA-1–2022)

Quality Assurance Requirements for Nuclear Facility Applications

AN AMERICAN NATIONAL STANDARD

The American Society of Mechanical Engineers

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Quality Assurance Requirements for Nuclear Facility Applications

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The American Society of Mechanical Engineers
Two Park Avenue • New York, NY • 10016 USA

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The next edition of this Standard is scheduled for publication in 2026.

This code or standard was developed under procedures accredited as meeting the criteria for American National Standards. The standards committee that approved the code or standard was balanced to ensure that individuals from competent and concerned interests had an opportunity to participate. The proposed code or standard was made available for public review and comment, which provided an opportunity for additional public input from industry, academia, regulatory agencies, and the public-at-large.

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The endnotes and preamble in this document (if any) are part of this American National Standard.

ASME Collective Membership Mark

The American Society of Mechanical Engineers
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FOREWORD

This Standard is intended to serve the global nuclear industry responsible for the safety and quality of nuclear facilities and activities.

It is intended to be applied to any structure, system, component, activity, or organization that is essential to the safe, reliable, and efficient performance of a nuclear facility and any activities independent of a facility that may affect performance. It is also intended to be applied to all phases of a nuclear facility life cycle and to related activities.

This Standard reflects industry experience and current understanding of the quality assurance requirements necessary to achieve safe, reliable, and efficient utilization of nuclear energy and management and processing of radioactive materials. The Committee on Nuclear Quality Assurance (NQA) actively endorses the growing worldwide movement toward rational, cost-effective quality assurance practices — practices that focus on results. The NQA Committee also maintains liaison with national and international groups that have similar interests in quality to assure consistency and maximum applicability of the Standard in a global setting. Consequently, the NQA Committee has regularly updated and revised the Standard since its first edition was issued in 1979 to improve its utility, effect on nuclear safety, and value to the nuclear industry.

This Standard includes requirements and guidance and is organized in the following four parts:

(a) Part I contains requirements for a Quality Assurance Program for nuclear facility applications.

(b) Part II contains additional quality assurance requirements for the planning and conduct of specific work activities conducted under a Quality Assurance Program developed in accordance with Part I.

(c) Part III contains guidance for implementing the requirements of Parts I and II.

(d) Part IV contains guidance for the application of ASME NQA-1 and comparisons of ASME NQA-1 with other quality requirements.

Early in 1975, the American National Standards Institute (ANSI) assigned overall responsibility for coordination among technical societies and development and maintenance of nuclear power quality assurance standards to the American Society of Mechanical Engineers (ASME). The ASME Committee on NQA was constituted on October 3, 1975, and assumed responsibility for the ANSI/ASME N45 series documents. Currently, the NQA Committee operates under the ASME requirements for Nuclear Codes and Standards Development Committees.

This Committee initially prepared

ANSI/ASME NQA-1–1979	Quality Assurance Program Requirements for Nuclear Power Plants
ANSI/ASME NQA-2–1983	Quality Assurance Requirements for Nuclear Power Plants
ANSI/ASME NQA-3–1989	Quality Assurance Requirements for High Level Waste Management

Requests for interpretation or suggestions for improvement of this Standard should be submitted in accordance with Correspondence With the NQA Committee.

Following approval by the ASME NQA Committee and ASME, and after public review, ASME NQA-1–2024 was approved by ANSI as an American National Standard on June 13, 2024.

For a listing of the NQA publication history, refer to the following table:

Historical Listing of ASME NQA Publications

NQA-1			NQA-2			NQA-3		
Editions and Addenda	**Designator**	**Issued**	**Editions and Addenda**	**Designator**	**Issued**	**Editions and Addenda**	**Designator**	**Issued**
1st Ed.	**NQA-1–1979**	8/31/1979	...	...	...	...	...	...
Add.	NQA-1a–1981	4/30/1981	...	...	...	...	...	...
Add.	NQA-1b–1981	1/31/1982	...	...	...	...	...	...
2nd Ed.	**NQA-1–1983**	7/1/1983	1st Ed.	**NQA-2–1983**	8/31/1983	...	...	...
Add.	NQA-1a–1983	12/31/1983	Add.	NQA-2a–1985	10/15/1985	...	...	...
Add.	NQA-1b–1984	3/15/1985	...	...	...	...	...	...
Add.	NQA-1c–1985	12/31/1985	...	...	...	...	...	...
3rd Ed.	**NQA-1–1986**	7/1/1986	2nd Ed.	**NQA-2–1986**	7/1/1986	...	...	...
Add.	NQA-1a–1986	2/15/1987	Add.	NQA-2a–1986	2/15/1987	...	...	...
Add.	NQA-1b–1987	3/15/1988	Add.	NQA-2b–1987	4/15/1988	...	...	...
Add.	NQA-1c–1988	2/28/1989	Add.	NQA-2c–1988	2/28/1989	...	...	...
4th Ed.	**NQA-1–1989**	9/15/1989	3rd Ed.	**NQA-2–1989**	9/30/1989	1st Ed.	**NQA-3-1989**	3/23/1990
Add.	NQA-1a–1989	3/31/1990	Add.	NQA-2a–1990	5/31/1990	...	...	...
Add.	NQA-1b–1991	4/15/1991	Add.	NQA-2b–1991	5/12/1992	...	...	...
Add.	NQA-1c–1992	9/30/1992	...	...	...	...	...	...
5th Ed.	**NQA-1–1994** [Note (1)]	7/29/1994	...	...	...	...	...	...
Add.	NQA-1a–1995	1/19/1996	...	...	...	...	...	...
6th Ed.	**NQA-1–1997**	12/31/1997	...	...	...	...	...	...
Add.	NQA-1a–1999	5/25/1999	...	...	...	...	...	...
7th Ed.	**NQA-1–2000**	5/21/2001	...	...	...	...	...	...
Add.	NQA-1a–2002	12/6/2002	...	...	...	...	...	...
8th Ed.	**NQA-1–2004**	12/22/2004	...	...	...	...	...	...
Add.	NQA-1a–2005	5/3/2006	...	...	...	...	...	...
Add.	NQA-1b–2007	6/1/2007	...	...	...	...	...	...
9th Ed.	**NQA-1–2008**	3/14/2008	...	...	...	...	...	...
Add.	NQA-1a–2009	7/20/2009	...	...	...	...	...	...
Add.	NQA-1b–2011	1/4/2011	...	...	...	...	...	...
10th Ed.	**NQA-1–2012**	3/15/2013	...	...	...	...	...	...
11th Ed.	**NQA-1–2015**	2/20/2015	...	...	...	...	...	...
12th Ed.	**NQA-1–2017**	1/18/2018	...	...	...	...	...	...
13th Ed.	**NQA-1–2019**	12/31/2019	...	...	...	...	...	...
14th Ed.	**NQA-1–2022**	6/30/2022	...	...	...	...	...	...
15th Ed.	**NQA-1–2024**	7/24/2024	...	...	...	...	...	...

GENERAL NOTE: NQA editions and addenda prior to 1989 were titled ANSI/ASME NQA.

NOTE: (1) This edition is a consolidation of ASME NQA-1 and ASME NQA-2.

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Revisions and Errata. The committee processes revisions to this Standard on a continuous basis to incorporate changes that appear necessary or desirable as demonstrated by the experience gained from the application of the Standard. Approved revisions will be published in the next edition of the Standard.

In addition, the committee may post errata on the committee web page. Errata become effective on the date posted. Users can register on the committee web page to receive e-mail notifications of posted errata.

This Standard is always open for comment, and the committee welcomes proposals for revisions. Such proposals should be as specific as possible, citing the paragraph number, the proposed wording, and a detailed description of the reasons for the proposal, including any pertinent background information and supporting documentation.

Cases. The committee does not issue cases for this Standard.

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ASME does not act as a consultant for specific engineering problems or for the general application or understanding of the Standard requirements. If, based on the information submitted, it is the opinion of the committee that the inquirer should seek assistance, the request will be returned with the recommendation that such assistance be obtained. Inquirers can track the status of their requests at https://go.asme.org/Interpretations.

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Interpretations are published in the ASME Interpretations Database at https://go.asme.org/Interpretations as they are issued.

Committee Meetings. The NQA Standards Committee regularly holds meetings that are open to the public. Persons wishing to attend any meeting should contact the secretary of the committee. Information on future committee meetings can be found on the committee web page at https://go.asme.org/NQAcommittee.

INTRODUCTION

This Standard is to be applied to any structure, system, component, activity, or organization that is essential to the safe, reliable, and efficient performance of a nuclear facility and any activities independent of a facility that may affect performance (e.g., transportation of nuclear materials) of those activities. The extent to which this Standard should be applied depends upon the specific type of facility, items, or services involved and the nature, scope, and relative importance of the activity being performed. It is also to be applied to all phases of a nuclear facility life cycle (e.g., siting, design, construction, operation, and decommissioning) and all types of activities (e.g., training, testing, software development or use).

The Standard also applies to activities that could affect the quality of nuclear material applications, structures, systems, and components of nuclear facilities.

Examples of nuclear facilities are those for power generation, spent fuel storage, waste management, fuel reprocessing, nuclear material processing, fuel fabrication, nuclear research, and other related facilities. Examples of activities include siting, designing, procuring, developing or using software, fabricating, constructing, handling, shipping, receiving, storing, cleaning, erecting, installing, inspecting, testing, operating, maintaining, repairing, refueling, modifying, and decommissioning.

This Standard is organized in the following four parts:

(a) Part I contains requirements for developing and implementing a Quality Assurance Program for nuclear facility applications.

(b) Part II contains additional quality assurance requirements for the planning and conduct of specific work activities under a Quality Assurance Program developed in accordance with Part I.

(c) Part III contains guidance for implementing the requirements of Parts I and II.

(d) Part IV contains guidance for application of ASME NQA-1 and comparisons of NQA-1 with other quality requirements.

The arrangement of the requirements in Parts I and II and the guidance in Parts III and IV permit the judicious application of the Standard or portions of the Standard. Applicable requirements of Parts I and II are to be implemented to ensure conformance with ASME NQA-1. The application of this Standard, or portions thereof, shall be invoked by written contracts, policies, procedures, specifications, or other appropriate documents.

This Standard reflects industry experience and current understanding of the quality assurance requirements necessary to achieve safe, reliable, and efficient utilization of nuclear energy and management and processing of radioactive materials. The Standard focuses on the achievement of results, emphasizes the role of the individual and line management in the achievement and sustainment of quality, and fosters the application of these requirements in a manner consistent with the relative importance of the item or activity (i.e., a “graded approach”).

ASME NQA-1–2024
SUMMARY OF CHANGES

Following approval by the ASME NQA Standards Committee and ASME, and after public review, ASME NQA-1–2024 was approved by the American National Standards Institute on June 13, 2024.

ASME NQA-1–2024 includes the following changes identified by a margin note, **(24)**.

Page	*Location*	*Change*
1	Part I, 400	(1) Definitions of *assure* and *ensure* added (2) Footnote (1) added, and subsequent footnotes renumbered
5	Part I, Requirement 1, 201	Subparagraph (d) revised
6	Part I, Requirement 2, 300	Revised
6	Part I, Requirement 2, 301	Revised
7	Part I, Requirement 2, 303.5	Subparagraph (c) revised
8	Part I, Requirement 2, 400	Revised in its entirety
12	Part I, Requirement 4, 100	Revised
12	Part I, Requirement 4, 200	Terms “Purchaser” and “Supplier” lowercased throughout
12	Part I, Requirement 4, 300	The term “Supplier” lowercased throughout
13	Part I, Requirement 5, 100	First sentence revised
18	Part I, Requirement 8, 100	Revised
18	Part I, Requirement 8, 200	Paragraphs 201 and 202 revised
19	Part I, Requirement 9, 100	Revised
19	Part I, Requirement 9, 200	Paragraphs 201 and 203 revised
19	Part I, Requirement 9, 300	Former para. 300 deleted, and former para. 400 revised and redesignated
20	Part I, Requirement 10, 500	Revised
20	Part I, Requirement 10, 700	Revised
20	Part I, Requirement 10, 800	Subparagraph (f) revised
22	Part I, Requirement 11, 100	Last sentence added
22	Part I, Requirement 11, 200	Subparagraph (a) revised
22	Part I, Requirement 11, 300	Title revised
22	Part I, Requirement 11, 400	Former section 400 deleted, and subsequent paragraphs redesignated
22	Part I, Requirement 11, 500	(1) Former para. 600 revised in its entirety (2) Former paras. 601 and 602 deleted
25	Part I, Requirement 13, 500	Revised
31	Part I, Requirement 18, 200	Second paragraph revised
31	Part I, Requirement 18, 201	Revised
31	Part I, Requirement 18, 301	Last sentence added
32	Part I, Requirement 18, 500	Subparagraph (c) revised
35	Part II, Subpart 2.1	Title revised
35	Part II, Subpart 2.1, 100	Revised

Page	Location	Change
35	Part II, Subpart 2.1, 101	In definition of *sensitized corrosion-resistant alloy*, ASTM specification updated
36	Part II, Subpart 2.1, 201	First paragraph revised
37	Part II, Subpart 2.1, 203	Second paragraph revised
37	Part II, Subpart 2.1, 204	Last sentence added
37	Part II, Subpart 2.1, 302.1	ASTM specifications updated
37	Part II, Subpart 2.1, 302.2	ASTM specifications updated throughout
38	Part II, Subpart 2.1, 302.4	(1) In subpara. (d), ASTM specification updated (2) Note revised
39	Part II, Subpart 2.1, Table 302.5	(1) Under "Rust," entries for Classes B and C revised (2) Under "Flushing Criteria," last entry corrected by errata (3) Note (3) added
40	Part II, Subpart 2.1, 400	First three paragraphs revised
44	Part II, Subpart 2.2, 201	Revised
47	Part II, Subpart 2.2, 304.1	Subparagraph (c) revised
48	Part II, Subpart 2.2, 306.3	Subparagraph (j) revised
50	Part II, Subpart 2.2, 309	Subparagraph (b)(3) revised
51	Part II, Subpart 2.2, 405	Revised
52	Part II, Subpart 2.2, 502.2	Subparagraph (b) revised
53	Part II, Subpart 2.2, 504	Revised
61	Part II, Subpart 2.5, 504	Subparagraph (f) revised
66	Part II, Subpart 2.5, 711	First paragraph revised
67	Part II, Subpart 2.5, 712	Revised
67	Part II, Subpart 2.5, 804	Fourth paragraph revised
68	Part II, Subpart 2.5, 804.1	Last paragraph revised
69	Part II, Subpart 2.5, 903	Revised
70	Part II, Subpart 2.7, 101	(1) Former paras. 101 and 102 transposed and cross-references updated throughout (2) Definition of *source code* added
72	Part II, Subpart 2.7, 203.1	Subparagraph (b)(3) added, and subsequent subparagraph redesignated
73	Part II, Subpart 2.7, 401	Revised
76	Part II, Subpart 2.7, 601	Second paragraph revised
76	Part II, Subpart 2.7, 700	Updated
88	Part II, Subpart 2.14, 900	Updated
96	Part II, Subpart 2.19, 201	(1) Subparagraph (a) revised (2) Subparagraphs (a)(3) and (b)(2) added, and subsequent subparagraphs redesignated
96	Part II, Subpart 2.19, 202	(1) Subparagraphs (a) and (a)(2) revised (2) Subparagraphs (a)(3) and (b)(2) added, and subsequent subparagraphs redesignated
99	Part II, Subpart 2.20, 300	Paragraphs 302 through 305 revised
107	Part II, Subpart 2.22, 500	Updated
119	Part III, Subpart 3.1-2.2, 100	Revised
120	Part III, Subpart 3.1-2.2, Figure 300	

Page	Location	Change
		Data in “Experience” and “Other Credentials of Professional Competence” boxes revised
122	Part III, Subpart 3.1-2.3, 100	Revised
122	Part III, Subpart 3.1-2.3, 300	Revised in its entirety
123	Part III, Subpart 3.1-2.3, 400	Subparagraph (a) revised
124	Part III, Subpart 3.1-2.4, 100	First paragraph revised
124	Part III, Subpart 3.1-2.4, 201	Revised
124	Part III, Subpart 3.1-2.4, 202	Titles of subparas. (a) through (c) revised
124	Part III, Subpart 3.1-2.4, 301	Last paragraph revised
125	Part III, Subpart 3.1-2.4, 302	Second and third paragraphs and subparas. (d) and (g) revised
125	Part III, Subpart 3.1-2.4, 401	First sentence and subparas. (f) and (g) revised
126	Part III, Subpart 3.1-2.4, 402	First sentence and subparas. (b) and (c) revised
127	Part III, Subpart 3.1-2.5, 101	Definitions of *HSS* and *LSS* revised
130	Part III, Subpart 3.1-2.5, 403.2	Second paragraph revised
132	Part III, Subpart 3.1-2.5, 602	Revised
132	Part III, Subpart 3.1-2.5, 700	Updated
134	Part III, Subpart 3.1-3.1, 300	Revised
136	Part III, Subpart 3.1-3.1, 401.2	Second paragraph deleted
136	Part III, Subpart 3.1-3.1, 401.3	Title revised
137	Part III, Subpart 3.1-3.1, 700	First sentence revised
138	Part III, Subpart 3.1-3.1, 1000	(1) Title revised (2) Updated
139	Part III, Subpart 3.1-4.1, 301	First paragraph and subparas. (c) and (h) revised
139	Part III, Subpart 3.1-4.1, 302	Subparagraph (d) revised
140	Part III, Subpart 3.1-4.1, 400	First sentence revised
144	Part III, Subpart 3.1-7.1, 100	Revised
145	Part III, Subpart 3.1-7.1, 700	Revised
145	Part III, Subpart 3.1-7.1, 701	Paragraph and subparagraph designations revised in their entirety
146	Part III, Subpart 3.1-7.1, 704	First sentence revised
158	Part III, Subpart 3.1-16.2, 800	Updated
168	Part III, Subpart 3.1-18.1, 200	Added, and subsequent paragraphs redesignated
168	Part III, Subpart 3.1-18.1, 303	In former para. 203, first paragraph revised
169	Part III, Subpart 3.1-18.1, 305	Former subpara. 205(e) revised
170	Part III, Subpart 3.1-18.1, 402.1	Former para. 302.1 revised
170	Part III, Subpart 3.1-18.1, 402.2	In former para. 302.2, first paragraph revised
170	Part III, Subpart 3.1-18.1, 402.5	In former para. 302.5, second paragraph revised
170	Part III, Subpart 3.1-18.1, 402.6	Former para. 302.6 revised
171	Part III, Subpart 3.1-18.1, 403	Former para. 303 revised
171	Part III, Subpart 3.1-18.1, 503.1	Former para. 403.1 revised
171	Part III, Subpart 3.1-18.1, 503.3	Added
172	Part III, Subpart 3.1-18.1, 504	Former para. 404 revised
172	Part III, Subpart 3.1-18.1, 600	Former para. 500 revised
172	Part III, Subpart 3.1-18.1, 800	In former para. 700, first paragraph revised, and subparas. (c) and (d) revised

Page	*Location*	*Change*
179	Part III, Subpart 3.2-2.1	Deleted
180	Part III, Subpart 3.2-2.7.1, 100	Text formerly in Introduction moved to section 100, and remainder of section 100 revised in its entirety
182	Part III, Subpart 3.2-2.7.1, 202	Revised
183	Part III, Subpart 3.2-2.7.1, 300	First paragraph revised
183	Part III, Subpart 3.2-2.7.1, 302	Revised
184	Part III, Subpart 3.2-2.7.1, 403	Subparagraph (a) revised
185	Part III, Subpart 3.2-2.7.1, 405.1.1	Revised
186	Part III, Subpart 3.2-2.7.1, 405.1.5	Revised
187	Part III, Subpart 3.2-2.7.1, 406.1	Paragraphs 406.1.1 and 406.1.2 and in-text table added
188	Part III, Subpart 3.2-2.7.1, 406.2	Former para. 406.3 revised and redesignated
188	Part III, Subpart 3.2-2.7.1, 406.3	Former para. 406.2 redesignated
189	Part III, Subpart 3.2-2.7.1, 601	Revised
189	Part III, Subpart 3.2-2.7.1, 700	Updated
190	Part III, Subpart 3.2-2.7.2	Title revised
190	Part III, Subpart 3.2-2.7.2, 100	Text formerly in Introduction moved to section 100, and remainder of paragraph revised
212	Part III, Subpart 3.2-2.14, 100	Revised in its entirety
216	Part III, Subpart 3.2-2.14, Table 501	In rows D-1, D-2, and D-9, “code” revised to “source code”
213	Part III, Subpart 3.2-2.14, 300	First paragraph revised
222	Part III, Subpart 3.2-2.14, 802	First paragraph revised
222	Part III, Subpart 3.2-2.14, 900	Updated
227	Part III, Subpart 3.2-2.20	Title revised
227	Part III, Subpart 3.2-2.20, 200	Revised
228	Part III, Subpart 3.3	Deleted
249	Part IV, Subpart 4.1.3	Title revised
249	Part IV, Subpart 4.1.3, 100	Revised
249	Part IV, Subpart 4.1.3, 300	Second and third paragraphs revised
301	Part IV, Subpart 4.2.1, 603.1	Cross-reference to Section 800 deleted by errata
309	Part IV, Subpart 4.2.4, 400	Subparagraph (h) revised
320	Part IV, Subpart 4.2.7, 200	Definition of *peer review plan* revised
321	Part IV, Subpart 4.2.7, 302.1	Second paragraph revised
322	Part IV, Subpart 4.2.7, 500	Revised
327	Part IV, Subpart 4.2.8, 600	Updated

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PART I
REQUIREMENTS FOR QUALITY ASSURANCE PROGRAMS FOR NUCLEAR FACILITIES (FROM FORMER NQA-1)

INTRODUCTION

This Standard reflects industry experience and current understanding of the quality assurance requirements necessary to achieve safe, reliable, and efficient utilization of nuclear energy, and management and processing of radioactive materials. The Standard focuses on the achievement of results, emphasizes the role of the individual and line management in the achievement of quality, and fosters the application of these requirements in a manner consistent with the relative importance of the item or activity.

100 PURPOSE

Part I — this Part — establishes requirements for the development and implementation of a Quality Assurance Program (QAP) for nuclear facility applications. It is arranged by Requirements 1 through 18.

Part II contains additional quality assurance requirements for the planning and conduct of specific work activities under a Quality Assurance Program developed in accordance with Part I. It is arranged by Subparts.

Part III contains guidance for implementing the requirements of Parts I and II. It is arranged by Subparts.

Part IV contains guidance for the application of NQA-1 and comparisons of NQA-1 with other quality requirements. It is arranged by Subparts.

200 APPLICABILITY

Part I is applied using a graded approach to any structure, system, component, activity, or organization that is essential to the safe, reliable, and efficient performance of a nuclear facility and to any activities independent of a facility that may affect performance (e.g., transportation of nuclear materials) of those activities. It is also applied using a graded approach to all phases of a nuclear facility life cycle (e.g., siting, design, construction, operation, and decommissioning) and to all types of activities (e.g., training, testing, software development and use). A Quality Assurance Program developed in accordance with Part I is applied when implementing Part II requirements.

300 RESPONSIBILITY

The user or implementing organization invoking this Standard shall determine and document applicable Part I Requirements and appropriately relate them to specific items, activities, and services. The organization implementing this Part and applicable Part II requirements as determined by scope of work, contract, legal, and regulatory requirements shall be responsible for complying with the specific requirements to achieve quality results in compliance with this Standard

400 TERMS AND DEFINITIONS (24)

The following definitions are provided to assure a uniform understanding of select terms as they are used in this Standard.

acceptance criteria: specified limits placed on the performance, results, or other characteristics of an item, process, or service defined in codes, standards, or other requirement documents.

assessment: an all-inclusive term that may include review, evaluation, inspection, test, check, surveillance, or audit to determine and document whether items, processes, systems, or services meet specified requirements and perform effectively.

assure[1]*:* to promise or state with certainty by one person or organization to another person or organization; to remove the doubt of an outcome. Contrast with *ensure*. For example, “The tester assures the designer that all tests have passed.”

[1] This definition has been adapted from IEEE Std 730-2014, IEEE Standard for Software Quality Assurance Processes, with the permission of IEEE.

audit: a planned and documented activity performed to determine by investigation, examination, or evaluation of objective evidence the adequacy of and compliance with established procedures, instructions, drawings, and other applicable documents, and the effectiveness of implementation. An audit should not be confused with surveillance or inspection activities performed for the sole purpose of process control or product acceptance.

audit, external: an audit of those portions of another organization's quality assurance program not under the direct control or within the organizational structure of the auditing organization.

audit, internal: an audit of those portions of an organization's quality assurance program retained under its direct control and within its organizational structure.

audit finding: a condition adverse to quality identified during an audit requiring follow-up by or for the auditing organization.

Certificate of Conformance: a document signed or otherwise authenticated by an authorized individual certifying the degree to which items or services meet specified requirements.

certification: the act of determining, verifying, and attesting in writing to the qualifications of personnel, processes, procedures, or items in accordance with specified requirements.

characteristic: any property or attribute of an item, process, or service that is distinct, desirable, and measurable.

commercial grade item[2, 3]*:* a structure, system, component, or part thereof that affects its safety function, that was not designed and manufactured as a basic component. Commercial grade items do not include items where the design and manufacturing process require in-process inspections and verifications to ensure that defects or failures to comply are identified and corrected (i.e., one or more critical characteristics of the item cannot be verified).

commercial grade item[2, 4]*:* an item satisfying the following:

(a) not subject to design or specification requirements that are unique to those facilities or activities

(b) used in applications other than those facilities or activities

(c) to be ordered from the manufacturer/supplier on the basis of specifications set forth in the manufacturer's published product description (e.g., a catalog)

commercial grade item[2, 5]*:* a structure, system, component, or part thereof, that affects its safety function, that was not designed and manufactured in accordance with the requirements of this Standard.

commercial grade service[2]*:* a service that was not provided in accordance with the requirements of this Standard.

computer program[6, 7, 8]*:* a combination of computer instructions and data definitions that enables computer hardware to perform computational or control functions.

condition adverse to quality: an all-inclusive term used in reference to any of the following: failures, malfunctions, deficiencies, defective items, and nonconformances. A significant condition adverse to quality is one that, if uncorrected, could have a serious effect on safety or operability.

configuration: the physical, functional, and operational characteristics of the structures, systems, components, or parts of the existing facility.

configuration item (software)[7]*:* a collection of hardware or software elements treated as a unit for the purpose of configuration control.

configuration management: the process that controls the activities, and interfaces, among design, construction, procurement, training, licensing, operations, and maintenance to ensure that the configuration of the facility is established, approved, and maintained.

corrective action: measures taken to rectify conditions adverse to quality and, where necessary, to preclude repetition.

critical characteristics: important design, material, and performance characteristics of a commercial grade item or service that, once verified, will provide reasonable assurance that the item or service will perform its intended safety function.

design, final: approved design output documents and approved changes thereto.

[2] See Part II, Subpart 2.14, Quality Assurance Requirements for Commercial Grade Items and Services for other definitions related to the dedication of commercial grade items.

[3] This definition is applicable to nuclear power plants and activities licensed pursuant to 10 CFR Part 30, 40, 50, 52, or 60.

[4] This definition is applicable to nuclear facilities and activities licensed pursuant to 10 CFR Parts 30, 40, 50 (other than nuclear power plants), 60, 61, 63, 70, 71, or 72.

[5] This definition is applicable to Department of Energy nuclear facilities and activities regulated under 10 CFR 830, Nuclear Safety Management.

[6] Computer programs covered by this Standard are those used for

(a) design analysis

(b) operations or process control, or

(c) database or document control registers when used as the controlled source of quality information for (a) or (b)

[7] This definition has been copied from ANSI/IEEE 610.12-1990, Glossary of Software Engineering Terminology, with the permission of IEEE.

[8] To the extent that computer programs are a physical part of plant systems (e.g., digital reactor protection systems, digital instrumentation), they are included in the term *item*.

design authority: the organization having the responsibility and authority for approving the design bases, the configuration, and changes thereto.

design bases: that information identifying the specific functions to be performed by a structure, system, or component of a facility, and the specific values or ranges of values chosen for controlling parameters as reference bounds for design. These values may be

(a) restraints derived from generally accepted "state-of-the-art" practices for achieving functional goals; or

(b) requirements derived from analysis (based on calculations and/or experiments) of the effects of a postulated accident for which a structure, system, or component must meet its functional goals.

design change: any revision or alteration of the technical requirements defined by approved and issued design output documents and approved and issued changes thereto.

design input: those criteria, performance requirements, codes and standards, design bases, regulatory requirements, or other design requirements upon which detailed final design is based.

design output: drawings, specifications, and other documents used to define technical requirements of structures, systems, components, and computer programs.

design process: technical and management processes that commence with identification of design input and that lead to and include the issuance of design output documents.

design review: a critical review to provide assurance that the final design is correct and satisfactory.

deviation: a departure from specified requirements.

document: any written, pictorial, or electronic information describing, defining, specifying, reporting, or certifying activities, requirements, procedures, or results. A document is not considered to be a quality assurance record until it satisfies the definition of a quality assurance record as defined in this Standard.

document control: the act of assuring that documents are reviewed for adequacy, approved for release by authorized personnel, and distributed to and used at the location where the prescribed activity is performed.

electronic document: a document stored in a form (e.g., magnetic or optical media) that is typically accessible only by a computer.

electronic signature[9]*:* an electronic sound, symbol, or process attached to or logically associated with a record and executed or adopted by a person with the intent to sign the record.

ensure[1]*:* to make certain that things occur or events take place; to guarantee that the desired task occurs. Contrast with *assure*. For example, "The tester ensures that the complete set of tests is executed."

graded approach[10]*:* the process employed, once the applicability of the requirement to the scope of the organization's activity has been determined, to ensure that the levels of analyses, documentation, and actions used to comply with requirements are commensurate with the following:

(a) the relative importance to nuclear safety
(b) the magnitude of any hazard involved
(c) the life-cycle stage of a facility or item
(d) the mission of a facility
(e) the particular characteristics of a facility or item
(f) the relative importance to radiological and nonradiological hazards
(g) any other relevant factors

guidance: a suggested practice that is not mandatory in programs intended to comply with this Standard. The word *should* denotes guidance; the word *shall* denotes a requirement; and the word *may* denotes permission.

inspection: examination or measurement to verify whether an item or activity conforms to specified requirements.

inspector: a person who performs inspection activities to verify conformance to specific requirements.

item[11]*:* an all-inclusive term used in place of any of the following: appurtenance, assembly, component, equipment, material, module, part, structure, subassembly, subsystem, system, or unit.

may: see *guidance*.

measuring and test equipment (M&TE): devices or systems used to calibrate, measure, gage, test, or inspect in order to control or acquire data to verify conformance to specified requirements.

nonconformance: a deficiency in characteristic, documentation, or procedure that renders the quality of an item or activity unacceptable or indeterminate.

objective evidence: any documented statement of fact, other information, or record, either quantitative or qualitative, pertaining to the quality of an item or activity, based on observations, measurements, or tests that can be verified.

Owner[11]*:* the organization legally responsible for the construction and/or operation of a nuclear facility including but not limited to one who has applied for, or who has been granted, a construction permit or

[9] Public Law 106–229 (June 30, 2000), Electronic Signature in Global and National Commerce Act (ESIGN) defines electronic signature.

[10] When used with Part II, Subpart 2.22 of this Standard, the definition in 10 CFR 830 shall apply.

[11] When used with ASME BPVC Section III, the definition in NCA-9000 shall apply.

operating license by the regulatory authority having lawful jurisdiction.

procedure: a document that specifies or describes how an activity is to be performed.

procurement document: purchase requisitions, purchase orders, drawings, contracts, specifications, or instructions used to define requirements for purchase.

Purchaser: the organization responsible for establishment of procurement requirements and for issuance or administration, or both, of procurement documents.

qualification, personnel: the characteristics or abilities gained through education, training, or experience, as measured against established requirements, such as standards or tests, that qualify an individual to perform a required function.

qualified automated means: automated methods of controlling or monitoring processes that have been demonstrated to produce required quality within controlled limits.

qualified procedure: an approved procedure that has been demonstrated to meet the specified requirements for its intended purpose.

quality assurance (QA)[11]*:* all those planned and systematic actions necessary to provide adequate confidence that a structure, system, or component will perform satisfactorily in service.

quality assurance record: a completed document that furnishes evidence of the quality of items and/or activities affecting quality. Types of record media may include paper, electronic (e.g., magnetic or optical), or specially processed media, such as radiographs, photographs, negatives, and microforms. The term *record*, as used throughout the Standard, is to be interpreted as quality assurance record.

quality standard: a code or standard that provides design inputs, acceptance criteria, or other criteria necessary to assure the quality of the designated item.

receiving: taking delivery of an item at a designated location.

repair[11]*:* the process of restoring a nonconforming characteristic to a condition such that the capability of an item to function reliably and safely is unimpaired, even though that item still does not conform to the original requirement.

rework[11]*:* the process by which an item is made to conform to original requirements by completion or correction.

right of access: the right of a Purchaser or designated representative to enter the premises of a Supplier for the purpose of inspection, surveillance, or quality assurance audit.

safety function: the performance of an item or service necessary to achieve safe, reliable, and effective utilization of nuclear energy and nuclear material processing.

service[11]*:* the performance of activities such as design, fabrication, inspection, nondestructive examination, repair, or installation.

shall: see *guidance*.

should: see *guidance.*

software[7]*:* computer programs and associated documentation and data pertaining to the operation of a computer system.

special process: a process, the results of which are highly dependent on the control of the process or the skill of the operators, or both, and in which the specified quality cannot be readily determined by inspection or test of the product.

supplier: any individual or organization who furnishes items or services in accordance with a procurement document. An all-inclusive term used in place of any of the following: vendor, seller, contractor, subcontractor, fabricator, consultant, and their subtier levels.

surveillance: the act of monitoring or observing to verify whether an item or activity conforms to specified requirements.

survey, commercial grade[2]*:* a documented evaluation of an organization's ability to perform activities as verified by a determination of the adequacy of the organization's

(a) quality program and/or
(b) ability to meet specified requirements

testing: an element of verification for the determination of the capability of an item to meet specified requirements by subjecting the item to a set of physical, chemical, environmental, or operating conditions.

traceability: the ability to trace the history, application, or location of an item and like items or activities by means of recorded identification.

use-as-is[11]*:* a disposition permitted for a nonconforming item when it has been established that the item is satisfactory for its intended use.

verification: the act of reviewing, inspecting, testing, checking, auditing, or otherwise determining and documenting whether items, processes, services, or documents conform to specified requirements.

waiver: documented authorization to depart from specified requirements.

REQUIREMENT 1
Organization

100 GENERAL

Responsibilities for the establishment and implementation of the quality assurance program shall be defined. The organizational structure, functional responsibilities, levels of authority, and lines of communications for activities affecting quality shall be documented.

200 STRUCTURE AND RESPONSIBILITY

(24) 201 General

The organizational structure and responsibility assignments shall be such that

(a) senior management establishes overall expectations for effective implementation of the quality assurance program and is responsible for obtaining the desired end result

(b) quality is achieved and maintained by those assigned responsibility for performing work

(c) quality achievement is verified by those not directly responsible for performing the work

(d) those responsible for assuring that an appropriate quality assurance program has been established and those verifying activities affecting quality have sufficient authority, direct access to responsible levels of management, organizational freedom, and access to work to perform these functions, including sufficient independence from cost and schedule when opposed to safety function considerations. These functions include the following:

(1) identifying quality problems

(2) initiating, recommending, or providing solutions to quality problems through designated channels

(3) verifying implementation of solutions

(4) assuring that further processing, delivery, installation, or use is controlled until proper disposition of a nonconformance, deficiency, or unsatisfactory condition has occurred.

202 Delegation of Work

The individual(s) or organization(s) responsible for establishing and executing a quality assurance program under this Standard may delegate any or all of the work to others but shall retain responsibility thereof.

300 INTERFACE CONTROL

Where more than one organization is involved in the execution of activities, the responsibilities, interfaces, and authority of each organization shall be clearly defined and documented.

The external interfaces between organizations and the internal interfaces between organizational units, and changes thereto, shall be documented.

REQUIREMENT 2
Quality Assurance Program

100 GENERAL

(a) A documented quality assurance program shall be planned, implemented, and maintained in accordance with this Part (Part I), or portions thereof. The program shall identify the activities and items to which it applies. The program shall provide control over activities affecting quality to an extent consistent with their importance. The program shall include monitoring activities against acceptance criteria in a manner sufficient to provide assurance that the activities affecting quality are performed satisfactorily. The program shall be established at the earliest time consistent with the schedule for accomplishing the activities.

The program shall provide for the planning and accomplishment of activities affecting quality under suitably controlled conditions. Controlled conditions include the use of appropriate equipment, suitable environmental conditions for accomplishing the activity, and assurance that prerequisites for the given activity have been satisfied. The program shall provide for any special controls, processes, test equipment, tools, and skills to attain the required quality of activities and items and for verification of that quality. The organization shall establish and implement processes to detect and correct quality problems.

(b) The program shall provide for indoctrination, training, and qualification as necessary of personnel performing or managing activities affecting quality to ensure that suitable proficiency is achieved and maintained.

(c) Management shall regularly assess the adequacy and effective implementation of the quality assurance program.

200 INDOCTRINATION AND TRAINING

Indoctrination and training shall be commensurate with scope, complexity, importance of the activities, and the education, experience, and proficiency of the person.

201 Indoctrination

Personnel performing or managing activities affecting quality shall receive indoctrination in their job responsibilities and authority that includes general criteria, technical objectives, requirements of applicable codes and standards, regulatory commitments, company procedures, and quality assurance program requirements.

202 Training

The need for a formal training program for personnel performing or managing activities affecting quality shall be determined. Training shall be provided, if needed, to achieve initial proficiency, maintain proficiency, and adapt to changes in technology, methods, or job responsibilities. On-the-job training shall be used if direct hands-on applications or experience is needed to achieve and maintain proficiency.

300 QUALIFICATION REQUIREMENTS (24)

The responsible organization shall

(a) designate those activities that require qualification of personnel and the associated minimum requirements for such personnel

(b) establish written procedures for the qualification of personnel

(c) assure that only those personnel who meet the qualification requirements are permitted to perform the designated activities

In addition to the requirements in (a) through (c), specific qualification requirements for personnel performing nondestructive examination; inspection and tests to verify quality of structures, systems, and components; and auditing are specified in paras. 301 through 304 of this Requirement.

301 Nondestructive Examination (NDE) (24)

This paragraph specifies requirements for the qualification of personnel who perform radiographic (RT), magnetic particle (MT), ultrasonic (UT), liquid penetrant (PT), electromagnetic (ET), neutron radiographic (NR), leak testing (LT), acoustic emission (AE), and visual testing (VT) to verify conformance to the specified requirements. The American Society of Nondestructive Testing (ASNT) Recommended Practices or Standards provide acceptable qualification requirements for NDE personnel. Applicable Codes and Standards or design criteria controlling the qualification of NDE personnel shall be utilized to establish the applicable ASNT qualification requirement and edition or to specify an equivalent alternative requirement.

302 Inspection and Test

The initial capabilities of a candidate shall be determined by an evaluation of the candidate's education, experience, training, and either test results or capability demonstration. The job performance of inspection and test personnel shall be reevaluated at periodic intervals not to exceed 3 yr. Reevaluation shall be by evidence of continued satisfactory performance or redetermination of capability in accordance with the requirements of section 200 of this Requirement. If during this evaluation or at any other time, it is determined by the responsible organization that the capabilities of an individual are not in accordance with the qualification requirements specified for the job, that person shall be removed from that activity until such time as the required capability has been demonstrated. Any person who has not performed inspection or testing activities in the qualified area for a period of 1 yr shall be reevaluated.

303 Lead Auditor

The Lead Auditor organizes and directs audits, reports audit findings, and evaluates corrective action. An individual shall meet the requirements of paras. 303.1 through 303.4 of this Requirement prior to being designated a Lead Auditor. Lead Auditors shall maintain proficiency in accordance with the requirements of para. 303.5 of this Requirement or requalify in accordance with the requirements of para. 303.6 of this Requirement, as applicable.

303.1 Communication Skills. The prospective Lead Auditor shall be capable of communicating effectively, both in writing and orally. These skills shall be attested to in writing by the Lead Auditor's employer.

303.2 Training. Prospective Lead Auditors shall receive training to the extent necessary to assure auditing competence including

(a) knowledge and understanding of this Standard and other nuclear-related codes, standards, regulations, and regulatory guides, as applicable

(b) general structure of quality assurance programs as a whole and applicable elements as defined in this Standard

(c) auditing techniques of examining, questioning, evaluating, and reporting; methods of identifying and following up on corrective action items; and closing out audit findings

(d) planning audits of activities affecting quality

(e) on-the-job training to include applicable elements of the audit program

303.3 Audit Participation. Prospective Lead Auditors shall participate in a minimum of five quality assurance audits within a period of time not to exceed 3 yr prior to the date of qualification, one of which shall be a nuclear quality assurance audit within the year prior to qualification.

Participation in independent assessments including team assessment activities such as operations readiness reviews and regulatory inspections/surveys may be used to satisfy up to four of the five required quality assurance audits, provided that the activities can demonstrate the following:

(a) independence from the functional areas being assessed

(b) planning that establishes the scope of the activities and associated evaluation criteria

(c) performance by technically qualified and experienced personnel

(d) results that are documented and reported to management

(e) appropriate corrective action initiated and tracked to resolution

Such participation shall be subject to review and acceptance by the organization responsible for quality assurance audits and/or the certifying authority prior to their use for qualification.

303.4 Examination. Prospective Lead Auditors shall pass an examination that evaluates the comprehension of and ability to apply the body of knowledge identified in paras. 303.2(a) through 303.2(d) of this Requirement. The examination may be oral, written, practical, or any combination thereof.

303.5 Maintenance of Proficiency. Lead Auditors shall maintain their proficiency through one or more of the following: (24)

(a) regular and active participation in the audit process

(b) review and study of codes, standards, procedures, instructions, and other documents related to quality assurance program and program auditing

(c) participation in training program(s)

Based on annual assessment, the responsible organization or the authority for certifying qualification may extend the qualification, require retraining, or require requalification.

303.6 Requalification. Lead Auditors who fail to maintain their proficiency for a period of 2 yr or more shall require requalification. Requalification shall include retraining in accordance with the requirements of para. 303.2 of this Requirement, reexamination in accordance with para. 303.4 of this Requirement, and participation as an Auditor in at least one nuclear quality assurance audit.

304 Auditors

Auditors are participants in an audit. Auditors shall have, or be given, appropriate training or orientation to develop their competence for performing audits. Competence of personnel for performance of the various auditing functions shall be developed by one or more of the following methods:

(a) orientation to provide a working knowledge and understanding of this Standard and the auditing organization's procedures for implementing audits and reporting results.

(b) general and specialized training in audit performance where the general training shall include fundamentals, objectives, characteristics, organization, performance, and results of quality auditing and the specialized training shall include methods of examining, questioning, evaluating, and documenting specific audit items and methods of closing out audit findings.

(c) on-the-job training, guidance, and counseling under the direct supervision of a Lead Auditor. Such training shall include planning, performing, reporting, and follow-up action involved in conducting audits.

305 Technical Specialists

The responsible auditing organization shall establish the qualifications and requirements for use of technical specialists to accomplish the auditing of quality assurance programs.

(24)

400 RECORDS OF QUALIFICATION

(a) The qualification of NDE personnel shall be certified in writing in accordance with the applicable ASNT or equivalent requirements as noted in para. 301.

(b) The qualification of inspection, test, and Lead Auditor personnel shall be certified in writing and include the following information:

(1) employer's name

(2) identification of person being certified

(3) activities certified to perform

(4) signature of employer's designated representative

(c) In addition to the requirements in (b), specific requirements for each qualification that are to be certified in writing are specified in paras. 401 and 402 of this Requirement.

(d) The employer may delegate qualification examination activities to an independent certifying agency but shall retain responsibility for conformance of the examination and its administration. Integrity of the examination shall be maintained by the employer or certifying agency through appropriate confidentiality of files and, where applicable, proctoring of examinations. Copies of the objective evidence regarding the type(s) and content of the examination(s) shall be retained by the employer in accordance with the requirements of section 500 of this Requirement.

401 Inspection and Test Personnel

Additional requirements to those listed in para. 400 of this Requirement shall include the following:

(a) education

(b) work experience

(c) training

(d) demonstration of capabilities

(e) date of certification/recertification

(f) any special physical requirements needed in the performance of each activity, including the need for initial and subsequent physical examination

(g) certification expiration

402 Lead Auditor Personnel

Additional requirements to those listed in para. 400 of this Requirement shall include the following:

(a) education

(b) work experience

(c) training

(d) audit participation

(e) examination results

(f) date of certification/recertification

(g) annual assessment of proficiency maintenance

500 RECORDS

Records of indoctrination and training shall include one or more of the following:

(a) attendance sheets

(b) training logs

(c) personnel training records

The employer shall establish and maintain records for indoctrination and training, Auditor and Lead Auditor qualification and requalification, and inspection and test personnel qualification and requalification.

REQUIREMENT 3
Design Control

100 GENERAL

The design shall be defined, controlled, and verified. Design inputs shall be specified on a timely basis and translated into design documents. Design interfaces shall be identified and controlled. Design adequacy shall be verified by individuals other than those who designed the item or computer program. Design changes shall be governed by control measures commensurate with those applied to the original design.

200 DESIGN INPUT

Applicable design inputs shall be identified and documented, and their selection reviewed and approved. The design input shall be specified to the level of detail necessary to permit the design activities to be carried out in a correct manner and to provide a consistent basis for making design decisions, accomplishing design verification measures, and evaluating design changes.

300 DESIGN PROCESS

(a) The responsible design organization shall prescribe and document the design activities to the level of detail necessary to permit the design process to be carried out in a correct manner, and to permit verification that the design meets requirements. Design documents shall support facility design, construction, and operation. Appropriate quality standards shall be identified and documented, and their selection reviewed and approved.

(b) The design methods, materials, parts, equipment, and processes that are essential to the function of the items shall be selected and reviewed for suitability of application. Applicable information derived from experience, as set forth in reports or other documentation, shall be made available to cognizant design personnel.

(c) The final design shall

(1) be relatable to the design input by documentation in sufficient detail to permit design verification.

(2) specify required inspections and tests and include or reference appropriate acceptance criteria.

(3) identify assemblies and/or components that are part of the item being designed.

400 DESIGN ANALYSES

Design analyses shall be sufficiently detailed such that a person technically qualified in the subject can review and understand the analyses and verify the adequacy of the results without recourse to the originator.

401 Use of Computer Programs

Each computer program used for design analysis shall be accepted for use and controlled by applying the applicable requirements of Parts I and II prior to use, or the computer program's results shall be independently verified with the design analysis for each application.

The acceptance of controlled computer programs used for design analysis, and verification methods applied to the results of unproven programs, shall meet the following requirements:

(a) The computer program, or the verification method applied to the computer program results, shall be shown to produce correct solutions for the applied mathematical model within defined limits for each parameter employed.

(b) The applied mathematical model shall be shown to produce a valid solution to the physical problem associated with the particular application.

402 Documentation of Design Analyses

Documentation of design analyses shall include the following:

(a) the objective of the analyses

(b) design inputs and their sources

(c) results of literature searches or other applicable background data

(d) assumptions and indication of those assumptions that must be verified as the design proceeds

(e) identification of any computer calculation, including identification of the computer type, computer program name, and revision, inputs, outputs, evidence of or reference to computer program verification, and the bases (of reference thereto) supporting application of the computer program to the specific physical problem

(f) review and approval

500 DESIGN VERIFICATION

(a) The responsible design organization shall identify and document the particular design verification method(s) used. The results of design verification shall be documented with the identification of the verifier clearly indicated. Design verification shall be performed by any competent individual(s) or group(s) other than those who performed the original design but who may be from the same organization. This verification may be performed by the originator's supervisor, provided

(1) the supervisor did not specify a singular design approach or rule out certain design considerations and did not establish the design inputs used in the design; or

(2) the supervisor is the only individual in the organization competent to perform the verification.

Cursory supervisory reviews do not satisfy the intent of this Standard.

(b) Design verification shall be performed prior to releasing the design for procurement, manufacture, construction, or use by another design organization, except where this timing cannot be met, such as when insufficient data exist. In those cases, the unverified portion of the design shall be identified and controlled. In all cases the design verification shall be completed prior to relying upon the component, system, structure, or computer program to perform its function.

(c) If the design is modified to resolve verification findings, the modified design shall be verified prior to release or use.

(d) Extent of Design Verification. The extent of the design verification shall be a function of the importance to safety, the complexity of the design, the degree of standardization, the state of the art, and the similarity with previously proved designs. Where the design has been subjected to a verification process in accordance with this Part (Part I), the verification process need not be duplicated for identical designs. However, the applicability of standardized or previously proven designs, with respect to meeting pertinent design inputs, shall be verified for each application. Known problems affecting the standard or previously proved designs and their effects on other features shall be considered. The original design and associated verification documentation shall be referenced in records of subsequent application of the design.

501 Methods

Acceptable verification methods include, but are not limited to, any one or a combination of the following:

(a) design reviews
(b) alternate calculations
(c) qualification testing

501.1 Design Reviews. Design reviews shall provide assurance that the final design is correct and satisfactory by addressing, where applicable, (a) through (g) of this Requirement.

(a) Were the design inputs correctly selected?

(b) Are assumptions necessary to perform the design activity adequately described and reasonable? Where necessary, are the assumptions identified for subsequent reverifications when the detailed design activities are completed?

(c) Were appropriate design methods and computer programs used?

(d) Were the design inputs correctly incorporated into the design?

(e) Is the design output reasonable compared to design inputs?

(f) Are the necessary design inputs for interfacing organizations specified in the design documents or in supporting procedures or instructions?

(g) Have suitable materials, parts, processes, and inspection and testing criteria been specified?

501.2 Alternate Calculations. Alternate calculations shall use alternate methods to verify correctness of the original calculations or analyses. The appropriateness of assumptions; input data used; and the computer program, its associated computer hardware and system software, or other calculation method used shall also be reviewed.

501.3 Qualification Tests. Testing shall demonstrate adequacy of performance under conditions that simulate the most adverse design conditions. Operating modes and environmental conditions shall be considered in determining the most adverse conditions. Where the test is intended to verify only specific design features, the other features of the design shall be verified by other means. When tests are being performed on models or mockups, scaling laws shall be established and verified. The results of model test work shall be subject to error analysis, where applicable, prior to use in the final design.

600 CHANGE CONTROL

(a) Changes to design inputs, final designs, field changes, and temporary and permanent modifications to operating facilities shall be justified and subject to design control measures commensurate with those applied to the original design. These measures shall include evaluation of effects of those changes on the overall design and on any analysis upon which the design is based. The evaluation shall include facility configurations that occur during operation, maintenance, test, surveillance, and inspection activities. Changes shall be approved by the same affected groups or organizations that reviewed and approved the original design documents. When the organization originally responsible

for review and approval of the original design documents is no longer responsible, the owner or his designee shall have responsibility or designate a new responsible organization. The design organization approving the change shall have demonstrated competence in the specific design area of interest and have an adequate understanding of the requirements and intent of the original design.

(b) When a design change is approved other than by revision to the affected design documents, measures shall be established to incorporate the change into these documents, where such incorporation is appropriate.

(c) Where a significant design change is necessary because of an incorrect design, the design process and verification procedure shall be reviewed and modified as necessary.

601 Configuration Management of Operating Facilities

Procedures implementing configuration management requirements shall be established and documented at the earliest practical time prior to facility operation. These procedures shall include the responsibilities and authority of the organizations whose functions affect the configuration of the facility including activities such as operations, design, maintenance, construction, licensing, and procurement.

601.1 Configuration management requirements shall include measures to ensure changes that may affect the approved configuration are recognized and processed.

601.2 The configuration shall be established and approved at the earliest practical time prior to initial operation of the facility, and maintained for the life of the facility.

601.3 The configuration shall include, as applicable, characteristics derived from regulatory requirements and commitments, calculations and analyses, design inputs, installation and test requirements, supplier manuals and instructions, operating and maintenance requirements, and other applicable sources.

601.4 Interface controls shall include the integration of activities of organizations that can affect the approved configuration.

601.5 Documentation shall identify the design bases and the approved configuration for the approved modes of operation.

601.6 Measures shall be established and implemented to ensure that proposed changes to the configuration are evaluated for their conformance to the design bases.

601.7 The implementation sequence for approved configuration changes shall be reviewed to determine that the configuration conforms to the design bases.

601.8 Approval by the design authority shall be required prior to implementation of a change to the design bases.

601.9 The configuration of the facility shall be documented in drawings, specifications, procedures, and other documents that reflect the operational status of the facility. The process used to control the current revision and issuance of these documents shall take into account the use of the document and the need for revision in support of operation.

700 INTERFACE CONTROL

Interface controls shall include assignment of responsibility and establishment of procedures among participating design organizations for review, approval, release, distribution, and revision of documents involving design interfaces.

Design information transmitted across interfaces shall identify the status of the design information or document provided, and identify incomplete items that require further evaluation, review, or approval. Where it is necessary to initially transmit design information orally or by other informal means, the transmittal shall be confirmed promptly by a controlled document.

800 SOFTWARE DESIGN CONTROL

The requirements of Part II, Subpart 2.7 apply to computer software design control and shall be used instead of sections 200, 300, 500, and 600.

900 DOCUMENTATION AND RECORDS

Design documentation and records shall include not only final design documents, such as drawings and specifications, and revisions to those documents, but also documentation that identifies the important steps in the design process, including sources of design inputs that support the final design.

REQUIREMENT 4
Procurement Document Control

(24) 100 GENERAL

Procurement documents shall include or reference applicable design bases and other requirements necessary to assure adequate quality. To the extent necessary, procurement documents shall require suppliers to have a quality assurance program consistent with the applicable requirements of this Standard.

(24) 200 CONTENT OF THE PROCUREMENT DOCUMENTS

Procurement documents issued at all tiers of procurement shall include provisions for the following, as deemed necessary by the purchaser.

201 Scope of Work

Procurement documents shall include a statement of the scope of the work to be performed by the supplier.

202 Technical Requirements

Technical requirements shall be specified in the procurement documents. These requirements shall be specified, as appropriate by reference to specific drawings, specifications, codes, standards, regulations, procedures, or instructions, including revisions thereto, that describe the items or services to be furnished. The procurement documents shall identify appropriate test, inspection, and acceptance criteria for determining acceptability of the item or service.

203 Quality Assurance Program Requirements

Quality assurance program requirements shall be specified in the procurement documents. These requirements shall be consistent with importance and/or complexity of the item or service being procured. The procurement documents shall require the supplier to incorporate appropriate quality assurance program requirements in subtier procurement documents.

204 Right of Access

The procurement documents shall provide for access to the supplier's and subtier supplier's facilities and records for surveillance, inspection, or audit by the purchaser, its designated representative, and others authorized by the purchaser.

205 Documentation Requirements

The procurement documents shall identify the documentation required to be submitted for information, review, or approval by the purchaser. The time of submittal shall also be established. When the purchaser requires the supplier to maintain specific records, the retention times and disposition requirements shall be prescribed.

206 Nonconformances

The procurement documents shall specify the purchaser's requirements for the supplier's reporting of nonconformances.

207 Spare and Replacement Parts

The procurement documents shall specify the supplier's requirements to identify spare and replacement parts or assemblies and the related data required for ordering these parts or assemblies.

300 PROCUREMENT DOCUMENT REVIEW (24)

A review of the procurement documents, and changes thereto, shall be made and documented prior to award to assure that documents transmitted to prospective suppliers include appropriate provisions to assure that items or services will meet the specified requirements.

Technical or quality assurance program changes made as a result of bid evaluations or negotiations shall be incorporated into the procurement documents prior to their issuance to the supplier.

Procurement document review shall be performed by personnel who have access to pertinent information and who have an adequate understanding of the requirements and intent of the procurement documents.

400 PROCUREMENT DOCUMENT CHANGES

Procurement document changes affecting the technical or quality assurance program requirements shall be subject to the same degree of control as utilized in the preparation of the original documents.

REQUIREMENT 5
Instructions, Procedures, and Drawings

(24) **100 GENERAL**

Activities affecting quality shall be prescribed by and performed in accordance with documented instructions, procedures, or drawings that include or reference appropriate quantitative or qualitative acceptance criteria for determining that prescribed activities have been satisfactorily accomplished. The activity shall be described to a level of detail commensurate with the complexity of the activity and the need to assure consistent and acceptable results. The need for, and level of detail in, written procedures or instructions shall be determined based upon complexity of the task, the significance of the item or activity, work environment, and worker proficiency and capability (education, training, experience).

REQUIREMENT 6
Document Control

100 GENERAL

The preparation, issuance, and change of documents that specify quality requirements or prescribe activities affecting quality such as instructions, procedures, and drawings shall be controlled to ensure that correct documents are being employed. Such documents, including changes thereto, shall be reviewed for adequacy by a cognizant individual other than the originator, and approved for release by authorized personnel.

200 DOCUMENT CONTROL

The following controls shall be applied to documents and changes thereto:

(a) the unique identification of the controlled documents, including a revision control identifier

(b) the specified distribution of controlled documents for use at the appropriate location

(c) the identification of the individual roles responsible for the preparation, review, approval, and distribution of controlled documents

(d) the review of controlled documents for adequacy and completeness prior to approval, distribution, or processing

(e) a method to ensure the correct document and revision is being used

300 DOCUMENT CHANGES

301 Major Changes

Changes to documents, other than those defined as minor changes, are considered major changes and shall be reviewed and approved by the same organizations that performed the original review and approval unless other organizations are specifically designated. The reviewing organization shall have access to pertinent background data or information upon which to base their approval.

302 Minor Changes

Minor changes to documents that do not change their applicability, meaning, intent, or technical content (such as editorial corrections) shall not require that the revised documents receive the same review and approval as the original documents. The types of changes to be considered "Minor" shall be specified.

REQUIREMENT 7
Control of Purchased Items and Services

100 GENERAL

The procurement of items and services shall be controlled to ensure conformance with specified requirements. Such control shall provide for the following as appropriate: source evaluation and selection, evaluation of objective evidence of quality furnished by the Supplier, source inspection, audit, and examination of items or services upon delivery or completion.

200 SUPPLIER EVALUATION AND SELECTION

Prior to award of a contract, the Purchaser shall evaluate the Supplier's capability to provide items or services in accordance with the requirements of the procurement documents. Supplier evaluation and selection and the results therefrom shall be documented and shall include one or more of the following:

(a) Supplier's history of providing an identical or similar product that performs satisfactorily in actual use. The Supplier's history shall reflect current capability.

(b) Supplier's current quality records supported by documented qualitative and quantitative information that can be objectively evaluated and may include current third-party certificates that recognize the Supplier's quality assurance program (QAP) or other technical certifications.

(c) Supplier's technical and quality capability as determined by a direct evaluation of the facilities, personnel, and the implementation of the Supplier's QAP.

300 BID EVALUATION

If bids are solicited, the bid evaluation shall include a determination of the Supplier's capability to conform to the technical and quality assurance requirements. Prior to the award of the contract, the Purchaser shall resolve or obtain commitments to resolve unacceptable technical and quality assurance conditions resulting from the bid evaluation.

400 CONTROL OF SUPPLIER-GENERATED DOCUMENTS

Controls shall be implemented to ensure that the submittal and evaluation of Supplier-generated documents and changes are accomplished in accordance with the procurement document requirements. These controls shall provide for the acquisition, processing, and recorded evaluation of the quality assurance, technical, inspection, and test documentation or data against acceptance criteria.

500 ACCEPTANCE OF ITEM OR SERVICE

501 General

Prior to offering the item or service for acceptance, the Supplier shall verify that the item or service being furnished complies with the procurement requirements. The extent of the verification activities by the Purchaser shall be a function of the relative importance, complexity, and quantity of the item or services procured and the Supplier's quality performance. Where required by code, regulation, or contract requirement, documentary evidence that items conform to procurement requirements shall be available at the nuclear facility site prior to installation or use.

502 Methods of Acceptance

Purchaser methods used to accept an item or service from a Supplier shall be a Supplier Certificate of Conformance, source verification, receiving inspection, or post-installation test at the nuclear facility site, or a combination of these methods.

503 Certificate of Conformance

When a Certificate of Conformance is used, the minimum criteria of (a) through (f) shall be met.

(a) The certificate shall identify the purchased material or equipment, such as by the purchase order number.

(b) The certificate shall identify the specific procurement requirements met by the purchased material or equipment, such as codes, standards, and other specifications. This may be accomplished by including a list of the specific requirements or by providing, on-site, a copy of the purchase order and the procurement specifications or drawings, together with a suitable certificate. The procurement requirements identified shall include any approved changes, waivers, or deviations applicable to the subject material or equipment.

(c) The certificate shall identify any procurement requirements that have not been met, together with an explanation and the means for resolving the nonconformances.

(d) The certificate shall be signed or otherwise authenticated by a person who is responsible for this quality assurance function and whose function and position are described in the Purchaser's or Supplier's quality assurance program.

(e) The certification system, including the procedures to be followed in filling out a certificate and the administrative procedures for review and approval of the certificates, shall be described in the Purchaser's or Supplier's quality assurance program.

(f) Means shall be provided to verify the validity of Supplier certificates and the effectiveness of the certification system, such as during the performance of audits of the Supplier or independent inspection or test of the items. Such verification shall be conducted by the Purchaser at intervals commensurate with the Supplier's past quality performance.

504 Source Verification

When source verification is used, it shall be performed at intervals consistent with the importance and complexity of the item or service, and shall include monitoring, witnessing, or observing selected activities. Source verification shall be implemented in accordance with plans to perform inspections, examinations, or tests at predetermined points. Upon Purchaser acceptance of source verification, documented evidence of acceptance shall be furnished to the receiving destination of the item, to the Purchaser, and to the Supplier.

505 Receiving Inspection

When receiving inspection is used, purchased items shall be inspected as necessary to verify conformance to specified requirements, taking into account source verification and audit activities and the demonstrated quality performance of the Supplier. Receiving inspection shall verify by objective evidence such features as

(a) configuration
(b) identification
(c) dimensional, physical, and other characteristics
(d) freedom from shipping damage
(e) cleanliness

Receiving inspection shall be coordinated with a review of Supplier documentation when procurement documents require such documentation to be furnished prior to receiving inspection.

506 Postinstallation Testing

When postinstallation testing is used, postinstallation test requirements and acceptance documentation shall be mutually established by the Purchaser and Supplier.

507 Acceptance of Services Only

In cases involving procurement of services only, such as third-party inspection; engineering and consulting services; auditing; and installation, repair, overhaul, or maintenance work, the Purchaser shall accept the service by any or all of the following methods:

(a) technical verification of data produced
(b) surveillance and/or audit of the activity
(c) review of objective evidence for conformance to the procurement document requirements

600 CONTROL OF SUPPLIER NONCONFORMANCES

Methods for control and disposition of Supplier nonconformances for items and services that do not meet procurement document requirements shall include (a) through (e).

(a) evaluation of nonconforming items.

(b) submittal of nonconformance notice to Purchaser by Supplier as directed by the Purchaser. These submittals shall include Supplier-recommended disposition (e.g., use-as-is or repair) and technical justification. Nonconformances to the procurement requirements or Purchaser-approved documents, which consist of one or more of the following, shall be submitted to the Purchaser for approval of the recommended disposition:

(1) technical or material requirement is violated

(2) requirement in Supplier documents, which has been approved by the Purchaser, is violated

(3) nonconformance cannot be corrected by continuation of the original manufacturing process or by rework

(4) the item does not conform to the original requirement even though the item can be restored to a condition such that the capability of the item to function is unimpaired

(c) Purchaser disposition of Supplier recommendation.

(d) verification of the implementation of the disposition.

(e) maintenance of records of Supplier-submitted nonconformances.

700 COMMERCIAL GRADE ITEMS AND SERVICES

When dedication is used for accepting commercial grade items or services, the requirements of Part II, Subpart 2.14 shall apply.

800 RECORDS

Records shall be established and maintained to indicate the performance of the following functions:

(a) supplier evaluation and selection

(b) acceptance of items or services

(c) supplier nonconformances to procurement document requirements, including their evaluation and disposition

REQUIREMENT 8
Identification and Control of Items

(24) ## 100 GENERAL

Controls shall be established to ensure that only correct and accepted items are used or installed.

Identification shall be maintained on the items or in documents traceable to the items, or in a manner that ensures that identification is established and maintained.

(24) ## 200 IDENTIFICATION METHODS

201 Item Identification

Items of production (batch, lot, heat, component, computer program[1], part) shall be identified from the initial receipt and fabrication of items up to and including installation and use. This identification shall relate an item to an applicable design or other pertinent specifying document.

202 Physical Identification

Physical identification shall be used to the maximum extent possible. Physical identification methods include, but are not limited to, written markings, etching, affixing stickers with barcode or quick response (QR) codes, stamping, and tagging, including Radio Frequency Identification tags. Where physical identification on the item is either impractical or insufficient, physical separation, procedural control, or other appropriate means shall be employed. Identification markings shall be applied using materials and methods that provide a clear and legible identification and do not degrade the function or service life of the item. Markings shall be transferred to each part of an identified item when subdivided and shall not be obliterated or hidden by surface treatment or coating unless other means of identification are substituted.

300 SPECIFIC REQUIREMENTS

301 Identification and Traceability of Items

When codes, standards, or specifications include specific identification or traceability requirements (such as identification or traceability of the item to applicable specification and grade of material; heat, batch, lot, part, or serial number; or specified inspection, test, or other records), the program shall provide such identification and traceability control.

302 Limited Life Items

Items having limited calendar or operating life or cycles shall be identified and controlled to preclude use of items whose shelf life or operating life has expired.

303 Maintaining Identification of Stored Items

Provisions shall be made for the control of item identification consistent with the planned duration and conditions of storage, such as

(a) provisions for maintenance or replacement of markings and identification records due to damage during handling or aging

(b) protection of identifications on items subject to excessive deterioration due to environmental exposure

(c) provisions for updating existing plant records

[1] To the extent that computer programs are a physical part of plant systems (e.g., digital reactor protection systems, digital instrumentation), they are included in the term item. Refer to Part II, Subpart 2.7, paras. 203, 300, and 407.

REQUIREMENT 9
Control of Special Processes

(24) **100 GENERAL**

Special processes that control or verify quality shall be performed by qualified personnel using qualified procedures in accordance with specified requirements.

(24) **200 PROCESS CONTROL**

201 Special Processes

Special processes shall be controlled by instructions, procedures, drawings, checklists, travelers, or other appropriate means. These controls shall include or reference procedure, and personnel qualification requirements. Conditions necessary for accomplishment of the process shall be included. These conditions may include equipment qualification, controlled parameters of the process, specified environment, and calibration requirements.

202 Acceptance Criteria

The requirements of applicable codes and standards, including acceptance criteria for the process, shall be specified or referenced in procedures or instructions.

203 Special Requirements

Personnel, procedure, and equipment qualification requirements shall be specified or referenced for special processes not covered by existing codes and standards.

300 RECORDS (24)

Records shall be maintained for the qualified personnel, procedures, and equipment of each special process.

REQUIREMENT 10
Inspection

100 GENERAL

Inspections required to verify conformance of an item or activity to specified requirements or continued acceptability of items in service shall be planned and executed. Characteristics subject to inspection and inspection methods shall be specified. Inspection results shall be documented. Inspection for acceptance shall be performed by qualified persons other than those who performed or directly supervised the work being inspected.

200 INSPECTION REQUIREMENTS

Inspection requirements and acceptance criteria shall include specified requirements contained in the applicable design documents or other pertinent technical documents approved by the responsible design organization.

300 INSPECTION HOLD POINTS

If mandatory inspection hold points are required beyond which work shall not proceed without the specific consent of the designated representative, the specific hold points shall be indicated in appropriate documents. Consent to waive specified hold points shall be recorded prior to continuation of work beyond the designated hold point.

400 INSPECTION PLANNING

401 Planning

Characteristics to be inspected, methods of inspection, and acceptance criteria shall be identified during the inspection planning process.

402 Sampling

Sampling procedures, when used, shall be based upon standard statistical methods with engineering approval.

(24) 500 IN-PROCESS INSPECTION

In-process inspection of items shall be performed as necessary to verify quality. If inspection of processed items is impossible or disadvantageous, indirect control by monitoring of processing methods, equipment, and personnel shall be provided. When process monitoring is used to verify quality, it shall be performed by qualified personnel independent from the personnel performing the process controls or by qualified automated means. Both inspection and process monitoring shall be provided when quality verification is inadequate without both.

600 FINAL INSPECTIONS

601 Resolution of Nonconformances

Final inspections shall include a records review of the results and resolution of nonconformances identified by prior inspections.

602 Inspection Requirements

Completed items shall be inspected for completeness, markings, calibration, adjustments, protection from damage, or other characteristics as required to verify the quality and conformance of the item to specified requirements.

603 Modifications, Repairs, or Replacements

Any modifications, repairs, or replacements of items performed subsequent to final inspection shall require reinspection or retest, as appropriate, to verify acceptability.

604 Acceptance

The acceptance of the item shall be approved by authorized personnel.

700 INSPECTIONS DURING OPERATIONS (24)

Periodic inspections (e.g., in-service inspections) or surveillances of items shall be planned and executed to ensure the continued performance of their required functions.

800 RECORDS (24)

Appropriate records shall be established, maintained, and, as a minimum, identify the following:

(a) item inspected
(b) date of inspection
(c) inspector

(d) type of observation
(e) results or acceptability
(f) reference to any nonconformances identified

REQUIREMENT 11
Test Control

(24) 100 GENERAL

Tests required to collect data such as for siting or design input, to verify conformance of an item or computer program to specified requirements, or to demonstrate satisfactory performance for service shall be planned and executed. Characteristics to be tested and test methods to be employed shall be specified. Test results shall be documented and their conformance with test requirements and acceptance criteria shall be evaluated. Requirements for computer program test requirements, procedures, results, and records are defined in Part II, Subpart 2.7.

(24) 200 TEST REQUIREMENTS

(a) Test requirements and acceptance criteria shall be provided or approved by the responsible design organization. Required tests including, as appropriate, prototype qualification tests, production tests, proof tests prior to installation, construction tests, preoperational tests, and operational tests shall be controlled. Required tests shall be controlled under appropriate environmental conditions using the tools and equipment necessary to conduct the test in a manner to fulfill test requirements and acceptance criteria. The tests performed shall obtain the necessary data with sufficient accuracy for evaluation and acceptance.

(b) Test requirements and acceptance criteria shall be based upon specified requirements contained in applicable design documents or other pertinent technical documents that provide approved requirements.

(c) If temporary changes to the approved configuration of a facility are required for testing purposes, approval by the design authority is required prior to performing the test.

(24) 300 TEST PROCEDURES

(a) Test procedures shall include or reference the test configuration and test objectives. Test procedures shall also include provisions for assuring that prerequisites and suitable environmental conditions are met, adequate instrumentation is available and used, appropriate tests and equipment are used, and necessary monitoring is performed. Prerequisites shall include the following, as applicable:

(1) calibrated instrumentation
(2) appropriate equipment
(3) trained personnel
(4) condition of test equipment and the item to be tested
(5) suitable environmental conditions
(6) provisions for data acquisition

(b) As an alternative to (a), appropriate sections of related documents, such as ASTM methods, Supplier manuals, equipment maintenance instructions, or approved drawings or travelers with acceptance criteria, may be used. Such documents shall include or be supplemented with appropriate criteria from (a) to assure adequate procedures for the test are used.

400 TEST RESULTS (24)

Test results shall be documented and maintained. Test results shall be evaluated by the responsible authority to ensure that test requirements have been satisfied.

500 TEST RECORDS (24)

Test records shall be established and maintained to indicate the ability of the item to satisfactorily perform its intended function or to meet its documented requirements. Test records vary depending on the test type, purpose, and application, but shall contain the following information, as a minimum.

(a) item tested
(b) date of test
(c) tester or data recorder
(d) type of observation
(e) results and acceptability
(f) action taken in connection with any deviations
(g) person evaluating test results

REQUIREMENT 12
Control of Measuring and Test Equipment

100 GENERAL

Tools, gages, instruments, and other measuring and test equipment used for activities affecting quality shall be controlled, calibrated at specific periods, adjusted, and maintained to required accuracy limits.

200 SELECTION

Selection of measuring and test equipment shall be based on the type, range, and accuracy needed to accomplish the required measurements for determining conformance to specified requirements.

300 CALIBRATION AND CONTROL

301 Calibration

Measuring and test equipment shall be calibrated at prescribed times or intervals and whenever the accuracy of the results obtained using the measuring and test equipment is suspect. Calibration shall be against and traceable to certified equipment or reference standards having known valid relationships to nationally recognized standards, or to international standards known to be equivalent to and verified against corresponding nationally recognized standards. Where no such standards exist, the basis for calibration shall be defined.

302 Reference Standards

Reference standards used to calibrate measuring and test equipment shall have a minimum accuracy four times greater than that of the measuring and test equipment being calibrated. This is to ensure that errors in the reference standards contribute no more than one-fourth of the allowable calibration tolerance. Where this 4:1 ratio cannot be maintained, the basis for selection of the standard in question shall be technically justified.

303 Control

Calibration procedures shall identify or reference required accuracy and shall define methods and frequency of checking accuracy. The calibration method and interval of calibration shall be based on the type of equipment, stability characteristics, required accuracy, intended use, and other conditions affecting performance. Measuring and test equipment, which is overdue for calibration or found to be out-of-calibration, shall be tagged and/or segregated, or removed from service, and not used until it has been recalibrated. Measuring or test equipment consistently found to be out-of-calibration shall be repaired or replaced.

303.1 Application. Measuring and test equipment shall be traceable to its application and use.

303.2 Corrective Action. When measuring and test equipment is lost, damaged, or found to be out-of-calibration, the validity of previous measurement, inspection, or test results, and the acceptability of items previously inspected or tested shall be evaluated. This evaluation shall be from at least the last acceptable calibration of the M&TE. The evaluation and resulting actions shall be commensurate with the significance of the condition.

303.3 Handling and Storage. Measuring and test equipment shall be properly handled and stored to maintain accuracy.

303.4 Environmental Controls. Measuring and test equipment shall be used and calibrated in environments that are controlled to the extent necessary to ensure that the required accuracy and precision are maintained.

303.5 Precalibration Checks. Measuring and test equipment and reference standards submitted for calibration shall be checked and the results recorded before any required adjustments or repairs are made.

303.6 Status Indication. Measuring and test equipment shall be suitably marked, tagged, labeled, or otherwise identified to indicate calibration status and establish traceability to calibration records.

304 Commercial Devices

Calibration and control measures are not required for commercial equipment such as rulers, tape measures, levels, etc., if such equipment provides the required accuracy.

400 RECORDS

401 General

Records shall be established and maintained to indicate calibration status and the capability of measuring and test equipment to satisfactorily perform its intended function.

402 Reports and Certificates

Calibration reports and certificates reporting the results of calibrations shall include the information and data necessary for interpretation of the calibration results and verification of conformance to applicable requirements. The calibration record report shall include as found calibration data when calibrated items are found to be out of tolerance.

REQUIREMENT 13
Handling, Storage, and Shipping

100 GENERAL

Handling, storage, cleaning, packaging, shipping, and preservation of items shall be controlled to prevent damage or loss and to minimize deterioration. These activities shall be conducted in accordance with established work and inspection instructions, drawings, specifications, shipment instructions, or other pertinent documents or procedures specified for use in conducting the activity.

200 SPECIAL REQUIREMENTS

When required, special equipment (such as containers, shock absorbers, and accelerometers) and special protective environments (such as inert gas atmosphere, specific moisture content levels, and temperature levels) shall be specified and provided and their existence verified.

300 PROCEDURES

When required for critical, sensitive, perishable, or high-value items, specific procedures for handling, storage, packaging, shipping, and preservation shall be used.

400 TOOLS AND EQUIPMENT

Special handling tools and equipment shall be utilized and controlled where necessary to ensure safe and adequate handling. Special handling tools and equipment shall be inspected and tested in accordance with procedures at specified time intervals or prior to use.

500 OPERATORS (24)

Operators of special handling tools and lifting equipment shall be experienced or trained in the use of the equipment.

600 MARKING OR LABELING

Marking or labeling shall be utilized as necessary to adequately maintain and preserve the item, including indication of the presence of special environments or the need for special controls.

REQUIREMENT 14
Inspection, Test, and Operating Status

100 GENERAL

The status of inspection and test activities shall be identified either on the items or in documents traceable to the items where it is necessary to ensure that required inspections and tests are performed and to ensure that items that have not passed the required inspections and tests are not inadvertently installed, used, or operated.

The operating status of nuclear facility structures, systems, and components shall be identified to prevent inadvertent operation.

200 AUTHORITY

The authority for application and removal of status indicators shall be specified.

300 STATUS INDICATION

Status indication shall be maintained through physical means such as tags, markings, labels, stamps, or other suitable methods to prevent inadvertent installation, use, or operation.

REQUIREMENT 15
Control of Nonconforming Items

100 GENERAL

Items that do not conform to specified requirements shall be controlled to prevent inadvertent installation or use. Controls shall provide for identification, documentation, evaluation, segregation when practical, and disposition of nonconforming items, and for notification to affected organizations.

200 IDENTIFICATION

Nonconforming items shall be identified by legible marking, tagging, or other methods, such as identifying and controlling the item as nonconforming in an electronic system. If identification of each nonconforming item is not practical, the container or the package containing the item shall be identified. The identification method shall not be detrimental to the item.

300 SEGREGATION

(a) Nonconforming items shall be segregated, when practical, by placing them in a clearly identified and designated hold area until properly dispositioned.

(b) When segregation is impractical or impossible due to physical conditions such as size, weight, or access limitations, other precautions shall be employed to prevent inadvertent use of a nonconforming item.

400 DISPOSITION

401 Control

Nonconforming items shall be evaluated and recommended dispositions shall be proposed. Further processing, delivery, installation, or use of a nonconforming item shall be controlled pending the evaluation and an approved disposition by authorized personnel.

402 Responsibility and Authority

The responsibility and authority for the evaluation and disposition of nonconforming items shall be defined. Responsibility for the control of further processing, delivery, installation, or use of nonconforming items shall be designated in writing.

403 Personnel

Personnel performing evaluations to determine a disposition shall have:

(a) demonstrated competence in the specific area they are evaluating;

(b) an adequate understanding of the requirements; and

(c) access to pertinent background information.

404 Disposition

A disposition, such as use-as-is, reject, repair, or rework of nonconforming items shall be made and documented. Technical justification for the acceptability of a nonconforming item dispositioned as repair or as use-as-is shall be documented. Nonconformances to design requirements dispositioned as use-as-is or repair shall be subject to design control measures commensurate with those applied to the original design. Required as-built records shall reflect the use-as-is or repair condition.

405 Reexamination

Reworked items shall be reexamined in accordance with applicable procedures and with the original acceptance criteria.

Repaired items shall be reexamined in accordance with applicable procedures and with the original acceptance criteria unless the disposition has established alternate acceptance criteria.

REQUIREMENT 16
Corrective Action

100 GENERAL

Conditions adverse to quality shall be identified promptly and corrected as soon as practicable. In the case of a significant condition adverse to quality, the cause of the condition shall be determined and corrective action taken to preclude recurrence. The identification, cause, and corrective action for significant conditions adverse to quality shall be documented and reported to appropriate levels of management. Completion of corrective actions shall be verified.

REQUIREMENT 17
Quality Assurance Records

100 GENERAL

The control of quality assurance records shall be established consistently with the schedule for accomplishing work activities. Quality assurance records shall furnish documentary evidence that items or activities meet specified quality requirements. Quality assurance records shall be identified, generated, authenticated, and maintained, and their final disposition specified. Record control requirements and responsibilities for these activities shall be documented.

200 GENERATION OF RECORDS

(a) Records shall be legible.

(b) Records shall be traceable to associated items and activities and accurately reflect the work accomplished or information required.

(c) Records to be generated, supplied, or maintained shall be specified in applicable documents, such as design specifications, procurement documents, test procedures, and operational procedures.

300 AUTHENTICATION OF RECORDS

(a) Documents shall be considered valid records only if stamped, initialed, or signed and dated by authorized personnel or otherwise authenticated. Corrections to documents shall be reviewed and approved by the responsible individual from the originating or authorized organization.

(b) Electronic documents shall be authenticated with comparable information as in (a), as appropriate

(1) with identification on the media or

(2) with authentication information contained within or linked to the document itself

400 CLASSIFICATION

Records shall be classified as *lifetime* or *nonpermanent* and maintained by the Owner, or authorized agent, in accordance with the criteria given in paras. 401 and 402 of this Requirement and consistent with applicable regulatory requirements.

401 Lifetime Records

401.1 Lifetime records are those that meet one or more of the following criteria:

(a) those that would be of significant value in demonstrating capability for safe operation

(b) those that would be of significant value in maintaining, reworking, repairing, replacing, or modifying an item

(c) those that would be of significant value in determining the cause of an accident or malfunction of an item

(d) those that provide required baseline data for inservice inspections

401.2 Lifetime records are required to be maintained for the life of the particular item while it is installed in the facility or stored for future use.

402 Nonpermanent Records

Nonpermanent records are those required to show evidence that an activity was performed in accordance with the applicable requirements but need not be retained for the life of the item because they do not meet the criteria for lifetime records. Nonpermanent records shall be maintained for the identified retention period.

500 RECEIPT CONTROL OF RECORDS

Each organization responsible for the receipt of records shall designate a person or organization responsible for receiving the records. The designee shall be responsible for organizing and implementing receipt controls for permanent and temporary storage. Receipt controls shall provide a method for identifying the records received, receipt and inspection of incoming records, and submittal of records to storage.

600 STORAGE

601 General

(a) Records shall be stored at a predetermined location(s) in facilities, containers, or a combination thereof, constructed and maintained in a manner that minimizes the risk of loss, damage, or destruction from

(1) natural disasters such as winds, floods, or fires

(2) environmental conditions such as high and low temperatures and humidity

(3) infestation of insects, mold, or rodents
(4) dust or airborne particles

(b) Activities detrimental to the records shall be prohibited in the storage area.

(c) Access to the processing, storage, and retrieval of records shall be limited to authorized personnel.

(d) Provisions shall be made to prevent damage from harmful conditions (such as excessive light, stacking, electromagnetic fields, temperature, and humidity), as applicable to the specific media utilized for record storage.

602 Facility Types

There are two equally satisfactory methods of providing storage, single or dual.

602.1 Single storage consists of a storage facility, vault, room, or container(s) with a minimum two-hour fire rating. The design and construction of a single storage facility, vault room, or container shall be reviewed for adequacy by a person competent in fire protection or contain a certification or rating from an accredited organization.

602.2 Dual facilities, containers, or a combination thereof shall be at locations sufficiently remote from each other to eliminate the chance exposure to a simultaneous hazard. Facilities used for dual storage are not required to satisfy the requirements of para. 602.1, but shall meet the requirements of para. 601.

603 Temporary Storage

When temporary storage of records (such as for processing, review, or use) is required, the storage facility or container shall provide a one-hour fire rating, unless dual storage requirements of para. 602.2 are met.

700 RETENTION

(a) Record retention periods shall be documented.

(b) Records shall be maintained for their retention periods.

800 MAINTENANCE OF RECORDS

(a) Records shall be protected from damage or loss.

(b) Record controls shall provide for retrievability within planned retrieval times based upon the record type or content.

(c) The methods for record changes shall be documented.

(d) Provisions shall be established to ensure that no unacceptable degradation of the electronic record media occurs during the established retention period.

(e) Provisions shall be made to ensure that the records remain retrievable after hardware, software, or technology changes.

(f) Provisions shall be established to ensure the following when records are duplicated or transferred to the same media or to a different media for the purposes of maintenance or storage:

(1) duplication or transfer is appropriately authorized
(2) record content, legibility, and retrievability are maintained

REQUIREMENT 18
Audits

100 GENERAL

Audits shall be performed to verify compliance to quality assurance program requirements, to verify that performance criteria are met, and to determine the effectiveness of the program. These audits shall be performed in accordance with written procedures or checklists by personnel who do not have direct responsibility for performing the activities being audited. Audit results shall be documented and reported to and reviewed by responsible management. Follow-up action shall be taken where indicated.

(24) 200 SCHEDULING

Audits shall be scheduled in a manner to provide coverage and coordination with ongoing activities, based on the status and importance of the activity. Scheduled audits shall be supplemented by additional audits of specific subjects when necessary to provide adequate coverage.

A grace period of 90 days may be applied to scheduled internal audits, supplier audits, and annual evaluations of supplier performance. When the grace period is used, the next scheduled date for the activity shall be based on the activity schedule date and not on the date the activity was actually performed. If the activity is performed early, the next schedule date shall be based on the date the activity was actually performed.

(24) 201 Internal Audits

Except where specific regulatory guidance exists or code restrictions apply, organizations shall audit internal activities at the following intervals.

201.1 Nuclear Facilities Prior to Placing the Facility Into Operation. All applicable quality assurance program elements shall be audited at least once each year or at least once during the life of the activity, whichever is shorter.

201.2 Nuclear Facilities After Placing the Facility Into Operation. All applicable quality assurance program elements for each functional area[1] shall be audited within a period of 2 yr. For well-established activities, the period may be extended 1 yr at a time beyond the 2-yr interval based on the results of an annual evaluation of the applicable functional area and objective evidence that the functional area activities are being satisfactorily accomplished. However, the internal audit interval shall not exceed a maximum of 4 yr.

201.3 Suppliers and Other Nuclear Support Organizations. All applicable quality assurance program elements shall be audited at least once each year or at least once during the life of the activity, whichever is shorter. This interval may be extended up to 2 yr based on the results of an annual evaluation and objective evidence that the activities are being satisfactorily accomplished in accordance with the applicable quality assurance program elements.

202 External Audits

External audits (e.g., Supplier audits) shall be performed on a triennial basis and supplemented by annual evaluations of the Supplier's performance to determine if the regular schedule audit frequency shall be maintained or decreased or if other corrective action is required. A continuous or ongoing evaluation of the Supplier's performance may be conducted in lieu of the annual evaluations, provided that the results are reviewed in order to determine if corrective action is required.

300 PREPARATION

301 Audit Plan (24)

The auditing organization shall develop an audit plan for each audit. This plan shall identify the audit scope, requirements, audit personnel, activities to be audited, organizations to be notified, applicable documents, schedule, and written procedures or checklists. The plan shall be approved by the Lead Auditor or responsible management.

302 Personnel

Audit personnel shall have sufficient authority and organizational freedom to make the audit process meaningful and effective.

[1] "Functional area" denotes activities such as engineering, construction, procurement, operations, maintenance, radiological protection, chemistry, and security.

303 Selection of Audit Team

An audit team shall be identified prior to the beginning of each audit. This team shall contain one or more Auditors, one being designated Lead Auditor who organizes and directs the audit. The audit team shall have experience or training commensurate with the scope, complexity, or special nature of the activities to be audited.

400 PERFORMANCE

Elements selected for audit shall be evaluated against specified requirements. Objective evidence shall be examined to the depth necessary to determine if these elements are being implemented effectively. Conditions requiring prompt corrective action shall be reported immediately to management of the audited organization.

(24) 500 REPORTING

The audit report shall be signed or otherwise endorsed by the Lead Auditor and issued to the audited organization. The contents of the report shall

(a) describe the audit scope.

(b) identify Auditors and persons contacted.

(c) summarize audit results, including conclusions on the effectiveness of the quality assurance program for the areas audited. When it is concluded that portions of the program are ineffective, the basis for the conclusion shall be identified.

(d) describe each audit finding.

600 RESPONSE

Management of the audited organization or activity shall investigate audit findings, schedule corrective action, including measures to prevent recurrence of significant conditions adverse to quality, and notify the appropriate organization in writing of action taken or planned. Audit responses shall be evaluated by or for the auditing organization.

700 FOLLOW-UP ACTION

Follow-up action shall be taken to verify that corrective action is accomplished as scheduled.

800 RECORDS

Audit records shall include audit plans, audit reports, written replies, and the record of completion of corrective action.

PART II
QUALITY ASSURANCE REQUIREMENTS FOR NUCLEAR FACILITY APPLICATIONS

INTRODUCTION

100 PURPOSE

Part I establishes requirements for the development and implementation of a Quality Assurance Program (QAP) for nuclear facility applications. It is arranged by Requirements 1 through 18.

Part II — this Part — contains additional quality assurance requirements for the planning and conduct of specific work activities under a Quality Assurance Program developed in accordance with Part I. It is arranged by Subparts.

Part III contains guidance for implementing the requirements of Parts I and II. It is arranged by Subparts.

Part IV contains guidance for the application of NQA-1 and comparisons of NQA-1 with other quality requirements. It is arranged by Subparts.

200 APPLICABILITY

Subparts of Part II are applied using a graded approach to any structure, system, component, activity, or organization that is essential to the safe, reliable, and efficient performance of a nuclear facility and any activities independent of a facility that may affect performance (e.g., transportation of nuclear materials) of those activities. It is also applied to all phases of a nuclear facility life cycle (e.g., siting, design, construction, operation, and decommissioning) and related activities (e.g., training, testing, software development or use). The Quality Assurance Program developed in accordance with Part I is applied to the implementation of Part II requirements.

300 RESPONSIBILITY

The user or implementing organization invoking this Standard shall determine and document applicable Subparts based on the scope of the work, contract, rules, and regulatory requirements as they relate to specific items, activities, and services. Implementation of applicable Parts I and II requirements is necessary for the Quality Assurance Program to comply with this Standard.

400 PLANNING AND PROCEDURES

401 Planning

A plan shall be developed outlining the work to be performed and the work procedures or instructions required to comply with the requirements of the defined work scope.

Planning for activities such as fabrication, installation, operation, modification, repair, maintenance, decommissioning, inspection, testing, and software verification and validation shall include a review of structure, system or component design and procurement specifications, materials lists, drawings, construction work plans, and schedules to ensure that appropriate activities have been incorporated; that the work can be accomplished as specified; and that time and resources, plus training, are sufficient to accomplish the work in accordance with the specified requirements.

Planning shall define the operations to be performed, the systematic sequential progression of operations, and the overall measures to be used to preserve the quality of the work.

402 Procedures

Procedures and work instructions identified during planning shall be prepared. Preparation and approval of the procedures/instructions shall be in advance of the need to use the documents. The documents shall be kept current and revised as necessary to assure that the work is performed in accordance with the latest approved information.

The documents shall include the following, as applicable:

(a) personnel safety and structure or facility protection considerations

(b) precautions to be observed

(c) work requirements such as those included in specifications, procedures, and instructions for performing an activity

(d) sequence of activities to be followed and steps within a given activity

(e) prerequisites
(f) software verification and validation
(g) test and inspection objectives
(h) special equipment required
(i) identification of inspection and test equipment and related calibration requirements including recalibration dates
(j) sequence and frequency of activities for verification
(k) acceptance criteria and methods for verification
(l) responsibility and required qualifications of personnel
(m) approvals and authorizing or verifying signatures
(n) specific document references
(o) data or test report forms
(p) information to be collected for facility records
(q) processing inspection and test data and their analysis, evaluation, and final acceptance, including software verification and validation

500 DEFINITIONS

Definitions unique to the activities described in Part II are included in the section dealing with that activity. Definitions generic to quality assurance activities are included in Part I, Introduction, section 400, Terms and Definitions.

600 MULTIUNIT FACILITY PROVISIONS

For construction, outage, or decommissioning activities in nuclear facilities where one or more units are already operating or has reached a stage where the fuel has been loaded in the facility and associated systems energized, the following measures shall be taken in addition to the provisions defined elsewhere in this Part.

601 Planning and Preparation

Instructions, procedures, or drawings shall be prepared to control installation, maintenance, modification, decommissioning, inspection, and testing activities at areas of interface between units. These instructions, procedures, or drawings shall define the following, as applicable:

(a) the areas of interface between units
(b) access control and authority for work at these interface areas
(c) nature of potential hazards to or from the operating equipment; precautions required to be taken during installation, maintenance, modification, or decommissioning; supplementary objectives for inspection and testing

602 Documentation

602.1 The instructions, procedures, or drawings described in para. 601 of this Introduction shall be kept current.

602.2 The equipment or systems that are associated with the operating unit(s) that are electrically energized or charged with pressurized or radioactive fluids and that are in the vicinity of the construction, outage, or decommissioning activity associated with the new or nonoperating unit shall be properly tagged or identified as energized or operational.

602.3 The documents associated with activities described in para. 602.2 of this Introduction shall also include

(a) identification of the equipment or system defined in para. 602.2 above that poses a potential hazard in the vicinity of current construction, outage, or decommissioning activities
(b) identification of the potential hazard of neighboring energized systems such as voltage, radiation level, fluid pressure, or temperatures

602.4 Authorizations for access to and work at the area of interface between the new and existing units shall be documented.

603 Installation

603.1 Suitable protective barriers shall be erected, where needed, to prevent damage to equipment or systems associated with the existing unit(s).

603.2 When working in an area common to the new and existing units, care shall be exercised to avoid interference with existing facilities, to maintain required separation (where appropriate) between the systems associated with existing and new units, and to prevent disturbing the operation of equipment or systems associated with the existing unit(s); construction workers shall be instructed with regard to the hazards present.

604 Inspection

Inspection shall be performed to verify that the requirements have been satisfied and that the existing facilities are properly protected from construction activities.

SUBPART 2.1
Quality Assurance Requirements for Cleaning and Cleanness Control of Fluid Systems and Associated Components for Nuclear Facilities (24)

(24) 100 GENERAL

This Subpart provides amplified requirements for the cleaning and cleanness control of fluid systems and associated components for nuclear facilities during manufacturing, construction, repairs, and modifications. It supplements the requirements of Part I and shall be used in conjunction with applicable sections of Part I when and to the extent specified by the organization invoking this Subpart. The sensitivity to contaminants of the systems/components involved shall be considered when specifying cleanness requirements or invoking this Subpart.

(24) 101 Definitions

The following definitions are provided to ensure a uniform understanding of unique terms as they are used in this Subpart.

acid cleaning: the removal of metal oxides by either dissolution of the oxide or undercutting the oxide by dissolution of the base metal with an acid solution.

alkaline cleaning: the removal of organic contaminants by converting them to an emulsion with an alkaline solution such as trisodium phosphate.

chelate cleaning: the removal of slightly soluble compounds such as iron oxide, by complexing the metallic ions with organic chelating compounds such as ethylene diamine tetra-acetic acid (EDTA).

chemical conditioning: the addition of chemicals in low concentration to flush, rinse, or lay up water to inhibit precipitation of dissolved solids, corrosion, and other detrimental effects.

cleaning: the removal of any contaminants that might have a deleterious effect on operation of the facility.

contamination: any unwanted or undesirable foreign material on the surface of an item, in the atmosphere, or in process liquids or gases.

corrosion-resistant alloys: materials that inherently resist oxidation or chemical attack in water, air, and the operating environment, such as stainless steel, nickel-base alloys, or cobalt-base alloys.

crevice: a narrow opening in a surface or an open juncture between mating surfaces in which solutions or contaminants can be trapped and not readily removed during rinsing or flushing operations (for example, the annular spaces in threaded connections and socket assemblies, tube-to-tubesheet joints, and tube-to-tube support joints).

dead leg: an area that does not have flow during the cleaning operation or that cannot be drained without special provisions.

fluid: any gas or liquid.

flushing: flowing fluid through a component or system at adequate velocity to suspend and carry away anticipated contaminants.

inaccessible area: an area or opening in an item that is not directly accessible for cleaning or inspection.

inhibitor: a chemical additive that retards some specific chemical reaction.

layup: the protection of an item after it has been cleaned to prevent corrosion of interior surfaces while the item is out of service or awaiting subsequent operations.

mechanical cleaning: a method in which contaminant removal is accomplished solely by mechanical means, including wiping, abrasive blasting, high pressure water jetting, brushing, sanding, grinding, and chipping.

pitting: surface defects resulting from localized corrosion.

rinsing:

(a) filling and draining an item with water until soluble contaminants in the effluent water are reduced to some predetermined concentration; or

(b) flowing water through the system or component until water-soluble contaminants in the effluent water are reduced to some predetermined concentration.

rust: corrosion products consisting largely of iron oxide. Such oxides may vary in color from red to black and may form anything from a loosely adherent heavy covering to a tightly adherent light film. Pitting or general surface roughening may or may not be present.

sensitized corrosion-resistant alloy: a corrosion-resistant alloy that has been subjected to heating that causes intergranular precipitation of chromium carbides in sufficient quantities to be detected by Practice B, C, E, or F of ASTM A262-15(R2021), Standard Practices for Detecting Susceptibility to Intergranular Attack in Austenitic Stainless Steels.

solvent cleaning: removing contaminants with an organic solvent.

200 GENERAL REQUIREMENTS

The work and quality assurance requirements for the cleaning of components and systems and for the control of their cleanness shall be established in order to

(a) ensure the removal of deleterious contaminants

(b) minimize recontamination of cleaned surfaces

(c) minimize the cleaning required after installation, repair, or modification

The cleanness classification of each item shall be specified in accordance with para. 302 of this Subpart.

(24) 201 Planning

Cleaning and cleanness control activities for each phase (manufacturing, construction, modification, repair, etc.) shall be planned in accordance with the requirements of the Introduction to this Part (Part II). The plan(s) shall define the cleaning and inspection operations to be used, the system, the responsibilities of the parties concerned for each operation, and the measures to be employed to preserve the cleanness of cleaned surfaces. In addition, planning shall consider the following factors, as appropriate, recognizing that this list may neither be complete nor applicable to each phase covered by this Subpart:

(a) adequacy of vents, drains, inspection access points, and bypass or recirculation lines

(b) facilities for filters and flushing and drain connections in locations where dead legs are unavoidable

(c) design and installation of piping in a manner that minimizes the necessity for installing temporary piping during the cleaning operations, such as dividing the system into a number of separate cleaning circuits to facilitate cleanability

(d) sequencing of installation operations to provide for visual inspection of inside surfaces of large diameter piping

(e) control of installation operations so that piping and components that have already been installed are not subject to contamination when subsequent installation operations are performed

(f) adequacy of pumping and heating capacities when these are important factors in the cleaning operations

(g) disposal of cleaning solutions and waste water

(h) safety, fire protection, and other hazards

202 Procedures and Instructions

202.1 Written procedures and instructions for cleaning, cleanness control, inspections, and tests to verify cleanness of items shall be prepared in accordance with the requirements of the Introduction to this Part.

202.2 Preparation of the actual cleaning procedures or instructions shall consider the following:

(a) work practices, housekeeping, access control, and prevention of contamination and recontamination

(b) effectiveness of cleaning methods for removal of the contaminants

(c) effects of residual quantities of cutting fluids, liquid penetrants, weld fluxes, precleaning solutions, engineering test fluids, and other process compounds that may have been intentionally or advertently applied to the surface of the item during prior steps of manufacture, installation, or use

(d) corrosiveness of cleaning solutions in contact with the material of an item, particularly in the case of dissimilar metals and entrapment of cleaning solutions

(e) chemical composition, concentration, and temperature limits of cleaning solutions to avoid deleterious effects

(f) solution and metal temperatures, solution concentrations, velocity, and contact times during cleaning

(g) methods for monitoring cleaning solution concentration, temperatures, and velocities during cleaning operations

(h) identification of the items for which the procedures are to be used

(i) sequence of operations and methods of filling system circulation, draining, and flushing

(j) consideration should also be given to

(1) equipment isolation

(2) location of

(-a) temporary piping and valves

(-b) strainers

(-c) temporary equipment

(-d) connections for filling, flushing, rinsing, and draining equipment

(k) activities to be prohibited or constrained before, during, and after cleaning operations

(l) methods for rinsing and neutralizing, including estimated number of rinses

(m) methods for verifying cleanness

(n) methods for drying and layup

(o) methods for protecting installed items that are not involved in the cleaning operation

(p) method of disposal of cleaning solution

(24) **203 Rectification of Unacceptable Cleanness**

If indications of contamination in excess of specified limits are observed at the end of a cleaning operation or at any subsequent inspections for cleanness, the item shall be recleaned using an approved procedure. If such indications are observed at the anticipated end of a cleaning operation, continued cleaning shall be performed to reduce the level to the specified limit.

When continued cleaning does not result in acceptable cleanness, the condition shall be documented as a nonconformance and corrective action taken, including action to prevent recurrence when appropriate.

(24) **204 Control of Cleaning Solutions**

Cleaning solutions shall be prepared in accordance with the applicable cleaning procedure and shall be checked for proper chemical composition and effectiveness of inhibitors, if used. Solution temperatures shall be maintained and controlled to ensure adequate cleaning and to prevent cleaning agent decomposition and possible damage to the item. When necessary, shelf-life requirements shall be established.

300 CLEANNESS CRITERIA

301 Cleanness Classification

The level of cleanness required for any particular application is a function of the particular item under consideration. The assignment of a cleanness classification shall consider the following:

(a) the function of the item to be cleaned

(b) the susceptibility of its materials of construction to various forms of corrosion, including intergranular cracking, or stress corrosion cracking under fabrication, installation, or operating conditions

(c) the consequences of malfunction or failure of the item

(d) the possibility of contaminants (introduced during fabrication, storage, installation, repairs, or service) contributing to or causing such malfunction or failure

Four classes of surface cleanness (Classes A, B, C, and D) with criteria for each are provided in this Subpart. The cleanness class or classes applicable to the item or specific parts of the item shall be established and specified in the applicable drawings, specifications, or other appropriate documents. Different cleanness classes may be assigned to internal and external surfaces, or to different parts of the same item based on the cleanness needs of the specific item. Guidelines for assigning cleanness classifications are listed in Part III, Subpart 3.2-2.1.

302 Cleanness Class Criteria

302.1 Class A. A very high level of cleanness as (24) evidenced by the freedom from all types of surface contamination, according to the acceptance criteria of the inspection methods specified in the procedures required by para. 202.1 of this Subpart. If close control of particulate contamination is required, a clean room, in accordance with para. 8.5.5 of ASTM A380/A380M-17, Practice for Cleaning and Descaling Stainless Steel Parts, Equipment, and Systems, shall be employed during the manufacturing, assembly, and installation operations when particulate contamination could occur. Gross and precision inspection methods applicable to Class A are described in ASTM A380/A380M-17, paras. 7.2 and 7.3; other special tests shall be specified as necessary. Where the cleanness of internal surfaces is evaluated by flushing, criteria shall be specified in the cleaning procedure.

302.2 Class B. A high level of cleanness as evidenced by (24) the following characteristics:

(a) Corrosion-Resistant Alloys

(1) The surface shall appear metal clean and free of organic films and contaminants when examined in accordance with para. 7.2.1 of ASTM A380/A380M-17, Practice for Cleaning and Descaling Stainless Steel Parts, Equipment, and Systems, except light deposits of atmospheric dust are permissible and shall show no evidence of deleterious contamination when subjected to the wipe test of ASTM A380/A380M-17, para. 7.2.2. When visual inspection is impossible but surfaces are accessible for wipe tests, sufficient wipe tests in different areas of the item shall be made to evaluate the general cleanness level of the surface. Scattered areas of rust are permissible, provided the aggregate area does not exceed 2 $in.^2$ in any 1 ft^2 area (14 cm^2 per 1 000 cm^2). Temper films and discolorations resulting from welding are acceptable.

(2) If flushing is the only practical means for evaluating the cleanness of internal surfaces, a 20-mesh (850 μm, ASTM E11-22, Standard Specification for Woven Wire Test Sieve Cloths and Test Sieves) or finer filter (or the equivalent) shall be installed and the item flushed with water or other fluid meeting the requirements of para. 304 of this Subpart. The item shall be flushed at the design velocity (or other flow velocity if specified in the procedure) until the screen shows no more than slight speckling (as specified in the procedure in qualitative or quantitative terms, such as the number of particles per unit surface of the screen) and no more than slight rust staining. There shall be no particles larger than $^1/_{32}$ in. × $^1/_{16}$ in. long (0.8 mm × 1.6 mm). In water-flushed systems there shall be no visual evidence of contamination (e.g., oil, discoloration) of the effluent flush water or screen.

(b) Carbon and Low-Alloy Steels

(1) The surface shall appear metal clean when examined in accordance with ASTM A380/A380M-17, para. 7.2.1, except light deposits of atmospheric dust are permissible, and shall show no deleterious contamination when subjected to the wipe test of ASTM A380/A380M-17, para. 7.2.2. Wipe tests shall be made prior to the application of any preservative film (some type of protective film may be required in order to maintain a clean carbon or low-alloy steel surface at Class B level). When visual inspection is impossible, but surfaces are accessible for a wipe test, sufficient wipes of different areas of the item shall be made to evaluate the general cleanness of the surface. Scattered areas of rust are permissible, provided the aggregate area does not exceed 2 $in.^2$ in any 1 ft^2 area (14 cm^2 per 1 000 cm^2).

(2) If flushing is the only practical means for evaluating the cleanness of internal surfaces, a 20-mesh (850 μm, ASTM E11-22, Standard Specification for Woven Wire Test Sieve Cloths and Test Sieves) or finer filter (or the equivalent) shall be installed and the item flushed with water or other fluid meeting the requirements of para. 304 of this Subpart. The item shall be flushed at the design velocity (or other flow velocity if specified in the procedure) until the screen shows no more than slight speckling (as specified in the procedure in qualitative or quantitative terms, such as the number of particles per unit area of the screen) and no more than slight rust staining. There shall be no particles larger than $\frac{1}{32}$ in. × $\frac{1}{16}$ in. long (0.8 mm × 1.6 mm). In water-flushed systems there shall be no visual evidence of contamination (e.g., oil, discoloration) of the effluent flush water or screen.

NOTE: Class A or Class B cleanness should be specified for carbon steel and low-alloy steel surfaces only in special cases because of the difficulty in maintaining such surfaces in either condition after they have been cleaned.

302.3 Class C. An intermediate level of cleanness in which the surfaces meet the requirements for Class B, except

(a) Corrosion-Resistant Alloys. Scattered areas of rust are permissible, provided the aggregate area does not exceed 15 $in.^2$ per 1 ft^2 area (100 cm^2 per 1 000 cm^2).

(b) Carbon and Low-Alloy Steels. A uniform light rust bloom that can be removed by brushing or wiping is acceptable.

(c) Corrosion-Resistant Alloys and Carbon and Low-Alloy Steels. Screens installed for evaluation of internal surfaces by flushing may exhibit considerable particle speckling (as specified in the procedures in qualitative or quantitative terms, such as the number of particles per unit area of the screen) and considerable rust staining.

302.4 Class D. A nominal level of cleanness in which the following are acceptable: (24)

(a) rust films on both corrosion-resistant alloys and carbon and low-alloy steel surfaces

(b) tightly adherent mill scale on nonmachined carbon and low-alloy steel surfaces that resist removal by hand scrubbing with a stiff wire brush

(c) paint or preservative coatings on carbon or low alloy steel surfaces that will not peel or flake when subjected to cold water flushing

(d) particles no larger than $\frac{1}{16}$ in. × $\frac{1}{8}$ in. long (1.6 mm × 3.2 mm) on a 14-mesh (1.4 mm, ASTM E11-22) or finer filter (or the equivalent)

302.5 Summary. The cleanness classes are summarized in Table 302.5 of this Subpart.

303 Hydraulic, Instrument Control, and Lubrication Lines and Systems

The preceding cleanness classifications and criteria in para. 302 of this Subpart are primarily applicable to relatively large items that are generally amenable to visual inspection of internal surfaces at some time during manufacture and installation operations. Interior surfaces of hydraulic, instrument control, and lubrication systems are generally not accessible for visual inspection during manufacture and installation, and may have much more stringent requirements on particulate contamination than those specified in the preceding cleanness classes. Where special characteristics and specific requirements are needed for such systems, they shall be specified. Guidelines for classifying hydraulic, instrument, and lubrication cleanness are presented in Part III, Subpart 3.2-2.1.

304 Cleaning and Flushing Fluid Quality Requirements

304.1 Water. The water quality for mixing cleaning solutions, rinsing, and flushing shall be specified by the organization responsible for cleaning unless otherwise stipulated in procurement documents or approved procedures. Table 304.1 of this Subpart lists water quality requirements commonly used for such purposes in nuclear cleaning operations. The water quality for final flushes of fluid systems and associated components shall be at least equivalent to the quality of the operating system water. To minimize the possible adverse effects of halogens, the chemical requirements for water including the use of halogen stress-cracking inhibitors used on components or systems containing austenitic stainless steel or corrosion-resistant alloy shall be as determined by technical evaluation.

304.2 Gaseous Fluids. The requirements for gaseous fluids used for flushing are dependent upon the particular item being flushed. The requirements for any given item

shall incorporate restrictions on particulate contaminants, organic contaminants, water-soluble contaminants, and water content as appropriate for the item.

Table 302.5
Summary Table for Cleanness Classes (24)

Class	Surface Appearance	Rust	Paints or Preservatives	Mill Scale	Flushing Criteria
Class A					
Corrosion-resistant alloys	Metal clean	[Note (1)]	[Note (1)]	[Note (1)]	Specified in cleaning procedure
Carbon and low-alloy steels [Note (2)]	Metal clean	[Note (1)]	No paints; preservative if specified	[Note (1)]	Specified in cleaning procedure
Class B					
Corrosion-resistant alloys	Metal clean [Note (3)]	2 $in.^2$/1 ft^2 (scattered) (14 cm^2/1 000 cm^2)	[Note (1)]	[Note (1)]	No particles larger than $\frac{1}{32}$ in. × $\frac{1}{16}$ in. (0.8 mm × 1.6 mm)
Carbon and low-alloy steels [Note (2)]	Metal clean [Note (3)]	2 $in.^2$/1 ft^2 (scattered) (14 cm^2/1 000 cm^2)	No paints; preservative if specified	[Note (1)]	No particles larger than $\frac{1}{32}$ in. × $\frac{1}{16}$ in. (0.8 mm × 1.6 mm)
Class C					
Corrosion-resistant alloys	Metal clean [Note (3)]	15 $in.^2$/1 ft^2 (scattered) (100 cm^2/1 000 cm^2)	[Note (1)]	[Note (1)]	No particles larger than $\frac{1}{32}$ in. × $\frac{1}{16}$ in. (0.8 mm × 1.6 mm)
Carbon and low-alloy steels	No visible particles	Uniform soft film	No paints; preservative if specified	[Note (1)]	No particles larger than $\frac{1}{32}$ in. × $\frac{1}{16}$ in. (0.8 mm × 1.6 mm)
Class D					
Corrosion-resistant alloys	[Note (1)] (unless specified by purchaser)	[Note (1)]	[Note (1)]	[Note (1)]	No particles larger than $\frac{1}{16}$ in. × $\frac{1}{8}$ in. (1.6 mm × 3.2 mm)
Carbon and low-alloy steels	[Note (1)] (unless specified by purchaser)	[Note (1)]	Acceptable	Acceptable if adherent	No particles larger than $\frac{1}{16}$ in. × $\frac{1}{8}$ in. (1.6 mm × 3.2 mm)

NOTES:
(1) No requirement.
(2) While Classes A and B cleanness levels can be achieved on carbon and low-alloy steel surfaces, maintenance of these levels is very difficult. Assignment of Classes A and B levels to such surfaces should be made with discretion.
(3) Temper films are acceptable.

Table 304.1
Water Requirements

Fresh Water [Note (1)] — Minimum Requirements	
pH at 25°C (77°F)	6.5 to 8.5
Chloride	Less than 250 ppm
Fluoride	Less than 2 ppm
Sulfate	Less than 250 ppm
Total dissolved solids	Less than 500 ppm
High-Quality Water — Minimum Requirements at Point of Entry Into Item	
pH at 25°C (77°F)	5.5 to 8.0
Chloride	Less than 1 ppm
Fluoride	Less than 1 ppm
Sulfide	Less than 1 ppm
Conductivity at 25°C (77°F)	Less than 3 μmho/cm
Silica	Less than 0.05 ppm
Total suspended solids	Less than 3 ppm

NOTE: (1) Fresh water that meets U.S. Environmental Protection Agency, 40 CFR 143.3, Secondary Maximum Containment Levels (for Public Water Systems), may be utilized for any application where fresh water is specified.

304.3 Organic Fluids. Requirements for organic fluids used for flushing are dependent upon the particular item being flushed. The requirements for any given item shall incorporate restrictions on particulate contaminants, water-soluble contaminants, and water content as appropriate for the item.

304.4 Fluids for Hydraulic, Instrument Control, and Lubrication Systems. In addition to the requirements of para. 304.1, para. 304.2, or para. 304.3 of this Subpart, as applicable for the system being flushed, fluids used for final flushing or rinsing of components and installed systems covered by this paragraph shall meet the particulate contamination limits specified in Table 304.4 of this Subpart for the system class specified.

304.5 Acid Cleaning. If acid cleaning is used, particular attention shall be given to

(a) avoidance of entrapment of acids in crevices

(b) effects on either welded or sensitized corrosion-resistant alloys and nonferrous materials

(c) complete removal of any residual acid solution from the item

(d) neutralizing treatment followed by thorough rinsing or flushing

304.6 The use of contaminated tools shall be avoided. Tools that contain, or that may become contaminated with, materials that could contribute to stress-corrosion or intergranular cracking shall not be used on corrosion-resistant alloys.

400 MANUFACTURING PHASE CLEANNESS (24)

The cleanness of an item at the point of manufacture is critical to the final cleanness level ultimately attained after installation. Where practicable, the cleanness classification of an item listed in the procurement documents shall be the same as that for final service. The capability of construction site cleaning operations may not be sufficient to upgrade the cleanness level of a complex item since a much wider variety of cleaning facilities and procedures are generally available for use at the manufacturer's shops than at the construction sites.

Procurement documents shall specify the required as-shipped cleanness level for the item. Shop cleaning procedures shall be in accordance with para. 202 of this Subpart, and inspection and test results shall be documented, as appropriate, in accordance with approved procedures.

Listed below are cleaning considerations that are appropriate to all manufacturing operations. Additional information is presented in ASTM A380/A380M-17; where applicable, it shall be considered.

(a) Operations that generate chemical or particulate contaminant, such as welding and grinding, shall be controlled during fabrication steps, after which removal of such contaminants becomes difficult because of limited access. Under such conditions, protection of openings shall be provided to prevent entry of contaminants, especially particulate contaminants. If practical, manufacturing sequence shall be based on considerations related to cleaning of individual items as the component is assembled, unless the component is readily cleanable in its final assembled state.

(b) Cleaning methods and materials used during manufacture shall be compatible with the materials of construction of the item being cleaned (see para. 202.2 of this Subpart). Cutting fluids, lubricants, liquid penetrants, marking materials, precleaning solutions, engineering test fluids, tools, and other materials and process compounds to be used on surfaces of items made from austenitic stainless steel or corrosion-resistant alloy during manufacture shall be evaluated from the standpoint of potentially harmful contaminants. Such contaminants include chlorides, fluorides, and low melting point materials such as sulfur, lead, zinc, copper, and mercury. Where potentially harmful quantities of such contaminants can be leached or are in a form in which they could be released by breakdown of the compound during subsequent manufacturing, installation, or operation, they shall not be used. Paint, chalk, scribing inks, and other temporary marking materials shall be removed from the affected surfaces prior to heat treatment or welding.

(c) Use of tools (such as those used for grinding, polishing, filing, deburring, and brushing) during manufacture shall be controlled when surface contamination of the item from such tools is considered an important factor.

Table 304.4
Flushing Requirements for Hydraulic, Instrument Control, and Lubrication Systems

System Class	Generic Description	Maximum Number of Particles Per 100 cc Particle Size				
		5–10 μm	10–25 μm	25–50 μm	50–100 μm	100 μm
0	Super clean	2 700	670	93	16	1
1	MIL-H-5606B	4 600	1 340	210	28	3
2	High reliability	9 700	2 680	380	56	5
3	Critical	24 000	5 360	780	110	11
4	Less critical	32 000	10 700	1 510	225	21
5	Moderate reliability	97 000	21 400	3 130	430	41
6	Industrial	128 000	24 000	6 500	1 000	92

GENERAL NOTES:
(a) Adapted from ASTM STP 491, Maintenance of Cleanliness of Hydraulic Fluids and Systems. Classes 2 and 5 of the table in STP 491 are described as Good Missile and Poor Missile, respectively. While these criteria are based on a specified volume of liquid (100 cc), they can also be applied to gaseous flushes. When used in this manner, the cleaning procedure shall specify the flushing velocity and time upon which the evaluation shall be based.
(b) The above system Class designations do not directly correspond to the cleanness class criteria classes of this Subpart.

(d) The quality of fluid used for final flushing or rinsing shall meet or exceed the requirements of para. 304.1 of this Subpart. Particular attention shall be paid to flushing of pockets, crevices, or dead legs to ensure that cleaning solutions are not trapped in such areas.

(e) Fresh water may be used for mixing oil cleaning solutions and for initial rinsing and flushing when permitted by approved procedures.

(f) The final cleaned item shall be sealed in a dried condition to prevent subsequent recontamination and then packaged in accordance with the requirements established in the procurement documents.

500 CLEANNESS PRIOR TO INSTALLATION

From a cleanness standpoint, consideration shall be given as to whether items should be delivered to the point of installation sooner than necessary, i.e., whether the installation location is a better storage area (see Part II, Subpart 2.2). Inspections and tests, as appropriate, shall be made immediately prior to installation to determine the cleanness of the item. If potentially harmful contaminants are detected, they shall be removed if they will not be removed in subsequent cleaning operations. Items having surfaces to which temporary paint or preservative coatings have been applied shall be identified. The composition of the coating and methods for its removal shall be determined and removal of coatings, when required, recorded in the inspection report. Unless otherwise required by the job specifications, the temporary coatings shall be removed prior to installation of items.

600 CLEANNESS DURING INSTALLATION

The installation process represents an opportunity for the introduction of contaminants into a cleaned item, and care shall be taken to minimize contamination. Operations that generate particulate matter, such as grinding and welding, shall be controlled. Cleanup of locally contaminated areas as installation progresses is recommended (rather than one cleanup operation when installation is completed). Consideration shall be given to sequencing of installation and erection operations to facilitate cleaning, cleanness control, and inspection. Insofar as practicable, internal surfaces of a portion of a system that can be blocked or obscured by subsequent operations shall be visually inspected and verified as being clean before the access points are closed. Openings and pipe ends shall be sealed at all times except when they must be unsealed to carry out necessary operations.

Precautions shall be taken to avoid contamination of crevices, blind holes, dead legs, undrainable cavities, and inaccessible areas. When grinding, sanding, chipping, or wire brushing, the item shall be so oriented that chips fall away from the openings, or covers shall be provided for the openings.

The use of cleaning methods and materials, cutting fluids, lubricants, liquid penetrants, marking materials, precleaning solutions, engineering test fluids, tools, and other materials and process compounds used during installation of items made from austenitic stainless steel or other corrosion-resistant alloys shall be subject to the limitations on such methods and materials specified in section 400 of this Subpart.

Surfaces shall be visually inspected upon completion of work on them, and obvious contamination removed before proceeding to the next installation or construction step. The use of mineral acids and organic acids to clean austenitic stainless steel and nickel alloys shall be

evaluated and approved prior to use. Precleaning and postcleaning of weld joint areas and welds shall be performed by wire brushing and scrubbing with a solvent-moistened clean cloth unless otherwise specified.

Large openings shall be protected against falling and windblown contaminants.

700 MAINTENANCE OF INSTALLATION CLEANNESS

After any isolable item has been installed in a clean condition, cleanness control measures and access control shall be established to minimize the introduction of contaminants between the time of system isolation and preoperational testing. Where environmental contamination could cause degradation of quality, seals shall be installed to prevent contamination of interior surfaces. Materials used for sealing items made from austenitic stainless steel or other corrosion-resistant alloys shall be subject to the limitations specified in section 400 of this Subpart. Seals shall be installed in a manner to prevent accidental removal. Removal shall be only with proper authorization.

If access to such sealed items is required, precautions shall be taken to prevent introduction of contaminants. Such precautions include masking and tenting of surrounding areas with plastic film or tape, cleanup of the immediate surroundings to remove particulate matter that can be introduced into the opening, requiring personnel to wear clean outer clothing and shoe covers, etc. Control of tools, loose items, and access shall be maintained in accordance with applicable requirements.

When the necessary work is completed, the interior surface shall be locally cleaned, if necessary, to its original condition and the item resealed.

800 PREOPERATIONAL CLEANING

801 Preparations

Insofar as practicable, cleaning and flushing operations shall be scheduled so as to minimize interference from other facility operations. Areas in which cleaning operations are being performed shall be isolated and marked to the extent that personnel performing other construction phase operations are aware that the cleaning operations are being conducted.

Personnel shall be familiarized with the intended procedure and associated hazards. Means for communicating shall be provided between the local areas in which the cleaning is performed and any remote areas (e.g., control rooms) that may be related to the cleaning operations. Tools and other loose items in controlled areas shall be controlled as specified in section 700 of this Subpart.

The actual circulating flow path shall be checked for agreement with specified requirements with regard to location, position, and status of all components. Critical valves, controls, and switches shall be tagged to prevent inadvertent actuation during the cleaning operation. The interior of all accessible components (e.g., tanks) and large diameter piping shall be inspected for cleanness. All debris and contamination shall be removed.

Demineralizers, filters, instruments, valve internals, and other items that may be damaged by the cleaning process shall be blanked off, bypassed, or removed. Protective screens shall be installed on the suction side of all pumps and other components that may be subject to damage during the cleaning operations. Instrumentation (e.g., pressure, differential pressure, temperature, and flow) shall be used as necessary to monitor flushing and circulatory cleaning operations. Instrumentation installed in the system but not used to monitor the cleaning operations shall be isolated where necessary. Cleaning of the reactor vessel and reactor vessel internals shall be completed before installation of fuel and control rods.

Provisions shall be made to collect liquid leakage and to prevent wetting of insulation.

Where the use of installed facility components such as pumps may be affected by the cleaning operations, recommendations shall be obtained from the component manufacturers regarding precautions to be taken for the use of their components. Procedures shall be established to protect or isolate installed components that could be adversely affected by cleaning or flushing operations.

802 Flushing and Cleaning Methods

802.1 Flushing. If the intended level of cleanness has been maintained during erection of the facility, only flushing or rinsing will normally be required. The system shall be filled with fluid of the type and quality specified and flushed in accordance with approved procedures. Completion of flushing shall be determined by filter, turbidimetric or chemical analysis, or any combination of these, as applicable.

If flushes are directed toward the large components, provisions shall be made to prevent contaminants from collecting in areas where they cannot be removed in subsequent cleaning operations. Provisions shall be made to ensure that organics do not remain on the surfaces.

After system flushing is completed, but before draining, all pockets and dead legs shall be thoroughly flushed. Where conditioned water is used, particular attention should be given to ensure that large volumes of solvent do not remain trapped in the system.

After cleaning, the item shall be sealed where appropriate to prevent the subsequent entry of contaminants. If no further cleaning is required, system layup shall be performed if specified.

802.2 Alkaline Cleaning. Although it is the intent of those involved in erecting the nuclear facility to install piping systems and components in a clean condition, this may not be fully achieved. Common sources of organic contamination in items are lubrication oils from air tools, preservative films, and valve lubricants. When immediate local cleanup is not performed, full item cleaning to remove such organic contaminants may be necessary. Such cleaning shall be performed according to the cleaning procedures established for the operation, and the procedure shall ensure that quantities of organic contaminants do not remain on the surfaces.

Alkaline cleaning consists of the circulation of an appropriately heated solution until a selected area represented by the worst contamination or a coupon contaminated with the expected contamination is cleaned by the cleaning solution to the specified cleanness level.

After item cleaning is completed, the item shall be flushed with water of the specified quality in accordance with para. 304.1 of this Subpart to remove the cleaning agents. In particular, all pockets and dead legs shall be flushed and attention given to ensure that large volumes of solution do not remain.

Where appropriate, the item shall be sealed to prevent subsequent contamination. If no further cleaning is required, system layup shall be performed, if specified.

Alkaline cleaning compounds that contain free caustic shall not be used on components or systems in which cleaning solutions may be entrapped. Cleaners based on compounds that produce alkaline solutions by hydrolysis, such as phosphate compounds, are acceptable. If heavy organic contaminants are present, the addition of an emulsifier and a wetting agent is required.

802.3 Chelate Cleaning. If chelate cleaning is used, attention shall be given to all pockets and dead legs to ensure that large volumes of solution do not remain in the item. Unless it is considered desirable to leave a film of chelating agent on the surfaces as a protective film, the item shall be flushed with water of a quality consistent with para. 304.1 of this Subpart to remove residual chelating agents.

Where appropriate, items shall be sealed to prevent subsequent contamination. If no further cleaning is required, layup shall be performed, if specified.

Acid-chelating agent shall not be used on welded or furnace-sensitized stainless steels and nickel-based alloys.

900 LAYUP AND POSTLAYUP CLEANING

Upon completion of preoperational cleaning, unless the item is to be released for the next series of operations or tests, the item shall be placed in layup condition by filling with dry, contaminant-free inert gas or air; the process fluid that will be used in the system during operation; fluid of purity equivalent to that used to make up the system; chemically conditioned fluid; or other specified method.

Prior to the next series of operations or tests, residual cleaning solutions or layup media shall be removed, if required, from the item by flushing or by draining and filling until the effluent fluid from the item meets the preoperational test fluid quality requirements for the system.

1000 POSTOPERATIONAL REPAIRS AND MODIFICATIONS

This Subpart does not address radioactive decontamination operations that may be required prior to postoperational repairs or system modifications, although some of its requirements may be applicable to such decontamination operations. For the purposes of maintenance of cleanness as defined in this Subpart, postoperational repairs or system modifications shall be considered identical to preoperational installation procedures and treated in accordance with sections 500, 600, and 700 of this Subpart.

If system cleaning following repair or modification operations is deemed necessary, such cleaning shall be performed in accordance with section 800 of this Subpart, except that flushes directed toward equipment that is particularly sensitive to contaminants (e.g., reactor vessels) shall, to the extent possible, first be preceded with flushes directed away from the equipment until expected contamination is removed and the specified water quality level is achieved. If layup is deemed necessary, it shall be performed in accordance with section 900 of this Subpart.

1100 RECORDS

The following shall be prepared:

(a) record copies of procedures
(b) reports
(c) test equipment calibration records
(d) test deviation or exception records
(e) inspection or examination records
(f) other records necessary to document the cleaning and cleanness history of the items during manufacture, shipment, storage, installation, preoperational cleaning, modifications, and repairs

These records shall be retained with other project records as required by code, standard, specification, or project procedures.

SUBPART 2.2
Quality Assurance Requirements for Packaging, Shipping, Receiving, Storage, and Handling of Items for Nuclear Facilities

100 GENERAL

This Subpart provides amplified requirements for packaging, shipping, receiving, storage, and handling of nuclear facility items. Controls identified within this Subpart shall be applied to maintain acceptable equipment condition. This Subpart supplements the requirements of Part I and shall be used in conjunction with applicable sections of Part I when and to the extent specified by the organization invoking this Subpart.

101 Definitions

The following definitions are provided to ensure a uniform understanding of unique terms as they are used in this Subpart.

barrier: a material designed to withstand the penetration of water, water vapor, grease, or harmful gases.

carrier: the transporting agency.

classification: the organization of items according to their susceptibility to damage during shipping, receiving, and storage only. It does not relate to the function of the item in the completed system.

dynamic load test: a test wherein designated loads are hoisted, rotated, or transported through motions and accelerations required to simulate handling of the intended item.

storage: the act of holding items in storage facilities.

storage facilities: warehouse, yard, or other areas designated and prepared for holding of items.

transportation mode: a method identified by the conveyance used for transportation of items and includes any motor vehicles, ships, railroad cars, or aircraft. Each cargo-carrying body (trailer, van, boxcar, etc.) is a separate vehicle.

wrap: a flexible material formed around the item or package to exclude solid contaminants and to facilitate handling, marking, or labeling.

200 GENERAL REQUIREMENTS

Measures shall be established and implemented for the packaging, shipping, receiving, storage, and handling of specified items to be incorporated in nuclear facilities, and for the inspection, testing, and documentation to verify conformance to specified requirements.

201 Classification of Items (24)

Requirements are divided into four levels with respect to protective measures to prevent damage, deterioration, or contamination of the items based upon the important physical characteristics, and not upon the importance of the item to safety, reliability, and operations. It should be recognized, however, that within the scope of each level there may be a range of controls, and that the detailed requirements for an item are dependent on the importance of the item to safety, reliability, and operation. For example, even though a reactor vessel and structural steel are classified as Level D, the degree of protection and control over the reactor vessel should exceed that of the structural steel. Each of the specific items governed by this Subpart shall be classified into one of these four levels by the purchaser or the contractor. The manufacturer's documented standard or minimum requirements shall be considered when classifying the items. Items, once classified at a level, shall be restricted to that level or a higher level for each of the packaging, shipping, receiving, storage, and handling operations. Any package unit or assembly made up of items of different levels shall be classified to the highest level designated for any of the respective items. If the unit is disassembled, a level shall be indicated for each part.

Items covered by this Subpart shall be categorized under the following levels.

201.1 Level A. Items classified to Level A are those that are exceptionally sensitive to environmental conditions and require special measures for protection from one or more of the following effects: temperatures outside required limits; sudden temperature changes; humidity and vapors; accelerating forces; physical damage; airborne contamination (e.g., rain, snow, dust, dirt, salt spray, fumes).

Types of items to be categorized under this classification level are

(a) special electronic/electrical equipment and instrumentation

(b) special materials, such as chemicals, that are sensitive to environmental conditions

(c) special nuclear material and sources

The requirements of the NRC fuel license and conditions and of other governmental agencies shall be met.

201.2 Level B. Items classified to Level B are those that are sensitive to environmental conditions and require measures for protection from the effects of temperature extremes, humidity and vapors, accelerating forces, physical damage, and airborne contamination, and do not require special protection required for Level A items.

Types of items to be categorized under this classification level are

(a) electronic equipment and instrumentation

(b) electrical equipment

(c) batteries

(d) welding electrode and wire (welding electrodes hermetically sealed in metal containers may be stored under conditions described for Level C, unless other storage requirements are specified by the manufacturers)

(e) control rod drives

(f) motor control centers, switchgear, and control panels

(g) motors and generators

(h) precision machine parts

(i) spares, such as gaskets, O-rings

(j) air-handling filters

(k) computers

201.3 Level C. Items classified to Level C are those that require protection from exposure to the environment, airborne contamination, acceleration forces, and physical damage. Protection from water vapor and condensation is not as important as for Level B items.

Types of items to be categorized under this classification level are

(a) pumps

(b) valves

(c) fluid filters

(d) reactor internals

(e) compressors

(f) auxiliary turbines

(g) instrument cable (unjacketed)

(h) refueling equipment

(i) thermal insulation

(j) fans and blowers

(k) cement

(l) fabricated fuel rods and assemblies

201.4 Level D. Items classified to Level D are those that are less sensitive to the environment than those for Level C. These items require protection against the weather, acceleration forces, airborne contamination, and physical damage.

Types of items to be categorized under this classification level are

(a) tanks

(b) heat exchangers and parts

(c) accumulators

(d) demineralizers

(e) reactor vessel

(f) evaporators

(g) steam generators

(h) pressurizers

(i) piping

(j) electrical cable (jacketed)

(k) structural items

(l) reinforcing steel

(m) aggregates

300 PACKAGING

301 General

This section contains the requirements for packaging of items for protection against corrosion, contamination, physical damage, or any effect that would lower the quality or cause the items to deteriorate during the time they are shipped, handled, and stored. The degree of protection specified will vary according to conditions and duration of storage, shipping environment, and handling conditions.

Implementation of this section is accomplished by identifying the item and the appropriate packaging level, and then applying the appropriate criteria contained herein concerning cleaning, preservatives, desiccants, inert gas blankets, cushioning, caps and plugs, barrier and wrapping materials, tapes, blocking and bracing, containers, marking, other quality assurance provisions, and documentation. When more than one type of item is included in a package (such as equipment shipped with related parts like seals, gaskets, lubricants, or mounting hardware), precautions shall be taken to ensure smaller items are not introduced into openings or cavities of larger parts or equipment.

302 Levels of Packaging

The packaging requirements shall be based on the protection that is necessary during shipping, handling, and storage of the item to satisfy Levels A, B, C, and D protection requirements set forth below. The requirements herein are intended to be in addition to industry classifications or tariff rules for rail, truck, air, and water shipments and regulatory agency rules already established in the transportation industry; and in no way are they intended to reduce the minimum standards established by these regulatory agency rules.

The following packaging criteria are divided into four levels corresponding to the classification categories of para. 201 of this Subpart.

302.1 Level A Items. Level A items require the highest degree of protection and shall conform to the following criteria:

(a) Package design requirements shall be for extraordinary environmental protection to avoid the deleterious effects of shock and vibration, to control temperature or humidity within specified limits, or for any other special requirements.

(b) Items shall have been inspected for cleanness immediately before packaging. Dirt, oil residue, metal chips, or other forms of contamination shall have been removed by approved cleaning methods. Any entrapped water shall have been removed.

(c) Items that are not immediately packaged shall be protected from contamination.

(d) Items requiring protection from water vapor, salt air, dust, dirt, and other forms of contamination penetrating the package shall be packaged with a barrier.

(e) Items that require protection from damage during shipping and handling shall be packaged in containers or crates (see para. 307 of this Subpart).

(f) Items that can be damaged by condensation trapped within the package shall be packaged with approved desiccant inside the sealed waterproof and vaporproof barrier or by an equivalent method.

(g) All openings into items shall be capped, plugged, or sealed. Weld end preparations shall be protected against corrosion and physical damage.

(h) Items packed in containers shall be blocked, anchored, braced, or cushioned to prevent physical damage to the item or barrier.

(i) Items and their container shall be identified by marking.

302.2 Level B Items. Level B items require a high degree of protection, and the package shall be designed to avoid the deleterious effects of shock, vibration, physical damage, water vapor, salt spray, condensation, and weather during shipping, handling, and storage. This packaging shall be equivalent to that for Level A, except that the package design requirements need not be equivalent to satisfy the level of extraordinary environmental protection indicated in para. 302.1(a) of this Subpart where such protection is not justified. Shipment of Level B items in fully enclosed vehicles or equivalent protective enclosure or packaging is acceptable, provided the above-stated high degree of protection for Level B items is maintained throughout shipment, and the shipment goes through to destination in the original vehicle and Level B storage facilities are available on site. If transfer becomes necessary to transit, transfer procedures shall be subject to purchaser acceptance.

302.3 Level C Items. Level C items require protection from exposure to salt spray, rain, dust, dirt, and other contaminants. Protection from water vapor and condensation is less important than for Level B items. The following criteria shall apply:

(a) Criteria (b), (c), (e), (g), (h), and (i) for Level A items (para 302.1 of this Subpart) shall apply to Level C items.

(b) Items shall be packaged with a waterproof barrier so that water, salt spray, dust, dirt, and other forms of contamination do not penetrate the item.

(c) Items subject to detrimental corrosion, either internal or external, shall be suitably protected.

302.4 Level D Items. Level D items require protection from physical and mechanical damage. The following criteria shall apply:

(a) Items, just before packaging, shall have been inspected for cleanness according to the requirements specified in the purchasing document. Dirt, oil residue, metal chips, or other forms of contamination shall have been removed by approved cleaning methods. Any entrapped water shall have been removed.

(b) All openings into items shall be capped, plugged, and sealed. Weld end preparations shall be protected from corrosion and physical damage.

(c) Items subject to detrimental contamination or corrosion, either internal or external, shall be suitably protected.

(d) Items packed in containers shall be blocked, braced, or cushioned to prevent damage.

(e) The identity of the item shall be maintained by marking or other appropriate means.

303 Cleaning

Cleaning includes the preparation of items for preservation or packaging, or both, to minimize the requirements for site cleaning. Items shall be inspected for cleanness immediately before packaging according to the cleaning requirements specified in the procurement documents. Any dirt, oil residue, metal chips, or other forms of contamination shall be removed by documented cleaning methods. Any entrapped water shall be removed.

The following general criteria shall apply as part of the manufacturing specifications for cleaning procedures:

(a) The cleaning process, including cleaning compounds chosen, shall in no way damage the item during cleaning or subsequent service when considering the composition, surface finish, complexity, or other inherent features, or other interface equipment after installation.

(b) The cleaning process or processes chosen shall remove loose mill and heat scale, oil, rust, grease, paint, welding fluxes, chalk, abrasives, carbon deposits, coatings used for nondestructive testing processes, and other contaminants that would render ineffective the

method or preservation and packaging or other specified requirements.

(c) Item surfaces after cleaning shall be free of cleaning media, such as aluminum oxide, silica, grit, cleaning cloth residual, chemical cleaning residue, and petroleum solvent residue, etc.

(d) After cleaning, the item shall be protected from contamination until preservation or packaging is complete.

304 Methods of Preservation

Items subject to deleterious corrosion shall be protected by using either contact preservatives, inert gas blankets, or vaporproof barriers with desiccants.

(24) **304.1 Contact Preservations.** Contact preservatives are compounds applied to bare metal surfaces to prevent surface corrosion during shipping and storage and generally require removal prior to installation.

The following criteria shall be used when considering the type of contact preservative to be used:

(a) The contact preservative shall be compatible with the material on which it is applied.

(b) Contact preservatives that are nondrying shall require a neutral greaseproof protective wrap when packaged.

(c) The procedure for applying contact preservatives shall not require disassembly of the item nor shall it be necessary to disassemble the item at the site for complete removal. An exception would be for long-term storage protection to be agreed upon by the Owner, purchaser, and Manufacturer.

(d) The method of contact preservative removal shall be accomplished with approved solvents and wiping cloths, or by flushing internal cavities with solvents that are not deleterious to the item or other interconnecting material. However, preservatives for inaccessible inside surfaces of pumps, valves, and piping for systems containing reactor coolant water shall be the water-flushable type.

(e) The name of the preservative used shall be provided to facilitate touch-up.

(f) When motors, pumps, turbines, etc., are shipped with oil reservoirs and bearing cavities filled with preservative oil, the item shall be so tagged and instructions for draining, flushing, refilling, and periodic rotation shall be included with the item.

(g) When it is anticipated that the item might require an extended storage period (6 months or longer), a preservative needed for the long-term protection of the item shall be applied or arrangements shall be made to periodically reapply the preservatives.

304.2 Inert Gas Blankets. Purging and pressurizing the interior of an item or its container, or both, with a dry inert gas provides a means of preventing moisture or corrosive atmospheres from acting on sensitive, bare metal surfaces or other materials. The item or its container shall be either evacuated prior to filling with the inert gas or adequately purged with the same gas prior to applying the gas blanket.

When inert gas blankets are used, the following criteria shall apply:

(a) Inert gas blankets shall be used only when the exterior shell of the item or its container can be tightly sealed or an inert gas blanket can otherwise be maintained.

(b) Only dry, oil free, inert gas shall be used.

(c) Provisions shall be made for measuring and maintaining the blanket pressure within the required range and within each pressurized purged item or container. Closures and seals, when used to maintain a static pressure, shall be tightly secured so that the absolute pressure (by mass) after final seal is maintained for 24 hr, without adding gas, prior to shipping the item from the manufacturer's plant.

(d) The item or container shall be marked in bold letters cautioning that an inert gas blanket has been used. The required pressure range also shall be marked on the item or container.

305 Caps, Plugs, Tapes, and Adhesives

These items shall be of materials that enable them to perform their intended function adequately, without causing deleterious effects on the items or system operation.

305.1 Caps and Plugs. Caps and plugs shall be used to seal openings in items having sensitive internal surfaces and to protect threads and weld end preparations.

Caps and plugs shall conform to the following criteria:

(a) Nonmetallic plugs and caps shall be brightly or contrastingly colored. Clear plastic closures are not to be used except when specified for a special purpose, e.g., as a window for humidity indicator cards. Special attention shall be given in the control of these closures.

(b) Metallic plugs and caps contacting metal surfaces shall not cause galvanic corrosion at the contact areas. Gasketing or other nonmetallic materials used in conjunction with metallic caps or plugs shall exhibit no corrosive effect on the material.

(c) Simplicity of installation, inspection, and removal without damage to the item shall be considered.

(d) Provisions shall be made to preclude the plug or cap from falling into or being pushed into the opening after its installation.

(e) Plugs or caps shall be secured with tape or other means as necessary to prevent accidental removal.

(f) All plugs and caps shall be clean and free of visible contamination such as, but not limited to, dust, dirt, stains, rust, discoloration, or scale.

(g) Plugs and caps used in contact with austenitic stainless steel or nickel alloys shall be made from nonhalogenated materials or stainless steel.

(h) Caps and plugs shall be clearly visible, e.g., not painted over, during production processes. Caps and plugs that have been painted over shall be replaced or otherwise be made clearly visible.

305.2 Tapes and Adhesives. Pressure-sensitive, removable tape shall be used in lieu of adhesives in contact with bare metal surfaces. Tapes or adhesives that could have damaging effects on the item or system shall not be used. Tapes near a weld shall be removed completely, immediately prior to performing a weld. Tapes used for identification rather than sealing that are not near a welding operation may remain until system testing is complete, but shall be removed before facility operations unless qualified for operating conditions.

Tapes and adhesives shall conform to the following criteria:

(a) When contacting austenitic stainless steel and nickel alloy surfaces

(1) tapes shall not be compounded from, or treated with chemical compounds containing elements in such quantities that harmful concentrations are leachable, or that they could be released by breakdown under expected environmental conditions and could contribute to intergranular cracking or stress corrosion cracking, such as those containing fluorides, chlorides, sulfur, lead, zinc, copper, and mercury [paperbacked (masking) tape shall not be used]

(2) upon removal of tape, all residual adhesive shall be removed by wiping with a nonhalogenated solvent (acetone, alcohol, or equal)

(3) starch, silicone, and epoxy tape material may be used for tape adhesive

(b) When contacting other surfaces and containers

(1) tapes and adhesives used to seal nonaustenitic materials, nickel alloys, or containers are not subject to the above restrictions

(2) tape shall be impervious to water and not subject to cracking or drying out if exposed to sunlight, heat, or cold

(c) When used on surfaces of items, tapes shall be visibly distinguishable from the materials on which they are used.

306 Barrier and Wrap Materials and Desiccants

Material thickness shall be selected on the basis of type, size, and weight of equipment or item to be protected, such that the barrier or wrap will not easily be damaged by puncture, abrasion, weathering, cracking, temperature extremes, wind conditions, and the like. Barrier and wrap materials shall be noncorrosive and shall not be otherwise harmful to the item packaged. When barrier and wrap materials are used in direct contact with austenitic stainless steels, the total and water leachable content of halogen shall not be harmful to the item packaged. Also, barrier and wrap materials shall not readily support combustion. Vaporproof barrier materials used with desiccants constitute another preservation system that protects against potential damage by water vapor condensate.

306.1 Waterproof Barrier Material. Waterproof barrier material shall be resistant to grease and water; it shall protect items from airborne and windblown soils.

306.2 Vaporproof Barrier Material. Vaporproof barrier materials shall be sealable, and the edge of the barrier that normally will be opened at destination shall be of sufficient area to permit at least two subsequent sealing operations. When maximum vapor protection is required, barrier material shall meet the maximum water vapor transmission rate of 0.05 g/100 in.^{2} per 24 hr required by ASTM E96, Test Methods for Water Vapor Transmission of Materials, Procedure E, and shall be packaged with an approved desiccant. Vaporproof barrier material should be colored to contrast with the material on which it is used.

306.3 Desiccants. Desiccants shall be used within a vaporproof barrier when condensation or high humidity could damage an item by corrosion, mold, or mildew. (24)

Desiccants shall consist of nondeliquescent, nondusting, chemically inert, dehydrating agents. The following criteria shall apply:

(a) The desiccant bag shall be made of puncture-, tear-, and burst-resistant material.

(b) When used with austenitic stainless steel and nickel alloy materials, tapes, desiccants, and the materials for the desiccant bag shall not be compounded from or treated with chemical compounds containing elements in such quantities that harmful concentrations are leachable, or they could be released by breakdown under expected environmental conditions and could contribute to intergranular cracking or stress corrosion cracking, such as those containing fluorides, chlorides, sulfur, lead, zinc, copper, and mercury.

(c) The reactivation temperature and time shall be marked on the desiccant container.

(d) Canisters used to contain desiccants shall be placed so as to cause no deleterious effects such as galvanic corrosion, even when the desiccant has reached its absorptive capacity for water vapor.

(e) Desiccant bags and canisters, when used, shall be secured to prevent movement, rupture of the bags, or damage to the item being protected.

(f) Waterproof and vaporproof barriers shall be used to seal items containing desiccants. The included air volume within the barrier shall be kept to a minimum.

(g) Items that contain desiccants shall have all openings securely sealed. When flange connections are a part of the barriers, O-rings or gaskets shall be used with all bolts in place and tightened sufficiently to ensure a waterproof and vaporproof seal. Weld end preparations, after

capping, shall be covered with a waterproof and vaporproof seal.

(h) Packages and items containing desiccants shall be marked. The total number of separate bags or containers of desiccants in the package shall be indicated.

(i) The minimum quantity of desiccant for use in each package shall be determined in accordance with Formula I or Formula II, as applicable.

(1) Formula I: to determine minimum units of desiccant for use with other than sealed rigid metal barrier:

$$U = 1.6A + XD \quad (1)$$

(2) Formula II: to determine minimum units of desiccant for use with sealed rigid metal barrier:

$$U = KV + XD \quad (2)$$

where

A = area of barrier, ft^2 ($m^2 \times 0.0929$)
D = dunnage (other than metal) within barrier, lb (kg × 2.2)
K = 0.0007 when volume is given in $in.^3$
= 1.2 when volume is given in ft^3
= 0.0000425 when volume is given in cm^3 (42.5 in m^3)
U = number of units of desiccant to be used (see Note)
V = volume within barrier in $in.^3$ or ft^3 (cm^3 or m^3)
X = 8 for hair felt, cellulosic material (including wood), and other material not categorized below
= 6 for bound fibers (animal hair, synthetic fiber, or vegetable fiber bound with rubber)
= 2 for glass fiber
= 0.5 for synthetic foams and rubber

NOTE: A *desiccant unit* is that quantity of desiccant, as received, that will absorb at equilibrium with air at 78°F (25°C) at least the following quantities of water vapor: 3.00 g at 20% relative humidity and 6.00 g at 40% relative humidity.

(j) A humidity indicator or detector shall be included in every waterproof and vaporproof envelope containing desiccant. As applicable, the indicator or detector shall be located behind inspection windows or immediately within the closing edge, face, or cover of the barrier and, as far as practical, from the nearest unit of desiccant to provide an effective warning of excessive moisture.

307 Containers, Crating, and Skids

307.1 Containers. Containers shall be used when maximum protection for the item or its barrier is required. Container types shall include, but not be limited to, the following:

(a) cleated, sheathed boxes [500 lb (227 kg) maximum net weight]
(b) nailed, screwed, or bolted wood boxes
(c) wood-cleated solid fiberboard boxes
(d) metal or fiber drums
(e) crates
(f) wire-bound boxes [200 lb (91 kg) maximum net weight]
(g) other specially designed containers for special equipment
(h) fiberboard boxes [120 lb (54.5 kg) maximum net weight]. The following criteria shall apply for fiberboard boxes used as exterior containers:

(1) Boxes shall be weather-resistant fiberboard preferably from the grade types (or compliance symbol): V2 s, V3 s, or V3 c (ASTM D5118 and ASTM D1974).

(2) Box style shall be RSC regular slotted box (outer flaps meet, inner flaps and outer flaps are of equal length).

(3) Fiberboard boxes shall be securely closed with a water-resistant adhesive applied to the entire area of contact between the flaps. All seams and joints shall be further sealed with not less than 2 in. (5 cm) wide, water-resistant tape.

(4) Boxes shall be strapped with pressure-sensitive reinforced tape, lengthwise (top, bottom, and ends), girthwise (top, bottom, and sides), and horizontal sides and ends.

(5) Wood cleating on fiberboard boxes shall be fabricated from structurally sound, seasoned or treated lumber. Cleated boxes in excess of 50 lb (22.7 kg) shall be bound with steel strapping, or equivalent, around the container at not less than two places.

307.2 Crates and Skids. Crates or skids shall be used for equipment in excess of 500 lb (227 kg). Skids or runners shall be used on crates with a gross weight of 100 lb (45.5 kg) or more, allowing a minimum floor clearance for forklift tines as provided by 4 in. (10 cm) lumber.

308 Cushioning, Blocking, Bracing, and Anchoring

308.1 Cushioning. Cushioning shall be used where protection from shock and vibration is required. The cushioning materials shall have sufficient strength to perform this function.

Selection of cushioning material shall be based on the following:

(a) It shall exhibit no corrosive effect when in contact with the item being cushioned.
(b) It shall have low moisture content and exhibit low moisture absorption properties, or if the cushioning material has some moisture-absorbing capacity, the item shall be protected with a water-vaporproof barrier.
(c) It shall have negligible dusting characteristics.
(d) It shall not readily support combustion.

308.2 Blocking and Bracing. Blocking and bracing used for protection of the load to be supported shall be compatible with the size, shape, and strength of bearing areas of the shipment. The blocking and bracing used to prevent item movement shall withstand thrust and impact applied in any direction. Blocking and

bracing used in direct contact with the item being blocked shall not have a corrosive effect on the item.

308.3 Anchoring. Anchoring of the item within a crate or on a skid shall adequately fasten the item during shipment and protect the item from potential damage due to rough handling.

When bolts are used for anchoring, the following criteria shall apply:

(a) If precision bolt holes in the item are used for anchoring, precaution shall be taken to ensure that properly fitting bolts of the correct dimension and characteristics are used to prevent marring or elongation of the holes.

(b) Holes bored through containers or mounting bases shall provide a snug fit.

(c) When mounting items to container bases equipped with skids, bolts shall be extended through the skids whenever practical. In such instances, countersinking of the bolts in the sliding surface of the skid shall be done.

(d) Washers shall be used under the nuts to decrease the possibility of the bolt pulling through the wood.

(e) Nuts shall be properly tightened. To prevent their loosening during shipment, locknuts, lock washers, cotter pins, or staking shall be employed.

Temporary cushioning, blocking, bracing, or anchoring placed on an item for shipping protection that needs to be removed prior to operation of the item shall be identified by warnings placed in a conspicuous manner to affect proper removal of the packing material.

(24) **309 Marking**

(a) To maintain proper identification and instructions, or both, during shipping, receiving, and storage and to provide for identification after the outside of the container has been removed, the item and the outside of the containers shall be marked. If equipment does not lend itself to marking, records shall be maintained that are uniquely identifiable to the item.

(b) Items shall be marked to preserve identity in accordance with the following criteria:

(1) The specified identification shall be stamped, etched, stenciled, or otherwise marked on the item or on tags to be affixed securely to the item in plain, unobstructed view. When metal stamps are employed, low stress stamps shall be used when the item proper is marked. When vibrating marking tools are used, they shall be fitted with carbide marking tip or its equivalent, and shall be designed to provide a rounded impression not to exceed 0.010 in. (0.25 mm) in depth. Etching, including electrochemical etching on nickel alloys, weld areas, or sensitized areas of stainless steel, may only be used, provided appropriate cleaning is performed of etching solutions. Electric-arc marking pencils shall not be used.

(2) The marking shall neither be deleterious to the material nor violate any other section of this Subpart.

(3) When tags are employed, they shall be of a material that will retain the marking; will withstand weather, deterioration, and other normal handling, storage, and shipping effects; and will not be detrimental to the item.

(4) The English language shall be used. Duplicate marking may be made in other languages.

(5) References to weights shall be in avoirdupois units. Duplicate markings in other systems may also be indicated.

(c) Markings on the outside container shall be in accordance with the following criteria:

(1) Container markings shall appear on a minimum of two sides of a container, preferably on one side and one end.

(2) The English language shall be used. Duplicate marking may be made in other languages or in pictorial marking according to ISO Recommendation R780, Pictorial Markings for Handling of Goods (General Symbols) or ASTM D5445.

(3) References to weights shall be in avoirdupois or System International (SI) units. Duplicate markings in other systems may also be indicated.

(4) Container markings shall be applied with waterproof ink or paint in characters that are legible. When information relative to handling and special instructions is required, such information shall be preceded by the word CAUTION in letters that are at least $\frac{1}{2}$ in. (12.7 mm), as permitted by container size.

(5) Where tags or labels are used, they shall be affixed to the container using a waterproof adhesive, tacks where practical, or a corrosion-resistant wire.

(6) Container markings shall include the following information:

(-a) destination

(-b) return address

(-c) package numbers showing the purchase order number, followed by the package number and the total number of packages

(-d) material identification number

(-e) handling instructions (e.g., Fragile, Center of Gravity, Keep Dry, This Side Up, Sling Here, Do Not Freeze) and stacking limitations, as appropriate

(-f) weight of package [in excess of 100 lb (45.5 kg)]

(-g) special instructions (Desiccant Inside, Remove Items Packaged Inside Prior to Installation, Remove Caps and Plugs Prior to Installation, Special Inspection, Storage, Unpacking Restrictions, etc.) as appropriate; if items are repackaged for storage, provisions shall be made for retention or transfer of the special instructions

(d) Marking of items not within a container, such as pipe, tanks, and heat exchangers, shall exhibit specified information in a location that is in plain unobstructed view. Marking may be applied directly to bare metal

surfaces, provided it has been established that the marking material is not deleterious to the item.

400 SHIPPING

401 General

This section covers the requirements for loading and shipment of items as defined in para. 201 of this Subpart.

The mode of transportation used shall be consistent with the protection classification of the item and with the packaging methods employed. Special shipping instructions from the manufacturer, approved alternatives should be addressed while meeting the requirements of section 400 of this Subpart.

402 Transportation Requirements

402.1 Open Carriers. For shipment on open carriers where items may be exposed to adverse environmental conditions, the following shall apply:

(a) Levels A, B, and C items shall be covered for protection from environmental conditions. Tarpaulins, when used, shall be fire retardant, and they shall be installed in a manner to provide drainage and to ensure air circulation to prevent condensation.

(b) Barrier and wrapped materials subject to transportation damage shall be covered with waterproof shrouds, such as tarpaulins, so that they are not exposed directly to the environment.

402.2 Closed Carriers. For shipment on closed carriers, the following shall apply:

When Levels A, B, and C items cannot be adequately protected from weather or environment on open carriers, closed carriers or fully enclosed vehicles shall be used.

402.3 Special Shipments. Items that exceed established weight or size limitations for railroads or highways or require special handling shall be given additional consideration in the following areas:

(a) The type of bracing and tie-down methods to be used with the mode of transportation selected for special shipments shall be specified.

(b) NO HUMPING shall be specified on rail shipments of these items, and NO HUMPING signs shall be prominently displayed.

(c) Use of impact recording devices shall be specified on shipments of heavy or relatively large items incorporating delicate factory-installed instrumentation. Devices, when specified, shall be installed prior to loading (to record any rough handling during loading). Procedures shall be established to interpret recorded data and to thoroughly check the integrity of an item when there is evidence of rough handling. A notice that impact recording devices are being used shall be prominently displayed. Special recording devices with operating time limits greater than the expected transit time shall be specified or, if the expected transit time exceeds the operating time limit of the recorders being used, provisions shall be made to service the devices during transit.

(d) For special shipments, the conveyance used for transport shall be certified to be structurally adequate to take the loads imposed during loading, while en route, and during unloading. Prior to shipment, the route shall have been investigated to ensure safe transit.

403 Precautions During Loading and Transit

403.1 Loading. The weight, lifting points, or center of gravity indicated by the shipper on the crate, skid, or package by the shipper shall be utilized to ensure proper handling during loading, transfer between carriers, and unloading.

403.2 Rigging. Carbon steel rigging equipment shall not come in direct contact with stainless steel, except when attached to lifting lugs, eyes, or pads in order to avoid surface damage.

403.3 Handling Precautions. All austenitic stainless steel and nickel-base alloy materials shall be handled in such a manner that they are not in contact with lead, zinc, copper, mercury, or other low melting point elements, carbon steel, alloys, or halogenated material having a water-leachable content harmful to the material.

403.4 Package and Preservative Coatings. Package or preservative coatings shall be visually inspected after loading and damaged areas repaired prior to shipment. Items shipped with desiccants shall be inspected after loading to ensure that sealed areas are intact.

403.5 Sealed Openings. Sealed openings shall be visually inspected after loading to ensure closures are intact. Materials used for resealing shall be in accordance with section 300 of this Subpart.

403.6 Stacking. Where special care is deemed necessary to avert damage, written instructions concerning the location or stacking limits for crates or boxes shall be marked on the containers.

403.7 Theft and Vandalism. Precautions shall be taken to minimize the possibility of theft and vandalism during shipment of items.

404 Identification and Markings

Identification and markings on the outside of all packages, skids, or protective covering shall be maintained.

405 Nuclear Material Shipments (24)

Special nuclear material and sources shall be shipped as specified by the Regulatory Authority having jurisdiction.

500 RECEIVING

501 General

This section covers the requirements that shall be fulfilled by the organization(s) responsible for the receiving of items. Receiving starts when the items arrive at a storage facility or construction site before unloading or unpacking.

502 Receiving Inspection Requirements

502.1 Shipping Damage Inspection. Preliminary visual inspection shall be performed prior to or immediately after unloading to determine if any damage occurred during shipping. Observations for unusual conditions shall include the following:

(a) fire: charred paper, wood, or paint, indicating exposure to fire or high temperature

(b) excessive exposure: weather-beaten, frayed, rusted, or stained containers, indicating prolonged exposure during transit

(c) environmental damage: water or oil marks, damp conditions, dirty areas, or salt film, indicating exposure to sea water or winter road salt chemicals

(d) tie-down failure: shifted, broken, loose, or twisted shipping ties, and worn material under ties, indicating improper blocking and tie down during shipment

(e) rough handling: splintered, torn, or crushed containers, indicating improper handling

(f) review of impact recording device readings against established criteria

(g) review of humidity recording data against established criteria

(24) **502.2 Item Inspection**

(a) Unless the package marking prohibits unpacking, the contents of all shipments shall be visually inspected to verify that the specified packaging and shipping requirements have been maintained. When items are contained in transparent, separate, moistureproof bags or envelopes, visual inspection without unpacking the contents shall be acceptable. Where specific inspection requirements can be achieved, statistical sampling methods may be used for groups of similar items. Care shall be taken to avoid contamination of the items during inspection. The inspection shall be performed in an area equivalent to the level of storage requirement for the item. If an appropriate area is not available, the inspection shall be performed in a manner and environment that does not endanger the required quality of the item. These inspections and examinations shall include the following, as appropriate:

(1) identification and marking: verification that identification and markings are in accordance with applicable codes, specifications, purchase orders, and drawings, and with requirements in this Part (Part II).

(2) manufacturing documentations: assurance that the item received was fabricated, tested, and inspected prior to shipment in accordance with applicable code, specification, purchase order, or drawings.

(3) protective covers and seals: visual inspection to ensure that covers and seals meet their intended function.

(4) coatings and preservatives: verification that coatings and preservatives are applied in accordance with specifications, purchase orders, or manufacturer's instructions.

(5) inert gas blanket: verification that the inert gas blanket pressure is within the acceptable limits.

(6) desiccant: verification that the desiccant is not saturated, as indicated, through the use of humidity indicators. Desiccants shall be regenerated or replaced as necessary in accordance with special instructions.

(7) physical damage: visual inspection to ensure that parts of items are not broken, cracked, missing, deformed, or misaligned, and that rotating parts turn without binding. Accessible internal and external areas shall be free of detrimental gouges, dents, scratches, and burrs.

(8) cleanness: visual inspection to ensure that accessible internal and external areas are within the specification requirements for dirt, soil, mill scale, weld splatter, oil, grease, or stains. If inspection for cleanness was performed prior to sealing and shipping, and inspection upon receipt indicates that there has been no penetration of the sealed boundary, then inspection for internal cleanness is optional.

(b) Unless the completed item was inspected at the source by the purchaser or the purchaser's representative, it shall be inspected upon receipt to verify that the following characteristics conform to the specified requirements. These inspections shall include such items as

(1) physical properties: assurance that physical properties conform to the specified requirements and that chemical and physical test reports, if required, meet the requirements

(2) dimensions: random visual inspection to ensure that important dimensions conform with drawings and specifications, i.e., baseplate mounting holes, overall external size, and configuration and orientation of parts

(3) weld preparations: random verification that weld preparations are in accordance with applicable drawings and specifications

(4) workmanship: visual inspection of accessible areas to ensure that the workmanship is satisfactory to meet the intent of the requirements

(5) lubricants and oils: verification of presence of proper lubricants and oils, if required, by either specification, purchase order, or manufacturer's instructions

(6) electrical insulation: performance of insulation resistance tests for motors, generators, and control and power cable to ensure conformance with specifications

502.3 Special Inspection. Where receiving inspection in addition to that described above is required, the special inspection procedure, complete with documentation instructions, shall be attached to the item or container. This is in addition to the copy sent through normal channels. The special inspection shall be performed, and the results of the inspection shall be documented.

503 Disposition of Received Items

503.1 Acceptable. Containers and items inspected and found in conformance with specified requirements shall be identified as acceptable and placed in a storage area for acceptable items, or moved to the final location for installation or use.

503.2 Nonconforming. Items that do not conform to the specified requirements shall be controlled in accordance with Part I, Requirement 15 of this Standard.

503.3 Conditional Release. If the nonconformance that caused the item to be classified unacceptable can be corrected after installation, the item may be released for installation on a conditional release basis. A statement documenting the authority and technical justification for the Conditional Release of the item for installation shall be prepared and made part of the documentation.

(24) **504 Status-Indicating System**

A status-indicating system shall be used for identifying the status of items (e.g., an inventory management system, tagging, labeling, color coding, etc.). The system shall clearly indicate whether items are acceptable or unacceptable for installation. A controlled physical separation is an acceptable equivalent method. The system shall provide for indication of the date the item was placed in the acceptable or unacceptable installation status and the conditional release of the items for installation pending the subsequent correction of the nonconformance. When tags are used, the stock shall be made from material that will not deteriorate during storage. The stock used shall not be deleterious to the item. Tags shall be securely affixed to the items and displayed in an area that is readily accessible.

505 Marking

Changing, correcting, or any other marking on nameplates shall be prohibited, unless authorized by the manufacturer of the item.

506 Documentation

A written record of the receiving inspection, package identification, tagging, corrective actions, and justification for conditional acceptance shall be prepared.

600 STORAGE

601 General

601.1 Scope. This section contains requirements that shall be fulfilled by the organization responsible for performing the storage of items. Levels and methods of storage are defined to minimize the possibility of damage or lowering of quality due to corrosion, contamination, deterioration, or physical damage from the time an item is stored upon receipt until the time the item is removed from storage and placed in its final location. Special storage instructions from the manufacturer, if specified, shall be addressed as part of the storage process for both short- and long-term storage of items.

601.2 Levels of Storage. Environmental conditions for items classified as Levels A through D shall meet the requirements as described in the following paragraphs:

(a) Level A items shall be stored under special conditions similar to those described for Level B items but with additional requirements such as temperature and humidity control within specified limits, a ventilation system with filters to provide an atmosphere free of dust and harmful vapors, and any other appropriate requirements.

(b) Level B items shall be stored within a fire-resistant, tear-resistant, weather-tight, and well-ventilated building or equivalent enclosure. Precautions shall be taken against vandalism. This area shall be situated and constructed so that it will not be subject to flooding; the floor shall be paved or equal, and well drained. Items shall be placed on pallets or shoring to permit air circulation. The area shall be provided with uniform heating and temperature control or its equivalent to prevent condensation and corrosion. The minimum temperature shall be 40°F (5°C), and the maximum temperature shall be 140°F (60°C) or less if so stipulated by the manufacturer.

(c) Level C items shall be stored indoors or in an equivalent environment with all provisions and requirements as set forth for Level B items, except that heat and temperature control is not required.

(d) Level D items may be stored outdoors in an area marked and designated for storage that is well drained, preferably gravel covered or paved, and reasonably removed from the actual construction area and traffic so that the possibility of damage from construction equipment is minimized. Items shall be stored on cribbing or equivalent to allow for air circulation and to avoid trapping water.

602 Storage Areas

Periodic inspections shall be performed to ensure that storage areas are being maintained in accordance with applicable requirements.

602.1 Access to Storage Areas. Access to storage areas for Levels A, B, and C items shall be controlled and limited only to personnel designated by the responsible organization. Access to storage areas involving Level D items shall be controlled as designated by the responsible organization.

602.2 Cleanliness and Housekeeping Practices. Cleanliness and good housekeeping practices shall be enforced at all times in the storage areas. The storage areas shall be cleaned as required to avoid the accumulation of trash, discarded packaging materials, and other detrimental soil.

602.3 Fire Protection. Fire protection commensurate with the type of storage area and the material involved shall be provided and maintained.

602.4 Storage of Food and Associated Items. The use or storage of food, drinks, and salt tablet dispensers in controlled storage areas shall not be permitted.

602.5 Measures to Prevent Entrance of Animals. Measures shall be taken to prevent the entrance of rodents and other animals into indoor storage areas or equipment to minimize possible contamination and mechanical damage to stored material.

603 Storage Methods

Storage methods and procedures shall comply with the requirements described in paras. 603.1 through 603.6 of this Subpart.

603.1 Ready Access to Stored Items. All items shall be stored in such a manner as to permit ready access for inspection or maintenance without excessive handling to minimize risk of damage.

603.2 Arrangement of Items. Items stacked for storage shall be arranged so that racks, cribbing, or crates are bearing the full weight without distortion of the item.

603.3 Storage of Hazardous Material. Hazardous chemicals, paints, solvents, and other materials of a like nature shall be stored in well-ventilated areas and not in close proximity to important nuclear facility items.

603.4 Identification. Items and their containers shall be plainly marked so that they are easily identified without excessive handling or unnecessary opening of crates and boxes.

603.5 Coverings. Weatherproof coverings, when used for outdoor storage, shall be the flame-resistant type of sheeting or tarpaulins. They shall be placed so as to provide drainage and to ensure air circulation to minimize condensation. They shall be tied down to prevent moisture from entering laps and to protect the coverings from wind damage.

603.6 Outdoor Storage. Items stored outdoors shall be positioned or covered to avoid trapping moisture in pockets or internally. For example, valves shall be positioned such that water does not collect under the bonnet but can drain from the valve packing area.

604 Control of Items in Storage

Control of items in storage is described in paras. 604.1 through 604.3 of this Subpart.

604.1 Inspections. Inspections shall be performed and documented on a periodic basis to ensure that the integrity of the item and its container, as provided for under section 300 of this Subpart, is being maintained. Deficiencies noted shall be corrected and documented. The characteristics verified during this inspection shall include such items as

(a) identification and marking
(b) protective covers and seals
(c) coatings and preservatives
(d) desiccants and inert gas blankets
(e) physical damage
(f) cleanliness

604.2 Care of Items. Requirements for proper maintenance during storage shall be documented. Care of items in storage (includes storage in place) shall be exercised in accordance with the following:

(a) Items in storage shall have all covers, caps, plugs, or other closures intact. Methods used to seal openings shall be in accordance with section 300 of this Subpart. Covers removed for internal access shall be immediately replaced and resealed after completion of the purpose for removal.

(b) Temporary preservatives shall be left intact during storage. Should reapplication of preservatives be required at the site, only those previously approved shall be used.

(c) Items pressurized with inert gas shall be monitored at such a frequency as to ensure that the gas pressure is maintained within specified limits during storage. Desiccant humidity indicators shall also be monitored, and desiccants shall be changed or reprocessed when specified.

(d) Instrumentation racks shall be energized as specified by the manufacturer.

(e) Space heaters enclosed in electrical items shall be energized.

(f) Rotating electrical equipment shall be given insulation resistance tests on a scheduled basis.

(g) The shafts of rotating equipment shall be rotated on a periodic basis. The degree of turn shall be established so that the parts receive a coating of lubrication, where applicable, and so that the shaft does not come to rest in a previous position (90-deg and 450-deg rotations are examples).

(h) Other maintenance requirements specified by the manufacturer's instructions for the item shall be performed.

604.3 Post-Fire Evaluation. In the event that a fire should occur in the storage area at any time, each item known to have been heated to an ambient temperature of over 150°F (65°C) or subjected to smoke contamination shall be withheld from installation or use until it has been thoroughly examined, and the item has been verified to be in conformance with specified requirements.

605 Removal of Items From Storage

Only items that have been inspected and are considered acceptable for installation or use in accordance with the receiving inspection procedure shall be removed from storage for installation or use (see section 500 of this Subpart). Items released from storage and placed in their final locations and items stored in place within the nuclear facility shall be inspected and cared for in accordance with the requirements of paras. 604.1 and 604.2 of this Subpart and other standards, as applicable.

606 Storage Records

Written records shall be prepared that include such pertinent information as storage location, results of inspections, results of in-storage maintenance to include the results of configuration control activities for the item while in storage, protection requirements, changes in item ownership including (if applicable) certificates of conformance, and personnel authorized access to the storage location(s).

700 HANDLING

The requirements that shall be fulfilled by the organizations responsible for handling items are contained in Part II, Subpart 2.15.

800 RECORDS

Record copies of procedures, reports, personnel qualification records, test equipment calibration records, test deviation or exception records, storage and maintenance records, and inspection records shall be prepared as required by this Subpart. These records shall be retained with other project or operations records as required by code, standard, specification, or project procedures.

SUBPART 2.3
Quality Assurance Requirements for Housekeeping at Nuclear Facilities

100 GENERAL

This Subpart provides housekeeping requirements for the control of work conditions and environments that can affect the quality of important parts of a nuclear facility. It supplements the requirements of Part I and shall be used in conjunction with applicable sections of Part I when and to the extent specified by the organizations invoking this Subpart.

200 GENERAL REQUIREMENTS

Housekeeping encompasses activities related to the control of cleanliness of the site area, the facility, materials, and equipment and fire prevention and protection, including collection and disposal of combustible material and debris, control of access to areas, and protection of equipment. Housekeeping activities shall include documented methods and techniques for control of the site area, the facility, and the materials and equipment being incorporated in the facility to preserve the requisite quality of the items being constructed or installed. Personnel working in zone-controlled areas shall be familiar with the necessities and requirements for cleanness control applicable to the various zones. Training programs shall be used for this purpose, where appropriate.

201 Planning and Procedures

Planning and procedure preparation shall be in accordance with the requirements of the Introduction to this Part (Part II). Procedures and instructions shall contain sufficient detail to provide for control of the site area, the facility, and the materials and equipment being incorporated in the facility to preserve the requisite quality of the item being constructed or installed. Procedures and instructions providing for the control of site areas, site preparation, fire prevention and protection, and records shall be in force with the start of the construction activity. Other procedures and instructions shall be prepared and approved no later than the start of equipment installation work.

202 Classification of Cleanness

Cleanness requirements for housekeeping activities shall be established on the basis of the following zone designations. The five zones are primarily for construction and generally not applicable for the operations. The timing for implementation of the zone designations shall be as required by the need for cleanness.

	Zones				
Restriction List	**I**	**II**	**III**	**IV**	**V**
Clothing change	Yes	No	No	No	No
Clean gloves, shoe covers, head covering	Yes	Yes	No	No	No
Filtered air	Yes	No	No	No	No
Material precleaning	Yes	Yes	No	No	No
Material accountability	Yes	Yes	Yes	No	No
Personnel accountability	Yes	Yes	Yes	No	No
Use of tobacco or eating	Yes	Yes	Yes	Yes	No

(a) Zone I. Areas requiring the highest order of cleanness shall be equipped with a clean clothing change facility at the vestibule or entrance. Such areas shall provide for complete outer change of clothing by personnel, including the use of shoe covers, head covers, and gloves to protect all equipment surfaces from outside contamination. Material entering this zone shall have been appropriately cleaned prior to entry.

(b) Zone II. Intermediate cleanness requirements less restrictive than Zone I, but where foreign matter may have detrimental effects.

(c) Zone III. Areas less restrictive than Zones I and II, but requiring access control over personnel and materials.

(d) Zone IV. Areas where it is desired to regulate the use of tobacco and eating of food for material and equipment protection or for health and fire hazards.

(e) Zone V. Unrestricted construction areas requiring good construction site housekeeping practices only.

300 REQUIREMENTS

301 Control of Site Area

Areas for specific activities shall be assigned and regulated. Areas that shall be designated include, where appropriate, refuse and garbage dumps, refuse burning sites, storage locations, parking lots, eating places, nonsmoking areas, subcontractor work areas, common areas, and waste collection container locations. Personnel entrance to controlled areas, admission of visitors to the work site, and identification of all personnel shall be controlled in accordance with established procedures and instructions.

For Zones I, II, and III a written record of the entry and exit of all personnel and material shall be established and maintained.

Grading, drainage, roads, construction facilities, facility fencing, and utilities shall be provided in accordance with specified requirements and shall be maintained as required in good condition throughout the construction phase or until replaced with the permanent facilities.

302 Control of Facilities

Control of work and storage areas where important items are handled shall be established and maintained to conform to the appropriate zone defined in para. 202 of this Subpart. Atmospheric control shall be provided where necessary.

The control of tools, equipment, materials, and supplies that are used in Zones I, II, and III shall be maintained to prevent the inadvertent inclusion of deleterious materials or objects in critical systems. Appropriate control measures shall be provided through use of such items as log books and tethered tools.

302.1 Cleanness. The work areas shall be kept sufficiently clean and orderly so that construction activity can proceed in an efficient manner that will produce and maintain quality in conformance with specified requirements. Where large accumulations of materials occur on a nonroutine basis, such as the stripping of concrete forms, the material shall be promptly removed or stored neatly. Garbage, trash, scrap, litter, and other excess materials shall be collected, removed from the job site, or disposed of in accordance with specified requirements or planned practices. Such excess material shall not be allowed to accumulate and create conditions that will adversely affect quality. The disposal of cleaning chemicals shall be accomplished so additional hazards are not created at the disposal site.

302.2 Environment. Areas of activity shall be adequately lighted, ventilated, protected, and accessible as appropriate for the work being performed. Temporary lighting may be used but shall be installed and maintained to provide good visibility. Ventilation shall be provided where necessary to prevent accumulation of dust, noxious fumes, and temperature extremes. Adequate working space for construction personnel shall be provided using proper work scaffolds and platforms having accessibility by stairs or ladders. Barriers, screens, shields, restricted access, or other protection shall be provided as necessary for isolation of areas where noise, welding arcs, dust, inclement weather, or other conditions may affect the quality of work being performed.

302.3 Fire Protection and Prevention. Equipment and instruction for the protection from, and prevention of, damage by fire shall be provided in accordance with the requirements of the NFPA National Fire Codes. Procedures or instructions for fire protection shall include provisions for fighting fires involving the use of available community fire departments, trained project brigades, and others. Procedures or instructions shall include plans for provision of water supplies, hydrants, automatic sprinklers, access for firefighting, and distribution of extinguishers and firefighting equipment. Fire surveillance during and immediately following operations such as welding and heat treating shall be provided when materials are located where flames, flying sparks, weld spatter, or excessive heat resulting from the operation could cause combustion, with resulting damage to items of the nuclear facility. Fire protection facilities shall be in service beginning with the initial stages of permanent construction. Prefire planning shall be conducted as a requirement of the fire protection procedures or instructions, which shall include evacuation of confined areas.

303 Material and Equipment

Materials and equipment delivered to the work area shall be so positioned, or protected when necessary, to ensure that the quality of the item will not be degraded by the construction activity. The cleaning of important materials and equipment for the facility that is necessary during receiving, storage, and handling activities shall be in accordance with applicable requirements.

304 Construction Tools, Supplies, and Equipment

The use, location, and deployment of construction tools, supplies, and equipment shall be controlled to keep access and work areas clear and to prevent conditions that will adversely affect quality. These provisions shall include, but are not limited to, such items as the movement of materials to the work area, welding and stress-relieving leads, power leads, temporary heating equipment, pumps, air and water hoses, welding machines, air compressors, hoisting equipment, air tools, grinding tools, and burning tools.

305 Surveillance and Inspections

Periodic inspection of work areas and construction practices shall be performed at scheduled intervals to ensure adequacy of cleanness and housekeeping practices. These inspections shall include the following, as appropriate:

(a) inspection of construction site roads, accessways, and ramps for conditions that may result in damage to items being transported or handled

(b) inspection of storage and work areas for conformance to procedures and instructions in the following categories:

(1) adequacy of access control

(2) evidence of damage or deterioration

(3) adequacy of protection from fires, weather, movement of equipment, and other factors that may result in damage to stored and installed items

(4) adequacy of hazardous chemicals, paints, and solvent storage facilities

(c) inspection of work areas for maintenance of environmental conditions within specified limits

(d) surveillance of installed items to ensure the adequacy of

(1) maintenance of protection

(2) preservation of precautionary signs

(3) preservation of item identity

(4) protection from fire, weather, movement of materials or equipment, and other factors that may result in damage to installed items

400 RECORDS

Record copies of procedures, reports, personnel qualification records, zone control registries, fire and accident investigations, surveillance, and inspection records shall be prepared as required in this Part (Part II). These records shall be retained with other project records as required by code, standard, specification, or project procedures.

SUBPART 2.5
Quality Assurance Requirements for Installation, Inspection, and Testing of Structural Concrete, Structural Steel, Soils, and Foundations for Nuclear Facilities

100 GENERAL

This Subpart provides amplified requirements for installation, inspection, and testing of structural concrete, structural steel, soils, and foundations. It supplements the requirements of Part I and shall be used in conjunction with applicable sections of Part I when and to the extent specified by the organization invoking this Subpart.

101 Definitions

The following definitions are provided to ensure a uniform understanding of unique terms as they are used in this Subpart.

class of concrete: identifies each individual concrete mix design.

correlation testing: comparison testing of two samples obtained from the same batch of concrete but from different sampling locations. Usually performed to check or confirm the effects of a conveyance system, such as a pump system, on plastic concrete properties specified at the point of placement.

curing: the process of maintaining a satisfactory moisture content and a favorable temperature in concrete during hydration of the cementitious materials so that desired properties of the concrete are developed.

delivery point: the point of discharge from a bulk concrete delivery container. These containers include a truck mixing unit/ready-mix truck, truck-agitating unit, or nonagitating unit. For sampling purposes, delivery point and placement point can be considered coincident when no conveyance system is used or if correlation testing shows no significant change to the concrete properties following conveyance.

NOTE: "Buckets" are not considered bulk delivery containers but rather are considered a conveyance system.

finishing: the process of obtaining specified surface characteristics of hardened concrete.

in-process tests: tests performed during the course of construction to determine compliance with specified requirements and maintain control of materials. These tests may be performed by the Purchaser (or his agent), constructor, manufacturer, or Supplier, but samples for these tests must be taken from the lot or batch of materials supplied and used at the site of construction.

mixing point: the point of discharge of plastic concrete from a central mix plant. For truck-mixed concrete, the mixing point and delivery point are defined as coincident. When a truck agitator unit is used in the transit of concrete, the delivery and mixing points are considered coincident when

(a) the delivery point is not more than a distance of 2 mi (3.22 km) and a maximum time of ½ hr in transit from the mixing point

(b) the delivered concrete commences to be placed within a maximum time of ½ hr from the time the transporting vehicle arrives at the delivery point

When a nonagitating unit is used, the delivery point and mixing point shall not be considered coincident.

nonagitating unit: containers, mounted on trucks or other vehicles, for delivering central-mixed concrete, not constructed or equipped to keep the mass of concrete in motion in the container.

NOTE: "Buckets" are not considered as nonagitating delivery units.

placement point: the point of discharge of plastic concrete into the forms. Except for pumped concrete, the placement point and the delivery point are considered coincident when 5 min or less is used in transit of the concrete from the delivery point to the placement point. Correlation testing may be employed to demonstrate that placement point and delivery point of pumped concrete are coincident.

qualification tests: tests performed to qualify the basic material source or manufacturer to ensure conformance to specification requirements.

ready-mix truck: concrete mixers on trucks or other vehicles, capable of uniformly mixing concrete ingredients after they have been batched at the plant.

truck-agitating unit: drums or containers, mounted on trucks or other vehicles, in which central-mixed concrete is kept sufficiently in motion during delivery to prevent segregation.

200 GENERAL REQUIREMENTS

The requirements of this Subpart apply to any organization or individual participating in work relating to production, preparation, placement, installation, inspection, and testing of structural concrete, structural steel, soils, and foundations, and applies to the following:

(a) formwork
(b) steel reinforcement
(c) embedded items
(d) foundation preparation
(e) concrete
(f) structural steel
(g) soils and earthwork
(h) special foundations, including piles and caissons as identified in para. 601 of this Subpart
(i) foundation underpinning

300 REQUIREMENTS

Measures shall be established and implemented for documenting installation, inspection, and testing activities to verify conformance to specified requirements. Applicable codes and standards are referenced or invoked throughout this Subpart. If the referenced or invoked code or standard becomes superseded or canceled, the design authority or contracting authority may retain the superseded or canceled code or standard, or invoke a different code or standard.

301 Planning and Procedures

Planning and procedure preparation shall be in accordance with the Introduction to Part II.

302 Control of Measuring and Test Equipment

Measuring and test equipment used to implement the requirements of this Subpart that affect quality shall be controlled, calibrated at specific periods, adjusted, and maintained to required accuracy limits per Part I, Requirement 12. This includes, but is not limited to, thermometers, balances, scales, air entrainment meters, volumetric buckets, field measuring devices, pressure gages, and torque wrenches.

303 Laboratory Testing

Laboratory operations and testing associated with concrete and soils shall be controlled using a quality assurance program. Such testing laboratories shall conform to ASTM C1077 and D3740.

400 PRECONSTRUCTION VERIFICATION

401 General

Receipt and interim storage inspections shall be used to verify that items are in a satisfactory condition for installation. The verification shall include the following:

(a) visual inspection of material for proper identification, physical damage, and contamination
(b) review of manufacturer's documentation, test reports, or other evidence of quality conformance for correctness and compliance with specifications if not reviewed at time of receipt

402 Materials Suitability

To ensure that materials meet specified requirements, preconstruction qualification tests and inspections of the materials to be used and in-process tests of materials being used shall be conducted.

Qualification tests shall be performed and the results evaluated prior to the initial use of the material to establish conformance of the materials to the specified requirements. These tests are mandatory unless current documentary test data are available to establish complete confidence in conformance to specification requirements. The specifications shall identify the required qualification tests and the frequency for their repetition. The tests required for concrete, concrete constituents, materials for reinforcing systems, materials for prestressing systems, and welding materials shall be in accordance with the ASME Boiler and Pressure Vessel Code, Section III, Division 2 (ACI Standard 359).

Concrete mix designs shall be batched and mixed in accordance with ASTM C94, Standard Specification for Ready Mix Concrete, or ASTM C685, Standard Specification for Concrete Made by Volumetric Batching and Continuous Mixing.

Normal, heavyweight, and mass concrete mix designs shall be proportioned in accordance with ACI 211.1, Standard Practice for Selecting Proportions for Normal, Heavyweight, and Mass Concrete.

Lightweight concrete mix designs shall be proportioned in accordance with ACI 211.2, Standard Practice for Selecting Proportions for Structural Lightweight Concrete. Lightweight concrete aggregates shall be qualified by tests for conformance with ASTM C330. When splitting tensile strengths are required for lightweight concrete mix, the methods given in ASTM C330 shall be used. Additional tests may be required to qualify materials for special application.

403 Construction Processes

Inspections shall be performed to verify that the prerequisites for control of construction processes such as welding, structural bolting, mechanical splicing of reinforcement, and concrete measuring, mixing, transporting,

placing, and curing have been accomplished. These inspections shall include verification of the following:

(a) the process has been qualified as required

(b) process controls are in effect

(c) approved procedures, instruction manuals, or both, if required for specific equipment, are available for use during construction

(d) the process is suitable for the particular application

(e) manpower, equipment (including measuring and testing equipment), and materials are readily available and adequate to perform the work in accordance with drawing and specification requirements

500 INSPECTION OF SOILS AND EARTHWORK

501 General

Inspection of soils and earthwork shall include preparations for earthwork, as well as in-process inspections of placing and compacting operation, to ensure conformance to specified requirements.

502 Materials

Inspections and qualification testing of stockpiles or borrow pits shall be performed to verify conformance to specified requirements. Qualification tests of soil fill materials shall be performed for

(a) grain size analysis using ASTM D422

(b) moisture-density relationship of soil using ASTM D698 or D1557

(c) maximum and minimum index density of soils using ASTM D4253 and D4254

(d) liquid limit, plastic limit, and plasticity index of soils using ASTM D4318

(e) unified soil classification using ASTM D653, D2487, and D2488

Other qualification tests of soil fill materials may be used when specified.

503 Placing and Compacting Equipment

Inspections shall be performed prior to compacting operations to verify the adequacy of compacting equipment. These inspections shall include the following:

(a) inspections to verify that compacting equipment has specified weight, if applicable

(b) inspections to verify that the specified type of equipment is available and in operating condition

(c) inspections of vibratory compaction equipment to verify proper functionality and that the correct vibration frequency setting is being used, if specified

(24) 504 Preplacement Preparations

Inspections of preparations for fill placement shall include the following:

(a) inspections to ensure compliance with site preparation requirements

(b) inspections to ensure that the subgrade surface is within specified limits

(c) inspections to ensure that the subgrade is free of deleterious materials and voids and in compliance with specified requirements

(d) inspections to ensure that the subgrade is free of excess moisture, snow, frost, or frozen lumps

(e) inspections to verify that subgrade preparation meets specified requirements

(f) documentation of the inspections required by (a) through (e) shall be verified as being complete and indicating that all inspection results are satisfactory

505 Soil Compaction

Inspections of soil compaction during construction shall be performed to verify the following:

(a) fill material meets specified requirements

(b) segregation of the fill material does not occur as it is dumped and spread

(c) specified lift thicknesses are not exceeded

(d) when specified, a knitting technique is used when joining lifts and where fill is placed against existing earth slopes or adjacent to previously compacted fills

(e) proper location and installation of underdrains, where specified

(f) the compacting equipment makes the specified number of passes over each lift and that passes overlap

(g) heavy compaction equipment is not operated adjacent to concrete until concrete has achieved the appropriate specified strength prior to being subjected to compaction loads

(h) heavy compaction equipment does not exceed maximum loads specified for buried structures

(i) moisture control during compaction

506 In-Process Tests on Compacted Fill

In-process tests shall be performed during the course of construction to maintain control of soil compaction. A list of the in-process tests for soils is shown in Table 506 of this Subpart. The need for each specific test shall be established in the specifications. In-process tests shall be performed more frequently if the test results are erratic, or if the trend of results or an apparent change in material characteristics indicates that the frequency should be increased.

Table 506
Required In-Process Tests for Compacted Fill

Material	Requirements	Test Method	Test Frequency
Soil	Moisture-density relationship of soils or maximum-minimum index density of soils	ASTM D698 or D1557; Method A, B, C, or D, or ASTM D4253 and D4254, as specified	At least one for each soil type and whenever soil type visually changes or is otherwise questionable
	Grain size	ASTM D422 hydrometer or sieve, as appropriate	One for each density relationship test
	Plasticity index	ASTM D4318	One for each density relationship test and when volume change characteristics are questionable
	Soil moisture	ASTM D6938 or ASTM D2216, as specified (ASTM D6938 shall be correlated to results obtained using ASTM D2216)	One for each field density test and when moisture content changes are questionable
	Field density test	ASTM D1556 or D2167, supplemented by ASTM D6938 or D2937, as specified	Test as specified in owner's specification with the following as minimum: *(a)* one for every 2,000 yd^3 of material placed for mass earthwork *(b)* one for every 1,000 yd^3 of material in relatively thin sections for canal or reservoir lining *(c)* one for every 200 yd^3 to 300 yd^3 of backfill in trenches or surrounding structures *(d)* at least one test for every lift of compaction operations on mass earthwork *(e)* one test whenever there is a suspicion of the quality of moisture control or effectiveness of compaction
	Fines content	ASTM D1140	One for each density relationship test and every 100,000 ft^2 (9 290 m^2)

GENERAL NOTE: These test frequencies shall be considered minimum unless documentary test data are available to establish adequate confidence in conformance with specification requirements.

600 INSPECTION OF FOUNDATION PILE AND CAISSON CONSTRUCTION[1]

601 Piles

601.1 Pile Receiving, Handling, and Storage. Inspections shall be performed to verify that the specified material has been received and to verify the adequacy and proper handling techniques. These inspections shall include the following:

(a) receiving inspection

(b) inspection of handling procedure to verify that proper lifting points and lifting techniques are used

(c) inspection of storage procedure to verify that suitable storage areas have been designated, that blocking is adequately and properly located, and that piles can be rehandled without damage

(d) inspection of procedure for transporting piles from storage area to driving location to verify that proper support and lifting points are utilized, that proper lifting technique is used to position the pile for driving, and that the pile to be driven is undamaged and as specified

601.2 Pile Driving and Cast-in-Place Pile Construction. Pile driving and cast-in-place pile construction shall be inspected to verify that the specified piles are properly located from site baselines and elevation benches (located according to length and capacity), that the surface from which the piles will be driven has been properly prepared, excavated to the designated driving elevation, and drained or dewatered, as specified, and that pile driving equipment in compliance with the specification is available.

601.2.1 Installation of Wood, Steel, and Precast Concrete Piles, and Cast-in-Place Concrete Piles With Permanent Casing and Shell. The installation of wood, steel, and precast concrete piles, and the shells or casing for cast-in-place concrete piles shall be inspected to verify the following:

(a) the specified pile hammer is being used and is operating at the required speed (blows/minute) and stroke, if specified

[1] Applicable for nonreactor containment structures only. This section is not applicable to reactor containment structures because piles and caissons are typically not used for U.S. commercial nuclear reactor containment structures.

(b) the pile being installed is the specified type and length

(c) the pile is installed within specified tolerances of locations, plumb, and rotation or to the specified batter and tip elevation, and that the blow counts are as specified

(d) the proper type of cushioning materials is used between the hammer and the pile and to ensure that piles are not being damaged during driving

(e) the follower used on piles with the final top elevation below the existing grade is compatible with the driving characteristics of the pile

(f) the piles that are adjacent to the pile being installed are checked for heave and reinstalled if required

(g) the sequence of pile installation is as specified in order to avoid displacement of piles in place

(h) documentation and reporting of any observed damage to adjacent structures that may have been caused or worsened due to pile-driving operations

(i) drilling and jetting are only done when specified and are performed in accordance with the specifications

(j) complete records are made of pile driving resistance

601.2.2 Concrete Placement in Cast-in-Place Piles With Permanent Casing. Prior to concreting cast-in-place concrete piles, inspection shall be performed to verify the following:

(a) the casing has not buckled or ruptured

(b) the casing is straight

(c) the casing is dewatered and cleaned to the tip elevation

(d) the reinforcement is installed and positioned as specified and is secured against displacement during concreting

(e) the volume of concrete used is consistent with the estimated required volume

The placement of concrete in the pile casing shall be inspected to verify that it conforms with paras. 705 and 707 of this Subpart, as applicable.

601.2.3 Concrete Placement for Cast-in-Place Piles Without Permanent Casing. The construction of cast-in-place piles without permanent casing shall be inspected to verify the following:

(a) the volume of concrete used is consistent with the estimated required volume

(b) the method for withdrawing the casing will not cause separation of the pile concrete, nor alter the position of the reinforcing steel

(c) the method for withdrawing the casing during the placing of the concrete maintains a level of concrete sufficiently above the bottom of the casing to avoid separation of the pile concrete, soil intruding or necking down the concrete pile, and movement of the reinforcing steel, if placed

(d) the placement of concrete in the pile casing conforms with paras. 705 and 707 of this Subpart

(e) grouting pressure or compaction energy used to form the pile is specified

601.2.4 Pile Splicing. The construction of composite piles and the splicing of piles with the specified section above and below the splice shall be inspected to verify the following:

(a) the top section is properly aligned with the bottom section

(b) the splice interface is clean and is properly prepared and spaced for application of the splicing material

(c) the pile is at the specified temperature limits for splicing and that the splice is installed in accordance with applicable standards and specifications

601.2.5 Inspection of Concrete Construction. Concrete construction of cast-in-place piles and protective concrete cast around piles shall be inspected in accordance with section 700 of this Subpart.

601.2.6 Test Piles. Test piles shall be inspected to verify that

(a) load tests are made on piles driven or cast-in-place in the same manner as production piles

(b) the driving or construction is in accordance with the applicable paragraphs above

(c) the performance of load testing and integrity testing is in accordance with ASTM D1143, Method of Testing Piles Under Static Axial Compressive Load

602 Caissons

602.1 Caisson excavation shall be inspected to verify that

(a) caissons are correctly located

(b) the caisson shaft is straight and plumb, or to the specified batter, and suitable means are employed to maintain the shaft diameter

(c) the bottom of the caisson is at the specified elevation and is level, or is excavated in steps as necessary to provide level and uniform bearing over the full base area

(d) there are no unacceptable voids, caverns, or strata of compressible material below the bottom of the caisson

(e) underreamed caissons have the specified bottom diameter and side slope

(f) the rock socket of drilled-in caissons is the specified diameter and depth

(g) the shear rings of friction caissons are the specified size and spacing

602.2 Caisson concrete construction shall be inspected in accordance with section 700 of this Subpart. Also, the performance of load testing and integrity testing shall be conducted in accordance with specified requirements.

In addition, caisson concrete shall be inspected to verify that

(a) all loose soil has been removed from the bottom of the caisson excavation prior to concreting

(b) the caisson excavation has been dewatered or that approved means of placing concrete underwater are employed

(c) sufficient head of concrete is maintained above the bottom of the casing while it is being withdrawn to avoid soil intrusion or necking down of the concrete shaft

(d) method of withdrawal of the casing prevents voids in or separation of the concrete shaft

(e) approved methods of proportioning and placing concrete are employed in slurry-stabilized caisson to prevent segregation or mixing with slurry and to ensure specified concrete strength

(f) the volume of concrete used is consistent with the estimated required volume

603 Required Qualification Tests

The required qualification tests are as follows:

(a) Wood piles shall conform to specifications such as ASTM D25, and AWPA U1, and ASTM D1760 for wood preservation treatment.

(b) Steel piles shall conform to specifications such as ASTM A252 for pipe, and ASTM A6 and A36 for structural shapes.

(c) Concrete piles (precast, cast in place, and prestressed) shall conform to approved specifications used in the manufacturer's certification (e.g., ACI 543, Design, Manufacture, and Installation of Concrete Piles), or as specified.

700 INSPECTION OF CONCRETE CONSTRUCTION

701 General

Inspection of concrete construction shall include inspection of preparations for concreting, as well as inprocess inspections of concrete measuring, mixing, transporting, placement, curing, and protection to ensure conformance to specified requirements. The inspection of pretensioning or post-tensioning systems shall be included, if applicable. The inspection shall follow ACI Standard 311.4, Guide for Concrete Inspection; PCI MNL-116; and MNL-117.

702 Protection of Materials

Inspections shall be performed to verify the adequacy and proper maintenance of material storage conditions and handling techniques. These inspections shall include the following:

(a) inspection of cement storage facilities to verify weathertightness, cement temperature, and the absence of lumps, and review of records to verify type and age of cement

(b) inspection of aggregate stockpiles to verify that

(1) handling techniques are not resulting in segregation

(2) storage and handling adequately prevent contamination with deleterious substances or mixing with other aggregates

(3) specified temperature and uniform moisture control are maintained

(4) use of frozen materials is prevented

(c) inspection of admixture storage and handling facilities to verify that deterioration and contamination are prevented and that admixtures are protected from freezing

(d) inspection of water sources and cooling and heating facilities to verify the specified water quality and to ensure that the specifications for concrete temperatures are met

(e) inspection of reinforcing material, embedments, and prestressing systems materials (wire, strand, tendons, tendon tubes, and temporary or permanent anchor hardware) to verify protection against excessive corrosion, contamination, and physical damage

703 Measuring, Mixing, and Transporting Equipment

Concrete batching and mixing facilities shall be certified to be in accordance with the requirements of the National Ready-Mix Concrete Association (NRMCA). Inspections shall be performed prior to and during the production of concrete to verify the adequacy and proper operation of measuring, mixing, and transporting equipment in accordance with ACI 304, ASTM C94, and the NRMCA Plant Certification Checklist. These inspections shall include the following:

(a) inspection of measuring facilities for the specified accuracy of measuring, weighing, and weight recording devices to control the following:

(1) proportions of cement, water, and aggregates

(2) quantities of admixtures

(3) aggregate moisture compensation

(4) mixing time

(5) temperature control, heating or cooling of concrete

(6) method of adding water when batching lightweight aggregates in accordance with ACI Standard 301

(b) inspection of central mix plant and truck mixers for wear of drum blades, availability of revolution counter and water-measuring devices, proper speed of rotation, and ability to mix concrete completely in the specified time.

704 Preplacement Preparations

Inspection of preparations for concrete placement shall include the following:

(a) inspection of the compacted structural fill or undisturbed soil to verify correct condition

(b) inspection and field testing, in accordance with the specifications of all structural fill, undisturbed soil, and rock surfaces that will be in contact with structural concrete to verify surface cleanness, removal of loose

rock and free water, correct contour, and specified subgrade condition

(c) inspection of previously placed concrete to verify proper joint preparation

(d) inspection of formwork to verify

(1) correct location and configuration, dimensional accuracy, and proper line and grade of formwork

(2) installation and integrity of water stops and membrane waterproofing

(3) condition of form material to produce the specified concrete finish, installation of ties, anchors, bracing, shoring, and supports to prevent movement during concrete placement

(4) correct location and dimensions of blockouts, proper form coating, and cleanness inspection of forms for tightness and placement of grout and vent pipes when preplaced aggregate concrete is used

(e) inspection of reinforcing steel, prestressing components (if applicable), and other embedded items to verify

(1) correct size, number, material (ASTM bar specification), location, position, cleanness, and leak tightness, if applicable

(2) proper stringing and absence of physical damage to pretensioning strands or tendons

(f) inspection of mechanical reinforcing bar splicing operations to verify conformance to the requirements or para. 712 of this Subpart

(g) inspection by use of a mandrel or similar device to ensure that the tendon conduits are open and remain open during the concrete placing operation

(h) inspection of pretensioning load cells and pressure gages for accuracy and calibration, if applicable

(i) inspection of pretensioning system strand vises for cleanness, proper lubrication, wear, distortion, and cracking, if applicable

(j) inspection of the pretensioning operation, if applicable, to verify

(1) initial tensioning of each strand to eliminate slack and to provide a uniform initial stress condition in all strands prior to final stressing

(2) proper measurement and correlation of jack pressure (or load cell reading) and strand or tendon elongation

(3) proper correction for elongation losses, due to strand slippage in the rises and movement of anchorage abutments

(k) inspection of groundwater control, as specified

(l) inspection for embedments

Documentation of the inspections required by (a) through (l) shall be verified as being complete and indicating that all inspection results are satisfactory.

705 Concrete Placement

Inspection of concrete placement shall be performed to verify the following:

(a) specified tests of concrete have been performed

(b) adherence to specified requirements for class of concrete, time of placement from batching, mixing revolutions, rate of placement, lift height, placing sequence, concrete temperature, and hot or cold weather concreting practice (ACI Standard 305 or 306, respectively)

(c) proper use of adequate conveying and placing equipment

(d) materials harmful to the concrete are not used in covering or placing the concrete

(e) adequate concrete consolidation equipment and technique of operation (ACI Standard 309)

(f) neither embedded items are disturbed nor forms are displaced

706 Finishing and Repairs

Inspections shall be performed to verify that specified finishes are obtained, i.e., wood float, steel trowel, as cast, or other type. After forms have been removed, inspections shall be performed to verify that the formed surfaces have been repaired and finished in accordance with specified requirements.

Any indication of honeycomb, voids, or contamination, such as at a construction joint, shall be explored by physical removal of concrete, if necessary, to determine the extent of such voids or contamination. Appropriate repairs shall be made. Noncosmetic repairs, such as those extending behind reinforcement or damaged induced by loading or other type of stress, shall be as directed by the responsible design organization if not covered by approved repair procedures.

707 Curing

Qualification tests shall be performed on liquid membrane forming curing compounds and sheet materials for concrete curing for compliance with ASTM C309 or ASTM C171, as applicable.

Inspections shall be performed throughout the specified curing period to verify the following:

(a) correct curing method is used, i.e., use of ponding, fog spray, wet burlap, curing compound, or other methods in accordance with specified requirements

(b) concrete is kept continuously, i.e., not periodically, wet during the entire curing period, if one of the wet curing methods is used

(c) membrane curing compounds are specifically approved for use prior to application

(d) curing temperature is maintained within specified limits during the entire curing period

(e) shoring and forms are left in place, and precast concrete members are left in the forms until concrete has reached specified strength necessary to preclude the possibility of damage from construction loads

(f) concrete test cylinders are subjected to the same curing process as the placed concrete when field-cured cylinders are required to evaluate curing methods

708 Stress Transfer of Pretensioned Members

If applicable, inspections shall be performed to verify the following:

(a) the concrete strength, as indicated by test cylinders, is in accordance with the specified transfer strength prior to the transfer of prestressing load to the member

(b) stress transfer is performed within the specified temperature limits for heat-cured members

(c) forms, ties, inserts, hold downs, or other devices that would restrict longitudinal movement of the member(s) are removed, or loosened in a specific sequence to or in conjunction with stress transfer

(d) the stress transfer is performed following an approved stressing procedure and sequence

709 Post-Tensioning

Inspections shall be performed prior to and during post-tensioning, if applicable, to verify the following:

(a) the concrete strength, as indicated by test cylinders, is in accordance with the specified strength at the time of prestress or at the time of post-tensioning.

(b) the tendons and tendon ducts of ungrouted tendons have been treated with the specified lubricant, or corrosion-inhibiting compound, prior to tendon installation.

(c) the tendons are tensioned (from both ends if so specified) in accordance with the specified prestressing sequence.

(d) there is proper measurement and correlation of jack pressure (or load cell reading) and tendon elongation as well as proper correction for elongation, or prestress seating losses.

(e) the anchorage details (buttonheads, friction grip, wedge grip, threaded, etc.) are in accordance with the specified requirements both prior to and after tensioning.

(f) the grouted tendon ducts are free from excessive moisture prior to grouting. The grout material and the grouting operation are in accordance with specified requirements.

710 Shipping and Handling of Precast Concrete Members

Inspections shall be performed prior to and during erection to verify that

(a) members are handled only by means of approved devices at designated locations or pick-up points

(b) suitable foundations are provided for storage of precast members

(c) stacked members are separated and supported by battens placed across the full width of the designated bearing points

(d) cracking, spalling, and other defects caused by shipping and handling of the precast members do not exceed the specified limits

711 In-Process Tests on Concrete (24)

In-process tests shall be performed during the course of construction to maintain control of structural, prestressed, and precast concrete. The tests that are required and the frequency shall be in accordance with the ASME Boiler and Pressure Vessel Code, Section III, Division 2 (ACI Standard 359) and Code Requirements for Nuclear Safety-Related Concrete Structures (ACI 349-06) and Commentary, except as follows:

The ASME Boiler and Pressure Vessel Code, Section III, Division 2 (ACI Standard 359) test frequencies for the following tests shall be considered minimum, unless current documentary test data are available to establish adequate confidence in conformance of materials to specified requirements:

(a) for concrete materials: unit weight/yield

(b) for aggregate materials

(1) unit weight of aggregate

(2) fixed water and iron content of aggregate only for radiation-shielding concrete

(3) organic impurities

(4) flat and elongated particles

(5) lightweight particles

(6) specific gravity and absorption

(7) Los Angeles abrasion

(8) potential reactivity

(9) soundness

The reduction of frequency of testing must be documented, and referenced documentation must be representative of the material currently being certified with the results of prior testing.

Additionally, mixing water and ice, if not potable, shall be tested per the requirements and frequencies of ASTM C1602, Standard Specification for Mixing Water Used in the Production of Hydraulic Cement Concrete, for effect on compressive strength, deviation on time of set, chloride content, sulfate content, total dissolved solids, and alkalies.

In-process tests shall be performed more frequently if test results are erratic or if the trend of results indicates an apparent change in material characteristics.

In-process tests shall be performed on samples of concrete aggregates designated for construction use to ensure they conform to specifications prior to use. Periodic correlation tests shall be conducted to ensure the uniformity of the concrete aggregates is maintained from aggregate supply source to concrete batch plant.

Samples for in-process tests of concrete shall be taken following the procedures of ASTM C172, except as defined herein regarding location of sampling. No water or other ingredients may be added to any concrete batch after obtaining the in-process sample. Samples shall not be taken from concrete deposited in the form. Except as noted below, the sampling point for taking in-process test samples of plastic concrete shall be performed at the placement point or other points coincident thereto.

For sampling purposes, delivery point and placement point can be considered coincident when placement is by chute, wheelbarrow, or bucket, and time of conveyance to the forms does not exceed 5 min or when correlation testing shows no significant change to the concrete properties following conveyance (1-in. maximum variance in slump; 1.0% maximum variance in air content).

Where conveyance systems with the potential of significantly altering concrete properties are employed, correlation testing shall be conducted daily to establish concrete properties needed at the delivery point to provide concrete as specified at the point of placement. Correlation testing shall be repeated whenever the equipment or conveyance delivery configuration significantly changes or whenever concrete quality is in question.

Where correlation tests of slump, air content, or temperature of concrete placed by a conveyance system show changes beyond specified allowances, repeat correlation testing every 100 yd^3 (75.6 m^3) or until changes return to allowable limits.

(24) **712 Mechanical Splice Testing**

The mechanical splice testing for permitted splice systems shall be done in accordance with the requirements of the ASME Boiler and Pressure Vessel Code, Section III, Division 2 (ACI Standard 359) and Code Requirements for Nuclear Safety-Related Concrete Structures (ACI 349–06) and Commentary.

713 Welded Reinforcing Bar Splices

Welded reinforcing bar splices shall be subject to the requirements of para. 805 of this Subpart, except that provisions of the ASME Boiler and Pressure Vessel Code, Section III, Division 2 (ACI Standard 359), shall also apply.

714 Bending of Reinforcement

Bending of reinforcing bars shall comply with provisions of the ASME Boiler and Pressure Vessel Code, Section III, Division 2 (ACI Standard 359), subsubarticle CC-4320. Field bending of bars partially embedded in set concrete shall not be permitted except as specifically approved by the responsible design organization.

800 INSPECTION OF STEEL CONSTRUCTION

801 General

Structural steel qualification shall be documented by manufacturer's certification showing conformance to specifications such as ASTM A36, ASTM A441, or as otherwise specified.

Inspection of steel construction in accordance with the AISC 360, Specification for Structural Steel Buildings, shall include inspection of assembly and erection operations, fastening or connecting operations such as high strength bolting and welding, and finishing operations such as cleaning and protective painting or coating.

Inspection of steel construction shall include inspection of related items, such as anchor bolts and baseplates, that may be part of the supporting structure and installed as part of the structural concrete work.

802 Supporting Structures

Prior to erection of steel, anchor bolts, baseplates, and other structural embedments shall be checked for correct orientation, spacing, and elevation. Baseplate surfaces and supporting concrete surfaces shall be checked to verify satisfactory conditions for grouting.

Grouting of baseplates, beam pockets, etc., shall be controlled and inspected to verify that only specified materials are used, proportioned properly, placed correctly, and cured properly to achieve the specified compressive strength.

803 Assembly and Erection

Assembly and erection operations shall be inspected to verify compliance with installation procedures and work instructions. Alignment operations shall be carried out early enough and as often as is necessary as erection progresses to ensure that specified requirements are met.

Particular attention shall be given to verification of the condition of contact surfaces of friction-type connections and bolt hole alignment. Correction of fabrication errors shall be closely controlled to prevent correction of misaligned holes by reaming in excess of AISC tolerances. Burning of bolt holes is not permitted. Equipment used in connecting operations shall be inspected to verify conformance with specification requirements. For example, air compressors shall be of sufficient capacity to maintain the required operating pressures for impact tools.

Control and monitoring of type of contact surface coating (to provide adequate friction in slip critical joints) shall be conducted.

804 High-Strength Bolting (24)

Installation of high-strength bolts shall be in accordance with Research Council on Structural Connections (RCSC), Specification for Structural Joints Using ASTM A325 or A490 Bolts, and with AISC N690, Specification for Safety-Related Steel Structures for Nuclear Facilities. Manufacturer's certifications for bolting materials shall be provided with each lot received.

For snug-tight installations, the inspector shall verify that proper bolting materials are used and that all plies of metal are brought together. Snug condition shall be verified by checking 10% or a minimum of two bolts at each connection, whichever is greater.

For fully tensioned connections, a calibrated tension-measuring device shall be required at all job sites. As verified by the inspector, the contractor shall demonstrate that required tension is achieved by the specified or selected installation method being employed.

Procedures for verifying tension installation and establishing a job inspection torque for checking installations in question shall be as given in AISC N690. The inspector shall monitor the installation of fully tensioned bolts to verify that the selected installation procedure is properly applied, proper bolting materials are used, and all plies of metal are brought together.

For turn-of-the-nut installations, a marking system shall be employed that allows confirmation of proper rotation from the snug-tight condition.

(24) **804.1 Inspection of Bolting.** Inspection of bolting shall include visual inspection of bolting operations and torque wrench inspection of completed connections. Connection points shall be visually inspected for the following items:

(a) bolts are long enough as indicated by the point of the bolts being flush with or outside the face of the nuts

(b) correct type bolt is used as indicated by the manufacturer's marking on the head

(c) torque has been applied as indicated by the burnishing or peening of the corners of the nut

(d) turning elements are on the correct face; properly sized washers are used when required

Bolt tension inspection shall be as specified in the RCSC Specification for Structural Joints Using ASTM A325 or A490 Bolts and with AISC N690, Specification for Safety-Related Steel Structures for Nuclear Facilities. In addition, during the initial phase of bolting operations, all bolts tightened by each bolting crew shall be checked until the results are consistently acceptable.

804.2 Inspection Tools and Procedure. Hand torque wrenches used for inspection shall be controlled in accordance with Part I and shall be calibrated at least weekly, more often if deemed necessary. Impact torque wrenches used for inspection shall be calibrated at least twice daily. Feeler gauges used for inspection of direct-tension indicators shall be controlled.

805 Welding

Inspection of structural steel welding shall be performed in accordance with the provisions of Section 6.0 of AWS D1.1, Structural Welding Code — Steel. This inspection shall include visual examination of preparations, welding processes, postwelding operations, and, if deemed necessary, some NDE inspections that are appropriate to the application. Prior to welding, verification of welding procedure and welder qualification shall be documented and shall include all essential variables identified in the procedures. In-process inspections shall include acceptability of environmental conditions, joint fit-up prior to start of welding, preheat and interpass temperature requirements, filler metal, control of distortion, postweld heat treatment, and cleaning requirements. Procedures shall be established to control the purchase, receiving, distribution, storage, and use of welding electrodes.

Weld repairs necessitated by visual or nondestructive examinations shall be made in accordance with the procedure used to perform the original weld or a qualified repair procedure and reinspected by the same method that disclosed the repairable defect. All weld repairs necessitated by nondestructive examination shall be documented.

900 DATA ANALYSIS AND EVALUATION

901 General

Procedures shall be established for processing inspection and test data and their analysis and evaluation. These procedures shall provide for acquisitions and preparation of inspection and test data for prompt evaluation against acceptance criteria, operating limits, and performance standards. The data processing procedures shall provide for on-the-spot evaluation to determine the validity of the inspection and test results and the appropriateness of continuing the inspection or test. The data shall be analyzed and evaluated to verify completeness of results and achievement of inspection and test objectives; and to identify additional inspection and tests required, and necessary changes to the installation inspection or test procedures. Inspection and test results that include inspection and test data, together with a report of data analysis and evaluation, shall be provided as specified in section 1000 of this Subpart. When test data are found to not meet acceptance criteria, steps shall be taken to assess the implications of such and take appropriate corrective and preventive measures.

902 Concrete and Mechanical Splice Test Data Evaluation and Analysis

902.1 Evaluation of Concrete Test Results. Standard deviation data shall be developed, evaluated, and maintained for permanent records in accordance with ACI Standard 214. Concrete quality and acceptance criteria shall conform to the requirements of ACI Standard 318, Chapter 4.

902.2 Evaluation of Mechanical Splice Test Results. The evaluation of mechanical splice test results shall be in accordance with ASME Boiler and Pressure Vessel Code, Section III, Division 2 (ACI Standard 359).

902.3 Evaluations of Aggregate Test Results. When any aggregate tests specified fail to meet the specified requirements, two additional tests shall be made from samples of the same lot of aggregate. If one or both of the two additional tests fail to meet the specified

requirements, the data shall be submitted to the responsible engineering organization for evaluation and corrective action.

(24) **903 Steel Construction Test Data Evaluation and Analysis**

This data shall be evaluated for conformance to project specifications of AISC 325, Steel Construction Manual, and AWS D1.1, Structural Welding Code — Steel.

904 Soils Test Data Evaluation and Analysis

This data shall be evaluated daily during progress of the work for conformance to project specifications. The control techniques given in the specifications, such as specific test methods for the type of soil compacted, shall be verified. Data shall include determination of parameters specified, including use of proper materials, amounts and uniformity of soil moisture, and thickness of layers being placed. In-place compacted fill density shall be determined using standard approved methods and the results evaluated for compliance to specified requirements. Data shall include verification that the soils are fully compacted or consolidated to contours and the grades specified. When statistical methods are required by the specification, the desired level of confidence shall be specified.

1000 RECORDS

Record copies of procedures, reports, personnel qualification records, test equipment calibration records, test deviation or exception records, and inspection and examination records shall be prepared. These shall be retained with other project records as required by code, standard, specification, or project procedures.

SUBPART 2.7
Quality Assurance Requirements for Computer Software for Nuclear Facility Applications

100 GENERAL

This Subpart provides requirements for the acquisition, development, operation, maintenance, and retirement of software. The appropriate requirements of this Subpart shall be implemented through the policies, procedures, plans, specifications, or work practices, etc., that provide the framework for software engineering activities. This Subpart supplements the requirements of Part I and shall be used in conjunction with applicable Requirements of Part I when and to the extent specified by the organization invoking the Subpart.

(24) 101 Definitions

The following definitions are provided to ensure a uniform understanding of unique terms as they are used in this Subpart.

acceptance testing: a manual or automated process for exercising or evaluating a system or system component to ensure that specified requirements are satisfied in the operating environment and to determine if it performs satisfactorily. Also called *software validation*.

baseline[1]*:* a specification or product that has been formally reviewed and agreed upon, that thereafter serves as the basis for use and further development, and that can be changed only by using an approved change control process.

change control[1]*:* an element of configuration management consisting of the evaluation, coordination, approval or disapproval, and implementation of changes to configuration items after formal establishment of their configuration identification. Also called *configuration control*.

computer program unit[1, 2]*:* a logically separable part of a computer program.

configuration item[1]*:* a collection of hardware or software elements treated as a unit for the purpose of configuration control.

configuration management (software): the process of identifying and defining the configuration items in a system (i.e., software and hardware), controlling the release and change of these items throughout the system's life cycle, and recording and reporting the status of configuration items and change requests.

control point[1]*:* a point in the software life cycle at which specified agreements or controls (typically a test or review) are applied to the software configuration items being developed, e.g., an approved baseline or release of a specified document or computer program.

error: a condition deviating from an established baseline, including deviations from the current approved computer program and its baseline requirements.

in-use testing: the process of exercising or evaluating a computer program by manual or automated means to confirm the computer program functions as intended in the operating environment.

operating environment: a collection of support software, firmware, and hardware elements that provide for the execution of computer programs.

regression testing[1]*:* selective retesting to detect errors introduced during modification of the computer program or to verify that the modified computer program still meets its specified requirements.

software development cycle[1]*:* period of time that begins with the decision to develop a software product and ends when the software is delivered. The software development cycle typically includes

(a) software requirements
(b) software design
(c) software design implementation
(d) test
(e) sometimes installation and checkout

These phases may overlap or be performed iteratively, depending upon the software development approach used.

software engineering[1]*:* the application of a systematic, disciplined, quantifiable approach to the development, operation, and maintenance of software; that is, the application of engineering to software

[1] This definition has been copied or adapted from ISO/IEC/IEEE Std. 24765:2010(E), Systems and Software Engineering — Vocabulary, with the permission of IEEE.

[2] Term is also interchangeable with *computer program component*.

software life cycle[1]*:* the period of time that begins when a software product is conceived and ends when the software is no longer available for use. The life cycle typically includes a concept phase, requirements phase, design phase, implementation phase, test phase, installation and checkout phase, operation and maintenance phase, and, sometimes, retirement phase. These phases may overlap or be performed iteratively, depending on the software development approach used.

software tool[1]*:* a computer program used to support development, testing, analysis, or maintenance of a program or its documentation.

source code[1]*:* computer instructions and data definitions expressed in a form suitable for input to an assembler, compiler, or other translator.

system software[1]*:* software designed to facilitate the operation and maintenance of a computer system and its associated computer programs.

test case[1]*:* a set of test inputs, execution conditions, and expected results developed for a particular objective, such as to exercise a particular program path or to verify compliance with a specific requirement.

testing (software)[1]*:* the process of

(a) operating a system (i.e., software and hardware) or system component under specified conditions

(b) observing and recording the results

(c) making an evaluation of some aspect of the system (i.e., software and hardware) or system component in order to verify that it satisfies specified requirements and to identify errors

test plan: a document that describes the approach to be followed for testing a system or component. Typically the document identifies the items to be tested, tasks to be performed, and responsibilities for the testing activities.

102 Software Engineering

The scope of software engineering activities includes the following elements as appropriate:

(a) software acquisition method(s) for controlling the acquisition process for software and software services

(b) software engineering method(s) used to manage the software life-cycle activities

(c) application of standards, conventions, and other work practices to support the software life cycle

(d) controls for support software used to develop, operate, and maintain computer programs

200 GENERAL REQUIREMENTS

The following general requirements shall be applied to the software engineering elements described in para. 102 of this Subpart.

201 Documentation and Records

The appropriate software engineering elements, described in para. 102 of this Subpart, shall define the baseline documents that are to be controlled in accordance with Part I, Requirement 6, and maintained as records, in accordance with Part I, Requirement 17. Although multiple documentation requirements are specified within this Subpart, they can be provided as separate or as combined documents.

202 Verification

The appropriate software engineering elements, described in para. 102 of this Subpart, shall define the control points and associated software verification activities. Software verification shall include, as appropriate, verification activities of the completeness and testability of the software requirements, verification of the technical adequacy of the design, verification that the software design and test cases are traceable to the software requirements, and verification of the maintainability and correctness of the software. Software verification shall include review of test results. The software verification activities shall be completed prior to approval of the software for use.

Software verification shall be performed by a competent individual(s) or group(s) other than those who performed and documented the software life-cycle activity but who may be from the same organization. This verification may be performed by the originator's supervisor, provided

(a) the supervisor did not specify a singular approach or rule out certain considerations and did not establish the inputs used in the software life-cycle activity, or

(b) the supervisor is the only individual in the organization competent to perform the verification

Cursory supervisory reviews do not satisfy the intent of this Standard.

The results of verification shall be documented with the identification of the verifier. Software verification methods shall include any one or a combination of reviews, alternate calculations, and tests.

202.1 Reviews. Reviews of software shall ensure compliance with the approved software requirements. Reviews may be performed and documented separately or combined, as appropriate, based on the defined software engineering method. The following two reviews are required:

(a) The first review shall provide assurance of satisfactory completion of the software requirements, software design, and software design implementation activities in preparing the computer program for acceptance testing.

(b) The second review shall provide assurance of the satisfactory completion of the software development cycle including final acceptance testing.

Individual(s) familiar with the intended use of the software and, when feasible, familiar with the software design shall be included in the reviews.

Reviews shall identify the participants and their specific review responsibilities. Documentation of review comments and their disposition shall be retained until they are incorporated into the updated software. Comments not incorporated and their disposition shall be retained until the software is approved for use. When review alone is not adequate to determine if requirements are met, alternate calculations shall be used, or tests shall be developed and integrated into the appropriate activities of the software development cycle.

Tests performed in support of a review can be used to complement acceptance testing. The tests and test results shall be included in the acceptance testing documentation. Such tests shall be subjected to the same criteria as the acceptance tests. These tests do not substitute for performing the comprehensive end-of-development acceptance test.

203 Software Configuration Management

Software configuration management shall include, but is not limited to, configuration identification, change control, and configuration status control. Configuration items shall be maintained under configuration management until the software is retired.

(24) **203.1 Configuration Identification**

(a) A labeling system for configuration items shall be implemented that

(1) uniquely identifies each configuration item

(2) identifies changes to configuration items by revision

(3) provides the ability to uniquely identify each configuration of the revised software available for use

(b) The appropriate software engineering elements, described in para. 102 of this Subpart, shall identify when configuration baselines are to be established. At a minimum, a baseline shall be established prior to acceptance testing. A baseline shall define an approved software configuration. Configuration items to be controlled as part of the baseline shall include, as appropriate

(1) documentation (e.g., software requirement, software design description, instructions for computer program use, test plans, and results)

(2) computer program(s) (e.g., source and object)

(3) data

(4) support software

Approved changes implemented to configuration items subsequent to the baseline shall be added to the baseline.

203.2 Configuration Change Control

(a) The software configuration change control process shall be documented and include

(1) initiation, evaluation, and disposition of a change request

(2) control and approval of changes prior to implementation

(3) requirements for retesting (e.g., regression testing) and acceptance of the test results

(b) Changes to software shall be formally documented. The documentation shall include

(1) a description of the change

(2) the rationale for the change

(3) the identification of affected software baselines

The change shall be formally evaluated and approved by the organization responsible for the original software activities, unless an alternate organization has been given the authority to approve the changes. Only authorized changes shall be made to software baselines. Appropriate verification activities shall be performed for the change. The change shall be appropriately reflected in software documentation, and traceability of the change to the software requirement shall be maintained. Appropriate acceptance testing shall be performed for the change.

203.3 Configuration Status Control. The status of configuration items shall be maintained current. Configuration item changes shall be controlled until they are incorporated into the approved product baseline. The controls shall include a process for maintaining the status of changes that are proposed and approved but not implemented. The controls shall also provide for notification of this information to affected organizations.

204 Problem Reporting and Corrective Action

(a) Method(s) for documenting, evaluating, and correcting software problems shall

(1) describe the evaluation process for determining whether a reported problem is an error or other type of problem (e.g., user mistake)

(2) define the responsibilities for disposition of the problem reports, including notification to the originator of the results of the evaluation

(b) When the problem is determined to be an error, the method shall provide, as appropriate, for

(1) how the error relates to appropriate software engineering elements

(2) how the error impacts past and present use of the computer program

(3) how the corrective action impacts previous development activities

(4) how the users are notified of the identified error, its impact, and how to avoid the error, pending implementation of corrective actions

The problem reporting and corrective action process shall address the appropriate requirements of Part I, Requirement 16.

300 SOFTWARE ACQUISITION

Software acquisition includes software or software services procured in accordance with Part I, or otherwise acquired for use in activities within the scope of Part I.

301 Procured Software and Software Services

Part I, Requirements 4 and 7 for items and services shall be applied to the procurement of software and software services. The Purchaser shall be responsible for the appropriate requirements of this Subpart upon acceptance of the software or related item (e.g., programmable device). Procurement documents shall identify requirements for Supplier's reporting of software errors to the Purchaser and, as appropriate, the Purchaser's reporting of software errors to the Supplier.

302 Otherwise Acquired Software

Otherwise acquired software is software that has not been previously approved under a program consistent with Part I of this Standard for use in its intended application. This includes computer programs not obtained using the procurement requirements of Part I, such as freeware, shareware, and computer programs from corporate repositories.

Part I, Requirement 7, and Part II, Subpart 2.14, and para. 302.1 of this Subpart shall apply to otherwise acquired computer programs that perform a safety function. Otherwise acquired computer programs that do not perform a safety function, but perform a function related to quality, shall be evaluated in accordance with para. 302.2 of this Subpart.

Otherwise acquired computer programs whose results are verified with the design analysis for each application as specified in Part I, Requirement 3, para. 401 are excluded from the requirements of this Subpart.

302.1 Dedication Process. Otherwise acquired computer programs that perform a safety function shall be identified and controlled during the dedication process.

The dedication process shall be documented and include the following:

(a) identification of the capabilities and limitations for intended use as critical characteristics

(b) utilization of test plans and test cases as the method of acceptance to demonstrate the capabilities within the limitations

(c) instructions for use (e.g., user manual) within the limits of the dedicated capabilities

The results of the above dedication process and the performance of the actions necessary to accept the software shall be reviewed and approved.

The dedication process documentation and associated computer program(s) shall establish the current baseline.

Subsequent revisions of otherwise acquired computer programs that have not been previously approved under a program consistent with this Standard shall be dedicated in accordance with this section.

302.2 Evaluation Process. Otherwise acquired computer programs that do not perform a safety function but perform a function related to quality shall be identified and controlled during the evaluation process.

The evaluation specified by this section shall be performed and documented for otherwise acquired computer programs that perform a function related to quality. The evaluation shall determine adequacy to support operation and maintenance and identify the activities to be performed and the documentation that is needed.

This evaluation shall be documented and shall identify the following as a minimum:

(a) capabilities and limitations for intended use

(b) testing used to demonstrate the capabilities within the limitations

(c) instructions for use within the limits of the specified capabilities

(d) exceptions to the documentation requirements of this Subpart

(e) justification for accepting the software

The results of the above evaluation and the performance of the actions necessary to accept the software shall be reviewed and approved.

The resulting documentation and associated computer program(s) shall establish the current baseline.

Subsequent revisions of otherwise acquired computer programs shall be evaluated in accordance with this section.

400 SOFTWARE ENGINEERING METHOD

The selected software engineering method shall ensure that software life-cycle activities are planned and performed in a traceable and orderly manner.

The software engineering method shall include, as appropriate, the activities described in paras. 401 through 408 of this Subpart. Paragraphs 403 and 404 of this Subpart are not applicable to acquired software.

401 Planning (24)

Planning includes documenting the activities to be performed (e.g., software requirements identification, software design definition, software design implementation, verification and validation), the systematic progression of those activities, and the overall measures to be performed during software development, acquisition, and operations and maintenance to assure the quality of the software deliverables. The planning documentation shall be approved by the responsible organization and shall be sufficient to accomplish the work. This

documentation may provide additional information such as schedules, resources, and training.

402 Software Requirements

Software requirements shall specify technical and software engineering (i.e., para. 102 of this Subpart) requirements. The software requirements shall identify the operating system, function, interfaces, performance requirements, installation considerations, security requirements, design inputs, and any design constraints of the computer program. Security requirements shall be specified commensurate with the risk from unauthorized access or use. The software requirements shall identify applicable reference drawings, specifications, codes, standards, regulations, procedures, or instructions that establish software requirement test, inspection, and acceptance criteria. Software requirements shall be traceable throughout the software life cycle. Software requirements shall be identified and documented and their selection reviewed and approved. The review of the requirements shall be performed in accordance with para. 202 of this Subpart.

403 Software Design

The software design activities shall document a design that meets the requirements and provides the basis for the software development activity. The software architecture and design shall be documented and shall include the following:

(a) description of the major computer program components and interfaces

(b) definition of the computational sequence necessary to meet the software requirements

(c) design considerations for the computer program's operating environment including security requirements

(d) measures to mitigate the consequences of problems as identified through analysis (these potential problems include external and internal abnormal conditions and events that can affect the computer program)

(e) assumptions, numerical methods, mathematical models, physical models, control flow, control logic, data flow, process flow, data structures, process structures, and applicable relationships between data structures and process structures, as applicable

The design shall be documented and reviewed. The review of the design shall be performed in accordance with para. 202 of this Subpart.

404 Software Design Implementation

The software design shall be translated into computer program(s) using the programming standards and conventions established per section 500 of this Subpart.

The implementation activity shall produce computer program source code or equivalent (e.g., ladder logic, calculations, and scripts) and user documentation. A review shall be performed in accordance with para. 202 of this Subpart.

405 Computer Program Testing

The requirements of this section and subparagraphs shall apply at a minimum to acceptance testing.

405.1 Testing Process. The type of computer program testing activities to be performed shall include acceptance testing at a minimum and verification that the computer program adequately and correctly implements the approved software requirements. Testing activities shall be documented, controlled, and performed in accordance with the documented software engineering method prior to approval of the software for use.

The computer program testing activities shall consist of the process of exercising or evaluating a system or system component by manual or automated means to ensure that it satisfies the specified requirements and to identify differences between expected and actual results in the operating environment.

Computer program testing shall demonstrate, as appropriate, that the computer program

(a) properly handles abnormal conditions and events as well as credible failures

(b) does not perform adverse unintended functions

(c) does not degrade the system either by itself or in combination with other functions or configuration items

(d) provides valid results for test problems encompassing the range of documented permitted usage

The configuration items included as part of the testing activity shall be under change control in accordance with para. 203 of this Subpart.

405.2 Test Plans and Test Cases. The requirements of this paragraph apply to testing of computer programs and, as appropriate, the computer hardware and operating system.

Computer program test cases shall provide for demonstrating the adherence of the computer program to the approved software requirements. Computer program test cases shall provide for ensuring that the computer program performs as expected over its documented range of use. The test cases shall also provide for evaluating technical adequacy through comparison of test results from alternative methods, such as hand calculations, calculations using comparable proven programs, or empirical data and information from technical literature.

Test plans and test cases shall be documented, reviewed, and approved prior to execution of the test cases.

(a) The test plans shall specify the following, as applicable:

(1) planned testing activities and progression

(2) identification of the stages at which testing is required

(3) requirements for testing logic branches
(4) requirements for hardware and system integration
(5) requirements for input simulation
(6) criteria for accepting the software
(7) reports, records, standard formatting, and conventions

(b) The test cases shall specify the following, as applicable:
(1) prerequisites for performing the test case
(2) steps to be performed including the steps to restore the system or data to its original state prior to the test case
(3) required ranges of input parameters
(4) expected results
(5) acceptance criteria for the test case
(6) reports, records, standard formatting, and conventions

405.3 Test Results and Test Reports. Test reports including test results shall be documented. Observations of unexpected or unintended results shall be documented and dispositioned prior to test result approval. Test results shall be reviewed and approved by the responsible organization prior to use of the software. Test results shall be reviewed to ensure that test requirements have been satisfied.

Test reports shall include
(a) computer program tested including system software used
(b) computer hardware used
(c) test equipment and calibrations, where applicable
(d) date of test
(e) name of the tester or data recorder
(f) simulation models used, where applicable
(g) test problems and traceability to requirements
(h) results
(i) action taken in connection with any deviations noted
(j) name of the person evaluating test results
(k) acceptability

Computer program test reports shall be controlled and maintained as records in accordance with para. 201 of this Subpart. Test records shall be established and maintained to indicate that the computer program adequately and correctly implemented the approved software requirements.

406 Operation

After the software is approved for use and installed in the operating environment, the use of the software shall be controlled in accordance with approved procedures and instructions. These include, as appropriate
(a) operational documentation (e.g., event log, diagnostics)
(b) user documentation
(c) access control specifications
(c) computer system vulnerability protections
(e) problem reporting and corrective action
(f) in-use tests
(g) the configuration change control process

406.1 In-Use Testing. In-use test cases shall be developed and documented to permit confirmation of acceptable performance of the computer program in the operating environment. In-use test cases shall be performed after the computer program is installed on a different computer or when there are significant changes in the operating environment. Changes in the operating environment shall be evaluated and the need for in-use testing shall be determined based on established criteria that consider the type, scope, and magnitude of the change. Periodic in-use manual or automatic self-check tests shall be prescribed and performed for those computer programs where computer program errors, data errors, computer hardware failures, or instrument drift can affect required performance.

406.2 User Documentation. User and system documentation shall include instructions to ensure proper installation, administration, operation, and uninstallation of the software.

407 Maintenance

The appropriate software engineering elements, as described in para. 102 of this Subpart, shall identify how changes to the software are controlled.

407.1 Testing of Changes. The testing of changes to the computer program shall be performed in accordance with the software engineering method and include validation of the change and performance of regression testing. Such testing shall
(a) verify that a modified system(s) or system component(s) still meets specified software design requirements
(b) provide assurance that the changes have not caused unintended adverse effects in the computer program

The applicable verification activities specified in para. 202 of this Subpart shall be performed for any resulting changes to affected documentation.

408 Retirement

During retirement, support for the software shall be terminated, and the routine use of the software shall be prevented.

500 STANDARDS, CONVENTIONS, AND OTHER WORK PRACTICES

As appropriate, the software engineering method, software acquisition method, or both shall establish the need for standards, conventions, and other required work practices to facilitate software life-cycle activities (e.g.,

software design and implementation activities). Standards, conventions, and other required work practices shall be documented.

600 SUPPORT SOFTWARE

Support software includes software tools and system software. The software engineering method, software acquisition method, or both shall establish the need for support software.

(24) **601 Software Tools**

Software tools shall be evaluated, reviewed, tested, accepted for use, and placed under configuration control as part of the software development cycle of a new or revised software product. Software tools that do not affect the performance of the software need not be placed under configuration control.

Changes to a software tool that is under configuration control shall be evaluated for impact on the computer program to determine the level of reviews and retesting that will be required.

602 System Software

System software shall be evaluated, reviewed, tested, accepted for use, and placed under configuration control as part of the software development cycle of a new or revised software product. Changes to the system software shall be evaluated for impact on the software product to determine the level of reviews and retesting that will be required.

700 REFERENCE (24)

The following publication is referenced in this Subpart:

ISO/IEC/IEEE 24765:2010(E). Systems and software engineering — Vocabulary. Institute of Electrical and Electronics Engineers, Inc.

SUBPART 2.8
Quality Assurance Requirements for Installation, Inspection, and Testing of Mechanical Items for Nuclear Facilities

100 GENERAL

This Subpart provides amplified requirements for installation, inspection, and testing of mechanical items. It supplements the requirements of Part I and shall be used in conjunction with applicable Requirements of Part I to the extent specified by the organization invoking this Subpart.

101 Definitions

The following definitions are provided to ensure a uniform understanding of unique terms as they are used in this Subpart.

checks: the tests, measurements, verifications, or controls placed on an activity by means of investigations, comparisons, or examinations to determine satisfactory condition, accuracy, safety, or performance.

engineering limitations: restrictions that, if disregarded, may result in damage to the item, shortening the life of the item, or preventing the item from functioning as intended.

examination: an element of inspection consisting of investigation of materials, components, supplies, and services to determine conformance to those specified requirements that can be determined by such investigation. Examination is usually nondestructive and includes simple physical manipulation, gaging, and measurement.

mechanical items: parts, components, or systems that function primarily for pressure retaining, mass moving, or heat exchange purposes. Examples of mechanical items are rotating equipment (motors, pumps, blowers), handling equipment (cranes, hoists, conveyors), piping systems (pipe, valves, hangers), fuel handling systems, and waste effluent systems.

200 GENERAL REQUIREMENTS

Measures shall be established and implemented for documenting the necessary installation, inspection, and testing to verify conformance to specified requirements.

201 Planning and Procedures

Planning and procedure preparation shall be in accordance with the requirements of the Introduction to Part II.

202 Prerequisites

The following minimum conditions shall have been met, or evidence thereof shall be available as applicable, before the requirements set forth in this Subpart are applied:

(a) Qualification of individuals, organizations, and procedures has been completed in accordance with the requirements of applicable codes and standards.

(b) Mechanical items have been designed and engineered in accordance with applicable codes, standards, and specifications.

(c) Materials have been selected and equipment has been fabricated and assembled in accordance with the design specifications and the applicable published codes and standards, the conformance to which has been demonstrated by the responsible organization.

(d) Engineering limitations, as applicable, have been incorporated in the procedures and instructions. These limitations and requirements shall include, as a minimum, installation, testing, and on-site fabrication processes such as cleaning, welding, nondestructive examination, and parameters such as pressure, flow, speed, load limits (static and dynamic), travel limits, physical clearances, control and alarm settings, and environmental and thermal limits, which are included in design specifications, manufacturer's data sheets, instruction manual, and design reports.

(e) To substantiate (b) and (c), the following documents relating to the specific stage of installation activity for the mechanical item shall be available at the work site:

(1) latest applicable approved drawings

(2) equipment/design specifications

(3) manufacturer's installation instructions

(4) installation procedures

(5) evidence of compliance by manufacturer with purchase requirements, including quality assurance requirements

(6) evidence that engineering or design changes are documented and approved prior to installation

(7) records of inspections and tests during on-site receiving, storage, and handling

(8) release of mechanical items for installation

(9) evidence that nonconformances have been satisfactorily resolved or controlled

300 PREINSTALLATION VERIFICATION

301 General

Prior to the actual installation of mechanical items, there are certain preliminary inspections, checks, and similar activities that shall be completed to verify that the item and the installation area conform to specified requirements, and the necessary resources are available to ensure that the quality of the mechanical item will be maintained as the installation proceeds.

The quality requirements and quality assurance actions that are necessary during installation shall be reviewed and planned so that they are understood by responsible individuals.

302 Identification

Checks shall be made to verify that the identity of received mechanical materials and equipment has been maintained and is in accordance with the latest approved drawings, equipment lists, specifications, and established procedures. If these checks disclose apparent loss of identification, the identity shall be reaffirmed prior to release for installation.

Checks shall be made to verify that a control system for maintaining identification of mechanical items through installation has been established, including provisions for control of substitution or exchange of equipment or materials. The procedures for control of identification shall provide a system of traceability to drawings, specifications, or other records when identification or markings must be destroyed, hidden, or removed from an item.

303 Installation Process Control

Consistent with the installation activities schedule, inspections or checks shall be performed to verify that processes are ready when needed for use in the installation of mechanical items. These inspections or checks shall include, but not be limited to, the following verifications:

(a) Approved procedures, drawings, manuals, or other work instructions are provided to the installer at the work site.

(b) Special instructions and checklists as required are available at the installation area or attached to the item.

(c) Approved procedures and instructions for special processes such as coating, welding, heat treating, and nondestructive examination are available at the site.

(d) Where applicable, personnel, procedures, and instructions shall have been qualified through the preparation of workmanship standards, samples, or mockups that simulate actual job conditions.

(e) Installation preparations have been completed, including such tasks as removal of packaging, conditioning, cleaning, and preliminary positioning.

(f) Jigs, fixtures, and equipment for special processes, if required, are available at the site and conform to specified requirements.

(g) Equipment for handling and placement of mechanical items is available at the site and is adequate to perform the work in accordance with specified requirements.

(h) Warnings and safety notices appropriate to the activity are posted.

(i) Inspection hold/witness points are identified in work instructions.

(j) The status of installation, inspections, examinations, or tests is clearly indicated or identified.

(k) The installation, inspection, and testing sequences are being maintained.

(l) Identification, appropriate segregation, and disposition of nonconforming items are being maintained.

(m) As-built information is being captured and processed.

(n) Documents such as installation records and inspection and test reports are current, accurate, and complete.

304 Physical Condition

Inspections or checks, as appropriate, shall be performed to verify that mechanical items at installation are in accordance with the specified requirements and that quality has been maintained.

These inspections or checks shall include, but not be limited to, the following verifications:

(a) Protective measures and physical integrity during storage have been maintained in conformance with specified requirements.

(b) Nonconformances have been satisfactorily dispositioned or controlled.

(c) Items have been cleaned in accordance with specified requirements.

305 Installation Area Conditions

Inspections or checks, as appropriate, shall be performed to verify that conditions of the installation area conform to specified requirements and precautions have been taken to prevent conditions that will adversely affect the quality of the items during installation. These inspections or checks shall include, but not be limited to, verification of the following:

(a) Protection from adjacent activities is being provided, including implementation of appropriate exclusion and area cleanness requirements.

(b) Protection from inclement weather and other ambient conditions adverse to quality is being provided.

(c) Materials that may be deleterious to the mechanical items being installed are controlled.

(d) Installation of the mechanical item will not adversely affect the subsequent installation of materials and equipment, and repair or rework on any nonconforming items can be performed satisfactorily.

(e) Adequate permanent or approved temporary supports and mountings have been installed that will properly interface with the mechanical item.

(f) Controls for foreign material exclusion (FME) are in place.

(g) Mating parts, such as couplings and flanges, are properly positioned and conditioned.

(h) Servicing or maintenance activity related to installation has been performed.

400 INSTALLATION INSPECTIONS

401 General

Checking and examination of testing activities shall be performed during the installation of mechanical items to ensure that the required quality is being obtained in accordance with prescribed procedures. These activities shall be performed in a systematic manner to ensure surveillance throughout the installation process. A procedure shall be provided for the coordination and sequencing of these activities at established inspection points in successive stages of installation.

A method shall be implemented to ensure that engineering and design changes during installation are documented and controlled.

402 Process and Procedures Control

Inspections shall be made to verify that a system of controls has been established and is being maintained at the construction site to ensure that

(a) the applicable revision of approved procedures, drawings, and instructions is being followed

(b) qualified and approved processes, materials, tools, and other equipment are being used by qualified personnel

(c) the status of installation, inspections, examinations, or tests is clearly indicated or identified in inspection reports

(d) the installation, inspection, and testing sequences are being maintained

(e) identification, appropriate segregation, and disposition of nonconforming items are being maintained

(f) as-built information is being processed

(g) inspection and test reports are current, accurate, and complete

403 Inspection

Inspections of the work areas and the work in progress shall be performed to verify that mechanical items are being located, installed, assembled, or connected in compliance with the latest approved drawings, manufacturer's instructions, and procedures. Inspections performed shall include as appropriate, but not be limited to, the following:

(a) identification

(b) location and orientation of components

(c) leveling and alignment

(d) clearances and tolerances

(e) tightness of connections and fastenings

(f) fluid levels and pressures

(g) absence of leakage

(h) physical integrity

(i) cleanness

(j) welding operations, including materials and process controls, adequate purging, and the removal of purge dams on completion

(k) adequacy of protective measures to ensure that the item will not be damaged during installation

(l) adequacy of housekeeping, barriers, and protective equipment to ensure that items will not be damaged or contaminated as a result of adjacent activities

404 Installation Checks

Checks shall be performed to verify that mechanical items have been correctly installed and will function properly so that the initial starting of items and preoperational testing can proceed with a minimum amount of problems and delays. If construction or an associated activity affects the results of these checks, the checks shall be repeated, if necessary, to ensure that the quality has not been adversely affected.

These activities shall include as appropriate, but not be limited to, the following:

(a) Procedures are prepared and approved to verify correctness of installation and ability to function per design.

(b) Proper greasing or lubrication has been completed.

(c) Protection strainers are installed where necessary.

(d) Rotation of prime movers is correct.

(e) Item is correctly valved and isolated.

(f) Casings, reservoirs, etc., are primed, vented, and filled.

(g) Piping system alignment is correct.

(h) Pipe hangers are installed per design.

(i) Seismic anchors and restraints are properly installed.

(j) Valve glands and packing are installed.

(k) Pneumatic lines are verified free of debris and dry.

(l) Valve stroking, actuation, and settings are proper.

(m) Pump seals and packing are properly installed.

404.1 Cleaning. Mechanical items shall be cleaned, flushed, and conditioned according to applicable requirements. Special attention shall be given to the following requirements:

(a) Chemical Conditioning Procedures shall be prepared including the scope, acceptance criteria, sequence, temperatures, soak periods, and neutralizing solutions to be used. Checks shall be made to verify that the proper chemicals at the designated strength and temperature are being used in the conditioning operations.

Other operations shall be performed as specified in (c) of this Subpart.

(b) Flushing. Procedures shall be prepared including routes, boundaries, velocities and acceptance criteria, restoration, and layup for high integrity systems, where appropriate. Checks shall be made to verify that mechanical items are being flushed in accordance with specified requirements so that contaminants or flow velocities will not adversely affect subsequent operations.

Other operations shall be performed as specified in (c) of this Subpart.

(c) Process Controls. Checks shall be performed to verify that controls are functioning for the following:

(1) removal and installation of parts or components such as metering devices, orifice plates, and valve internals that are removed from the system to facilitate flushing

(2) installation and removal of temporary strainers, blind flanges, and piping

(3) isolation of sensitive instrumentation

(4) water and chemical quality

(5) acceptance data, specimens, or progressive samples, if required

Where appropriate for disassembly and reassembly of mechanical items, procedures or instructions shall be prepared or manufacturer's technical manuals shall be used to ensure adherence to match marks, protection of seats, and proper reassembly and to preclude damage to the mechanical item.

404.2 Pressure Testing. Checks shall be made to verify that mechanical items are being pressure tested in accordance with specified requirements to ensure that the strength and integrity of the installed systems or portions thereof conform to specified requirements. The purpose of the test, scope, test boundary, duration for inspection, acceptance criteria, restoration, and layup shall be clearly established and documented. Checks shall include, but not be limited to, the following:

(a) Appropriate pressures, temperatures, water chemistry, and pressure test cycles are established.

(b) Sufficient time at test pressure is specified to determine acceptance.

(c) Provisions are available to protect and isolate instrumentation during hydrostatic testing.

(d) Items external to test boundary are protected to prevent inadvertent overpressurization.

(e) Relief devices are controlled to prevent overpressurization.

(f) Gagging and ungagging of relief valves has been performed.

(g) Piping and equipment supports have hydrostatic pins installed where applicable for testing and are to be removed upon completion of testing.

(h) Evidence of calibration of measuring and test equipment has been determined.

405 Care of Mechanical Items

Items on which inspection and testing activities are performed shall be protected from personnel traffic, weather, and adjacent activities such as sandblasting, acid cleaning, welding, jack hammering, chipping, burning, and stress relieving, which would adversely affect the quality of the item or test results. Such protection shall be provided through good cleanliness and housekeeping practices, temporary packaging, erection of barriers, protective covers, and walkways, as required.

Temporary use of equipment or facilities to which this Part applies, which are to become part of the completed project, may be desirable. Authorization for such usage shall be as provided for in the contract or by written approval from the responsible organization. Such temporary use shall not subject the mechanical items to conditions for which they were not designed.

The temporary use authorization shall include

(a) conditions of use or operation

(b) maintenance requirements

(c) inspections and tests as required to maintain operability and quality during the period of temporary use of item

When temporary use is completed, conditions of temporary use shall be evaluated to verify that the permanent equipment continues to satisfy specified requirements.

500 SYSTEMS TURNOVER INSPECTION AND TESTS

501 General

Following the installation of mechanical items, the checking, inspection, and testing activities shall be performed to verify that the completed systems are in conformance with specified requirements. This is a final verification that the requirements defined by licensing commitments, drawings, specifications, and other contract documents are reflected in the completed installation. It is also a time to verify that field modifications and other changes made and controlled during installation activities have been incorporated in the as-built documents.

Controls shall be provided for the identification, documentation, and resolution of nonconformances disclosed by inspections or tests.

Tests shall be conducted on completed plant systems. Test procedures shall identify prerequisites for system testing including required completed construction

activities. The test procedures shall identify and describe any temporary or simulated condition or equipment. If not previously planned, a documented notice shall be prepared and issued with approval of the responsible organization stating the substitutions that existed for the test. Written verification shall also be provided that temporary installations have been satisfactorily replaced by permanent installations.

Checks and inspections shall be performed to verify the operational readiness and completeness of components and systems. These systems or partial systems shall be identified, tagged, and released for operational testing. These checks and inspections shall be performed to verify the following as a minimum:

(a) Equipment and materials have not sustained external physical damage.

(b) The installation has been made in accordance with specified requirements.

(c) All nonconforming conditions have been satisfactorily dispositioned.

(d) Internal and external restrictions and obstructions to flow and full travel have been removed.

(e) Supports and restraints are properly installed.

(f) Interfacing connections with adjacent systems are compatible.

(g) Original materials and component identification have been preserved with provisions for traceability throughout the installed systems.

(h) Safety features such as interlocks, cable separations, guards, warning devices, and lockouts have been installed, are being used, and comply with applicable codes and regulations.

(i) Temporary connections, such as jumpers and bypass lines, and temporary trip points of control equipment are identified and documented so that their final condition can be verified.

(j) System water chemistry is appropriate for operational testing.

(k) External surface chemistry requirements have been maintained.

(l) Permits and authorizations have been obtained.

502 Preoperational Testing

This testing involves the operation of all items in a system(s) or partial system(s) to ensure that operation is in accordance with the design criteria and functional requirements. The testing shall include, but not be limited to, the following:

(a) systems integrity

(b) in-line instrument installation is consistent with specified flow directions

(c) sensing lines are phased correctly to in-line elements and sensors

(d) service requirements for initial operation such as flow alignments, limiting flow orificing, and relief devices have been performed

(e) operation of controls, valves, dampers, operators, and load limiting devices

(f) rotating equipment (motors, pumps, blowers), rotation, speed, vibration, noise, and no-load operation

(g) handling equipment (load tests of cranes, hoists, conveyors, hooks, handling adapters, and accessories)

(h) containment systems

(i) air handling systems

(j) fuel storage and handling systems

(k) reactor component handling systems

(l) instrument air systems

(m) fluid service systems

(n) waste effluent systems

(o) auxiliary building systems

Where mechanical equipment and systems interface with, and their operation must coordinate with, nonmechanical equipment or systems, the test performed shall include verifying the compatibility of interfacing equipment and functions.

503 Cold Functional Tests

Typically, a nuclear facility will have a cold startup process where nonradioactive materials or gases are used to check the system, followed by a hot startup when radioactive materials are used. These tests follow preoperational testing of individual systems, including reactor coolant systems. This testing shall be performed to obtain operational data of equipment and maximum allowable simultaneous operation of interfacing systems and equipment, and the final verification of functional performance of these systems.

503.1 Reactor Coolant System Hydrostatic Tests. As applicable to reactor system type, hydrostatic tests to verify conformance to specified requirements, when performed on the reactor coolant system, shall include all or parts of connected systems that cannot be isolated from the test pressure. The applicable test requirements are contained in Section III of the ASME Boiler and Pressure Vessel Code.

503.2 Functional and Flow Testing. The required individual systems shall be tested to demonstrate cold functional operability of individual components, subsystems, and systems, and to demonstrate compatibility with other systems. These tests, where appropriate, shall demonstrate the following:

(a) system pressure drop

(b) flow rate

(c) controls and throttling device settings

(d) function of interlocks, alarms, and automatic features

(e) instrument calibration

(f) setting of meter biases

(g) system stability

(h) adequacy of pipe and equipment support settings

(i) heat runs on rotating equipment

(j) adequacy of ventilation, lubrication, and cooling systems under sustained operating conditions
(k) ability to meet water chemistry requirements

504 Hot Functional Tests

Typically, a nuclear facility will use radioactive materials for hot startup. These tests are not applicable to BWR and HTGR nuclear plants because these plants use nuclear heat to produce the system temperatures. Hot functional tests for PWR plants follow cold functional tests and simulate plant operating conditions at elevated temperatures and pressures. All auxiliary and support systems exclusive of those required for precriticality testing must be available for these tests. If any of these systems is not available, the responsible organization shall specifically authorize exclusion of these systems from testing and document those exceptions.

These systems shall include the following as a minimum:

(a) system pressure drop
(b) flow rate
(c) controls and throttling device settings
(d) function of interlocks, alarms, and automatic features
(e) instrument calibration
(f) setting of meter biases
(g) system stability
(h) adequacy of pipe and equipment support settings
(i) heat runs on rotating equipment
(j) verification of heat exchanger performance
(k) verification of boron control system performance
(l) thermal insulation effectiveness
(m) set points of temperature, pressure, and level devices
(n) system heatup tests
(o) system cooldown tests
(p) hot flow tests
(q) setting protective devices
(r) hot clearances
(s) vibration measurements of major equipment and piping, as applicable

600 DATA ANALYSIS AND EVALUATION

Procedures shall be established for processing inspection and test data and their analysis, evaluation, and final acceptance. These procedures shall identify individuals or organizations responsible for documentation of inspection and test data and evaluation against acceptance criteria, operating limits, and performance standards. The data processing procedure shall provide for preliminary evaluation to determine the validity of the inspection and test results and the appropriateness of continuing the inspection or test. The data shall be analyzed and evaluated to verify completeness of results, achievement of inspection and test objectives, and operational proficiency of equipment and systems; to identify additional inspection or test requirements or both; and to identify necessary changes to the installation inspection or test procedures. Inspection and test results supported by the inspection and test data, together with a report of data analysis and evaluation, shall be provided as specified in section 700 of this Subpart.

700 RECORDS

Record copies of procedures, reports, required qualification records, test equipment calibration records, test deviation or exception records, and inspection, examination, and check records shall be prepared. These records shall be retained with other project records as required by code, standard, specification, or project procedures.

SUBPART 2.14
Quality Assurance Requirements for Commercial Grade Items and Services

100 GENERAL

This Subpart provides amplified requirements to provide reasonable assurance that a commercial grade item (CGI) or service will perform its safety function. These requirements are intended to supplement the requirements of Part I and shall be used in conjunction with the applicable requirements of Part I by organizations performing commercial grade dedication for accepting items or services.

The amplified requirements specified in this Subpart are considered adequate for nuclear facilities identified in Part I, Introduction, section 200.

101 Definitions[1]

The following definitions are provided to ensure a uniform understanding of unique terms as they are used in this Subpart.

basic component: a structure, system, component, or part thereof that affects its safety function, that was designed and manufactured in accordance with the requirements of this Standard, or commercial grade items that have successfully completed the dedication process.

commercial grade item[2]*:* a structure, system, component, or part thereof that affects its safety function, that was not designed and manufactured (i.e., controlled) as a basic component. Commercial grade items do not include items where the design and manufacturing process require in-process inspections and verifications to ensure that defects or failures to comply are identified and corrected (i.e., one or more critical characteristics of the item cannot be verified).

commercial grade item[3]*:* an item satisfying the following:

(a) not subject to design or specification requirements that are unique to those facilities or activities

(b) used in applications other than those facilities or activities

(c) to be ordered from the manufacturer/supplier on the basis of specifications set forth in the manufacturer's published product description (e.g., a catalog)

commercial grade item[4]*:* a structure, system, or component, or part thereof, that affects its safety function, that was not designed and manufactured (i.e., controlled) in accordance with the requirements of this Standard.

commercial grade service: a service that was not provided in accordance with the requirements of this Standard that affects the safety function of a basic component.

critical characteristics: important design, material, and performance characteristics of a commercial grade item or service that, once verified, will provide reasonable assurance that the item or service will perform its intended safety function.

dedicating entity: the organization that performs the dedication process. Dedication may be performed by the manufacturer of the item, a third-party dedicating entity, or by the facility.

dedication: an acceptance process performed in accordance with this Standard to provide reasonable assurance that a commercial grade item or service will perform its intended safety function and, in this respect, is deemed equivalent to an item or service designed and manufactured or provided under the requirements of this Standard. This assurance is achieved by identifying the critical characteristics of the item and verifying their acceptability by inspections, tests, or analyses performed by the purchaser or third-party dedicating entity after delivery, supplemented as necessary by one or more of the following: commercial grade surveys; product

[1] United States (U.S.) nuclear facilities are regulated and licensed under the Code of Federal Regulation (CFR) based on the facility function or purpose. Regulations can vary based on the type of facility, applicable CFR, and regulatory agency. Regulation 10 CFR Part 21, Reporting of Defects and Noncompliance, establishes criteria for commercial grade item definition and dedication activities that are based on the facility types per 10 CFR Parts 30, 40, 50, 52, 60, 61, 63, 70, 71, and 72, unless specifically provided otherwise in the regulations. United States licensed facilities and other entities supporting the licensed facilities are required to comply with the appropriate regulations. It is the responsibility of the U.S. facility management to determine the applicability of this Subpart to meet the U.S. facility regulatory requirements, including all pertinent definitions.

[2] This definition is applicable to nuclear power plants and activities licensed pursuant to 10 CFR Part 30, 40, 50, 52, or 60.

[3] This definition is applicable to nuclear facilities and activities licensed pursuant to 10 CFR Part 30, 40, 50 (other than nuclear power plants), 60, 61, 63, 70, 71, or 72.

[4] This definition is applicable to Department of Energy nuclear facilities and activities regulated under 10 CFR 830, Nuclear Safety Management.

inspections or witness at hold-points at the manufacturer's facility, and analysis of historical records for acceptable performance. In all cases, the dedication process must be conducted in accordance with the applicable provisions of Part I.

equivalency evaluation: a technical evaluation performed to confirm that a replacement item (not identical to the original) can satisfactorily perform its intended functions, including its safety functions.

equivalent replacement: a replacement item not physically identical to the original. These replacement items require an equivalency evaluation to ensure that the intended functions, including its safety function, will be maintained.

identical item: an item that exhibits the same technical and physical characteristics (physically identical).

like-for-like replacement: the replacement of an item with an item that is identical.

200 CGI DEFINITION APPLICATIONS

A facility utilizing commercial grade items or services shall utilize the appropriate commercial grade item definitions to determine if the item or service can be procured commercial grade. An item or service performing a safety function that does not meet the commercial grade definition is subject to the requirements in Part I.

300 UTILIZATION

As an alternative to the acceptance measures in Part I, controls providing reasonable assurance that the item or service will perform its intended safety function can be implemented for the acceptance of a commercial grade item that performs a safety function. These controls shall include the following:

(a) determination of the item's or service's design requirements or safety function

(b) confirmation that the item or service meets the applicable commercial grade item definitions

(c) identification and documentation of the critical characteristics, including acceptance criteria

(d) selection, performance, acceptance, and documentation of the dedication method(s) for determining compliance with the critical characteristic acceptance criteria.

Only items or services that perform a safety function and meet the commercial grade definitions shall be considered for commercial grade dedication. A dedication plan shall be developed for the item or service that identifies the critical characteristics and dedication methods, including acceptance criteria. Dedication plans may be developed for a specific item, service, or for a generic group of items or services. Dedication requirements shall be included in applicable procurement and technical documents as necessary to support the dedication.

Items or services that successfully complete the dedication process are subsequently subject to the controls of Part I and Part II.

400 TECHNICAL EVALUATION

401 General

The technical evaluation(s) shall be performed by the responsible engineering organization to

(a) determine the design requirements or safety function(s) of the item or service

(b) identify performance requirements, the component/part functional classification, and applicable service conditions

(c) confirm that the item or service meets the commercial grade definition criteria

(d) identify the critical characteristics, including acceptance criteria

(e) identify the dedication method(s) for verification of the acceptance criteria

(f) determine if a replacement item is a like-for-like or equivalent item

The requirements of this Subpart are only applicable to commercial grade items or services that perform a safety function. Design output documents, supplier technical information, and other relevant industry technical and operating experience information, as appropriate, shall be utilized to prepare the technical evaluation.

Components that perform a safety function can contain items that do not perform a safety function. Replacement items shall be evaluated to determine their individual safety function in relation to the component or equipment.

The credible failure modes of an item in its operating environment and the effects of these failure modes on the safety function shall be considered in the technical evaluation for the selection of the critical characteristics. Services shall be evaluated to determine if the failure or improper performance of the service could have an adverse impact on the safety function of equipment, materials, or the facility operations.

If the design criteria for the commercial grade item are known by the dedicating entity, then the item may be dedicated to these criteria in lieu of defining a specific safety function. In this case, consideration of failure modes is not required and the item's design parameters and allowables become the critical characteristics and acceptance criteria.

If the design criteria or safety function of the original item have changed, the replacement item must meet the new design criteria and safety function. Like-for-like and equivalent items are not a design change subject to Part I, Requirement 3, section 600.

402 Like-for-Like Items

Items may be considered identical or like-for-like if one of the following applies:

(a) The item is provided from the original equipment manufacturer (successor companies that maintain equivalent quality controls are acceptable), and has not been subject to design, materials, manufacturing, or nomenclature changes.

(b) The item was purchased at the same time and from the same supplier, as determined by the purchase date, shipping date, date code, or batch/lot identification.

(c) Evaluation of the item confirms that no changes in the design, materials, or manufacturing process have occurred since the procurement of the original item.

A like-for-like determination shall not be based solely on the selection of a commercial-grade vendor with items manufactured to meet the same industry standards of the original item. Meeting the same industry standards may be a necessary condition, but is not a sufficient condition for a like-for-like determination.

If the dedicating entity can demonstrate that the replacement item is identical, then the safety function, design requirements, and critical characteristics need not be re-determined. However, verification of the identified critical characteristics by an appropriate dedication method(s) is required to verify the acceptability of the replacement item.

403 Equivalent Items

When difference(s) exist from the original item, an equivalency evaluation is required to determine if any changes in design, material, manufacturing process, form, fit, or function could prevent the replacement item from being interchangeable under the design condition of the original items and performing its required safety function.

The equivalency evaluation shall be documented and include the following:

(a) identification of the change(s) in design, material, manufacturing process, configuration, form, fit, or function of the replacement item that is different from the original item

(b) evaluation of the change(s)

(c) confirmation that the change(s) does not adversely affect the current design or safety function of the item

If the change(s) adversely affects or is not bounded by the current approved design bases, the replacement item is not equivalent and must be rejected or processed as a design change in accordance with Part I, Requirement 3, section 600.

Equivalency evaluations can determine the acceptability of the difference in the item to perform its safety function and identify critical characteristics for acceptance for the replacement item. Equivalency evaluations are not to be used as the sole basis to accept a commercial grade item. Selection and verification of the identified critical characteristics by an appropriate dedication method(s) is required to verify the acceptability of the replacement item.

500 CRITICAL CHARACTERISTICS

Critical characteristics selected for acceptance shall be identifiable and measurable attributes based on the complexity, application, function, and performance of the item or service for its intended safety function. Critical characteristics of an item for acceptance shall include physical and performance characteristics, as appropriate. Dependability characteristics applicable to computer programs are discussed in Part III, Subpart 3.2-2.14.

The critical characteristic acceptance criteria shall include tolerances, when appropriate. Commercial grade items or services can have numerous design characteristics. Critical characteristics are a subset of design characteristics that, when verified, provide reasonable assurance that the item or service will perform its intended safety function.

In cases where the critical characteristics and acceptance criteria cannot be determined from the manufacturer's documentation or other documentation, the dedicating entity may perform an engineering evaluation, examination, or test (or any combination thereof) of the original item to develop the critical characteristics and acceptance criteria. Commercial grade items designated for installation or installed in seismically or environmentally qualified equipment or in locations which require such qualification shall include the selection of appropriate critical characteristics required to maintain the qualification of the component or equipment.

600 METHODS OF ACCEPTING COMMERCIAL GRADE ITEMS AND SERVICES

601 Dedication

(a) To provide reasonable assurance that a commercial grade item or service will perform its intended safety function, the dedicating entity shall verify that the commercial grade item or service meets the acceptance criteria for the identified critical characteristics by one or more of the following dedication methods:

(1) Method 1: inspections, tests, or analyses performed after delivery

(2) Method 2: commercial grade survey of the supplier

(3) Method 3: source verification of the item or service

(4) Method 4: acceptable supplier/item performance record

(b) Prior to classifying the item or service as acceptable to perform its safety function, the dedicating entity shall determine that the following have been successfully performed, as applicable:

(1) Damage was not sustained during shipment.

(2) The item or service has satisfied the specified acceptance criteria for the identified critical characteristics.

(3) Specified documentation was received and is acceptable.

(c) The dedication method(s) described in paras. 602 through 605 of this Subpart shall provide a means to assure that the commercial grade item or service meets the acceptance criteria for the selected critical characteristics. The selection of acceptance method(s) shall be planned and based on the type of critical characteristics to be verified, available supplier information, quality history, and degree of standardization. If a critical characteristic cannot be verified by the selected dedication method, the dedicating entity may select another or combination of dedication methods to verify the critical characteristic.

(d) The organization that performs or directs the dedication activity and determines the item or service has satisfactorily met the acceptance criteria for the selected critical characteristics is the dedicating entity. The dedicating entity can be the manufacturer, a third-party organization, the purchaser, or the nuclear facility organization.

602 Method 1: Special Test(s), Inspection(s), and/or Analyses

Special test(s), inspection(s), or analyses either individually or in combination shall be conducted upon or after receipt of an item to verify conformance with the acceptance criteria for the identified critical characteristics. The special test(s), inspection(s), and/or analyses may include postinstallation testing and may be performed utilizing a sampling plan, when appropriate.

Special inspections may include receipt inspection activities to verify adequate criteria associated with procurement activities. The receipt inspection activities may be included in the dedication plan.

Sampling plans utilized to select items for special test(s), inspection(s) and/or analyses shall be based upon standard statistical methods with supporting engineering justification and shall consider lot/batch traceability, homogeneity, and the complexity of the item.

When postinstallation test(s) are used to verify acceptance criteria for the critical characteristics, the commercial grade item or service shall be identified and controlled to preclude inadvertent use prior to satisfactory completion of the dedication activities.

When critical characteristics acceptance criteria is based on certified material test reports or certificates of conformance, the criteria of Part I, Requirement 7, section 503 shall be met.

Services can result in a deliverable product that can be evaluated upon receipt or result in an activity that can be evaluated during or at the conclusion of its performance.

603 Method 2: Commercial Grade Survey of the Supplier

(a) A commercial grade survey is a method to verify critical characteristics by evaluating the adequacy and effectiveness of the supplier's commercial quality controls. A commercial grade survey is performed in accordance with a checklist or plan at the supplier's facility and includes or addresses the following:

(1) identification of the item(s), or product line, or service included within the scope of the survey

(2) identification of the critical characteristics to be controlled by the supplier

(3) verification that the supplier's processes and controls to assure quality are effectively implemented for control of the critical characteristics

(4) identification of the survey methods or verification activities performed with results obtained

(5) documentation of the adequacy of the supplier's processes and controls

(b) A commercial grade survey shall not be employed as a method for accepting commercial grade items or services from suppliers with undocumented quality programs or with programs that do not effectively implement the supplier's own specified processes and controls. After a supplier's processes and controls have been determined to be adequate, the dedicating entity shall invoke or reference the verified processes and controls including revision level as a part of the purchase order or control requirements for the commercial grade item or service and require the supplier to provide a Certificate of Conformance attesting to the implementation of the identified processes and controls.

(c) When critical characteristics acceptance criteria are based on certified material test reports or certificates of conformance, the criteria of Part I, Requirement 7, section 503 shall be met.

(d) Surveys shall not be employed as a method for accepting items from distributors unless the survey includes the manufacturer and the survey confirms adequate processes and controls by both the distributor and the manufacturer. A survey of the distributor may not be necessary if

(1) the distributor acts only as a broker and does not warehouse or repackage the items

(2) in cases where traceability can be established by other means such as verification of the manufacturer's markings or shipping records

(e) Surveys performed by organizations other than the dedicating entity may be used as a basis for acceptance if the survey results of the critical characteristics, survey scope, supplier's processes and controls, and acceptance criteria are evaluated by the dedicating entity to be

acceptable and consistent with the dedicating entity's dedication requirements.

(f) The scope of the survey shall be determined by the dedicating entity based upon the item or service and critical characteristics to be verified. The survey shall be specific to the scope of the commercial grade item or service being procured. When several items or services are purchased from a supplier, a survey of representative groups of commercial grade items or services can be sufficient to demonstrate that adequate processes and controls exist. The survey report shall provide objective evidence that the critical characteristics are verified and controlled by the supplier.

(g) If the scope of the survey cannot verify a designated critical characteristic due to controls by the supplier's subsupplier(s), the dedicating entity shall extend the survey to the subsupplier(s) or select another dedication method(s) to verify the critical characteristic.

(h) Organizations performing surveys shall establish processes for performing those surveys. Collectively, personnel assigned to conduct commercial grade surveys shall have the necessary capabilities in auditing functions and shall have appropriate technical knowledge to evaluate the supplier's controls associated with the critical characteristics to be verified.

(i) The dedicating entity shall establish a survey frequency to ensure that process controls applicable to the critical characteristics of the item or service procured continue to be effectively implemented. Factors to be considered in determining the frequency of commercial grade surveys include the complexity of the item or service, frequency of procurement, receipt inspection, performance history, and knowledge of changes in the supplier's process and controls. The survey frequency interval may be the same used for supplier audits, but shall not exceed the frequency interval for supplier audits.

(j) For a supplier of calibration or testing services, the Purchaser may utilize the requirements of Part II, Subpart 2.19 as an alternative to the commercial grade survey requirements of (a).

604 Method 3: Source Verification

Source verification is a method of acceptance conducted at the supplier's facility or other applicable location to verify conformance with the identified critical characteristics and acceptance criteria. The scope of the source verifications shall include activities such as witnessing the fabrication and assembly processes, nondestructive examinations, performance tests, or final inspections, as applicable. It shall also include verification of the supplier's design, procurement, calibration, and material process and control methods employed for the particular commercial grade item or service being purchased, as applicable to the identified critical characteristics.

Organizations performing source verification shall develop criteria for the personnel qualifications and processes used to perform source verification. Source verification documentation shall provide objective evidence that the supplier's activities for the identified characteristics were observed and evaluated for acceptance.

Source verification is only applicable to the actual item(s) or service(s) that are verified at the supplier's facility or other applicable location. Source verification shall be performed in accordance with a checklist or plan with the documented evidence of the source verification furnished to the dedicating entity and shall include or address the following:

(a) identification of the item(s) or service(s) included within the scope of the source verification

(b) identification of the critical characteristics, including acceptance criteria, being controlled by the supplier

(c) verification that the supplier's processes and controls are effectively implemented for the identified critical characteristics

(d) identification of the activities witnessed during the source verification and the results obtained

(e) identification of mandatory hold points to verify critical characteristics during manufacture and/or testing for those characteristics that cannot be verified by evaluation of the completed item

(f) documentation of the adequacy of the supplier's processes and controls associated with the critical characteristics and acceptance criteria

605 Method 4: Acceptable Supplier Item or Service Performance Record

A documented supplier item or service performance record is a method of acceptance to verify conformance with the identified critical characteristics and acceptance criteria of a commercial grade item or service against the supplier's performance record for identical or similar services. This allows the dedicating entity to have reasonable assurance of the item's or service's performance based upon historical performance gained from the successful utilization of other acceptance methods, and/or pertinent industry-wide performance data.

Acceptable data for historical performance may be compiled utilizing monitored performance of the item, industry product tests, certification to national codes and standards (non-nuclear specific), and other industry records or databases. The supplier item or service performance record or data shall be from the condition of service, environmental condition, failure mode, maintenance program, testing, or other conditions equivalent to the intended application of the commercial grade item or service.

(a) An acceptable supplier item or service performance record shall include the following:

(1) identification of the supplier item or service being evaluated

(2) identification of previously established critical characteristics specific to the supplier item or service

(3) identification of data examined to evaluate the supplier item or service

(4) identification of basis for determining that performance data substantiates acceptability of the supplier item or service

(5) documentation of the adequacy and acceptance of the supplier/item/service performance record

(b) An acceptable item or service performance record shall not be employed alone as a method of acceptance unless

(1) the established historical record is based on industry-wide performance data that is directly applicable to the critical characteristics and the intended facility application, i.e., single sources of information are not adequate to demonstrate satisfactory performance.

(2) the manufacturer's/supplier's measures for the control of applicable design, process, and material change have been accepted by the dedicating entity, as verified by survey.

Continued application of an acceptable supplier/item/service performance record as a method of acceptance shall include a documented periodic update and review to assure the supplier/item/service maintains an acceptable performance record.

606 Supplier Deficiency Correction

Deficiencies with the supplier's processes and controls identified by the acceptance method(s) shall be corrected by the supplier if it affects the acceptance criteria for critical characteristic(s) utilized for commercial grade dedication. Corrective actions shall be evaluated for acceptability by the dedicating entity. Uncorrected deficiencies in processes or controls may result in the selection of another dedication method for determining acceptance.

700 COMMERCIAL GRADE SERVICES

Some examples of services that may be provided as commercial grade include training, calibration, testing, engineering, computer software support, and other technical support activities. Services on equipment or items, including installation, repair, cleaning, or maintenance, that do not physically alter an item's critical characteristics are additional examples. Personnel qualification, activity controls, independent certifications, and documents are typical examples of critical characteristic for dedication of services.

Part I, Requirement 7, section 507 shall be reviewed to determine if this requirement is applicable before considering the dedication of a service. As an alternative to commercial grade dedication, services may be performed under the dedicating entity's or other organization's quality program and procedures that meet the requirements of this Standard.

Physical, mechanical, or other service activities that alter or create new critical characteristics of an item that can be used to determine the acceptability of the service that produced the critical characteristic shall not be considered a commercial grade service. For example, if a plate is rolled to a defined radius, the new critical characteristic produced is the radius of the rolled plate and not the rolling process or service that produced the curvature. Original critical characteristics of the plate material and the plate thickness can remain unchanged or be specified by the design organization for the rolled plate. Another example of a commercial grade service is the repair or calibration of an installed instrument by the manufacturer's service representative. The instrument could have been previously dedicated, but now requires service using special tools from the manufacturer that does not have a quality assurance program that meets the requirements of this Standard. The successful results of the calibration service to return the item to the original performance characteristics can be verified by the dedicating entity for acceptance of the commercial grade service.

800 DOCUMENTATION

Documentation of the commercial grade item or service dedication process shall be traceable to the item, group of items, or services and shall contain the following types of documents, depending on the applicable dedication method:

(a) dedication plans or procedures including the essential elements of the dedication process

(b) commercial grade item or service procurement documents

(c) technical evaluations

(d) critical characteristic identification and acceptance criteria

(e) test reports or results, inspection reports, analysis reports

(f) commercial grade survey reports

(g) source verification reports

(h) historical performance information

(i) dedication report containing sufficient data to accept the item or service

900 REFERENCES (24)

The following is a listing of documents and publications utilized in the development of this Subpart.

10 CFR 21, Reporting of Defects and Noncompliance. U.S. Nuclear Regulatory Commission.

Generic Letter 89-02, Actions to Improve the Detection of Counterfeit and Fraudulently Marketed Products. Washington, DC. March 21, 1989. U.S. Nuclear Regulatory Commission.

Generic Letter 91-05, Licensee Commercial-Grade Procurement and Dedication Programs. Washington, DC. April 9, 1991. U.S. Nuclear Regulatory Commission.

NRC Inspection Procedure (IP) 43004, Inspection of Commercial-Grade Dedication Programs. U.S. Nuclear Regulatory Commission.

EPRI 3002002982. Plant Engineering: Guideline for the Acceptance of Commercial-Grade Items in Nuclear Safety-Related Applications: Revision 1 to EPRI NP-5652 and TR-102260. Electric Power Research Institute.

EPRI TR-017218-R1. Guideline for Sampling in the Commercial-Grade Item Acceptance Process. Electric Power Research Institute.

EPRI Technical Report 1008256. Plant Support Engineering: Guidelines for the Technical Evaluation of Replacement Items in Nuclear Power Plants Revision 1 (Revision of EPRI NP-6406). Electric Power Research Institute.

U.S. Department of Energy Guide G 414.1-2a. U.S. Department of Energy.

SUBPART 2.15
Quality Assurance Requirements for Hoisting, Rigging, and Transporting of Items for Nuclear Power Plants

Subpart 2.15 has been replaced with ASME HRT-1–2016, Rules for Hoisting, Rigging, and Transporting Equipment for Nuclear Facilities. Copies of this standard may be obtained from The American Society of Mechanical Engineers (ASME), www.asme.org.

SUBPART 2.17
Quality Assurance Requirements for Electronic Quality Assurance Records Systems

100 GENERAL

This Subpart requirements apply to organizations utilizing electronic records systems. It provides amplified requirements used to maintain the integrity of electronic records and their supporting information. It supplements and shall be used in conjunction with the Requirements of Part I for the specified requirements relating to the control of electronic quality assurance records management. The specified attributes included in this Subpart consist of record recovery, access control, retrieval, digital and physical security, data integrity, disposal, and maintenance.[1]

101 Definitions

The following definitions are provided to ensure a uniform understanding of unique terms as they are used in this Subpart.

electronic records: records created, generated, sent, communicated, received, or stored in a form that only a computer can process.

electronic records system: a combination of hardware and software used to manage electronic records and associated information.

metadata: a set of data that describes and gives information about other data that are established in the record data elements.

offline storage: a storage system isolated from the normal network access that is not immediately available and requires intervention to become accessible by authorized individuals.

records program: the procedures and retention schedules established to implement the quality assurance records requirements of this Standard.

200 GENERAL REQUIREMENTS

Facility environments for electronic storage shall be specified in the controls for the environment at each authorized location.[2] The facilities shall be so constructed or located to protect the electronic records systems to minimize the risk of loss, damage, or destruction as stated in Part I, Requirement 17.

Storage management controls shall

(a) include

(1) record recovery
(2) access control
(3) retrieval
(4) digital and physical security
(5) designation of responsible personnel
(6) facility-supporting equipment
(7) specified environmental ranges to ensure functionality of digital storage equipment

(b) establish the locations authorized for lifetime,[3] nonpermanent,[4] and temporary storage.[5] Temporary storage of electronic records shall be based on specific criteria to ensure that the integrity of the electronic records is maintained.

(c) include controls to maintain the content and integrity of electronic records. The electronic records shall be in a sustainable format based on recognized industry standards. Electronic records stored in multiple locations shall be identical in content. Records stored in offline storage shall accurately reflect the online electronic record. Offline storage requires additional controls to validate that the electronic records have not been altered.

(d) establish periodic records storage assessments to ensure record files are retrievable and useable and that the electronic records system is effective.

300 RECORD RECOVERY

Electronic records shall be recoverable after any event that causes disruption to the electronic records system, including a complete loss of a record storage facility.

[1] See 36 CFR Part 1236 Subpart B — Records Management and Preservation Considerations for Designing and Implementing Electronic Information Systems.

[2] See 36 CFR 1236 Subpart C — Additional Requirements for Electronic Records.

[3] See Part I, Requirement 17, section 401.

[4] See Part I, Requirement 17, section 402.

[5] See Part I, Requirement 17, section 603.

The supporting systems for electronic records shall be described so the system can be returned to service and accessed by authorized personnel in accordance with time frames established in the records program and record recovery plan.

301 Record Recovery Plan

A record recovery plan shall be established to provide the necessary activities required to

(a) establish procedures or instructions for the resumption of the storage and retrieval functions in the event of a system disruption

(b) establish the necessary hardware and software

(c) recover or reconstruct the electronic records within established time frames

400 ACCESS CONTROL AND RETRIEVAL

The electronic records system shall establish user permissions allowing or preventing users, as appropriate, from creating, accessing, modifying, or destroying electronic records.[6]

401 Access Control

Access controls in Part I are acknowledged; however, electronic records require additional considerations. Controls shall establish levels of access and the authority associated with each level of access, including but not limited to

(a) processing of records

(b) content access

(c) metadata changes

(d) records disposal

(e) system hardware access

(f) administration of system software

402 Retrieval

The electronic records system shall ensure the characteristics of content and location are accurately reflected in the metadata associated with electronic records. The electronic records system shall be designed with data search considerations based on the size and purpose of the records program to enable data searching commensurate with the expected retrieval time frames.

500 DIGITAL AND PHYSICAL SECURITY

Digital controls of electronic records systems are addressed in this Subpart. Access permission is addressed in section 400 of this Subpart. Physical security controls of the electronic record storage locations are addressed in Part I, Requirement 17.

600 ELECTRONIC DATA INTEGRITY

Methods, techniques, or applications shall be used to monitor, collect, and analyze stored data to ensure integrity of the metadata and content relationship, such that records are accurate, sustainable, and retrievable.

700 DISPOSAL OF RECORDS

Record final disposition is not specified in Part I, Requirement 17; however, disposal may occur as part of the final record life cycle. Electronic records shall be destroyed in accordance with the records program. The records program shall have means to suspend destruction to recognize legal holds.[7]

800 ACQUISITION, DEVELOPMENT, AND MAINTENANCE OF ELECTRONIC RECORDS SYSTEMS

Based on their need, the user shall document and implement the applicable hardware and software quality assurance requirements of Part I and Part II, Subpart 2.7. Electronic records systems shall have documented processes for refreshing media to ensure that the electronic records are sustainable and retrievable for the duration of the record retention period.

[6] See 36 CFR 1236.20.

[7] See NIST Special Publication 800-88.

SUBPART 2.18
Quality Assurance Requirements for Maintenance of Nuclear Facilities

100 GENERAL

This Subpart provides amplified requirements for the maintenance of nuclear facility components and systems. Maintenance consists of actions necessary to maintain or restore an item to acceptable conditions. This Subpart supplements the requirements of Part I and shall be used in conjunction with applicable sections of Part I when and to the extent specified by the organization invoking this Subpart. This Subpart does not apply to controlling modifications that may be determined to be needed during the performance of maintenance.

200 GENERAL REQUIREMENTS

Design or modification information shall be available to the operating organization so that it can review the adequacy of provisions for the maintenance program in accordance with the requirements of this Subpart.[1]

201 Responsibilities

Responsibilities shall be assigned for establishing and implementing the maintenance program. These responsibilities shall include the following:

(a) the review of the maintenance program to ensure that changes to facility design or modifications are taken into consideration

(b) the development and updating of appropriate maintenance plans, procedures, and schedules

(c) the review of planned maintenance activities to ensure that radiation exposures to personnel will be as low as reasonably achievable

(d) the conduct of the program of maintenance activities and other inspections and tests as necessary to verify satisfactory performance

(e) the assurance that activities are performed by qualified personnel, using approved processes and calibrated test equipment and tools

(f) the assurance that properly acquired, controlled, and identified materials are used

(g) the assurance that environmental or seismic qualification requirements of equipment are not compromised

(h) the development of provisions for installation and removal of temporary conditions (e.g., jumpers, transferring of control switch position) and returning equipment and systems to service

(i) the recording of all maintenance examination and test results including corrective actions required and actions taken

(j) the assessment and evaluation of the results of maintenance, examinations, postmaintenance tests, and equipment history

(k) the development and trending of performance indicators

(l) the retention of records

202 Procedures

(a) Procedures and/or written instructions shall be established for performance of maintenance activities. Requirements for procedure format and content shall be established. Additional guidance regarding procedural requirements is contained in ANS 3.2-2012.

(b) Checks shall be made to verify that

(1) procedures and/or written instructions with an appropriate level of detail have been provided

(2) procedures include applicable format and content elements

(c) All changes, including temporary changes, shall be controlled.

(d) Provisions shall be made for documenting data to assist in ensuring satisfactory completion of the work. Such data shall include, as applicable

(1) parts used (e.g., serial no., part no., lot no.)

(2) identification number of measuring and test equipment used

(3) “as found” condition

(4) “as left” condition

(5) adjustments, repairs, replacements made

(6) postmaintenance clean-up and final inspection

(7) postmaintenance testing and acceptance results

Recorded data shall be reviewed for completeness and acceptability. The review shall be conducted by personnel who are familiar with the design and operation of the equipment, including acceptance criteria for its design features and operating characteristics. Administrative

[1] 10 CFR 50.65, Requirements for Monitoring the Effectiveness of Maintenance at Nuclear Power Plants, provides regulatory requirements for U.S.-licensed nuclear power plants.

procedures shall require documentation of the acceptance of results.

203 Cleanness Control

(a) Controls to minimize the introduction of foreign materials and to maintain cleanness during maintenance shall be in accordance with Part II, Subpart 2.1. Verification methods shall be established to ensure that these requirements are met.

(b) Immediately prior to closure of equipment, the absence of foreign materials shall be verified. The results of the verification shall be documented.

204 Environmental and Seismic Qualifications

Procedures shall be established to ensure that environmental and/or seismic qualification of equipment is not voided in performing maintenance. Such procedures shall include identification of the qualified items, methods for reestablishing qualifications, and verification of qualification status.

205 Work Authorization

(a) Procedures shall be established for the authorization of maintenance work. The work authorization shall be documented and serve as the identification of authorized work for the purposes of work planning, scheduling, and control.

(b) The work authorization shall contain the following information as a minimum:

(1) unique work authorization identifier or number

(2) description of work, including identification and quality designation of the specific equipment on which the work is to be performed

(3) identification of performing organizations and their specific roles

(4) approval by authorized personnel

(c) Interface concerns such as facility operations, health physics/as low as reasonably achievable (ALARA), security, industrial safety, effluent control, fire protection, and quality control requirements shall be considered for applicability by authorized individuals prior to approval of the work authorization document.

(d) The description of work shall reference the applicable maintenance procedure(s). If a separate procedure is not required, the work authorization shall contain or reference necessary and sufficient information (design drawings, equipment manuals, etc.) to perform the work.

(e) Provision shall be made for verifying the completeness of work authorization documents prior to starting the maintenance work.

(f) The work authorization approval process shall provide for approving substantive changes in the work requirements commensurate with the original scope of work.

206 Equipment History

A system shall be established to identify equipment for which equipment history files shall be maintained. Files shall be established as early in the life of equipment as possible to maintain the history of maintenance activities on each specific item. Information to be entered in the files shall be specifically identified and mechanisms established for their incorporation into the files. The files shall be organized to facilitate information retrieval.

207 Verification of Maintenance Work

Verification shall be performed, as appropriate, to ensure that equipment on which maintenance has been performed conforms to specified requirements. This verification shall include inspection, testing, or document review as necessary.

Documentation of verification activities shall be in accordance with para. 202 of this Subpart.

When maintenance involves installation, inspection shall be conducted in accordance with the applicable elements defined in Part II, Subparts 2.5 and 2.8.

208 Updating of Maintenance Procedures From Vendor Technical Manuals and Industry Bulletins

Controls shall ensure that updated information (vendor technical manuals, industry bulletins, etc.) is received, reviewed, and incorporated where appropriate into maintenance procedures.

300 PREVENTIVE MAINTENANCE

301 General

Preventive maintenance includes all those activities performed on designated equipment needed to maintain it within specified design limits.

302 Plans and Procedures

Plans and procedures shall be developed to identify the equipment that requires preventive maintenance, to establish the frequency and kind of preventive maintenance to be performed on the equipment, and to document those actions.

302.1 Equipment. Equipment shall be evaluated to determine its preventive maintenance requirements. That evaluation shall include the vendor recommendations as delineated in their technical manual and bulletins, applicable industry standards and operational experience, and maintenance experience and equipment history files. Equipment shall be monitored and evaluated for degradation of performance because of age, as appropriate.

Equipment that is purchased for future installation or spares shall be evaluated to determine the preventive maintenance requirements associated with its storage.

302.2 Frequency. A preventive maintenance schedule shall be established to uniquely identify the equipment, frequency, and preventive maintenance to be performed.

302.3 Evaluation. The effectiveness of preventive maintenance actions on equipment shall be evaluated. The evaluation results shall be documented and be the basis for future preventive maintenance practices.

302.4 Corrective Action. When discrepancies or failures are identified as part of preventive maintenance activities, they shall be corrected in accordance with section 400 of this Subpart.

400 CORRECTIVE MAINTENANCE

401 General

The following requirements apply to maintenance performed to restore an item to an intended condition following failure of the item. The term *failure*, as used herein, applies to any condition in which an item is determined to be unable to perform within its specified limits.

402 Identification, Reporting, and Documenting of Equipment or Systems Requiring Corrective Maintenance

Procedures shall be established for

(a) promptly identifying (e.g., tagging or other physical marking) the failed item and controlling it to preclude its inadvertent use

(b) documenting and reporting of failures, in accordance with pre-established criteria, to

(1) designated levels of management responsible for failure analyses, authorization of corrective action, and performance of corrective action

(2) Supplier and/or regulatory authority, as required

(c) entering the failure and the attributed cause in equipment history records

(d) verifying that failures are appropriately identified and reported as prescribed above to the extent necessary to ensure appropriate attention

403 Assessments and Evaluations

403.1 Assessment. An assessment of failure cause and required maintenance shall be made consistent with the type of item failure and the importance of the item. The assessment shall also include, as appropriate, the possibility of similar failure in other items. Assessments shall be performed in accordance with documented procedures and shall be appropriately reviewed.

403.2 Engineering Evaluation. For failures identified that could have serious effect on safety or operability, an engineering evaluation shall be performed and documented to substantiate or revise the failure assessment and corrective action planning.

404 Implementing Corrective Maintenance

404.1 Corrective maintenance shall be performed using work procedures developed in accordance with para. 202 of this Subpart.

404.2 Provisions shall be made for emergency maintenance work, e.g., work that must be performed immediately to eliminate a threat to the safety of personnel or facilities. These provisions shall be documented to identify

(a) the minimum controls applicable to the authorization, planning, and performance of the work

(b) requirements to ensure effective accomplishment of the work

Emergency work shall be reviewed and evaluated immediately after work accomplishment for adequacy.

500 RECORDS

(a) Maintenance records shall be maintained to establish an equipment history (see paras. 202 and 206 of this Subpart) and assist in performance evaluation and trend analysis. Maintenance records shall include work authorization documents and shall identify the equipment, type of maintenance performed, tools, measuring and test equipment, parts and material, date of performance, observation, failure cause, postmaintenance testing results, and the person who performed the maintenance.

(b) Records shall be maintained in accordance with Part I, Requirement 17.

SUBPART 2.19
Quality Assurance Requirements for the Use of Supplier Accreditation for Calibration or Testing Services

100 GENERAL

This Subpart provides amplified requirements for a purchaser to accept supplier accreditation for calibration or testing services as an alternative to supplier evaluation and selection requirements. It supplements the requirements of Part I and shall be used in conjunction with applicable requirements of Part I when and to the extent specified by the organization invoking this Subpart.

In this Subpart, the applicable edition of ISO/IEC 17025 is 2017.

200 REQUIREMENTS

Purchasers that intend to utilize the requirements of this Subpart shall document this alternative method in their quality assurance program in accordance with the following.

(24) **201 Calibration Services**

For a supplier of calibration services, the Purchaser may accept accreditation by accrediting bodies recognized by the International Laboratory Accreditation Cooperation (ILAC) Mutual Recognition Arrangement (MRA), provided the following minimum requirements are met:

(a) A documented review of the supplier's accreditation shall be performed by the Purchaser and shall include verification that

(1) the accreditation is to ISO/IEC 17025, General Requirements for the Competence of Testing and Calibration Laboratories, from an accredited body recognized by the ILAC MRA

(2) the published scope of accreditation for the calibration laboratory covers the needed measurement parameters, ranges, and uncertainties

(3) the accreditation has been achieved based on an on-site accreditation assessment by the accrediting body within the past 48 months, and the laboratory's accreditation cannot be based on two consecutive remote accreditation assessments

(b) The Purchaser's procurement documents shall specify the following as a minimum:

(1) that the calibration service must be provided in accordance with the accredited ISO/IEC 17025 program and scope of accreditation

(2) that an on-site accreditation assessment by the accrediting body has been performed within the past 48 months

(3) that the calibration certificate/report shall include identification of the laboratory equipment/standards used

(4) that the calibration certificate/report shall include as-found calibration data when calibrated items are found to be out-of-tolerance

(5) that the calibration service supplier shall not subcontract the service to any other supplier

(6) that the Purchaser must be notified of any condition that adversely impacts the calibration laboratory's ability to maintain the scope of accreditation

(7) additional technical and quality requirements, as necessary, based on a review of the procured scope of services, including, but not limited to, tolerances, accuracies, ranges, and industry standards

(c) During acceptance of the calibration service, the Purchaser shall be responsible for validating that the supplier's documentation certifies

(1) that the calibration service was performed in accordance with the supplier's ISO/IEC 17025 program and scope of accreditation

(2) conformance to the Purchaser's procurement document's requirements

202 Testing Services (24)

For a supplier of testing services, the Purchaser may accept accreditation by accrediting bodies recognized by the ILAC MRA, provided the following minimum requirements are met:

(a) A documented review of the supplier's accreditation shall be performed by the Purchaser and shall include verification that

(1) the accreditation is to ISO/IEC 17025, General Requirements for the Competence of Testing and Calibration Laboratories, from an accredited body recognized by the ILAC MRA

(2) the published scope of accreditation for the testing laboratory covers the needed testing services, including test methodology

(3) the accreditation has been achieved based on an on-site accreditation assessment by the accrediting body within the past 48 months, and the laboratory's accreditation cannot be based on two consecutive remote accreditation assessments

(b) The Purchaser's procurement documents shall specify the following as a minimum:

(1) that the testing service must be provided in accordance with the accredited ISO/IEC 17025 program and scope of accreditation

(2) that an on-site accreditation assessment by the accrediting body has been performed within the past 48 months

(3) that the testing service supplier shall not subcontract the service to any other supplier

(4) that the Purchaser must be notified of any condition that adversely impacts the testing laboratory's ability to maintain the scope of accreditation

(5) additional technical and quality requirements, as necessary, based on a review of the procured scope of services, including, but not limited to, tolerances, accuracies, ranges, and industry standards

(c) During acceptance of the testing service, the Purchaser shall be responsible for validating that the supplier's documentation certifies

(1) that the testing service was performed in accordance with the supplier's ISO/IEC 17025 program and scope of accreditation

(2) conformance to the Purchaser's procurement document's requirements

SUBPART 2.20
Quality Assurance Requirements for Subsurface Investigations for Nuclear Facilities

100 GENERAL

This Subpart provides amplified requirements related to subsurface investigations but is not applicable to contaminated soil investigations. It supplements the requirements of Part I and shall be used in conjunction with applicable sections of Part I when and to the extent specified by the organization invoking this Subpart.

101 Definitions

The following definitions are provided to ensure a uniform understanding of unique terms as they are used in this Subpart.

borings: circular holes augered, washed, chopped, or drilled in or through soil or rock by the action of cutting tools for purposes of exploration.

geophysical survey: the use of geophysical instruments, methods, and techniques to determine subsurface conditions by measurement of seismic or electrical phenomena, or by measurement of the earth's gravitation or magnetic fields or by any other geophysical methods.

penetration and probes: cone penetration tests, dilatometer soundings, and vane shear testing in soil.

subsurface investigation: the determination, correlation, and interpretation of soil, rock, and groundwater features as disclosed or inferred by exploratory excavating (test pits), drilling, sampling, testing, direct push, and geophysical surveying.

subsurface model: a computer model, a physical, graphic, or descriptive representation depicting subsurface features identified in the subsurface investigation.

200 GENERAL REQUIREMENTS

The requirements of this Subpart apply to the work of any organization or individual participating in subsurface investigations such as drilling, coring, sampling, trenching, logging, geophysical methods, testing, or interpreting results of subsurface investigations. This Subpart is intended to apply to any of these activities that will be used to formulate design bases for the plant. The extent to which the individual requirements of this Subpart apply will depend on the nature and scope of work to be performed and the importance of the item or service involved.

Documentation of all program elements shall be made. These elements shall include, but not be limited to, program plan, organization and qualification of personnel, identification, control and storage of project documents and records, and use of procedures conforming to applicable specifications.

201 Planning

A plan shall be developed for outlining project-specific tasks for which procedures or work instructions will be required in accordance with the requirements of the Introduction to this Part (Part II).

In addition, planning shall include

(a) definition of work scope and tasks

(b) identification of roles and responsibilities

(c) identification of engineering data required for design

(d) identification of appropriate field and laboratory testing equipment

(e) identification of standard methods or procedures for field, laboratory, and engineering sampling, testing, and analysis activities

(f) definition of required records and documentation

(g) the preparation of exploratory work plans

The plan shall include provisions for control and documentation of any changes.

202 Procedures and Instructions

A program of procedures and work instructions shall be established and documented for those activities falling within the scope of this Subpart in accordance with the requirements of the Introduction to this Part. In addition, these documents shall include, as appropriate, the following:

(a) field exploration operations such as surveying, drilling, boring, excavating, sampling, classifying and logging activities, shipping of samples, and in-situ testing

(b) laboratory testing activities such as preparing, classifying, testing and storing samples; recording, calculating, verifying, and reporting test results; and controlling and calibrating measuring and test equipment

(c) engineering evaluation and analysis activities such as evaluation of field and laboratory data; analysis of subsurface conditions; development of conclusions and recommendations; and preparations and presentation of the subsurface investigation report

(d) quality assurance activities such as audit plans and schedules, verification and surveillance procedures, and corrective action requirements

203 Results

Field activities and test results shall be documented in test reports and data sheets. Each report shall identify the activity to which it applies, the procedures or instructions followed in performing the task, and the identification of the following:

(a) pertinent test data such as identification of sample giving boring or test pit number, location, depth and elevation, test results, testing equipment identification, and description of sample

(b) date of test or activity

(c) test completion signatures

(d) results of test

(e) unusual conditions encountered

The signature of an approving reviewer (checker) constitutes a certification that the techniques used met the field and laboratory procedures. The evaluation regarding the adequacy of the results is covered in section 600 of this Subpart.

204 Personnel Qualifications

Personnel directing the overall program, including the performance of field activities and tests required by this Subpart, shall be qualified engineers and geologists with experience in subsurface investigations as described in section 200 of this Subpart. Personnel shall meet qualification requirements defined in ASTM D3740, Standard Practice for Minimum Requirements for Agencies Engaged in Testing and/or Inspection of Soils and Rock Used in Engineering Design and Construction, or equivalent alternative qualification requirements.

(24) 300 VERIFICATION

301 General

A quality assurance program shall require that frequency of checking and verifying field, laboratory, and engineering activities be established and be commensurate with the complexity of the soil/rock conditions being investigated and the volume of geotechnical activity. For example, procedures established for checking and verification of activities such as drilling and sampling equipment, field boring logs, boring locations, and sample storage and marking shall include provisions on frequency requirements of such activities.

302 Preinvestigation

Prior to the actual performance of subsurface explorations, it shall be verified that surveillance procedures have been established in accordance with the requirements of paras. 201 and 202 of this Subpart and that activities will be performed by appropriately qualified personnel, using specified equipment, in accordance with procedures. Verification shall establish that

(a) a complete and comprehensive program or design plan has been prepared

(b) the requirements and specifications of the plan have been translated into work instructions and procedures for all quality-related activities

(c) personnel have been qualified and certified as required in accordance with applicable procedures

(d) the equipment to be used meets applicable standards, specifications, or requirements

303 Field Investigation

During the actual performance of subsurface explorations, it is necessary to provide surveillance to ensure that the activities are being performed according to procedures by qualified personnel using specified equipment. Checks of subsurface investigation activities shall be made at the site in accordance with procedures to ensure conformance to the requirements of sections 200 and 400 of this Subpart.

(a) Checks shall be performed prior to and during field operations to verify the adequacy, accuracy, and proper operation of field equipment. These checks shall, as a minimum, ensure that

(1) sampling, measuring, and test equipment meet the applicable ASTM standards or have been evaluated as being acceptable to the procedures, requirements, and specifications of section 200 of this Subpart

(2) drilling, coring, and excavating equipment meet applicable ASTM standards or have been evaluated as being acceptable to the procedures, requirements, and specifications of section 200 of this Subpart

(b) Checks shall be performed to verify that the organization, execution, and documentation of all field activities and operations are in accordance with applicable standards, procedures, and project requirements and specifications. The items and activities to be checked and verified shall include, but are not limited to, the following:

(1) general compliance with the program plan and procedures

(2) qualification of personnel

(3) identification and control of project documents

(4) surveying activities

(5) drilling and excavation operations

(6) soil, rock, and groundwater sampling and testing methods and activities

(7) classifying, logging, and reporting methods and activities

(8) identification, handling, storage of samples and materials, and verification of the quality of these samples

Records of field operation verification activities shall be verified as complete prior to the termination of field activities.

304 Laboratory Testing

During the actual performance of laboratory testing operations, surveillance shall be performed to ensure that the activities are being conducted according to procedures by qualified personnel using specified equipment. Checks of testing activities shall be conducted at the laboratory in accordance with procedures to ensure conformance to the requirements of sections 200 and 500 of this Subpart.

Checks shall be performed to verify that the elements of the laboratory testing program are in compliance with the applicable technical and quality standards, specifications, and requirements. The elements to be checked and verified shall include, but are not limited to, the following:

(a) organization of the laboratory quality assurance program

(b) qualification of laboratory personnel

(c) control and calibration of measuring and test equipment

(d) identification, control, and storage of samples

(e) identification, control, and storage of project documents

(f) implementation of standard test methods or qualified test procedures conforming to applicable specifications and requirements

(g) documentation and verification of test data, results, conditions, and observations

Records of the laboratory test program verification activities shall be verified as complete prior to the termination of the laboratory test program.

305 Engineering Evaluation and Analysis

During the performance of engineering evaluation and analysis of the results of the field and laboratory operations, surveillance shall be performed to ensure that the engineering activities are being conducted by qualified personnel according to procedures. Checks of engineering evaluation and analysis activities shall be made in accordance with approved procedures to ensure conformance to the requirements of sections 200 and 600 of this Subpart.

Checks shall be made to verify that the elements of the evaluation and analysis program are in compliance with applicable technical and quality standards, specifications, and requirements. The elements to be checked and verified shall include, but not be limited to, the following:

(a) organization of the quality assurance program

(b) qualification of personnel

(c) identification, control, and storage of project documents

(d) use of procedures conforming to applicable specifications and requirements

(e) documentation and verification of field and laboratory data and results, engineering calculations and analyses, conclusions, and recommendations

(f) preparation and presentation of reports of data, calculations, analyses, conclusions, and recommendations

Records of the verification of the engineering evaluation and analysis activities shall be verified as complete prior to presentation of the final subsurface investigation report.

400 FIELD INVESTIGATION

401 General

The organization that conducts the field exploration activities inherent to a subsurface investigation shall be controlled by a quality assurance program. This organization shall be responsible for establishing and implementing a documented quality assurance program, and shall furnish the necessary resources such as personnel, equipment, procedures and instructions, and other services necessary to implement the requirements of the quality assurance program.

402 Field Operations

The scope of the quality-related operations required as a part of a subsurface investigation will depend upon the purposes of the investigations and subsurface conditions encountered. The operations may consist of, but not be limited to, any or all of the following activities:

(a) review of existing geotechnical data

(b) surveying

(c) auger, wash, core borings, and direct push methods

(d) test pits, trenches, and excavations

(e) soil, rock, and groundwater in-situ testing

(f) geophysical surveys

(g) classifying, logging, mapping, and recording conditions encountered

Pertinent records of field activities shall be maintained as the work progresses, and shall be verified as being complete. Any unusual circumstances encountered during field activities shall be recorded and reported as required by the governing procedures and applicable ASTM standards. Checks of field activities shall be performed while the work is in progress to ensure compliance with technical and quality requirements and task specifications.

Standard and nationally recognized methods shall be used unless specified otherwise, in accordance with procedures identified in the requirements of para. 202 of this Subpart. These may include, but not be limited to, applicable ASTM standards.

403 Field Equipment

The type of field equipment required for a subsurface investigation will depend upon the purposes of the investigation and the conditions encountered. Field equipment may consist of, but not be limited to, any or all of the following items:

(a) small hand tools
(b) surveying equipment
(c) hand and power augers, direct push equipment, hammer drills, and rotary drills
(d) power trenching and excavating equipment
(e) soil, rock, and groundwater sampling devices
(f) soil, rock, and groundwater in-situ testing devices
(g) geophysical survey equipment
(h) special sampling and testing equipment
(i) field support equipment and vehicles

Pertinent records of field equipment that have a direct bearing on the quality of the work shall be maintained as the work progresses and shall be verified as being complete. Any unusual or nonconforming equipment conditions shall be recorded and reported as required by the specifications. Checks of field equipment shall be performed as required before, during, and after the execution of related field activities to ensure compliance with technical and quality requirements and specifications.

404 Surveying

A permanent system of horizontal and vertical controls, such as baselines and benchmarks, shall be established, maintained, and used in accordance with procedures in order to obtain an accurate location and relocation of explorations, installations, and geological features.

Installations and explorations requiring accurate horizontal and vertical location shall include, but not be limited to, the following items:

(a) auger, wash, core borings, and direct push exploration points
(b) test pits, trenches, and excavations
(c) observation wells, piezometers, gages, and weirs
(d) changes in surface and subsurface soil, rock, and groundwater conditions
(e) soil, rock, and groundwater samples
(f) soil, rock, and groundwater in-situ tests
(g) geophysical surveys
(h) previous and existing structures
(i) unusual or unexpected conditions or occurrences that may affect the accuracy or interpretation of the survey results

Pertinent records of surveying activities shall be maintained as the work progresses and shall be verified as being complete. Checks of surveying activities shall be performed while the work is in progress to ensure compliance with requirements and specifications.

405 Boring and Excavating

The type and number of borings, excavations, and other subsurface explorations required for a field investigation will depend upon the purposes of the investigation and the subsurface conditions encountered. Subsurface explorations include, but are not limited to auger, wash, and core borings; direct push methods; test pits; trenches; shafts; and excavations.

All subsurface explorations shall be located with an accuracy commensurate with the program plan and instructions specified in section 200 of this Subpart. All explorations shall, after completion, be consistently and uniquely numbered or identified.

Unless otherwise specified in the program plan, instructions, or procedures, borings shall be advanced in such a manner as to satisfy the requirements of ASTM D420, ASTM D1452, ASTM D1586, ASTM D1587, ASTM D6151, ASTM D2113, ASTM D2573, ASTM D6635, ASTM D5778, or other accepted standards.

Pertinent records of boring and excavating operations shall be maintained as the work progresses and shall be verified as being complete. Checks of boring and excavating operations shall be performed while the work is in progress to ensure compliance with requirements and specifications.

406 Sampling and Testing

The type and number of samples and tests required during the field portion of the subsurface investigation will depend upon the purposes of the investigation and the subsurface conditions encountered. The soil, rock, and groundwater sampling and test operations may include, but not be limited to, any or all of the following activities:

(a) split barrel sampling
(b) thin-walled tube sampling
(c) core barrel sampling
(d) groundwater sampling for physiochemical analysis
(e) vane shear testing
(f) cone penetration testing
(g) standard penetration testing
(h) permeability testing
(i) water level determinations
(j) pressure testing
(k) geophysical logging
(l) dilatometer testing

Sampling and testing shall be performed in compliance with the applicable requirements, specifications, standards, instructions, procedures, and program plan.

407 Classification and Reporting

This paragraph develops the requirements for classifying, logging, and reporting of borings, excavations, samples, tests, surveys, and other field investigation activities. Classifying, logging, and reporting activities shall be

performed in accordance with procedures identified in the requirements of section 200 of this Subpart.

A field log shall be developed for borings and excavations with a detailed record of the stratigraphic units encountered during the field operations. This log shall also describe the type, location, and condition of recovery of all samples or tests conducted. For example, the boring log shall include, but not be restricted to, a heading containing the following information: boring number and location; project; boring contractor; date started and date finished; names of driller and sample logger; elevation; and any pertinent groundwater information or other data that may affect the use of the site.

In addition, a description of the method of advancing the boring should be included. The body of the log should include, in particular, information as to size and location of casting used, in-situ test results, and drilling abnormalities such as loss of fluid or artesian groundwater conditions that are detected.

Samples shall be controlled and cataloged by field logs, lists, or summaries. Procedures and consistent formats shall be used to label and identify all samples. Samples shall be systematically and uniquely identified with respect to project, sample number, location sampled, type of sample, and date sampled. Samples shall be handled, shipped, and stored in accordance with procedures identified in the requirements of section 200 of this Subpart and in such a manner as to minimize or prevent disturbance or changes in material properties.

Classification of soils shall be based on ASTM D2488 or other recognized methods. It is not necessary for field logs to contain the refinements that can only be determined by laboratory testing; however, where possible, the system for classifying soils contained in ASTM D2487 should be used, except when geological classification is specified. The logging and classification of groundwater and rock samples and tests shall be performed in accordance with procedures.

The reports of field tests and other activities shall include all specified results and shall be reported in a form to include the following items:

(a) identification of the applicable standard methods or qualified procedures

(b) all pertinent data and notes

(c) test calculation results in the form of tables and curves where required

(d) discussion to include significant conditions encountered, such as any specific difficulties, errors introduced, accuracy of results, and any specific soil, rock, or groundwater characteristics observed

500 LABORATORY TESTING

501 General

The laboratory in which tests are conducted shall be controlled by a quality assurance program in conformance with the applicable requirements of Part I. The laboratory shall be responsible for establishing and implementing a documented quality assurance program. The laboratory shall furnish the necessary resources such as personnel, equipment, documented procedures and instructions, and other services necessary to implement the requirements of the quality assurance program.

Laboratories involved in subsurface investigations and testing of soil and rock materials shall be accredited or inspected for conformance to requirements of ASTM D3740 or equivalent.

502 Scope

Laboratory testing of subsurface materials shall be made to determine their properties to provide data for engineering design. This requires a reliable procedure and a systematic approach, which should include the elements specified in paras. 502.1 through 502.4 of this Subpart.

502.1 Soil Identification and Description. A unified soil classification standard, such as ASTM D2487, shall be used.

502.2 Storage of Soil/Rock Samples. Identification of samples shall be affixed to the sample tubes or containers, which will maintain the integrity of the samples for the specified period of storage. Samples shall be stored in locations where they will be protected from damage.

502.3 Handling of Undisturbed Samples. Labels shall be affixed to sample tubes with all pertinent information. Tube and boring numbers shall be marked in duplicate. Undisturbed samples shall be stored vertically in a suitably controlled environment in which the ambient temperature and humidity are maintained at predetermined levels to preserve critical sample characteristics. Samples shall be transported vertically and protected with suitable resilient packing material to reduce shock, vibration, and disturbance. Appropriate measurements or observations shall be made prior to and following transportation, and the samples shall be evaluated for disturbance. Test specimens shall be prepared in accordance with applicable ASTM standards unless otherwise specified.

502.4 Determination of Standard Properties for Engineering Evaluation. Soils classification and testing shall conform to guidelines established in paras. 202 and 407 of this Subpart.

503 Test Methods

Standard and nationally recognized test methods shall be used unless otherwise specified by procedure identified in accordance with the requirements of para. 202 of this Subpart. These may include but not be limited to the applicable and approved ASTM standards.

504 Report of Laboratory Tests

The report of tests made shall include all specified test results and shall be reported in a form to include the following items:

(a) identification of samples tested, date tested, test personnel, test equipment, and test procedures used

(b) laboratory test results

(c) test and calculation results in the form of tables and curves as required

(d) discussion to include significant conditions encountered in the testing, such as any specific difficulties, errors introduced, test accuracy, and any specific characteristics of soil observed during testing

600 ENGINEERING EVALUATION AND ANALYSIS

601 General

The organization that conducts the evaluations and analyses of the subsurface investigation and laboratory test data shall implement a quality assurance program in conformance with the applicable requirements of Part I. This organization shall be responsible for furnishing the necessary resources such as personnel, equipment, documented procedures and instructions, and other services necessary to implement the requirements of the quality assurance program.

602 Analysis of Subsurface Conditions

Procedures shall be established to develop a generalized model of the subsurface conditions at the site for use in performing various engineering design analyses and evaluations. The development of the subsurface model shall include, but not be limited to, consideration and assessment of the following areas:

(a) the basic seismic, geologic, geotechnical, and hydrologic features in the vicinity of the site

(b) the specific soil, rock, and groundwater conditions encountered at the site

(c) the static and dynamic engineering properties and loading responses of the materials and strata underlying the site

(d) the interrelationship of the above geophysical features, subsurface conditions, engineering properties, loading responses, and the structural foundations for the facilities at the site

603 Report of Evaluation and Analysis

An analysis and evaluation of the subsurface investigation and foundation aspects of the site shall be presented along with the basic data supporting all conclusions and recommendations. Sufficient information shall be provided to allow for independent analyses and evaluations for design verification consistent with Part I.

700 RECORDS

Record copies of procedures; program or design plans; qualified investigation procedures; procurement control records; measuring and test equipment control and calibration records; work instructions and orders; field and laboratory logs and test data; test deviations or exception records; results of engineering analyses and evaluations; checks, verifications, and examination records; reports; and other specified documents shall be prepared. These records shall be retained with other project records as required by code, standard, specification, or project procedures.

SUBPART 2.22
Quality Assurance Requirements for Management Assessment and Quality Improvement for Compliance With 10 CFR 830 and Department of Energy (DOE) Order 414.1 for DOE Nuclear Facilities

100 GENERAL

This Subpart establishes requirements for implementing Management Assessment and Quality Improvement quality criteria for the Department of Energy (DOE) activities and organizations supporting DOE. It supplements the following related requirements of Part I: 2, 4, 7, 15, 16, and 18, which do not fully address[1] DOE Management Assessment and Quality Improvement criteria.

This Subpart applies to DOE activities regulated under Title 10 CFR 830, Nuclear Safety Management, including Subpart A, Quality Assurance Requirements, and Subpart B, Safety Basis Requirements (DOE QA rule), and for activities performed DOE Order 414.1, Quality Assurance (DOE QA Order). DOE rule and Order quality Criterion 3, Quality Improvement, and Criterion 9, Management Assessment, are addressed in this Subpart.

This Subpart shall be used with Part I when and to the extent specified by DOE regulation or contract, or by the organization invoking this Subpart. This Subpart is not applicable to nuclear generation facilities licensed to 10 CFR 50 or 10 CFR 52 and other specific activities regulated by the Nuclear Regulatory Commission.

101 Definitions

The following DOE-specific definitions are provided to supplement or replace the definitions in Part I, Introduction, 400 when implementing this Subpart.

assessment: a review, evaluation, inspection, test, check, surveillance, or audit to determine and document whether items, processes, systems, or services meet specified requirements and perform effectively (10 CFR 830).

graded approach: the process of ensuring that the level of analysis, documentation, and actions used to comply with a requirement is commensurate with

(a) the relative importance to safety, safeguards, and security

(b) the magnitude of any hazard involved

(c) the life-cycle stage of a facility or item

(d) the programmatic mission of a facility

(e) the particular characteristics of a facility or item

(f) the relative importance of radiological and nonradiological hazards

(g) any other relevant factors (10 CFR 830; DOE Order 414.1D, 2011).

item: an all-inclusive term used in place of any of the following: appurtenance, assembly, component, equipment, material, module, part, product, software, structure, subassembly, subsystem, support system, system, or unit (replaces Part I definition for use in this Subpart; 10 CFR 830; DOE Order 414.1D, 2011).

management assessment: an assessment conducted by managers of their management processes to identify and correct problems that hinder the organization from achieving its objectives (10 CFR 830; DOE Order 414.1D, 2011).

nonreactor nuclear facility: those facilities, activities, or operations that involve, or will involve, radioactive and/or fissionable materials in such form and quantity that a nuclear or a nuclear explosive hazard potentially exists to workers, the public, or the environment but does not include accelerators and their operations nor activities involving only incidental use and generation of radioactive materials or radiation, such as check and calibration sources, use of radioactive sources in research and experimental and analytical laboratory activities, electron microscopes, and X-ray machines (10 CFR 830).

nuclear facility: a reactor or nonreactor facility where an activity is conducted for or on behalf of DOE and includes any related area, structure, facility, or activity to the extent necessary to ensure proper implementation of the requirements established by 10 CFR 830.

process: a series of actions that achieves an end or result (10 CFR 830).

quality: the condition achieved when an item, service, or process meets or exceeds the user's requirements and expectations (10 CFR 830).

[1] Refer to Part IV, Subpart 4.1.2 for a detailed comparison.

quality assurance: all those actions that provide confidence that quality is achieved (replaces Part I definition for use in this Subpart; 10 CFR 830).

quality improvement: an iterative, disciplined management process used to promote efficiency and prevent potential future problems by eliminating error precursors. Quality improvement consists of planning work, evaluating/measuring the work process implementation for potential improvements, identifying item services and processes needing improvement, modifying how work is performed based on factual information, and evaluating the effectiveness of the modifications.

work: a defined task or activity such as research and development; operations; environmental remediation; maintenance and repair; administration; safety software development, validation, testing, and use; inspection; safeguards and security; or data collection and analysis (DOE Order 414.1D, 2011).

200 MANAGEMENT ASSESSMENT REQUIREMENTS

201 General

Managers shall assess their management processes to identify and correct problems that hinder the organization from achieving its objectives. Management assessments shall determine how effectively the organization is in meeting performance expectations and mission objectives and shall identify strengths and weaknesses. Management assessments shall be used to enhance safety, identify problems, and contribute to the organization's overall improvement of quality. The management assessment process shall use a graded approach as determined by the manager to provide an appropriate degree of flexibility in the level of detail for assessment planning, implementation, documentation, and reporting.

202 Assessment Planning and Scheduling

202.1 Planning. Senior management is responsible for

(a) establishing and implementing the management assessment program

(b) emphasizing the importance of assessments to the management team

(c) setting overall expectations and schedule

(d) ensuring necessary resources (including personnel and training) are available to develop the program, perform the assessments, and act on results

(e) communicating assessment schedule to appropriate individuals in time to permit sufficient time to prepare

(f) participating in the evaluation of assessment results from subordinate managers

202.2 Topic Selection and Scheduling. Managers performing assessments are responsible for

(a) evaluating performance information from internal and external sources (e.g., regulators, audits, clients, performance metrics, etc.) and the relative importance of current and planned activities to the organization's objectives.

(b) selecting the management processes to be assessed. Processes or topics that influence performance that could be included are strategic and operational planning; work environment; human resource allocation; financial and material resource allocation; communications between customers, community, suppliers, and regulators; quality and safety culture; and internal and external organizational interfaces.

(c) determining the degree of formality necessary to plan, conduct, document, and report the assessment.

(d) coordinating interfaces when assessments involve multiple organizations.

(e) setting the assessment schedule.

202.3 Assessment Personnel. Management assessments shall be performed by managers of the organization, processes, or activities being assessed. Managers shall remain personally involved in conducting the assessment and shall be responsible for evaluating the results when employees and/or consultants are used to assist with the assessment.

203 Assessment Process

203.1 Assessment Focus Areas. Assessment focus areas to be considered during a management assessment shall include one or a combination of the following:

(a) Have critiques and/or self-assessments been performed by employees related to assessing the effectiveness of the organization?

(b) What is the level of management participation in QA program implementation?

(c) Are the plans and goals of the organization still appropriate and valid?

(d) Are managers regularly monitoring the organizational plans and goals and the achievement of these goals?

(e) Do individuals understand the organizational plans, goals, and objectives?

(f) Is the overall performance focused effectively on meeting plans and goals?

(g) What is expected of individuals in the organization, and are these expectations aligned with mission objectives?

(h) Are these expectations being met?

(i) What opportunities are there for enhancing safety and improving quality?

(j) Are there risk assessments or declining trends related to effective and safe performance?

(k) How could the organization make better use of its human resource allocations?

203.2 Issue Identification. Areas of weakness and strength and compliance issues are documented during a management assessment. Management assessment results are evaluated by the manager to determine whether there are problems that are hindering the organization from achieving its objectives, goals, and plans. Actions are taken to resolve those problems. Senior managers shall ensure that any specific QA program compliance issues or environment, safety, and health issues are promptly entered into the corrective action tracking program (or similar tracking system) to facilitate a timely resolution.

203.3 Assessment Reporting. Management assessment results shall be shared with the next highest level of management to support effective problem resolution. The assessment results shall be documented in a report that includes

(a) the scope and criteria of the assessment

(b) strengths, weaknesses, and problems affecting mission achievement that require resolution

(c) a summary statement that describes how effectively the organization is in meeting its objectives and those quality performance expectations that assist in meeting its mission objectives, goals, and plans

204 Evaluation of Assessment Results

204.1 The manager performing the assessment determines which results warrant further action, either as improvement or corrective action.

204.2 Senior management shall ensure the management assessment results are used to improve the organization's performance, promote quality improvement, and remove barriers that inhibit the organization from achieving its objectives, goals, and plans. Indicators of the effectiveness of the assessment process include

(a) eliminating the recurrence of problems from previous assessments

(b) benchmarking of assessment performance with that of other internal and external organizations to determine whether assessments reflect best industry practices

(c) incorporating assessment results into organizational goals, strategies, objectives, plans, and processes

(d) periodically reviewing the results of assessments with individuals and organizations that may benefit from the results and improve their performance

300 QUALITY IMPROVEMENT

301 General

Measures shall be established and implemented to govern quality improvement activities. Quality improvement ensures work that affects quality is planned, performed, evaluated, and improved upon to increase effectiveness and prevent problems before they occur. Requirements for quality improvement are

(a) establish and implement processes to detect and prevent quality problems

(b) identify, control, and correct items, services, and processes that do not meet established requirements

(c) identify the causes of the problems, and work to prevent recurrence as a part of correcting the problem

(d) review item characteristics, process implementation, and other quality related information to identify items, services, and processes needing improvement

Management shall decide which work activities will be evaluated for quality improvements. Priority shall be given to those activities that are most important to the organization's mission and safety, those with known existing problems, and those where trending or performance metrics indicate the potential for future problems.

302 Evaluation of Work

Work shall be formally evaluated with a focus on identifying potential sources of errors that may impact quality. Evaluations shall consider procedures, equipment, materials, work environment, management, communication, resource allocation, human performance factors, and other attributes with the potential to adversely impact quality. Evaluation methods shall include, but are not limited to, the following:

(a) audits

(b) surveillances

(c) management assessments

(d) trending and analysis of performance metrics, error rates, or other measured data

(e) other established quality evaluation methods to determine the cause of the condition or issue

303 Quality Improvement Tools

Processes or tools shall be selected to assist organizations in improving quality performance. One or more of the following tools shall be used for this purpose:

(a) Benchmarking (Internal and External). The purpose of benchmarking is to improve performance. Benchmarking provides a mechanism to learn about an organization in relation to other similar organizations. Benchmarking can identify those organizations that perform effectively for similar activities.

(b) Brainstorming. Brainstorming is a way of developing creative solutions to a problem. It works by focusing on a problem statement and developing radical solutions to it. Ideas are generated by all participants in a brainstorming session. There should be no criticism of ideas. Brainstorming identifies possibilities and minimizes assumptions within the limits of the problem statement.

(c) Bar Charts. Bar charts are useful when comparing groups of data. By using bar charts, a class or group of data can be grouped into a single category of data, or they can

be broken down further into multiple categories for greater depth of analysis.

(d) Cause-and-Effect (Fishbone) Diagrams. A cause-and-effect diagram is a picture composed of lines and words in a fishbone design to represent a meaningful relationship between and possible causes and the effect (problem) in terms of people, methods, machines, materials, and environment.

(e) Five Whys. This simple technique is used to identify the real issue behind a problem by starting with the issue and asking why it occurred and then continuing to ask why until there is no further response to the question. This generally occurs around the fifth why, but can occur sooner or later.

(f) Lessons Learned. A lesson learned is a good work practice or innovative approach that is captured and shared to provide repeat application. A lesson learned may also be an adverse work practice or experience that is captured and shared to avoid recurrence.

(g) Flowchart (also known as a Process Map). A flowchart is a map of a process that is simply a graphical way of representing the process flows and activities throughout a process using common symbols. It is used to document processes and helps analyze and standardize a process and plan improvements. It is a tool to understand a process.

(h) Failure Mode and Effect Analysis (FMEA). FMEA is a systematic approach that identifies potential failure modes in a system, a product, or manufacturing/assembling operation caused by design or manufacturing deficiencies. It also identifies critical or significant design or process characteristics that require special controls to prevent or detect failure modes. FMEA is a tool used to prevent problems from occurring.

(i) Gap Analysis (also known as Change Analysis). Gap analysis provides a detailed breakdown of both the qualitative and quantitative aspects of the difference between what is and what is desired.

(j) Gantt Project Timeline Chart (sometimes referred to as a Bar Chart). The Gantt chart offers a graphical display of activities and duration illustrating timelines for proposals and projects.

(k) Histograms. A graphical summary of the results from a checklist.

(l) Pareto Charts. A Pareto chart is used to graphically summarize and display the relative importance of the differences between groups of data. The basis for a Pareto chart is the 80-20 rule, where 80% of the problems result from 20% of the causes. It assists in determining significance and identifying the potential items to improve first.

(m) Plan-Do-Check-Act (PDCA). The PDCA cycle is the foundation for continual improvement and can be applied to the development or improvement of any process. "Plan" represents the need to think through exactly what you are going to do before you do it. "Do" represents the undertaking of the activity that has been planned and to ensure that it happens as planned. "Check" represents the need to review the results and impact of the activity in an objective and analytical manner. "Act" represents the need to make changes to future plans in order to incorporate the learning from the "Check" phase of the cycle.

304 Improvement Identification and Implementation

Management shall determine which of the identified problems or weaknesses warrant quality improvement. This determination shall consider the likelihood and significance of the potential problems, safety considerations, mission priorities, process efficiency, and resource availability. Alternate actions shall be explored to determine the best solution to address the error precursor. The determination shall be documented. Improvements will be incorporated as determined by management and may include equipment or facility modification, updated training, or changes to institutionalized work controls (such as policies, programs, plans, procedures, or guidelines).

305 Improvement Evaluation

Management shall ensure quality improvement initiatives are evaluated or periodically monitored to determine whether the intended results are achieved and to check for unforeseen adverse impacts. Effective implementation eliminates potential problems and/or reduces their adverse impact.

400 RECORDS

Records of management assessment and quality improvement activities are considered quality records and shall be controlled in accordance with the requirements of Part I, Requirement 17. Management assessment records include assessment schedules and reports. Quality improvement records include reports utilized to record and track improvements.

500 REFERENCES (24)

The following is a list of publications referenced in this Subpart:

10 CFR 830. Nuclear Safety Management.
DOE Order 414.1D (2011, April). Quality Assurance. U.S. Department of Energy.

SUBPART 2.25
Quality Assurance Requirements for High-Level Waste Custodians

100 GENERAL

This Subpart provides quality assurance requirements for high-level waste (HLW) custodians while producing, storing, or otherwise managing high-level waste.

This Subpart supplements the requirements of Part I and shall be used in conjunction with applicable sections of Part I when and to the extent specified by the organization invoking Subpart 2.25.

101 Definitions

The following terms are used in this Subpart.

high-level waste: one of the following:

(a) the highly radioactive material resulting from the reprocessing of spent nuclear fuel, including liquid waste produced directly in reprocessing and any solid material derived from such liquid waste that contains fission products in sufficient concentrations

(b) irradiated reactor fuel

(c) other highly radioactive material consistent with existing law that requires permanent isolation

HLW custodian: an organization excluding NRC-licensed commercial nuclear utilities that is in possession of HLW prior to its planned disposition at a geologic repository.

repository owner: the federal agency or office that is the Nuclear Regulatory Commission's (NRC) licensee for a HLW repository.

waste acceptance elements (WAE): items, activities, or services that affect or impact acceptance of the HLW by the repository owner.

200 REQUIREMENTS

201 Organization: Interface Control

Interfaces to other organizations or positions responsible for activities affecting quality of WAE shall be defined. The interface definitions shall include, at a minimum, responsibilities, information to be transferred, and any material transfers between the organizations.

202 Program

The QA program shall identify the WAE to which these additional requirements apply. These elements include but are not limited to

(a) structures, systems, or components (SSCs) that are part of the waste isolation

(b) activities related to SSCs, which include facility and equipment design and construction (i.e., designing; purchasing; fabricating; processes for handling, packaging, shipping, receiving, storing, cleaning, erecting, installing, inspecting, testing, maintaining, repairing, and modifying)

(c) HLW forms and related activities including

(1) HLW characterization

(2) acquisition, control, and analysis of samples and data

(3) tests and experiments

(4) scientific studies

(5) qualification of characterization inputs

(6) HLW performance confirmation

(7) conditioning, treatment, and/or canisterization

(d) activities related to documenting compliance of HLW forms (i.e., waste form development through qualification, waste form production, and waste form acceptance)

(e) records that demonstrate compliance with HLW acceptance criteria

Characterization measurements of HLW used solely for the purpose of satisfying safeguards-related material control and accountability requirements are not activities related to WAE.

Waste custodians shall maintain an items and services list that are subject to this Subpart. The process for resolution of disputes concerning quality of WAE shall be defined in the QA program.

A matrix or other similar cross-reference describing the relationship between this Subpart and its implementation in procedures shall be maintained.

Periodic assessments that include independent technical experts to verify proper implementation of ongoing work related to WAE shall be performed.

Senior management of waste custodians shall, on a biennial basis, perform or direct the performance of management assessments using Part II as applied to WAE. These

assessments shall be performed by personnel above or outside the QA organization, and shall evaluate the adequacy of resources and personnel devoted to the QA program.

202.1 Nondestructive Assay. Nondestructive assay methods for determining the acceptability of WAE are forms of inspection and testing.

203 Design Control

The scope of design activities subject to Part I, Requirement 3 shall include WAE. At a minimum, these activities shall include

(a) engineered barriers that are WAE

(b) software developed for use in WAE

(c) features to facilitate monitoring and performance evaluation of WAE

203.1 Design Input. Data from scientific investigation activities not performed under this Standard and used as design input shall be qualified using Part IV, Subpart 4.2.3 or an equivalent method approved by the repository owner. Data not qualified prior to use in a design product, shall be identified as such and tracked until qualified.

Design inputs based on assumptions or unqualified data that require confirmation shall be identified and controlled as the design proceeds.

203.2 Use of Computer Programs. Computer programs used in WAE shall be controlled in accordance with the software requirements contained in Part II, Subpart 2.7.

203.3 Sampling Plans. Development of sampling plans for WAE is a design activity. The basis, including any supporting analysis, for the use of sampling plans shall be documented. Sampling plans for WAE shall be approved by the repository owner. At a minimum, sampling plans shall include

(a) description of the confidence interval and the rationale for its use

(b) description of the representativeness of the sampling plan to the population as a whole

204 Procurement Document Control

Part I, Requirement 4 for control of procurement documents and this Subpart apply to the procurement documents related to WAE including Interagency Agreements or other documents.

204.1 Content of the Procurement Documents. Procurement documents shall include a requirement for suppliers to establish controls to mitigate the procurement and installation of counterfeit or fraudulent items. Procurement documents shall identify procurement methods, responsibilities, and interfaces between the procurer and supplier.

204.2 Procurement Document Review. Procurement documents shall be reviewed by trained and qualified individuals or groups other than those who generated the document. Reviews shall ensure that applicable requirements are correctly stated, verifiable, and controllable; that there are adequate acceptance and rejection criteria; and that the procurement document has been prepared, reviewed, and approved in accordance with the requirements of para. 204 of this Subpart.

Procurement document review shall include participation of representatives from the technical organizations and individuals that are trained and qualified in QA practices and concepts.

204.3 Procurement Document Changes. Changes made as a result of proposal/bid evaluations or precontract negotiations shall be incorporated into the procurement documents. An evaluation of these changes and the resulting impact shall be completed before the contract is awarded. The evaluation shall consider

(a) appropriate requirements as specified in para. 204 of this Subpart

(b) additional or modified design criteria

(c) analysis of exceptions or changes requested or specified by suppliers and a determination of the impact such changes have on the intent of the procurement documents or quality of the item or service to be furnished

204.4 Spare and Replacement Parts. WAE spare and replacement parts shall be subject to QA program controls, codes and standards, and technical requirements equal to or greater than the original requirements, or as required to preclude repetition of defects.

205 Instructions, Procedures, and Drawings

Provisions for suspension of work that cannot be accomplished as described in controlled implementing documents (i.e., instructions, procedures, and drawings) shall be included in appropriate plans and procedures.

Instructions, procedures, and drawings used in WAE shall be consistent with the requirements in the QA program description document and shall include the following information as appropriate to the work to be performed:

(a) responsibilities and organizational interfaces of the organizations affected by the document

(b) identification of the quality records generated by the implementing document

206 Document Control

Reviews of controlled documents shall be performed by knowledgeable individuals other than the preparer. The document control program shall define retention of comments related to review and approval of documents consistent with their importance to WAE. Effective dates

shall be established for approved implementing documents.

206.1 Document Changes. Implementing documents shall require that a history of changes to QA program documents, including the reasons for the changes, be documented and maintained. This document history shall be reviewed each time additional changes to the document are proposed.

If an activity cannot be performed as prescribed in a document and the change process would cause unreasonable delays, an expedited change may be made at the work location by responsible management. Implementing documents shall describe the process to control expedited changes according to the following requirements:

(a) The level of management with the authority to make expedited changes shall be identified.

(b) The time limits for processing expedited changes through the normal change process shall be specified.

(c) An evaluation of the work shall be performed if the normal review process results in a change that is different from the expedited change.

207 Control of Purchased Items and Services

When an Interagency Agreement or other such document serves as a procurement document between the waste custodian and other federal agencies, the technical and quality requirements, responsibilities, and interfaces specified in these documents shall be verified to be satisfactorily incorporated into the applicable federal agency's QA program description document prior to starting work.

207.1 Bid Evaluation. The proposal/bid evaluation process shall be performed by designated, technically qualified individuals or organizations, including individuals that are trained and qualified in QA practices and concepts including

(a) technical considerations
(b) QA program requirements
(c) supplier personnel
(d) supplier production capability
(e) supplier past performance
(f) alternatives
(g) exceptions

207.2 Supplier Performance Evaluation

(a) The purchaser of items and services shall establish measures to interface with the supplier to verify performance as deemed necessary by the purchaser. The measures shall include

(1) reviewing supplier documents that are prepared or processed during work performed to fulfill procurement document requirements

(2) identifying and processing necessary change information

(3) establishing the method to be used to document information exchanges between purchaser and supplier

(4) establishing the extent of source surveillance and inspection

(b) The extent of verifications shall be a function of the relative importance, complexity, and quantity of items or services being procured and supplier quality performance.

(1) Verification activities shall be accomplished by qualified personnel assigned to check, inspect, audit, or witness supplier activities.

(2) Verifications shall be conducted as early as practical and shall not relieve suppliers of their responsibility for quality achievement.

(3) Verifications shall include the use of audits to evaluate supplier performance and evaluation of purchaser documentation to aid in the determination of the effectiveness of the supplier QA program. This documentation shall include documentation of source surveillance and inspections, audits, receiving inspections, nonconformances, dispositions, waivers, and corrective actions.

(c) An annual performance evaluation shall be performed on each supplier to determine the need to schedule additional verifications. This evaluation shall be documented and based on

(1) review of supplier-furnished documents and records (e.g., certificates of conformance, ASME Certificate of Authorization, ASME Quality System Certificate, nonconformance notices, and corrective actions)

(2) results of previous source verifications, audits, management assessments, and receiving inspections, including results of audits performed by other parties

(3) operating experience of identical or similar products furnished by the same supplier

(d) The use of commercial grade items for WAE shall be controlled per Part II, Subpart 2.14.

208 Inspection

208.1 Inspection Planning. Inspection plans for WAE shall be developed and maintained as controlled documents. Representatives of the interested technical organizations and individuals that are trained and qualified in QA practices and concepts shall participate in developing and approving inspection plans. Applicable codes, standards, specifications, and design documents shall be used to develop inspection plans. The elements of inspection plans shall identify

(a) mandatory hold points, when required

(b) measuring and test equipment (M&TE) to be used for the inspection to ensure that the equipment is of the proper type, range, accuracy, and tolerance to accomplish the intended function

(c) identification of sampling plans developed in accordance with para. 203.3 of this Subpart, if applicable

(d) methods to record inspection results

208.2 Records. Inspection records shall identify the specific M&TE used during the inspection including the most recent calibration date.

209 Test Control

209.1 Test Planning. Test plans and procedures for WAE shall be developed as controlled documents and include

(a) identification of the documents to be developed to control and perform tests

(b) criteria for determining the precision and accuracy requirements of test equipment

(c) timing, sequencing, and methods for performing the tests

(d) identification of the item to be tested and the test requirements and acceptance limits contained in applicable design and procurement documents

(e) test prerequisites shall include

(1) personnel qualifications

(2) status of the item and status of other equipment or systems that may affect test performance

(3) suitably controlled environmental conditions

(4) provisions for data acquisition and storage

(f) mandatory inspection hold-points for witnessing by the designated organization

(g) provisions for ensuring that test prerequisites have been met

209.2 Test Records. Test records shall identify the specific M&TE used during the test including the most recent calibration date.

210 Control of Measuring and Test Equipment (M&TE)

210.1 Calibration. The basis for the calibration acceptance shall be documented and authorized by responsible management. The level of management authorized to perform this function shall be identified. Embedded computer programs developed or modified by the user shall be controlled in accordance with the software requirements in Parts I and II.

210.2 Records. M&TE calibration documentation used in verifying WAE shall include the following information:

(a) identification of the measuring or test equipment calibrated

(b) traceability to the calibration standard used

(c) calibration data

(d) identification of the individual performing the calibration

(e) identification of the date of calibration and the recalibration due date or interval, as appropriate

(f) results of the calibration and statement of acceptability

(g) reference to any actions taken in connection with out-of-calibration or nonconforming M&TE, including evaluation results and repeated inspections or tests, as appropriate

(h) identification of the implementing document (including revision level) used in performing the calibration

211 Control of Nonconforming Items

(a) Identification. Nonconformance documentation shall clearly identify and describe the characteristics that do not conform to specified criteria.

(b) Disposition. Disposition of WAE that does not meet waste acceptance criteria shall be agreed to by the repository owner and the waste custodian.

212 Corrective Action

Measures shall be established to document, track, classify, report to appropriate levels of management, and resolve conditions adverse to quality. Significant conditions adverse to quality shall be evaluated to determine whether stopping work is warranted. Stop-work orders shall be issued to responsible management after a stop-work condition has been identified on WAE. Management shall take appropriate action to lift and close (in part or total) the stop-work issue based on the resolution of the related significant condition adverse to quality. Responsible management shall perform investigative action to determine the extent and impact of conditions adverse to quality in WAE.

212.1 Quality Trending. Criteria shall be established for determining adverse quality trends on WAE. Reports of nonconformance and conditions adverse to quality shall be evaluated to identify adverse quality trends. Trend evaluation shall be performed in a manner and at a frequency that provides for prompt identification of adverse quality trends and assists in identifying root cause. Trend evaluations shall be distributed in a timely manner for review and appropriate corrective action.

213 Records

Organizations originating QA records for WAE shall develop implementing documents that identify means for replacement, restoration, or substitution of lost or damaged QA records. Records describing compliance of WAE with waste acceptance criteria shall be managed in accordance with Part I, Requirement 17, section 600.

213.1 Records Classification. Lifetime QA records shall also include those

(a) directly related to waste form or other items that will be supplied to the repository owner. These records shall be transferred to the repository owner for retention and maintenance.

(b) that provide evidence of the quality of WAE.

(c) that provide evidence of the quality of HLW characterization data and samples.

(d) that provide evidence of the quality of the production process for the HLW and acceptability of the HLW product.

(e) that provide evidence of the quality of those activities associated with characterization of waste being emplaced in the repository.

(f) that provide evidence of those activities that provide data used to assess the potential dispersion of radioactive materials from the licensed facility.

Lifetime QA records related to (a) through (f) shall be retained and maintained by the waste custodian until transferred to the repository owner.

213.2 Electronic Records Systems. Electronic records systems used to store records of WAE shall be managed using Part II, Subpart 2.17 and Part III, Subpart 3.1-17.2, or an equivalent method approved by the repository owner.

214 Audits

(a) Audit Plan. Audits and internal audits shall include technical evaluations of the applicable procedures, instructions, activities, and items.

(b) Audit Scheduling. Audit at each waste-generating site shall be conducted annually, unless a decrease in the frequency of oversight activities is determined acceptable by the repository owner based on the scope, performance, and complexity of work. In no case shall the frequency be less than once every 3 yr for a site performing work on WAE.

(c) Personnel. The auditing organization shall select and assign auditors who are independent of any direct responsibility for performance of the activity being audited.

215 Scientific Investigations and Data Qualification

Scientific investigations used for WAE shall be performed using Part IV, Subpart 4.2.4 or an equivalent process approved by the repository owner. Data acquisition and control applications integral to the operations, maintenance, or calibration of scientific investigation testing apparatus shall be verified or validated in conjunction with the M&TE or test hardware as an operating unit.

Qualification of existing data, including data of indeterminate quality, for use in WAE shall be performed using Part IV, Subpart 4.2.3 or an equivalent method approved by the repository owner. Peer reviews to qualify data or scientific information for use on WAE shall be performed using Part IV, Subpart 4.2.7 or an equivalent process approved by the repository owner.

PART III
GUIDANCE FOR IMPLEMENTING PARTS I AND II REQUIREMENTS

INTRODUCTION

100 PURPOSE

Part I establishes requirements for the development and implementation of a Quality Assurance Program (QAP) for nuclear facility applications. It is arranged by Requirements 1 through 18.

Part II contains additional quality assurance requirements for the planning and conduct of specific work activities under a Quality Assurance Program developed in accordance with Part I. It is arranged by Subparts.

Part III — this Part — contains guidance for implementing the requirements of Parts I and II. It is arranged by Subparts. This part contains nonmandatory guidance on approaches and methods to implement the requirements of Parts I and II. Consistent with its intent to provide nonmandatory guidance, the terms *must*, *require*, and *shall* are not used in statements of action in this Part. Alternative approaches and methods may be used to satisfy Parts I and II requirements.

Part IV contains guidance for application of NQA-1 and comparisons of NQA-1 with other quality requirements. It is arranged by Subparts.

200 APPLICABILITY

Application of this Part's — Part III — guidance may be achieved by either or both of the following approaches when implementing Parts I and II requirements:

(a) as content within the Quality Assurance Program document to provide details relevant to an organization's activities

(b) as content in policies, protocols, instructions, and procedures that establish controls for activities affecting quality

This Part contains details of proven methods and activities to achieve compliance with Parts I and II requirements and provides proven principles and practices that may be used to establish an efficient and cost-effective Quality Assurance Program. Part III reflects industry experience, proven methods of performance, technology changes and regulatory considerations, and insights into the intent of the NQA Committee in formulating Parts I and II requirements. It does not, however, limit the Standard user from utilizing alternate methods and activities that can be proven to provide results consistent with Parts I and II requirements.

SUBPART 3.1
Guidance for Implementing Part I Requirements

The following Subparts provide nonmandatory guidance that may be used in conjunction with the applicable Requirements of Part I.

SUBPART 3.1-1.1
Implementing Guidance for Part I, Requirement 1: Organization

100 GENERAL

This Subpart provides nonmandatory guidance on organization as specified in Part I, Requirement 1.

200 ORGANIZATIONAL STRUCTURE

In structuring the organization and assigning responsibility, quality assurance should be recognized as an interdisciplinary function involving many organizational components and, therefore, should not be regarded as the sole domain of a single quality assurance group. The quality assurance group (or groups), however, should be designated to describe, integrate, and monitor the agreed-upon quality assurance activities of the various disciplines and functions.

Quality assurance encompasses many functions and should extend to all levels that perform activities affecting quality from senior management down, including, but not limited to, the following: designers, computer programmers, welders, inspectors, facility operators, craftsmen, and auditors, who perform activities affecting quality.

Different organizational structures may be effective, depending on the portion of the project or job in which the implementing organization is involved.

The organization's members should know, understand, and work to the documented quality assurance program and its interfaces.

300 BASIC PRINCIPLES

301 Management Functions

Designated management should have the authority and responsibility to identify or approve the following:

(a) quality assurance program scope and appropriate quality levels

(b) characteristics to be verified and acceptance criteria

(c) actions to resolve quality problems

(d) determination of the validity and disposition of nonconforming items and services

302 Quality Achievement Functions

Those performing quality achievement functions should have the following:

(a) means to monitor or check the quality of work

(b) authority and responsibility to identify and control defective work products

(c) responsibility to correct quality problems in their area of responsibility, whether self-identified or reported to them by others

(d) freedom to provide or recommend solutions to quality problems outside their area of responsibility

SUBPART 3.1-2.1
Implementing Guidance for Part I, Requirement 2: Quality Assurance Programs

100 GENERAL

This Subpart provides nonmandatory guidance on Part I, Requirement 2.

200 PROGRAM FORMAT

The format of NQA-1 has retained the original eighteen criteria. Other recently developed quality assurance requirements documents use different formats.

One such format example is

(a) management
(b) performance
(c) assessment

Another format example is

(a) program
(b) personnel training and qualification
(c) quality improvement
(d) documents and records
(e) work processes
(f) design
(g) procurement
(h) inspection and acceptance testing
(i) management assessment
(j) independent assessment

Still another format uses twenty elements to describe a quality assurance program. Regardless of how the requirements are grouped and formatted, the important success factor is to adequately address all imposed requirements. This Standard does not restrict the development of quality assurance programs to the format of requirements specified herein, provided the technical contents of the requirements imposed by the organization invoking this Standard are met.

Frequently, one quality assurance program can be adapted to satisfy the needs of more than one standard, or customer. Because of its broad base of requirements, NQA-1 provides a core program that can be related to other standards and customer specifications. A relationship matrix can be used to demonstrate programmatic comparability with other source requirement documents.

The following are examples of other source document relationship matrices:

Subpart 4.1.1 Guidance to Modification of an ISO 9001:2015, Quality Management System for Compliance with NQA-1–2015, Part I.

Subpart 4.1.2 Guidance on the Use of NQA-1–2008/1a–2009 for Compliance with Department of Energy Quality Assurance Requirements 10 CFR 830, Subpart A and DOE O 414.1

Subpart 4.1.4 Guidance to Modification of an IAEA GS-R-3 Quality Program to Meet NQA-1a–2009 Requirements and Modification of an NQA-1a–2009 Quality Program to Meet IAEA GS-R-3 Requirements

Subpart 4.1.5 Guidance to Modification of an ANSI/ANS-15.8–1995 (R2005; R2013) Quality Program to Meet NQA-1–2012 Requirements

Accommodating multiple customer needs with one quality assurance program has several benefits: consistency of application to minimize performance errors, minimization of training, and process cost effectiveness.

300 PROGRAM DEVELOPMENT

301 Purpose and Scope

The quality assurance program should be developed to meet customer requirements and user needs. Application of management controls and the degree of program formality should be graded to satisfy criteria based on the defined risks associated with meeting specified requirements.

Most quality assurance applications will have multiple customers and users (stakeholders). To meet the intended purpose of the quality assurance program, customer needs should be viewed individually and then collectively. Customers can be internal or external to the quality assurance program applied to the work process. Internal users of the quality assurance program will have different needs (i.e., performance) than external customers, who are recipients of the products (i.e., items or services) of the work process to which the quality assurance program applies. A regulator should be viewed as a customer with a defined set of requirements and expectations to be met.

The quality assurance program should describe the organizational structure, functional responsibilities, authority levels and relationships, and communication

interfaces needed to accomplish the work and quality objectives.

Generally, functional interfaces should be identified to link with key customer communication points. This will promote performance-based operations and reporting if used effectively to communicate performance status and resolution of issues.

302 Timing

The primary reason for establishing a quality assurance program is to ensure that items and services are developed and provided for use in compliance with specified requirements. To achieve this objective, control and verification measures should be planned, documented, and implemented at predetermined points throughout the life cycle of the work process. The program should provide control from initiation of activities through their completion.

The quality assurance program should specify an orderly and timely sequence for the implementation of applicable requirements and standards; for example, as a nuclear project moves through its various stages, activities affecting quality will change as the type of work dictates.

400 WORK REQUIREMENTS AND PERFORMANCE

401 Basis and Structure

The structure, graded content, and application of a quality assurance program should be based on a defined baseline of requirements to accomplish performance objectives. Tasks derived as the step-wise methods to achieve performance objectives can be logically collected into a work process to form the basis for defining work functions. These functions are the building blocks of an organization framework. Work task relationships are frequently described in work breakdown structure that relates process requirements, tasks, and work products and provides the basis for work scheduling, cost control, and performance measurement.

Each work requirement should be related to a customer, an end product, a work task, and a work process. Progress toward achieving a work product should be measurable to determine how effectively work objectives are met.

402 Planning

Work activities should be planned to ensure a systematic approach. Planning should result in the documented identification of methods and functional responsibilities. Planning should determine what is to be accomplished, who is to accomplish it, how it is to be accomplished, when it is to be accomplished, how to measure performance and progress, and how to determine acceptance criteria have been fulfilled.

Planning should be performed as early as practicable and prior to the start of the activities to be controlled to ensure functional interface compatibility and satisfactory coverage of governing requirements.

Planning for a quality assurance program should take into consideration

(a) applicable quality and technical requirements, including governing specifications, codes, standards, and practices

(b) the need for special procedures, work instructions, controls, processes, equipment, qualifications, or certifications required to achieve quality requirements

(c) the documentation needed to demonstrate the quality of the work performed and the items and services provided for use

(d) the assignment of task and performance responsibilities

(e) the methods to be used to verify conformance with quality and technical requirements, and program effectiveness for their equivalency should be documented

500 WORK PROCESSES

501 Process Management

The input to a work process consists of requirements and the output is a product that meets those requirements. Quality assurance is the discipline to ensure a product meets specified requirements. Thus, quality assurance ties should be embedded in the work process for optimal effectiveness. Being embedded means that quality assurance is designed into all aspects of work planning, management, performance, validation, verification, documentation, close-out, and product delivery. The quality assurance discipline provides dedicated systematic oversight for achieving performance objectives.

The quality assurance program should describe the scope (i.e., breadth and depth) of its application, including coverage of administrative services, if that is what is needed to meet customer performance expectations.

502 Graded Approach

Items and services may require varying degrees of control and verification to ensure compliance with requirements. Examples of factors that should be considered in determining appropriate levels of control and verification include but are not limited to

(a) the hazards associated with doing the work or using the results of the work

(b) the consequences of malfunction or failure of the item, or inappropriate use of the results of services provided

(c) the probability of the occurrence of the postulated consequences

(d) the design and fabrication complexity or uniqueness of the item, or difficulty to perform services

(e) the need for special controls and oversight of processes, equipment, and performance

(f) the degree to which functional compliance can be demonstrated by inspection, test, or performance verification

(g) the quality history and degree of standardization of items and services

(h) the difficulty of repair, replacement, or replication of the items or services

600 TRAINING AND QUALIFICATION

The definition of work requirements, individual work tasks, and their collection into a work process should be used to determine the individual and collective training and qualification needs.

The accumulation of knowledge and skills through experience is an effective way of becoming proficient in a work activity. On-the-job training (including mentoring) is an effective training method and should be documented as well as classroom training.

Demonstrated proficiency and consistent performance are two primary measures of good training and qualification practices. Controlling process variability may be a good indication that the training and qualification practices are adequate to reach performance objectives.

Requirements for Qualification Records are found in Part I, Requirement 2, section 400.

700 ASSESSMENT OF PERFORMANCE

Work task objectives should be clearly established with in-process and final acceptance criteria. Progress toward meeting objectives should be measured against parameters that are meaningful to the work process. If work task and performance objectives, and work responsibilities have been defined, performance measurement should automatically follow.

Those doing the work should have first-line responsibility for the acceptability of their work. Their managers should regularly assess work performance.

Management assessments can be continuous measurements of performance or periodic efforts, depending on the scope of the work and process complexity as well as risk management considerations.

A clear understanding of hazards and risks of achieving or not achieving work objectives should be used as the basis for establishing a management assessment process, and the nature of that process.

Frequently, a well-developed (and well-coordinated) management assessment process can be linked to customer reporting needs to avoid duplicate performance measurement programs.

Management may choose to use individuals who have no direct responsibility for accomplishing work tasks or objectives to assist in the management assessment process. Assessments can have a process or technical focus, depending on the nature and scope of the assessment. In either case, the individual performing the assessment should have assessment skills, and work process and product/customer understanding to conduct an effective assessment.

SUBPART 3.1-2.2
Implementing Guidance for Part I, Requirement 2: Quality Assurance Programs, Lead Auditor Qualification

(24) ## 100 GENERAL

This Subpart provides nonmandatory guidance on the education and experience that may be used for the qualification of Lead Auditors. This Subpart may be used in conjunction with Part I, Requirement 2, para. 303.

200 EDUCATION AND EXPERIENCE

The prospective Lead Auditor should have verifiable evidence that a minimum of 10 credits under the following score system have been accumulated.

201 Education (4 Credits Maximum)

(a) an associate degree from an accredited institution
(1) score 1 credit
(2) score 2 credits, if the degree is in engineering, physical sciences, mathematics, or quality assurance
(b) a bachelor's degree from an accredited institution
(1) score 2 credits
(2) score 3 credits, if the degree is in engineering, physical sciences, mathematics, or quality assurance
(3) score 1 additional credit for a master's degree in engineering, physical sciences, business management, or quality assurance from an accredited institution

202 Experience (9 Credits Maximum)

(a) Technical experience in engineering, manufacturing, construction, operation, or maintenance: score 1 credit for each full year with a maximum of 5 credits for technical experience.
(b) Specialized technical experience scores 1 to 4 additional credits as follows:
(1) score 1 additional credit if 2 yr of this experience have been in the nuclear field
(2) score 2 additional credits if 2 yr of this experience have been in quality assurance
(3) score 3 additional credits if 2 yr of this experience have been in auditing
(4) score 3 additional credits if 2 yr of this experience have been in nuclear quality assurance
(5) score 4 additional credits if 2 yr of this experience have been in nuclear quality assurance auditing

203 Other Credentials of Professional Competence (2 Credits Maximum)

For certification of competency in engineering science, or quality assurance specialties issued and approved by a state agency or national professional or technical society: score 2 credits.

204 Rights of Management (2 Credits Maximum)

The Lead Auditor's employer may grant up to 2 credits for other performance factors applicable to auditing, which may not be explicitly called out in this Subpart. Examples of these factors are leadership, sound judgment, maturity, analytical ability, tenacity, past performance, and quality assurance training courses completed or presented.

300 RECORDS

The sample form shown in Figure 300 of this Subpart is provided for utilization as a record of Lead Auditor qualification.

(24)

Figure 300
Sample Form for Record of Lead Auditor Qualification

RECORD OF LEAD AUDITOR QUALIFICATION				
☐ **Initial Qualification** ☐ **Requalification**	Name:			
EMPLOYER:				
QUALIFICATION POINT REQUIREMENTS				Credits
Education:			4 Credits Max.	
Accredited Institution/Degree:			Degree Date:	
Experience			9 Credits Max.	
Technical experience (1 credit for each full year of experience up to 5 maximum):				
Additional credits for technical experience in any one of (1) through (5):	(1) 2 yr nuclear field (1 credit) (2) 2 yr quality assurance (2 credits) (3) 2 yr auditing (3 credits)	(4) 2 yr nuclear quality assurance (3 credits) (5) 2 yr nuclear quality assurance auditing (4 credits)		
Company/Experience:			Dates:	
Other Credentials of Professional Competence			2 Credits Max.	
	Certificate		Date	
1. State Agency				
2. National Professional or Technical Society				
Rights of Management			2 Credits Max.	
Justification:				
Evaluated by (Name and Title):			Date:	
Total Credits				

AUDIT COMMUNICATION SKILLS	
Evaluation Statement:	
Evaluated by (Name and Title):	Date:

AUDIT TRAINING COURSES	
Course Title or Topic:	Date

AUDIT or ASSESSMENT PARTICIPATION			
Audit or Assessment Type	Description/Audit or Assessment Number	Nuclear (Yes/No)	Date(s) Start and Completion
1.			
2.			
3.			
4.			
5.			

EXAMINATION: ☐ Written ☐ Oral ☐ Practical	**Passed (Y/N):**	**Date:**

The individual listed above is certified as a Lead Auditor to organize and direct audits, report audit findings, and evaluate corrective actions.	
QUALIFICATION CERTIFIED BY: (Signature and Title)	**Date Certified:**

Figure 300
Sample Form for Record of Lead Auditor Qualification (Cont'd)

LEAD AUDITOR ANNUAL ASSESSMENT OF PROFICIENCY
Lead Auditor Name:
Maintenance of Proficiency (year/time period assessed): (Note: Lead auditors who fail to maintain their proficiency for a period of 2 yr or more require requalification.)
☐ Review and study of codes, standards, procedures, instructions, and other documents related to quality assurance program and program auditing:
☐ Audit training:
☐ Audit process participation:
☐ Proficiency not maintained since last evaluation:
Evaluation Result: ☐ Retraining required Training required: Retraining accepted by: _____ Name/Title/Date ☐ Qualification extended 1 yr ☐ Requalification required
Assessment performed by: _____ Name/Title/Date

SUBPART 3.1-2.3
Implementing Guidance for Part I, Requirement 2: Quality Assurance Programs, Inspection, and Test Personnel Qualification

(24) 100 GENERAL

This Subpart provides nonmandatory guidance on the qualifications and use of inspection and test personnel, as specified in Part I, Requirement 2, para. 302.

200 FUNCTIONAL QUALIFICATIONS

Three levels of qualification may be utilized depending on the complexity of the functions involved. The recommendations for each level focus on functional inspection or test activities, not on organizational position or professional status.

201 Level I Personnel Capabilities

A Level I inspector or tester should be capable of performing and documenting the results of inspections or tests that are required to be performed in accordance with documented procedures, acceptance standards, and/or industry practices as defined in the organization's written procedures.

202 Level II Personnel Capabilities

(a) A Level II inspector or tester should have all of the capabilities of a Level I inspector or tester for the designated inspection or test activity.

(b) A Level II inspector or tester should have additional demonstrated capabilities in

(1) planning inspections and tests

(2) setting up tests, including preparation and setup of related equipment, as appropriate

(3) supervising or maintaining surveillance over the inspections and tests

(4) supervising and certifying lower level personnel

(5) evaluating the validity and acceptability of inspection and test results

203 Level III Personnel Capabilities

(a) A Level III inspector or tester should have all of the capabilities of a Level II inspector or tester for the designated inspection or test activity.

(b) In addition, a Level III inspector or tester should be capable of evaluating the adequacy of specific programs used to train and certify inspection and test personnel whose qualifications are covered by this Subpart.

300 EDUCATION AND EXPERIENCE QUALIFICATIONS (24)

(a) Education and experience, which supports qualification in the inspection/test discipline, should be considered, including such factors as inspection/test scope, complexity, or the special nature of the activity to establish reasonable assurance that a person can competently perform a particular task. Education and experience providing the basis for qualification should be documented.

(b) Other factors that may demonstrate capability in a given inspection or test function include previous performance or satisfactory completion of capability testing. These factors and their basis for supporting the qualification should be documented.

301 Level I

(a) Two years of experience related to equivalent inspection or testing activities; or

(b) High school (or equivalent) diploma plus 6 months of experience in equivalent inspection or testing activities; or

(c) Completion of college/university level work leading to an associate degree from an accredited institution (or equivalent) in a technical discipline plus 3 months of experience in equivalent inspection or testing activities.

302 Level II

(a) One year of satisfactory performance as a Level I in the corresponding inspection or test activity; or

(b) High school (or equivalent) diploma plus 3 years of experience related to equivalent inspection or testing activities; or

(c) Completion of college/university level work leading to an associate degree from an accredited institution (or equivalent) in a technical discipline plus 1 year of experience in equivalent inspection or testing activities; or

(d) Completion of a 4-yr college degree from an accredited institution (or equivalent) in a technical discipline plus 6 months of experience in equivalent inspection or testing activities.

303 Level III

(a) Six years of satisfactory performance as a Level II in the corresponding inspection or test activity; or

(b) High school (or equivalent) diploma plus 10 years of experience in equivalent inspection or testing activities; or

(c) High school (or equivalent) diploma plus 8 years of experience in equivalent inspection or testing activities with at least 2 yr as a Level II and with at least 2 yr associated with nuclear facilities — or, without nuclear facilities experience, at least sufficient training to be acquainted with the relevant quality assurance aspects of a nuclear facility; or

(d) Completion of college/university level work leading to an associate degree from an accredited institution (or equivalent) in a technical discipline and 7 yr of experience in equivalent inspection or testing activities with at least 2 yr of this experience associated with nuclear facilities — or, without nuclear facilities experience, at least sufficient training to be acquainted with the relevant quality assurance aspects of a nuclear facility; or

(e) Completion of a 4-yr college degree from an accredited institution (or equivalent) in a technical discipline plus 5 yr of experience in equivalent inspection or testing activities with at least 2 yr of this experience associated with nuclear facilities — or, without nuclear facilities experience, at least sufficient training to be acquainted with the relevant quality assurance aspects of a nuclear facility.

400 USE OF INSPECTION AND TEST PERSONNEL (24)

(a) Prior to assigning personnel to perform inspection and test activities, supervision should determine that the individuals have the experience and training commensurate with the scope, complexity, or special nature of the activities.

(b) When a single inspection or test requires implementation by a team or a group, personnel not yet meeting the requirements of Part I, Requirement 2, section 300, may be used in data-taking assignments or in plant or equipment operation, provided they are supervised or overseen by a qualified individual.

(c) Appropriate training, which may include on-the-job training, should be conducted as needed to qualify personnel to perform inspections and tests. The use of personnel performing inspections and tests during on-the-job training qualification should be under the observation and supervision of a qualified person, since the verification of conformance is the responsibility of a qualified person.

SUBPART 3.1-2.4
Implementing Guidance for Part I, Requirement 2: Quality Assurance Programs, Management Assessment of the QA Program

(24) 100 GENERAL

This Subpart establishes nonmandatory guidance for performing QA program management assessments required by Part I, Requirement 2, para. 100(c) to assess the adequacy and effectiveness of the QA program. Additionally, this Subpart provides guidance on other types of management assessments that some organizations find useful to supplement the required QA program management assessment process or to satisfy regulatory commitments. These include: individual assessments, management "walk-around" assessments, and functional area assessments.[1]

This Subpart does not apply to internal or external audits performed per Part I, Requirement 18. However, the QA program management assessments should include an evaluation of previously completed audit results.

200 TYPES OF MANAGEMENT ASSESSMENT

(24) 201 QA Program Management Assessment

The assessment is performed periodically to assess the adequacy and effectiveness of the overall QA program. This should include a review and evaluation of some of the following inputs: internal audits and assessments, customer audits, supplier performance, corrective action results, and trend analysis. This type of assessment should be performed by an individual or team with subject matter expertise to determine the adequacy and effectiveness of the program element(s) being assessed.

The emphasis of a management assessment is on processes that affect the performance of an activity or process, or personnel qualification and training, staffing and skills mix, communication, organizational interfaces, completion of mission objectives, or other elements of the QA program.

202 Supplemental Management Assessments (24)

The following assessment types may be used to supplement the QA program management assessment or to satisfy other regulatory commitments:

(a) Individual Assessment. This type of assessment is when an individual performs an assessment. This is a quick-hit assessment, usually directed by management, and focused on a limited area or process. It can be used to gather information or data for additional evaluation or to determine the status of an activity.

(b) Management "Walk-Around" Assessment. This type of assessment is similar to individual assessments but does not need a specific plan or schedule. It is predominately a visual assessment used to determine the status or implementation of management direction or requirements.

(c) Functional Area Assessment. This type of assessment is used for the review of a limited process or a functional area. For example, the implementation of the work package process or the review of selected training and qualifications. This type of assessment should consist of an individual or team with subject matter expertise to help determine the adequacy and effectiveness of the program or process being assessed.

300 SCHEDULING AND PLANNING

301 Scheduling (24)

Management should identify the focus area and performance period (i.e., schedule) of functional- and program-type assessments so that adequate time is available to select an appropriate team or individual and to develop an effective assessment plan.

Management should establish expectations for type, length, and periodicity of the assessments. The assessment team leader or responsible individual should coordinate with the management of the assessed organization to agree on a timeframe for the assessment.

Some assessments may be in response to events or situations and should be scheduled to support management direction.

[1] When performing a Department of Energy Order 414.1 assessment, Part II, Subpart 2.22 of this Standard takes precedence over the guidance of this Subpart.

Table 301

Type of Assessment	Recommended Documents			Participants
	Schedule [Note (1)]	Plan	Evidence of Completion	Team Leader
QA program management assessments	Yes	Yes	Yes. This report should also incorporate or reference other reports or data gathered throughout the year.	Yes [Note (2)]
Individual self-assessments	Yes [Note (3)]	Yes [Note (3)]	Yes. Report should be sent to the supervisor, then to records.	No [Note (4)]
Manager assessments (walk-around assessments)	Yes [Note (3)]	Yes [Note (3)]	Yes. Report should be sent to records when completed.	No [Note (4)]
Functional area assessments	Yes	Yes	Yes	Yes

NOTES:
(1) Schedule does not imply a periodic activity: one-time assessments should have a projected completion date.
(2) If performed by an individual, the individual is the team leader.
(3) This should be a simple plan or schedule that documents what will be reviewed, and when it will be reviewed.
(4) The individual performing the assessment assumes the role of the team leader.

(24) **302 Planning Assessments**

The extent and scope of the assessment is determined by management and is based upon the assessment type and the importance of the activity being assessed.

Management assessments should be planned to the depth, breadth, and rigor necessary, with emphasis on adequacy and effectiveness. To determine if management's goals are being achieved, objective criteria may need to be developed.

Assessment planning should ensure that actions for the assessment cover the depth, breath, and scope of the assessment as determined by management. Aspects of the program or activity to be assessed should include but are not limited to

(a) determining how systems, processes, and procedures effectively meet stated requirements and accomplish work

(b) describing the clarity of the organizational mission, goals, and objectives

(c) identifying and correcting problems that hinder the organization from achieving its objectives

(d) determining the adequacy of procedural processes and evaluating their ability to meet management objectives

(e) implementing safety measures, human performance, a safety conscience work environment, and a nuclear safety culture

(f) determining the adequacy of training and qualification programs for personnel

(g) evaluating the implementation and effectiveness of planning processes and communication systems, including communication and coordination with external organizations

(h) determining compliance and adequacy of scheduling processes to assure project goals are met

(i) determining the adequacy of support processes and systems such as equipment maintenance, security, and operations

(j) evaluating an organization's capabilities to accomplish objectives

(k) evaluating leadership capabilities to enable the organization to meet internal or external objectives, requirements, and expectations

(l) if applicable, using a prior management assessment's criterion, information and/or results from that assessment to maintain consistency

400 ASSESSMENT PERFORMANCE

401 Assessment Team Responsibilities (24)

Assessment team leaders or designated individuals should

(a) select assessment team members for the assessment type being performed. Selection of team members should be based upon experience related to work scope, and should possess technical familiarity with the activities being assessed while not having direct responsibility for activity performance.

(b) acquire the required resources.

(c) acquire any other pertinent information that needs to be communicated to the team and organization being assessed.

(d) notify the manager(s) of the assessed organization(s) of the management assessment schedule.

(e) notify personnel, coordinate meeting locations, and schedule the assessment.

(f) utilize, as necessary, subject matter experts, and process or activity owners to help determine the status of the criterion being evaluated. Knowledgeable persons can be used for interviews or help during document reviews.

(g) keep affected managers apprised of the status of assessment efforts and results. This includes the affected manager of both the assessed organization and requesting organization, as applicable.

(h) immediately notify management of conditions requiring prompt corrective action.

The assessment team members should collect objective evidence within the limits imposed by the purpose and scope to address each assessment criterion.

(24) **402 Assessment Methodologies**

The assessment team should use one or more of the following methodologies to evaluate the criteria established in the assessment plan:

(a) Work Observation. Provides direct observation of work (both physical and/or process) when it is practical and available. This method is considered the most effective technique for determining whether performance is adequate. Assessors should understand the effect their presence has on the person being observed and convey an attitude that is helpful, constructive, positive, and unbiased. The primary goal of work observation is to obtain the most complete picture possible of the performance, which should then be put into perspective relative to the overall program, system, or process. Before drawing final conclusions, the assessor should verify the results through at least one other technique, if possible.

(b) Document Review. Provides the objective evidence to substantiate compliance with applicable requirements. This technique should be combined with interviews and observations (work and/or field observations) to complete the performance picture. Records and documents should be selected carefully to ensure that they adequately characterize the program, system, or process being assessed.

(c) Interview. Provides the means of verifying the results of work observation, document review, and/or field observation. Interviews allow the responsible person to explain and clarify those results, help to eliminate misunderstandings about program implementation, and provide a venue where apparent conflicts or recent changes can be discussed, and organization and program expectations can be described.

500 REPORTING

Summarize assessment results, including a statement on the adequacy and effectiveness of the areas assessed. The report should be signed by the assessment team leader or designated individual and issued to the manager responsible for the area assessed, and other management personnel as deemed appropriate.

(a) The contents of the report should include the following, as appropriate:

(1) describe the assessment scope

(2) identify assessment team members and persons contacted, documents reviewed, and activities observed

(3) summarize assessment results, including a statement on the effectiveness of the areas assessed

(4) describe each issue (strength, deficiency, or weakness) identified during the assessment

(b) Typical classification of assessment issue includes:

(1) Strength — fully meets and exceeds the related performance criteria.

(2) Acceptable — performing acceptably (or prepared to perform acceptably) and personnel in this area are capable of meeting project mission goals and objectives. Procedures, processes, and staffing are adequate and meet program or contract requirements.

(3) Deficiency — condition adverse to quality as described in Part 1, Requirement 16, Corrective Action. The expectation is that conditions adverse will be entered into the appropriate corrective action program.

(4) Weakness — marginal, underperforming, or some elements are missing to be successful.

SUBPART 3.1-2.5
Risk-Informed Approach for the Treatment of Structures, Systems, and Components for Nuclear Facilities Not Subject to NRC Regulation[1]

100 GENERAL

This nonmandatory guidance describes a method for implementing a risk-informed categorization and treatment of structures, systems, and components not subject to NRC regulation. This guidance is based on the principles in 10 CFR 50.69[2] and takes advantage of recent advances in computing capability that enable larger scale use of probabilistic risk assessments.

Users of this nonmandatory guidance should consider adapting the information in the references for their facility and application needs.

(24) 101 Definitions

The definitions below are applicable to implementers of a risk-informed approach and provide a more specific methodology than the "graded approach" definition found in Part I. Because nuclear facility operators often use several quality levels for QA activities, it is recommended that quality level nomenclature not use terms such as "safety-related" or "non-safety-related."

alternative treatment requirements: those requirements that meet section (d)(2) of 10 CFR 50.69.

HSS: refers to high safety significant

LSS: refers to low safety significant

risk-informed safety class (RISC)-1 structures, systems, and components (SSCs): safety-related SSCs that perform safety-significant functions.[2]

risk-informed safety class (RISC)-2 structures, systems, and components (SSCs): non-safety-related SSCs that perform safety-significant functions.[2]

risk-informed safety class (RISC)-3 structures, systems, and components (SSCs): safety-related SSCs that perform low safety-significant functions.[2]

risk-informed safety class (RISC)-4 structures, systems, and components (SSCs): non-safety-related SSCs that perform low safety-significant functions.[2]

safety-significant function: a function whose degradation or loss could result in a significant adverse effect on defense-in-depth, safety margin, or risk.[2]

special treatment requirements: current NRC requirements imposed on SSCs that go beyond industry-established (industrial) controls and measures for equipment classified as commercial grade and are intended to provide reasonable assurance that the equipment is capable of meeting its design bases functional requirements under design basis conditions. These additional special treatment requirements include design considerations, qualification, change control, documentation, reporting, maintenance, testing, surveillance, and quality assurance requirements.[3] The existing special treatment provisions for RISC-1 and RISC-2 SSCs are maintained or enhanced to provide reasonable assurance that the safety-significant functions identified in the 10 CFR 50.69 process will be satisfied.

These definitions are applicable to implementers of a risk-informed approach and provide a more specific methodology than the "graded approach" definition found in Part I.

Because nuclear facility operators often use several quality levels for QA activities, it is recommended that quality level nomenclature not use terms such as "safety-related" or "non-safety related."

102 RISC Descriptions

RISC-1 are SSCs found to be safety-related using criteria similar to that found in 10 CFR 50.2 or other facility-specific definitions and determined to be a significant contributor to facility safety, as determined in the facility risk-informed categorization process.

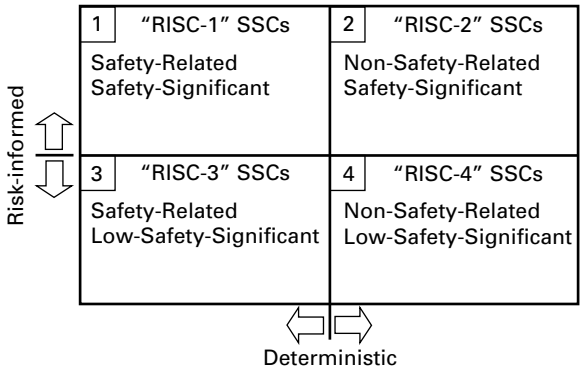
RISC-2 are SSCs determined to be not safety-related using criteria similar to that found in 10 CFR 50.2 or other facility-specific definitions, but determined to be

[1] NRC licensed users should consult NEI 00-04, 10 CFR 50.69 SSC Categorization Guideline

[2] 10 CFR 50.69, Risk-informed Categorization and Treatment of Structures, Systems, and Components for Nuclear Power Reactors

[3] NEI 00-04, 10 CFR 50.69 SSC Categorization Guidance, Rev. 0

Figure 102-1
§50.69 RISC Categories



GENERAL NOTE: Deterministic refers to safety classification consistent with 10 CFR 50.2 definition of Safety-related.

a significant contributor to facility safety, as determined in the facility risk-informed categorization process.

RISC-3 are SSCs determined to be safety-related using criteria similar to that found in 10 CFR 50.2 or other facility-specific definitions, but determined to not significantly contribute to facility safety, as determined in the facility risk-informed categorization process.

RISC-4 are SSCs determined to be not safety-related using criteria similar to that found in 10 CFR 50.2 or other facility-specific definitions, and determined to not significantly contribute to facility safety, as determined in the facility risk-informed categorization process.

This is captured graphically using Figure 102-1 from Regulatory Guide 1.201.

200 SSC CATEGORIZATION

Figure 200-1 from NEI 00-04 outlines a suggested RISC characterization process.[4]

The SSC categorization process should include the following primary steps:

(a) assembly of facility-specific inputs
(b) system engineering assessment
(c) component safety significance assessment
(d) defense-in-depth assessment
(e) preliminary engineering categorization of functions
(f) risk sensitivity study
(g) IDP review and approval
(h) SSC categorization

Each is covered in more detail in separate topic sections in NEI 00-04.

[4] The guidance in NEI 00-04 was intended to be implemented under specific NRC approvals. Users of NEI 00-04 should adapt this information to suit their facility and application needs.

201 SSC Categorization References

Implementers of the principles in 10 CFR 50.69 should consider using the guidance provided in the following documents for characterization of SSCs; all are available from the NRC website:

10 CFR 50.69, Risk-Informed Categorization and Treatment of Structures, Systems and Components for Nuclear Power Plant Reactors

NEI 00-04, 10 CFR 50.69 SSC Categorization Guideline, Rev. 0

NEI 06-14A, Quality Assurance Program Description, Rev. 7

Regulatory Guide 1.176, An Approach for Plant-Specific, Risk-Informed Decisionmaking: Graded Quality Assurance, 1998

Regulatory Guide 1.201, Guidelines for Categorizing Structures, Systems, and Components in Nuclear Power Plants According to Their Safety Significance, Rev. 1. Regulatory Guide 1.201 is issued for trial use; NEI-00-04, 10 CFR 50.69 SSC Categorization Guideline should also be consulted when using Regulatory Guide 1.201.

Regulatory Guide 1.174, An Approach for Using Probabilistic Risk Assessment in Risk Informed Decisions on Plant Specific Changes to the Licensing Basis, Rev. 3

Regulatory Guide 1.200, An Approach for Determining the Technical Adequacy of Probabilistic Risk Assessment Results for Risk-informed Activities, Rev. 2

202 SSC Categorization Direction

SSC categorization should be performed in accordance with applicable facility or organization procedures.

203 SSC Categorization Regulator Approval

SSC categorization process should receive regulatory review and/or approval dependent on the regulatory applicability for the facility.

204 SSC Categorization Records

Records of all SSC categorization actions and decision should be processed in accordance with applicable facility or organization procedures.

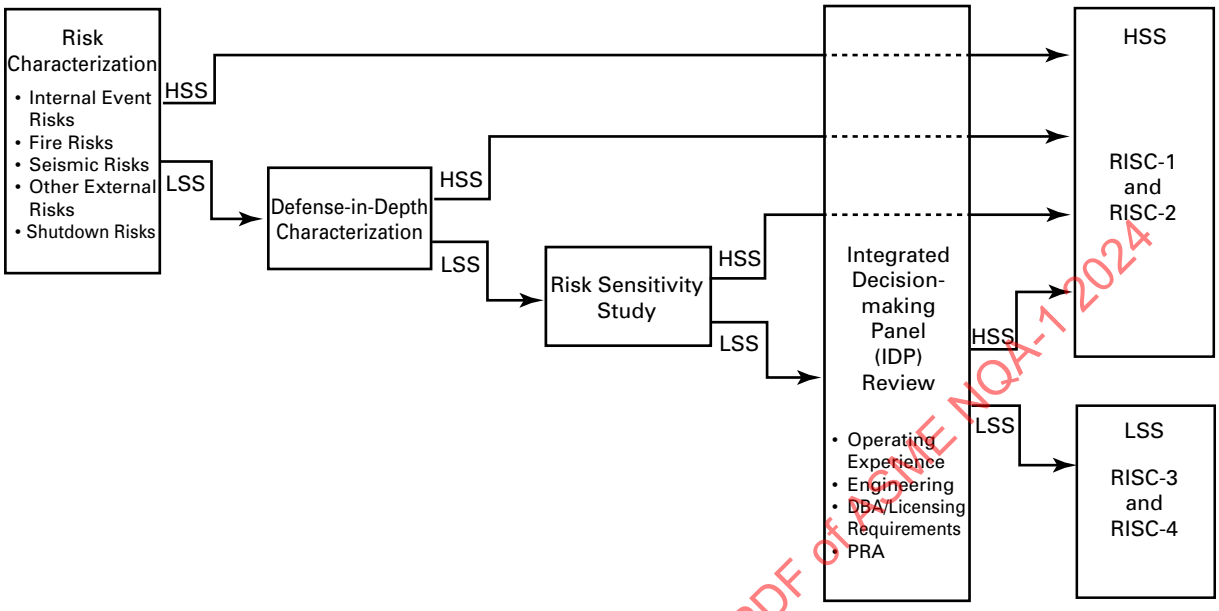
300 ADAPTATION

Alternative treatment of SSCs is the application of treatment for SSCs categorized as RISC-3, as defined in 10 CFR 50.69, para. (d)(2).

Nuclear facilities include structures, systems, and components that prevent or mitigate the consequences of postulated accidents that could cause undue risk to the health and safety of the public.

Facility owners and operators are expected to maintain a QA program that prevents or mitigates the consequences of postulated accidents that could cause undue risk to the health and safety of the public.

Figure 200-1
Summary of NEI 00-04 Categorization Process



GENERAL NOTE: NEI-00-04 is the intellectual property of NEI and is used here by permission from NEI.

It should be the policy of operators of nuclear facilities to assure a high degree of reliability and availability of their nuclear facilities while ensuring the health and safety of both their workers and the general public. To this end, selected elements of a facility operator's QA program can also be applied to equipment and activities that may not be safety-related or important to safety, but that support safe, economic, and reliable facility operations, or where other facility regulatory requirements establish program requirements.

After categorizing SSCs into the categories described in section 200, QA requirements for activities categorized as RISC-3 can be adjusted commensurate with their determined contribution to safety, as alternative treatment requirements.

Operators of facilities implementing risk-informed approach should not reduce their commitments to their regulator(s) or facility safety, without applicable regulator(s) approval.

301 Adaptation Application

The following paragraph (or similar) is recommended to be inserted into the scope or applicability section of the facility operator's QA program or manual to reflect the implementation of a risk-informed approach:

> [Facility Operator] has chosen to use the methodologies described in ASME NQA-1 2019, Subpart 3.1-2.5, Risk-Informed Approach for the Treatment of Structures, Systems, and Components (SSCs), to create a risk-informed approach for the treatment of SSCs. Within the provisions of this voluntary guidance, alternative approaches for establishing the requirements for treatment of an SSC, using a risk-informed method of categorization according to the described risk categories are implemented. The applicability and scope of this follows 10 CFR 50.69 para. (b)(1). Elements of the QA program are applied to components using approved facility procedures. Implementing documents establish program element applicability.[5]

400 IMPLEMENTATION GUIDANCE

The following sections provide guidance for RISC-1, -2, -3, and -4 SSCs.

401 RISC-1 SSCs

For RISC-1 SSCs, the user should maintain the existing requirements imposed by NQA-1 and applicable regulations. In addition, users should determine if additional requirements are necessary for these SSCs to ensure that their performance remains consistent with that assumed in the categorization process (including the PRA) for beyond design basis functions. The user

[5] NEI-00-04 is the intellectual property of NEI and is used here by permission from NEI.

should monitor the performance of RISC–1 SSCs and make adjustments as necessary to either the categorization or treatment processes so that the categorization process and results remain valid.

402 RISC-2 SSCs

For RISC-2 SSCs, the user should ensure that the SSCs perform their functions consistent with the categorization process assumptions by evaluating the treatment/controls being applied to these SSCs to ensure that it supports those attributes or functions that made the item risk-significant (e.g., functions credited in a PRA model). If additional treatment/controls are required, users should consider prudent application of controls specified in Parts I and II, as the processes, procedures, programs, etc. have been created to support RISC-1 SSCs. Additional treatment/controls should be applied in a timely manner.

The users corrective action or nonconformance program should be used to document/evaluate any event or condition that prevented, or would have prevented, a RISC–2 SSC from performing a safety significant function. If required by regulation, the user should submit an event report to the regulatory authority(ies).

403 RISC-3 SSCs

The following sections discuss how requirement areas in an NQA-1 QA program could be adapted to a Risk-informed approach for RISC-3 SSCs.

403.1 Organization. There are no particular organizational considerations or changes applicable to implementing alternative treatment requirements, other than the addition of a Probabilistic Risk function and an Integrated Decision-making Panel, to the QA function.

(24) **403.2 Quality Assurance Program.** The application of risk-informed approach to QA program requirements is the basis for implementing alternative treatment requirements. Performing a review of the safety significance of SSCs using a probabilistic risk assessment to determine initial SSC categorization, confirming categorization with an Integrated Decision-making Panel, and getting regulatory approval is the foundation for implementing alternative treatment requirements to SSCs. Section 200 of this Subpart describes a suggested approach for this.

After the SSCs have been categorized, development of alternative treatments for alternative treatment categorized items can begin. Although the QA rigor for alternative treatment categorized SSCs may be reduced in comparison to a special treatment approach, the facility operator must ensure that alternative treatment categorized SSCs remain capable of performing their safety-related functions with reasonable confidence under design basis conditions. QA program controls for training and qualification of personnel working on alternative treatment categorized SSCs should be adjusted to ensure adequate staff is qualified to work on special treatment categorized SSCs. This training should include the qualification and use of probabilistic risk assessments and qualifications of members of the Integrated Decision-making Panel.

Because nuclear facility operators often use several quality levels for QA activities, it is recommended that quality level nomenclature not use terms such as “safety-related” or “non-safety-related” following classification in the risk categories described previously.

The qualification of facility regulator staff in the use of probabilistic risk assessments, RISC categorization, and the application of Alternate Treatment Approach for SSCs should be considered by the regulator.

403.3 Design Control. Under a risk-informed approach, the changes to the implementation of design control requirements would be small as design of SSCs are largely unaffected by the 10 CFR 50.69 process.

The application of an alternative treatment approach for replacement items should not be used unless the replacement item is in fact a design change under current procedures.

403.4 Procurement Document Control. The application of a risk-informed approach is readily applied to procurement document control. The procurement document control approach to implementing alternative treatment requirements to SSCs can be reduced to an approach similar to commercial facilities.

403.5 Instructions, Procedures, and Drawings. The application of Instructions, Procedures, and Drawings to a risk-informed approach requires Instructions, Procedures, and Drawings for both special treatment and alternative treatment categorized SSCs.

403.6 Document Control. The impact of Document Control requirements on items and services subject to alternative treatment requirements could be minimal. Though requirement rigor for implanting alternative treatment requirements may be reduced, ensuring that controlled documents consistently meet a facility’s operational requirement needs are not.

403.7 Control of Purchased Items and Services. A risk-informed approach to Control of Items and Services has a broad application. The rigor applied to alternative treatment categorized SSCs could be reduced to an approach similar to commercial facilities.

Facility operators still need to assure with reasonable confidence, that alternative treatment categorized SSCs remain capable of performing their safety functions under design basis conditions.

403.8 Identification & Control of Items. The application of a risk-informed approach to Identification & Control of Items is limited. From a practical standpoint, items subjected to special or alternative treatment

requirements need to be identified and controlled so that applicable requirements are matched to the item.

403.9 Control of Special Processes. Under the alternative treatment requirement provisions for special processes (including welding, heat treating, and nondestructive testing) should be controlled to the degree necessary to achieve reasonable confidence that the material, parts, and components meets applicable design requirements. Personnel performing special process activities should be suitably proficient in performing the process so that there is confidence in the quality of the work. A less stringent "qualification" and "certification" process may not be appropriate for alternative treatment categorized SSCs. Alternative treatment procedures and required worker skills should be consistent with applicable industrial codes and standards.

403.10 Inspection. Periodic inspection activities should be conducted to determine that alternative treatment SSCs remain capable of performing their safety functions under design basis conditions, with reasonable confidence, throughout their service life. An appropriate level of inspection should be performed to ensure that treatments are properly applied, and that sufficient data is collected so that the applicable risk-informed actions and assumptions can be validated, and acceptable levels of SSC reliability are maintained. Alternative treatment categorized SSCs may use a less rigorous approach to inspector proficiency and qualification than for special treatment SSCs.

For alternative treatment categorized SSCs, in-process inspections at critical points by qualified personnel, including peer inspections, self-checking methods, and/or engineering personnel, could be an alternative treatment to traditional QC hold points and inspections. If an inspection activity is part of the alternative treatment for SSCs, then processes should exist that ensure that the inspection is satisfactorily performed.

Significant reductions in reliability due to reduced inspections could invalidate the initial risk-informed categorization, requiring a component or process to be recategorized to a higher RISC class and additional inspection activities re-established to improve reliability. See section 600 of this Subpart.

403.11 Test Control. The application of a risk-informed approach to Test Control has a broad application. Although levels of testing for alternative treatment SSCs may be reduced compared to special treatment items. Activities that ensure applicable risk-informed actions and assumptions are valid should be completed. Testing activities should be conducted to determine that alternative treatment SSCs will remain capable of performing their safety-related functions under design basis conditions.

403.12 Control of Measuring and Test Equipment. The application of a risk-informed approach to Control of Measuring and Equipment may be limited by economic and implementation considerations.

Special treatment required activities require a fully compliant NQA-1 program for Measuring and Test equipment. Alternative treatment categorized items less so.

Having some Measuring and Test Equipment that meets special treatment requirements, and some that do not, would require multiple measuring devices with the same capability. Ensuring that measuring and test equipment meeting alternative treatment requirements for Measuring and Testing Equipment is only used where it is intended is a consideration.

403.13 Handling, Storage, and Shipping. A risk-informed approach to Handling, Storage, and Shipping has a broad application.

Handling, Storage, and Shipping requirements for alternative treatment SSCs could be significantly reduced similar to non-nuclear facilities.

403.14 Inspection, Test, and Operating Status. Even though a reduction in requirement extent and rigor for alternative treatment SSCs may be supported by alternative treatment methodologies, fundamental safety and requirements from other sources, typically applicable to commercial applications, may limit this reduction.

403.15 Control of Nonconforming Items. For reliable and safe operation of a nuclear facility, it is necessary to identify and control materials, parts, or components that do not conform to requirements to prevent their use or installation. There is little benefit to handling alternative treatment nonconforming SSC items significantly different than for special treatment SSCs.

403.16 Corrective Action. For reliable and safe operation of a nuclear facility, it is necessary to correct parts or processes that do not conform to requirements. There is little benefit to handling alternative treatment related SSC corrective actions different than for special treatment SSCs.

403.17 Quality Assurance Records. Records are necessary to demonstrate compliance with QA and regulatory requirements. Therefore, the facility operator's overall QA record processes and retention measure would not change significantly for alternative treatment activities.

Because of the importance of RISC categorization and its associated decisions, and Feedback and Adjustment activities, QA records associated with these should be addressed.

403.18 Audits. Audit procedures and auditor qualifications could be adjusted for alternative treatment SSCs. For some RISC-3 categorized items self-assessments could be appropriate.

404 RISC-4 SSCs

For RISC-4 SSCs, no additional treatment considerations or actions are required. Any changes must be made in accordance with the change control process for the licensing basis document which imposes such requirements.

500 COMPUTER SOFTWARE

The requirements in Subpart 2.7 should be applied to computer software used in performing probabilistic risk assessments and the tracking of SSC items categorization and treatment.

Users should evaluate the use of Probabilistic Risk Assessment software and SSC tracking software for RISC classification based on their facility defined use, using approved procedures.

The adequacy of Probabilistic Risk Assessment software can be evaluated using the approach outlined in Reg Guide 1.200, An Approach for Determining the Technical Adequacy of Probabilistic Risk Assessment Results for Risk-informed Activities. Another acceptable approach is benchmarking the proposed Probabilistic Risk Assessment Software against codes known to produced valid results.

The possibility that some Instrumentation and Control software could be categorized as RISC-3, should be evaluated.

600 FEEDBACK AND PROGRESS ADJUSTMENT

The facility operator should review changes to the facility, operational practices, applicable facility and industry operational experience, and as appropriate, update the Probabilistic Risk Assessment, SSC categorization and treatment of SSCs and associated processes. The facility operator should perform this review in a timely manner and at intervals negotiated with the facility regulator(s).

601 Monitor RISC-1 and RISC-2 Item Performance

The facility operator should monitor the performance of RISC–1 and RISC–2 SSCs, making adjustments as necessary to either their categorization or treatment processes so that the categorization process and results remain valid.

602 Evaluate RISC-3 Related Inspections (24)

The facility operator should review and evaluate data collected that is associated with alternative treatment SSC inspections to determine if there are any adverse changes in performance or reliability such that the SSC unreliability values approach or exceed the values used in prior evaluations and that calculated large early release frequency resulting from changes in treatment are small.

700 10 CFR 50.69 IMPLEMENTATION REFERENCES FROM EPRI (24)

EPRI 3002012990 (2018, July). 10CFR50.69 Alternative Treatment Case Studies. Electric Power Research Institute.[6]

EPRI 1015099 (2007, December). “Option 2, 10 CFR50.69 Special Treatment Guidelines.” Electric Power Research Institute.[4]

EPRI 1011234 (2006, January). Program on Technology Innovation: 10CFR50.69 Implementation Guidance for Treatment of Structures, Systems and Components. Electric Power Research Institute.

EPRI 1009748 (2005, October). “Guidance for Accident Function Assessment for RISC-3 Applications, Alternate Treatment to Environmental Qualification for RISC-3 Applications.” Electric Power Research Institute.

EPRI 1011783 (2005, December). “RISC-3 Seismic Assessment Guidelines.” Electric Power Research Institute.

[6] Not free to the public.

SUBPART 3.1-3.1
Implementing Guidance for Part I, Requirement 3: Design Control

100 GENERAL

This Subpart provides nonmandatory guidance on design control as specified in Part I, Requirement 3.

Some factors to be considered in establishing the design control measures may include the following:

(a) nature of the organization, such as the facility Owner(s), major equipment designer(s) or facility designer, and the design interfaces among them

(b) importance of design activity to safety

(c) state of the art such as experimental, developmental, or standard design

(d) nature of design activity, such as conceptual, preliminary, detailed design, field engineering, or modifications to operating facilities

(e) nature of interaction between design, operation, and construction activities

(f) the effect of design change implementation on the safe operation of the facility

(g) nature of analysis, such as analysis supporting the design or predictive analysis of an existing design

200 DESIGN INPUT

Design inputs include many characteristics and functions of an item or system. These inputs vary depending on the application; however, the nuclear industry has found it desirable to consider at least the following listed inputs as they apply to specific items or systems:

(a) basic functions of each structure, system, and component

(b) performance requirements such as capacity, rating, and system output

(c) regulatory requirements, and commitments or responses to federal, state, and local regulations. For example, these may include, but are not limited to

(1) safety analysis report

(2) NRC's Safety Evaluation Report and supplements thereto

(3) environmental report

(4) NRC's environmental statement and supplements thereto

(5) technical specifications

(6) regulatory guides

(7) code of federal regulations

(8) NRC bulletins, circulars, notices, and generic letters

(9) commitments in correspondence with NRC

(d) codes and standards. For example, these may include, but are not limited to

(1) ASME codes and standards

(2) ACI, AISC, ANSI, ASNT, ASTM, AWS, IEEE, ISO, NFPA, and others by similar societies or organizations

(e) design conditions such as pressure, temperature, flow, fluid chemistry, and voltage

(f) loads such as seismic, wind, thermal, and dynamic; the cumulative effect of design changes on the analytical design basis, e.g., the addition of a load to an existing wall or the addition of an instrument to a cabinet

(g) environmental conditions anticipated during storage, construction, operation, and accident conditions, such as pressure, temperature, humidity, corrosiveness, site elevation, wind direction, exposure to weather, flooding, nuclear radiation, electromagnetic radiation, and duration of exposure; qualification test requirements; shelf or service life limitations

(h) interface requirements including definition of the functional and physical interfaces involving structures, systems, and components

(1) the effect on existing plant equipment capability, such as DC battery loads, AC bus capacity, available stored water inventory, service instrument air capacity, water systems capability (intake, service, and component cooling water), and HVAC capability

(2) the effect of cumulative tolerances in the design

(3) the effect on design and safety analyses to ensure the analytical bases remain valid

(4) the compatibility with unimplemented design changes to specify any required sequence for implementation

(5) compatibility with technical specification requirements

(i) material requirements including such items as compatibility, electrical insulation properties, protective coating, and corrosion resistance

(j) mechanical requirements such as vibration, stress, shock, and reaction forces

(k) structural requirements covering such items as equipment foundations and pipe supports

(l) hydraulic requirements such as pump net positive suction heads (NPSH), allowable pressure drops, and allowable fluid velocities

(m) chemistry requirements including provisions for system flushing, batch sampling, and in-line sampling; power plant water chemistry treatment for primary systems, steam generator, and plant limitations on water chemistry

(n) electrical requirements such as source of power, load profile voltage, electrical insulation, motor requirements, physical and electrical separation of circuits and equipment; the effect of cable routing or rerouting on the cable tray system (loading, seismic capability, and capacity limitations)

(o) layout and arrangement requirements

(p) operational requirements under various conditions, such as startup, normal operation, shutdown, maintenance, abnormal or emergency operation, special or infrequent operation including installation of design changes, and the effect of system interaction

(q) instrumentation and control requirements including indicating instruments, controls, and alarms required for operation, testing, and maintenance, other requirements such as the type of instrument, installed spares, range of measurement, location of indication, and set point determination are included

(r) security requirements to include access and administrative control requirements and system design requirements including redundancy, power supplies, support system requirements, emergency operational modes, and personnel accountability

(s) redundancy, diversity, and separation requirements of structures, systems, and components

(t) failure effects requirements of structures, systems, and components including a definition of those events and accidents that they must be designed to withstand

(u) test requirements including preoperational and subsequent periodic tests and the conditions under which they will be performed

(v) accessibility, maintenance, repair, and preservice and inservice inspection requirements for the facility including the conditions under which these will be performed

(w) personnel requirements and limitations including the qualification and number of personnel available for operation, maintenance, testing and inspection, and radiation exposures to the public and facility personnel

(x) transportability requirements such as size and shipping weight, limitation, and I.C.C. regulations

(y) fire protection or resistance requirements

(1) safe shutdown analyses, the introduction of safe shutdown equipment into fire areas

(2) routing of piping and electrical cables and the necessity for cable fireproofing and/or fire stops

(3) fire detection and fire suppression capability

(4) fire barrier capability including fire door installation

(5) fire dampers

(6) access to firefighting and emergency equipment

(7) use of noncombustible materials

(8) introducing combustible materials into safe shutdown areas by design or during installation or operation

(9) smoke and toxic gas generation

(z) handling, storage, cleaning, and shipping requirements

(aa) other requirements to prevent undue risk to the health and safety of the public

(bb) materials, processes, parts, and equipment suitable for application

(cc) safety requirements for preventing personnel injury including such items as radiation safety, minimizing radiation exposure to personnel, criticality safety, restricting the use of dangerous materials, escape provisions from enclosures, and grounding of electrical systems

(dd) quality and quality assurance requirements

(ee) reliability requirements of structures, systems, and components including their interactions, which may impair functions important to safety

(ff) interface requirements between equipment and operation and maintenance personnel

(gg) requirements for criticality control and accountability of nuclear materials

(hh) load path requirements for installation, removal, and repair of equipment and replacement of major components

(ii) qualification test requirements

300 DESIGN PROCESS (24)

The design activities may be prescribed in job specifications, work instructions, planning sheets, procedure manuals, test procedures, or any other form that provides adequate control and permits reviewing, checking, or verifying the results of the activity.

(a) Subjects normally covered by procedures for the preparation and control of drawings include the following:

(1) drafting room standards

(2) standardized symbols

(3) identification system

(4) indication of status

(5) checking methods

(6) review and approval requirements

(7) issuance and distribution control

(8) storage and control of originals or master copies

(9) revisions

(10) as-built drawings

(11) control of computer-aided design and engineering tools

(b) Subjects normally covered by procedures for the preparation and control of specifications and other design documents include the following:

(1) format requirements

(2) identification system

(3) review and approval requirements

(4) issuance and distribution

(5) revisions

(6) indication of status
(7) storage and control of originals or master copies

(c) Design documents should include information that may subsequently be needed to support facility operations such as

(1) control room operations
(2) maintenance
(3) spare and replacement parts
(4) environmental qualification of equipment
(5) outage planning and scheduling
(6) safety evaluations
(7) facility modifications
(8) personnel training and qualification

400 DESIGN ANALYSIS

Design analysis should be performed in a planned, controlled, and documented manner. Design analysis should identify the purpose, methods, assumptions, design inputs, references, units used, and any restrictions or limitations on the use of the results. Calculations should be identifiable by subject (including structure, system, or component to which the calculation applies), originator, reviewer, and dates or by other data such that calculations are retrievable.

401 Use of Computer Programs

When a computer program is used in a design analysis, the correctness of the computer-generated results may be demonstrated in either of the following two ways:

(a) *Case (1):* by virtue of the program's acceptance testing and configuration management in its as-installed configuration (i.e., it is controlled) in accordance with the applicable requirements of Parts I and II prior to use, or

(b) *Case (2):* by applying a known trustworthy means to independently verify the computer-generated results with the design analysis for each application of the computer program, in accordance with Part I, Requirement 3, section 500

These two cases are further clarified below. Additionally, in either case, it is advisable to have a properly qualified person assess the reasonableness of the results in light of the analyzed conditions.

Computer programs that are used to preprocess input or postprocess output (such as scripts that are written in macro languages, such as Microsoft VBA, Python, and the command shell) used in a design analysis are subject to these same requirements.

401.1 Case (1): Acceptance of Computer Programs by Applying the Applicable Parts I and II Requirements Prior to Use. Case (1) is applicable only if all of the following are satisfied:

(a) The computer program's acceptance testing documentation shows that it produces correct solutions for the applied mathematical model within defined limits for each parameter employed [i.e., Requirement 3, para. 401(a)].

(b) The applied mathematical model has been shown to produce a valid solution to the physical problem associated with the particular application [i.e., Part I, Requirement 3, para. 401(b)].

(c) The design analysis uses the computer program in a manner consistent with the scope of its acceptance testing.

(d) The computer program's acceptance testing was performed in accordance with Part II, Subpart 2.7, para. 404 and, if applicable, Part II, Subpart 2.14.

(e) The computer program is maintained under configuration management in its as-installed configuration in accordance with Part II, Subpart 2.7, para. 203.

(f) The design analysis uses the computer program in a controlled environment equivalent (i.e., with an identical configuration item list) to that in which it was tested.

When all of the above conditions are met, a reference to the computer program's configuration management and acceptance testing record should be sufficient to justify its use in the analysis. Acceptance testing performed during either NQA-1 compliant software development or computer program commercial grade dedication processes may be used to satisfy the requirements of Part I, Requirement 3, paras. 401(a) and 401(b).

For computer programs that are developed under a QA program compliant with Parts I and II, verification and validation performed during the computer program's development should demonstrate its acceptability in accordance with Requirement 3, para. 401(a) within defined limits for each parameter employed. For computer programs acquired as commercial-grade, activities performed during the dedication process, including documented technical evaluations and acceptance activities, should provide evidence that the computer program correctly performs within its defined limits in accordance with Requirement 3, para. 401(a).

For each computer program either developed under an NQA-1 compliant program or procured as commercial-grade, acceptance activities must show that the applied mathematical model produces a valid solution to the physical problem in accordance with Requirement 3, para. 401(b). This may be performed through literature searches, textbook references, qualification testing, comparison of computer program results against a reliable reference such as alternate mathematical model results or physical system measurements, or other such methods that provide assurance that the applied mathematical model in the computer program is appropriate for the physical problem being analyzed.

A spreadsheet calculation may be considered an accepted and controlled computer program if, in addition to satisfying the criteria specified above, all of the cells that contain formulas are locked and password-protected to prevent changes. Only the input parameter cells should allow user input.

(24) **401.2 Case (2): Verification of Computer Program Results for Each Application.** Case (2) applies to computer programs for which any one or more of the criteria specified in Case (1) is not satisfied. The affected computer-generated results are verified through the design verification process for each application by applying either para. 501.2 or para. 501.3 of Part I, Requirement 3. The focus is on the results, which are verified by known trustworthy means that are both independent of the unproven computer program and demonstrated to be technically correct in accordance with Part I, Requirement 3, paras. 401(a) and 401(b).

The verification methodology is shown to produce correct solutions for the applied mathematical model within defined limits for each parameter employed [i.e., Requirement 3, para. 401(a)], and the applied mathematical model is shown to produce a valid solution to the physical problem associated with that application [i.e., Requirement 3, para. 401(b)]. Such independent verification of results for a particular design analysis should satisfy the computer program verification requirement in Requirement 3, para. 402(e) for the current verified design analysis only; it is not sufficient evidence to qualify the computer program for use in other design analyses.

In addition to the above, the verification of a spreadsheet calculation should include confirmation that the mathematical model's formulas are properly represented in the spreadsheet's symbology and that the correct cell references are incorporated into each instance of each formula.

The software requirements in Part II, Subpart 2.7 are optional for computer programs whose results are verified with the design analysis for each application.

(24) **401.3 Changes to Computer Program or Defined Limits.** Where changes to a previously accepted computer program are performed, the new version requires verification in accordance with Part I, Requirement 3, para. 401.

Any use of an accepted and controlled computer program beyond the limits previously verified must be justified, either by performing additional acceptance testing, as in Case (1), for the newly defined limits or by independently verifying, as in Case (2), all results that could be affected by such usage. Justification should be provided for judging any results to be unaffected by the out-of-scope usage.

401.4 Documentation. Documentation of the computer program verification activities described above should be in accordance with Part I, Requirement 3, para. 402.

Table 401.4 summarizes the acceptability of methods that may be used to meet the requirements of Part I, Requirement 3, paras. 401(a) and 401(b) for each of five hypothetical scenarios.

500 DESIGN VERIFICATION

The purpose of design verification is to provide a confirmatory check of design adequacy by a person(s) competent to have prepared the design being verified but sufficiently independent such that they are not verifying their own work. Accordingly, design verifiers may be a supervisor, a subordinate, or any other individual from inside or outside the organization, provided they are competent, they are not verifying their own work, and they have access to the necessary design information.

Design verification for some designs or specific design features may be achieved by suitable qualification testing of a prototype or initial production unit.

Qualification testing may be used in combination with other verification methods. For example, it may be most effective to verify that an instrumentation cabinet is designed to withstand the maximum earthquake-caused vibratory motions by actually subjecting the cabinet and its associated components to shaker tests that correspond to these vibratory motions. The shaker tests will not, however, verify that the circuitry is designed correctly or that the component in the cabinet will perform its intended function. Other tests or verification means are required to confirm that remaining design functions are adequately performed by the instrumentation and that those components perform the intended functions under the varying conditions to which they are subjected.

If qualification testing indicates that modifications to the item are necessary to obtain acceptable performance, the modification should be documented and the item modified and retested or otherwise verified to ensure satisfactory performance.

600 CHANGE CONTROL

Design documents should be maintained current to ensure their availability to support facility design, construction, and operation. However, design changes may be approved without revision to the affected document(s). When this occurs, procedures should be established to ensure that a determination of the final design or as-built condition can be made, consistent with the user's needs. Since not all affected documents require revision, procedures should identify those design documents that are subject to revision. Measures may include, but are not limited to, imposing a time limit for updating the affected document(s), limiting the number of design changes allowed to accumulate prior to revising the affected document, or providing for a process that continually updates the affected document(s).

During the operational phase, attention should be given to system modifications, mechanical and electrical temporary alterations, and instrument setpoint changes to ensure that design changes are processed in accordance with design control requirements.

Table 401.4
Scenarios for Use of Computer Programs in Design Analysis

Scenario	Use of Computer Program for Design Analysis (Part I, Requirement 3, Para. 401)	Design Verification Method (Part I, Requirement 3, Section 500)	Acceptable?	Comment
1	Case (1)	Design review, alternate calculation, or qualification testing	Yes	Satisfies Case (1) and meets Part I, Requirement 3, paras. 401(a) and 401(b) through prior acceptance testing for design analyses within the acceptance testing scope.
2	Case (2)	Design review	No	Does not satisfy Case (1) or Case (2). The appropriate design inputs may be verified; however, a trustworthy method has not been used to verify results. Additional method required to verify correct solutions for the applied mathematical model and physical problem.
3	Case (2)	Alternate calculation: another computer program that has had the appropriate requirements of Parts I and II applied prior to use	Yes	Satisfies Case (2) and meets Part I, Requirement 3, paras. 401(a) and 401(b) through the verification method for the current verified design analysis.
4	Case (2)	Alternate calculation: hand calculation	Yes	Satisfies Case (2) and meets Part I, Requirement 3, paras. 401(a) and 401(b) through the verification method for the current verified design analysis, provided that the hand calculation verifies the applicability of its mathematical model to the physical problem through textbook references, literature searches, or other reliable methods.
5	Case (2)	Qualification testing	Yes	Satisfies Case (2) and meets Part I, Requirement 3, paras. 401(a) and 401(b) through the verification method for the current verified design analysis.

Proposed modifications, alterations, and changes may overlap and may not be installed in the sequence that they were designed; therefore, it is incumbent upon the design organization and plant/facility Owner to control approved (but not installed) design changes to ensure that changes do not conflict with each other. Where modifications, alterations, or changes must be installed in a particular sequence, the sequence should be specified. Partial installation of design changes should be approved by the design organization. Controls should ensure that documents that are required to support operation reflect the as-built condition of the facility. Temporary and permanent repair work and parts replacement should be reviewed to determine if these activities constitute design changes.

Assessment of the cumulative effects of individual changes should be conducted to determine the impact on the final design.

700 USE OF REVERSE-ENGINEERING TECHNIQUES (24)

Reverse-engineering techniques involve examination of an item as well as review and analysis of information available about the item's design, design functions, and interfaces to enable manufacture (or otherwise facilitate acquisition) of a replacement item. Risk is inherent in the application of reverse-engineering techniques as they are applied in situations where complete, original design information is not available. Subjecting reverse-engineered replacement items to the same design control measures as other replacement items will mitigate risk. An evaluation of an item's design should be performed based on the application of reverse-engineering techniques to establish confidence that the design supports known functions, in-situ conditions, and interfaces. Activities sufficient to demonstrate

functionality of a design based on reverse-engineering should be planned, documented, and completed. The operator of the nuclear facility in which the reverse-engineered replacement item will be installed is responsible for providing pertinent information to the reverse-engineering entity such as in-situ environmental conditions, over/under voltage conditions, etc. See section 1000 of this Subpart for guidance.

800 INTERFACE CONTROL

During the construction and operational phases, attention should be given to defining and controlling the design interfaces between organizations participating in design changes/modifications and to defining the responsibility for the overall control of the design. The responsibility for the design of the facility should be divided in a way that is suited to the individual capabilities of the participating organizations and the status of construction or operations. Participating organizations may include

(a) Owner's design organization
(b) construction engineering group
(c) operating organization
(d) architect engineer
(e) reactor manufacturer (NSSS)
(f) equipment design
(g) other design contractor

The documentation of the assignment of design responsibilities may be accomplished in procedures, internal or external correspondence, contracts, or other suitable documents.

900 DOCUMENTATION AND RECORDS

The documentation and records for a facility should include provisions for as-built documentation. These provisions should address what documents are required, the depth of information required for the as-built documentation, the internal or other measure for updating, and the identification of those documents that are to become lifetime or nonpermanent records. As-built documents may include documents such as the following:

(a) drawings required for facility operation
(b) modification packages
(c) manufacturer operation and maintenance instructions
(d) manufacturer vendor manuals
(e) manufacturer technical bulletins
(f) equipment and instrumentation listings
(g) environmental qualification listings
(h) spare and replacement parts listings

The status of the approved design should be readily available to the participating design organization(s). In addition, for the operation phase, the as-built configuration and the status of modifications being implemented should be readily available to the operating organization.

1000 ADDITIONAL GUIDANCE AND RECOMMENDED READING (24)

EPRI Technical Report 3002011678 (2018, May). Guidance for the Use of Reverse-Engineering Techniques: Revision 1 to EPRI TR-107372. Electric Power Research Institute.

SUBPART 3.1-4.1
Implementing Guidance for Part I, Requirement 4: Procurement Document Control

100 GENERAL

This Subpart provides nonmandatory guidance on controlling quality assurance requirements in procurement documents as specified in Part I, Requirement 4.

200 PROCUREMENT DOCUMENT REVIEW

The review of procurement documents should be performed as early in the document preparation as practicable. Technical and quality assurance reviews should normally be performed on the procurement documents prior to issuance for bid.

Prior to contract award, reviews of changes made resulting from bid evaluations or negotiations should include consideration of the following:

(a) applicable provisions described in Part I, Requirement 4, section 200

(b) determination of any additional or modified design criteria

(c) analysis of exceptions or changes requested or specified by the bidder and determination of the effects such changes may have on the intent of the procurement documents or quality of the item or service to be furnished

Documentation of reviews performed should provide objective evidence of satisfactory accomplishment of such reviews prior to contract award.

300 TYPICAL SCOPE OF PROCUREMENT EFFORT

The complexity of a nuclear facility dictates the need for a multitude of tasks that should be performed during various phases of design, construction, testing, and operations. One of the major tasks is the procurement of items and services. Each major phase involves a procurement effort that should be responsive to the special needs of that phase and that should provide items and services that meet code, regulatory, and special requirements. Examples of the items and services procured during these phases are given in paras. 301 and 302 of this Subpart.

301 Design, Construction, and Testing Phases (24)

The following are examples of the items and services procured during design, construction, and testing phases:

(a) design and engineering services

(b) site investigations, such as those required to determine the engineering requirements for the structure (i.e., soil investigation, environmental studies, both field work and laboratory effort)

(c) long-lead items such as the nuclear steam supply system, process equipment, including major equipment fabrication and test, and high-level waste storage tanks

(d) construction of the main structure of the facility, including structural steel erection and concrete production and placement

(e) specific site erection and installation tasks, such as piping and mechanical and electrical equipment

(f) services for nondestructive examination and required laboratory tests

(g) hardware, such as valves, piping, tanks, and miscellaneous hardware

(h) software, such as development of facility operating procedures, technical manuals, and computer programs

(i) services of various consultants to assist in setting up management systems (i.e., quality assurance program and operator training)

(j) preoperational and start-up tests

(k) baseline inspection equipment or services

302 Operational Phase (24)

The following are examples of the items and services provided during operational phases:

(a) fuel, equipment, and services for power plant fueling operations; special fuel grapples and cask yokes at reprocessing plants, fuel components, and subassemblies at fuel fabrication plants; chemicals used in fuel processing and reprocessing cycles; special packaging for nuclear materials, radioactive products, and radioactive by-products

(b) in-service inspection equipment or services

(c) items and services for facility maintenance, modifications, or changes

(d) special services such as environmental monitoring, radioactive waste disposal, and facility decontamination

The examples given in paras. 301 and 302 of this Subpart are not meant to be all inclusive but only indicative of the wide variety of procurements for the above phases. Similarly, it should be realized that the phases and types of procurements listed above are not distinct in scope and timing and that there may be considerable overlap depending upon the needs of a particular situation.

(24) 400 CATEGORIZATION OF PROCUREMENT ACTIONS

The types of procurements listed in para. 302 of this Subpart may also be categorized in terms of what is supplied by the Supplier, e.g., hardware, services, installation, and total system supply or combinations thereof. Such a categorization, wherein the procurement efforts are grouped by what is supplied, can be of assistance in identifying the logical steps that should be performed in properly specifying the quality assurance requirements in the procurement documents. For example, the procurement of services, such as for soil investigations or pipe stress calculations, can have certain quality assurance program features in common that may be different for the program feature of a pure hardware procurement.

500 GENERAL LOGIC CONSIDERATIONS

The quality assurance requirements should be compatible with the particular type of item or service that is to be supplied. Certain items and services may require extensive controls throughout all stages of development, while others may require only a limited quality assurance effort in selected phases of development. The factors that determine the extent of a quality assurance effort are specified in paras. 501 through 505 of this Subpart.

501 Importance of Malfunction or Failure of the Item to Plant Safety

Each item to be procured should be evaluated to determine whether or not it is important to plant safety. For those items that are important to plant safety, applicable requirements of this Standard should be specified in the procurement document. This safety determination should be made by the engineering staff of the appropriate organization having primary responsibility for specifying the design requirements for the item.

502 Complexity or Uniqueness of the Item

In developing specific quality assurance requirements for a particular item, complexity and uniqueness should be considered.

502.1 The extent of controls needed to ensure the quality of those characteristics that are necessary for proper functioning and long-term performance may depend heavily upon the complexity of the item, the margin of safety incorporated into its design, and the industry experience, or lack thereof, in accomplishing the quality-related activity. If a design effort is required to develop the item or accomplish the activity, design quality assurance requirements should be included in the procurement document.

502.2 Items that require a complex manufacturing plan may require extensive control over important characteristics. The control over important characteristics should extend beyond the manufacturing phase when it is necessary to preclude damage to those characteristics during packaging, shipping, handling, and storage.

502.3 In determining the extent of quality assurance to be applied, past experience in the development of similar items should be considered. An item being developed for the first time will probably require much more control over important characteristics than one that has had a past history of successful performance. The complexity or uniqueness of the item may also affect the extent of personnel training and indoctrination required.

503 Need for Special Controls and Surveillance Over Processes and Equipment

503.1 Certain work operations require the use of special processes such as a welding, nondestructive examination, passivation, brazing and soldering, hardness and tensile testing, protective coating, and heat treatment.

503.2 Special processes may also include certain in-process operations such as chemical batch process, plating operating, and electric insulation impregnation. These processes should be accomplished under specially controlled conditions. Controlled conditions include the use of appropriate equipment, suitable environmental conditions, definitive procedures, qualified personnel, and assurance that prerequisites have been satisfied.

504 Degree to Which Functional Compliance Can Be Demonstrated by Inspection and Test

It may be possible to demonstrate the quality of certain characteristics of an item by an appropriate inspection or test. In such cases, the in-process control effort may be reduced if any appropriate inspection and test will be sufficient to provide assurance of quality. A limiting case is an end-product test that can properly assess the degrees of compliance to quality requirements, thereby eliminating the need for in-process control.

505 Quality History and Degree of Standardization of the Item

The ability to use historical data in evaluating the quality experience of an item is based in part upon the degree of standardization of the item. If a manufacturer has been producing a particular standard item for a long

period and if the operational quality history of the item indicates that its significant characteristics perform satisfactorily, the quality assurance program may be tailored to reflect this satisfactory performance history. Conversely, if certain characteristics are determined to be unsatisfactory based upon operational data, additional quality assurance effort may be required to correct these deficiencies.

The general logic considerations outlined above should be applied for each procurement action. If all or most of these considerations apply to a particular action, the overall method of para. 700(a) of this Subpart should be applied in specifying the quality assurance requirements in the procedure document. However, if these considerations have only limited applicability to a particular procurement action, the unique order method of para. 700(b) of this Subpart may be used to specify the quality assurance requirements of the procurement document.

600 LOGIC CHART

Figure 600 of this Subpart provides a pictorial illustration of the logic process described in section 500 of this Subpart. This chart illustrates an example for procurement of hardware items only; however, a similar logic flow can also be used for other types of procurements such as design, inspection, test, and installation services or total system supply. It should be noted that this chart is provided for guidance and illustration only, and does not necessarily present all considerations that have to be made for this type of procurement.

700 METHODS OF SPECIFYING QUALITY ASSURANCE PROGRAM REQUIREMENTS

There are various ways in which the Purchaser can specify and obtain suitable Supplier quality assurance program requirements. Two of the most prevalent methods are as follows:

(a) Overall Method. The Purchaser may incorporate into the procurement documents a complete quality assurance program standard, such as Part I, and require the Supplier to apply the requirements of the quality assurance standard as appropriate to the items or services being procured.

(b) Unique Order Method. The Purchaser may incorporate into the procurement documents selected portions of a quality assurance standard, such as Part I, that are unique to the items or services being procured. For example, when the Purchaser's order is limited to design work only, Part I, Requirements 1, 2, 3, 5, 6, 16, 17, and 18 could be applied.

701 Example of Specifying the Overall Method

For procurement actions where the scope of work requires a broad range of skills and facilities to be furnished by the Supplier, most or all of the requirements of Part I may apply in varying degrees to the item or service being procured. An example would be the procurement of a major primary coolant pump or valve, which requires the Supplier to design, manufacture, inspect, and test the equipment in accordance with the Purchaser's engineering specification.

EXAMPLE: For the example given in para. 701 of this Subpart, the overall method could be used to specify the quality assurance program required of the Supplier by use of the provisions given in (a) through (f) of this Example.

(a) The Supplier shall establish and maintain a quality assurance program conforming to this Standard.

(b) This Standard is applicable only to the extent that the Purchaser's order requires work that is governed by the sections and elements. For example, when the Purchaser's order does not require design work of the Supplier, the requirements of Part I, Requirement 3 do not apply.

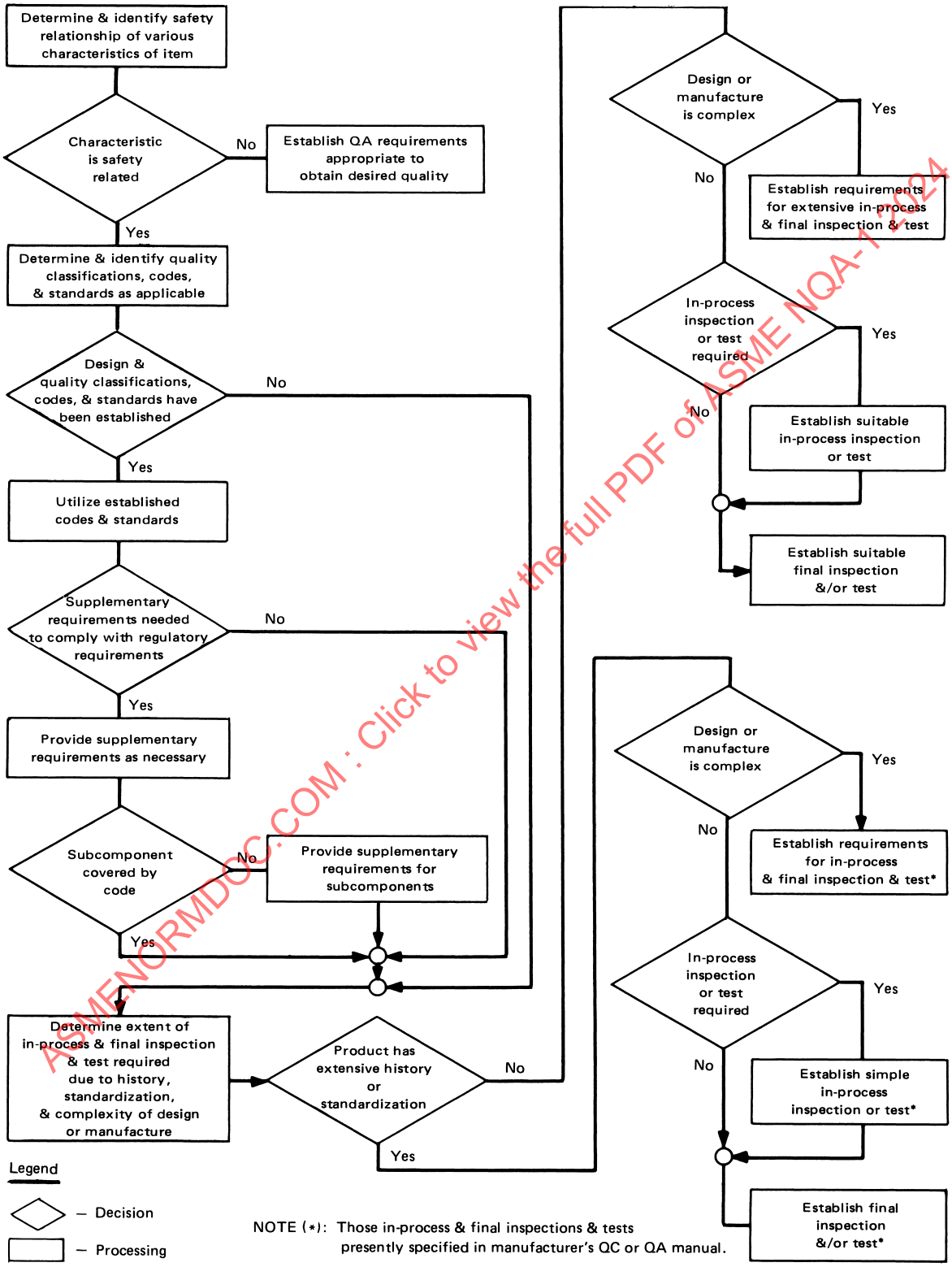
(c) The Supplier shall document a quality assurance program sufficient to conform to the applicable requirements of Parts I and II and to the Purchaser's technical and administrative requirements contained in the purchase order and referenced documents.

(d) The Supplier shall submit a description of their quality assurance program (QAP) to the Purchaser with the Supplier's bid response for the Purchaser's review. If the Supplier's description of their QAP has been previously submitted, the Supplier shall update it or submit a statement that the QAP has not changed since the last evaluation. A third party (e.g., ASME) certificate recognizing a supplier's NQA-1 QAP may be used upon evaluation that it satisfies the NQA-1 requirement for having a documented QAP description. Where the Supplier holds a valid Certificate of Authorization for ASME Boiler and Pressure Vessel Code Section III, the Supplier's ASME Quality Assurance Manual containing a copy of the Certificate of Authorization may be submitted to satisfy the requirements for a documented QAP description. The Supplier's ASME Code Section III QAP should be supplemented to extend the QAP requirements to other activities not covered by the Code as necessary to satisfy the Purchaser's procurement requirements.

(e) The Purchaser shall evaluate the QAP of the successful bidder, including consideration of any relevant third party certification that may claim compliance with quality and technical requirements, and provide comments if modifications are required. The Supplier should resolve the Purchaser's comments and implement them prior to the start of any work affected by the comments. Subsequent changes to the Supplier's QAP shall be subject to the same degree of Purchaser control.

(f) The Supplier shall identify and pass on to the subtier Suppliers all applicable quality assurance program requirements.

Figure 600
Logic Chart for Determining Appropriate Quality Requirements



NOTE (*): Those in-process & final inspections & tests presently specified in manufacturer's QC or QA manual.

702 Example of Specifying the Unique Order Method

For procurement actions where the scope of work requires only limited, even though specialized, skills and facilities to be furnished by the Supplier, only part of the requirements of Part I may apply to the item or service being purchased.

EXAMPLE: An example of the scope of work described in para. 702 of this Subpart might be as in (a) through (d) of this Example.

(a) Perform an independent design review of the following:

(1) the equipment described by the drawings and specifications referenced in this purchase order

(2) the equipment design and stress calculations submitted with this purchase order

(b) Establish a procedure and technique and conduct, subject to the Purchaser's approval, an experimental test to determine stress levels at representative locations of the equipment under conditions corresponding to 100% system design pressure and coolant temperature of 100°F through 200°F. The Purchaser will provide the Supplier with the equipment to be tested.

(c) Prepare a complete report describing the work performed in (a) and (b) of this Example. The report should confirm whether the equipment meets the specified design requirements and make recommendations as to further investigations or design requirements considered necessary.

(d) For the above example, the unique order method could be used to specify the quality assurance program required of the Supplier by use of provisions given in (1) through (5).

(1) The Supplier shall establish and maintain a documented quality assurance program conforming to the Requirements of Part I that are listed below. These Requirements shall be applied to the extent that the Purchaser's order requires work that is governed by the following Requirements:

1 Organization
2 Quality Assurance Program
3 Design Control
5 Instructions, Procedures, and Drawings
6 Document Control
11 Test Control
12 Control of Measuring and Test Equipment
15 Control of Nonconforming Items
16 Corrective Action
17 Quality Assurance Records
18 Audits

(2) The Supplier shall submit his quality assurance program description to the Purchaser with the Supplier's bid response for the Purchaser's review. If the Supplier's quality assurance program description has been previously submitted, the Supplier shall update it or submit a statement that the quality assurance program has not changed since the last evaluation.

(3) The Purchaser shall evaluate the program of the successful bidder and will provide comments if changes or supplements are required. The Supplier shall resolve the Purchaser's comments and implement them prior to the start of any work affected by the comments.

(4) The Supplier shall, during the performance of the order, submit all proposed changes of his quality assurance program to the Purchaser for information prior to implementing the changes to the Purchaser's order.

(5) The Supplier shall identify and pass on to the Supplier's subtier Suppliers all applicable quality assurance program requirements.

SUBPART 3.1-7.1
Implementing Guidance for Part I, Requirement 7: Control of Purchased Items and Services

(24) ## 100 GENERAL

This Subpart provides nonmandatory guidance on the control of procurement activities as specified in Part I, Requirement 7.

200 PROCUREMENT PLANNING

Procurement activities should be planned and documented to ensure a systematic approach to the procurement process. Procurement planning should result in the documented identification of procurement methods and organizational responsibilities.

Planning should consider the following: what is to be accomplished; who is to accomplish it; how it is to be accomplished; when it is to be accomplished.

Planning should be accomplished as early as practicable, and no later than at the start of those procurement activities that are required to be controlled, to ensure interface compatibility and a uniform approach to the procurement process.

Planning should result in the document identification of methods to be used in procurement activities, sequence of actions and milestones indicating the completion of these activities, and the preparation of applicable procedures prior to the initiation of each individual activity listed below. Planning would provide for the integration of the following:

(a) procurement document preparation, review, and change control
(b) selection of procurement sources
(c) bid evaluation and award
(d) Purchaser control of Supplier performance
(e) verification (surveillance, inspection, or audit) activities by Purchaser, including notification for hold and witness points
(f) control of nonconformances
(g) corrective action
(h) acceptance of item or service
(i) quality assurance records

300 SUPPLIER SELECTION

One method most commonly used to ensure the suitability of Supplier selection is source evaluation prior to selection. Where the evaluation involves more than one organization of the Purchaser, it is desirable to develop interface descriptions and sufficient program procedures to control the evaluations and define responsibilities.

There are many ways available for use in evaluating a potential Supplier. Some of the most common are given in paras. 301 through 303 of this Subpart.

301 Performance History

Evaluate the Supplier's history of providing a product that performs satisfactorily in actual use. Information evaluated should include either of the following:

(a) the experience of users of identical or similar products of the prospective Supplier
(b) the Purchaser's records that have been accumulated in connection with previous procurement actions and product operating experience

Quality performance is highly dependent upon the Supplier's personnel capabilities, the physical conditions of the manufacturing facility and equipment, and management attitude toward quality. Historical data should be representative of the Supplier's current capability. If there has been no recent experience with the Supplier or if he is a new Supplier, the prospective Supplier should be requested to submit information on a similar item or service for evidence of his current capabilities.

302 Quality Records

Objectively evaluate the Supplier's current quality records supported by documented qualitative and quantitative information. This may include review and evaluation of the Supplier's quality assurance program (QAP), manual, and procedures, as appropriate. When reviewing quality records, third party QAP certificates should be included in the review. The degree of reliance placed upon such certificates to satisfy the quality records evaluation should be based on a review of the third party process and limited to the scope of activity identified on the certificate. Examples of third party certificates include, but are not limited to, QAPs developed using the following standards and codes: ASME NQA-1, ASME Boiler and Pressure Vessel Code Section III, ISO 17025, and ISO 9001. NQA-1, Part IV provides comparisons of some other standards with NQA-1 to facilitate the evaluation of

certificates. Certificates issued to standards other than NQA-1 should be evaluated to understand the differences in requirements and define actions necessary to address those differences affecting the purchase. A third party certificate issued specifying that the supplier's QAP is based on NQA-1 should be the most useful as evidence that it conforms to NQA-1.

303 Facility Survey

Evaluate the Supplier's technical quality capability, which is determined by a direct evaluation of his facilities and personnel, and the implementation of his quality assurance program.

400 BID EVALUATION

The bid evaluation should consider the following performance and schedule considerations, which have the potential to affect the procurement quality:

(a) Supplier's personnel
(b) Supplier's production capability
(c) Supplier's past performance
(d) Supplier's alternates and exceptions

500 PURCHASER/SUPPLIER COMMUNICATIONS

Depending on the complexity or scope of the item or service, the Purchaser may initiate preaward and postaward activities. These activities may take the form of meetings or other communications to establish that the Supplier understands the procurement requirements; the intent of the Purchaser in monitoring and evaluating the Supplier's performance; and the planning and manufacturing techniques, tests, inspections, and processes to be employed by the Supplier in meeting procurement requirements. When Purchaser notification points, including hold and witness points, are required, they should be identified at this time. The depth and necessity of preaward and postaward communication depend on the uniqueness, complexity, and frequency of procurement with the same Supplier, and past Supplier performance for the specific items or services covered by the procurement document.

600 CONTROL OF CHANGES IN ITEMS OR SERVICES

601 Bid Evaluation Changes

Changes agreed upon by the Purchaser and Supplier during the bid evaluation process should be incorporated into a revision of the appropriate procurement documents.

602 Control of Changes

Changes to procurement documents should be subject to the same level of controls utilized for their development, except for editorial, price, delivery, or other minor changes that do not affect technical or quality requirements.

603 In Process Control of Deviations

Supplier-generated requests for deviations, changes, or exceptions to procurement documents should be controlled in accordance with para. 702 of this Subpart. The Purchaser should evaluate the need to maintain agreement between the procurement documents, and approved Supplier and Purchaser changes.

700 PRODUCT ACCEPTANCE (24)

The methods used in the nuclear industry to accept an item or service from a Supplier are source verification, receiving inspection, Supplier Certificate of Conformance, postinstallation testing at the end-use nuclear facility site, or a combination thereof.

701 Source Verification (24)

(a) Acceptance by source verification may be most desirable when the item or service is one of the following:
(1) vital to plant safety
(2) difficult to verify quality characteristics after delivery
(3) complex in design, manufacture, and test

(b) Source verification may not be necessary when the quality of the item can be verified by review of test reports, inspections upon receipt, or other means.

(c) The source verification activities may include the following checks:
(1) Documentation has been submitted as required and provides verification of approvals, material, applicable inspections, and tests.
(2) Fabrication procedures and processes have been approved and complied with and the applicable qualifications, process records, and certifications are available.
(3) Components and assemblies have been inspected, examined, and tested as required and applicable inspection, test, and certification records are available.
(4) Nonconformances have been dispositioned as required.
(5) Components and assemblies are cleaned, preserved, packed, and identified in accordance with specified requirements.

702 Receiving Inspection

Acceptance solely by receiving inspection should be considered only when the items or services are as follows:

(a) relatively simple or standard in design, manufacture, and test

(b) adaptable to standard or automated inspections and/or tests of the end product to verify quality characteristics after delivery

(c) such that receiving inspection does not require operations that could adversely affect the integrity, function, or cleanness of the item

703 Certificate of Conformance

In certain procurement actions that do not involve source verification by the Purchaser, the Purchaser may accept an item or service from a Supplier based on a receiving inspection and a Supplier's Certificate of Conformance stating that the specified requirements have been met. However, specific supplemental documentation, such as material certificates or reports of tests performed, may be required by procurement documents. Acceptance by this method is satisfactory when the item or service is of simple design and involves standard materials, processes, and tests. Such items may be fabricated subject to selected qualification, sample, or batch testing to establish or maintain maximum quality.

(24)

704 Postinstallation Testing

Acceptance by postinstallation testing is satisfactory when performed following the accomplishment of at least one of the preceding methods and when

(a) it is difficult to verify the quality characteristics of the item without it being installed and in use

(b) the item requires an integrated system checkout or test with other items to verify its quality characteristics or

(c) the item cannot demonstrate its ability to perform its intended function except when in use

705 Determining Authenticity

Measures to ensure products are authentic and reduce the risk of introducing counterfeit or fraudulent items include

(a) procedures for detection and prevention of counterfeit and fraudulent items

(b) instructing staff on the issue of counterfeit and fraudulent items and providing information on incidents of suspected counterfeit items that have been received or experienced by others

(c) purchasing items directly from the manufacturer or an authorized manufacturer's distributor/representative

(1) confirming with the manufacturer or via other independent means that the item supplier is currently authorized by the manufacturer for the scope or type of item to be provided

(2) requiring additional receipt inspection for items being procured from a source other than the item manufacturer or the manufacturer's authorized distributor/representative

(d) inspecting items upon receipt for signs of potential counterfeiting or fraud. Inspections should include the following checks for indications that the item may not be authentic:

(1) nameplates, labels, and tags for signs of alteration, which can be an indication that items may not be authentic

(2) obvious attempts at beautification

(3) evidence of hand-tool marks on fasteners and other parts of an assembly

(4) use of dissimilar parts in the same application

(5) poor fit between assembled items

(6) evidence of handmade parts

(7) software identifiers, such as version numbers that do not match

(e) processing of returned items, including the following:

(1) inspection and screening for authenticity

(2) rejecting returns of items in quantities greater than those originally purchased by the customer

(f) when an item suspected of being counterfeit or fraudulent is identified, measures including segregation and control of the suspect item as nonconforming material

SUBPART 3.1-10.1
Implementing Guidance for Part I, Requirement 10: Inspection

100 GENERAL

This Subpart provides nonmandatory guidance on the inspection, monitoring, and in-service inspection activities as specified in Part I, Requirement 10.

200 INSPECTION AND PROCESS MONITORING

When inspection and process monitoring are used, they should be performed in a systematic manner to ensure that the specified requirements for control of the process and quality of the item are being achieved throughout the duration of the process.

Controls, where required, should be established and documented for the control and sequencing of these activities at established inspection points during successive stages of the conducted process or construction.

When process monitoring is used for the acceptance method it should be performed by personnel who are not directly responsible for performing the process operation consistent with Part I, Requirement 10, section 100.

300 IN-SERVICE INSPECTION

Inspection methods should be established and executed to verify that the characteristics of an item continue to remain within specified limits. Inspection methods should include evaluations of performance capability of essential emergency and safety systems and equipment, verification of calibration and integrity of instruments and instrument systems, and verification of maintenance, as appropriate.

SUBPART 3.1-15.1
Implementing Guidance for Part I, Requirement 15: Control of Nonconforming Items

100 GENERAL

This Subpart provides nonmandatory guidance on control of nonconforming items as specified in Part I, Requirement 15. The guidance in this Subpart is limited to nonconforming items (e.g., material, parts, or components). Figure 100 of this Subpart depicts a representative nonconforming item process as described in this Subpart.

Nonconforming items should be evaluated to determine the extent to which the nonconformance represents a condition adverse to quality as defined under condition adverse to quality in Part I, Introduction and described in Part III, Subpart 3.1-16.1.

200 IDENTIFICATION

Unless otherwise specified in the governing procedure or instruction, an item should no longer be considered in-process when it is presented to the entity responsible for performing independent inspection or there is no means by which the requirement(s) of the item can be met.

As maintenance consists of actions necessary to maintain or restore an item to acceptable conditions, degradations, discrepancies, and failures of an item(s) discovered during the performance of maintenance activities at an operating nuclear facility should be controlled and documented by Part II, Subpart 2.18.

201 Validation

Methods for identifying nonconforming items are identified as described in Part I, Requirement 15. Nonconforming items should be evaluated for validity by the appropriate authority(ies) under the quality program. If the basis for a nonconformance is determined to be invalid, the originator should be notified.

202 Evaluation

When a nonconforming condition is identified, prompt notifications should be made to potentially affected personnel/organizations. The seriousness of the situation should drive the urgency of the notifications. Notifications should include, as applicable and appropriate, the area work supervisor, the organization owning the item, the purchasing organization, regulatory or oversight organizations, and others who may be impacted by the nonconforming condition. Although an evaluation of extent of condition is not required by Part I, Requirement 15, Part I, Requirement 16 applies to conditions adverse to quality, including nonconforming items. See Part III, Subpart 3.1-16.1 for further guidance on extent of condition. The use of an individual item may proceed after the requirements of Part I, Requirement 15 have been satisfied; cause evaluation and corrective action as described in Part I, Requirement 16 may be conducted separately.

300 SEGREGATION

Where physical segregation is impractical or impossible, alternate methods may be used, such as electronic processes that control further processing, delivery, installation, or use of nonconforming items.

400 DISPOSITION

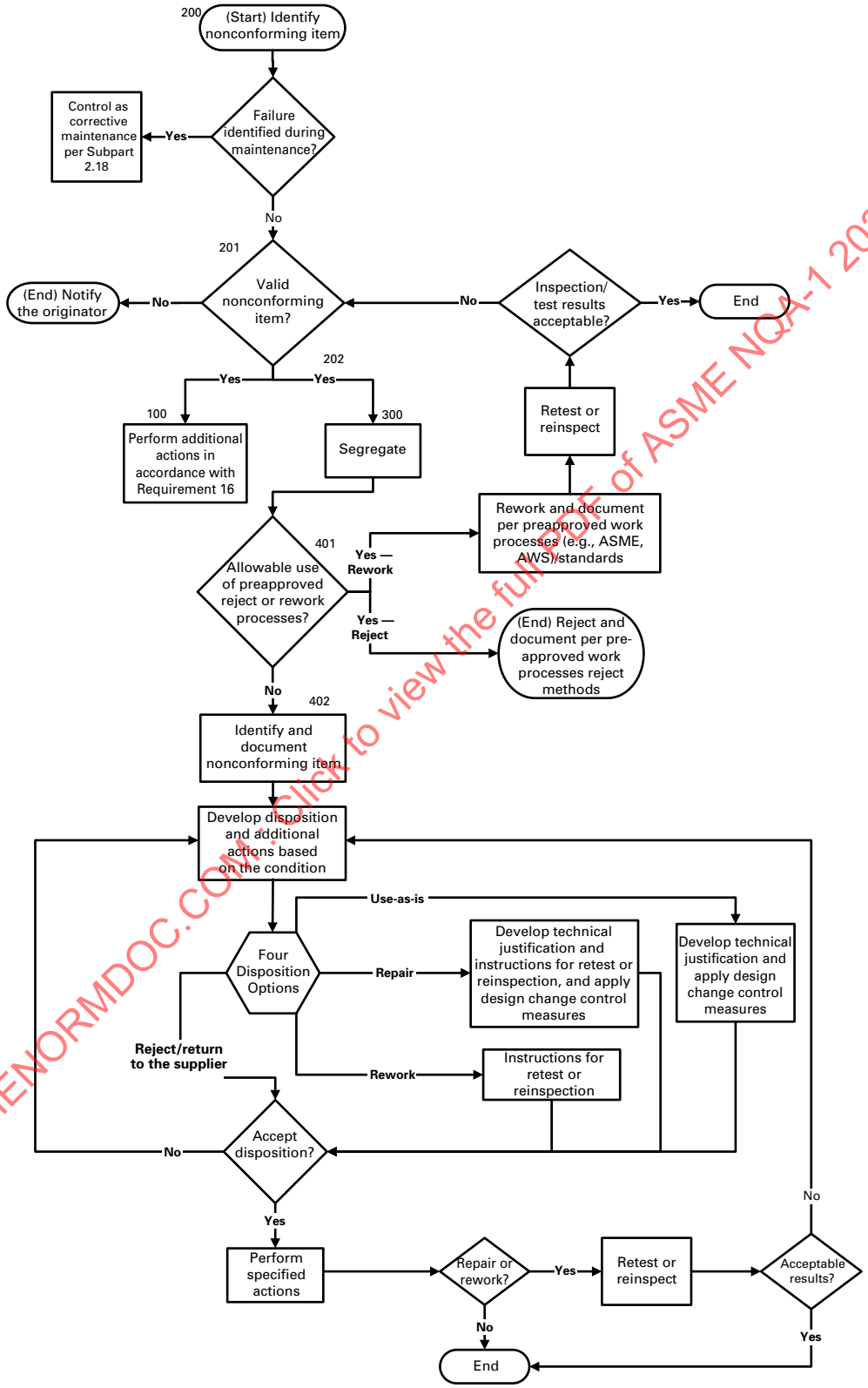
401 Allowable Use and Documentation of Preapproved Reject or Rework Process

Some construction, manufacturing, and fabrication activities may result in the identification of typical nonconforming items. These nonconforming items may be corrected as part of preapproved work-control processes that implement appropriate quality assurance requirements. These processes (e.g., procedures and work instructions) should include requirements for identifying, documenting, and either reworking or rejecting, as appropriate, these nonconforming items as part of the work process in a manner that permits evaluation or trending on a periodic basis. (See Part III, Subpart 3.1-16.1, para. 309 for further guidance on trend analysis.)

(a) When a nonconformance is identified and rejected within an approved work process, the procedures or work instruction should define the type(s) of reject actions that may be conducted and the instructions for completing the rejections, e.g., items found to be nonconforming during receipt inspection.

(b) When a nonconformance is identified and reworked within the approved work process, the procedures or work instruction should define the type(s) of rework that may be conducted and the instructions for

Figure 100
Nonconforming Item Process Chart



completing the rework. The work process should document rework and evaluation of the process to the acceptance requirements. The following are examples of nonconforming items that may be corrected within the work process, provided the rework process has been approved implementing appropriate quality assurance requirements:

(1) welds with unsatisfactory inspection or nondestructive examination results to predetermined criteria that can be reworked in accordance with a preapproved welding process (e.g., in such situations as excessive undercut, undersized weld, linear indication, lack of penetration, arc strikes, or scratches)

(2) fabricated components with unacceptable dimensional inspection results that can be reworked in accordance with a preapproved work process

(3) surfaces with improper preparation for coating application identified within the process that can be recoated in accordance with a preapproved work process

(4) parts with unacceptable cleanliness inspection results that can be reworked within a preapproved work process

(5) equipment with conditions or problems identified during tests (equipment functional and preoperational testing problems) that can be corrected within the approved test plan

In cases where in-process correction fails to restore the item to the acceptance standards, the nonconforming item should be identified and processed as described in para. 402 of this Subpart.

402 Disposition Control, Documentation, and Closure

Nonconforming items that cannot be corrected as part of the preapproved reject or rework process as described in para. 401 of this Subpart should be documented, e.g., Nonconformance Report (NCR), Condition Report (CR), etc., and processed in accordance with Part I, Requirement 15.

Documentation of nonconforming items should include sufficient information to identify the nonconformance, disposition, and means to record completion of nonconformance disposition. Documentation should include the following information as applicable (authentication is as described in Part I, Requirement 17):

(a) Identify the nonconformance traceable to the item.

(b) Describe the nonconformance.

(c) Reference the requirement that was not met.

(d) Name the identifier and the date identified.

(e) Authenticate the validation of the nonconformance by an appropriate authority.

(f) Describe the means of segregation.

(g) Evaluate the contractual reporting requirements.

(h) Propose a disposition of the nonconformance (i.e., use-as-is, repair, rework, reject).

(i) For repair or rework dispositions, describe the work process or instructions to be performed.

(j) For a repair or use-as-is disposition, a technical justification including applicable design control measures should be developed, documented, and authenticated by the responsible organization.

(k) Approve and authenticate the disposition by the responsible organization(s).

(l) Once the item has been reworked or repaired, document and authenticate the results of the reexamined item.

(m) For use-as-is or repair dispositions, update and authenticate appropriate records, e.g., as built drawings and design documents.

(n) Authenticate the verification of closure activities.

Once the authentication of a valid nonconformance is documented, the document should be controlled and protected.

SUBPART 3.1-16.1
Implementing Guidance for Part I, Requirement 16: Corrective Action

100 GENERAL

This Subpart provides nonmandatory guidance on corrective action as specified in Part I, Requirement 16. While conditions adverse to quality are required to be identified promptly and corrected as soon as practicable, Requirement 16 also calls for a response to conditions adverse to quality appropriate to their significance.

200 CORRECTIVE ACTION

Corrective action should be integrated into all aspects of the quality assurance program. It consists of the following basic elements:

(a) identification and documentation
(b) significance classification
(c) report to management
(d) determination of extent of condition
(e) cause determination
(f) corrections
(g) follow-up
(h) effectiveness review
(i) closure
(j) trend analysis

Corrective action activities should be documented in a manner that permits the review, verification of implementation, and verification of effectiveness of these activities.

300 BASIC CORRECTIVE ACTION ELEMENTS

This section provides additional guidance on the basic elements of corrective action processes. Figure 300 of this Subpart depicts a representative corrective action process as described in sections 300 and 400 of this Subpart.

301 Identification and Documentation

Conditions adverse to quality (see definition in Introduction) should be promptly identified, documented, and corrected.

Where conditions adverse to quality have been identified, the extent to which other items and activities may be affected should be evaluated so that appropriate action may be taken, including measures to control any affected work in process, if necessary.

The extent of the condition may be identified by internal or external organizations and may include documentation resulting from audits, inspections, tests, design reviews, individual observations, operational events, maintenance activities, and other information that could indicate conditions adverse to quality.

302 Classification

302.1 Criteria for classifying conditions and trends adverse to quality as to significance should be established and, as a minimum, as conditions adverse to quality and significant conditions adverse to quality. Classifying the conditions should consider the following:

(a) impact on health and safety of the public, workers, or the environment

(b) impact on reliability, availability, or maintainability, or safety function of the equipment or facility

(c) impact and likelihood of not meeting regulatory requirements

(d) repetition of specific conditions adverse to quality and the consequence of recurrence, as well as the relationship or similarity between different adverse conditions and causes

(e) the extent to which the adverse condition or cause may apply to and impact other items or activities beyond the specific occurrence or work in progress

302.2 Conditions adverse to quality identified under para. 301 of this Subpart should be classified according to significance using the established criteria. Examples of conditions that may be significant under certain conditions include

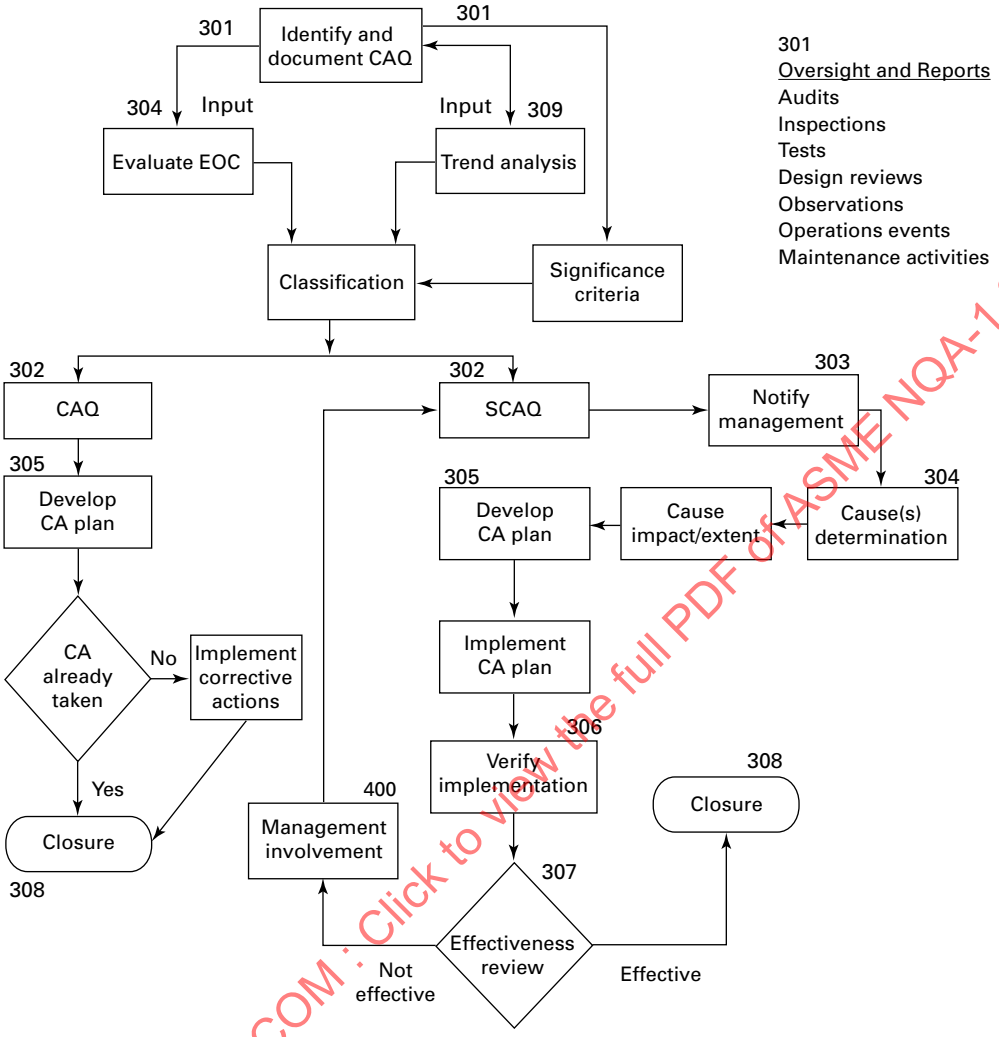
(a) deficiencies in design, manufacturing, construction, testing, or process requiring substantial rework, repair, or replacement

(b) damage to a structure, system, component, or facility requiring substantial rework, repairs, or replacement

(c) a nonconservative error detected in a computer program after it has been released for use that impacts the criteria of paras. 302.1(a) through 302.1(d) of this Subpart

(d) the loss of essential data

Figure 300
Corrective Action Process Chart



Legend:
CA = corrective action
CAQ = condition adverse to quality
EOC = extent of condition
SCAQ = significant condition adverse to quality

(e) repeated failures to implement approved procedures, quality program documents, or technical requirements documents

303 Report to Management

Significant conditions adverse to quality should be promptly reported to appropriate levels of management.

304 Cause Determination

The cause(s) (including apparent, contributing, and root causes based on the significance of the condition) should be identified and used to determine the action(s) necessary to correct the condition reported and preclude recurrence. Causes, corrective action(s), and follow-up action(s) should be documented.

Cause analysis should be conducted and may include apparent, contributing, and root causes based on the significance of the condition. An extent of condition should be performed, and the impact of such conditions on completed and/or related items and activities should be evaluated. The causes, corrective action(s), and follow-up action(s) should be documented.

At a minimum, methods and measures should be developed for determining the root cause(s) of significant conditions adverse to quality. Typical root cause categories may include

(a) inadequate management or supervision
(b) inadequate human performance capability or skill
(c) procedure inadequacy or error
(d) inadequate training or qualification of personnel performing work
(e) equipment or processing malfunction, inadequacy, or misuse
(f) inappropriate, self-imposed requirements or acceptance criteria
(g) unrealistic schedules that adversely impact safety or quality
(h) worker fatigue
(i) latent organizational or equipment issues
(j) safety culture impacts

305 Corrective Action Plan

The remedial action(s) should be determined, documented, and promptly implemented. The overall roles and responsibilities for implementation of corrective actions should be identified and documented. For significant conditions adverse to quality, action(s) necessary to eliminate the cause(s) should be implemented to preclude recurrence.

Where corrective or preventive measures have already been completed to address conditions adverse to quality, based on design, nonconformance, or audit program elements, further action is not required unless the conditions are judged to be significant or are determined to be ineffective. The analysis to determine the action(s) to be taken to preclude recurrence of significant conditions adverse to quality may include studies, simulations, investigations, experimentations, trending, and personnel interviews. The analysis and identified actions should be documented and may include

(a) identification of action to preclude recurrence
(b) a determination that generic implications have been considered
(c) a determination that action taken will preclude recurrence

306 Verification of Implementation

Corrective action status should be monitored. Corrective action and implementation should be verified as complete only when the actions to correct the significant condition adverse to quality, including actions to preclude recurrence, are complete and documented. When completion of corrective action cannot be promptly verified due to an extended delay from the responsible organization, modification of the original schedule and communication to the affected organization(s) should be made. Compensatory (interim) measures may be identified and implemented to allow for work activities to proceed under controlled conditions.

307 Effectiveness Review

After verification of completion of corrective action for significant conditions adverse to quality, effectiveness reviews, surveillance, or supplemental audits should be performed to determine whether actions taken have been and continue to be effective. When corrective actions have not been effective, further analysis should be performed to identify and correct the cause. In addition, the problem should receive escalated management attention.

308 Closure

After the corrective action(s) have been implemented, the corrective action(s) should be closed. For significant conditions adverse to quality, closure should not occur until after corrective action(s) have been determined to be effective in accordance with para. 307 of this Subpart.

309 Trend Analysis

Conditions adverse to quality should be reviewed periodically to determine the existence of adverse trends and repeat occurrences. Trends should be evaluated in a manner and at a frequency that ensures that significant adverse trends are identified promptly and evaluated in accordance with para. 301 of this Subpart.

400 MANAGEMENT INVOLVEMENT

Appropriate levels of management should be involved in the corrective action process, and their roles and responsibilities should be documented.

500 PROCESS CHART

Figure 300 of this Subpart depicts the flow of activities through the basic elements described in sections 300 and 400 of this Subpart. The logic process illustrates a typical corrective action program and is provided for guidance and illustration only.

SUBPART 3.1-16.2
Implementing Guidance for Part I, Requirement 16: Trend Analysis

100 GENERAL

This Subpart provides nonmandatory guidance on trend analysis of conditions adverse to quality and other indications of quality. This guidance intends to aid in the prompt identification and correction of conditions adverse to quality that may not be readily apparent without a more thorough analysis. The guidance includes information on data collection methods, cause coding, trend thresholds, analysis frequency, reporting, and actions to address adverse trends. This guidance is not related to identifying metrics, collecting performance data, and determining trends related to process improvements in manufacturing or system performance.

Implementation of a process to evaluate assessment reports, issues, and conditions adverse to quality increases the probability of identifying conditions adverse to quality that otherwise may remain undiscovered.

200 DEFINITIONS

The following terms are used in this Subpart.

adverse trend: conditions adverse to quality that are of a repetitive nature and/or number that exceeds an established criteria or threshold, taking into consideration time frames and significance levels. General examples include

(a) recurring conditions adverse to quality that appear to be related to a common cause, or are of a like nature and are identified in multiple work activities

(b) increasing number of conditions adverse to quality that are not expected because of new or special work programs or increased quality verification activities

(c) conditions adverse to quality that are of a programmatic nature and apparently not limited to a specific organization

trend: a variable's tendency over time to increase, decrease, or remain unchanged; a pattern of events, incidents, items, activities, processes, corrective actions, or causes reflected by corrective action program data, reported nonconformances, and/or other applicable quality data. A trend could be either negative or positive.

trend analysis: a process to detect recurrence of conditions adverse to quality, as well as the relationship or similarity between different conditions in order to assure adverse trends that could result in a significant condition adverse to quality are identified and evaluated for appropriate correction (NEI 08-02).

300 TRENDING PROGRAM

A trending program should be developed and implemented to identify adverse trends or issues significant to quality (such as repetitive failures or process weaknesses). This review should be conducted to identify generic issues and vulnerabilities before significant problems result. Management personnel responsible for the work activities should be responsible for identification of thresholds for trending to determine the presence of adverse trends, repetitive failures, process weaknesses, or other indicators of extent of cause or condition beyond the immediate problem identified. To identify patterns that warrant broad corrective actions, trending could also be accomplished using detailed codes and data analysis techniques for certain work processes.

Adverse trends should be reported to management responsible for the work process and documented in accordance with the organization's corrective action program. Management should provide oversight of the trending process to assure the process is properly implemented. Each organization that implements a trending program should develop process that addresses the following basic elements:

(a) Determine what quality data to collect and how to collect it.

(b) Using an organization-specific definition of trend, create thresholds or minimum/maximum values that require more detailed analysis to determine if a trend exists.

(c) Identify trend analysis expectations and reporting time frames.

(d) Define the trend analysis techniques; consider using root-cause analysis techniques and qualified analysts.

(e) Document procedural steps for the data collection and analysis process, and include the minimal information to include in trend analysis reports.

(f) Define steps to take upon identification of a potential or adverse quality trend, including allowing for more analysis before declaring that a potential trend is an adverse trend.

400 DATA COLLECTION

401 Program and Preparation for Effective Trending

The organizations responsible for trend analysis should take the following steps to develop a trending program:

(a) Determine the data to be trended. First determine what data are available by taking into consideration benchmarking, or consulting with other similar organizations/entities to identify potential data to collect.

(b) Identify data sources. Typical sources used in trend analysis processes are conditions adverse to quality, such as audit findings, corrective action reports, nonconformance reports, occurrences, and supplier issues. Other sources that may not specifically identify adverse quality items but could provide early indication of potential issues or future issues include independent and management assessment reports, work travelers, software trouble logs, and/or periodic reports to management (e.g., progress reports where information is provided to management on impediments to completing tasks).

(1) Although corrective action reports and nonconformance reports typically provide specific data on item or condition and may provide cause information, additional background information might need to be researched. Additional information such as location, organization, event or issue codes, and/or cause codes, can be helpful in sorting and evaluating information for trends. If this information is not available in a deficiency database (or similar), then a more detailed review of the deficiency reports is needed to collect this data for use in trending.

(2) Although the primary driver for trend analysis is for the discovery of adverse trends, review of data and the identification of potential positive trends may aid in determining corrective action effectiveness.

(3) Traditionally, trend data is based on audit findings, corrective action reports, and nonconformance reports. The review of assessment reports and similar reports may identify data that could be potential issues, such as observations and recommendations that do not, at the time, meet the definition of a finding/noncompliance but could provide insight into the implementation of a program and aid in determining adverse trends.

402 Data Collection Sources and Methods

Nonconformance reports, corrective action reports, audit findings, and similar issue systems are the typical resources of trend input data; however, information from other systems should also be considered (e.g., occurrence reports, health and safety issue reporting, test or inspection defect reports, assessment reports, and/or nontraditional issue information). A system of trend codes should be developed and disseminated to provide consistent and clearly defined sets of codes. Trend codes should include both cause codes and event codes. Since these codes are normally entered by a human, reassessment of the codes may be needed during trend analysis to ensure that the codes used are supported by the issue data.

Although raw information from these sources can be used in the trending process, providing additional information to aid in sorting the issues could result in a more effective and efficient trend analysis process. The following additional sorting categories should be considered:

(a) organization
(b) process/procedure
(c) locations
(d) dates/times

500 TREND ANALYSIS PROCESS

501 Graded Approach to Trending

One type or technique of trending may not be practical for all conditions or organizations. Therefore, a thoughtful approach to trending, which takes into consideration requirements and/or industry best practices, should be implemented by each organization performing trend analysis. Organizations developing a trend analysis program should consider a graded approach that considers risk as related to the formality of trend analysis performance, the identification of trends, and actions to be taken when potential and adverse trends are found.

502 Trend Analysis Staff and Teams

Analysts performing trending should have appropriate training and skills. In addition to understanding the trending process and procedures, personnel performing trending should have an understanding of the data being trended, corrective action processes, and cause-analysis techniques. Skills or training in statistics and Six Sigma processes may be useful.

503 Data Sorting and Categorization

Trend analysis should be performed on a regular basis, using consistent staff whenever possible, and supplemented as needed by subject matter experts. Consideration should be given to using analysis teams that include representatives from a standard set of disciplines or management representatives.

The end result of the quantitative and qualitative analysis of the data should be the confirmation that an adverse trend does or does not exist. When an adverse trend is identified, an analysis of its significance should

be performed. Trend analysis may also identify potential trends requiring further investigation or continued monitoring.

(a) Analytic tools should be considered and used if appropriate. These tools include, but are not limited to, time-based reviews of data, histograms, Pareto charts, bar charts, statistical control charts, and trend charts.

(b) Trend charts compare the number of events over time. They could be used to measure the significance of performance (effectiveness) in a single point of time compared to the past, and to project future performance. Using a trend chart, the analyst could determine the impact of actions taken and whether corrective actions are effective. In evaluating trend charts, one must consider what variables may affect the number of events identified. If the definition of the event is changed or an activity has been added to increase the likelihood of identification and reporting, the trend results would be affected.

(c) A bar chart that displays trends by frequency or quantity, in descending order, would identify the most frequent defects. This chart-type would be used to identify whether the Pareto principle is evident in the data. A Pareto chart would be used to graphically summarize and display the relative importance of the differences between groups of data. In a Pareto chart, the analyst would graph the number of items (events, causes codes, facilities/operations/organizations) within a chosen grouping. Pareto charts could be used to visually display the major contributor to a grouping and help identify areas for further analysis.

(d) The data should then be reviewed to determine the presence of adverse or potential trends including

(1) repetitive issues, when taken collectively,

(-a) indicate a programmatic failure to properly implement the quality assurance program

(-b) may be precursors for a significant technical deficiency or problem

(-c) may reduce the margin of safety;

(-d) indicate programmatic and/or systemic issues or undesirable business risk

(2) recurrences of an event, failure, problem, or adverse condition that involves similar tasks, causes, and/or corrective actions that are significant in nature or are critical to the success of the activity as determined by management, including programmatic or systemic conditions

(3) an unacceptable or undesirable pattern (e.g., events, incidents, items, activities, processes, or causes) that is important to the degree that corrective action is deemed appropriate by management

Root cause analysis tools such as brainstorming, barrier analysis, and other cause analysis tools may be helpful in evaluating the data. The analyst should ensure that predefined trend thresholds are used in determining adverse or potential trends. Analysts or analysis teams should consider the importance of sorting data and ensuring it is reviewed at the appropriate level; not rolling up issues to such a high level that an adverse trend could not be found or so low that trends are apparent everywhere.

Trend program developers and analysts should also consider the importance of human involvement and not overly rely on cause and event codes. Human-involved cognitive analysis should be an important aspect of trending.

504 Trend Significance Analysis

Although analysts may identify adverse or potential trends as a result of their data reviews, determining the significance of the identified trends is important to help management, and those responsible for corrective action plans, to focus the appropriate resources on the identified adverse or potential trend. Adverse trends should be reported to management responsible for the work process and documented in accordance with the organization's corrective action program. Management should provide oversight of the trending process to assure the process is properly implemented.

600 TREND REPORTING

601 Report Content

Identification of the minimum information to include in trend reports is important for the long-term continuation of the trending process. Information on the data used, the process used to determine trends, and general notes (trend determination rationale) on the results of analysis is important and should be included in trend reports so that future trend analysts have a base to understand past trend analysis. Minimum information should include the data used in the trend analysis, identification of potential trends, identification of confirmed trends, and identification of conditions adverse to quality generated as a result of trending. Identification of information that warrants further investigation or continued monitoring should also be considered.

602 Reporting Frequency

The frequency of analysis and reporting should be based on the size of the organization and the quantity of documented conditions adverse to quality or nonconformances. Some organizations may need to perform some level of trending on a monthly or quarterly basis, while other organizations may use a semiannual or annual frequency to effectively identify potential trends. Completion of the trending process and issuance of a trend report annually could be helpful as an input to the management assessment of the adequacy and effectiveness of the quality assurance program, as required by Part I, Requirement 2.

700 RECORDS

In addition to periodic trend reports, the program should define the records to be maintained that would be beneficial to personnel performing subsequent trend analysis, such as identification of potential trends, adverse trends, and discussion of methods used to evaluate trends; reference to corrective action documents; or other actions taken.

(24) 800 REFERENCES AND RECOMMENDED READING

DOE G 120.1-5. Guidelines for Performance Measurement. U.S. Department of Energy.

DOE G 231.1-2. Occurrence Reporting Causal Analysis Guide. U.S. Department of Energy.

EFCOG Guidance Document (2008, April 8). Contractor Guide for Performance Analysis, Rev 0. Energy Facility Contractor's Group.

EFCOG Guidance Document (2011, February 1). Development and Use of Leading Indicators. Energy Facility Contractor's Group.

INPO 09-011 (2009, September). Achieving Excellence in Performance Improvement. Institute of Nuclear Power Operations.

NEI 08-02, Rev. 3. Corrective Action Processes for New Nuclear Power Plants During Construction. Nuclear Energy Institute.

NSAC 119 (1998, June 30). Guidelines for Analyzing and Trending Incidents in Nuclear Power Plants. Electric Power Research Institute.

SUBPART 3.1-17.1
Implementing Guidance for Part I, Requirement 17: Quality Assurance Records

100 GENERAL

This Subpart provides nonmandatory guidance on records as specified in Part I, Requirement 17 for records that are generated and maintained in an electronic format as addressed in Subpart 2.17. Management controls should address how records are identified, generated, authenticated, stored, maintained, and retained per an established records program. Organizations that generate and maintain quality assurance records in an electronic format should develop controls and associated procedures that address the unique capabilities and requirements of this technology. See Part III, Subpart 3.1-17.2 for electronic record processing guidance.

101 Generation of Records

Documents produced in or transformed to electronic format should be processed in accordance with Part II, Subparts 2.7 and 2.17. Documents that are designated to become records should be legible, accurate, and completed appropriate to the work accomplished so that they can be read, understood, and traceable to the associated items or activities. Documents produced in or transformed to electronic format should be processed in accordance with a defined process with software meeting quality assurance requirements commensurate with the software use.

Electronic records systems may be used to index and store electronic records but is not limited to electronic metadata. The records system content may contain an image in a sustainable format, e.g., Tagged Image Format (TIF), Portable Document Format (PDF), or an electronic address of the location where the image is stored. Controls should be in place to ensure that the record system is maintained.

102 Authentication of Records

Statements of authenticity, handwritten signatures, electronic signatures, or any other means that ensures traceability to a specific individual or organization of authentication and associated date are acceptable methods of authentication, such that the authentication provides positive identification to the individual or organization.

If initials or codes are used for identification, then a system should be established to ensure traceability to the authenticating individual or organization. The records program should provide methods for authenticating copies of original records when the original record is contaminated or lost and a copy of the original record is available.

103 Indexing

A cataloging scheme should be developed that is an index of information about each record that will aid in retrieval of the record and associated relevant retention information. The indexing can take many forms, including directories or listings. Indices should identify summary information for the records, such as the associated item or activity, title or description, originating individual or organization, retention period (lifetime or nonpermanent), location, and the media used for retention. For nonpermanent records, the period of retention should be defined.

104 Corrected Information in Records

When records are corrected, corrections should include the date and identification of the person authorized to issue such corrections.

105 Storage

A written storage procedure should be prepared and responsibility assigned for the implementing procedure. Storage procedures are suggested that include

(a) a description of the storage facility and/or electronic records system

(b) the filing methodology to be used

(c) a method for verifying that the records received are in agreement with the transmittal process and that the records are legible

(d) a method of verifying that the records are those designated

(e) the rules governing access to and control of the files

(f) a method for maintaining control of and accountability for records removed from the storage facility or electronic records system

(g) a method for filing supplemental information and disposing of records that have met retention requirements

106 Preservation and Safekeeping

To help ensure the preservation and safekeeping of records, the following should be considered:

(a) placement of physical records for storage in steel file cabinets or in suitable containers on shelving

(b) prevention of damage from environmental conditions

(c) manufacturer's recommendations on storage

(d) measures to preclude the entry of unauthorized personnel into the records system or storage area for protection from larceny or vandalism may include access lists, locked entry, attendant security, or a combination of these measures

(e) measures for replacement restoration, or substitution of lost or damaged records

(f) inspections of records to detect deterioration and ensure sustainability

107 Facilities and Containers

Current industry practices identify the use of two methods of providing storage facilities, single or dual.

(a) Single Facilities and Containers. NFPA-232 provides a set of methods that may be used for the storage of records in vaults, file rooms, or records protection containers. Where file rooms are used, an exception to NFPA-232 should be applied to permit forced air circulation system to be used, provided it is dampered in accordance with the room rating.

(b) Dual Facilities. If storage at dual facilities for either physical or electronic records is provided, the establishment of sufficiently remote storage facilities depends on the type of hazard, such as earthquakes, fires, tornadoes, loss of power, etc., and the probability for occurrence of these hazards.

108 Retrieval

A key function of a records system is to ensure that records are retrievable through their life cycle. Records maintained at a Supplier's facility or other location should be accessible to the Owner, Purchaser, or a designated alternate.

109 Records Transfer to Owner or Purchaser

Records accumulated at various locations, prior to transfer, should be made accessible to the Owner or Purchaser directly or through the procuring organization. For records transferred to the Owner or Purchaser, it is recommended that the Owner or Purchaser inventory the submittals, and acknowledge receipt.

Prior to transfer of the Supplier's records, the Supplier should consider the following:

(a) ASME Boiler and Pressure Vessel Code requirements are met

(b) regulatory requirements are satisfied

(c) operational requirements are satisfied

(d) warranty consideration is satisfied

(e) Owner's or Purchaser's requirements are satisfied

110 Record Destruction

Records may be destroyed once all retention requirements are met and in accordance with the records program, which should contain a record retention schedule, procedural guidance for obtaining final disposition approvals, and final record disposition mechanisms commensurate with the actual records index and computer program used.

The records program should have a means to suspend the destruction of specified information in the case of foreseeable, pending, or actual litigation or government investigation, commonly referred to as a legal or litigation hold.

A process should be established to destroy records to document required approvals, such as department owner, legal reviews, business needs, and the destruction.

200 LIST OF TYPICAL LIFETIME RECORDS

The following is a list of typical lifetime records categories and example record types or titles containing information meeting Part I, Requirement 17. Other records are also listed in Part I sections. The nomenclature of these may vary.

201 Design and Safety Basis Records

(a) applicable codes and standards used in design

(b) computer programs or corresponding mathematical model

(c) design drawings

(d) design calculations and record of checks

(e) approved design change requests

(f) design deviations

(g) design reports

(h) design verification data

(i) design criteria or design input data

(j) design specifications and amendments

(k) safety, hazards, and accident analysis reports

(l) stress reports for code items

(m) systems descriptions

(n) systems process and instrumentation diagrams

(o) technical analysis, evaluations, and reports

(p) software evaluation reports and acceptance test plans and reports

(q) computer program verification and validation data

202 Procurement Records

(a) procurement specifications

(b) purchase order and contracts (unpriced) including amendments
(c) evaluated supplier listing

203 Manufacturing Records

(a) applicable code data reports
(b) as-built drawings and records
(c) Certificate of Compliance
(d) inspection and test data
(e) heat treatment records
(f) location of weld filler material
(g) major defect repair records
(h) nonconformance reports
(i) performance test procedure and results records
(j) pipe and fitting location report
(k) pressure test results (hydrostatic or pneumatic)
(l) NDE final results or review/evaluation results
(m) welding procedures
(n) welder qualification reports
(o) certified material test report

204 Installation Construction Records

204.1 Civil

(a) check-off sheets for tendon installation
(b) concrete design mix reports, cylinder test reports, and charts
(c) concrete placement records
(d) inspection reports for channel pressure tests
(e) material property reports
(f) pile drive log and load test reports
(g) procedure for containment vessel pressure proof test and leak rate tests and results
(h) reports for periodic tendon inspection and testing
(i) subsurface investigation results
(j) embed as-builts

204.2 Welding

(a) test results
(b) heat treatment records
(c) NDE procedures
(d) material property records
(e) NDE final results or review/evaluation results
(f) weld location diagrams
(g) weld procedures
(h) welding qualification

204.3 Mechanical

(a) cleaning procedures and results
(b) code data reports
(c) installed lifting and handling equipment procedures, inspection, and test data
(d) lubrication procedures
(e) material properties records
(f) pipe and fitting location reports
(g) pipe hanger and restraint data
(h) pressure test results (hydrostatic or pneumatic)
(i) safety valve response test procedures
(j) NDE final results or review/evaluation results

204.4 Electrical and I & C

(a) cable installation procedures and results; pulling tension data, separation data, splicing procedures, and terminating procedures
(b) certified cable test reports
(c) relay test procedures
(d) voltage breakdown test results on liquid insulation

204.5 General

(a) as-built drawings and records
(b) final inspection reports and releases
(c) nonconformance reports, causal analysis, and trending
(d) specifications and drawings
(e) construction records

205 Preoperational and Start-Up Test Records

(a) power source procedures and results
(b) final system adjustment data
(c) pressure test results (hydrostatic or pneumatic)
(d) initial start-up heat procedures and results
(e) initial reactor/facility loading data, test procedures, and results
(f) instrument AC system and inverter test procedures and reports
(g) on-site emergency power source energizing procedures and test reports
(h) facility load ramp change data
(i) facility load step change data
(j) power transmission substation test procedures and results
(k) preoperational test procedures and results
(l) primary and secondary auxiliary power test procedures and results
(m) reactor/facility protection system tests and results
(n) start-up logs
(o) start-up test procedures and results
(p) station battery and DC power distribution test procedures and reports
(q) water chemistry report

206 Operation Records

(a) records and drawing changes identifying facility design modifications made to systems and equipment described in the Final Safety Analysis Report
(b) new and irradiated fuel/nuclear material inventory, fuel/nuclear material transfers, and assembly fuel/nuclear material-depletion history records
(c) off-site environmental monitoring survey records
(d) spent fuel/nuclear material shipment records
(e) facility radiation and contamination survey results

(f) radiation exposure records for individuals entering radiation control areas

(g) records of gaseous and liquid radioactive material released to the environs

(h) records of transient or operational cycles for those facility components designed for a limited number of transients or cycles

(i) training and qualification records for current members of the facility-operating staff

(j) in-service inspection records

(k) records of reviews performed for changes made to procedures or equipment, or reviews of tests and experiments

(l) surveillance activities, inspections, and calibrations required by the technical specifications records

(m) records of reactor/facility tests and experiments

(n) changes made to operating procedures

(o) low-level radioactive waste shipments records

(p) sealed source leak test results

(q) records of annual physical inventory of all sealed source material

(r) logs of facility operation covering time interval at each power level

(s) records and logs of maintenance activities, inspections, repair, and replacement of principal items of structures, systems, and components

(t) water chemistry reports

(u) operational, shift supervisor, and control room logs

(v) event reports

(w) fire protection records

(x) nonconformance/corrective action reports

(y) facility equipment operations instructions

(z) emergency plan and procedures

(aa) quality assurance and quality control manuals

(bb) applicable records noted in other sections of this Subpart for any modifications or new construction applicable to structures, systems, or components

(cc) evaluation of results of reportable safety concerns as required by regulations

(dd) annual environmental operating report

(ee) annual facility operating plan

(ff) records to support licensing conditions such as safeguards and special nuclear material accountability

(gg) results for in-use testing

207 Decommissioning and Destruction

(a) radiological survey results prior and during destruction

(b) waste container inspection and test reports

(c) waste packing inspection results

(d) nondestructive assay results for processed waste

(e) nonconformance reports

(f) waste form documentation and compliance certification

(g) waste labeling and tracking

(h) waste management record

SUBPART 3.1-17.2
Implementing Guidance for Part I, Requirement 17: Quality Assurance Records, Electronic Records

100 GENERAL

This Subpart provides nonmandatory guidance on records, as specified in Part I, Requirement 17 that are generated and maintained in an electronic format, as addressed in Part II, Subpart 2.17.

Organizations that generate and maintain quality assurance records in an electronic format should develop controls and associated procedures that address the unique capabilities and requirements of this technology. Electronic record controls should address how electronic records are identified, generated, authenticated, stored, and maintained per the required retention schedule. Part III, Subpart 3.1-17.1 also includes standard record processes that apply to all records regardless of format or medium and should be used in conjunction with this Subpart.[1,2]

101 Definitions

The following definitions are provided to ensure a uniform understanding of unique terms as they are used in this Subpart.

electronic signature: an electronic sound, symbol, or process, attached to or logically associated with a contract or other records and executed or adopted by a person with the intent to sign the record.

sustainable format: computer program file format that meets as many of the following criteria as possible:

(a) publicly and openly documented
(b) nonproprietary
(c) widespread use
(d) self-documenting
(e) can be opened, read, and accessed with readily available tools
(f) longevity of use and support is favorable

Examples of sustainable format are Tagged Image Format (TIF) or Portable Document Format (PDF).

200 AUTHENTICATION OF RECORDS

Provisions for the authentication of electronic records should provide for the use of automated systems for the identification and signature recognition of the personnel performing the record authentication.

201 Electronic Signatures

If electronic codes or user account information (e.g., username and password) is used for identification, controls should be established to ensure traceability to the authenticating individual or organization. Consideration should be given to periodically requiring the establishment of new user passwords. Methods for authenticating electronic records should meet applicable regulations and laws, such as the U.S. eSIGN law,[3] with electronic methods documented in applicable processes.

Electronic signatures based on biometrics should have a documented process to associate the initial biometric capture to the individual.

Electronic signatures that are not based on biometrics should employ at least two distinct verification components, such as user identification and password. Electronic signatures based upon biometrics should be controlled to ensure that they cannot be used by anyone other than the legitimate owners.

Digital signatures with public/private key technology are acceptable. Appropriate digital signature certificate authority use, unique user identification, information technology infrastructure, and file security controls to invalidate signature on change of file content are required.

The integrity of the records in the new system or media should be verified. It is recommended that a not easily alterable format be used to ensure that the content, context, and structure are maintained consistently with the original record copy. A sustainable format should be used commensurate with the retention period of the record.

When a record is converted to electronic media, the authentication of that record does not need to be reperformed.

[1] Adams Accession No. ML15099A561, Safety Evaluation of Duke Energy Carolinas, LLC — Amendment 40 to the Quality Assurance Topical Report.

[2] Adams Accession No. ML16194A323, Palo Verde Nuclear Generating Station, Units 1, 2, and 3 — Request to Change the Quality Assurance Program Description.

[3] Electronic Signatures in Global and National Commerce Act, Public Law 106-229.

300 GENERATION OF RECORDS

Electronic records may be generated using several different methods. These methods may include direct digital conversion from a source format to a sustainable record format, electronic data compilation, electronic mail, and records resulting from the conversion from one media type to another.

Electronic data designated to be records should be traceable or related to the associated items or activities. This can be accomplished by developing a naming scheme for both the electronic data itself and the media (e.g., file folders and CDs) that are used to store the electronic data.

301 Electronic Records Systems

The electronic records system consists of an electronic database and digital repository with the functionality to create and maintain human-readable, formatted electronic records and metadata.

Controls should be in place to ensure that the electronic records system establishes and maintains the electronic record content, context, and structure.

(a) The content is the digital file (image, text, graphics) in a sustainable format.

(b) The context is the metadata held within the file, such as the actual file properties, data fields, or tagged fields. The record file context may also be represented in the database table properties as data fields when the file lacks the rich metadata structure (e.g., image scans) or the records system does not have robust content searching capabilities.

(c) The structure is the file functionality needed to properly convey the content and context into a human-readable form and format.

Electronic mail may be used as a quality record if the controls provided in this Subpart are utilized. Electronic mail should be traceable to the subject of the record, originator, recipient(s), and date of origination. The information content and metadata contained in the electronic mail are acceptable as a record, provided that the electronic mail system prevents unauthorized alterations or changes. Corrections to e-mail should be processed in the same manner as the original and should amend/supplement the original record.

302 Conversion of Media

Conversion of a record from one media type to another should include verification to ensure that content, context, and structure are maintained. The conversion process includes conversion from/to various media forms, including hardcopy, photographic, optical, magnetic, or other media forms. The conversion process may involve scanning the original hardcopy record to create digital content in a sustainable record format. The conversion may include methods for converting scanned text to searchable formats (e.g., optical character recognition).

Verification should include reviews of the page, paragraph, and individual record configuration to ensure such information adequately represents the original document. This also applies to the situation where an electronic record is the original. When the conversion involves an electronic migration, a statistically valid sample set should be selected for verification purposes. Any recognized sampling standard that provides requirements for inspection and acceptance sample size may be used as a basis for the development of a sample set verification plan. To prevent data corruption or loss during the conversion process, the records program owner should approve any changes to the database context or structure.

303 Indexing Records

Electronic records should be indexed to provide for the timely retrieval of the record. Organizations should develop and document external and/or internal indexing methods using standard nomenclature for the index system(s).

External indexing includes the labeling of records stored on external off-line media. External labeling should be developed and attached to the media used. For example, magnetic tapes should include the recording density, number of tracks, block size, types of internal labels, and if the tape is part of a multi-reel set. Internal indexing of electronic records should enable the user to identify and access a specific record by using a table of contents, directory, metadata (e.g., record identifier, key word, etc.), or other index strategy. In some cases, the index may be automatically created by the system, while in other cases, the originator may generate it.

400 RECEIPT CONTROL OF RECORDS

Part I requirements for receipt controls remain applicable for electronic records; however, additional transfer processes utilizing automated methods may also be utilized.

The records submittal and receipt process may be entirely electronic using, but not limited to, the following methods:

(a) record-by-record processing using human interaction to place records into records system where some indexing functions are automated

(b) record-by-record processing using computer program transfer based on completion of source documents in source system, e.g., specified data field capture in an XML file that will pair index data with the record content file that is ingested into the records system

(c) workflow process output to records system, e.g., document approval workflow using electronic or digital signatures and e-mail capture and ingestion into the records system using rule-based processes

(d) automated batch processing from source system periodically (e.g., nightly, weekly, and monthly) where no human interaction is involved, e.g., weekly capture of completed documents or data from source system using nonpeak batch routine

Records processing may include the index data with manual processing of content or both the index and content as one submittal action.

Automated routines that replace normal submittal and receipt should be developed in accordance with established software quality assurance procedures.

500 STORAGE

Dual storage is suggested and, in accordance with Part I, Requirement 17 requires duplicate media or systems remotely located from each other such that one event does not destroy both simultaneously. Storage of electronic records, in accordance with Part II, Subpart 2.17, requires both media and compatible processing systems. The media containing the electronic records and compatible processing systems access should translate the records into an appropriate retrievable, legible, and sustainable format. A typical processing system may consist of a computer and its associated software.

The types of media utilized for electronic record storage should be identified in the records management program. The selection of the storage media should consider the record retention, shelf-life, or operational duration of the media and manufacturer's recommended qualified life. If a single storage method is utilized, then all of these statements apply, with the exception of an additional location.

501 Environmental Considerations

The facility structure containing the electronic record system hardware and infrastructure should conform to the requirements of NFPA 75, Standard for the Fire Protection of Information Technology Equipment. Appropriate environmental controls should be established for each type of electronic media to prevent damage to electronic media from environmental conditions, such as light, heat, humidity, or electromagnetic fields. Recommendations from the media manufacturer should be considered in establishing environmental controls. All electronic processing systems should also have power isolation devices to minimize the risk of damage from voltage surges, spikes, and other power-line disturbances.

502 Facility and System Access

The level of user access and security of the compatible processing systems may also impact the required controls for the storage of electronic records.

Controls for remote access, local access, and secure processing systems should be established to prevent the alteration, damage, or loss of electronic records. Remote access systems store records on a network server, which are accessible to multiple users through a network or internet hub. Local access systems store records on a local area network server that is accessible only to local users. Secure processing systems are standalone processing systems that are not accessible through a local area network or internet hub.

503 Temporary Storage

Temporary storage as defined in Part I, Requirement 17 is still applicable and may be used for electronic records in order to meet various conditions that occur. Some examples include, but are not limited to, the following:

(a) Removal of portable media from primary storage location to another location where access to primary storage is not available for storage during use. Return to primary storage is expected upon completion of temporary use.

(b) Duplication of primary electronic record system content to establish a second repository should an event occur on one of the dual locations. This could be any type of loss or system/hardware/facility maintenance that renders that location unacceptable for use.

Temporary storage media and systems for electronic records should address actions to limit exposure to computer program viruses and inadvertent alteration.

504 Portable Electronic Media

The degradation of portable electronic media varies by type of media and may start immediately after manufacture. Electronic records should be migrated onto new media before the manufacturer's recommended useful life is exceeded.

Two sets of electronic records should be maintained to ensure timely recovery in the event they are damaged or lost. These sets may be established in processing systems installed on separate servers, standalone computer program platforms, off-line storage, or in a removable media format.

600 ACCESS CONTROL AND RETRIEVAL

Maintaining records in an electronic format enables users to retrieve records more efficiently. A records system should provide searches of some or all metadata fields and may also provide for content search of the actual text of the record.

Indexing should be sufficient to ensure that each record is uniquely identified and retrievable. Records that utilize Optical Character Recognition (OCR) allow for content-based retrieval (full text searching).

Records system access should be controlled to grant access to personnel with a need to access records. System access is typically controlled by network infrastructure protection (i.e., firewall) and user login to access the system.

Records access permission should be established with considerations for the following access levels:

(a) Limited metadata access. Allows users to see index entry but not content for sensitive records (e.g., confidential, proprietary, and restricted).

(b) Normal user read access to metadata and content. Enables efficient search, print, and extract/export of record content without records department interaction. Update of record metadata and content is not allowed for normal user access.

(c) Version and/or write access for records management personnel to perform record content and/or metadata corrections. This action should be tightly controlled to limit access to only those authorized personnel that fully understand the records integrity requirements.

(d) Deletion rights should be extremely limited and strictly controlled to preclude unauthorized or inadvertent deletion of the record. Deletion actions may be enforced by the server device type (write only format) or via system security controls.

700 DISPOSAL OF RECORDS

Part I, Requirement 17 establishes record retention and does not mandate disposal of the record. In consideration of quality records requirements of this Standard, there is no requirement to include complete erasure and disk destruction. The electronic deletion and, therefore, the deletion of the record in the electronic records system is satisfied by a simple deletion action in the associated computer program.

In consideration of legal implications and record discovery rules, the deletion action should enforce standards that permanently remove the record from the electronic records system such that the record cannot be reproduced from the electronic record system.

Guidance stated in regard to record disposal reflects the minimal standard requirements and provides additional optional guidance, where specifically noted, to reflect the overall records life cycle, legal considerations, and storage limitations.

If the records are to be disposed following end of retention, then the following guidelines may be applied:

(a) Electronic records should be destroyed in accordance with the records program, records retention requirements, and established procedures for such actions.

(b) The destruction process should include reviews by the responsible records organization and affected departments to ensure that retention has been met and the records are no longer needed for business needs.

(c) The records program should have means to suspend the destruction of specified information in the case of foreseeable, pending, or actual litigation or government/regulator investigation (litigation hold).

(d) Electronic records system design should factor the destruction workflow process and logic into the program when possible and practical. The electronic destruction should also factor in the method and extent of record removal as the system design capabilities may lengthen the destruction time frame.

(e) Electronic record deletion typically consists of the following methods, depending on the computer program system design limitations, and is acceptable in meeting quality assurance record disposal.

(1) Deletion of the index entry and record content. This method requires documenting the records destroyed and recording the destruction listing as a record.

(2) Deletion of the record content only with the index remaining and data fields indicating the destruction status. This method can rely on the index metadata to track the deletion status.

701 Guidance Factors

The following are guidance factors in both the quality assurance requirement and additional legal expectations, exceeding the requirements of this Standard but providing a realistic process:

(a) Magnetic drive-stored records should be destroyed by either

(1) deleting the content files using an approved erasure program.

(2) deleting the pointer to the content file, then subsequently destroying the magnetic drive after transfer to a new drive has been verified. This method may be required for WORM-type (Write-Once, Read-Many) drives and records systems lacking a full erasure method. This method also requires a detailed file transfer to the new media to ensure deleted content is not transferred.

(b) Portable electronic media should be destroyed by physically destroying the media via burning, shredding, or other approved methods.

(c) Storage media previously used for electronic records containing sensitive or proprietary information should not be reused.

(d) A confirmation report may then be generated to verify that all records scheduled for destruction were indeed destroyed. A search sampling and disk sampling can then be implemented as a random check to ensure that the deleted electronic files no longer exist.

Refer to National Institute of Standards and Technology Special Publication NIST SP 800-88, Guidelines for Media Sanitization.

800 MAINTENANCE OF RECORDS SYSTEM

Electronic records required for long time periods (e.g., lifetime of component and term of license) should be reviewed periodically to ensure the files are retrievable and usable. Media and electronic record systems intended for storage of electronic records should be tested prior to use to ensure that it is free of errors, defects, and corruption.

Electronic record systems should include a review of all designed storage locations for the periodic legibility review. The periodic review should also include an accounting of files and metadata across multiple redundant locations to ensure that file fidelity is maintained.

900 SYSTEM INTEGRITY AND RECORD RECOVERY

Part I, Requirement 17 requires maintenance of records. For electronic records, the electronic system integrity and record recovery processes fall under the maintenance area but are specifically discussed in this Subpart to emphasize the additional guidance provided.

Processes should be established to address all ranges of normal system anomalies and major events that could cause data loss, corruption, or complete system failures.

The following two methods will typically exist:

(a) backup system or process

(b) record system recovery plan

The backup system or process should be established to periodically capture the data and content such that any system anomaly can be reconciled from a prior date/time. Many forms of data corruption are possible due to user interactions (intentional or otherwise), computer program bugs, or hardware malfunctions. Resolution of data problems may require use of data from a previous date to correct the problem. The data corruption may be replicated across all redundant storage as well, including off-site systems, and require correction on the redundant storage systems.

The record system recovery process should be established to address a major malfunction of one part of the records system with transfer to the redundant portion of the records system. The redundant storage may be online (cold or hot site) or offline storage and may be automatically and readily available or may require interactions to transfer the system for use. Any combination is acceptable. The key parameter is to establish the recovery method, time frame, personnel actions, hardware, and computer program requirements needed to perform the recovery.

Both the backup process and record system recovery process should be exercised periodically to ensure system capabilities are adequate for the system in use and meet the time frame and risk level for the content in the system.

SUBPART 3.1-18.1
Implementing Guidance for Part I, Requirement 18: Audits

100 GENERAL

This Subpart provides nonmandatory guidance on quality assurance audits as specified in Part I, Requirement 18.

(24) 200 DEFINITIONS

The following terms are used in this subpart:

adequacy: the degree to which QA program documents include or address NQA-1 and other applicable requirements. It may also be defined as the degree to which the QA program provides the necessary controls for items, services, and activities within the scope of the QA program.

compliance: the degree of implementation with written program requirements.

implementation effectiveness: the degree that implementation of processes, control systems, and other written measures of the quality assurance program achieve the intended purposes and QA Program objectives.

process or quality assurance program effectiveness criteria: measures or standards developed and used to determine if processes or quality assurance programs achieve the desired results.

300 AUDIT ADMINISTRATION

301 Purpose

Quality assurance audits should be performed to

(a) determine the status, adequacy, and implementation effectiveness of the quality assurance program that has been developed and documented

(b) verify by examination and evaluation of objective evidence whether quality assurance program elements, items, processes, work areas, or records, as appropriate, conform to specified requirements

(c) evaluate the effectiveness of the organizational controls and verification activities, as directed by management

(d) evaluate strengths and weaknesses of work processes, process monitoring, and process control systems

(e) determine whether the work processes and control systems are effective in producing a product of desired quality

(f) provide management with an evaluation of the performance of the product to specified requirements

(g) evaluate problems and errors in work process execution that will affect specified product performance

(h) evaluate management effectiveness in responding to independent audit results

(i) report audit results to all levels of management who should be informed and who should take corrective action

(j) verify that corrective action has been planned, initiated, or completed

302 Elements

Elements of audits administration should include the following:

(a) a management policy statement or procedure that establishes organizational independence and authority of the auditors and commits the organization to executing an effective audit system

(b) resources, funding, and facilities to implement the audit system

(c) identification of audit personnel and their qualifications

(d) provision for reasonable and timely access of audit personnel to facilities, documents, and personnel necessary in the planning and performance of the audits

(e) methods for reporting audit results to responsible management of both the audited and auditing organizations

(f) provision of access by the auditor(s) to levels of management of the auditing and audited organizations that have the responsibility and authority to assure corrective action

(g) methods for verification of effective corrective action on a timely basis

303 Frequency of Audits (24)

Auditing should begin as early in the life of the activity as practical and should be continued at intervals consistent with the schedule for accomplishing the activity.

Frequency of regularly scheduled internal and external audits should be commensurate with the status and importance of the associated activities and based upon annual evaluations of all applicable and active elements of the quality assurance program. These evaluations, whether conducted separately or via audits, should include an assessment of the adequacy and effective

implementation of the quality assurance program based upon review of information such as the following:

(a) previous audit results and their dispositions

(b) internal and supplier documents and records, such as nonconformance reports, corrective action reports, and their dispositions

(c) independent information (e.g., from external sources such as generic experience of the nuclear industry, ASME, peer organizations, and regulating bodies)

(d) supplier histories for similar products or services

(e) changes in responsibilities, resources, or management

304 Shared External Audits

If more than one Purchaser uses a Supplier, the Purchaser may arrange for an audit of the Supplier on behalf of itself and the other Purchasers to reduce the number of external Supplier audits. The scope of the audit should address the needs of all Purchasers and the report should be distributed to Purchasers for whom the audit was conducted. Each Purchaser relying on the results of such an audit remains individually responsible for the adequacy of the audit and for its use by their organization.

(24) 305 Supplemental Audits

Regularly scheduled audits should be supplemented by additional audits for any of the following conditions:

(a) to determine the capability of a Supplier's quality assurance program prior to awarding a contract or purchase order

(b) when, after award of a contract, sufficient time has elapsed for implementing the Supplier's quality assurance program and it is appropriate to determine that the organization is adequately performing the functions defined in the quality assurance program description, codes, standards, and other contract documents

(c) when significant changes are made in functional areas of the quality assurance program, such as reorganizations, process control changes, mission or work scope changes, or procedure revisions

(d) when it is suspected that the quality of a product is in jeopardy due to deficiencies in the quality assurance program

(e) when a systematic, independent evaluation of quality assurance program effectiveness is considered desirable

(f) when it is necessary to verify effectiveness of required corrective action

(g) when it is directed by management

306 Audit Equivalents

Audit equivalent activities such as independent assessments and technical surveillances may be used to satisfy part or all of an audit requirement provided

(a) they each meet the requirements for a quality assurance audit as defined in this Standard

(b) they are reviewed and approved for such use by the organization responsible for quality assurance audits

400 PREPARATION FOR AUDITING

401 Team Selection and Assignment

Prior to assigning personnel to perform audits, management should determine that the individuals have the experience or training commensurate with the scope, complexity, or special nature of the activities to be audited. The recommended practice is to include technical specialists who have directly related experience in the area to be audited as members of an audit team. For example, a design engineer, chemist, operator, etc., from one unit or department may be used to audit the corresponding activity of another unit or department.

In selecting personnel for audit assignments, consideration should be given to special abilities, specialized technical training, prior experience, personal characteristics, and education. Personnel assigned to audits should be sufficiently independent and not auditing work they have performed or for which they are directly responsible.

(a) Where a QA auditor is involved in review or development of procedures, process sheets, or other quality documents, that individual may subsequently audit implementation of those quality documents but would not be sufficiently independent to audit the adequacy of those quality documents.

(b) Audits of the QA function may be performed by individuals from the same organization provided they are not auditing their own work or work for which they are directly responsible. The following are examples of acceptable methods.

(1) use of personnel in one section or function of the quality assurance organization to audit other sections or functions

(2) use of appropriately qualified personnel from non-quality assurance organizations to audit the quality assurance organization

(3) use of a Lead Auditor from other company units (e.g., sister divisions) to audit the quality assurance organization

(4) use of a Lead Auditor from corporate headquarters quality organization to audit the quality assurance organization of a subordinate company unit (which reports to the headquarters quality organization management)

(c) Audits of the QA function may be performed by outside organization, e.g., a contractor or qualified auditor(s) from another company(ies). For subsequent audits of QA, care should be taken to assure that the individuals are not auditing their own work. The following are considerations:

(1) If an auditor performs an audit of an organization that includes the audit program, that same individual should not perform the next audit of that organization if the audit program cannot be adequately evaluated without including the audit previously performed by the auditor.

(2) If an audit program can be adequately evaluated without including the audit previously performed by the auditor and that audit is specifically excluded from the audit scope, then that same auditor may perform the next audit.

(3) For team audits, it is acceptable for the same audit team members to participate in the next audit, provided a different auditor is assigned to audit the audit function or the previous audit performed by that team is excluded from the audit scope. If the previous audit is included in the audit scope, the individual assigned to audit the audit function should be either an individual who did not participate on the previous audit team or an individual who participated on the previous audit team but was neither the Lead Auditor nor the individual who audited the audit function.

402 Planning the Audit

(24) **402.1 Team Familiarization.** Prior to commencing the audit, the Lead Auditor should ensure that the audit team is prepared. Pertinent information, including policies, procedures, standards, instructions, codes, regulatory requirements, prior audit reports/findings, scope of work, or audited organization responsibilities, should be made available for review by the auditors. Additionally, the Lead Auditor should ensure that the audit team understands the scope of the audit. This includes the need to evaluate the adequacy of the audited organization's QA program, compliance with written program requirements and procedures, and the effectiveness of processes in meeting requirements and any identified QA Program goals or objectives. The audit team should understand the audit plan, including applicable requirements, quality assurance and technical processes to be audited, depth of audit, development and use of checklists, and audit schedules related to preparation, conduct, and reporting.

The Lead Auditor should ensure that the audit team understands their responsibilities for providing audit report input, including an understanding of report conclusions, such as adequacy, compliance, and audited element implementation or program effectiveness. Methods to ensure that audit team members understand their responsibilities could include audit team meetings, auditor training, audit procedures and guidance, or predeveloped audit checklists that include guidance in addition to requirements to be audited.

(24) **402.2 Product Selection.** In planning for an audit, emphasis should be on the selection of the product to be evaluated and the performance criteria or metrics used to determine the capability, stability, and effectiveness of the work processes that produce this product. Risk relative to unavailability and unreliability of product applications should prevail in the product selection. Product selection is usually dependent on the following key factors:

(a) importance of intended function(s) of the product

(b) complexity of product attributes required to perform functions

(c) skill or complexity of work processes that impart these attributes

(d) capability of evaluating or inspecting work processes

402.3 Product Experience. Organization or industry experience with a product's performance should be considered in selecting it for auditing. Information on past performance may be obtained from various sources, such as audit and assessment reports, plant operation and maintenance records, trend data, equipment histories, personal knowledge, and external information, including regulatory agency notices. Nonconformance reports, inspection results, customer complaints, and warranty claims are other sources of input. Product performance information may be useful in determining which technical and quality requirements are most important to achieving satisfactory performance.

402.4 Process Effectiveness. When auditing a process, flowcharts are valuable information sources. The selected processes, item characteristics, and performance criteria should be discussed with those responsible for the technical requirements.

(24) **402.5 Audit Plan.** The audit plan should identify how the audit will be performed and those key processes and product characteristics that have the greatest influence on item performance. For example, the audit may focus on product manufacturing processes, such as a critical assembly technique. Conversely, if a specific process is routinely inspected and has a stable performance history, the process may not need to be evaluated during the audit.

When an audited organization holds a current NQA-1 QAP certificate (e.g., ASME) that is recognized by the auditor's organization, the Lead Auditor may consider tailoring the audit plan to adjust the scope, team, and/or audit duration. The tailored audit plan may then allow efforts to focus more on effective implementation of the functions and activities having the greatest impact on the quality of items or services.

(24) **402.6 Checklists.** Checklists should be used for evaluating processes based on defined criteria related to adequacy, performance, and implementation

effectiveness criteria and based on available work process flowcharts. Checklists could include a brief description of the investigative method necessary to gather information related to the performance or effectiveness criteria. Past and current performance results on items and work processes should be considered when developing audit checklists. Checklists are guidance and, if allowed by the audit organization, may be expanded or condensed during audit performance as circumstances warrant. In addition to identification of requirements to verify, for organizations that can change standard checklists, inclusion of questions or lines of inquiry may be added to the checklist to help guide the audit team in collection of evidence to support audit conclusions.

(24) **403 Audit Notification**

Except for unannounced audits, involved organizations should be notified of an audit a reasonable time before the audit is to be performed. This notification should be in writing and include such information as the scope and schedule of the audit and the names of the auditors, Lead Auditor, and other team members, if known. For unannounced audits, prior agreements should be reached by the parties involved.

500 AUDIT PERFORMANCE

501 Pre-Audit Conference

A pre-audit conference should be conducted with the management of the organization to be audited. The purpose of the conference should be to confirm the audit scope and planned dates, meet counterparts, discuss the sequence and duration of the audit, set the time for the post-audit conference, and establish channels of communication. During the conference, there should be an agreed-to agenda for the audit.

502 Methods

Audits should be performed in accordance with the audit plan using the following methods:

(a) review of documentation, including procedures and work instructions, for completeness and adequacy

(b) examination in work areas for evidence of implementation of procedures and instructions

(c) observation of processes for evidence of achievement of specified results and evidence that performance criteria are being met

(d) examination of personnel training and qualification records where special skills are required

(e) reexamination of selected work that has been accepted, such as product, design calculations and drawings for conformance with acceptance criteria, and other applicable requirements

(f) examination of process controls, and records to determine conformance with specifications

503 Audit Implementation

503.1 Evaluation. Audit team members or auditor (24) should review and evaluate product and process documentation. Auditors should interview workers, and observe the actual work process, and evaluate them against requirements, performance, and effectiveness criteria, if any. Complete and accurate understanding of the product or process being investigated is best achieved by open and objective interaction with the audited organization representatives. Potential areas for process improvement identified during the audit should be noted and discussed at audit team meetings and reported to management. Using any developed checklists, audit team members should collect evidence to develop and support their conclusions on status, adequacy, compliance, performance, and effectiveness, if any, for quality assurance program elements audited.

503.2 Problems and Errors. When an auditor or team member finds a systemic or technical problem with an item or the outcome of a work process, it is important that the auditor or team member inform the audited organization representatives so they may investigate the facts behind the problem.

503.3 Audit Conclusions. Part I, Requirement 18 (and (24) other regulatory requirements) states that a purpose of audits is to determine the effectiveness of the program. To provide evidence that the audit determined the effectiveness of the program, the audit report should include a conclusion on the elements of the program audited.

Audit team members should prepare for the Post-Audit Conference and report input to the Lead Auditor by reviewing completed checklists to aid in reaching a conclusion, as appropriate, on the status, adequacy, compliance, performance, and implementation effectiveness of the quality assurance program. The presence of audit findings should not automatically result in a conclusion of quality program element ineffectiveness. The audit team and particularly the Lead Auditor should be able to support and justify any status, adequacy, compliance, performance, and QA program implementation effectiveness conclusions made in the audit report, especially when there are multiple audit findings identified for an audited element.

Implementation effectiveness conclusions for audited QA elements are documented by the Lead Auditor based on input from the audit team, review of audit checklists and findings, and criteria, if available. Development and use of specific effectiveness criteria can help audited organizations better understand the audit conclusions. When findings are identified during an audit, the effectiveness conclusion is especially important for management of the audited organization to place the appropriate resources and focus on correcting the issue. The auditing organization and Lead Auditor should consider how to document effectiveness conclusions when implemen-

tation is found to be ineffective or less than fully effective. Lead Auditors should include effectiveness statements that allow the audited organization to understand the degree of effectiveness of the program or QA element. A conclusion such as "a program or QA element is effective except where it isn't as noted in the audit findings" does not clearly express what about the program or element is ineffective. An example of a clearer conclusion is, "Implementation of Requirement 15, Control of Nonconformances, was effective, except for nonconforming item segregation as noted in Audit Finding #1."

(24) **504 Post-Audit Conference**

At the conclusion of the audit, a post-audit conference should be held by the Lead Auditor or the audit team with management of the audited organization to present audit results and clarify any misunderstandings. It is desirable that agreement be reached on audit results at the post-audit conference.

(24) **600 REPORTING**

The audit report should be issued within a reasonable time following the audit, usually 30 days. The audit report should include a requested date for a documented response by the audited organization. The audit report should be distributed to responsible management of both the auditing and the audited organizations.

The audit report should express the audit results in terms of how well the audit objectives of the audited elements were satisfied, if the performance requirements were met, if the audited elements were determined to be adequate, and provide a clear conclusion on the effectiveness of process implementation. The Lead Auditor should consider providing an explanation about audit result conclusions along with justification, when appropriate, in the audit report, such as when there are multiple audit findings identified in an area audited. In addition to audit findings, audit results should include observed good practices, strengths, and weaknesses.

700 RESPONSE

Management of the audited organization should respond to the report by the requested date. Part III, Subpart 3.1-18.2 provides guidance for response content.

800 FOLLOW-UP ACTION (24)

Follow-up action by the Lead Auditor or management of the auditing organization should verify the following:

(a) timely written response to the audit report
(b) adequacy of the response
(c) accomplishment of corrective actions, as scheduled
(d) effectiveness of actions taken, as required

Part III, Subpart 3.1-18.2 provides an example of one acceptable approach for follow-up actions.

SUBPART 3.1-18.2
Implementing Guidance on Classification and Handling Audit Issues

100 GENERAL

This Subpart provides nonmandatory guidance for classifying and handling issues that are found during the course of an audit as indicated in Part I, Requirement 18, based upon lessons learned and industry experience.

200 INTRODUCTION

Auditors identify a variety of issues while performing audits. These issues can vary in significance from minor or isolated deviations from established performance standards to significant safety issues or major breakdowns in the QA Program. On the opposite end of the spectrum, the issues may include examples of strong performance.

This guidance provides an acceptable approach to classifying and handling various audit issues and the rationale or logic for applying these different classifications.

Other approaches are equally acceptable, such as entering conditions adverse to quality that were identified during the audit into a corrective action system, where management review determines the significance and level of corrective action needed. If this approach is used, the auditing organization should retain responsibility for reviewing the actions taken and determining if they are adequate to close the audit issue.

Whatever approach is taken by an organization for classifying and handling audit issues, the approach should be documented in implementing procedures.

300 CLASSIFICATION OF ISSUES

The terms *finding* and *observation* as used in this Subpart fall under the more general term of *finding* as defined and used in Part I. The various classifications are discussed in order of significance.

301 Finding

A finding is any defect, characteristic, noncompliance, or activity that is a condition adverse to quality of products and/or services, and could have a credible impact to the intended function of the product and/or service. A finding also includes an undesirable or abnormal pattern of events, conditions, and programmatic issues, such as failure to implement any aspect of an approved QA Program. See Part III, Subpart 3.1-16.1, para. 302 for classification of conditions adverse to quality as to significance.

The auditing organization should promptly notify affected management of the finding so they can take appropriate prompt action to correct the issue. Additionally, the auditing organization should consider the need to stop work to address any immediate safety concerns.

302 Observation

An observation is a deviation in the implementation of a QA Program requirement or a deviation in the implementation of a QA procedure including inadequate or conflicting procedures that does not impact the intended function of an item or activity, or is an isolated occurrence. Other terms for this classification include Concern, Deviation, or Weakness.

303 Opportunity for Improvement

When an issue is identified that is an opportunity for improving performance of a process based on the audit team's experience or known industry best practices, it may be considered an Opportunity for Improvement.

Any issue that does not impact the intended function of the item(s) or activity(ies) is not a deficiency. Other terms for this classification include Enhancement or Recommendation. Typically, such items do not require formal corrective action.

304 Strength

When a practice or performance is identified that exceeds requirements, expectations, or industry standards in a beneficial, safe, efficient, and effective manner, it may be considered a strength. Some organizations refer to this as a Good Practice.

One way to determine if a process or practice warrants being identified as a Strength is to ask: Would one recommend that other organizations benchmark this practice to improve performance?

400 RESPONSES TO ISSUES

The audited organization is responsible for evaluating all issues identified by the auditing organization and taking corrective actions, as applicable. The audited organization should provide written responses to audit issues, as requested by the auditing organization. Findings and observations should be entered into a corrective action system to ensure tracking and closure.

Paragraphs 401 through 404 of this Subpart provide guidance on a graded approach for the level of evaluation and response that may be appropriate for the various issues identified.

401 Finding Responses

When the auditing organization issues a finding, they should request a written response, typically within 30 days. This response time allows for a cause determination and the identification of corrective actions to resolve the issue. An acceptable response should include the following:

(a) the cause of the issue

(b) an extent-of-condition analysis, where appropriate

(c) corrective actions that have been taken or are planned to correct the issue

(d) corrective actions that have been completed or are planned to address the cause of the issue (corrective actions to prevent recurrence)

(e) a schedule for completing all actions specified in (c) and (d)

402 Observation Responses

When the auditing organization issues an audit observation, a written response is requested, typically within 30 days, if the condition has not been corrected during the course of the audit. This provides for a timely evaluation of the condition adverse to quality and the identification of corrective actions to resolve the issue. An acceptable response should include the following:

(a) corrective actions that have been taken or are planned to correct the issue

(b) a schedule for completing remaining incomplete corrective actions

403 Opportunities for Improvement

When the auditing organization issues an Opportunity for Improvement, they typically do not request a response. However, management should evaluate the merit of the issue identified and determine if the improvements or efficiency gains noted are worth the resources required to implement.

404 Strengths

When the auditing organization identifies a Strength, they do not request a response. However, management of the audited organization should take the opportunity to identify what other organizations or locations under the span of their control may benefit by implementing similar processes or approaches and how to leverage the practice to maximum benefit of the organization.

500 FOLLOW-UP

The auditing organization typically performs the following three types of follow-up activities for findings and observations:

(a) Evaluate the written response.

(b) Monitor corrective actions.

(c) Reaudit.

501 Evaluate the Written Response

The auditing organization typically schedules a follow-up to be completed within a week after the response is due. This follow-up evaluates the adequacy of the cause determination (if required), adequacy and timeliness of the proposed actions, and adequacy and timeliness of the actions to prevent recurrence.

If the response is late or does not appear to be adequate, the auditing organization may consider elevating or escalating the issue to senior management for additional support in resolving the issue.

502 Monitor Corrective Actions

Management of the audited organization is responsible for implementing the actions specified in the response to ensure timely and effective corrective actions.

The auditing organization typically schedules follow-up activities that correspond to key milestone dates provided in the response.

Follow-up activities monitor the implementation of the corrective actions to ensure that they are both timely and effective.

When corrective actions begin to deviate from the scheduled corrective actions or appear to be either inadequate or ineffective, the auditing organization may consider elevating or escalating the issue to senior management for additional support in resolving the issue.

503 Reaudit

Findings and observations are typically focus areas during the next regularly scheduled audit of the area. Some issues may warrant reaudit prior to the next regularly scheduled audit.

When the auditing organization finds recurrence of previously identified issues, they may consider escalating the issue due to the failure of management to correct the previously identified issue.

SUBPART 3.1-18.3
Implementing Guidance for Part I, Requirement 18: Audits, Use of Surveillance

100 GENERAL

This Subpart provides nonmandatory guidance on the use of surveillance to ensure the effective implementation of the quality assurance program. There are organizations that use "surveillances" to complement their audit program under Part I, Requirement 18. This Subpart can be used to complement that process if the personnel used to accomplish surveillances under this Subpart are trained and qualified in accordance with Part I, Requirement 2. This Subpart provides nonmandatory guidance for one method that may be used as an element in meeting the audit program requirement.

Surveillance as used in this Subpart is an assessment technique that uses observation or monitoring to provide confidence that ongoing processes and activities are adequately documented and effectively performed. Surveillance can be used effectively to complement the audit, review, inspection, and test functions.

In addition to supporting Part I, Requirement 18, surveillance may be used by managers and supervisors as part of their routine assessment activities as noted in Part I, Requirement 2 to provide timely data on performance and to identify quality issues before they have a significant impact on safety and reliability.

Surveillance has the following advantages:

(a) It is flexible, adaptable, and easy to use.

(b) It may be implemented quickly.

(c) It may be applied by line personnel and management as well as independent personnel.

(d) It is adaptable to a broad range of assessments including item acceptance and diagnostics for determination of extent and cause of nonconforming issues.

Examples of processes and activities suitable for surveillance include research and development, design, internal procurement process, manufacturing, plant operations, modifications and maintenance, radiological and industrial safety, safeguards and security, sampling, laboratory, inspection, testing, calibration, hazardous waste management, materials management, and environmental management.

200 PLANNING AND SCHEDULING

Planning and scheduling should be used to determine those processes and activities that would most benefit from surveillance, when and how frequently it should be performed, as well as who should perform or lead it. Surveillance plans may be integrated into the overall assessment program complementing other evaluation techniques as deemed useful and appropriate for the process or activity being covered.

201 Planning

Planning efforts should precede scheduling arrangements to determine what processes, activities, or conditions are important and which prerequisites are needed to be completed prior to performing a surveillance. Planning should consider aspects such as regulatory impact, safety and reliability significance, experience and previous history, follow-up of previous concerns, management commitments, line supervisory concerns, and related industry experience. Industry experience may be derived from inspection results, industry standards, and information networks. Selection of personnel to perform a surveillance should also be considered. Directly related experience is a desirable attribute for surveillance personnel. Consideration of other scheduled assessments also should be made to avoid duplication and to optimize timing of the surveillance.

202 Scheduling

Scheduling may be flexible and informal to implement the surveillance plans to coincide with ongoing activities. When used, schedules may be informally controlled, but detailed to the extent that opportunities are not missed and priorities are satisfied. Control of scheduling may be accomplished by simply indicating the month in which the surveillance is to be performed, who is assigned to perform the surveillance, and the need for additional technical expertise.

300 PREPARATION

A surveillance plan should include a purpose or objective of what will be observed or monitored and actions or attributes to be assessed. The amount of detail in the

surveillance plan should be commensurate with aspects such as the knowledge and experience of the personnel performing the surveillance and the complexity or uniqueness of the process or activity. The surveillance plan should be used as a tool to guide personnel through the surveillance and to ensure that the purpose or objectives are accomplished. The extent of the surveillance and related preparation should be consistent with its purpose and the importance of the processes and activities being observed.

Familiarization with management expectations, governing procedures, specifications, and other policy documents is desirable. The governing resource documents may include drawings, procedures, supplier manuals, system descriptions, license commitments, codes and standards, controls, research and experiment guidelines, as well as industry publications. Reports from previous or other assessments, both internal and industrywide, should be considered. Additionally, reports that provide performance indicators, status, trends, and histories may also be useful.

Methods of surveillance should also be considered with preference given to direct observation of performance. Direct observation may be augmented by discussions with personnel, observation of results, and review of documents.

Other preparation considerations may include the following:

(a) surveillance date(s) to coincide with performance of the process or activity

(b) need for additional assistance to include subject matter experts or other experienced personnel who can make accurate and meaningful assessments of performance

(c) orientation of surveillance personnel not yet familiar with the performance of surveillances by clarifying the reporting processes and the need to pursue identified concerns

(d) the need for observing processes and activities of groups performing the activity during all work periods

(e) generic attributes that apply to many or all surveillances but that are not specifically outlined in each plan

400 PERFORMANCE

401 Notification

Cognizant management or area supervision should be given sufficient notification prior to the surveillance being performed so that they can be adequately prepared. Ideally the surveillance plan would be included in this notification.

402 Conduct of Surveillance

402.1 Surveillance personnel should use the following guidelines, as appropriate:

(a) prior to starting the surveillance

(1) develop a clear understanding of the scope of the surveillance, the safety and reliability aspects of the work scope, the requirements and rules applicable to the facility and to the work to be observed, and the communication and reporting agreements made with the organization responsible for performing the work.

(2) inform personnel responsible for the activity or process, why the surveillance is being conducted, the scope of the surveillance, communication and reporting agreements, the authority of the person performing the surveillance (particularly in the area of Stop Work).

(3) allow activities to continue without interference unless it is apparent that immediate corrective or preventive action is necessary in accordance with governing procedures, or if a safety hazard is present. This provides the opportunity to confirm that all personnel involved understand the work, their roles, the risks, interfaces, and preparedness by having the correct tools, apparatus, and documentation required to accomplish the work.

(b) use checklists to enhance the documentation of the surveillance effort. However, a checklist should not preclude the opportunity to observe an unanticipated or unexpected event that may have the potential to yield additional performance data nor should the checklist prevent the immediate follow-up of an important or significant observation or concern.

(c) record observations on the checklist for reference and follow-up.

(d) pursue concerns and deficiencies sufficiently to characterize the nature and extent of each.

(e) exercise care in keeping facts separated from opinions or judgments. Where possible, confirmation of observations or perceptions should be sought prior to forming conclusions. This may be achieved through nondisruptive inquiries of personnel involved in the activity or by review of results.

(f) offer to review observations with the personnel involved at the end of the surveillance, noting the observed strengths, weaknesses, and recommendations for improvements. Indicate if formal corrective action is being considered and invite comments and questions.

(g) express appreciation for cooperation demonstrated during the surveillance.

402.2 Surveillances should consider the following, as appropriate:

(a) upon arrival at the workplace note

(1) the existence of any apparent hazards, such as radiation, chemicals, toxins, spills, electricity, leaks, tripping, combustibles and flammables, noise, overhead work, unsecured ladders or scaffolding, dangerous apparatus or tools, hot or cold surfaces or liquids, compressed gases, unguarded rotating equipment, and general housekeeping

(2) the application of barriers, such as isolations, tags, clearances, warning signs, locked or roped-off areas, and segregation of nonconforming materials

(3) the condition of facilities, such as cleanliness, ventilation, temperature, area alarms, public address system, availability of protective and emergency equipment, and current status of testing for fire protection and lifting equipment

(4) the availability and use of appropriate equipment and materials, such as apparatus and tools, calibrated tools and measuring and test equipment and instruments, shelf life, labeling and traceability of raw materials and samples

(5) the availability and use of documentation, such as current reference documents, instructions, procedures, drawings, specifications, and documentation required to authorize work or to record key results or data

(6) if not evaluated earlier under para. 402.1(d) of this Subpart, note such things as

(-a) supervisory involvement

(-b) worker preparedness and understanding of assigned tasks and associated risks

(-c) skills and expertise available

(-d) communications

(b) as the surveillance progresses

(1) the performance of the personnel conducting work and inspection should be observed. Some aspects that may be evaluated include

(-a) communications with supervision and supporting organizations

(-b) how accountability is established

(-c) adherence to rules and procedures

(-d) use of tools, apparatus, and equipment

(-e) handling of problems or unexpected events

(-f) inspection activities performed to verify that materials, parts, and components meet specifications

(2) the adequacy of procedures, specifications, and work instructions should be assessed.

(3) the adequacy of process controls used for activities that cannot be clearly delineated in procedures should be assessed. Controls for tests and experiments should support and validate the results and conclusions and provide sufficient data for replication and peer reviews when required. Controls during development, which are applied to the fabrication, construction, test, and operation of prototypes and test rigs, should support and validate the results and provide reliable data for subsequent production-line activities

(c) on completion of the surveillance

(1) the observations should be evaluated by the individual who performed the surveillance with the assistance of cognizant personnel, if necessary, to assess their validity, importance and significance, and impact on quality, safety, and reliability both individually and collectively.

(2) care should be taken to identify trends and isolated incidents that may have generic implications so that they may be appropriately followed up.

(3) consideration should also be given to reviewing other surveillances of similar work activities for identification of trends. This evaluation may identify conditions adverse to quality, nonconforming items, and quality program inadequacies. These should be processed in accordance with applicable corrective action procedures.

(4) observed strengths and positive trends should also be identified.

(5) issues not included in the above considerations, such as industrial safety, cost effectiveness, and process efficiency, should also be identified.

500 REPORTING AND COMMUNICATION

Reporting and communication may take many forms within the organization. The following elements should be considered:

(a) reaching agreement on communicating results during the surveillance

(b) providing immediate verbal feedback concerning strengths and weaknesses to first-line supervisors, managers, and workers, as appropriate

(c) notifying appropriate personnel of conditions adverse to quality in accordance with governing procedures

(d) considering giving the surveilled organization the opportunity to review and discuss the surveillance report for factual accuracy, prior to report finalization

(e) reporting details that should be sufficient for a knowledgeable individual to understand without recourse to the person who conducted the surveillance

600 RESOLUTION OF ISSUES

601 Response to Surveillance Reports

Issues that constitute or may constitute a condition adverse to quality should be entered into the corrective action system.

Issues should be resolved at the lowest level that has the authority to effectively resolve the issue.

Responses to identified issue should be made in a timely manner, with consideration given to the importance of the issues. Should there be a disagreement; resolution should be in accordance with governing procedures.

602 Follow-Up

Follow-up of important issues should be initiated as necessary to confirm their satisfactory resolution. Results from surveillances should be provided as inputs to existing corrective action, trending, or quality improvement programs in accordance with governing procedures.

SUBPART 3.2
Guidance for Implementing Part II Requirements

(Extracted From Former NQA-2.)

The following Subparts provide nonmandatory guidance that may be used in conjunction with the applicable Subparts of Part II.

SUBPART 3.2-2.1
Implementing Guidance for Part II, Requirement 2.1: Cleaning of Fluid Systems

(24)

DELETED

SUBPART 3.2-2.7.1
Implementing Guidance for Part II, Requirement 2.7: Quality Assurance Requirements for Computer Software for Nuclear Facility Applications

(24) 100 GENERAL

This Subpart structure is based on the main sections (e.g., 100, General; 200, General Requirements) and paragraphs (e.g., 201, Documentation and Records) of Part II, Subpart 2.7. In most cases, the paragraphs (e.g., 203.1, Configuration Identification) contained in Subpart 2.7 are provided as a one-to-one correspondence in this Subpart. Deviations may occur when additional paragraphs have been incorporated within Part II, Subpart 2.7 or this guidance.

This Subpart has been developed to provide organizations invoking NQA-1 with guidance on implementing Part II, Subpart 2.7 requirements and how the requirements may apply in various situations where software is used.[1] Part II, Subpart 2.7 is applicable to software when a failure or error in the software could adversely affect the quality of structures, systems, or components of nuclear facilities. Possible exceptions will be detailed in this Subpart. Applicability of Part II, Subpart 2.7 is not dependent upon the type of computer equipment (e.g., mainframe, personal computer, workstations, servers) that is installed.

The requirements of Part II, Subpart 2.7 should be applied in a manner to meet the requirements of IEEE Std 7-4.3.2-2003, IEEE Standard Criteria for Digital Computers and Safety Systems of Nuclear Power Generating Stations. This Subpart provides guidance to support meeting the requirements of that standard.

101 Definitions

Terms may have multiple interpretations even within a standard. Therefore, definitions provided in Part II, Subpart 2.7 and this Subpart should be considered in the use of this Subpart. To enhance understanding and ensure consistency in this Subpart, the characteristics of several common software-related terms are discussed.

integration testing[2]*:* testing in which computer program units, hardware components, or both are combined and tested to evaluate the interaction among them.

reusable code: a computer program unit that can be used in more than one computer program to provide the same functionality.

software library: a collection of computer program units, data, and related documentation that may be used in software development, use, or maintenance to provide functionality. These may include configuration data, help data, message templates, classes, functions, subroutines, and data values or type specifications.

system testing[2]*:* testing conducted on a complete, integrated system to evaluate the system's compliance with its specified requirements.

unit testing: testing of individual hardware or computer program units.

101.1 Software Characteristics. Software [see ISO/IEC/IEEE 24765:2010(E)] can be composed of three elements:

(a) a set of instructions that, when executed, provide a specified function or performance

(b) data pertaining to the operation of a computer program or computer system

(c) documents that describe the operation and use of the program

Software, therefore, is an all-inclusive term for the nonhardware elements of a computer-based system. A computer program differs from software in that software can include documents that describe the development, operation and maintenance, and retirement of a computer program. Computer programs do not include documents. Computer programs can be written in programming languages (e.g., C, C++, Java, Python, assembly). Although the more common term is "program," for clarity, "computer program" is used throughout this Standard.

[1] U.S. Nuclear Regulatory Commission (NRC) Regulatory Guide 1.152, Criteria for Use of Computers in Safety Systems of Nuclear Power Plants, and U.S. NRC Regulatory Guide 1.168, Verification, Validation, Reviews, and Audits for Digital Computer Software Used in Safety Systems of Nuclear Power Plants, provide guidance for nuclear power plant licensees and their suppliers on acceptable methods and techniques."

[2] This definition has been copied or adapted from ISO/IEC/IEEE Std 24765:2010(E), Systems and software engineering — Vocabulary, with the permission of IEEE.

101.2 Hardware Characteristics. Hardware consists of the physical elements that provide the computing capability and external interface (e.g., central processing units, memory, computer monitors, printers). Hardware is the physical equipment used to process, store, or transmit computer programs or data [see ISO/IEC/IEEE 24765:2010(E)]. In contrast, computer programs are characterized as logical rather than physical system elements.

101.3 Firmware Characteristics. Firmware is the combination of a hardware device, computer programs, and data that reside as read-only on that device. The firmware can perform very limited functions such as keypad controls, or can provide significant function and control capabilities for control rod drives or safety systems. In either case, if firmware is supplied under requirements of Part II, Subpart 2.7, the computer program aspect of firmware should be considered in an organization's software engineering method.

102 Software Engineering

A variety of software engineering methods may exist within an organization that implement the Quality Assurance requirements contained within NQA-1. The extent of application of the software engineering activities should be commensurate with the risk associated with the failure of the software. Factors affecting this risk include the potential impact on safety and/or operation, complexity of computer program design, degree of standardization, the state of the art, and similarity to previously proven computer programs. Part II, Subpart 2.7 users should consider establishing a software categorization method that includes

(a) software engineering methods applicable to given categories of software

(b) ensuring that the results of the categorization are documented

The software categorization method should consider safety significance and the relative importance of the software.

Paragraphs 102.1 through 102.8 of this Subpart provide additional considerations in developing a categorization method and determining software applicability.

102.1 Simple and easily understood computer programs (e.g., computer programs whose results can be easily confirmed through hand calculations) that are used in the design of systems, structures, and components, may be excluded from the controls of Part II, Subpart 2.7, if designs using these computer programs are individually verified (see Part I, Requirement 3, para. 401). Design verification documentation should include design inputs, the computer-program-generated results, and computer-generated evidence of the programmed algorithms or equations (e.g., computer program listings, spreadsheet cell contents). However, frequent use of the computer program may justify the application of Part II, Subpart 2.7 in order to simplify future use.

102.2 Complex computer programs used in the design of structures, systems, and components should be developed and approved for use in accordance with Part II, Subpart 2.7 unless verification and testing of the computer program (or parts thereof) independent of a specific application is not practical. In these cases each application of the computer program must be verified and documented in accordance with the requirements of Part I, Requirement 3, section 400.

102.3 Separate verification and tests may not be required for computer programs that are reviewed and tested in conjunction with hardware as a unit, in accordance with Part I or Part II (e.g., Measurement and Test Equipment) of this Standard.

102.4 Computer programs that have been verified and tested in accordance with other consensus standards may not require any additional verification and tests. However, an evaluation based upon the Part II, Subpart 2.7 verification and testing requirements should be performed to ensure compliance with Part II, Subpart 2.7.

102.5 Exceptions may also be warranted for support software (see section 600) if this software has a known and acceptable performance history. The basis for accepting the performance history should be documented and approved in conjunction with the software development cycle of the software using the support software. The resulting system, structures, or components should be submitted for design verification in accordance with Part I, Requirement 3, section 500, or the resulting software (application and the support software) should be developed and approved for use in accordance with Part II, Subpart 2.7.

If the organization implementing Part II, Subpart 2.7 has a software quality assurance program that is compliant with other industry standards, a review should be performed to assure consistency with the requirements of Part II, Subpart 2.7.

102.6 Firmware is dependent on the nature of the computer program and hardware device. Three possible approaches are described as follows:

(a) If the computer program can be changed after it is embedded, including at run time, all applicable controls of Part II, Subpart 2.7 should be applied.

(b) If the computer program cannot be changed after it is embedded, and testing of the completed device is not adequate for full acceptance, Part II, Subpart 2.7 software development controls should be applied.

(c) If the embedded computer program functions can be adequately verified by testing the completed unit and the computer program cannot be changed, including at run time, without repeating this verification, controls

beyond those used for hardware may not be necessary. This approach is the least desirable because it treats the computer program as hardware and does not recognize the need to apply controls to the computer program.

102.7 Documented evidence (e.g., supplier testing, applicable supplier experience) supporting the acceptance of commercial off-the-shelf software may be used to augment the acceptance requirements of Part II, Subpart 2.7, para. 302.

102.8 Software libraries and reusable code can be developed or acquired, and the applicable controls of Part II, Subpart 2.7 should be applied. If the software library or reusable code is acquired, the requirements of Part II, Subpart 2.7, section 300 should be applied for the acceptance. If the software library or reusable code is not able to stand alone, additional source code may be developed to facilitate acceptance. If additional source code is developed, applicable controls of Part II, Subpart 2.7 should be applied to this additional source code. It may be appropriate for testing to occur when the software library/reusable code is integrated into the final software product.

Software engineering activities should specify how computer program units are controlled to ensure that each is under configuration management, appropriately documented and tested, and software life cycle deliverables developed accordingly.

200 GENERAL REQUIREMENTS

201 Documentation and Records

The combined requirements of Part I and Part II, Subpart 2.7 establish the need for both controlled documents and records. The applicable software engineering method should define the software life-cycle documents that are to be considered a controlled document and/or record.

Controlled documents are governed by Part I, Requirements 5 and 6. In general, software planning documents (e.g., project plans, quality assurance plans, configuration management plans) are considered controlled documents. Additionally, organization policies, procedures, and instructions should be considered controlled documents.

Quality assurance records are governed by Part I, Requirement 17, and managed differently than controlled documents. Records providing evidence of quality-affecting activities include documentation of requirements and design, test plans, test reports, and user documentation. Part III, Subpart 3.1-17.1 identifies some suggested documents that should be managed as records including software procurement documentation and software verification and validation data and reports (e.g., system test and acceptance test reports).

202 Verification (24)

The purpose of software verification activities is to assure at defined control points the activities are complete and provide confidence that no defects have been inserted. The extent of verification and methods chosen are a function of the complexity of the software, degree of standardization, the risk of potential impact on safety and/or operation, and similarity with previously proven software.

202.1 Reviews. The purpose of software review activities is to provide adequate confidence that the software implements the approved software requirements, provides correct solutions, and does not perform or cause any adverse unintended functions.

Reviews should include assurance that any assumptions made during the performance of activities associated with the software engineering elements are consistent with the intended use of the software.

203 Software Configuration Management

Key activities of software configuration management include configuration identification, configuration change management, configuration status control, and configuration audits. This ensures that all elements of the product baseline, as defined in Part II, Subpart 2.7 are accounted for and properly reviewed and approved.

203.1 Configuration Identification. Part II, Subpart 2.7 requires the establishment of a configuration baseline at the established and agreed upon intervals or control points as defined in the software engineering method. Baselining means the assignment of a documented unique identifier to each software configuration item and its associated products and placing the software configuration item under control to ensure the approved software configuration item can be retrieved successfully and to avoid unauthorized changes.

Baselining applies to all identified software configuration items used to support the software development and/or software maintenance. Each configuration item should be identified, controlled, labeled, and documented as constituents of the final product baseline. In some instances, the unique identifier for a configuration item may be the date and time the configuration item was generated. Support software may use the vendor identifier as its unique identifier. A labeling system should delineate major changes from minor changes.

Support software (see section 600 of this Subpart) should be identified as part of the final product baseline. A key part of the overall configuration management process should be to identify how support software will remain available to support and, if necessary, rebuild and execute the program.

At the completion of software development activities, the final product baseline is the collection of previously baselined configuration items.

203.2 Configuration Change Control. In some cases, configuration items need to be changed in order to support a modification to the software. For example, a modification to enhance the execution performance of a program may be invisible to the user and may not require a change to the user documentation. As a result, the most recent revision of a particular configuration item may be part of more than one product baseline.

203.3 Configuration Status Control. The purpose of configuration status control is to be able to report on necessary information on the status of configuration items during the software development process. This information includes the approved configuration item list and the status of proposed and approved changes.

203.4 Configuration Audits. Configuration audits may be used to verify that

(a) documentation accurately describes configuration items and baselines

(b) change requests are resolved, and software products are ready for delivery

Functional configuration audits may be conducted to verify that the development of a configuration item has been completed satisfactorily, that the item has been shown to meet its requirements, and that software documentation is complete and satisfactory. Functional configuration audits are a type of verification review, which are discussed in Part II, Subpart 2.7, para. 202.1.

The purpose of the physical configuration audit is to confirm that the software documentation is consistent with the as-built software product, and that the product is ready for delivery (i.e., acceptable for use).

204 Problem Reporting and Corrective Action

The problem reporting and corrective action requirements of Part II, Subpart 2.7, para. 204 are intended to implement Part I, Requirement 16, as these requirements apply to software. Part II, Subpart 2.7 users need not develop an independent process to meet these requirements if their existing processes incorporate the requirements of Part II, Subpart 2.7, para. 204. Part II, Subpart 2.7 users may develop either supplementary procedures for software problem reporting and corrective action, or include software issues in their existing nonconformance and corrective action procedures. The problem-reporting process should be developed into a multitiered system (e.g., a system for dealing with potential improvements requested by software users, the system for documenting problems). The development of this multitiered system may lead to a corrective action prioritization process. For example, an error reported during the development process may not require the same level of reporting as one that is reported during testing or use (e.g., report to purchaser). The collection and analysis of information from this process can be useful in enhancing the organization's Part II, Subpart 2.7 processes.

300 SOFTWARE ACQUISITION (24)

Software acquisition includes the subcontracting of software development to the purchaser's design, purchase of commercial off-the-shelf software, and acquisition of software through other methods (e.g., source code centers, company repositories, and user groups).

This section provides guidance for software acquired in accordance with Part I and otherwise acquired software that was not developed in accordance with Part I.

301 Procured Software and Software Services

The development of software for the purchaser by a supplier should include detailed specifications in the purchase order that identify the software lifecycle documentation required to be submitted to the purchaser for approval. Requirements for the content of the purchase order and the process for evaluating, selecting, and approving the software product or service provided as defined in Part 1, Requirement 7 specifies methods for acceptance that are not always readily applied for software. For example, the purchase order specifications should define purchaser-approved methods of accepting software including software design reviews, factory (supplier) testing (e.g., source verification), and acceptance testing (e.g., post installation tests).

Acceptable methods for suppliers' reporting of errors include, but are not limited to, the following:

(a) e-mail direct to the purchaser's point of contact

(b) posting on the supplier's website

(c) other documented communication methods that have been agreed upon with the purchaser

302 Otherwise Acquired Software (24)

Otherwise acquired software includes computer programs that perform a safety function and computer programs that perform a function related to quality. Commercial Grade Dedication is required in accordance with Part II, Subpart 2.14, for otherwise acquired computer programs that perform a safety function. Otherwise Acquired Computer Programs that do not perform a safety function but perform a function related to quality are evaluated to assure that the product meets its intended use as described in para. 302.2 of this Subpart.

302.1 Part III, Subpart 3.2-2.14 provides guidance on performing commercial grade dedication of software in accordance with Part II, Subpart 2.14. Computer programs that perform a safety function include, but are not limited to, the following:

(a) software that is used to design basic components in a nuclear facility

(b) software that is used to perform safety analysis

(c) software that is used to test or operate basic components in a nuclear facility

302.2 This evaluation process applies to computer programs used to design or control systems, structures, and components whose failure would not create a situation adversely affecting public health and safety, but performs (or are used for) functions related to quality. For example, this could include computer programs used for the design of the chemical and volume control system, normal residual heat removal system, and startup (backup) feedwater system.

As per Part II, Subpart 2.7, para. 302.2, software and software services that have not been previously approved under a program consistent with the requirements of this Standard and that do not meet the criteria of para. 302.1 of this Subpart are evaluated to assure the software or software service is acceptable for its application.

The capabilities of the software may be found in system or facility operation process descriptions, interviews with expected software users, supplier product descriptions, and the user's manual. Limitations for use of the software should consider any restrictions associated with the computer hardware or operating environment, current known software errors, application to the domain of interest, cyber security, and user access.

Identifying the technical requirements, and documenting test plans, test cases, and installation test results may be sufficient, provided that the rigor of the evaluation is commensurate with the computer program's effect on quality. However, if access to the supplier is limited and documentation is not available for the acquired software, computer program testing activities may be the primary method to evaluate the computer program.

400 SOFTWARE ENGINEERING METHOD

401 Planning

The software engineering method should be defined and discussed in a quality or project planning document (e.g., project plan, software quality assurance plan).

Planning documentation should include the following, as applicable:

(a) project scope and objectives

(b) assumptions and constraints

(c) project deliverables

(d) schedule and budget

(e) organizational internal and external interfaces

(f) roles and responsibilities

(g) staff training plan

(h) methods, tools, and techniques

(i) requirements and design control

(j) risk management plan

(k) project metrics

(l) supporting process including acquisition, configuration management, verification and validation, quality assurance, problem resolution, subcontractor management, and retirement

402 Software Requirements

Software requirements should be unique (i.e., no overlap), unitary (i.e., addresses one thing only), complete, consistent, correct, unambiguous, traceable, and verifiable. Verification and validation activities should demonstrate that the software requirements have been satisfied at the conclusion of each phase of the software life cycle.

Technical requirements encompass both functional and nonfunctional requirements. Software functional requirements should comprehensively address all software functions (inputs, behavior, outputs). As appropriate, software nonfunctional requirements should address performance, usability, maintainability, scalability, availability, extensibility, security, serviceability, and portability.

403 Software Design (24)

Design documentation should be completed in a manner that facilitates the software verification process in accordance with Part II, Subpart 2.7. If any requirements are not met in the design activity, then those requirements should be revised to reflect the final product using the same approval process as the original requirements. The design documentation may be combined with the documentation of the software requirements or the source code or equivalent (e.g., ladder logic, calculations, scripts) resulting from implementation of the software design.

Software design should result in units that are

(a) low in complexity (e.g., lines of source code, number of decision paths)

(b) easily testable

(c) loosely coupled (i.e., requires little interaction with other units)

(d) highly cohesive (i.e., performs a single task)

(e) error tolerant (i.e., handles errors adequately and appropriately)

Safety components should be isolated from non-safety components. Design considerations should be included to ensure that the software is reliable, secure, and tamper resistant. Performance-monitoring requirements should be analyzed and specified prior to the initial system design.

Any pre-existing computer program components, e.g., application frameworks or software libraries, should be identified. For analysis and design software, a description of the physical problem and the encoded mathematical model(s) should be documented. The description should include a list of assumptions made in constructing

the model and all information necessary to enable verification.

404 Software Design Implementation

The target environment for the software should be identified and established prior to implementation. The target environment and reusable component should

(a) be tested for the intended application before use

(b) be selected from proven products with vendor support

(c) conform to a plan describing the strategy and the time period for which vendor support is obtained for the target environment and reusable products

(d) comply with industry interface standards, when they exist [e.g., IEEE Std 1003.1, IEEE Standard for Information Technology— Portable Operating System Interface (POSIX®)]

If a target environment or a reusable component was not developed in accordance with a process standard required for its development, then the development organization should analyze and test the software to ensure that the product complies with product standards and provide the necessary documentation.

405 Computer Program Testing

405.1 Testing Process. Computer program testing may include unit testing, integration testing, regression testing, system testing, factory acceptance testing, installation testing, and site acceptance testing, as applicable. Computer program testing is a testing activity that is planned during the software development activities. Testing ensures that the computer program functions as intended. Tests may range from a series of tests performed during computer program development to a single test of all software requirements. This series of tests would provide assurance of correct translation between states and proper function of individual units.

The extent of the computer program testing activities should be commensurate with the risk associated with the failure of the software. Factors affecting this risk include the potential impact on safety and/or operation, complexity of computer program design, degree of standardization, state of the art, and similarity with previously proven computer programs.

The responsible organization should be an integral part of the testing process. Computer program tests should be developed, and the test results evaluated by individuals who are familiar with the system specification. Test cases should include execution of extreme and boundary values, exception handling, long run times, utilization of shared resources, workloads with periods of high demand and extreme stress, and special timing conditions. Test coverage analysis should be developed that executes all functions to ensure adequate testing is performed commensurate with the risk of computer program failure. The test coverage should be monitored, and paths not executed identified. The risk associated with the nonexecuted paths should be evaluated.

405.1.1 Unit Testing. Unit testing is performed by the developer in the development environment and does not require independence. The object of unit testing is to test the lowest level unit of the computer program individually. The unit test effort should use both source code execution and source code review. Input and output stubs to mock up the interfaces are usually required for source code execution. Source code review can be accomplished using code walkthroughs or more formal inspections. Additional guidance on inspections may be found in IEEE Std 1028-2008, IEEE Standard for Software Reviews and Audits. (24)

Additional guidance on unit testing may be found in IEEE Std 1008, IEEE Standard for Software Unit Testing, and IEC-60880, Nuclear Power Plants—Instrumentation and Control Systems Important to Safety — Software Aspects for Computer-Based Systems Performing Category a Functions.

405.1.2 Integration Testing. Integration testing of computer program units is typically performed by the developer in the development environment and does not require independence. The main function or goal of integration testing is to exercise the interfaces between the units.

Once the units are unit tested, they are integrated one by one, until all the units are integrated, to check the combinational behavior, and to validate if the requirements are implemented correctly.

Integration testing is conducted simultaneously with the development of the units and does not require all units to be completed prior to the start of integration testing. A top-down approach to integration testing may require developing “stubs” for nonexisting units. A bottom-up approach may require developing “drivers” for the nonexisting units.

The integration test effort should identify problems with the interaction among units. Integration testing may not be required for small changes.

Additional guidance on integration testing may be found in IEEE Std 1012, IEEE Standard for Software Verification and Validation.

405.1.3 Regression Testing. Regression tests should be performed to ensure that a software change has no unintended effects, i.e., does not cause another portion of the program to stop working or generate erroneous or spurious results. The coverage required for regression testing should be determined during the development associated with a software change. The set of tests used for regression testing may be drawn from previously executed installation or site acceptance tests. The results of regression test execution should be compared against reference results from previous regression, installation, or

site acceptance tests. Automated execution of regression tests should be considered.

405.1.4 System Testing. System testing may be started as soon as the software product is completed. System testing should be performed by independent personnel and should include system users (i.e., operators and maintenance personnel) to evaluate interfaces, system performance, and system response.

System testing should include stress testing the system's performance to ensure software requirements are met under transient overload conditions. The response time to urgent events, the schedulability, the performance margin, and the stability of the system should be assessed. Computer program reliability should be measured during the software system test.

At the end of the software system test, integration testing with operational hardware and other computer program interfaces should be performed to ensure the computer program will properly perform in the intended operating environment. With multiple integrated systems, additional testing may be performed to ensure that all related systems exchange data seamlessly, verifying a system's ability to operate as expected with other systems within the same environment.

Additional guidance on system testing may be found in IEEE Std 1012, IEEE Standard for Software Verification and Validation.

(24) **405.1.5 Factory Acceptance Testing.** Acceptance testing may include factory acceptance testing (FAT) performed at the vendor's or supplier's facility under the control of the purchaser on the version of the computer program to be delivered. FAT should be considered for computer programs that are custom developed by a vendor. Frequently FAT is performed for acquired integrated hardware and software systems such as control systems or other real-time systems. FAT should include exercising the computer program in an environment comparable to the environment in which the computer program will be used. This testing may include testing of associated hardware, and simulation of data inputs or control signals. FAT should provide interim results that acquired software, and if applicable computer hardware, meet contract or purchase order specifications derived from the software requirements prior to delivery to the customer.

405.1.6 Installation Testing. Prior to site acceptance testing, the computer program should be deployed, installed, and controlled in the approved operating environment in accordance with approved procedures and instructions. Installation tests should be executed independently, to the extent practical. Installation tests should include tests for the presence of all necessary files, as well as the contents of the files; hardware devices; and all computer program components (e.g., underlying executive version, firmware in displays, and anything to which the software could be sensitive).

Installation tests should test response, calibration, functional operation, and interaction with other systems. Interfaces that were simulated during integration or factory acceptance testing should be exercised.

Installation data, including test results, should be under configuration control.

405.1.7 Site Acceptance Testing. Acceptance testing is performed at the end of the software development cycle to provide adequate confidence that the software satisfies the requirements and performs correctly in its operating environment. It is imperative that the acceptance testing be completed before releasing the software for use (i.e., the operation and maintenance activity).

Acceptance testing should be performed in an environment comparable to the environment in which the computer program will be used. Testing, using documented test plans, test cases, and results is the primary method of acceptance testing. These tests should also include exercising the computer program in an environment comparable to the environment in which the computer program will be used. This testing may include testing of associated hardware, and simulation of data inputs or control signals. Site acceptance testing performed by the purchaser should be done to ensure that no damage was incurred during shipment, and confirm proper implementation in the operating environment.

If testing is to be performed in a production environment, then extra rigor and due diligence are strongly recommended to ensure there are no unacceptable consequences from the testing.

Additional guidance on acceptance testing may be found in IEEE Std 1012, IEEE Standard for Software Verification and Validation.

405.2 Test Plans and Test Cases. Test planning should identify the types and level of testing to be performed over the life of the computer program, and as appropriate the computer hardware and operating system. Testing types include those discussed in para. 405.1 of this Subpart. Test planning should identify the basis for establishing the test criteria as well as the acceptance criteria for the overall testing activity. Test planning should identify required and optional reports and records, as well as any required report formatting and conventions. Test planning should be documented, independently reviewed, and approved by the appropriate organization prior to approval of the computer program for use.

Test cases may include

(a) written step-by-step instructions executed by a tester(s)

(b) test scripts executed by a test program or batch processing system that meets the requirements of Part II, Subpart 2.7, section 600

(c) other methods that cause the computer program to be executed producing results that are subsequently evaluated against the acceptance criteria

Unit test cases and integration test cases may not be required to be documented, reviewed, or approved. For system testing, installation testing, and site acceptance testing, test cases should be documented, independently reviewed, and approved by the appropriate organization.

Test cases should identify any preliminary steps to be completed or conditions to be present prior to performing the steps associated with the primary purpose of the test case, as well as any steps to place the computer program or test environment back to its original state. These prerequisite and post-test steps may include editing database values, placing hardware into a specific state, or ensuring an interface is available. Test cases should be executed to ensure that the required ranges of input parameters are exercised. This action may require that a test case is executed multiple times with different values for the input parameters. The test cases should also identify how to proceed in case of a test failure.

For each step in a test case, required ranges of input parameters, expected results, and acceptance criteria should be documented.

Test documentation may be documented separately or combined, as appropriate, in accordance to the defined software engineering method.

405.3 Test Results and Test Reports. The test report should include

(a) details of the testing activities, including the computer program tested with a unique identifier such as a version number or build date

(b) description of the test environment including

(1) any test equipment used

(2) calibration date, if applicable

(3) computer hardware and associated operating system

(c) other software used such as simulation models or test scripts

(d) software interfaces

(e) names of individual(s) performing the tests

(f) testing date(s)

(g) results from each of the test cases

The test results should be evaluated by a person not directly involved in performing the testing of the computer program to ensure the computer program meets the overall acceptability to meet the documented requirements. This independent person(s) should document, including their name and signature, the evaluation and acceptability. Acceptability of the software is based on meeting the defined acceptance criteria for the testing performed. If the test results do not match the expected results within the defined acceptance criteria, justification for declaring acceptability should be provided. This documentation should be included in the test report.

The test report should also address any problems encountered during testing, how those problems were resolved, and who approved the resolution. The test report should identify any deviations from the approved test plan or test cases and who approved those deviations. The test report should be considered a quality assurance record, managed as per Part I, Requirement 17, and maintained until the computer program has been retired.

406 Operation

406.1 Use of Software. The software engineering method should provide a means to ensure that the software usage remains consistent with the approved software design and the approved acceptance testing results. (24)

406.1.1 Identifying Changes in the Operating Environment. Changes to the operating environment (see Part II, Subpart 2.7, para. 203) include changes to the operating system, support software, interface software (e.g., graphical user interfaces, structured query language, and network protocols), firmware, or hardware used for the execution of the computer program.

Changes may be planned and managed by the organization responsible for the computer program, by other institutional organizations such as an information technology group, or by cloud-based service providers. Changes in the operating environment may influence the operation of a computer program. Operating system changes may, for example, lead to variations in calculated results or variations in expected system responses to computer program actions.

Changes to the operating environment may be categorized by the operating system supplier as minor (e.g., update patches, security patches) or major (e.g., new operating system version or build number). Regardless of the supplier's categorization, the change should be evaluated for impact to the verified and validated functions of installed computer programs. The following are examples of changes that should require evaluation:

(a) Support software (e.g., software tools and system software) change examples include changes to dynamic libraries associated with compilers and changes to platforms where computer programs are executed (e.g., database software, spreadsheet software, operating systems, networking protocols).

(b) Interface software change examples include changes to graphical user interfaces used to communicate between programs and operators and changes to structured query language used to communicate between programs and networks.

(c) Firmware or hardware changes include, for example, a change in the processor type, the chipset associated with a particular processor type, networking devices, and online storage devices.

Prior to a major patch or upgrade, the operating environment organization should inform organizations responsible for software programs of the timing and scope of the planned change in order to proactively evaluate the need for additional in-use testing (see para. 406.2).

406.1.2 Evaluating Changes in the Operating Environment. Organizations implementing this Standard should evaluate changes to the operating environment and the effect of those changes on installed computer programs (see Part II, Subpart 2.7, para. 602). Organizations should establish criteria for the evaluation of such changes and establish the level and type of in-use testing required. The criteria should include consideration of the type, scope, magnitude of the change, impact to software baselines, ability of the organization to control change to the computing environment, and the frequency of changes. Organizations should also establish actions to be taken in the event of a failed in-use test.

When establishing criteria related to changes in the operating environment, organizations should consider the impact of those changes on the computational or control functions of installed computer programs previously accepted for use. Organizations may determine that changes are not significant and do not require in-use testing if those changes do not affect the baseline. Organizations should evaluate the impact of multiple changes, which are determined not to be significant, as a collective and evaluate the cumulative impact to the operating environment and baseline.

The process for determining the significance of changes may include evaluating information from the operating system, support software, or hardware supplier about the change. Deploying a proposed change to a test group or test environment may also inform the evaluator regarding the significance of changes. The output of the evaluation should determine the significance of the change on the installed computer programs needed to identify additional reviews and retesting. For critical computer programs, the operating environment may need to be frozen at the version in effect during final acceptance testing. The following table illustrates potential outcomes and recommended actions:

Evaluation Outcome	Actions
Changes not significant	No in-use testing recommended
Changes can potentially impact expected responses	In-use testing recommended
Changes are not allowed	Freeze operating environment

(24) **406.2 In-Use Testing.** In-use testing should document who is responsible for performing the tests. The testing should consider real-time systems and control systems that interface with hardware components. In addition to changes to the operating environment of the software, in-use testing verifies that the changes in the hardware, drift of signals as a result of hardware degradation, and changes to operational parameters do not affect the correct operation of the software.

The responsible organization may use the following methods to initiate in-use testing. Various tests may be packaged into a batch process that allows for automated testing and results comparison.

(a) For frequently used software, in-use testing should be performed periodically at a frequency based on the importance of the software and the frequency of changes to the operating environment.

(b) For software that is used infrequently, such as for design analysis, in-use testing may be performed before each use of the software. When infrequently used software is changed to being used routinely, the requirement in (a) becomes applicable.

(24) **406.3 Access Control.** Access control should address both the security of the computer system and the critical data that resides on the system. Both electronic (e.g., firewalls, network security measures) and physical (e.g., console) access should be considered. One method of ensuring system integrity is by employing unique user identifications in combination with a reliable password system. The concept of least privilege can also be implemented, which grants each user access to only the resources for which he has a legitimate need, at the lowest access level (read, execute, write, delete, etc.) required to perform the function. Other methods of physical access control include locks, security badges, or other forms of access to the computer system itself (e.g., using security guards).

406.4 User Documentation. The development of user documentation should be initiated early in the software development cycle. User documentation for the computer program should include, as applicable

(a) installation and checkout

(b) a description of the computer program including purpose, function, and limitations

(c) user instructions that describe how to use the computer program

(d) input and output specifications

(e) a description of system limitations including hardware and operational environment

(f) a description of user messages initiated as a result of improper input and how the user can respond

(g) information for obtaining user and maintenance support

(h) known problems and identified workarounds

(i) description of theory, mathematics, and algorithms

407 Maintenance

Changes to software that have been approved for use are controlled, and the methods for doing so should be identified in the software engineering method. The

rigor required for changes should be commensurate with the risk being taken, and should consider the importance of the software, the nature and extent of the change, and the risk of an adverse effect being introduced by the change.

Typically, revisions are in response to any of the following:

(a) enhancement requests
(b) changes to software requirements
(c) changes to the operating environment
(d) changes to computer system vulnerability protections
(e) reported software problems that must be corrected

408 Retirement

Software is considered retired when the software is no longer supported and no longer meets the criteria for routine use as defined by the responsible organization.

A process should be established for retired software that defines responsibilities for reporting and managing of identified problems and assessing the problem's impact during the software's previous use.

500 STANDARDS, CONVENTIONS, AND OTHER WORK PRACTICES

Software engineering standards, conventions, and other required work practices to be used during the software life cycle should be documented in the planning documentation as specified in Part II, Subpart 2.7, para. 401. These standards, conventions, and other work practices may include software engineering consensus standards, organizational documentation standards, industry or organizational coding standards, and industry-accepted symbols for design documentation.

600 SUPPORT SOFTWARE

Support software that is critical to the successful development, operation, or maintenance of a software product should be identified and evaluated to determine the extent to which configuration management, acceptance testing, and any other parts of the software engineering method are applied. Based on the role of the support software, the appropriate elements of the software engineering methods should be applied.

An example of support software that is key to successful development, operations, and performance of the computer program is a compiler. Changes in compiler options or a new revision, even without a change in the source code can have negative impact on the computer program.

601 Software Tools (24)

Examples of types of software tools are integrated development environment (IDE), comparators, cross-reference generators, compilers, configuration and source code management software, decompilers, disassemblers, test case generators, dynamic analyzers, spreadsheet applications, document preparation, debuggers, and editors.

602 System Software

Examples of types of system software are interpreters, diagnostics, utilities, operating systems, device drivers, and assemblers.

700 REFERENCES (24)

The following is a list of publications referenced in this Subpart.

IEEE Std 7-4.3.2-2003. IEEE Standard Criteria for Digital Computers in Safety Systems of Nuclear Power Generating Stations. Institute of Electrical and Electronics Engineers, Inc.

IEEE Std 1003.1-2008. IEEE Standard for Information Technology — Portable Operating System Interface (POSIX(R)). Institute of Electrical and Electronics Engineers, Inc.

IEEE Std 1008-1987. IEEE Standard for Software Unit Testing. Institute of Electrical and Electronics Engineers, Inc.

IEEE Std 1012-2012. IEEE Standard for System and Software Verification and Validation. Institute of Electrical and Electronics Engineers, Inc.

IEEE Std 1028-2008. IEEE Standard for Software Reviews and Audits. Institute of Electrical and Electronics Engineers, Inc.

ISO/IEC/IEEE 24765:2010(E). Systems and software engineering — Vocabulary. Institute of Electrical and Electronics Engineers, Inc.

IEC 60880:2006. Nuclear Power Plants — Instrumentation and Control Systems Important to Safety — Software Aspects for Computer-Based Systems Performing Category A Functions. International Electrotechnical Commission.

SUBPART 3.2-2.7.2
Implementing Guidance on the Requirements of ASME NQA-1, (24) Parts I and II for Software Used for Nuclear Facility Applications

(24) 100 GENERAL

This Subpart provides nonmandatory guidance on identification, flow, and interdependency of the requirements for software used for nuclear facility applications. The Subpart is based on the NQA-1-2008 Edition with the 2009 Addenda of the Standard, but the information has some application to previous and subsequent editions of the Standard. While the Standard includes requirements for assuring quality of the items and services provided to support the overall organizational objectives, the Standard also includes those requirements for acquiring, developing, testing, verifying, validating, operating, maintaining, and retiring computer programs used in nuclear facility applications. These requirements for software are interspersed within the Standard. The Subpart discusses the requirements applicable to software within the 18 requirements of Part I, the supplemental requirements of Part II (Subparts 2.7 and 2.14), and the guidance of Part IV, Subpart 4.1 of the Standard.

101 Terms and Definitions

The Subpart introduces no new terms or definitions related to software or computer programs used for nuclear facility applications. The Subpart uses commonly accepted flowchart symbols that were first introduced by Frank Gilbreth to the members of ASME in 1921.[1] The legend associated with the flowchart identifies the symbols used and provides their corresponding meaning.

These diagrams represent the flow of information within the Standard, not the flow of the governed processes. Sometimes the information flow divides into parallel paths, one or more of which may be applied concurrently on an "as applicable" basis. Mandatory paths, processes, and deliverables (notated with solid lines) are always applicable, whereas optional paths, processes, and deliverables (notated with dashed lines) are contingent upon the circumstances.

[1] Frank Bunker Gilbreth, Lillian Moller Gilbreth (1921), presentation "Process Charts — First Steps in Finding the One Best Way," ASME.

200 FLOWCHART APPROACH

This Subpart organizes the requirements for software of the Standard into 12 software and NQA-1 related processes that are pictorially illustrated in a series of flowcharts. These 12 processes apply to software and include processes uniquely applicable to computer programs. The processes are

(a) software engineering
(b) software design requirements
(c) software configuration management
(d) support software and tools
(e) problem reporting and corrective action
(f) software design
(g) software reviews
(h) software design implementation
(i) computer program testing
(j) software operation, maintenance, and retirement
(k) software acquisition
(l) computer program use in design analysis

The flowcharts introduce no new requirements for software. The majority of the requirements presented in the flowcharts are in the exact language of the Standard. In those instances where the language of a requirement is modified, clarified, or interpreted, it is specifically noted. Each process or flowchart presents the initial requirement, illustrates how that requirement flows through the Standard, and finally, identifies any related requirements.

201 Flowcharts

Figures 201-1 through 201-12 provide a pictorial illustration of the Standard's computer program requirements in Parts I and II for the processes described above, their flow through the Standard, related requirements, and any interdependencies between these requirements. These flowcharts are provided for guidance and illustration only and do not necessarily present all considerations that have to be made to ensure compliance with the Standard.

202 Legend

Figure 202-1 of this Subpart provides the legend for the flowcharts described in section 201 of this Subpart.

Figure 201-1
Software Engineering

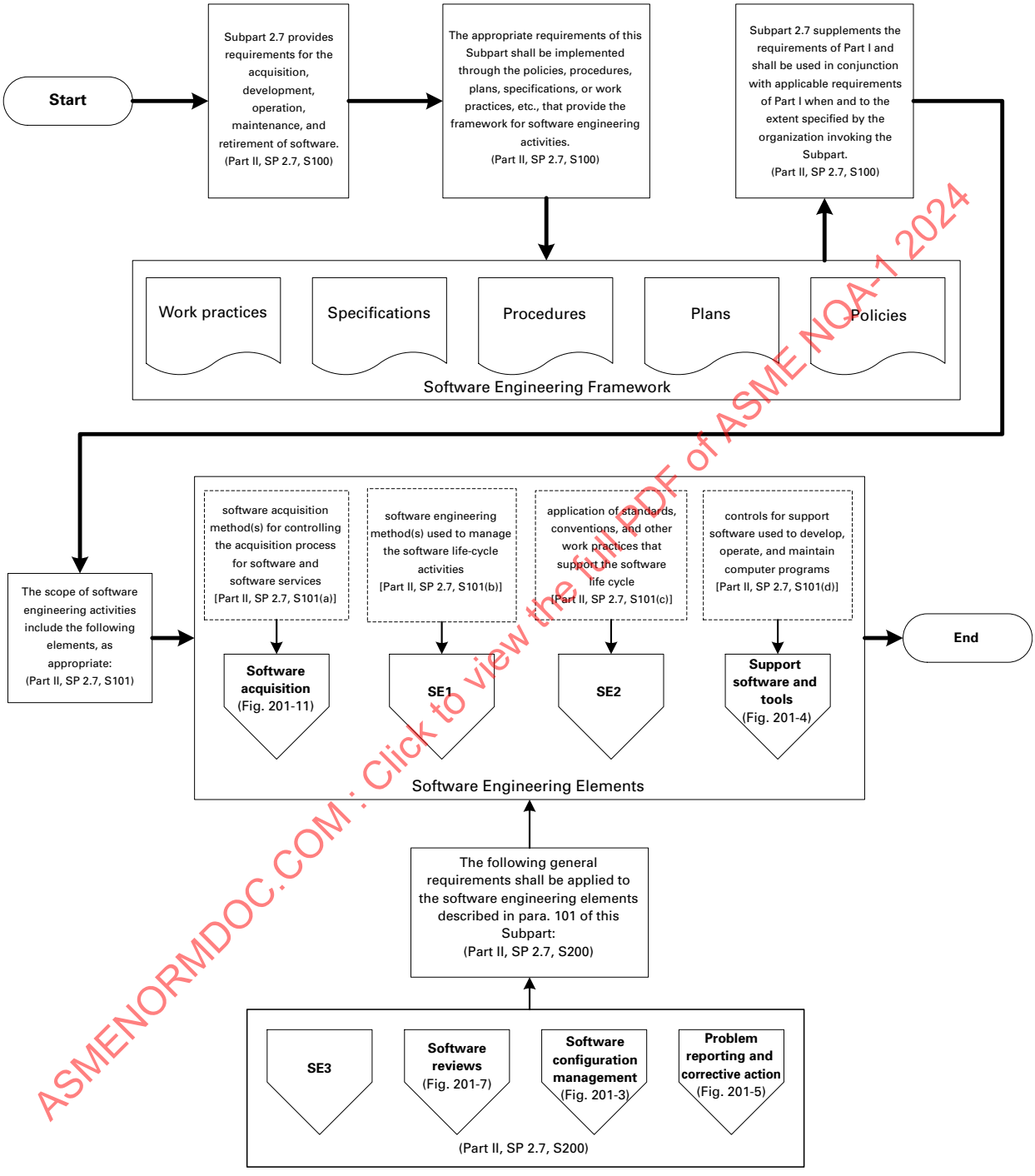


Figure 201-1
Software Engineering (Cont'd)

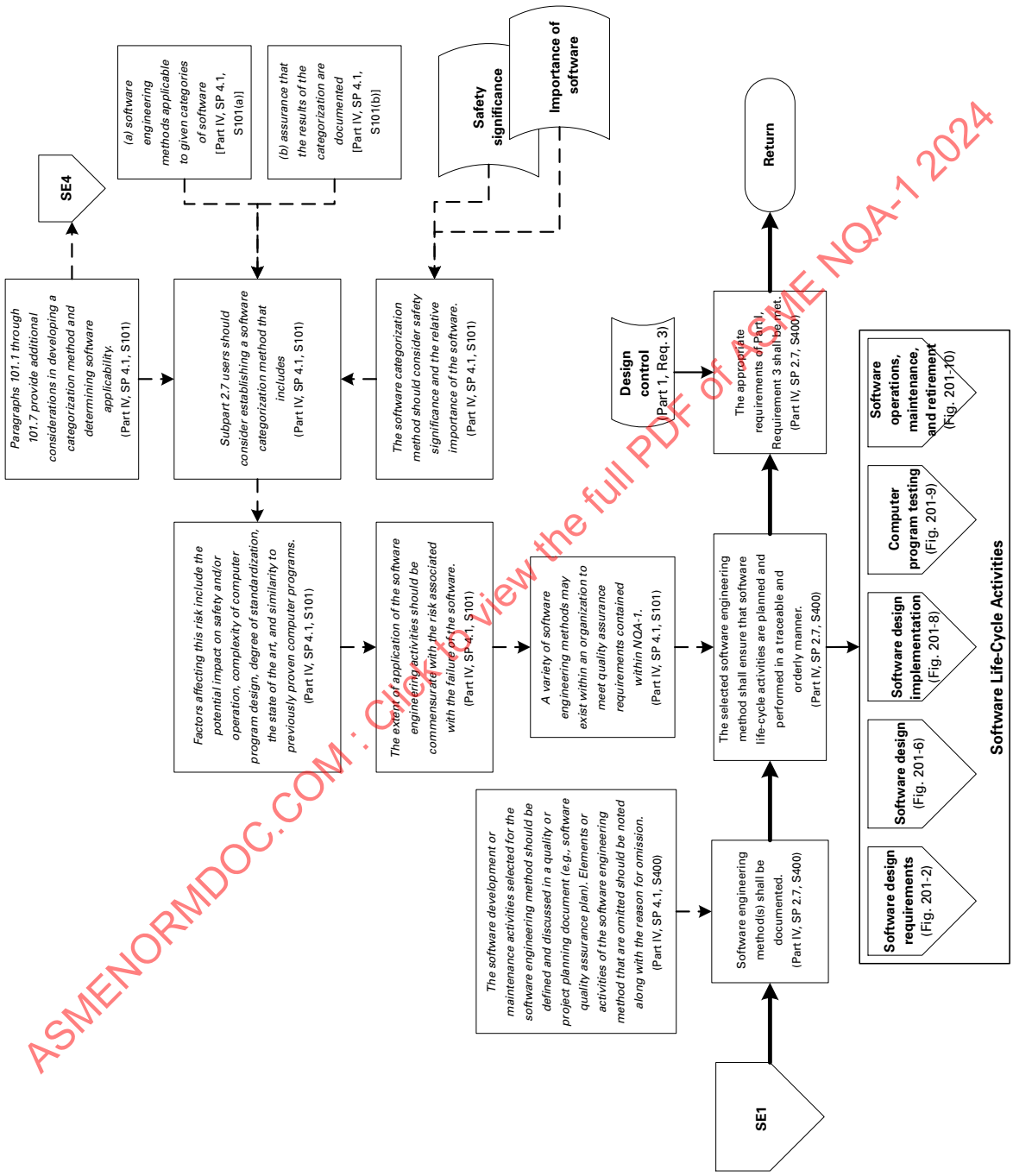


Figure 201-1
Software Engineering (Cont'd)

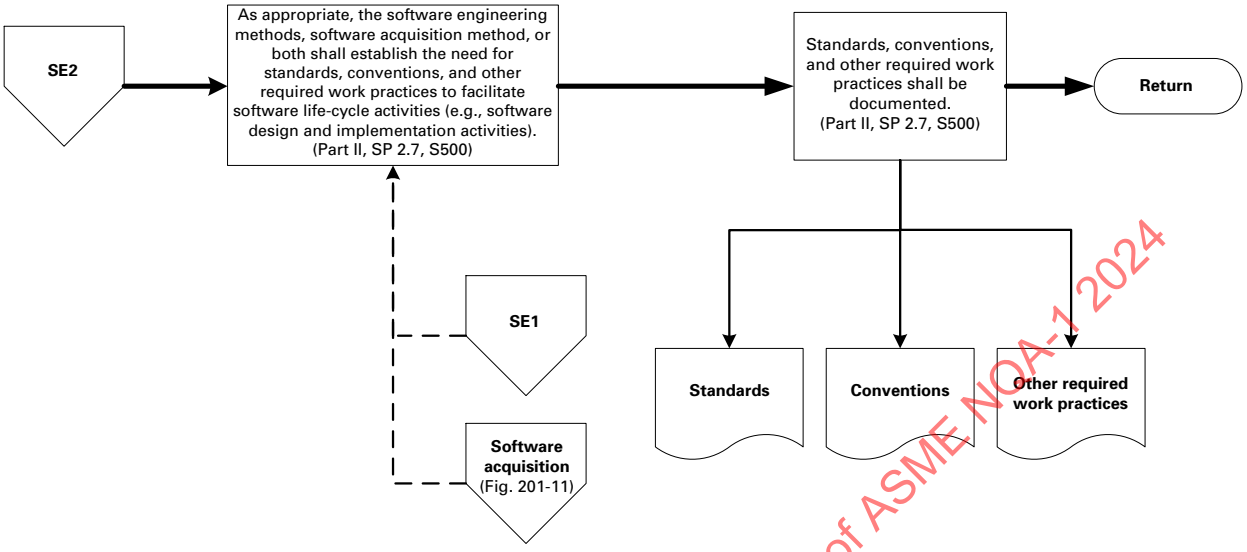


Figure 201-1
Software Engineering (Cont'd)

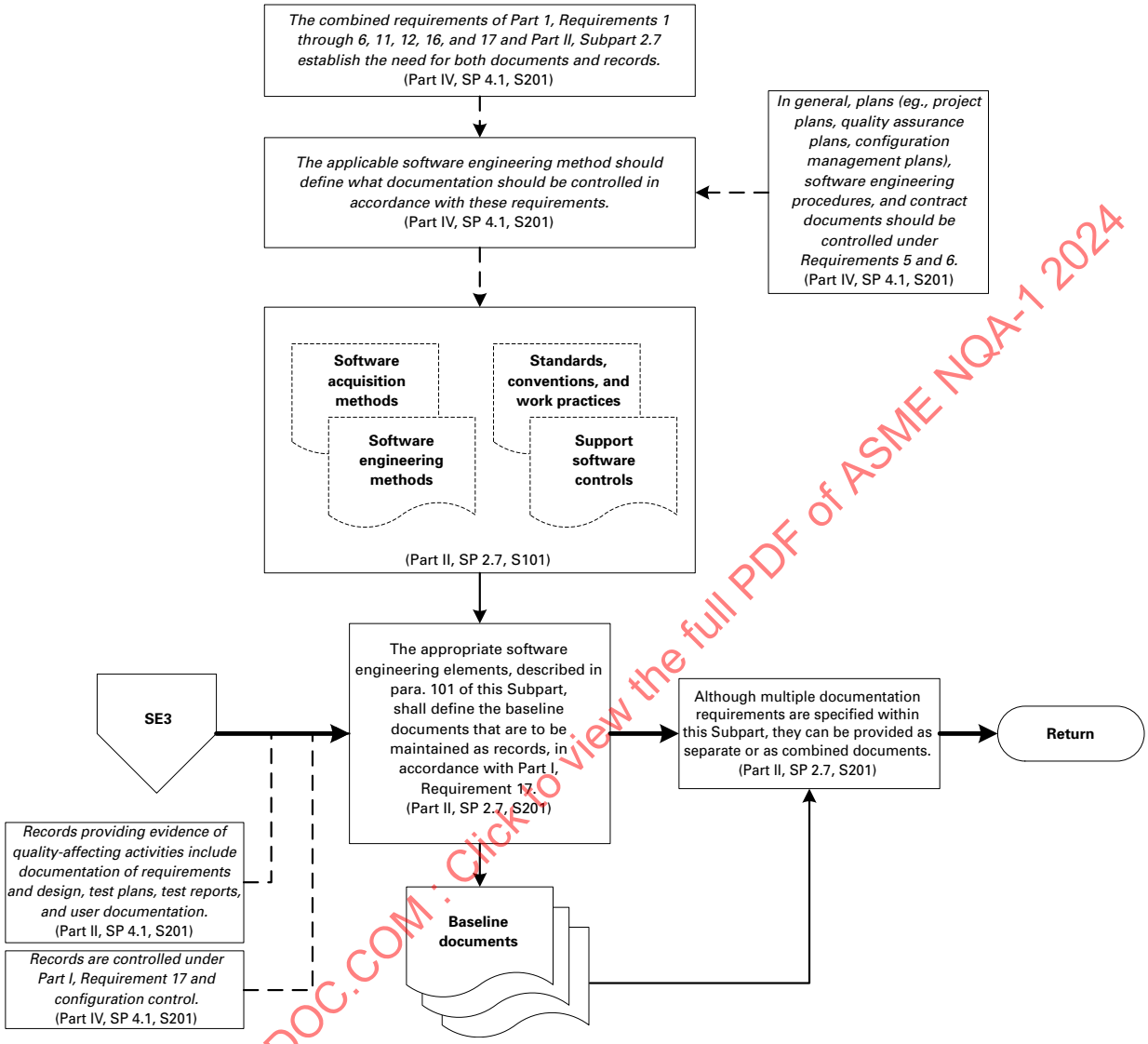


Figure 201-1
Software Engineering (Cont'd)

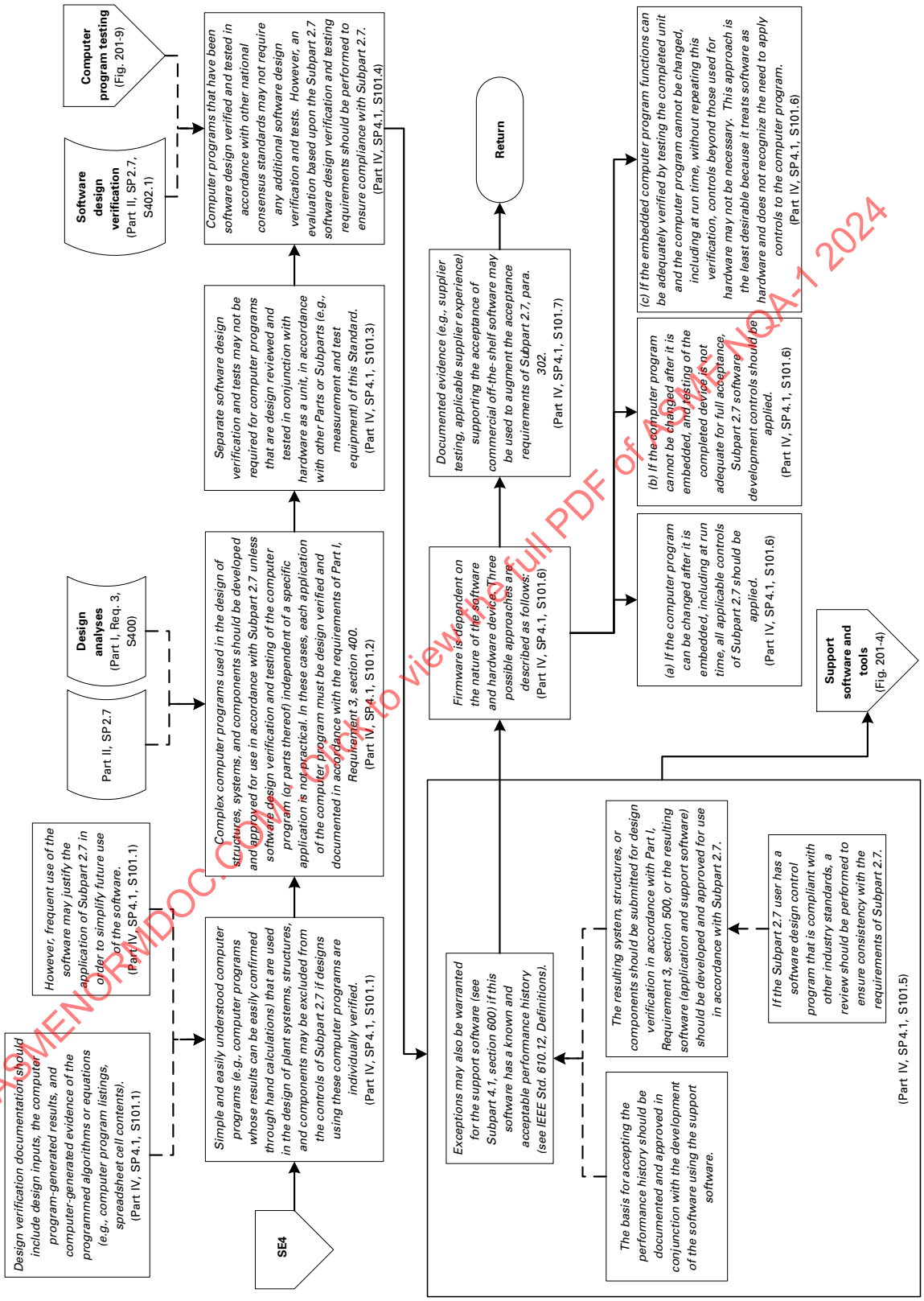
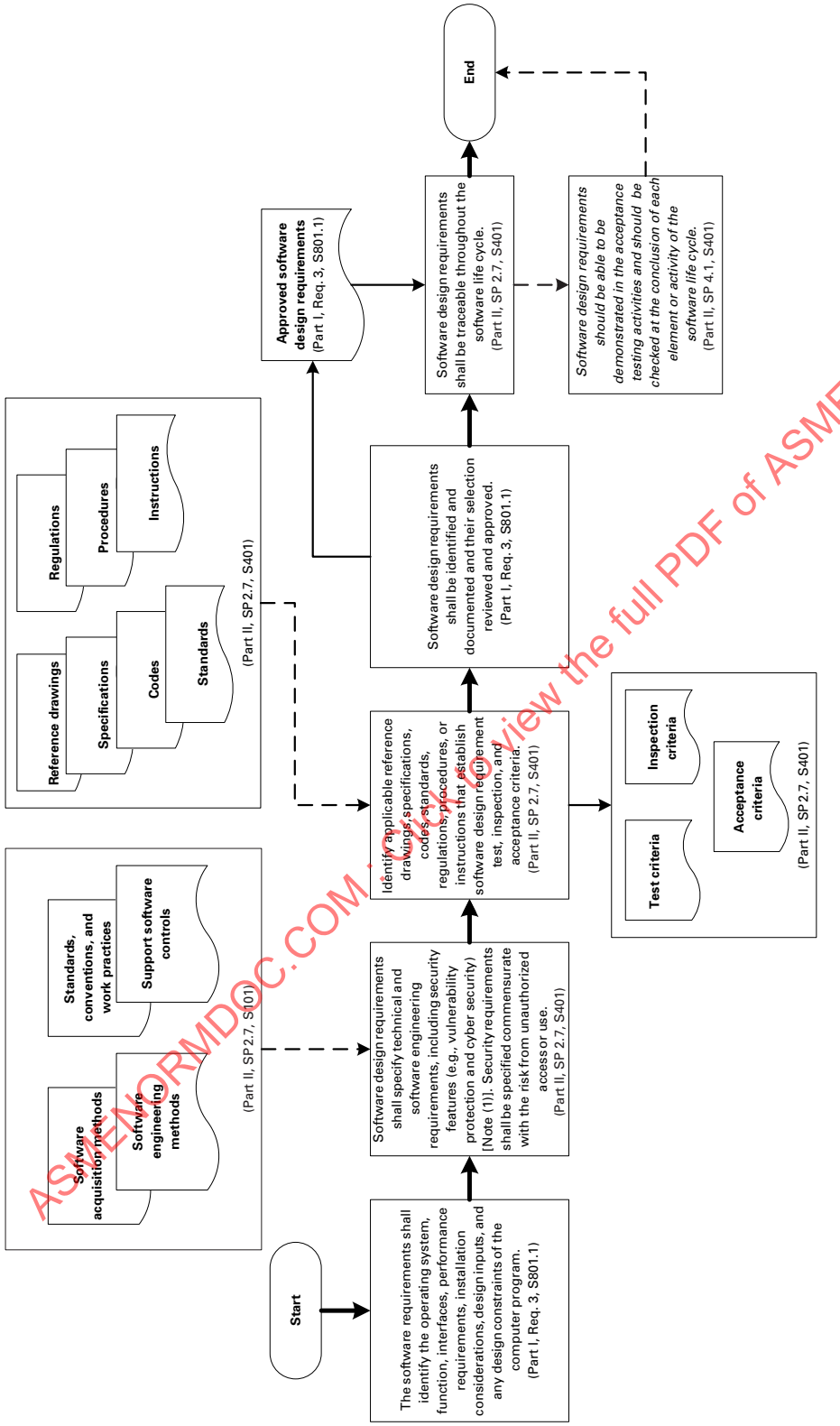


Figure 201-2
Software Design Requirements



NOTE: (1) See IEEE Std 7-4.3.2-1993, IEEE Standard Criteria for Digital Computers in Safety Systems of Nuclear Power Generating Stations.

Figure 201-3
Software Configuration Management

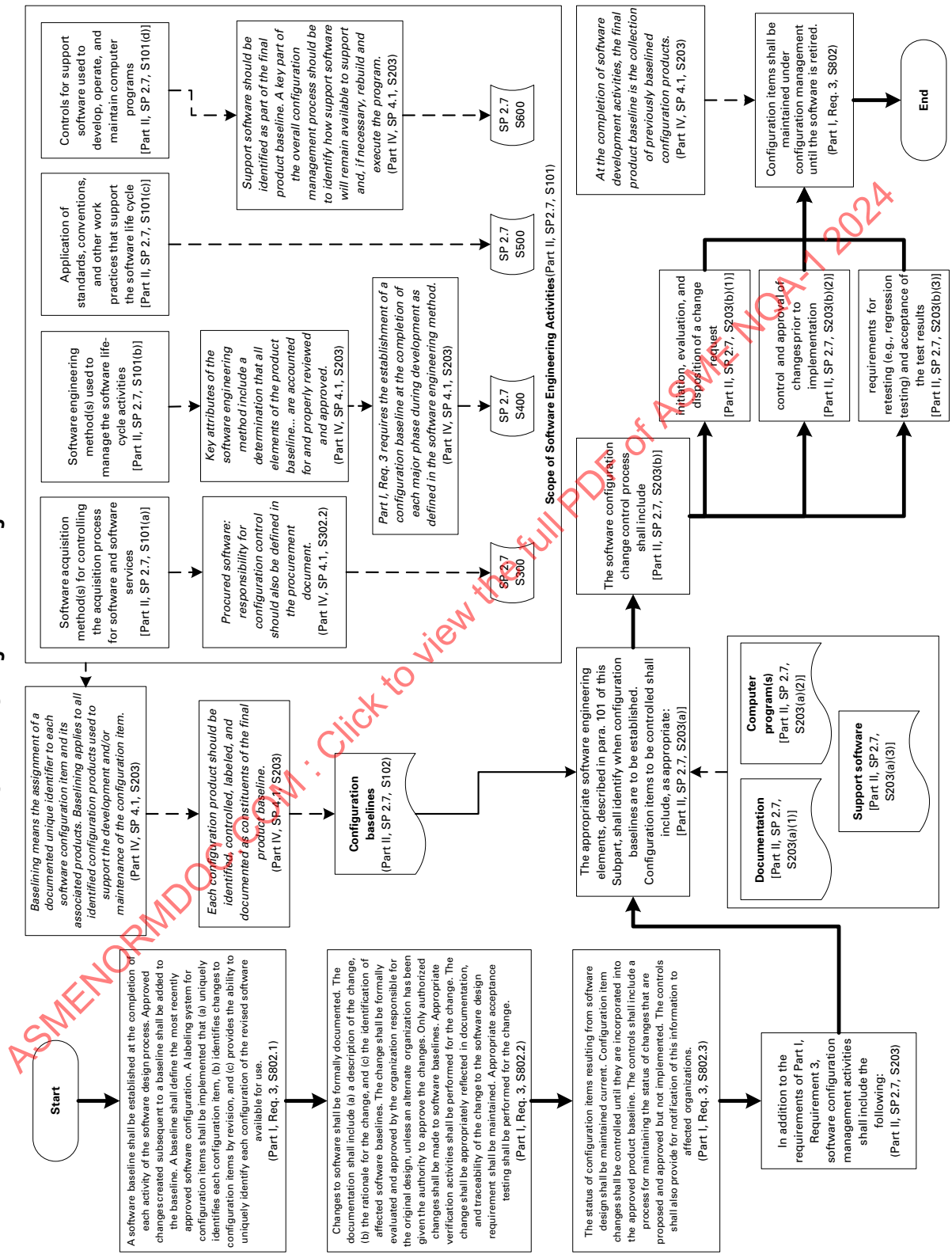


Figure 201-4
Support Software and Tools

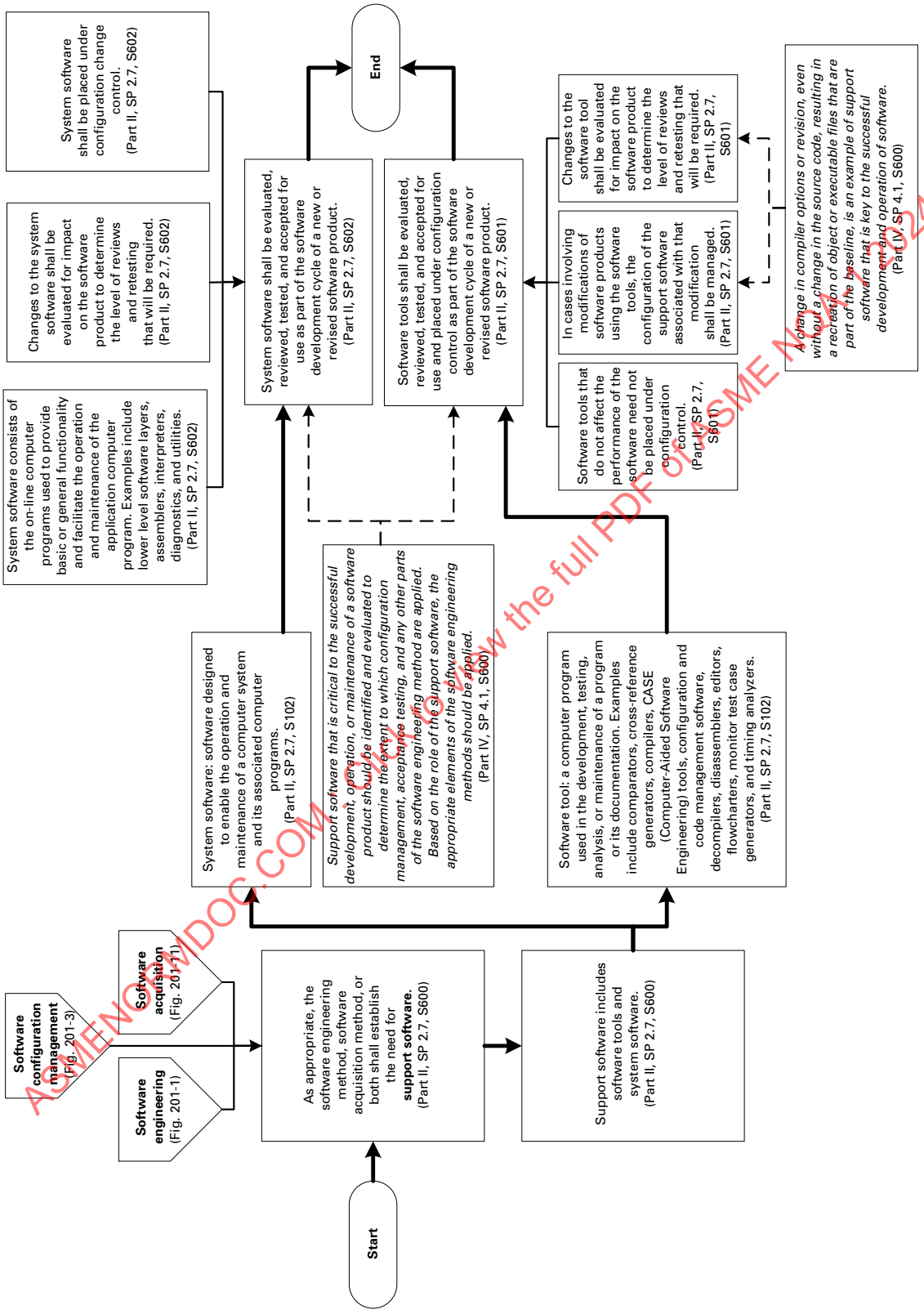


Figure 201-5
Problem Reporting and Corrective Action

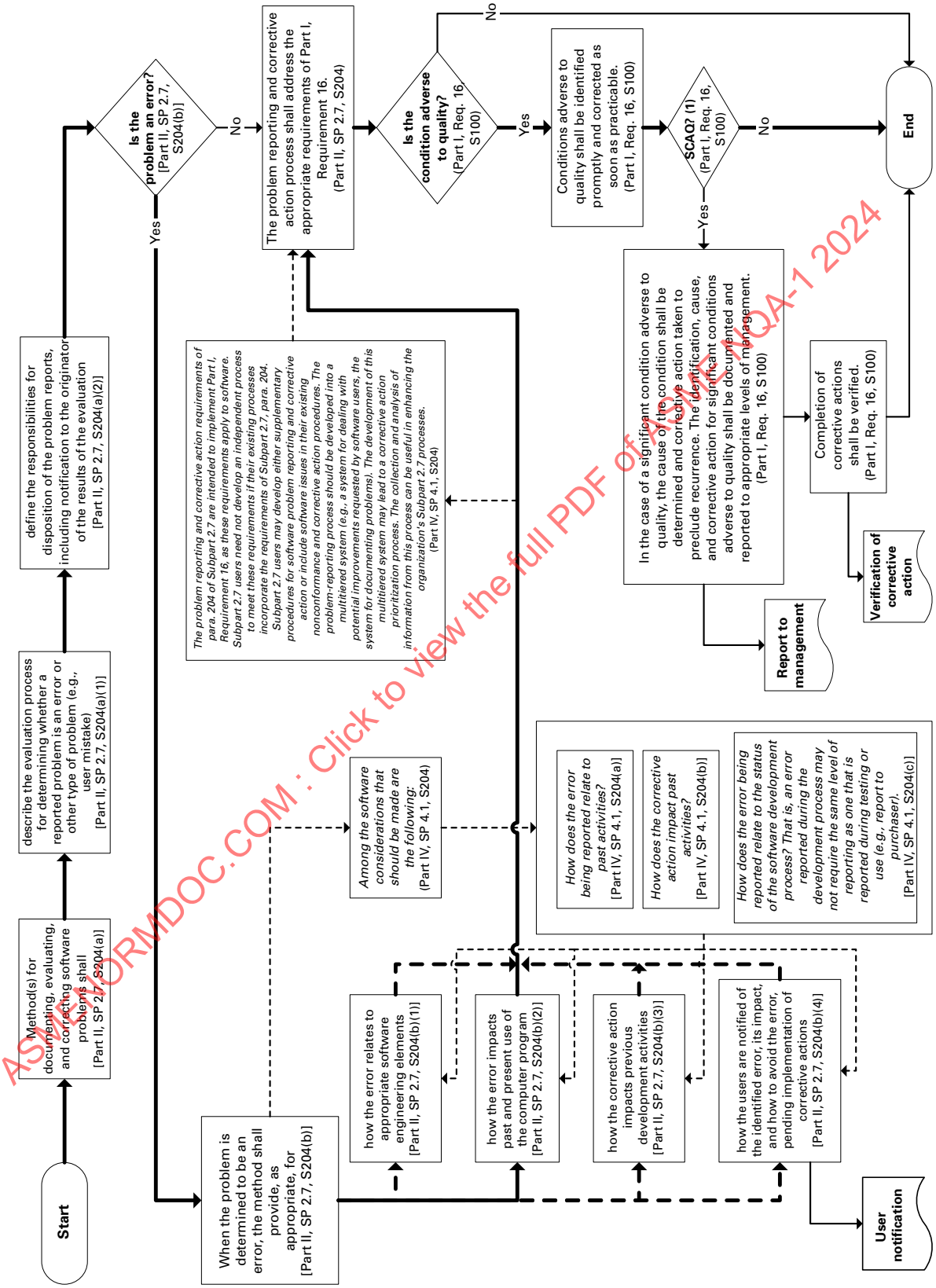


Figure 201-5
Problem Reporting and Corrective Action (Cont'd)

NOTE: (1) SCAQ = significant condition adverse to quality per Part I, Introduction, 400, definition of "condition adverse to quality."

Figure 201-6
Software Design

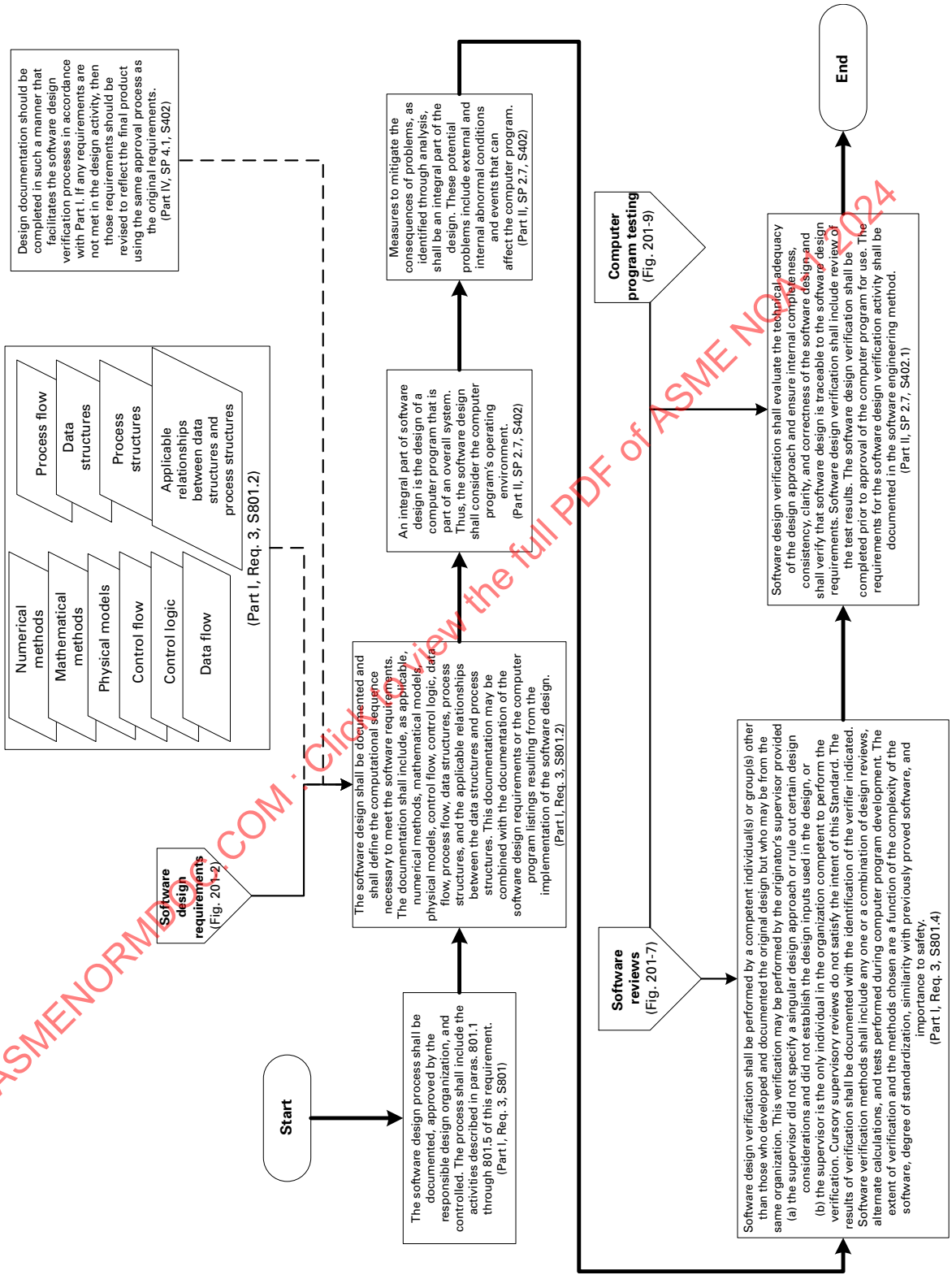


Figure 201-7
Software Reviews

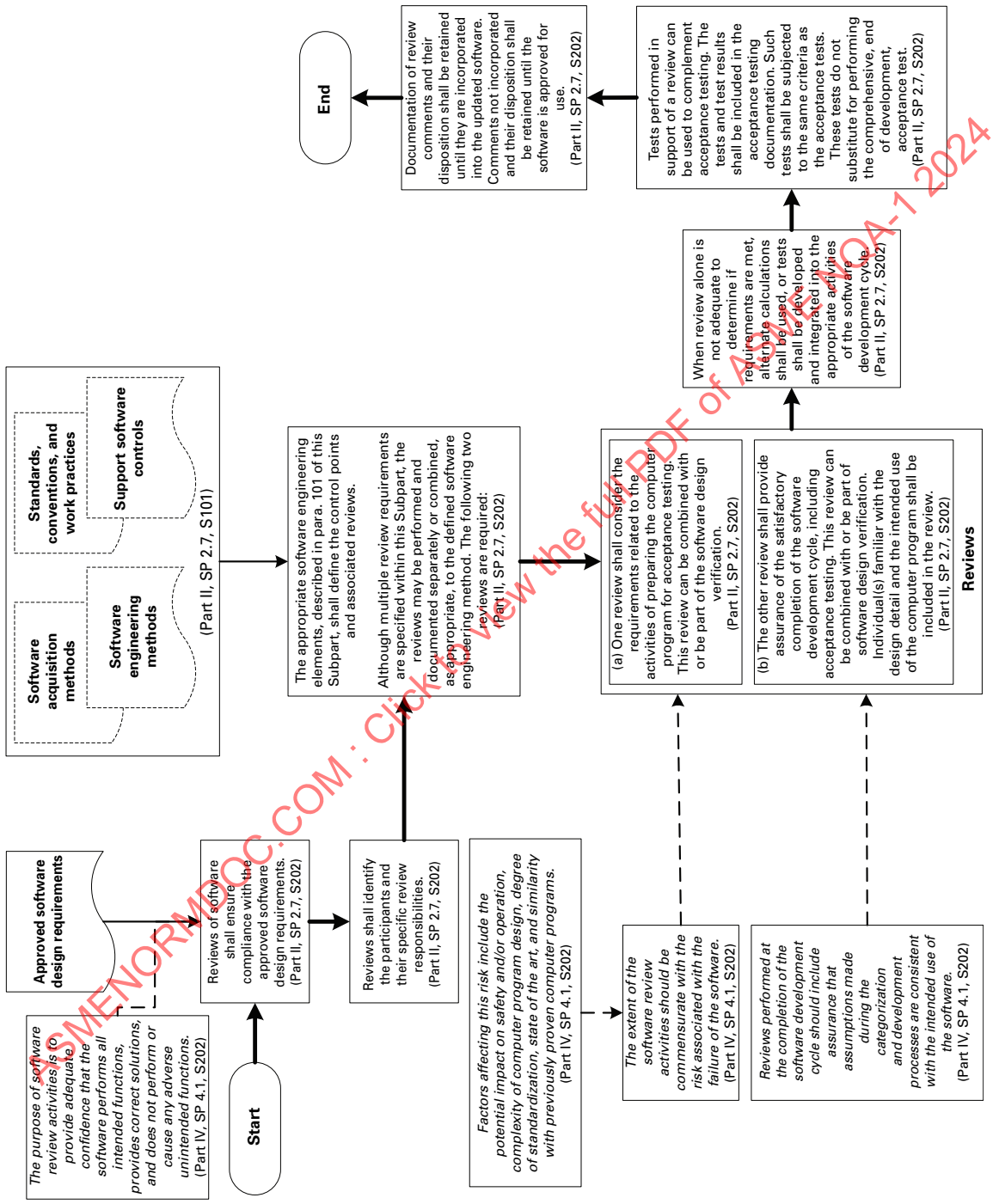


Figure 201-8
Software Design Implementation

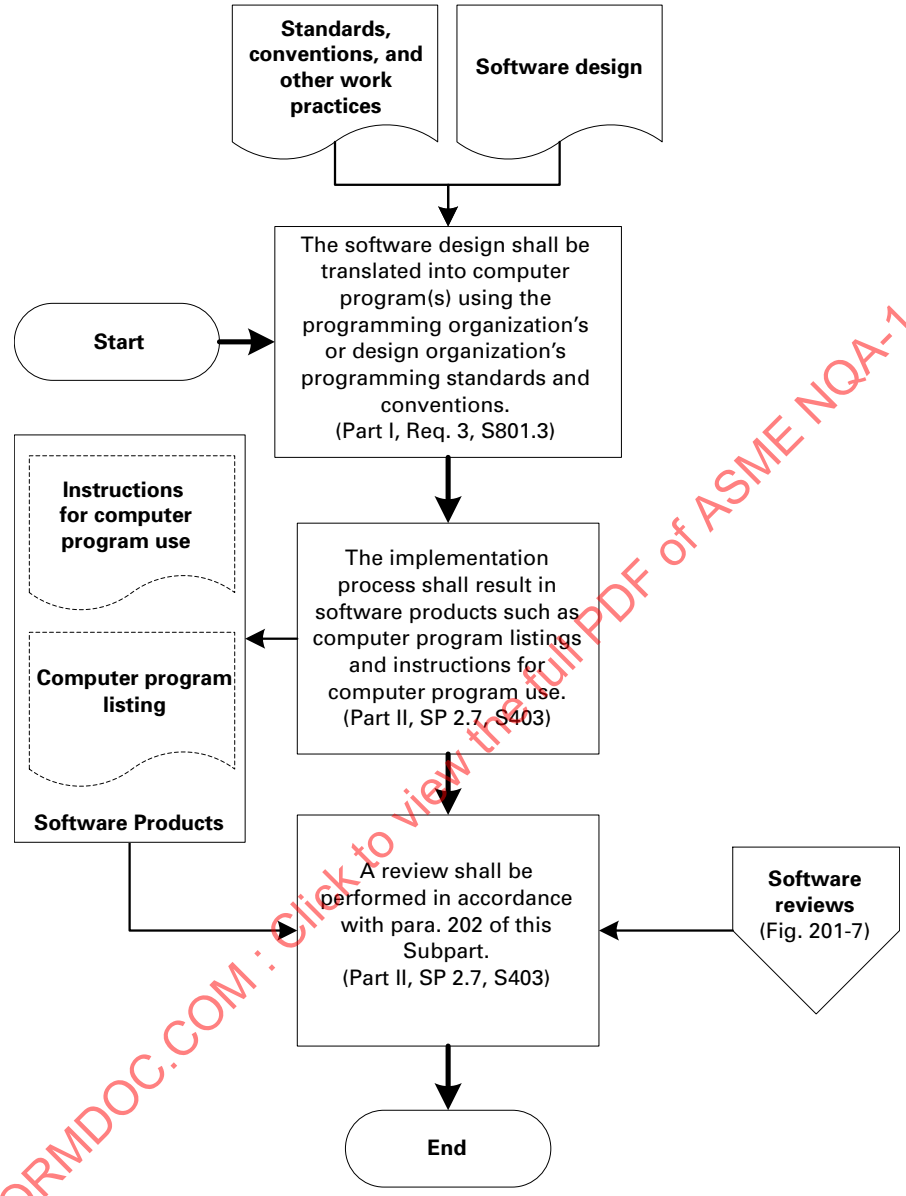


Figure 201-9
Computer Program Testing

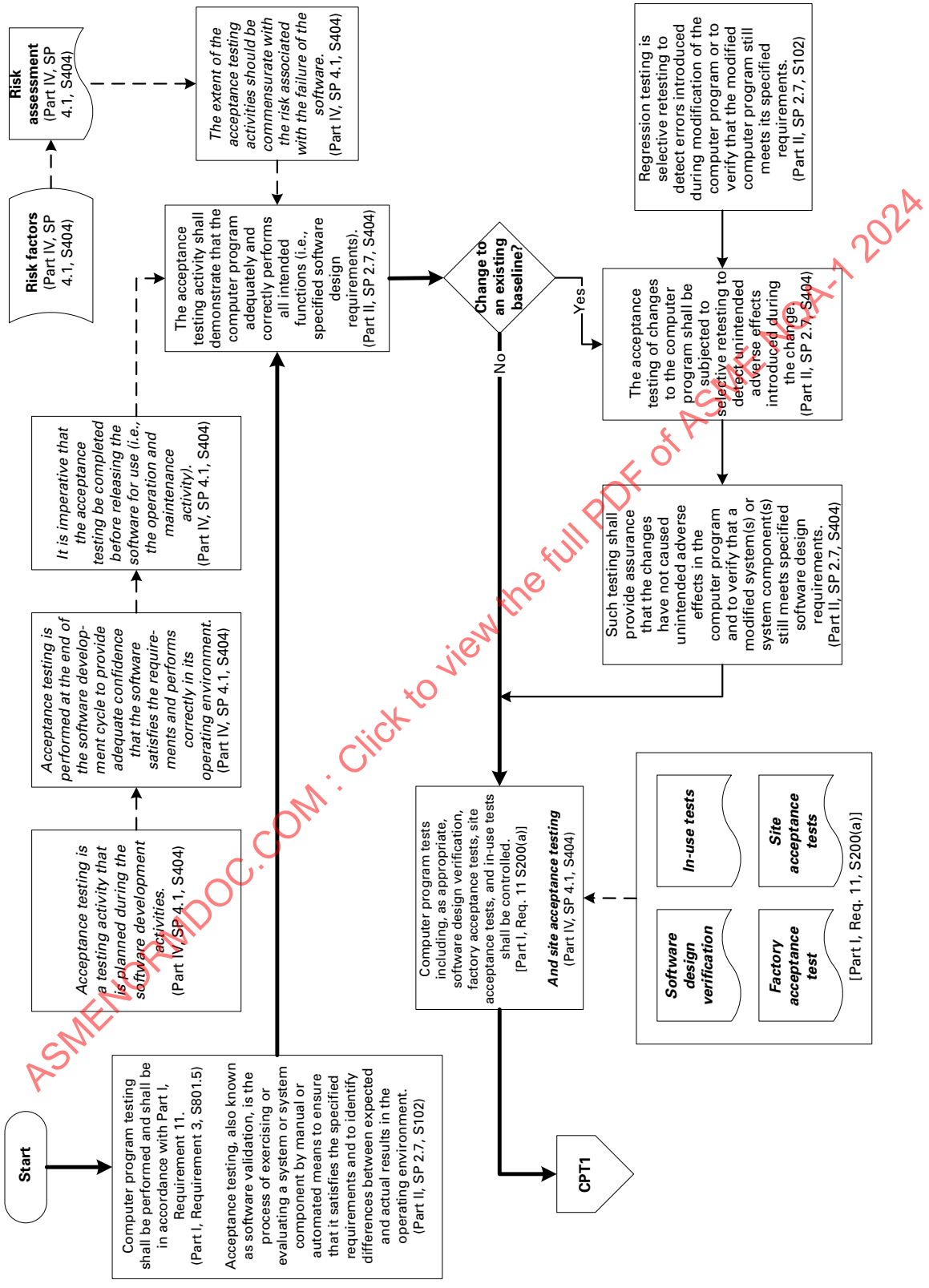


Figure 201-9
Computer Program Testing (Cont'd)

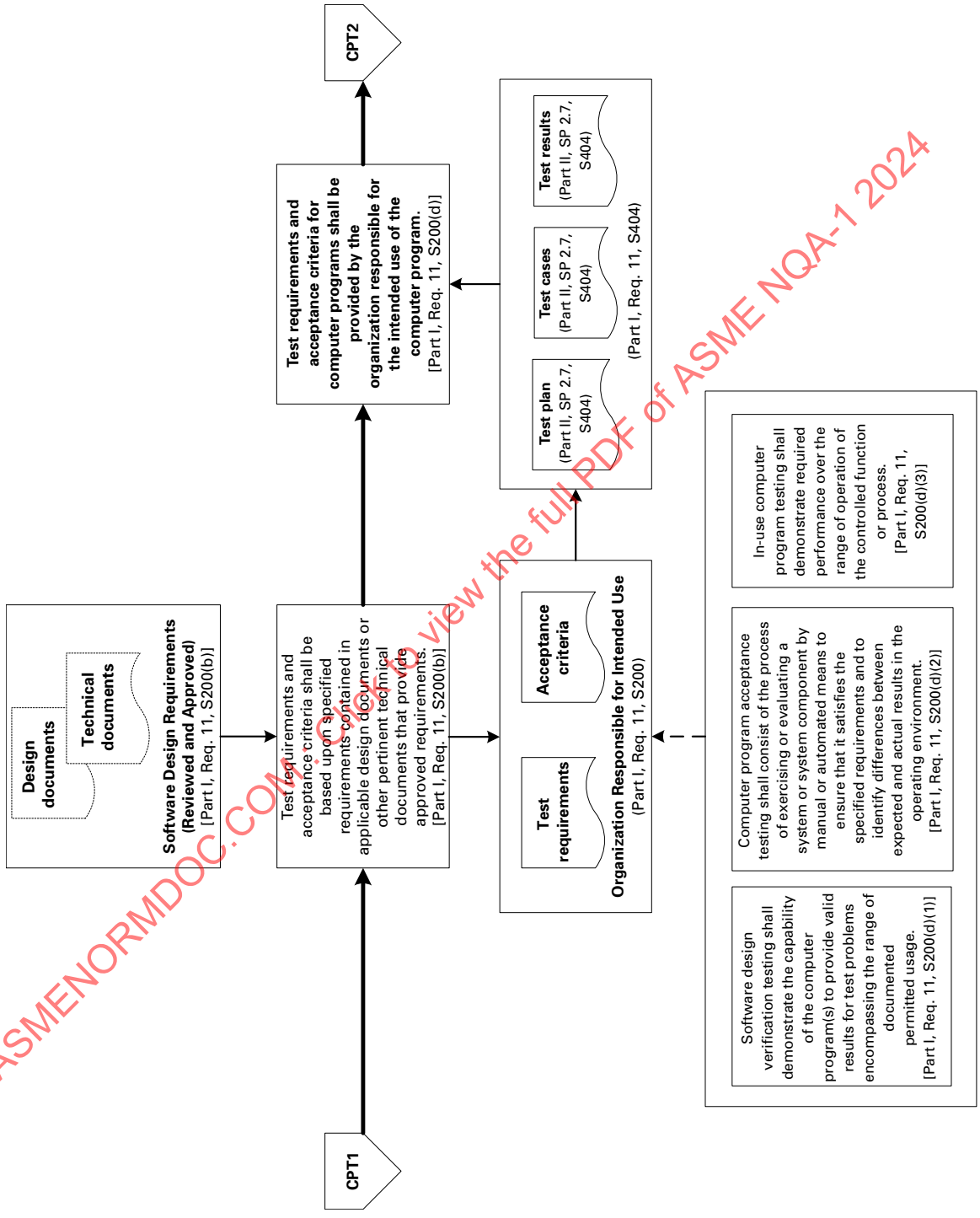


Figure 201-9
Computer Program Testing (Cont'd)

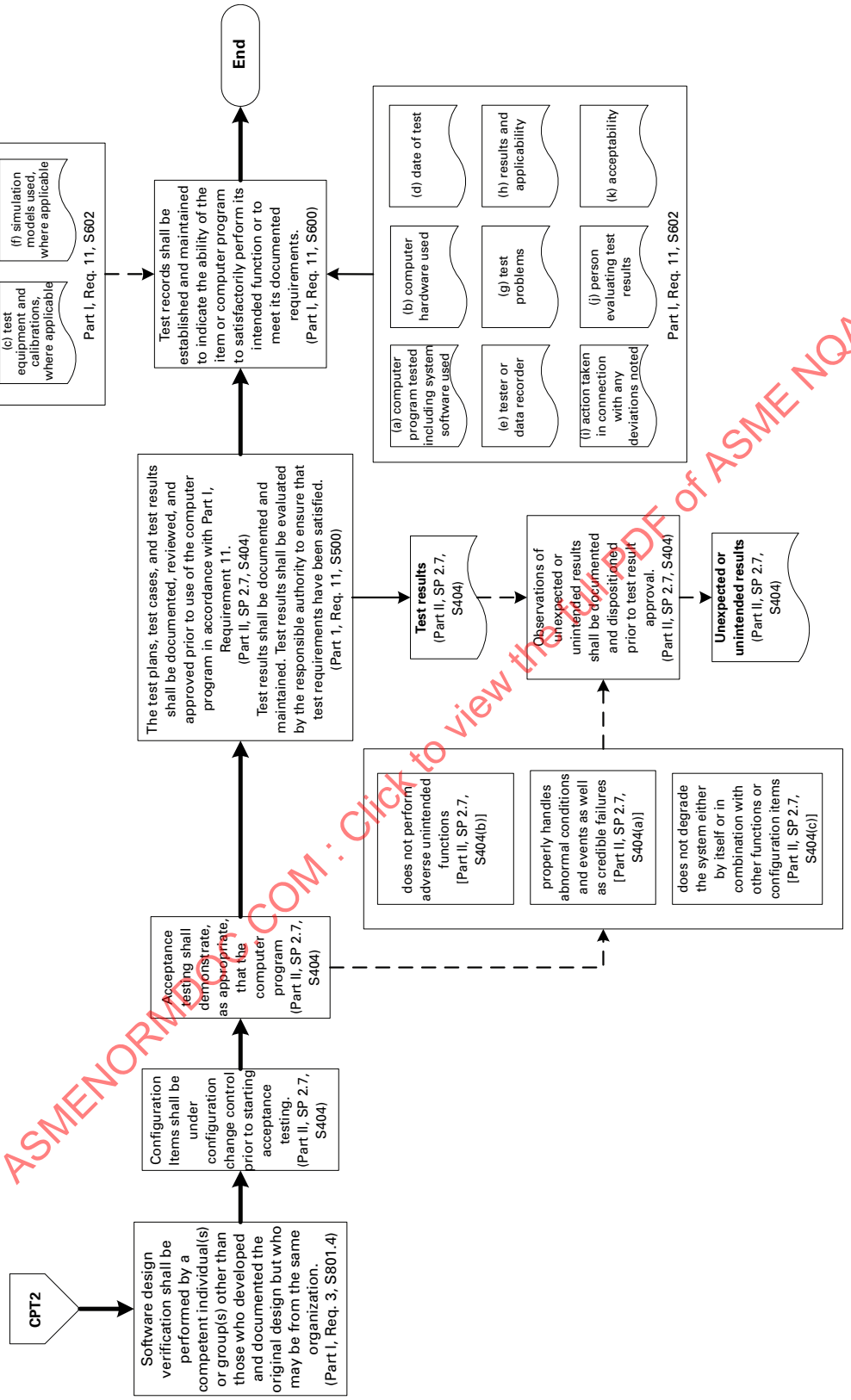
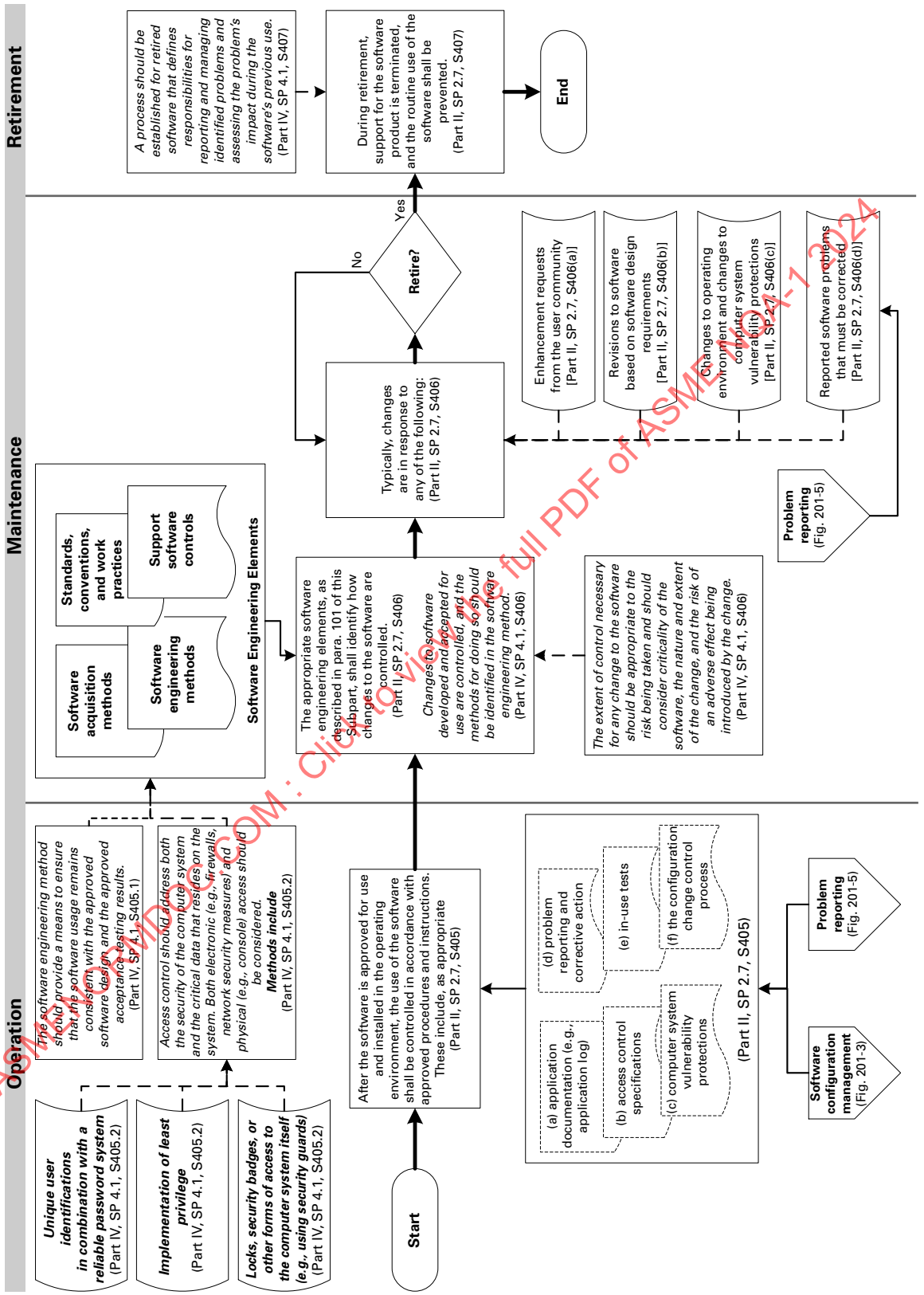


Figure 201-10
Software Operation, Maintenance, and Retirement



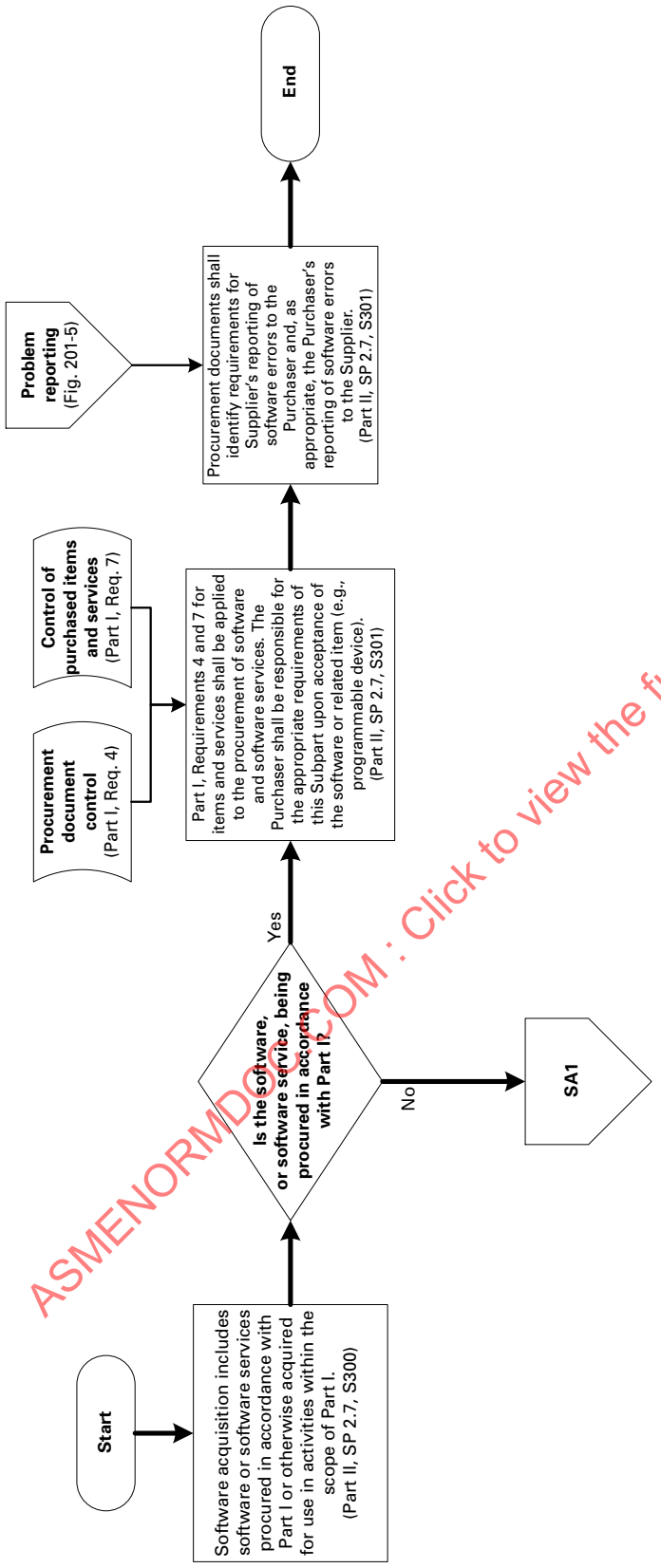
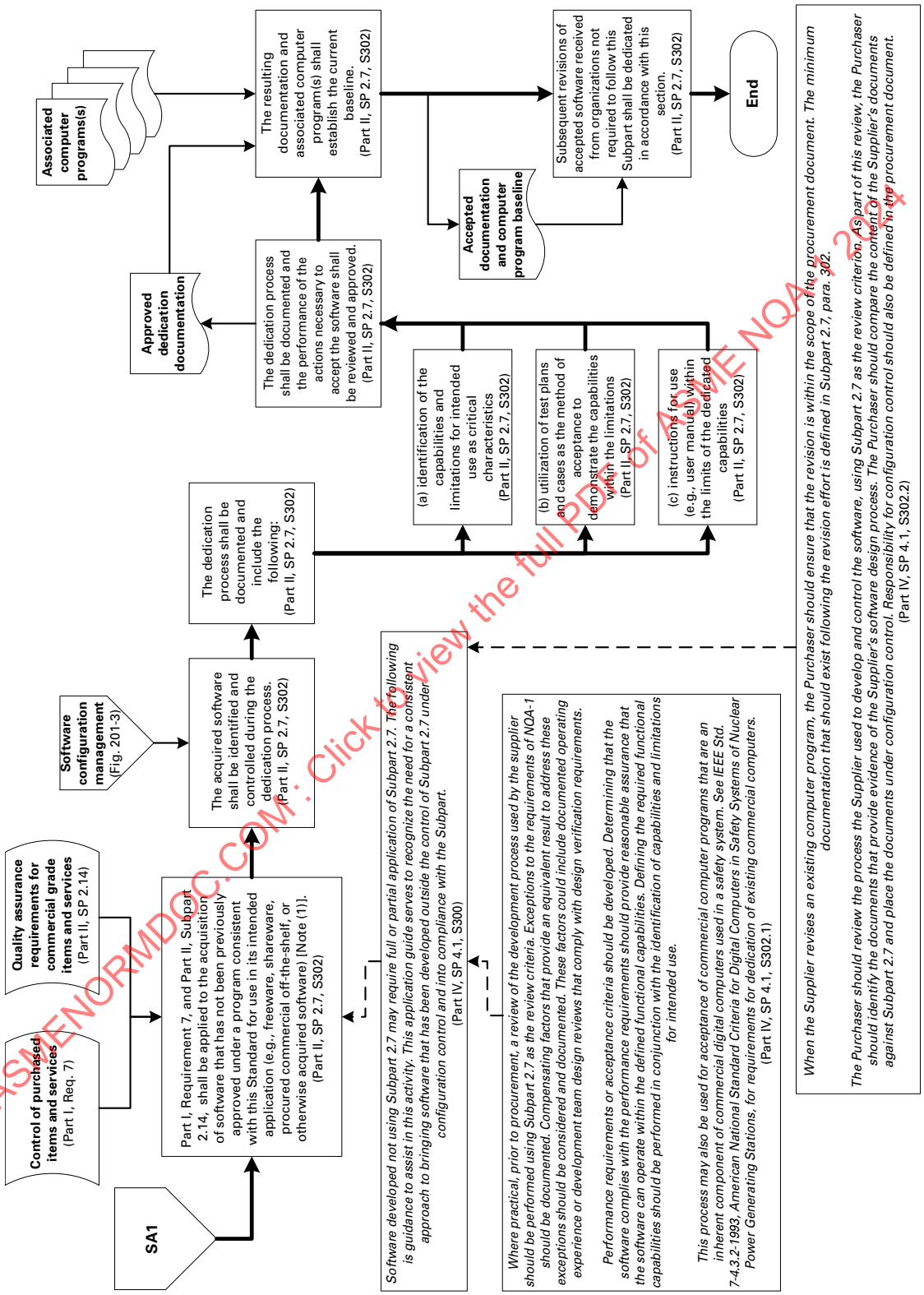


Figure 201-11
Software Acquisition

Figure 201-11
Software Acquisition (Cont'd)



NOTE: (1) NQA-1–2008 with the NQA-1a–2009 Addenda does not provide direction for otherwise acquired software that does not perform a safety function.

Figure 201-12
Computer Program Use in Design Analysis

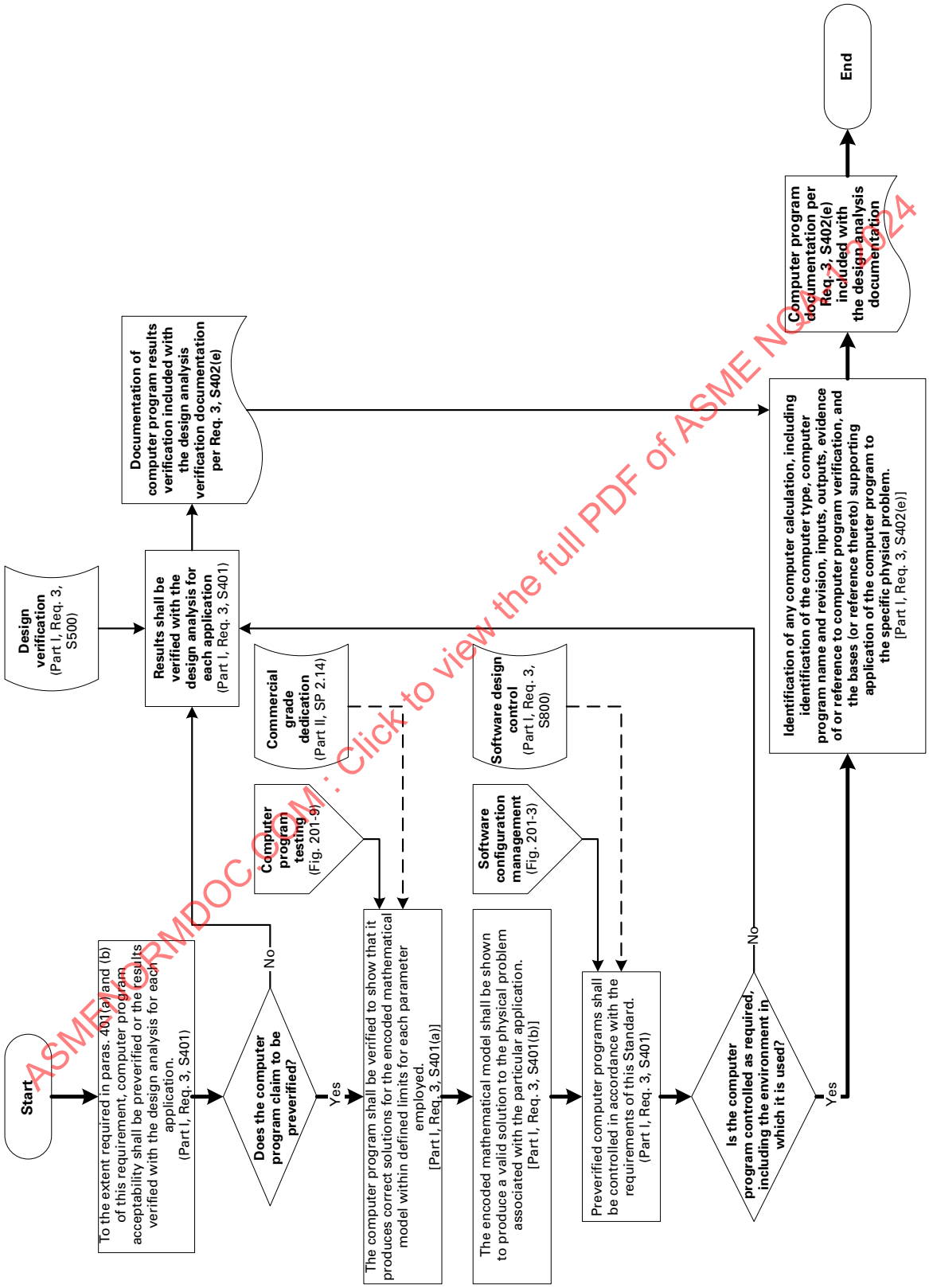
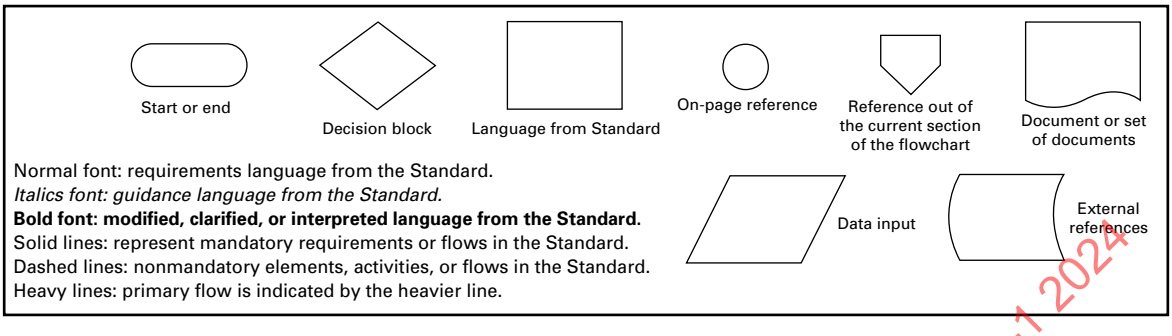


Figure 202-1
Legend for Flowcharts



SUBPART 3.2-2.14
Implementing Guidance for Part II, Requirement 2.14: Quality Assurance Requirements for Commercial Grade Items and Services, Commercial Grade Computer Programs, and Software Services

(24) 100 GENERAL

This Subpart provides nonmandatory guidance on applying Part II, Subpart 2.14 requirements to the dedication of commercial grade computer programs and software services as required by Part II, Subpart 2.7, para. 302. This Subpart applies to procured and acquired computer programs not installed in physical plant safety systems that support the performance of a safety function and that were not developed or approved under a program consistent with this Standard. The applicability of this Subpart is not dependent upon the type of computer equipment (e.g., mainframe, PC, networked workstations, controllers, or other digital equipment) on which the computer program resides.

As defined in this Standard, computer programs include real-time (e.g., operations or process control) as well as nonreal-time (e.g., design or analysis) computer programs. The application of commercial grade dedication for computer programs included in digital equipment that are installed in physical plant safety systems should be performed as part of the dedication process for that physical plant safety component. For these systems, the requirements of Part II, Subpart 2.14 apply, and existing industry guidance to meet the commercial grade dedication requirements of this Standard includes EPRI TR 106439, Guideline on Evaluation and Acceptance of Commercial Grade Digital Equipment for Nuclear Safety Applications, October 1996; IEEE 7-4.3.2-2010, Criteria for Digital Computers in Safety Systems of Nuclear Power Generating Stations, June 17, 2010; and EPRI TR 107330, Generic Requirements Specification for Qualifying a Commercially Available PLC for Safety-Related Applications in Nuclear Power Plants, December 1996. This Subpart does not provide guidance for real-time computer programs.

Part II, Subpart 2.7, paras. 302.1(a) through 302.1(c) describe the elements required for the computer program dedication process.

These elements can be addressed through implementing the commercial grade dedication process defined by Part II, Subpart 2.14. The identification of the capabilities and limitations for intended use should be addressed during the selection of the set of performance critical characteristics. Test plans and cases required to demonstrate those capabilities within the limitations should be exercised through special tests and surveys. Instructions for use within the limits of the capabilities should be identified through the selection of the physical or performance critical characteristic associated with a user's manual, online help, or other methods to assist the user in the proper operation of the computer program within the limits of the dedication.

101 Definitions

The following definitions are provided to ensure a uniform understanding of unique terms as they are used in this Subpart.

commercial grade computer program: a computer program that affects a safety function, which was not designed, developed, or approved in accordance with Part I and Part II, Subpart 2.7.

commercial grade computer program service: a service that was not provided in accordance with the requirements of this Standard and that affects the safety function of a computer program or the use of computer programs for design or analysis that supports a safety function.

dependability: a broad concept incorporating various characteristics of computer programs, including reliability, safety, availability, and maintainability (adapted from EPRI TR 106439).

digital equipment: equipment containing one or more computers.

200 DEFINITION APPLICATIONS

One of the concepts of a commercial grade dedication is a determination of whether the item meets the applicable definitions of a commercial grade item or service. Part I

states that computer programs that are a physical part of plant systems are included in the term *item*. It is recognized that computer programs that perform a design or analysis function in support of a safety function are not included in the definition of *item*. For this Subpart, the computer program should meet the definition of a commercial grade computer program or service to qualify for dedication. Computer programs that do not meet this definition are subject to the requirements of Part I.

(24) **300 UTILIZATION**

Part I, Requirement 3, para. 401 provides for two methods of verifying computer programs used in design or analysis of an SSC: preverification and verification of the computer program results after every use. Preverification of computer programs includes applying Part II, Subpart 2.7 in which this Subpart can provide needed guidance. When the results derived from the use of the computer program are independently verified for every use or application, the computer program is not required to be dedicated if the independent verification is performed to the requirement of this Standard. Using this latter method is not a substitute for commercial grade dedication of the computer program.

To utilize a commercial grade computer program or service, controls should be implemented to provide reasonable assurance that the computer program or service will support an SSC's intended safety function. This Subpart can also be applied to computer programs that control the management or administrative support of safety activities. These controls should include the following:

(a) determination that the computer program or service supports the performance of a safety function

(b) confirmation that the computer program or service meets the applicable commercial grade definitions

(c) identification and documentation of the critical characteristics, including acceptance criteria

(d) selection, performance, acceptance, and documentation of the dedication method(s) for determining compliance with the critical characteristic acceptance criteria

Only computer program or services that support the performance of a safety function and meet the commercial grade definitions should be considered for commercial grade dedication. A dedication plan should be developed for the computer program or service that identifies the critical characteristics, acceptance criteria, and dedication method(s). Dedication plans may be developed for a specific computer program application, a range of application or limits, a specific service, or for a generic group of services. Dedication requirements should be included in applicable procurement and technical documents as necessary to support the dedication.

Computer programs or services that successfully complete the dedication process are subsequently subject to the controls of Parts I and II.

400 TECHNICAL EVALUATION

A technical evaluation should be performed to determine the computer program's safety function, applicable requirements of this Standard, computer program and hardware requirements (as applicable), and the level and type of review and testing activities that are appropriate. This evaluation could range from a demonstration that the commercial grade computer program produces accurate and precise results for a predetermined set of verified problems with known solutions to a verification of program requirements, design, testing, and evaluation of test results. Credible failure modes for computer programs should consider the impact of the computer program's failure to produce correct results or an undetected defect within the computer program on the proper operation of the component being designed or the reliability of the analysis being performed.

401 Technical Evaluation Considerations

During the technical evaluation, if available, the following should be considered:

(a) the dedicating entity identifying if the computer program or service can impact a safety-related SSC

(b) conformance with the definitions for commercial grade computer program or service

(c) the mathematical model(s) on which the program is based

(d) the identification of the capabilities and limitations for intended use

(e) establish the class of problems for which the program is intended to be used

(f) confirm whether the computer program's solution methods are appropriate based on state-of-the-art knowledge

(g) determine whether adequate testing has been performed or if additional testing is needed to ensure adequate validation

(h) the acceptance criteria to be used in evaluating the range and validity of program responses

(i) basis for selection of validation cases

(j) the computer hardware and operating system in which the program will be utilized

(k) user interface requirements expected to take place in the use of the computer program

Before the dedicating entity begins the process of evaluating the computer program's adequacy for use, it should be placed in a configuration management process that provides traceability of the computer program's evaluation and testing activities. To ensure dependability, the dedicating entity should consider data and error reporting

associated with the computer program's performance as part of the dedication activities.

402 Technical Evaluation Documentation Review

The dedicating entity should review any available supplier documentation. Examples of supplier documentation supporting the technical evaluation include

(a) statement of problem
(b) requirements specification
(c) design specification
(d) source code
(e) test plan and test results
(f) configuration control

In situations where the above documentation is not available, computer program users' manuals should be reviewed for requirements and design information associated with the scientific, engineering, or mathematical models implemented, the code structure, and interfaces between high-level functions of the computer program. If these documents are not provided by the supplier, a search of publicly available documents should be used to supplement the supplier's documentation. If the supplier documentation cannot be adequately supplemented and the unavailable information is essential to determining reasonable assurance, dedication may not be possible. In the instance where a critical characteristic cannot be verified, the dedicating entity should consider alternate critical characteristics to provide the required reasonable assurance.

Part II, Subpart 2.14, para. 402 should only apply to computer programs if they are reinstalled in the same computer hardware and operating system (including patches), from the same distribution media, developed by the original company, and with the same configuration data. In this scenario, acceptance testing should still be performed to ensure that the computer program performs to the originally established requirements. If a failure has occurred and a backup is used to restore functionality, operational processes should be followed.

Part II, Subpart 2.14, para. 403 should not be used to accept different computer programs in safety-related applications, unless complete equivalency evaluation is possible.

500 CRITICAL CHARACTERISTICS

501 Computer Program Critical Characteristics

Critical characteristics should be identifiable, measurable attributes based on the intended safety function, complexity, application, and performance of the computer program and its data. Based upon the computer program's design and performance basis, a variety of critical characteristics can be identified. However, only a subset of those critical characteristics selected for acceptance (referred to as critical characteristics for acceptance) should be needed to provide the necessary level of reasonable assurance.

Critical characteristics associated with computer programs can be grouped into the following categories:

(a) identification
(b) physical
(c) performance/functional
(d) dependability

The computer program's identification (i.e., version, build date, release name, or part or catalog number) should be considered a critical characteristic if it provides a method for linking the computer program with the manufacturer's product description, user's manual, published data, or product specification. Physical characteristics are associated with the computer program's physical media (e.g., CDs, tapes, downloads, or remote access). Performance/functional characteristic examples include the required functionality of the computer program to perform its safety function and the accuracy of its results. Dependability characteristics are a category of critical characteristics unique to computer programs. The dependability category addresses the critical characteristics evaluated to develop judgment regarding built-in quality of the computer program. Dependability characteristics include both supplier and user attributes, such as a review of the computer program's life-cycle processes and output documentation at the supplier's facilities, review of the user's configuration management activities, supplier and user testing and verification and validation (V&V) activities, and other activities related to the supplier's software development process. Often, supplier dependability characteristics for computer programs cannot be verified through Method 1 [special test(s), inspection(s), and/or analyses; see section 600 of this Subpart] alone and are associated with the processes used to produce the computer program.

A prudent approach to achieving the necessary, reasonable assurance for the dedication process is to select multiple critical characteristics from all categories. This approach mitigates limitations of any single critical characteristic and the limitations on acceptance methods for individual characteristics.

Table 501 of this Subpart provides a list of critical characteristics to consider for computer programs. It is not intended to be an all-inclusive list of critical characteristics for acceptance. The table is intended to be used as a guide in selecting critical characteristics for acceptance that are appropriate for the commercial dedication process being performed by the users of this Subpart. This Subpart does not infer that the critical characteristics listed in Table 501 of this Subpart are a minimal set of critical characteristics for acceptance. The users of this Subpart should, consistent with section 400 of this Subpart, determine how the computer program supports the SSC's safety function, consider the critical characteristics in the table, determine which are appropriate to include for their dedication process, and evaluate whether additional critical characteristics for acceptance not included in Table 501 are needed to provide reasonable assurance that the computer program will adequately support the SSC's safety function.

The specific critical characteristics to be considered for acceptance should be identified through a review of the manufacturer's published software documentation or other technical information documents. For example, the manufacturer's test documentation should also provide important information necessary to define the critical characteristics, consistent with the computer program's application requirements.

502 Computer Program Acceptance Criteria

Each critical characteristic should have associated acceptance criteria to determine whether the computer program adequately meets the identified critical characteristic. Table 501 includes appropriate acceptance criteria for the identified critical characteristic.

The dedicating entity is responsible for determining whether the dedication method and results are adequate to meet the acceptance criteria.

600 METHODS FOR ACCEPTING COMMERCIAL GRADE ITEMS AND SERVICES

601 Dedication

To provide reasonable assurance that a commercial grade computer program will perform its intended safety function, the dedicating entity should verify that the commercial grade computer program meets the acceptance criteria for the identified critical characteristics by using one or more of the following dedication methods specified in Part II, Subpart 2.14:

(a) Method 1: Inspections, tests, or analyses performed after delivery

(b) Method 2: Commercial grade survey of the supplier

(c) Method 3: Source verification of the item or service

(d) Method 4: Acceptable supplier/item performance record

Once critical characteristics are verified, there is reasonable assurance that the computer program produces valid responses when used in the design or analysis of SSCs. At this point, the computer program can be accepted as a safety-related item and will be subject to the controls of Parts I and II.

Users of this Subpart should be aware that the method(s) of verification chosen may impact the procurement document content needed for the successful verification of the critical characteristics for acceptance.

Dedication activities will not be considered completed until the computer program is installed and found acceptable by the dedicating entity. Dedication is a safety-related activity, and Part II, Subpart 2.14 requires the dedicating entity to conduct the dedication process under a QA program that meets the requirements of Parts I and II.

602 Method 1: Special Test(s), Inspection(s), and/or Analyses

602.1 Special Tests. Tests to verify the adequacy of the commercial grade computer program should be documented in a test plan. Test plan activities that should be considered include the tests to be performed, the test method(s) to be utilized, verification of the identified critical characteristics for acceptance consistent with the acceptance criteria determined in the technical evaluation, demonstration that the mathematical equations are adequate to calculate critical parameters in an SSC, and documentation of test results. The dedicating entity should develop sufficient tests to determine whether the computer program produces valid responses when used in the design or analysis of SSCs.

Tests may be performed by third-party entities if they are documented and the tests are controlled in accordance with the requirements of this Standard. The use of test problems based on codes and standards or established technical references should provide an acceptable approach for some types of design and analysis computer programs. The test plan and results conducted by the dedicating entity or a third-party entity should be retained as part of the dedication documentation. If tests were performed by the supplier, the dedicating entity should verify the adequacy of test coverage consistent with the computer program's application requirements.

The dedicating entity should confirm that a representative testing set of anticipated program applications was carried out by the supplier and that important design features and major logical paths of the computer program were tested consistent with the technical evaluation and critical characteristics for acceptance. Retesting should be required to repeat some of the supplier's tests, and additional testing should also be required if a supplier's test coverage is found to be inadequate. When tests are used to verify acceptance criteria for the critical characteristics, the commercial grade computer program should be kept under configuration

(24)

Table 501
Typical Critical Characteristics to Consider for Computer Programs

No.	CC	Description	Acceptance Criteria	Method of Verification
		Typical Identification CC		
I-1	Host computer operating environment identifiers	The manufacturer, model number, operating system version, service packs, or patch identifiers of the host computer where the computer program is intended to be executed.	The host computer environment identifiers must match the purchase specification.	Verified through one or more of the following: *(a)* inspection of receipt inspection documentation (Method 1) *(b)* inspection of operating system identifiers (Method 1)
I-2	Computer program name and version identifier	The full name of the computer program and version identifier, including all patches. It should be the same identifier as used for during the procurement/acquisition process.	Computer program name and version identifier must match the product identifier from the supplier catalog or procurement documents. The version identifier can be the build date of the executable. The computer program version identifier includes the computer program name, major functional version, minor functional version, and correct revision.	Verified through one or more of the following: *(a)* inspection of receipt inspection documentation (Method 1) *(b)* inspection of operating system identifiers (Method 1)
I-3	Support tool name(s) and identifier(s)	The complete name, including version identifier of all support tools that are used during the commercial grade dedication process to assist in performing special tests or other support tools used in the operating environment. These tools, such as database management systems, could impact the correct operation of the safety functions performed by the computer program during special tests or operations.	The support tool name and identifier must match the product identifier from the supplier catalog or specification.	Verified through one or more of the following: *(a)* inspection of receipt inspection documentation (Method 1) *(b)* inspection of operating system identifiers (Method 1)
		Typical Physical CC		
P-1	Life cycle documentation	The documentation that is produced during all phases of the software life cycle. Documentation is evidence of the activities being performed. Documentation from multiple life cycle phases may be combined into one or more physical documents.	Life cycle documentation includes separate or combined documents that include software requirements specification, requirements traceability matrix, design documentation, architecture views, design description document, interface documentation, test plans, test reports, and user documentation.	Verified through the inspection of life cycle documents (Method 1).
P-2	Media	The physical object or distribution media received from the supplier that contains the computer program. This critical characteristic is applicable to all computer programs. Receipt media criteria are expressed as the method in which the computer program is distributed to the dedicating entity (e.g., CD, embedded, or downloadable).	Agreement with published catalogs or as specified in procurement documents.	Verified through the inspection of the received computer program (Method 1).
		Typical Performance/Functional CC		
F-1	Accuracy/precision/tolerance outputs	For accuracy, the degree to which there is a close correlation with the expected or desired outcome. For precision, the degree of repeatability or degree of measure. For tolerance, the allowable possible error in measurement.	As described in computer program requirements or supplier specification documentation. Criteria may be: accuracy ± 1%; precision ± 0.0001; tolerance ± 0.00001	Verified through a combination of one or more of the following: *(a)* observation and review of design (Method 3) *(b)* inspection and testing (Method 1) *(c)* review of the installed base to determine performance history (Method 4)

Table 501
Typical Critical Characteristics to Consider for Computer Programs (Cont'd)

No.	CC	Description	Acceptance Criteria	Method of Verification
		Typical Performance/Functional CC (Cont'd)		
F-2	Environmental compatibility: portability	The measure of the effort required to migrate the computer program to a different hardware platform, component, or environment. This critical characteristic may only be important for computer programs that are expected to be executed in a different environment.	As described in computer program requirements or supplier specification documentation. Portability criteria can be expressed as a unit of time (e.g., 16 hr or 15 days).	Verified through performing migration to one or more environments equivalent to the dedicating entities (Method 1).
F-3	Functionality: completeness and correctness	The degree to which the computer program requirements, design, and implementation have satisfied the allocated safety requirements. Formal techniques may be used to mathematically prove that the computer program satisfies its specified requirements. This critical characteristic is important to identify risks of the computer program failing to execute its safety functions.	Completeness and correctness are based upon how many of the computer program's requirements have been verified to be successfully implemented (e.g., 100% of allocated safety requirements are correctly implemented).	Verified through performing a review of the functional requirements traceability to test cases and verification that the test results indicate correct functionality. If requirements traceability is unavailable, the dedicating entity can develop the traceability matrix from the computer program's requirements or procurement specifications and test cases performed (Method 2).
F-4	Functionality: consistency with appropriate engineering, scientific research, and professional technical approaches	The degree to which the computer program's sample or complete data sets of results correlate with experimental data, expected data results, or professional analyses and to which any erroneous data sets do not correlate with the experimental data or professional analyses. This critical characteristic most likely is important to computer programs used to perform analysis of accident and structural integrity analyses for determining the proper design of safety components.	Consistency with research and professional technical approaches is based upon peer-reviewed published technical papers or industry-accepted computer programs performing a similar function. The output of the computer program can be viewed as how closely the computer program's output matches the technical report or baseline computer program output (e.g., computer program output correlates with experimental data to $\pm 3\sigma$).	Verified through a combination of one or more of the following: *(a)* a comparison of peer-reviewed technical publication detail results against the computer program's output for a similar problem being solved (Method 1). *(b)* a comparison of the baseline computer output against the computer program's output that is being dedicated. The baseline computer program must solve the same or closely similar physical problem as the dedicating computer program (Method 1). *(c)* a review of the computer program's current user base and its applicability to the intended use by the dedicating entity (Method 4).
F-5	Functionality: specific safety functions and algorithms	The critical functions or calculations that are performed. This includes time-dependent functions and functionality to only allow authorized users access to perform the safety functions.	As described in computer program requirements or procurement specification documentation. Functionality criterion may be similar to given source input data, calculate dose exposure at 10 m and 0 receptor height.	Verified through a combination of one or more of the following: *(a)* observation and review of design (Method 3) *(b)* inspection and testing (Method 1) *(c)* review of the installed base to determine performance history (Method 4)
F-6	Interfaces: critical input parameters and valid ranges	The set of input parameters that are used in the critical functions of the computer program and the range of their valid values. This critical characteristic is important to ensure that the computer program will function properly for all possible operational inputs.	As described in computer program requirements or procurement specification documentation. This criteria may be deposition receptor height (e.g., 0 ft to 1 ft), time (dd/mm/yyyy hh:mm:ss), and length (1.00 m to 5.00 m).	Verified through a combination of one or more of the following: *(a)* observation and review of design and/or implementation (Method 3) *(b)* inspection and testing (Method 1) *(c)* inspection of user's manual (Method 1) *(d)* review of the installed base to determine performance history (Method 4)

Table 501
Typical Critical Characteristics to Consider for Computer Programs (Cont'd)

No.	CC	Description	Acceptance Criteria	Method of Verification
		Typical Performance/Functional CC (Cont'd)		
F-7	Interfaces: output parameters	The characteristics of the critical output parameters. The characteristics of the critical output parameters include file formats and mathematical notations. This critical characteristic is important to ensure that the computer program output is in the expected format or units of measure.	As described in computer program requirements or procurement specification documentation. This criterion can consist of the output filename (e.g., 28 characters, case-insensitive with a file extension of pdf) or output format specification (e.g., comma-delimited) and units of measure.	Verified through a combination of one or more of the following: *(a)* observation and review of design (Method 3) *(b)* inspection and testing (Method 1) *(c)* inspection of user's manual (Method 1) *(d)* review of the installed base to determine performance history (Method 4)
		Typical Dependability CC		
D-1	Built-in quality: adherence to coding practices	The degree to which the computer program complies with the approved coding standards, use of source code libraries, or automated configuration management tool. This critical characteristic can be used to provide an indicator of the errors remaining in the computer program.	Coding practice criteria can be a percentage (e.g., 90%) of the supplier coding standards met, and, where appropriate, 100% of possible source code library modules are used instead of recoding.	Verified through the review of source code inspection reports or other supplier evidence that included reviews of coding practice for the subject source code modules. The dedicating entity during a survey may also review the source code module's compliance with the supplier's documented coding practices (Method 2).
D-2	Built-in quality: source code structure (complexity, conciseness)	The measure to which the computer program is legible, complexity is minimized, and source code length is minimized. This critical characteristic can be used to provide an indicator as to the difficulty to verify through reviews and testing that the source code will perform as expected.	Source code structure criteria can be quantitative, through the use of static analysis tools, or qualitative, through reviews of the documented design or inspection of the source code. Source code structure criteria may take the form of a number of internal subroutine interfaces, a number of do-loops, numbers of exits from a module, straight-forward flow of logic in source code module, and source code module depth and breadth.	Verified through the review of supplier-documented evidence from the use of a static analysis tool or the dedicating entity performing an inspection and manual analysis of the documented design or computer program source code (Method 2).
D-3	Built-in quality: conformance to national codes, standards, and industry-accepted certifications	The computer program's compliance with applicable national codes and standards or industry-accepted certifications.	Conformance criterion can be a measure of how well the computer program meets industry-accepted practices that provide a qualitative pedigree of the computer program. The criteria can be the degree in which a national code, standard, or third-party certification or recertification programs are achieved (e.g., 90% of achievement of compliance to CMMI SEI maturity level 4 or achieved ISO 9001).	Verified through one or more of the following: *(a)* inspection of supplier-performed assessments of the computer program against the national code or standard (Method 1) *(b)* review of computer program documentation and artifacts against the selected national code or standard (Method 2) *(c)* inspection of the proof of third-party certification (Method 1)
D-4	Built-in quality: existence of QA program	A QA program that includes documented procedures or process controls. QA program generally complies with a recognized standard (e.g., ISO 9001, IEEE 730, and IEEE 1012). This critical characteristic can be used to determine whether the foundation of a QA program exists.	QA program criteria are based upon the supplier's procedural compliance with a recognized standard that addresses development and quality assurance for computer programs. This criterion can be expressed in terms of the number of significant findings from a compliance audit against the chosen recognized standard or achievement of certification for the chosen recognized standard.	Verified through one or more of the following: *(a)* inspection of evidence of any third-party certification (Method 1) *(b)* review of internal or external audit reports (Method 2) *(c)* performance of a survey against the chosen recognized standard (Method 2)

Table 501
Typical Critical Characteristics to Consider for Computer Programs (Cont'd)

No.	CC	Description	Acceptance Criteria	Method of Verification
			Typical Dependability CC (Cont'd)	
D-5	Built-in quality: internal reviews and verifications	The degree to which static analysis methods (e.g., peer reviews) are performed during the computer program's development to identify errors and noncompliance with supplier procedures and standards.	Criteria for internal reviews and verifications of effectiveness are based upon the ratio of errors identified during the review/verification and the number of errors that are discovered in the next life cycle phase (e.g., ratio of the number of requirements errors identified during requirements review and the number of errors detected during the design phase).	Verified through the inspection and analysis of results from reviews or verification activities performed in two or more adjacent life cycle phases (Method 2 and/or Method 3).
D-6	Built-in quality: testability and thoroughness of testing	A measure of the completeness of the computer program verification, validation, and installation testing to ensure that the computer program is correct and complete. This critical characteristic may be appropriate to use for ensuring that tests were adequate to provide the reasonable assurance that the safety functions can be performed satisfactorily.	Testability criteria are based on the ease or difficulty in conducting verification and validation activities, as well as the breadth and depth of the testing performed. Testability criteria may include the number of hours needed to perform peer reviews, pretest a module, and develop test cases. The thoroughness of computer program testing criteria can be measures that identify the quantity of errors discovered during the various testing activities (e.g., trend analysis of errors per module, comparison of pre and postrelease errors) and traceability of tests performed to the safety requirements for the computer program (e.g., 95% of the requirements were tested).	Verified through one or more of the following: *(a)* inspection of documented review reports and test records that include the time spent to prepare, conduct, and perform postreview or test activities (Method 1). *(b)* review of the objective evidence of the errors identified during the testing processes or traceability of safety requirements to tests completed. If objective evidence is not available, the dedicating entity may be able to create the traceability of the safety requirements to tests performed from the computer program's documented requirements and test reports (Method 2).
D-7	Built-in quality: training, knowledge, and proficiency of personnel performing the work	Staff training, knowledge, and proficiency associated with the design, development, testing, oversight of the computer program, experience in similar projects, and familiarity with specific tools, languages used in design, and implementation. This critical characteristic can be used to provide an indicator of the errors remaining in the computer program.	Staff training, knowledge, and proficiency criteria may include how well the specific staff member satisfies the supplier's qualification requirements for the position held. The criterion can be the percentage of qualification requirements met.	Verified through the review of objective evidence of attendance at courses, staff resumes, and on-the-job training against the supplier qualification requirements to determine how well the staff member satisfies the requirements (Method 2).
D-8	Problem reporting: notification to customers	Notification by the supplier to customers of potential computer program errors or weaknesses.	This criterion may be the presence and use of a problem reporting system, use of problem reporting metrics, and number of notifications to the users over time.	Verification is performed by reviewing communications of errors with users, any website or other form of communication with the supplier, and a communications log (Method 2).
D-9	Supportability/maintainability	The ability for the supplier to continue supporting the computer program over the life of its use or the computer program design that provides for ease in performing modifications to the computer program. This critical characteristic may be more appropriate for computer programs whose failure could result in few or no alternatives or those alternatives that are not financially feasible.	Supportability/maintainability criteria can consist of the stability of the supplier based upon business longevity (e.g., 20 yr in business), size of customer base (e.g., 1,000 customers worldwide), planned future product releases (e.g., supplier R&D has updates scheduled for next 3 yr), supplier history of discontinuing products (e.g., cancelled three product lines over past 2 yr), or the time required to change the computer program (mean time to change or fix).	Verified through one or more of the following: *(a)* review of the supplier history for the specific computer program, as well as the history in supporting similar computer programs or products (Method 4) *(b)* review of supplier metrics associated with the length of time to evaluate the change/error correction, make the source code change/correction, test the change/correction, update all computer program documentation, and release the change (Method 2)

control to preclude inadvertent use or changes prior to satisfactory completion of the dedication activities and to prevent unauthorized release.

If the dedicating entity is testing a computer program in-house, test cases should be developed to determine the accuracy of the computer program's predictions based on the identified critical characteristics. In situations where computer program requirements include a clear specification of the range of validity for program responses, an evaluation of test results and documentation that states whether all results fall within the valid range should be acceptable. The range of validity could be determined based on physical observations, such as experimental benchmarks, by analytic means, or by other validated programs. In some instances, the range of validity is known only in very general terms. The computer program being reviewed is often the only computer program capable of analyzing the problems of interest and providing the needed responses. Physical observations may be available only for simplified, unrepresentative, or distorted problem conditions, and analytic results may be obtainable only for trivialized cases. In such situations, validation becomes a more subjective process dependent on the professional judgment of a professional engineer or other qualified staff of the dedicating entity. In such cases, the dedicating entity should evaluate the test results or conduct analyses to demonstrate that

(a) realistic test cases or test cases representative of the anticipated program used produce physically acceptable results (e.g., no negative temperatures or infinite pressure limits)

(b) simplified test cases produce understandable results when compared with physical observations or analytic predictions

Supplier acceptance tests and purchaser acceptance tests are activities that may be used during dedication. Method 2 should be used along with Method 1 if the dedicating entity wishes to take credit for supplier acceptance testing performed at the commercial supplier's facility.

602.2 Inspections. Inspections should include verification of objective evidence, including product identification and computer program revision date.

Receipt inspections should be included in the dedication plan and performed to accept the computer program. It is important to the process of implementing Method 1 to understand the difference between standard receipt inspections, computer program installation checkouts, and special tests and inspections performed after receipt. This Standard describes the standard receiving inspection in Part I, Requirement 7 as checking the quantity received, damage, general conditions of items, and part number. Computer program receipt inspections are as simple as checking that the computer program media have not been damaged and that the version identifiers are correct. Installation and checkout activities may or may not be part of dedication if it can be proven that these will not affect the computer program's application requirements or prevent the computer program's inadvertent use. Inspections for dedication go beyond the standard receiving inspection activities and installation checkouts to verify that the critical characteristics for acceptance are met. While the computer program version identifiers are attributes of a receipt inspection, they should also be part of the dedication process for the item. Even though receipt inspection and simple computer program installation checkouts are important to the dedication process, they are not adequate on their own for dedication.

602.3 Analyses. Analyses should include a review of the computer program design related to application requirements. As mentioned above, in cases where design specification documentation is not available, the available computer program documentation, such as a user's manual, should be reviewed to identify design specifications and application limits. The review of the applicable computer program life-cycle processes should demonstrate that all computer program requirements associated with the safety function were implemented adequately, ensure traceability to the computer program safety requirements, and clearly describe required functions, inputs, outputs, and options that are not used to potential users or block from use, as necessary.

603 Method 2: Commercial Grade Survey of the Supplier

Commercial grade surveys should be performed in accordance with the survey criteria of Part II, Subpart 2.14, which requires the supplier to have a documented and effective quality assurance program that controls the supplier's specific processes. The survey documentation should provide objective evidence that the life-cycle processes and controls implemented by the computer program's supplier for specified critical characteristics have been observed and evaluated for acceptance. Deficiencies identified in the supplier's process or controls should be corrected if the survey is used for acceptance of the identified critical characteristics.

The survey process should take advantage of available program documentation (such as development process artifacts), as well as user experience. Evidence should exist of software development standards and practices that were in place during the development of the computer program. Existing V&V activities carried out by the developer should be considered, evaluated, and credited as long as it is relevant to the computer program's application. This documentation should be identified and controlled.

Method 2 may be used when the dedicating entity relies on the commercial supplier for analyses, testing, and other activities that are related to the dedication process. Given

that the dedicating entity is responsible for verifying critical characteristics, delegation of such activity should come with a thorough assessment of the commercial supplier's process to effectively control critical characteristics.

604 Method 3: Source Verification

Source verification is a method of acceptance conducted at the supplier's facility or other applicable location to verify conformance with one or more identified critical characteristics and acceptance criteria. This method could be used to witness certain tests or computer program development processes that can only be performed at the supplier's location due to specialized equipment, trained personnel, etc. Source verification is only applicable to the actual activity related to the critical characteristic and acceptance criteria observed during the surveillance. The dedicating entity may establish a frequency in which to witness these activities to ensure that process controls applicable to the critical characteristics be effectively implemented for subsequent computer program revisions. An example of a surveillance would be to send representative(s) to evaluate the execution of the test problems for the new computer program or computer program revision.

This method may have limited application and is not applicable to computer programs that have already been developed since the computer development activities have been completed, for which access to the computer program life-cycle documentation may be restricted due to the proprietary nature of the documentation, or when there is an inability to interact with suppliers.

605 Method 4: Acceptable Supplier Item or Service Performance Record

Acceptable data for historical performance should evaluate the industry-monitored performance of the commercial grade computer program, industry product tests, certification to national codes and standards (nonnuclear-specific), and other industry records or databases. When a computer program has been demonstrated to be reliable based on its historical performance, it should be credited during dedication. Historical performance should be supported by the use of one of the other verification methods listed above.

This acceptance method should have a greater application for the dedication of computer programs used in design or analysis. Computer programs that are commercially available and that have industrywide application may be used successfully hundreds or even hundreds of thousands of times daily. The results of these uses and engineering judgment associated with the acceptance of the computer program should be considered with dedicating the computer program. Errors reported by the users to the supplier and failures associated with structures, systems, and components may be evaluated as part of the failure analysis investigation. This method is most effective when the supplier provides error reports to the purchaser for applicability and significance evaluation and when the users contact the supplier when computer program errors are suspected. A technical support agreement in the procurement documents provides assurance that there is adequate communication between the supplier and users.

700 COMMERCIAL GRADE SOFTWARE SERVICES

Commercial grade software services have a potential impact on the performance of computer programs and their ability to perform specified safety functions. Part II, Subpart 2.14 identifies computer software support as being one example of a service that may be provided as a commercial grade service. Commercial grade software services may include, but are not limited to, installation of computer programs, operating system updates and computer program patches, development or modification of computer programs that perform a safety function, performance of independent V&V activities, or other technical support activities. Alteration of a dedicated computer program's critical characteristics may be considered a commercial grade service. The dedicating entity should have qualified personnel who are knowledgeable of the services being provided in order to dedicate a service. Control of the activities performed by the service provider and the documentation from these activities should be considered critical characteristics to be verified during the dedication of the commercial grade service associated with computer programs.

800 DOCUMENTATION

801 Computer Program Procurement Documents

Depending on the critical characteristics selected and the dedication method, the purchaser's procurement documents for the computer program may need to include the following:

(a) a detailed description of the computer program name, title, release, version, or other descriptive identifiers

(b) technical specification requirements related to the computer program application

(c) the media or process used to provide the computer program to the purchaser

(d) identification of the supplier's QA program applicable to the computer program's development and support

(e) identification of the documentation to be provided with the computer program

(f) special shipping, storage, and handling requirements for media and any precautionary controls related to consideration of temperature, humidity, electromagnetic interference, etc., to be identified by the supplier

(g) right of access for performing surveys or surveillances

(h) need for the supplier to provide error reporting or technical support

(24) 802 Dedication Documentation

Documentation of the commercial grade computer program or service dedication process should be traceable to the computer program or services and should contain the following types of documents, depending on the applicable dedication method:

(a) dedication plans or procedures, including the essential elements of the dedication process

(1) scope and objectives for the dedication process

(2) requirements document for computer program or service dedication

(3) plans for a configuration management process for computer program or service dedication, including planned regression test requirements and expected results

(4) computer program V&V methodology

(b) commercial grade item or service procurement documents

(c) technical evaluations

(1) computer program requirements, summary, and review

(2) documentation referenced during the technical evaluation

(d) critical characteristic identification and acceptance criteria

(e) test plan(s), test specifications, test report(s) or results, inspection reports, and analysis reports

(1) review of test coverage

(2) evaluation of test results — validation

(f) commercial grade survey reports

(g) source verification reports

(h) historical performance information [e.g., availability and use of user experience(s)]

(i) dedication report containing sufficient data to accept the item or service

803 User Documentation

Limitations of the scope of the dedication of a computer program that are based on the critical characteristics should be communicated to the computer program users to ensure usage is within the dedication limits. The configuration control of the computer program can usually be used to control the version of the computer program. When limits on the computer program usage exist that are not blocked by the computer program's process controls, a users' manual with the specified limits should be available to the users.

900 REFERENCES (24)

ANSI/ANS-10.4. Verification and Validation of Non-Safety-Related Scientific and Engineering Computer Programs for the Nuclear Industry. American Nuclear Society.

ANSI/IEEE Std. 7-4.3.2-2010. IEEE Standard Criteria for Digital Computers and Safety Systems of Nuclear Power Generating Stations. Institute of Electrical and Electronics Engineers, Inc.

ANSI/IEEE Std. 730-2002. IEEE Standard for Software Quality Assurance Plans. Institute of Electrical and Electronics Engineers, Inc.

ANSI/IEEE Std. 1012-2004. IEEE Standard for Software Verification and Validation. Institute of Electrical and Electronics Engineers, Inc.

EPRI Technical Report 106439. Guideline on Evaluations and Acceptance of Commercial Grade Digital Equipment for Nuclear Safety Applications. Electric Power Research Institute.

EPRI Technical Report 107330. Generic Requirements Specification for Qualifying a Commercially Available PLC for Safety-Related Applications in Nuclear Power Plants. Electric Power Research Institute.

EPRI Technical Report 1025243. Guideline for the Acceptance of Commercial-Grade Design and Analysis Computer Programs Used in Nuclear Safety-Related Applications. Electric Power Research Institute.

ISO 9001:2008. Quality management systems — Requirements. International Organization for Standardization.

SEI CMMI, CMMI-DEV, Version 1.3 (2010, November). CMMI for Development. Carnegie Mellon University Software Engineering Institute.

SUBPART 3.2-2.15
Implementing Guidance for Part II, Requirement 2.15: Hoisting, Rigging, and Transportation

100 GENERAL

Subpart 3.2-2.15 has been deleted. Subpart 3.2-2.15 and Subpart 2.15 have been replaced with HRT-1-2016, Rules for Hoisting, Rigging, and Transporting Equipment for Nuclear Facilities. Copies of HRT-1-2016 can be obtained from the American Society of Mechanical Engineers (ASME), www.asme.org.

SUBPART 3.2-2.18.1
Implementing Guidance for Part II, Requirement 2.18: Maintenance of Nuclear Facilities, Establishing and Maintaining Equipment Histories

100 GENERAL

This Subpart provides nonmandatory guidance on establishing and maintaining equipment histories as specified by Part II, Subpart 2.18, para. 206.

200 DEVELOPING AN EQUIPMENT HISTORY

A listing should be developed to identify equipment on which historical data will be maintained. This listing should be established for both new and existing equipment as early in the life of the equipment as possible. The procedures for maintaining the historical data should identify the types of data to be collected for each piece of equipment.

300 MAINTAINING HISTORICAL DATA

In general, there are two categories of data for which historical data should be collected: periodic data denoting operating degradation and wear conditions; and abnormal occurrences such as failures.

Several types of documents may be used to collect historical data. These may include, but are not limited to, the following:

(a) work authorization documents
(b) completed maintenance records
(c) modification records
(d) postmaintenance test result records
(e) nonconformance reports
(f) replacement acceptability evaluation records
(g) vendor notices and bulletins
(h) lubrication records
(i) chemistry records
(j) surveillance, inspection, and test reports
(k) calibration reports
(l) reports of industry experience
(m) performance records (e.g., pump baseline curves, vibration monitoring results, thermal monitoring results, acoustics emission monitoring results)
(n) reports from external sources

Historical data do not have to be maintained in a single file or set of files. However, an individual or organization should have responsibility for collecting historical data and ensuring retrievability.

Historical files do not have to contain the actual documents from which the data are collected. The data may be extracted from the documents and used in a manner appropriate to the facility. However, the overall utility of the equipment history will depend upon maintaining adequate identification of the equipment and its traceability to the related data.

400 USING MAINTENANCE HISTORY

Maintenance history files may be used for several purposes, including, but not limited to, the following:

(a) failure analysis
(b) prevent maintenance needs and intervals
(c) outage planning
(d) support for facility life extension
(e) budget planning
(f) root cause analyses
(g) trending
(h) establish and maintain performance indicators
(i) input to the quality assurance grading process
(j) planning for decommissioning
(k) identifying the need for equipment modifications

SUBPART 3.2-2.18.2
Implementing Guidance for Part II, Requirement 2.18: Maintenance of Nuclear Facilities, Engineering Evaluations of Equipment Failures

100 INTRODUCTION

This Subpart provides nonmandatory guidance on performing engineering evaluations of equipment failures that have a serious effect on safety or operability, as specified in Part II, Subpart 2.18, para. 403.2.

200 ENGINEERING EVALUATIONS

201 Initiating Engineering Evaluations

Engineering evaluations are initiated whenever equipment or system failures are discovered that could have serious effects on safety and operability, and should also be considered when the potential for such failures is suspected. These actual or potential failures could be identified during normal facility operations. Additionally, they could be identified as a result of accidents; operations or maintenance surveillances; preventive or corrective maintenance actions; predictive maintenance monitoring; reviews of industry experience; and adverse conditions or serious failures of similar equipment in other systems or facilities.

202 Performing Engineering Evaluations

(a) Requirements and procedures for performing, documenting, and applying the results of engineering evaluations should be established and implemented.

(b) The evaluations should be promptly completed. The results should be factored into the bases for continued operation, shutdown, or restart of the equipment or systems affected by the actual or potential failures.

(c) The evaluations should include a systematic determination and analysis of failure causes, including failure symptoms, modes, and mechanisms. Failure Modes and Effects Analysis, Root Cause Analysis, Change Analysis, Barrier Analysis, Fault Tree Analysis, or other appropriate analytical techniques should be employed. Physical and chemical analyses, destructive or nondestructive examinations, and event simulation or reconstruction should be considered and conducted, as appropriate.

(d) The evaluations should be performed by technically competent personnel who are familiar with the design, operation, and maintenance history of the system or equipment involved, and who are skilled and experienced in the use of applicable analytical and investigative techniques.

(e) The evaluations should consider the operating conditions at the time of failure, and relevant contributing factors. Factors to consider may include, among others, the following:

(1) changes in environmental or facility conditions

(2) changes in equipment or system operating modes

(3) interactive effects from other items or events

(4) inadequacies in the original design or subsequent modifications

(5) failure to properly designate/identify critical components

(6) failure to properly factor modifications into the maintenance program

(7) failure to protect environmental or seismic qualifications

(8) operator errors

(9) inadequate predictive, preventive, or corrective maintenance

(10) inadequacies in the performance, application, or bases of previous analyses or assessments

(11) waivers, deferrals, or excessive backlogs of maintenance activities

(12) operation extending beyond equipment or component expected lifetimes

(13) previous operating anomalies that were not understood, followed up, or corrected

(14) changes in vendors or in vendors' processes or specifications for renewal and replacement parts

(f) The evaluations should recommend corrective actions to prevent recurrence of failures. Based on the causes of the failures, these recommendations should consider, as appropriate, the following:

(1) the potential for failure of other items of the same or similar design or service

(2) manufacturer recommendations and industry experience in the use of the item (or similar items), if available

(3) equipment history of the failed item (or similar items) to determine if replacement, repair, or other corrective methods previously used can be expected to restore the reliability of the item

(4) the need for modifications to improve the material, function, configuration, interfaces, location, or orientation of the failed item (or similar items)

(5) the need for improvements in the selection and acceptance criteria for renewal and replacement parts

(6) the need for incorporating redundancies, failure annunciators, or other engineered safety, compensatory, or mitigating features to enhance reliability

(7) the need for improving or increasing equipment or system performance monitoring, data analysis, and predictive maintenance capabilities

(8) the need for modifying preventive maintenance or its frequency

(9) the need for changing operating procedures or facility/environmental conditions

(10) the need for improved training or retraining of maintenance or operating personnel

(11) the need for changing resource allocations and priorities related to the performance of predictive, preventive, and corrective maintenance

203 Using Engineering Evaluation Results

(a) The results of the evaluations should be reviewed for approval by cognizant management to ensure that all applicable facts have been considered and that the recommended corrective actions are pertinent and achievable. Corrective actions should be approved by cognizant management and implemented in a timely manner.

(b) The results of the evaluations, including corrective actions taken, should be entered into the equipment history system. In addition, lessons learned from the evaluations should be disseminated to users of similar types of equipment within the organization and, where practical, to users in other organizations.

SUBPART 3.2-2.20
Implementing Guidance for Part II, Requirement 2.20: Subsurface Investigations for Nuclear Facilities, Sample Control and Identification (24)

100 GENERAL

This Subpart provides nonmandatory guidance for ensuring quality in the identification and control of samples collected for subsurface investigations.

(24) 200 CONTROL OF SUBSURFACE INVESTIGATIONS

The technical adequacy of procedures for conducting subsurface investigations and their implementation should be reviewed and approved by technically qualified persons other than those who prepared or selected the procedures.

300 IDENTIFICATION OF SAMPLES

Samples should be identified in a manner consistent with their intended use. Identification should be maintained throughout acquisition, handling, testing and analysis, preservation, shipment, transfer, storage, and disposition of samples.

Samples should be identified by placing the identification directly on the samples when possible, or on their container, or on a label or tag attached to the sample or their container. Sample identification should be verified and documented prior to release for testing or analysis. Identification methods should not affect sample characteristics or interface with the intended use.

Identification systems should ensure documented traceability of samples from the initial source, through final disposition. Samples that have lost their identification should not be used for input into the site investigation database.

400 CONTROL OF SAMPLES

Samples should be controlled during handling, acquisition, transfer of custody, shipment, storage, and disposition to preclude damage and loss (including loss of identity or associated documentation) and minimize deterioration. Responsibilities for control of samples should be defined.

Representative archival samples should be maintained from difficult-to-repeat samples collection activities such as principal bore holes.

Consideration should be given to the type of container, time constraints on perishable materials, and other environmental or safety considerations applicable to the sample.

Where multiple organizations are involved, appropriate procedures should describe interface and custody responsibilities. The identification of samples should be verified and maintained when samples are handled, transported, or transferred from one organization's responsibility to another's.

Sample characteristics, integrity, and identification should be maintained or controlled during storage. The controls applied should be consistent with the planned duration and conditions of storage and should describe action to be taken where samples have a maximum life expectancy while in storage. Storage methodology should be developed and implemented to ensure that essential sample characteristics are maintained to protect integrity. Samples should be controlled to preclude mixing of like samples. Samples on which analyses or tests have been performed should be identified and stored or disposed of as required by the procedures.

SUBPART 3.3

(24) # Nonmandatory Guidance on Quality Assurance Program Requirements for Collection of Scientific and Technical Information for Site Characterization of High-Level Nuclear Waste Repositories

DELETED

PART IV
GUIDANCE ON THE APPLICATION AND USE OF ASME NQA-1

INTRODUCTION

100 PURPOSE

Part I establishes requirements for the development and implementation of a Quality Assurance Program (QAP) for nuclear facility applications. It is arranged by Requirements 1 through 18. Part II contains additional quality assurance requirements for the planning and conduct of specific work activities under a Quality Assurance Program developed in accordance with Part I. It is arranged by Subparts.

Part III contains guidance for implementing the requirements of Parts I and II. It is arranged by Subparts.

Part IV — this Part — contains guidance for application of NQA-1 and comparisons of NQA-1 with other quality requirements. It is arranged by Subparts. It was developed using lessons learned, proven methods of performance, best practices, and insights of the NQA Committee to provide nonmandatory guidance on approaches and methods to apply Part I and/or Part II requirements to specific applications.

Consistent with its intent to provide nonmandatory guidance, the terms *must*, *require*, and *shall* are not used in statements of action in this Part. As such, alternative approaches and methods may be used to satisfy Parts I and II requirements. The Subparts provided in this Part are intended to be used as inputs and background in the development and implementation of Quality Assurance Programs, policies, protocols, instructions, and procedures. Information contained therein is designed to be of a guidance and explanatory nature and, as such, is not to be considered as requirements unless directly incorporated into an organization's requirement documents.

200 APPLICABILITY

Part IV applications and comparisons of quality requirements from other industry documents and government regulations do not alter or modify Part I or II requirements. Further, the differences identified in such comparisons are not intended to identify deficiencies in either document and relate only to the differences in the defined scope and application of the respective documents.

Part IV does not limit the Standard user from using alternate methods and activities that can be proven to provide results consistent with Parts I and II requirements.

SUBPART 4.1
Guides on Use and Comparison of NQA-1 With Other Quality Requirements

SUBPART 4.1.1
Guidance to Modification of an ISO 9001:2015 Quality Management System for Compliance With NQA-1, Part I

100 PURPOSE AND SCOPE

This Subpart provides guidance to organizations that have established a quality management system in accordance with ISO 9001 and additionally need to meet the requirements of NQA-1.

This Subpart compares the requirements of NQA-1, Part I, and of ISO 9001:2015. The purpose of this comparison is to identify equivalences and differences between those two standards. The guidance comprises practical recommendations on how to reconcile differing requirements when both standards are to be simultaneously implemented in an organization.

The comparison table was prepared using NQA-1-2015 and is valid through the 2019 edition of NQA-1.

200 BACKGROUND

The guidance provided in this Subpart is intended for parties involved in the nuclear industry. Unlike NQA-1, ISO 9001 is not specific to nuclear facilities or activities in a regulated environment and is not written with a primary commitment to ensure nuclear safety through implementation of quality assurance requirements.

ISO 9001 sets out the overall quality management system in an organization, its comprehensive processes, its interactions with other (strategic, risk, knowledge, etc.) management aspects and various stakeholders and its continuous improvement. NQA-1, on the other hand, primarily focuses on assuring the quality of items and services to provide adequate confidence that a structure, system, or component will perform satisfactorily in service. The related programmatic and management elements required are addressed on a detailed level. Consequently, it is conceivable that an NQA-1-based quality assurance program could be integrated into an ISO-based (quality) management system framework.

Reconciliation of the two standards is on the one hand facilitated by the emphasis of ISO 9001:2015 on the specific context in which an organization is active and on the engagement of any interested parties.

On the other hand, ISO 9001:2015 follows a new high-level structure and adopts different terms to ensure consistency across ISO management systems. With a focus on business and strategy in terms of leadership engagement and risk-based thinking, the commonalities with NQA-1 decrease in key areas, such as quality documentation and records.

300 TERMS AND DEFINITIONS

It should be noted that terms and definitions may differ between NQA-1, in particular Part I, Introduction, section 400 and ISO 9000:2015, Quality Management Systems — Fundamentals and Vocabulary.

While this Subpart contains only guidance, the word “shall” is used to denote that full implementation of the requirements of Part I is mandatory to comply with this Standard.

400 COMPARISON TABLES

Comparison Tables 400-1 through 400-18 of this Subpart reflect the 18 requirements of NQA-1, Part I. For each paragraph and subparagraph within a requirement, the corresponding clauses in ISO 9001 are referenced if available. Recommendations relevant to a requirement are given beneath the respective table.

Table 400-1
NQA-1, Part I, Requirement 1 (Organization) and Corresponding ISO 9001 Clauses

NQA-1–2015	ISO 9001:2015
100 General	4.1 Understanding the Organization and its Context
	4.3 Determining the Scope of the Quality Management System
	4.4 Quality Management System and its Processes
	5.5.1 Leadership — General
200 Structure and Responsibility	5.5.1 Leadership — General
201 General	5.3 Organizational Roles, Responsibilities, and Authorities
202 Delegation of Work	4.4.1 Quality Management System and its Processes
300 Interface Control	4.2 Understanding the Needs and Expectations of Interested Parties
	7.4 Communication

RECOMMENDATIONS: The following topics need to be addressed in more detail in an ISO 9001 management system to meet NQA-1:

(a) The organizational structure shall be documented to reflect functional responsibilities, levels of authority, and lines of communications for activities affecting quality.

(b) The management system shall define those individuals who are responsible for verifying quality achievement and that they have sufficient authority, direct access to management, organizational freedom, and access to the work to perform their function. Those individuals responsible for quality verification shall not be directly responsible for performing the work.

Table 400-2
NQA-1, Part I, Requirement 2 (Quality Assurance Program) and Corresponding ISO 9001 Clauses

NQA-1–2015	ISO 9001:2015
100 General	4.3 Determining the Scope of the Quality Management System 4.4 Quality Management System and its Processes 7.1 Resources 7.2 Competence 7.3 Awareness 9.1 Monitoring, Measurement, Analysis, and Evaluation 9.3 Management Review
200 Indoctrination and Training	7.1.6 Organizational Knowledge
201 Indoctrination	7.3 Awareness
202 Training	7.2 Competence
300 Qualification Requirements	7.2(d) Competence (general qualification requirements) 7.1.2 People 7.1.5.1 Monitoring and Measuring Resources — General
301 Nondestructive Examination (NDE) 302 Inspection and Test 303 Lead Auditor 304 Auditors 305 Technical Specialists	No corresponding ISO 9001 clause. For guidance, see ISO 19011:2011, Guidelines for Quality and/or Environmental Management Systems Auditing.
400 Records of Qualification	7.2(d) Competencee (general qualification requirements)
401 Inspection and Test Personnel	7.1.5.1 Monitoring and Measuring Resources — General
402 Lead Auditor Personnel	No corresponding ISO 9001:2015 clause
500 Records	No corresponding ISO 9001:2015 clause

RECOMMENDATIONS: The following topics need to be addressed in more detail in an ISO 9001 management system to meet NQA-1:

(a) The management system shall define and include the planning, implementation, and maintenance requirements of NQA-1.

(b) The management system shall include specific recognition, where necessary, of "controlled conditions" as it relates to the use of appropriate equipment or processes, suitable environmental conditions, and satisfaction of activity prerequisites.

(c) *Indoctrination and Training*

(1) The management system shall provide for documented indoctrination for personnel performing or managing quality-affecting activities to include job responsibilities and authority; general criteria, including applicable codes and standards; regulatory commitments; company procedures; and quality assurance program requirements.

(2) The training requirements of NQA-1 are more explicit and include determination of the need for formal training for personnel performing or managing quality-affecting activities. This training shall be provided to achieve initial capabilities and maintain proficiency and shall be adapted to changes to technology, methods, or job responsibilities.

(d) The management system shall include explicit qualification requirements for personnel performing nondestructive examinations, inspections, tests, and audits. Note that welders, welding operators, brazers, forming, and heat treatment operators may require training under NQA-1, Part I, Requirement 9. This shall be considered in the QA program.

Table 400-3
NQA-1, Part I, Requirement 3 (Design Control) and Corresponding ISO 9001 Clauses

NQA-1–2015	ISO 9001:2015
100 General	8.3.1 General 8.3.2 Design and Development Planning
200 Design Input	8.3.3 Design and Development Inputs
300 Design Process	8.3.3 Design and Development Inputs 8.3.5 Design and Development Outputs
400 Design Analyses	No corresponding ISO 9001 clause
401 Use of Computer Programs	There is a citation of ISO/IEC 90003 in clause "Bibliography" of ISO 9001. See also TickIT for more detailed information.
402 Documentation of Design Analyses	8.3.4(f) and Note Design and Development Controls
500 Design Verification	8.3.4(c) Design and Development Controls
501.1 Design Reviews	8.3.4(b), (c), and (d) Design and Development Controls
501.2 Alternate Calculations	No corresponding ISO 9001 clause
501.3 Qualification Tests	No corresponding ISO 9001 clause
600 Change Control	7.3.7 Control of Design and Development Changes 8.3.6 Design and Development Changes (design) 8.5.6 Control of Changes (production)
601 Configuration Management of Operating Facilities	No corresponding ISO 9001 clause
700 Interface Control	8.3.2(f) Design and Development Planning
800 Software Design Control	No corresponding ISO 9001 clause There is a citation of ISO/IEC 90003 in clause "Bibliography" of ISO 9001. See also TickIT for more detailed information.
900 Documentation and Records	8.3.5 Design and Development Outputs 8.3.6 Design and Development Changes

RECOMMENDATIONS: The scope of the design process is much broader and the required controls are more detailed in NQA-1. Inter alia, the following topics need to be addressed in more detail in an ISO 9001 management system to meet NQA-1:

(a) The management system shall provide for independence of personnel performing design adequacy verification activities.

(b) Design changes shall have at least the same level of control as applied to the original design and shall be incorporated into the appropriate documents in a timely manner. Those individuals approving design changes shall have demonstrated competence in the specific design area of interest and have adequate understanding of the requirements and intent of the original design.

(c) Design analysis, design verification processes, and interface controls shall be formalized and documented in detail. The use of computer programs in design analysis shall be defined and documented in detail, and the computer programs shall undergo a verification process, either generic or on each application.

(d) Design analysis shall be documented, including inputs, sources, assumptions, outputs, and those assumptions that require verification, review, and approval.

(e) The configuration management for the operating facility shall be established and documented prior to facility operation.

(f) The management system shall provide for the control of computer software design. Part II, Subpart 2.7 shall also be applied.

(g) Documentation and records of the design shall not only comprise final design documents, such as drawings and specifications, and revisions to those documents but also documentation that identifies the important steps in the design process, including sources of design inputs that support the final design.

(h) The management system shall provide for the procurement to the requirements of nuclear codes and standards. If dedication of commercial grade items is required, Part II, Subpart 2.14 shall also be applied.

Table 400-4
NQA-1, Part I, Requirement 4 (Procurement Document Control) and Corresponding ISO 9001 Clauses

NQA-1–2015	ISO 9001:2015
100 General	8.4.1 General
200 Content of the Procurement Documents	No corresponding ISO 9001:2015 clause
201 Scope of Work	8.4.3(a) Information for External Providers
202 Technical Requirements	No corresponding ISO 9001:2015 clause
203 Quality Assurance Program Requirements	No corresponding ISO 9001:2015 clause
204 Right of Access	No corresponding ISO 9001:2015 clause
205 Documentation Requirements	No corresponding ISO 9001:2015 clause
206 Nonconformances	No corresponding ISO 9001:2015 clause
207 Spare and Replacement Parts	No corresponding ISO 9001:2015 clause
300 Procurement Document Review	8.4.2 Type and Extent of Control
400 Procurement Document Changes	No corresponding ISO 9001:2015 clause

RECOMMENDATIONS: The following topics need to be addressed in more detail in an ISO 9001 management system to meet NQA-1:

(a) The management system shall define the procurement process and procurement documents to ensure appropriate documents and level of reviews and approvals. Key elements include the statements of scope of work, technical requirement specifications, and the appropriate test, inspection, and acceptance criteria.

(b) The management system shall define the controls of subtier suppliers, their reporting requirements and quality assurance responsibilities, along with a right to access supplier facilities and an obligation of the supplier to report nonconformances.

Table 400-5
NQA-1, Part I, Requirement 5 (Instructions, Procedures, and Drawings) and Corresponding ISO 9001 Clauses

NQA-1–2015	ISO 9001:2015
100 General	7.5 Documented Information 8.5.1 Control of Production and Service Provision

RECOMMENDATIONS: The management system shall require that all activities affecting quality and services are identified and prescribed by documented instructions, procedures, or drawings. These shall include acceptance criteria for determining that the activities have been satisfactorily accomplished.

Table 400-6
NQA-1, Part I, Requirement 6 (Document Control) and Corresponding ISO 9001 Clauses

NQA-1–2015	ISO 9001:2015
100 General	7.5.1 General
200 Document Control	7.5.2 Creating and Updating 7.5.3 Control of Documented Information
300 Document Changes	7.5.2(c) Creating and Updating
301 Major Changes	7.5.3.2(c) Control of Documented Information
302 Minor Changes	No corresponding ISO 9001:2015 clause

RECOMMENDATIONS: The following topics need to be addressed in more detail in an ISO 9001 management system to meet NQA-1:

(a) The management system shall define the following document controls:

(1) specified distribution of controlled documents for use at the appropriate location

(2) identification of individuals responsible for the preparation, review, approval, certification, and distribution of controlled documents

(b) The management system may distinguish major and minor changes.

(c) Particular consideration shall be given to the control of electronic documents, including their preparation, authentication, review, approval, access, distribution, changes, and archiving when used.

Table 400-7
NQA-1, Part I, Requirement 7 (Control of Purchased Items and Services) and Corresponding ISO 9001 Clauses

NQA-1–2015	ISO 9001:2015
100 General	8.4.1 Control of Externally Provided Processes, Products, and Services — General
200 Supplier Evaluation and Selection	8.4.1 Control of Externally Provided Processes, Products, and Services — General
300 Bid Evaluation	No corresponding ISO 9001:2015 clause
400 Control of Supplier-Generated Documents	8.5.1 Control of Production and Service Provision
500 Acceptance of Item or Service	
501 General	8.4.2 Type and Extent of Control
502 Methods of Acceptance	8.4.2(b) Type and Extent of Control
503 Certificate of Conformance	8.6 Release of Products and Services
504 Source Verification	8.5.2 Identification and Traceability
505 Receiving Inspection	8.5.1(c) Control of Production and Service Provision
506 Postinstallation Testing	8.5.5 Postdelivery Activities
507 Acceptance of Services Only	No corresponding ISO 9001:2015 clause
600 Control of Supplier Nonconformances	8.7 Control of Nonconforming Outputs
700 Commercial Grade Items and Services	No corresponding ISO 9001:2015 clause
800 Records	8.4.1 General 8.6 Release of Products and Services 8.7.2 Control of Nonconforming Outputs

RECOMMENDATIONS: The following topics need to be addressed in more detail in an ISO 9001 management system to meet NQA-1:

(a) The management system shall define how potential suppliers are evaluated prior to the award of a contract or during the bid evaluation process, including resolving discrepant conditions in the technical and/or quality programs.

(b) Suppliers of items and services shall be audited when appropriate, and the suppliers shall have a QA program with applicable elements in place.

(c) The management system shall define the control of supplier-generated documentation, such as submittal and evaluation of supplier-generated documents. These controls shall also provide for the acquisition, processing, and recorded evaluation of the quality assurance, technical, inspection, and test documentation or data against acceptance criteria.

(d) The management system shall define the acceptance of services and of commercial grade items if relevant.

(1) Services from a supplier shall be accepted based on a supplier's certificate of conformance, source verification, receiving inspection, or postinstallation test at the nuclear facility site or a combination of these methods.

(2) If commercial grade items are to be utilized, Part II, Subpart 2.14 shall also be applied.

Table 400-8
NQA-1, Part I, Requirement 8 (Identification and Control of Items) and Corresponding ISO 9001 Clauses

NQA-1–2015	ISO 9001:2015
100 General	8.5.2 Identification and Traceability
200 Identification Methods	
201 Item Identification	8.5.2 Identification and Traceability
202 Physical Identification	No corresponding ISO 9001:2015 clause
300 Specific Requirements	
301 Identification and Traceability of Items	8.5.2 Identification and Traceability
302 Limited Life Items	No corresponding ISO 9001:2015 clause
303 Maintaining Identification of Stored Items	No corresponding ISO 9001:2015 clause

RECOMMENDATIONS: The following topics need to be addressed in more detail in an ISO 9001 management system to meet NQA-1:

(a) The management system shall define within the process the identification and traceability, which covers three main areas: basic identification of traceability needs, methods of traceability, and special types of traceability requirements.

(b) Controls for items with limited shelf-life shall be addressed, if applicable.

Table 400-9
NQA-1, Part I, Requirement 9 (Control of Special Processes) and Corresponding ISO 9001 Clauses

NQA-1–2015	ISO 9001:2015
100 General	No corresponding ISO 9001:2015 clause
200 Process Control	
201 Special Processes	8.5.1 Control of Production and Service Provision
202 Acceptance Criteria	No corresponding ISO 9001:2015 clause
203 Special Requirements	No corresponding ISO 9001:2015 clause
300 Responsiblity	No corresponding ISO 9001:2015 clause
400 Records	7.5 Documented Information

RECOMMENDATIONS: The following topic needs to be addressed in more detail in an ISO 9001 management system to meet NQA-1: special processes such as welding, heat-treating, and nondestructive examination shall be identified and controlled if relevant. The management system shall include these special processes considerations as it relates to welding, heat treating, and nondestructive examination or other processes that are determined to be special processes and shall include the requirement that these processes shall be performed by qualified personnel using qualified procedures in accordance with specified requirements. These processes shall also be controlled by instructions, procedures, drawings, checklists, travelers, or other appropriate means.

Table 400-10
NQA-1, Part I, Requirement 10 (Inspection) and Corresponding ISO 9001 Clauses

NQA-1–2015	ISO 9001:2015
100 General	No corresponding ISO 9001:2015 clause
200 Inspection Requirements	No corresponding ISO 9001:2015 clause
300 Inspection Hold Points	No corresponding ISO 9001:2015 clause
400 Inspection Planning	No corresponding ISO 9001:2015 clause
500 In-Process Inspection	8.5.1 Control of Production and Service Provision
600 Final Inspections	
601 Resolution of Nonconformances	8.7.1 Control of Nonconforming Outputs (covers second part)
602 Inspection Requirements	No corresponding ISO 9001:2015 clause
603 Modifications, Repairs, or Replacements	8.7.1 Control of Nonconforming Outputs
604 Acceptance	No corresponding ISO 9001:2015 clause
700 Inspections During Operations	No corresponding ISO 9001:2015 clause
800 Records	No corresponding ISO 9001:2015 clause

RECOMMENDATIONS: The following major topics need to be addressed in more detail in an ISO 9001 management system to meet NQA-1:

(a) The management system shall define inspections that verify conformance of an item or activity to specified requirements or continued acceptability of items in service. The concept of inspections that verify quality is not given a separate consideration within ISO 9001. The key areas are personnel qualification (see Part I, Requirement 2), characteristics subject to inspection, inspection methods, and documented inspection results. Inspection records are required in detail.

(b) Inspection for acceptance shall be performed by qualified persons other than those who performed or directly supervised the work being inspected.

Table 400-11
NQA-1, Part I, Requirement 11 (Test Control) and Corresponding ISO 9001 Clauses

NQA-1–2015	ISO 9001:2015
100 General	No corresponding ISO 9001:2015 clause
200 Test Requirements	No corresponding ISO 9001:2015 clause
300 Test Procedures (Other Than for Computer Programs)	No corresponding ISO 9001:2015 clause
400 Computer Program Test Procedures	No corresponding ISO 9001:2015 clause
500 Test Results	No corresponding ISO 9001:2015 clause
600 Test Records	No corresponding ISO 9001:2015 clause

RECOMMENDATIONS: The following topic needs to be addressed in more detail in an ISO 9001 management system to meet NQA-1: tests required to collect data such as for siting or design input, to verify conformance of an item or computer program to specified requirements, or to demonstrate satisfactory performance for service are not given separate consideration within ISO 9001. The management system shall make provision for four key areas of test control: test requirements, test procedures, test results, and test records. The central theme is that characteristics shall be tested by qualified personnel (see Part I, Requirement 2) using specified test methods and equipment. Test results shall be documented, and their conformance with test requirements and acceptance criteria shall be evaluated by qualified personnel from a specific organization.

Table 400-12
NQA-1, Part I, Requirement 12 (Control of Measuring and Test Equipment) and Corresponding ISO 9001 Clauses

NQA-1–2015	ISO 9001:2015
100 General	7.1.5.2 Measurement Traceability 8.5.2 Identification and Traceability
200 Selection	7.1.5.2 Measurement Traceability
300 Calibration and Control	
301 Calibration	7.1.5.2 Measurement Traceability
302 Reference Standards	No corresponding ISO 9001:2015 clause
303 Control	
303.1	7.1.5.2 Measurement Traceability 8.5.2 Identification and Traceability
303.2	7.1.5.2 Measurement Traceability (last part)
303.3	7.1.5.2(c) Measurement Traceability
303.4	No corresponding ISO 9001:2015 clause
303.5	No corresponding ISO 9001:2015 clause
303.6	7.1.5.2(b) Measurement Traceability
400 Records	No corresponding ISO 9001:2015 clause
401 General	No corresponding ISO 9001:2015 clause
402 Reports and Certificates	No corresponding ISO 9001:2015 clause

RECOMMENDATIONS: The following topics need to be addressed in more detail in an ISO 9001 management system to meet NQA-1:

(a) The ISO term measuring devices is too general to meet NQA-1. The management system needs to clarify the definition of measuring and test equipment to include tools.

(b) Gages, instruments, and other measuring and test equipment used for activities affecting quality shall be controlled, calibrated at specified periods, adjusted, and maintained to required accuracy limits.

(c) Methods and frequency of checking accuracy shall be defined in procedures.

(d) The management system shall address out-of-calibration controls, which requires out-of-calibration devices to be tagged or segregated, or both, and not used until they have been recalibrated. These controls shall apply also to suspect, damaged, and lost equipment.

(e) Measuring or test equipment found to be out of calibration should be repaired or replaced. All measurements since the last valid calibration shall be re-evaluated to establish validity.

(f) Master instruments shall be four times more accurate than the equipment to be calibrated, or technical justification shall be given.

(g) Before repair and adjustment, the "as-found" condition shall be determined and documented.

(h) Calibration and control measures are not required for commercial equipment, such as rulers, tape measures, levels, etc., if such equipment provides the required accuracy.

(i) Records to be established and maintained shall indicate calibration status and capability of measuring and test equipment, as well as compliance with specified requirements.

Table 400-13
NQA-1, Part I, Requirement 13 (Handling, Storage, and Shipping) and Corresponding ISO 9001 Clauses

NQA-1–2015	ISO 9001:2015
100 General	No corresponding ISO 9001:2015 clause
200 Special Requirements	No corresponding ISO 9001:2015 clause
300 Procedures	No corresponding ISO 9001:2015 clause
400 Tools and Equipment	No corresponding ISO 9001:2015 clause
500 Operators	No corresponding ISO 9001:2015 clause
600 Marking or Labeling	No corresponding ISO 9001:2015 clause

RECOMMENDATIONS: The following topics need to be addressed in more detail in an ISO 9001 management system to meet NQA-1:

(a) Handling, storage, and shipping activities shall be conducted in accordance with established work and inspection instructions, drawings, specifications, shipment instructions, or other pertinent documents or procedures specified for use in conducting these activities.

(b) The management system shall define specific procedures where critical, sensitive, perishable, or high-value items are involved. Where the need for these procedures has determined the use of special handling tools and equipment, experienced or trained operators shall be addressed.

(c) Special protective packaging and equipment required for an item shall be specified and their existence verified.

(d) Marking or labeling shall be utilized as necessary to adequately maintain and preserve the item, including indication of the presence of special environments or the need for special controls.

Table 400-14
NQA-1, Part I, Requirement 14 (Inspection, Test, and Operating Status) and Corresponding ISO 9001 Clauses

NQA-1–2015	ISO 9001:2015
100 General	8.5.2 Identification and Traceability

RECOMMENDATIONS: Test and inspections status is not given separate consideration within ISO 9001 and shall be included in the management system.

Table 400-15
NQA-1, Part I, Requirement 15 (Control of Nonconforming Items) and Corresponding ISO 9001 Clauses

NQA-1–2015	ISO 9001:2015
100 General	8.7 Control of Nonconforming Outputs
	8.7.1 Control of Nonconforming Outputs
200 Identification	8.7.1 Control of Nonconforming Outputs
300 Segregation	8.7.1 Control of Nonconforming Outputs
400 Disposition	
401 Control	8.7.1 Control of Nonconforming Outputs
	8.7.2 Control of Nonconforming Outputs
402 Responsibility and Authority	8.7.2 Control of Nonconforming Outputs
403 Personnel	7.1.2 People
	7.2 Competence
	7.3 Awareness
	8.2.4 Changes to Requirements for Products and Services
	8.7.2 Control of Nonconforming Outputs
404 Disposition	8.7.1 Control of Nonconforming Outputs
405 Reexamination	10.2.1 Nonconformity and Corrective Action

RECOMMENDATIONS: The following topic needs to be addressed in more detail in an ISO 9001 management system to meet NQA-1: the management system shall define the controls for identification and segregation (when practical) of nonconforming items.

(a) The management system shall specify the identification of nonconforming items by legible marking, tagging, or other methods not detrimental to the item, on the item, the container, or the package containing the item. Authority and responsibility for marking and release shall be specified and documented.

(b) The controls shall include the technical justification of any "use-as-is" and "repair" dispositions.

(c) The management system shall specify the methods of segregation: where it is practical by placing them in a clearly identified and designated hold area until properly dispositioned or, where segregation is impractical or impossible due to physical conditions such as size, weight, or access limitations, by other precautions to preclude inadvertent use of the nonconforming item.

Table 400-16
NQA-1, Part I, Requirement 16 (Corrective Action) and Corresponding ISO 9001 Clauses

NQA-1–2015	ISO 9001:2015
100 General	6.1.1(c) Actions to Address Risks and Opportunities
	6.1.2 Actions to Address Risks and Opportunities
	9.1.3(e) Analysis and Evaluation
	10.2 Nonconformity and Corrective Action
	10.2.1 Nonconformity and Corrective Action
	10.2.2 Nonconformity and Corrective Action

Table 400-17
NQA-1, Part I, Requirement 17 (Quality Assurance Records) and Corresponding ISO 9001 Clauses

NQA-1–2015	ISO 9001:2015
100 General	7.5.3.1 Control of Documented Information
200 Generation of Records	7.5 Documented Information 7.5.1 General 7.5.2 Creating and Updating 7.5.3.2 Control of Documented Information 8.4.1 General
300 Authentication of Records	7.5.2 Creating and Updating 7.5.3 Control of Documented Information (esp. 7.5.3.1 and 7.5.3.2)
400 Classification	7.5 Documented Information
401 Lifetime Records	No corresponding ISO 9001:2015 clause
402 Nonpermanent Records	No corresponding ISO 9001:2015 clause
500 Receipt Control of Records	No corresponding ISO 9001:2015 clause
600 Storage	7.5.3.2 Control of Documented Information
601 General	No corresponding ISO 9001:2015 clause
602 Facility Types	No corresponding ISO 9001:2015 clause
603 Temporary Storage	No corresponding ISO 9001:2015 clause
700 Retention	No corresponding ISO 9001:2015 clause
800 Maintenance of Records	7.5.3.1 Control of Documented Information

RECOMMENDATIONS: The following topic needs to be addressed in more detail in an ISO 9001 management system to meet NQA-1: the management system shall include classification, receipt control, storage, retention, and maintenance of quality assurance records.

Table 400-18
NQA-1, Part I, Requirement 18 (Audits) and Corresponding ISO 9001 Clauses

NQA-1–2015	ISO 9001:2015
100 General	9.2.1 Internal Audit
200 Scheduling	9.2.2 Internal Audit
201 Internal Audits	9.2.2 Internal Audit
202 External Audits	No corresponding ISO 9001:2015 clause
301 Audit Plan	9.2.2 Internal Audit
302 Personnel	9.2.2(c) Internal Audit
303 Selection of Audit Team	9.2.2(c) Internal Audit
400 Performance	9.2.2(b) and (d) Internal Audit
500 Reporting	9.2.2(a) and (d) Internal Audit
600 Response	9.2.2(e) Internal Audit
700 Follow-Up Action	10.2.1(d) Nonconformity and Corrective Action
800 Records	9.2.2(f) Internal Audit

RECOMMENDATIONS: The following topics need to be addressed in more detail in an ISO 9001 management system to meet NQA-1; some of those may already be covered if the management systems follow the ISO 19011 guidance:

(a) The management system shall make provision not only for internal audits but also for audits of suppliers of items and services.

(b) Audits shall be scheduled to ensure coverage of all activities affecting quality and of suppliers of items and services at specified intervals. Audit plans are required before each audit, and the selection of the audit team (for qualification and certification, see Part I, Requirement 2) shall ensure independence from the area to be audited.

(c) The management system shall provide for documentation, follow-up, and verification of audit results.

SUBPART 4.1.2
Guidance on the Use of NQA-1–2008/1a–2009 for Compliance With Department of Energy Quality Assurance Requirements 10 CFR 830, Subpart A and DOE O 414.1

100 PURPOSE

This Subpart may be used by organizations intending to adopt NQA-1 as a national consensus Standard for development and implementation of a Quality Assurance Program (QAP) that meets the Department of Energy (DOE) Quality Assurance (QA) requirements. This Subpart describes how NQA-1–2008/1a–2009 addresses the DOE QA requirements and identifies DOE QA requirements that are not addressed by NQA-1.

200 INTRODUCTION

The Department of Energy (DOE) QA requirements for activities that affect, or may affect, quality, nuclear safety, or other site-specified criteria are established by rule, 10 CFR Part 830 Subpart A, dated January 10, 2001 (i.e., Rule). DOE also has requirements for all other federal and contractor activities in QA Order, O 414.1C, dated June 17, 2005 (i.e., Order). The DOE QA requirements and guides are available for review at www.directives.doe.gov.

The DOE's objective of the QA Rule and Order is for organizations to establish effective integrated Quality Assurance Programs (i.e., QAPs) to ensure that their products and services meet or exceed DOE's expectations. The objective is accomplished through performance-oriented quality assurance criteria, coupled with appropriate technical standards to manage, perform, and assess work activities. The DOE Rule requires the use of voluntary consensus standards in the development and implementation of the QAP. The NQA-1 Standard is a national voluntary Standard and should be considered for providing the essential implementing methods for a DOE QAP, including details for effective and reliable supporting processes and procedures, as presented in this Subpart. This Subpart does not intend to usurp the sole authority of DOE to issue guidance and interpretations for its rules.

300 DOE RULE AND ORDER GENERAL QAP REQUIREMENTS

The DOE Rule and Order include both administrative and regulatory quality requirements. Those administrative requirements relating to QAP approval authority, change control authority, and compliance should not be considered applicable to the scope of NQA-1. The general DOE QAP quality-related requirements that should be considered within the scope of NQA-1 are addressed in Table 300 of this Subpart.

400 DOE RULE AND ORDER QA CRITERIA

The DOE Rule and Order include ten QA criteria that are used to develop and implement a QAP. Table 400 of this Subpart identifies each of the ten DOE Rule and Order QA Critera and how they are addressed by the NQA-1, Part I. Differences in the documents and topics that should be addressed independently of the NQA-1 criteria to meet the DOE criteria are described. In some cases, the nonmandatory guidance in NQA-1, Part III may be appropriate to address the DOE requirements. Where an NQA-1, Part I Requirement addresses the DOE criterion, the associated NQA-1 nonmandatory guidance should also be considered to aid in addressing the DOE general requirement that the QAP describe how the QA criteria will be implemented.

Table 300
10 CFR 830 Subpart A, Dated January 10, 2001 §830.121, Quality Assurance Program; DOE O 414.1C, Dated June 17, 2005

DOE General Requirements (Summarized)	NQA-1 Requirements
Graded Approach (10 CFR 830.7) Where appropriate, a contractor must use a graded approach to implement the requirements of this Part, document the basis of the graded approach used, and submit that documentation to DOE.	**Part I, Introduction, and Requirements 1 and 2** provide for a graded approach to achieving quality by focusing on activities affecting quality and the application of requirements in a manner consistent with the relative importance of the item or activity. **Part III, Subpart 3.1-2.1**, Implementing Guidance for Part I, Requirement 2: Quality Assurance Programs, includes guidance on this topic. The cited text does allow for a graded approach; however, a DOE QAP will need to describe how the graded approach is applied and documented to meet the DOE requirement.
QAP Development and Implementation (10 CFR 830) The QAP must describe how the DOE QA criteria are satisfied.	The NQA-1 requirements partially meet the DOE requirement. **Requirement 2** requires that a documented QAP be planned, implemented, and maintained; and requires the QAP provide for the planning and accomplishment of activities affecting quality. **Requirement 5** requires that "Activities affecting quality and services shall be prescribed by and performed in accordance with documented instructions, procedures, or drawings that include or reference appropriate quantitative or qualitative acceptance criteria for determining that prescribed results have been satisfactorily accomplished." A DOE QAP will need to describe how the DOE criteria are satisfied.
Integrated Management Systems [DOE O 414.1C 4.2 (4)(2)] The QA Program must integrate the QA criteria with the Safety Management System (SMS), or describe how the QA criteria apply to the SMS.	The NQA-1 requirements do not address the DOE requirements for integrated management systems. The QAP must integrate S/CI prevention process, the Corrective Action Management Program, and Software Quality.
Ensuring Subcontractor and Supplier Quality (DOE O 414.1C) The QAP must describe how the contractor responsible for the nuclear facility ensures that subcontractors and suppliers satisfy the QA criteria.	**Requirements 1, 2, 4, 7, and 18:** The NQA-1 requirements meet the DOE requirement by the establishment of quality interfaces between organizations, by the inclusion of applicable QA requirements in procurement documents, supplier evaluation activities, and audits of suppliers. A DOE QAP will need to describe how subcontractors/suppliers satisfy the DOE criteria.

Table 400
10 CFR 830 Subpart A, Dated January 10, 2001 §830.122, Quality Assurance Criteria

DOE Quality Assurance Criteria	NQA-1 Requirements
Criterion 1: Management/Program (1) Establish an organizational structure, functional responsibilities, levels of authority, and interfaces for those managing, performing, and assessing work.	**NQA Requirements 1 and 2:** The NQA-1 requirements meet the DOE Criterion, as noted.
Comments: None	
(2) Establish management processes including, planning, scheduling, and providing resources for the work.	NQA-1, Requirement 1, para. 201 (General) and Requirement 2, section 100 (General) meet the DOE Criterion. NQA-1 requires senior management to establish overall expectations for effective implementation of the quality assurance program and is responsible for obtaining the desired end result. This implies that adequate resources are provided to obtain desired results.
Comments: A DOE QAP will need to describe the management process for providing resources.	
Criterion 2: Management/Personnel Training and Qualification (1) Train and qualify personnel to be capable of performing their assigned work. (2) Provide continuing training to personnel to maintain their job proficiency.	**NQA Requirement 2:** The NQA-1 requirements meet the DOE Criterion. The NQA-1 requirements satisfy both elements of the DOE Criterion.
Comments: None	
Criterion 3: Management/Quality Improvement (1) Establish and implement processes to detect and prevent quality problems.	**NQA Requirements 2, 4, 7, 15, and 16:** The NQA-1 requirements partially meet the DOE Criterion. NQA Requirements 15 and 16 partially meet the DOE Criterion; however, NQA-1 does not address preventing problems before they occur. Appendix 16 A-1 provides additional guidance for corrective action.
Comments: A DOE QA Program will need to extend the requirements of NQA-1 to ALL conditions adverse to quality, not just significant conditions adverse to Quality.	
(2) Identify, control, and correct items, services, and processes that do not meet established requirements.	The NQA-1 Requirements 4, 7, 15, and 16 satisfy this element of the DOE Criterion.
Comments: None	
(3) Identify the causes of problems and work to prevent recurrence as part of correcting the problem.	NQA requires actions to prevent recurrence for only significant conditions adverse to quality.
Comments: A DOE QA Program will need to extend the requirements of NQA-1 to ALL conditions adverse to quality, not just significant conditions adverse to Quality.	
(4) Review item characteristics, process implementation, and other quality-related information to identify items, services, and processes needing improvements.	The NQA requirements partially address this element of the DOE Criterion for known deficiencies.
Comments: A DOE QA Program will need to address collection and review of information, beyond deficiencies, to identify items, services, and processes needing improvements.	

Table 400
10 CFR 830 Subpart A, Dated January 10, 2001 §830.122, Quality Assurance Criteria (Cont'd)

DOE Quality Assurance Criteria	NQA-1 Requirements
Criterion 4: Management/Documents and Records	**NQA Requirements 5, 6, and 17:** The NQA-1 requirements meet the DOE Criterion.
(1) Prepare, review, approve, issue, use, and revise documents to prescribe processes, specify requirements, or establish design.	The NQA-1 requirements satisfy these elements of the DOE Criterion.
(2) Specify, prepare, review, approve, and maintain records.	
Comments: None	
Criterion 5: Performance/Work Processes	**NQA Requirements 5, 8, 9, 12, 13, and 14 and Part I, Introduction:** The NQA-1 requirements meet the DOE Criterion, as noted.
(1) Perform work consistent with technical standards, administrative controls, and other hazard controls adopted to meet regulatory or contract requirements, using approved instructions, procedures, or other appropriate means.	The NQA requirements address "work" as activities affecting quality.
Comments: A DOE QA Program will need to address "work" as broadly as the DOE Criterion, since the requirements for "work" are derived from multiple sources in the DOE Rule and Order.	
(2) Identify and control items to ensure their proper use.	The NQA-1 requirements satisfy this element of the DOE Criterion.
Comments: None	
(3) Maintain items to prevent their damage, loss, or deterioration.	The NQA-1 requirements satisfy this element of the DOE Criterion.
Comments: None	
(4) Calibrate and maintain equipment used for process monitoring or data collection.	The NQA-1 requirements satisfy this element of the DOE Criterion.
Comments: None	
Criterion 6: Performance/Design	**NQA Requirement 3:** The NQA-1 requirements meet the DOE Criterion.
(1) Design items and processes using sound engineering/scientific principles and appropriate standards.	
(2) Incorporate applicable requirements and design basis in design work and design changes.	
(3 Identify and control design interfaces.	
(4) Verify or validate the adequacy of design products using individuals or groups other than those who performed the work.	
(5) Verify or validate work before approval and implementation of the design.	
Comments: None	
Criterion 7: Performance/Procurement	**NQA Requirements 4 and 7:** The NQA-1 requirements meet the DOE Criterion.
(1) Procure items and services that meet established requirements and perform as specified.	
(2) Evaluate and select prospective suppliers on the basis of specified criteria.	
(3) Establish and implement processes to ensure that approved suppliers continue to provide acceptable items and services.	
Comments: None	

Table 400
10 CFR 830 Subpart A, Dated January 10, 2001 §830.122, Quality Assurance Criteria (Cont'd)

DOE Quality Assurance Criteria	NQA-1 Requirements
Criterion 8: Performance/Inspection and Acceptance Testing (1) Inspect and test specified items, services, and processes using established acceptance and performance criteria. (2) Calibrate and maintain equipment used for inspections and tests.	**NQA Requirements 8, 10, 11, and 12:** The NQA-1 requirements meet the DOE Criterion.
Comments: None	
Criterion 9: Assessment/Management Assessment Ensure managers assess their management processes and identify and correct problems that hinder the organization from achieving its objectives.	**NQA Requirements 2 and 18:** The NQA-1 requirements partially meet the DOE Criterion, as noted. While NQA-1, Requirement 2, para. 100(c) (General), requires management to regularly assess the adequacy and effective implementation of the quality assurance program, the DOE Criterion is broader in scope and intent.
Comments: While audits per Requirement 18 of NQA provide an input to this requirement, a DOE QAP will need to meet unique DOE requirements.	
Criterion 10: Assessment/Independent Assessment (1) Plan and conduct independent assessments to measure item and service quality, to measure the adequacy of work performance, and to promote improvement. (2) Establish sufficient authority, and freedom from line management, for the group performing independent assessments. (3) Ensure persons who perform independent assessments are technically qualified and knowledgeable in the areas to be assessed.	**NQA Requirements 1, 2, 10, 11, 15, 16, and 18:** The NQA-1 requirements meet the DOE Criterion. DOE defines assessment as a general term that includes a variety of evaluation methods (i.e.; reviewing, evaluating, inspecting, testing, checking, surveillance, auditing or otherwise determining and documenting). As such, several NQA-1 requirements may be necessary to address the various DOE independent assessment methods. These activities when combined with the NQA corrective action requirement have the intent of the DOE Criterion, to "promote improvement."
Comments: Assessment as a DOE activity for a DOE QAP will need to meet unique DOE requirements.	

SUBPART 4.1.3
Guidance on the Use of NQA-1–2015 for Compliance With 10 CFR 71 or 10 CFR 72 Requirements (24)

(24) 100 PURPOSE

This Subpart may be used by organizations intending to adopt NQA-1 as a national consensus Standard for development and implementation of a Quality Assurance Program that meets 10 CFR 71, "Packaging and Transportation of Radioactive Material, Subpart H, Quality Assurance" or 10 CFR 72, "Licensing Requirements for the Independent Storage of Spent Nuclear Fuel and High Level Radioactive Waste, Subpart G, Quality Assurance" requirements.

This Subpart describes how NQA-1–2015 addresses the 10 CFR 71 and 10 CFR 72 Quality Assurance requirements and identifies additional information an organization intending to adopt NQA-1 for the development and implementation of a Quality Assurance Program that meets the 10 CFR 71 or 10 CFR 72 requirements should consider.

200 INTRODUCTION

The Nuclear Regulatory Commission (NRC) establishes "requirements for packaging, preparation for shipment, and transportation of licensed material; and procedures and standards for NRC approval of packaging and shipping procedures for fissile material and for a quantity of other licensed material in excess of a Type A quantity" in 10 CFR 71. Subpart H of 10 CFR 71 describes quality assurance requirements. The 10 CFR 72 regulation states, "establish requirements, procedures, and criteria for the issuance of licenses to receive, transfer, and possess power reactor spent fuel and other radioactive materials associated with spent fuel storage in an independent spent fuel storage installation (ISFSI)." Subpart G of 10 CFR 72 describes quality assurance requirements.

The NRC's approval of an applicant's Quality Assurance Program requires acceptable standards of quality and a description of how the requirements will be met. The NQA-1 Standard is a national consensus Standard and should be considered for providing the essential implementing methods for a Quality Assurance Program including the details for effective and reliable supporting processes and procedures presented in this Subpart.

This Subpart does not usurp the sole authority of the NRC to issue guidance and interpretations for its regulations.

300 SUMMARY RESULTS (24)

In general, the regulations in 10 CFR 71, Subpart H, and 10 CFR 72, Subpart G, are nearly identical and are included within a Quality Assurance Program complying with NQA-1. However, a few differences exist due to the wording or level of detail required by the CFRs.

Table 300 of this Subpart summarizes each of the 10 CFR 71 and 10 CFR 72 criteria and how they are addressed by NQA-1. Differences in the documents and topics that should be addressed independently of the NQA-1 criteria to meet 10 CFR 71 or 10 CFR 72 criteria are described. Where an NQA-1 Part 1 requirement addresses the 10 CFR 71 or 10 CFR 72 criterion, the associated NQA-1 Nonmandatory Guidance should also be considered to aid in addressing the NRC requirement.

Overall, the implementer of a program complying with the requirements of NQA-1–2015 may meet the requirements of 10 CFR 71 (1-1-15 Edition) or 10 CFR 72 (1-1-15 Edition) with minimal program revisions. The differences cited are of administrative actions and prescriptive details in Parts 71 and 72. Refer to Table 300 for details.

Table 300
10 CFR 71 and 10 CFR 72 Criteria Addressed by ASME NQA-1

10 CFR 71 Regulation	10 CFR 72 Regulation	NQA-1 Requirements
Organization		
71.103, "Quality assurance organization" Describes responsibilities and functions of personnel involved in attaining quality objectives and the quality assurance functions.	*72.142, "Quality assurance organization"* Describes responsibilities and functions of personnel involved in attaining quality objectives and the quality assurance functions.	Requirement 1. "Organization" satisfies the elements of 10 CFR 71 and 10 CFR 72. Part III, Subpart 3.1-1.1, "Implementing Guidance for Part I, Requirement 1: Organization," provides additional guidance that may be used in conjunction with Requirement 1.
Comments: None		
Quality Assurance Program		
71.105, "Quality assurance program" Describes the requirements to establish a quality assurance program, provides controls over activities affecting the quality of materials and components in accordance with their importance to safety, and for the indoctrination and training of personnel performing activities affecting quality.	*71.144, "Quality assurance program"* Describes the requirements to establish a quality assurance program, provides controls over activities affecting the quality of materials and components in accordance with their importance to safety, and for the indoctrination and training of personnel performing activities affecting quality.	Requirement 2, "Quality Assurance Program" satisfies the elements of 10 CFR 71 and 10 CFR 72. Subpart 3.1-2.1, "Implementing Guidance for Part I, Requirement 2: Quality Assurance Programs"; Subpart 3.1-2.2, "Implementing Guidance for Part I, Requirement 2: Quality Assurance Programs, Lead Auditor Qualification"; and Subpart 3.1-2.3, "Implementing Guidance for Part I, Requirement 2: Quality Assurance Programs, Inspection, and Test Personnel Qualification."
Comments: None		
Design Control		
71.107, "Package design control" Describes the requirements of establishing measures to assure applicable regulatory requirements and the package design are correctly translated, establishing measures for the identification and control of design interfaces, and the control of design changes.	*72.146, "Design control"* Describes the requirements of establishing measures to assure applicable regulatory requirements and the design basis are correctly translated, establishing measures for the identification and control of design interfaces, and the control of design changes.	Requirement 3, "Design Control" satisfies the majority of the elements of 10 CFR 71 and 10 CFR 72. Minor differences in the requirements should be examined and are detailed below. Subpart 3.1-3.1, "Implementing Guidance for Part I, Requirement 3: Design Control" provides additional guidance that may be used in conjunction with Requirement 3.
Comments: None		
71.107(b) states, "The licensee shall apply any design control measures to items such as the following: criticality physics, radiation shielding, stress, thermal, hydraulic, and accident analyses; compatibility of materials; accessibility for inservice inspection, maintenance and repair, features to facilitate decontamination; and delineation of acceptance criteria for inspections and tests."	72.146 (b) states, "The licensee, applicant for a license, certificate holder, and applicant for a CoC shall apply design control measures to items such as the following: criticality physics, radiation shielding, stress, thermal, hydraulic, and accident analyses; compatibility of materials; accessibility for inservice inspection, maintenance and repair, features to facilitate decontamination; and delineation of acceptance criteria for inspections and tests."	NQA-1 does not call out specific items for the application of design control measures.
Comments: In using NQA to satisfy these requirements, additional detail would have to be provided by the user to address application of design control measures to items such as those listed in the CFRs.		

Table 300
10 CFR 71 and 10 CFR 72 Criteria Addressed by ASME NQA-1 (Cont'd)

10 CFR 71 Regulation	10 CFR 72 Regulation	NQA-1 Requirements
71.107(c) states, "The licensee shall subject design changes, including field changes, to design control measures commensurate with those applied to the original design. Changes in the conditions specified in the package approval require NRC approval."	72.146(c) states, "The licensee, applicant for a license, certificate holder, and applicant for a CoC shall subject design changes, including field changes, to design control measures commensurate with those applied to the original design. Changes in the conditions specified in the license or CoC require prior NRC approval."	Requirement 3, "Design Control." 600(a) states, "changes to design inputs, final designs, field changes, and temporary and permanent modifications to operating facilities shall be justified and subject to design control measures commensurate with those applied to the original design."
Comments: In using NQA-1 to satisfy these requirements, additional details would have to be provided by the user to address the fact that changes in conditions specified in the package approval, license, or CoC require NRC approval.		
Procurement Document Control		
71.109, "Procurement Document Control" Describes requirements to assure that adequate quality is required in the documents for procurement of material, equipment, and services.	*71.148, "Procurement Document Control"* Describes requirements to assure that adequate quality is required in the documents for procurement of material, equipment, and services.	Requirement 4, "Procurement Document Control," satisfies the elements of 10 CFR 71 and 10 CFR 72. Subpart 3.1-4.1, "Implementing Guidance for Part I, Requirement 4: Procurement Document Control," provides additional guidance that may be used in conjunction with Requirement 4.
Comments: None		
Instructions, Procedures, and Drawings		
71.111, "Instructions, procedures, and drawings" Describes requirements for prescribing activities affecting quality by documented instructions, procedures, or drawings of a type appropriate to the circumstances and for requiring that said documents be followed.	*72.150, "Instructions, procedures, and drawings"* Describes requirements for prescribing activities affecting quality by documented instructions, procedures, or drawings of a type appropriate to the circumstances and for requiring that said documents be followed.	Requirement 5, "Instructions, Procedures, and Drawings," satisfies the elements of 10 CFR 71 and 10 CFR 72.
Comments: None		
Document Control		
71.113, "Document control" Describes measures for the control and issuance of documents and to assure that documents, including changes, are reviewed for adequacy, approved for release, and distributed and used at the location where the activity is performed.	*72.152, "Document control"* Describes measures for the control and issuance of documents and to assure that documents, including changes, are reviewed for adequacy, approved for release, and distributed and used at the location where the activity is performed.	Requirement 6, "Document Control," satisfies the elements of 10 CFR 71 and 10 CFR 72.
Comments: None		
Control of Purchased Items and Services		
71.115, "Control of purchased material, equipment, and services" Requires measures to be established to assure that purchased material, equipment, and services conform to the procurement documents, measures to assure that material and equipment conform to procurement specifications before installation, and measures to assess the effectiveness of the control of quality at intervals consistent with the importance, complexity, and quantity of the product or service.	*72.154, "Control of purchased material, equipment, and services"* Requires measures to be established to assure that purchased material, equipment, and services conform to the procurement documents, measures to assure that material and equipment conform to procurement specifications before installation, and measures to assess the effectiveness of the control of quality at intervals consistent with the importance, complexity, and quantity of the product or service.	Requirement 7, "Control of Purchased Items and Services," satisfies the elements of 10 CFR 71 and 10 CFR 72. Subpart 3.1-7.1, "Implementing Guidance for Part I, Requirement 7: Control of Purchased Items and Services," provides additional guidance that may be used in conjunction with Requirement 7.

Table 300
10 CFR 71 and 10 CFR 72 Criteria Addressed by ASME NQA-1 (Cont'd)

10 CFR 71 Regulation	10 CFR 72 Regulation	NQA-1 Requirements
Comments: NQA-1 utilizes the terminology *Supplier* as "an all-inclusive term used in place of any of the following: vendor, seller, contractor, subcontractor, fabricator, consultant, and their subtier levels." Also, NQA-1 allows postinstallation, whereas 10 CFR 71 and 72 specifically state before installation.		
Identification and Control of Items		
71.117, "Identification and control of materials, parts, and components" Requires the establishment of measures for the identification and control of materials, parts, and components. These measures must be designed to prevent the use of incorrect or defective materials, parts, and components.	*72.156, "Identification and control of materials, parts, and components"* Requires the establishment of measures for the identification and control of materials, parts, and components. These measures must be designed to prevent the use of incorrect or defective materials, parts, and components.	Requirement 8, "Identification and Control of Items," satisfies the elements of 10 CFR 71 and 10 CFR 72.
Comments: None		
Control of Special Processes		
71.119, "Control of special processes" Requires the establishment of measures to assure that special processes are controlled and accomplished by qualified personnel using qualified procedures.	*72.158, "Control of special processes"* Requires the establishment of measures to assure that special processes are controlled and accomplished by qualified personnel using qualified procedures.	Requirement 9, "Control of Special Processes," satisfies the elements of 10 CFR 71 and 10 CFR 72.
Comments: None		
Inspection		
71.121, "Internal inspection" Requires the establishment and execution of a program for inspection of activities to verify conformance with the documents for accomplishing the activities.	*72.160, "Licensee Inspection"* Requires the establishment and execution of a program for inspection of activities to verify conformance with the documents for accomplishing the activities.	Requirement 10, "Inspection," satisfies the elements of 10 CFR 71 and 10 CFR 72. Subpart 3.1-10.1, "Implementing Guidance for Part I, Requirement 10: Inspection," provides additional guidance that may be used in conjunction with Requirement 10.
Comments: None		
Test Control		
71.123, "Test control" Describes the requirements for establishing a test program to assure that all required testing is identified and performed in accordance with written test procedures.	*72.162, "Test control"* Describes the requirements for establishing a test program to assure that all required testing is identified and performed in accordance with written test procedures.	Requirement 11, "Test Control," satisfies the elements of 10 CFR 71 and 10 CFR 72.
Comments: None		
Control of Measuring and Test Equipment		
71.125, "Control of measuring and test equipment" Requires that tools, gauges, instruments, and other measuring and testing devices used in activities affecting quality are properly controlled, calibrated, and adjusted at specified times to maintain accuracy.	*72.164, "Control of measuring and test equipment"* Requires that tools, gauges, instruments, and other measuring and testing devices used in activities affecting quality are properly controlled, calibrated, and adjusted at specified times to maintain accuracy.	Requirement 12, "Control of Measuring and Test Equipment," satisfies the elements of 10 CFR 71 and 10 CFR 72.
Comments: None		

Table 300
10 CFR 71 and 10 CFR 72 Criteria Addressed by ASME NQA-1 (Cont'd)

10 CFR 71 Regulation	10 CFR 72 Regulation	NQA-1 Requirements
Handling, Storage, and Shipping		
71.127, "Handling, storage, and shipping control" Requires the establishment of measures to control the handling, storage, shipping, cleaning, and preservation of materials and equipment to prevent damage or deterioration.	*72.166, "Handling, storage, and shipping control"* Requires the establishment of measures to control the handling, storage, shipping, cleaning, and preservation of materials and equipment to prevent damage or deterioration.	Requirement 13, "Handling, Storage, and Shipping," satisfies the elements of 10 CFR 71 and 10 CFR 72.
Comments: None		
Inspection, Test, and Operating Status		
71.129, "Inspection, test, and operating status" Requires the establishment of measures to indicate the status of inspection and tests and the operating status of components such as tags and valves to prevent inadvertent operation.	*72.168, "Inspection, test, and operating status"* Requires the establishment of measures to indicate the status of inspection and tests and the operating status of components such as tags and valves to prevent inadvertent operation.	Requirement 14, "Inspection, Test and Operating Status," satisfies the elements of 10 CFR 71 and 10 CFR 72.
Comments: None		
Control of Nonconforming Items		
71.131, "Nonconforming materials, parts, or components" Requires the establishment of measures to control materials, parts, or components that do not conform to requirements to prevent their inadvertent use or installation.	*72.170, "Nonconforming materials, parts, or components"* Requires the establishment of measures to control materials, parts, or components that do not conform to requirements to prevent their inadvertent use or installation.	Requirement 15, "Control of Nonconforming Items," satisfies the elements of 10 CFR 71 and 10 CFR 72.
Comments: None		
Corrective Action		
71.133, "Corrective action" Requires measures be established to assure that conditions adverse to quality are promptly identified and corrected.	*72.172, "Corrective action"* Requires measures be established to assure that conditions adverse to quality are promptly identified and corrected.	Requirement 16, "Corrective Action," satisfies the elements of 10 CFR 71 and 10 CFR 72. Subpart 3.1-16.1, "Implementing Guidance for Part I, Requirement 16: Corrective Action," provides additional guidance that may be used in conjunction with Requirement 16.
Comments: None		
Records		
71.135, "Quality assurance records" Describes the requirements for maintaining sufficient written records to describe the activities affecting quality.	*72.174, "Quality assurance records"* Describes the requirements for maintaining sufficient written records to describe the activities affecting quality.	Basic Requirement 17, "Quality Assurance Records," satisfies the majority of elements of 10 CFR 71 and 10 CFR 72. Subpart 3.1-17.1, "Implementing Guidance for Part I, Requirement 17: Quality Assurance Records," and Subpart 3.1-17.2, "Implementing Guidance for Part I, Requirement 17: Quality Assurance Records, Electronic Records," provide additional guidance that may be used in conjunction with Requirement 17. Minor differences in the requirements should be examined and are detailed below.
Comments: None		

Table 300
10 CFR 71 and 10 CFR 72 Criteria Addressed by ASME NQA-1 (Cont'd)

10 CFR 71 Regulation	10 CFR 72 Regulation	NQA-1 Requirements
71.135 states, "The records must include the instructions, procedures, and drawings required by paragraph 71.111 to prescribe quality assurance activities and must include closely related specifications such as required qualifications of personnel, procedures, and equipment. The records must include the instructions or procedures that establish a records retention program that is consistent with applicable regulations and designates factors such as duration, location, and assigned responsibility."	72.174 states, "The records must include the following: design records, records of use and the results of reviews, inspections, tests, audits, monitoring of work performance, and material analyses. The records must include closely related data such as qualifications of personnel, procedures, and equipment. Inspections and test records must, at a minimum, identify the inspector or data recorder, the type of observation, the results, the acceptability, and the actions taken in connection with any noted deficiencies."	NQA-1 Requirement 17, "Records," does not specifically mention that records include instructions, procedures, and drawings required by NQA-1 Requirement 5 as required in 10 CFR 71. Requirement 17 does require that record control requirements, including duration, location, and assigned responsibility be documented. NQA-1 Requirement 17 does not specifically mention that records include the results of material analysis as required by 10 CFR 72. NQA-1 Requirement 2, "QA Program," and Requirement 9, "Control of Special Processes," require qualifications of personnel, procedures, and equipment be maintained as records as required by both CFRs. NQA-1 Requirement 3, "Design Control," requires design documents be maintained as records as required by 10 CFR 72. NQA-1 Requirement 18, "Audits," requires audit results to be included as records as required by 10 CFR 72. Requirement 10, "Inspection," and Requirement 11, "Test Control," satisfy the minimum inspection and test record content required by 10 CFR 72.
Comments: In using NQA-1 to satisfy the requirements of 10 CFR 71, the user should include instructions, procedures, and drawings produced under Requirement 5 as QA records. In using NQA-1 to satisfy the requirements of 10 CFR 72, the user should include results of material analysis as QA records.		
71.135 states, "The licensee, certificate holder, and applicant for a CoC shall retain these records for 3 yr beyond the date when the licensee, certificate holder, and applicant for a CoC last engage in the activity for which the quality assurance program was developed. If any portion of the written procedures or instructions is superseded, the licensee, certificate holder, and applicant for a CoC shall retain the superseded material for 3 yr after it is superseded."	72.174 states, "Records pertaining to the design, fabrication, erection, testing, maintenance, and use of structures, systems, and components important to safety must be maintained by or under the control of the licensee or certificate holder until the NRC terminates the license or CoC."	NQA-1 Requirement 17 does not specifically address retention times as called out in the CFRs.
Comments: In using NQA-1 to satisfy these requirements, additional detail concerning the retention of superseded procedures or instructions for 3 yr and maintenance of records until NRC termination of license or CoC would have to be provided by the user concerning record control.		
Audits		
71.137, "Audits" Requires a comprehensive system of planned and periodic audits to verify compliance with all aspects of the quality assurance program, and to determine the effectiveness of the program.	*72.176, "Audits"* Requires a comprehensive system of planned and periodic audits to verify compliance with all aspects of the quality assurance program, and to determine the effectiveness of the program.	Requirement 18, "Audits," satisfies the elements of 10 CFR 71 and 10 CFR 72. Subpart 3.1-18.1, "Implementing Guidance for Part I, Requirement 18: Audits," and Subpart 3.1-18.2, "Implementing Guidance on Classification and Handling of Audit Issues," provide additional guidance that may be used in conjunction with Requirement 18.
Comments: None		

SUBPART 4.1.4
Guidance to Modification of an IAEA GS-R-3 Quality Program to Meet ASME NQA-1a–2009 Requirements and Modification of an NQA-1a–2009 Quality Program to Meet IAEA GS-R-3 Requirements

100 PURPOSE AND SCOPE

The purposes of this Subpart are to compare requirements of IAEA GS-R-3 2006-STI/PUB/1252 and NQA-1–2008, Part I with the NQA-1a–2009 Addenda, to identify the similarities and differences, and to identify where actions may be needed to address the differences. The comparisons are illustrated from the following two perspectives:

(a) how IAEA GS-R-3 requirements address NQA-1 requirements

(b) how NQA-1 requirements address IAEA GS-R-3 requirements

Two tables are included providing a detailed line-by-line comparison from each perspective. These same tables are used in IAEA Safety Report "Management Systems Standards: Comparison of IAEA GS-R-3 and NQA-1–2008 Requirements" to ensure a consistent understanding across the global nuclear community. The term NQA-1 will be used hereafter instead of NQA-1–2008, Part I with the NQA-1a–2009 Addenda. The term GS-R-3 will be used instead of (IAEA) Safety Standard GS-R-3, 2006-STI/PUB/1252.

NOTE: Some relevant parts of NQA-1, contained in Parts II through IV, are indicated in the recommendations, as were guidance documents for IAEA GS-R-3.

200 APPLICABILITY

The guidance is intended for all parties involved in the nuclear industry that are currently applying/implementing either NQA-1 or IAEA GS-R-3 requirements and are required to comply with other requirements.

This Subpart can also be used to achieve compliance with both sets of requirements simultaneously by providing information on the similarities and differences between IAEA GS-R-3 and NQA-1, thus allowing the organization to implement controls for the program differences.

300 BACKGROUND

301 Global Uses of NQA-1 and IAEA GS-R-3

As governments adopt or apply IAEA GS-R-3 requirements through regulations, facility operators and organizations providing nuclear items or products and services around the globe may be compelled to comply with the GS-R-3 management system requirements while maintaining certification or compliance of their activities, items, products, and services to an NQA-1 quality assurance program.

Consequently, many organizations will have to adopt both IAEA GS-R-3 and NQA-1 as the basis of their management system or QA Program. IAEA GS-R-3 requires these requirements to be integrated within one management system. There was therefore a need for guidance to assist organizations to satisfy these requirements.

302 Conceptual Approaches to the Development of NQA-1 and IAEA GS-R-3

IAEA GS-R-3 and NQA-1 apply to the life cycle of nuclear facilities and activities, including siting, design, construction, commissioning, operation, and decommissioning. IAEA GS-R-3 and NQA-1 foster the application of requirements in a manner that is consistent with the relative importance of the item or activity. Both IAEA GS-R-3 and NQA-1 can be invoked by contract, adopted voluntarily, or used as the basis for assessing a management system or quality assurance program.

NQA-1 defines requirements for an organization to establish, implement, and assess a Quality Assurance (QA) Program to achieve nuclear safety. NQA-1 reflects industry experience and current understanding of QA requirements for the safe, reliable, and efficient utilization of nuclear energy and management and processing of radioactive materials.

The NQA-1 approach applies quality assurance requirements to activities that could affect the quality of nuclear material applications, structures, systems, and components of nuclear facilities. Quality assurance requirements

are used to develop a Quality Assurance Program necessary to achieve safe, reliable, and efficient utilization of nuclear energy and management and processing of radioactive material.

IAEA GS-R-3 defines requirements for an organization to establish, implement, assess, and continually improve a management system that integrates safety, health, environmental, security, quality, and economic elements to ensure safety is not compromised. It fosters a strong safety culture and improved safety performance in all the activities of the organization.

IAEA GS-R-3 adopts an integrated management system approach to be applied to all work of the organization. IAEA GS-R-3 requires the integration of safety, health, environmental, security, quality, and economic elements of the management system to ensure that safety is properly taken into account in all activities. It specifies requirements designed to achieve and enhance safety, while enhancing the satisfaction of interested parties. A management system based on IAEA GS-R-3 includes safety culture, human performance, a process approach to the achievement of objectives, and continual improvement of the management system and its processes (www-pub.iaea.org/MTCD/publications/download.asp).

400 HOW TO USE THIS GUIDE TO ACHIEVE COMPLIANCE WITH IAEA GS-R-3 OR NQA-1

401 Two Perspectives and Two Tables

The requirements of both standards are listed in two tables and have been compared utilizing the 18-criteria format of NQA-1, Part I and the Process Approach of IAEA GS-R-3. Guidance for evaluating existing practices or supplementing each program is summarized below each requirement section. In most cases, the IAEA requirements are stated at a higher process level, and the user must determine the need to develop detailed practices for implementation of the NQA-1 requirements. In these cases, it is necessary to compare the implementing practices with the requirements of NQA-1 to determine compliance. Two examples of the perspectives that must be considered and addressed by the guidance are the following:

(a) a Purchaser considering a Supplier for a nuclear facility that meets one of the programs but also needs to meet the requirements governed by the Purchaser's program

(b) a Supplier wanting to provide items/services to a Purchaser who requires compliance with the program that is not the Supplier's current program

402 How to Use Tables I and II

Table I presents a column of the requirements of NQA-1, Part I on a line-by-line basis for all 18 requirements and each subparagraph of each requirement. Immediately adjacent to the column for the NQA-1 requirement is a second column that contains the corresponding GS-R-3 requirement that specifically addresses the NQA-1 requirement. In cases where GS-R-3 does not specifically meet the NQA-1 requirement, recommendations are provided that describe how best to meet the NQA-1 requirement within the GS-R-3 program. It should be noted here that the recommendation is for the GS-R-3 user to meet the NQA-1 requirement, as opposed to trying to meet some requirement that may not be considered acceptable.

Likewise, Table II lists all five elements of the GS-R-3 requirements, plus the specific subtier elements of each. In this table, where a particular NQA-1 requirement meets the specific GS-R-3 requirement, it is so stated. Where there is no corresponding NQA-1 element that meets the GS-R-3 requirement, a recommendation is provided as to how the GS-R-3 requirement should be met.

It should be noted that neither table provides any direction for introductory/informational material from the two documents.

Table I
The Extent to Which GS-R-3 Addresses NQA-1 Requirements

Requirement	NQA-1	GS-R-3 and Recommendations
1 Organization		
1-100 General	Keywords: responsibilities, organizational structure, functional responsibilities, levels of authority, and lines of communications	GS-R-3 Requirements 2.8, 3.12, and 3.14
1-200 Structure and Responsibility	**201 General** Keywords: *(a)* management expectations *(b)* quality achieved and maintained by *(c)* quality achievement is verified by *(d)* sufficient authority, direct access, organizational freedom, access to work, independence, verification functions **202 Delegation of Work**	GS-R-3 Requirements 2.1, 2.2, 2.4, 3.12, 3.13, 3.14, 5.7, 5.10, and 6.5 *Recommendations.* GS-R-3 users should address organizational freedom, independence of verification activities, and the following verification functions: *(a)* identifying quality problems *(b)* initiating, recommending, or providing solutions to quality problems through designated channels *(c)* verifying implementation of solutions *(d)* ensuring that further processing, delivery, installation, or use is controlled until proper disposition of a nonconformance, deficiency, or unsatisfactory condition has occurred
1-300 Interface Control		GS-R-3 Requirements 5.4, 5.5, and 5.10
2 Quality Assurance Program		
2-100 General	Keywords: *(a)* documented, planned, implemented, and maintained *(c)* management assess	GS-R-3 Requirements 2.1, 2.6, 2.7, 3.8, 4.1, 4.2, 4.4, 4.5, and 6 *Recommendations.* GS-R-3 users should establish the program at the earliest time consistent with the schedule for accomplishing the activities and provide for special controls, required by NQA-1 (see recommendations under 2-200, 2-300, 2-400, and 2-500 for additional details).
2-200 Indoctrination and Training	**201 Indoctrination** **202 Training**	GS-R-3 Requirements 4.3 and 4.4 *Recommendations.* GS-R-3 users should ensure indoctrination to job responsibilities, and authority includes general criteria, technical objectives, requirements of applicable codes and standards, regulatory commitments, company procedures, and quality assurance requirements, required by NQA-1. GS-R-3 users should conduct indoctrination and training commensurate with scope, complexity, importance of the activities, and the education, experience, and proficiency of the person consistent with the grading requirements in GS-R-3 2.6 and 2.7.
2-300 Qualification Requirements	Keywords: designate activities that require qualification, written procedures **301 Nondestructive Examination (NDE)** **302 Inspection and Test** **303 Lead Auditor** **303.1 Communication Skills** **303.2 Training** **303.3 Audit Participation** **303.4 Examination** **303.5 Maintenance of Proficiency** **303.6 Requalification** **304 Auditors** **305 Technical Specialists**	No corresponding requirement. *Recommendations.* GS-R-3 users should ensure the responsible organization designates those activities that require qualification. The minimum requirements for personnel to verify quality and auditing are specified in paras. 301 through 304 of this Requirement. Consult relevant parts of NQA-1 for guidance on implementation of this requirement.

Table I
The Extent to Which GS-R-3 Addresses NQA-1 Requirements (Cont'd)

Requirement	NQA-1	GS-R-3 and Recommendations
2-400 Records of Qualification		No corresponding requirement. *Recommendations*. GS-R-3 users should address this NQA-1 requirement. Consult relevant parts of NQA-1 for guidance on implementation of this requirement.
2-500 Records		GS-R-3 Requirement 5.21. *Recommendations*. GS-R-3 users should ensure records of the implementation for indoctrination and training include one or more of (a) through (c) of this requirement. The GS-R-3 users should establish and maintain records for auditor and lead auditor qualification and requalification and inspection and test personnel qualification and requalification.
3 Design Control		
3-100 General	Keywords: defined, controlled	No corresponding specific requirement. *Recommendations*. GS-R-3 Requirements 5.1 through 5.10 address process management in general. GS-R-3 users should address this NQA-1 requirement. Consult relevant parts of NQA-1 for guidance on implementation of this requirement.
3-200 Design Input		No corresponding specific requirement. *Recommendations*. GS-R-3 Requirement 5.4 addresses process inputs. GS-R-3 users should address this NQA-1 requirement. Consult relevant parts of NQA-1 for guidance on implementation of this requirement.
3-300 Design Process	Keywords: *(a)* prescribe and document the design activities *(b)* design methods *(c)* final design, commercial grade items, and services	No corresponding specific requirement. *Recommendations*. GS-R-3 Requirement 5.14 addresses control of products. GS-R-3 users should address this NQA-1 requirement. Consult relevant parts of NQA-1 for guidance on implementation of this requirement.
3-400 Design Analyses	**401 Use of Computer Programs** **402 Documentation of Design Analyses**	No corresponding specific requirement. *Recommendations*. GS-R-3 users should address this NQA-1 requirement. Consult relevant parts of NQA-1 for guidance on implementation of this requirement.
3-500 Design Verification	**501 Methods** **501.1 Design Reviews** **501.2 Alternate Calculations** **501.3 Qualification Tests**	No corresponding specific requirement. *Recommendations*. GS-R-3 users should address this NQA-1 requirement. Consult relevant parts of NQA-1 for guidance on implementation of this requirement.
3-600 Change Control	Keywords: *(a)* changes to design justified, evaluation of effects, approved, approving organization, demonstrated competence *(c)* incorrect design **601 Configuration Management of Operating Facilities**	No corresponding specific requirement. *Recommendations*. GS-R-3 Requirement 5.13 addresses changes to documents. GS-R-3 users should address this NQA-1 requirement. Consult relevant parts of NQA-1 for guidance on implementation of this requirement.
3-700 Interface Control	Keywords: responsibility, procedures, design information	No corresponding specific requirement. *Recommendations*. GS-R-3 Requirement 5.5 addresses the control of interfaces generally. GS-R-3 users should address this NQA-1 requirement. Consult relevant parts of NQA-1 for guidance on implementation of this requirement.

Table I
The Extent to Which GS-R-3 Addresses NQA-1 Requirements (Cont'd)

Requirement	NQA-1	GS-R-3 and Recommendations
3-800 Software Design Control		No corresponding requirement. *Recommendations.* GS-R-3 Requirements 5.3, 5.9, and 5.10 address process management in general. GS-R-3 users should address these NQA-1 requirements. Consult relevant parts of NQA-1 for guidance on implementation of this requirement.
3-900 Documentation and Records	Keywords: sources of design inputs	No corresponding specific requirement. *Recommendations.* GS-R-3 Requirements 5.6 through 5.10 address process management generically. These generic requirements address process documentation and records to demonstrate the achievement of process results. GS-R-3 Requirements 5.12 and 5.13 address document control, and Requirements 5.21 and 5.22 address records. GS-R-3 users should address this NQA-1 requirement. Consult relevant parts of NQA-1 for guidance on implementation of this requirement.
4 Procurement Document Control		
4-100 General	Keywords: design bases, suppliers, quality assurance program	GS-R-3 Requirements 5.23 and 5.24 *Recommendations.* GS-R-3 users should ensure design bases are addressed in the documents, if applicable.
4-200 Content of the Procurement Documents	Keywords: all tiers of procurement **201 Scope of Work** **202 Technical Requirements** **203 Quality Assurance Program Requirements** **204 Right of Access** **205 Documentation Requirements** **206 Nonconformances** **207 Spare and Replacement Parts**	GS-R-3 Requirements 5.24 and 5.25 *Recommendations.* GS-R-3 users should address these NQA-1 requirements. Procurement documents should include the scope, technical requirements, quality assurance requirements, purchaser right of access, documentation requirements, nonconformance reporting provisions, and spare and replacement parts. Consult relevant parts of NQA-1 for guidance on implementation of this requirement.
4-300 Procurement Document Review		No corresponding requirement. *Recommendations.* GS-R-3 users should address this NQA-1 requirement, including documented changes to procurement documents prior to award to ensure that documents transmitted to a prospective Supplier include the appropriate provisions for ensuring that items or services will meet the specified requirements. Consult relevant parts of NQA-1 for guidance on implementation of this requirement.
4-400 Procurement Document Changes		GS-R-3 Requirements 5.13 and 5.14
5 Instructions, Procedures, and Drawings		
5-100 General	Keywords: documented, quantitative or qualitative acceptance criteria, detail commensurate with the complexity	GS-R-3 Requirements 2.6 through 2.10, 4.3, 5.6, 5.7, and 5.9
6 Document Control		
6-100 General		GS-R-3 Requirements 5.12 and 5.13
6-200 Document Control		GS-R-3 Requirements 2.8, 2.9, and 5.12
6-300 Document Changes	**301 Major Changes** **302 Minor Changes**	GS-R-3 Requirement 5.13

Table I
The Extent to Which GS-R-3 Addresses NQA-1 Requirements (Cont'd)

Requirement	NQA-1	GS-R-3 and Recommendations
7 Control of Purchased Items and Services		
7-100 General		GS-R-3 Requirements 5.15, 5.16, 5.23, 5.24, and 6.3
7-200 Supplier Evaluation and Selection		GS-R-3 Requirements 5.23, 5.24, and 6.3 *Recommendations*. GS-R-3 users should address one or more of the following: Supplier's history, Supplier's current quality records, and Supplier's technical and quality capability.
7-300 Bid Evaluation		No corresponding requirement. *Recommendations*. GS-R-3 users should address this NQA-1 requirement. Consult relevant parts of NQA-1 for guidance on implementation of this requirement.
7-400 Control of Supplier-Generated Documents		No corresponding requirement. *Recommendations*. When Supplier documents are received, GS-R-3 Requirements 5.12, 5.21, and 5.24 provide the necessary controls. GS-R-3 users should address this NQA-1 requirement. Consult relevant parts of NQA-1 for guidance on implementation of this requirement.
7-500 Acceptance of Item or Service	**501 General** Keywords: Supplier shall verify **502 Methods of Acceptance** **503 Certificate of Conformance** **504 Source Verification** **505 Receiving Inspection** **506 Postinstallation Testing** **507 Acceptance of Services Only**	GS-R-3 Requirements 5.24 and 5.25 *Recommendations*. GS-R-3 users should address paras. 503 through 507.
7-600 Control of Supplier Nonconformances	Keywords: *(a)* evaluation *(b)* submittal *(c)* disposition *(d)* verification *(e)* records	GS-R-3 Requirements 5.25 and 6.11 through 6.16 *Recommendations*. GS-R-3 users should address paras. 600(a) through (e).
7-700 Commercial Grade Items and Services	**701 General**	No corresponding requirement. *Recommendations*. GS-R-3 users should address this NQA-1 requirement. Consult relevant parts of NQA-1 for guidance on implementation of this requirement.
7-800 Records		No corresponding requirement. *Recommendations*. GS-R-3 users should address this NQA-1 requirement. Consult relevant parts of NQA-1 for guidance on implementation of this requirement.
8 Identification and Control of Items		
8-100 General	Keywords: correct and accepted items	GS-R-3 Requirements 5.18 and 5.19
8-200 Identification Methods	**201 Item Identification** **202 Physical Identification**	No corresponding requirements. *Recommendations*. GS-R-3 users should address these NQA-1 requirements. Consult relevant parts of NQA-1 for guidance on implementation of this requirement.
8-300 Specific Requirements	**301 Identification and Traceability of Items** **302 Limited Life Items** **303 Maintaining Identification of Stored Items**	No corresponding requirements. *Recommendations*. GS-R-3 users should address these NQA-1 requirements. Consult relevant parts of NQA-1 for guidance on implementation of this requirement.

Table I
The Extent to Which GS-R-3 Addresses NQA-1 Requirements (Cont'd)

Requirement	NQA-1	GS-R-3 and Recommendations
9 Control of Special Processes		
9-100 General	Keywords: welding, heat treating, nondestructive examination, qualified personnel, qualified procedures	No corresponding requirements. *Recommendations*. GS-R-3 users should address this NQA-1 requirement. Consult relevant parts of NQA-1 for guidance on implementation of this requirement.
9-200 Process Control	**201 Special Processes** **202 Acceptance Criteria** **203 Special Requirements**	No corresponding requirements. *Recommendations*. GS-R-3 users should address these NQA-1 requirements. Consult relevant parts of NQA-1 for guidance on implementation of this requirement.
9-300 Responsibility		No corresponding requirement. *Recommendations*. GS-R-3 users should address this NQA-1 requirement. Consult relevant parts of NQA-1 for guidance on implementation of this requirement.
9-400 Records		No corresponding requirement. *Recommendations*. GS-R-3 users should address this NQA-1 requirement. Consult relevant parts of NQA-1 for guidance on implementation of this requirement.
10 Inspection		
10-100 General		GS-R-3 Requirements 5.7 and 5.15 *Recommendations*. GS-R-3 users should ensure that inspection for acceptance is performed by qualified persons other than those who performed or directly supervised the work.
10-200 Inspection Requirements		GS-R-3 Requirement 5.7 *Recommendations*. When specifying inspection requirements and acceptance criteria, GS-R-3 users should include specified requirements contained in the applicable design documents or other pertinent technical documents approved by the responsible design organization.
10-300 Inspection Hold Points		No corresponding requirements. *Recommendations*. GS-R-3 users should address this NQA-1 requirement. Specified hold points should be indicated in appropriate documents. Consult relevant parts of NQA-1 for guidance on implementation of this requirement.
10-400 Inspection Planning	**401 Planning** **402 Sampling**	No corresponding requirements. *Recommendations*. GS-R-3 users should address these NQA-1 requirements. Consult relevant parts of NQA-1 for guidance on implementation of this requirement.
10-500 In-Process Inspection		No corresponding requirements. *Recommendations*. GS-R-3 users should address this NQA-1 requirement. Consult relevant parts of NQA-1 for guidance on implementation of this requirement.
10-600 Final Inspections	**601 Resolution of Nonconformances** **602 Inspection Requirements** **603 Modifications, Repairs, or Replacements** **604 Acceptance**	No corresponding requirements. *Recommendations*. GS-R-3 users should address these NQA-1 requirements. Consult relevant parts of NQA-1 for guidance on implementation of this requirement.

Table I
The Extent to Which GS-R-3 Addresses NQA-1 Requirements (Cont'd)

Requirement	NQA-1	GS-R-3 and Recommendations
10-700 Inspections During Operations		No corresponding requirements. *Recommendations*. GS-R-3 users should address this NQA-1 requirement. Consult relevant parts of NQA-1 for guidance on implementation of this requirement.
10-800 Records		No corresponding requirement. *Recommendations*. GS-R-3 users should address this NQA-1 requirement. Consult relevant parts of NQA-1 for guidance on implementation of this requirement.
11 Test Control		
11-100 General	Keywords: collect data, verify conformance, demonstrate satisfactory performance	GS-R-3 Requirements 5.7 and 5.15 *Recommendations*. GS-R-3 users should specify characteristics to be tested and test methods to be employed. Test results shall be documented, and their conformance with test requirements and acceptance criteria shall be evaluated.
11-200 Test Requirements		No corresponding requirements. *Recommendations*. GS-R-3 users should address this NQA-1 requirement. Consult relevant parts of NQA-1 for guidance on implementation of this requirement.
11-300 Test Procedures (Other Than for Computer Programs)	Keywords: test configuration, test objectives, prerequisites	No corresponding requirements. *Recommendations*. GS-R-3 users should address this NQA-1 requirement. Consult relevant parts of NQA-1 for guidance on implementation of this requirement.
11-400 Computer Program Test Procedures		No corresponding requirements. *Recommendations*. GS-R-3 users should address this NQA-1 requirement. Consult relevant parts of NQA-1 for guidance on implementation of this requirement.
11-500 Test Result		No corresponding requirements. *Recommendations*. GS-R-3 users should address this NQA-1 requirement. Consult relevant parts of NQA-1 for guidance on implementation of this requirement.
11-600 Test Records	**601 Test Records** **602 Computer Program Test Records**	No corresponding requirement. *Recommendations*. GS-R-3 users should address these NQA-1 requirements. Consult relevant parts of NQA-1 for guidance on implementation of this requirement.
12 Control of Measuring and Test Equipment		
12-100 General		GS-R-3 Requirement 5.15 *Recommendations*. GS-R-3 users should address control, calibration at specific periods, adjustment, and maintenance of tools, gages, instruments, and other measuring and test equipment.
12-200 Selection		GS-R-3 Requirement 5.15

Table I
The Extent to Which GS-R-3 Addresses NQA-1 Requirements (Cont'd)

Requirement	NQA-1	GS-R-3 and Recommendations
12-300 Calibration and Control	**301 Calibration** **302 Reference Standards** **303 Control** **303.1 Application** **303.2 Corrective Action** **303.3 Handling and Storage** **303.4 Environmental Controls** **303.5 Precalibration Checks** **303.6 Status Indication** **304 Commercial Devices**	No corresponding requirements. *Recommendations.* GS-R-3 users should address these NQA-1 requirements. Consult relevant parts of NQA-1 for guidance on implementation of this requirement.
12-400 Records	**401 General** Keywords: status, capability **402 Reports and Certificates**	No corresponding requirement. *Recommendations.* GS-R-3 users should address these NQA-1 requirements. Consult relevant parts of NQA-1 for guidance on implementation of this requirement.
13 Handling, Storage, and Shipping		
13-100 General		GS-R-3 Requirements 5.9 and 5.20 *Recommendations.* GS-R-3 users should address cleaning and packaging of items.
13-200 Special Requirements	Keywords: equipment, protective environment	No corresponding requirements. *Recommendations.* GS-R-3 users should address this NQA-1 requirement. Consult relevant parts of NQA-1 for guidance on implementation of this requirement, as applicable.
13-300 Procedures		GS-R-3 Requirements 2.6, 5.9, and 5.20.
13-400 Tools and Equipment		No corresponding requirements. *Recommendations.* GS-R-3 users should address this NQA-1 requirement. Consult relevant parts of NQA-1 for guidance on implementation of this requirement.
13-500 Operators		No corresponding requirements. *Recommendations.* GS-R-3 users should address this NQA-1 requirement. Consult relevant parts of NQA-1 for guidance on implementation of this requirement.
13-600 Marking or Labeling		No corresponding requirements. *Recommendations.* GS-R-3 users should address this NQA-1 requirement. Consult relevant parts of NQA-1 for guidance on implementation of this requirement.
14 Inspection, Test, and Operating Status		
14-100 General	Keywords: identified, maintained through indicators, authority	GS-R-3 Requirements 5.15 and 5.18 *Recommendations.* GS-R-3 users should address inspection, test, and operating status, required by NQA-1.
15 Control of Nonconforming Items		
15-100 General		GS-R-3 Requirements 6.11 and 6.12 *Recommendations.* GS-R-3 users should address notification to affected organizations.
15-200 Identification		GS-R-3 Requirement 6.12 *Recommendations.* GS-R-3 users should address the use of identification methods not detrimental to the item, on the item, the container, or the package.

Table I
The Extent to Which GS-R-3 Addresses NQA-1 Requirements (Cont'd)

Requirement	NQA-1	GS-R-3 and Recommendations
15-300 Segregation		GS-R-3 Requirement 6.12 *Recommendations*. GS-R-3 users should employ other precautions to preclude inadvertent use of a nonconforming item in cases when segregation is impractical or impossible due to physical conditions, such as size, weight, or access limitations.
15-400 Disposition	**401 Control** **402 Responsibility and Authority** **403 Personnel** **404 Disposition** **405 Reexamination**	GS-R-3 Requirements 6.12 and 6.13 *Recommendations*. GS-R-3 users should address paras. 402 and 403.
16 Corrective Action		
16-100 General	Keywords: condition adverse to quality, significant	GS-R-3 Requirements 6.14 and 6.15 *Recommendations*. GS-R-3 users should address verification of completed corrective actions.
17 Quality Assurance Records		
17-100 General		GS-R-3 Requirements 5.6, 5.21, and 5.22 *Recommendations*. GS-R-3 users should address authentication.
17-200 Generation of Records		GS-R-3 Requirements 5.6 and 5.21
17-300 Authentication of Records	Keywords: *(a)* valid *(b)* electronic	No corresponding requirements. *Recommendations*. GS-R-3 users should address this NQA-1 requirement. Consult relevant parts of NQA-1 for guidance on implementation of this requirement.
17-400 Classification	**401 Lifetime Records** **402 Nonpermanent Records**	GS-R-S Requirement 5.22 *Recommendations*. GS-R-3 users should address paras. 401 and 402.
17-500 Receipt Control of Records		No corresponding requirements. *Recommendations*. GS-R-3 users should address this NQA-1 requirement. Consult relevant parts of NQA-1 for guidance on implementation of this requirement.
17-600 Storage	**601 General** Keywords: *(a)* location, minimize risk *(b)* detrimental activities *(c)* access *(d)* damage **602 Facility Types** Keywords: (602.1) single, (602.2) dual **603 Temporary Storage**	No corresponding requirements. *Recommendations*. GS-R-3 users should address these NQA-1 requirements. Consult relevant parts of NQA-1 for guidance on implementation of this requirement.
17-700 Retention		GS-R-3 Requirement 5.22
17-800 Maintenance of Records	Keywords: *(a)* protected *(b)* retrievability *(c)* methods for record changes *(d)* electronic record media *(e)* technology changes *(f)* duplicated	GS-R-3 Requirement 5.22 *Recommendations*. GS-R-3 users should address (b) through (f).
18 Audits		
18-100 General		GS-R-3 Requirements 5.9, 6.3, 6.5, and 6.6.
18-200 Scheduling		No corresponding requirements. *Recommendations*. GS-R-3 users should address this NQA-1 requirement. Consult relevant parts of NQA-1 for guidance on implementation of this requirement.

Table I
The Extent to Which GS-R-3 Addresses NQA-1 Requirements (Cont'd)

Requirement	NQA-1	GS-R-3 and Recommendations
18-300 Preparation	**301 Audit Plan** **302 Personnel** **303 Selection of Audit Team**	GS-R-3 Requirement 6.4 *Recommendations.* GS-R-3 users should address paras. 301 and 303.
18-400 Performance		No corresponding requirements. *Recommendations.* GS-R-3 users should address this NQA-1 requirement. Consult relevant parts of NQA-1 for guidance on implementation of this requirement.
18-500 Reporting		No corresponding requirement. *Recommendations.* GS-R-3 users should address this NQA-1 requirement. Consult relevant parts of NQA-1 for guidance on implementation of this requirement.
18-600 Response		GS-R-3 Requirements 6.6 and 6.14 *Recommendations.* GS-R-3 users should address evaluation of audit responses by or for the auditing organization.
18-700 Follow-Up Action		GS-R-3 Requirements 5.9 and 6.15
18-800 Records		No corresponding requirement. *Recommendations.* GS-R-3 users should address this NQA-1 requirement. Consult relevant parts of NQA-1 for guidance on implementation of this requirement.

GENERAL NOTE: Keywords are included as appropriate to help the user identify the nature of the requirements. Users should refer to NQA-1 for the full text of the requirements.

Table II
The Extent to Which NQA-1 Addresses GS-R-3 Requirements

Requirement	GS-R-3	NQA-1 and Recommendations
2.1–2.10 Management System General Requirement		
2.1	Keywords: management system, goals, managing organization, planned and systematic actions	NQA-1 Requirements 1 and 2 *Recommendations*. NQA-1 users should ensure that health, safety, environmental, security, and economic requirements will be implemented as part of continual improvement of the management system
2.2	Keywords: safety	No corresponding specific requirement, but Part I, Introduction addresses the safe utilization of nuclear energy and nuclear material processing. *Recommendations*. NQA-1 users should address safety to the extent described by GS-R-3 to ensure safety is paramount.
2.3	Keywords: management system, identify and integrate, statutory and regulatory requirements, interested parties, IAEA Safety Requirements, relevant codes and standards	No corresponding requirement *Recommendations*. NQA-1 users should address this GS-R-3 requirement. Consult GS-G-3.1, 2.1 through 2.6 and GS-G-3.1 Appendix I for guidance on implementation of this requirement.
2.4	Keywords: demonstrate the effective fulfillment	NQA-1 Requirement 2, section 100(c) *Recommendations*. NQA-1 users should address all aspects of management system requirements.
Safety Culture		
2.5	Keywords: graded, significance and complexity, hazards, potential impact, consequences	No corresponding requirement. *Recommendations*. NQA-1 users should address this GS-R-3 requirement. Consult GS-G-3.1, 2.32 through 2.36 for guidance on implementation of this requirement.
Grading the Application of Management System Requirements		
2.6	Keywords: graded, significance and complexity, hazards, potential impact, consequences	NQA-1 Requirement 2, section 100(a) Requirement 5, Part I, Introduction *Recommendations*. NQA-1 users should deploy appropriate resources based on the potential impact associated with the safety, health, environmental, security, and economics on product or activity in the application of the QA program. Also, see Part III, Subpart 3.1-2.1 for additional guidance.
2.7	Keywords: grading of application	NQA-1 Requirement 2, section 100(a); Requirement 5; Part I, Introduction NQA-1 Requirement 3, section 500(d) Requirement 3, para. 801.4(b); Requirement 4, para. 203; Requirement 6, section 300; Requirement 7, para. 501; and Requirement 7, para. 504 are requirements that are examples of a graded approach. *Recommendations*. NQA-1 users should address the potential impact associated with the safety, health, environmental, security, and economics on products and activities of each process in the application of the QA program. Also, see Part III, Subpart 3.1-2.1 for additional guidance.

Table II
The Extent to Which NQA-1 Addresses GS-R-3 Requirements (Cont'd)

Requirement	GS-R-3	NQA-1 and Recommendations
Documentation of the Management System		
2.8	Keywords: documentation, policy statements, description of management system and structure, description of functional responsibilities, accountabilities, levels of authority and interactions, description of processes, and supporting information	NQA-1 Requirements 1 and 2 Additionally, NQA-1 includes responsibilities specific to processes and activities in other requirements. *Recommendations*. NQA-1 users should address in the documentation of the management system all GS-R-3 requirements, e.g., policy statements, safety, health, environmental, security, and economic.
2.9	Keywords: developed documentation of management system, readable, readily identifiable, available	NQA-1 Requirements 1, 2, 6, and 17
2.10	Keywords: documentation reflects characteristics of organization, complexities of processes, and interactions	NQA-1 Requirement 2, section 100(a) and Part I, Introduction *Recommendations*. NQA-1 users should address in the documentation of the management system the potential impact associated with the safety, health, environmental, security, and economics on product in the processes. Also, see Part III, Subpart 3.1-2.1 for additional guidance. The organization should identify all processes and their interactions.
3.1–3.14 Management Responsibility Management Commitment		
3.1	Keywords: management, commitment, establishment, implementation, assessment, continual improvement, management system	NQA-1 Requirement 1 addresses commitment to the establishment and implementation of the quality assurance program. Requirement 2, section 100(c), addresses the assessment of the quality assurance program. *Recommendations*. NQA-1 users should address continual improvement, resource allocation, and all other areas of the management system.
3.2	Keywords: senior management, values, behavioral expectations, role models	No corresponding requirement. *Recommendations*. NQA-1, Requirement 1, para. 201(a) addresses "overall management expectations" for the quality assurance program. NQA-1 users should address this GS-R-3 requirement. Consult GS-G-3.1, 3.1 through 3.7 for guidance on implementation of this requirement.
3.3	Keywords: management, communicate, need to adopt, values	No corresponding requirement. *Recommendations*. NQA-1 users should address this GS-R-3 requirement. Consult GS-G-3.1, 3.1 through 3.7 for guidance on implementation of this requirement.
3.4	Keywords: management, involvement, individuals, implementation, continual improvement, management system	No corresponding requirement. *Recommendations*. NQA-1 users should address this GS-R-3 requirement. Consult GS-G-3.1, 3.1 through 3.7 for guidance on implementation of this requirement.
3.5	Keywords: senior management, clear when, how, and by whom; decisions; management system	NQA-1 Requirement 1