

The Detroit Edison Company
One Energy Plaza, Detroit, MI 48226-1279



10 CFR 52.79

November 19, 2010
NRC3-10-0054

U. S. Nuclear Regulatory Commission
Attention: Document Control Desk
Washington, DC 20555-0001

- References: 1) Fermi 3
Docket No. 52-033
- 2) Letter from Jerry Hale (NRC) to Jack M. Davis (Detroit Edison), "Request for Additional Information Letter No. 44 Related to the SRP Section 17.5 for the Fermi 3 Combined License Application," Dated October 25, 2010

Subject: Detroit Edison Company Response to NRC Requests for Additional Information Letter No. 44

In Reference 2, the NRC requested additional information to support the review of certain portions of the Fermi 3 Combined License Application (COLA). The responses to the Request for Additional Information (RAI) associated with Reference 2, SRP Section 17.5 are provided as Attachments 1 through 3 of this letter. Information contained in these responses will be incorporated into a future COLA submission as described in the attachments.

If you have any questions, or need additional information, please contact me at (313) 235-3341.

I state under penalty of perjury that the foregoing is true and correct. Executed on the 19th day of November 2010.

Sincerely,

A handwritten signature in black ink, appearing to read "PWS", written over a horizontal line.

Peter W. Smith, Director
Nuclear Development – Licensing & Engineering
Detroit Edison Company

- Attachments: 1) Response to RAI Letter No. 44, RAI Question No. 17.5-24
2) Response to RAI Letter No. 44, RAI Question No. 17.5-25
3) Response to RAI Letter No. 44, RAI Question No. 17.5-26

cc: Adrian Muniz, NRC Fermi 3 Project Manager
Jerry Hale, NRC Fermi 3 Project Manager
Bruce Olson, NRC Fermi 3 Environmental Project Manager
Fermi 2 Resident Inspector (w/o attachments)
NRC Region III Regional Administrator (w/o attachments)
NRC Region II Regional Administrator (w/o attachments)
Supervisor, Electric Operators, Michigan Public Service Commission (w/o attachments)
Michigan Department of Natural Resources & Environment, Radiological Protection
Section (w/o attachments)

**Attachment 1
NRC3-10-0054**

**Response to RAI Letter No. 44
(eRAI Tracking No. 5176)**

RAI Question No. 17.5-24

NRC RAI 17.5-24

SRP Section 17.5 and the Nuclear Energy Institute (NEI) QAPD template (NEI 06-14A, Revision 7, "Quality Assurance Program Description") are based upon the requirements of ASME standard NQA-1 "Quality Assurance Requirements for Nuclear Facility Applications" (1994 Edition).

The NRC endorsed the NEI QAPD template as a method for providing a QAPD that meets the requirements of 10 CFR Part 50, Appendix B. The NRC's Final Safety Evaluation Report (FSER) dated July 13, 2010 (ML101800497) endorsed the generic QAPD template in NEI 06-14, Revision 9. NEI 06-14A, Revision 7, dated August 2010 (ML102370305) published the accepted version of NEI 06-14, Revision 9, and incorporated the NRC's FSER for reference as Appendix 2.

The Fermi 3 Combined License Application, Part 2: Final Safety Analysis Report (FSAR), Chapter 17.5, Revision 2, states the QAPD applies to activities to adapt the design to specific plant implementation, construction, and operations is based on NEI 06-014A.

Proposed changes to the Fermi 3 QAPD (FSAR Appendix 1 7AA) Part IV, "Regulatory Commitments," provided as part of Attachment 16 to NRC3-10-0036, "Detroit Edison Company Response to NRC Request for Additional Information Letter No.39," dated September 2, 2010, states Fermi 3 complies with the listed regulatory guides to the "extent described or referenced" and that conformance and any exceptions are provided in FSAR Chapter 1.

Staff review noted that the extent of compliance is not clear in Part IV. Additionally, the proposed changes to FSAR Chapter 1 (also provided as part of Attachment 16 to NRC3-10-0036) do not clearly communicate the results of the conformance evaluation, nor clearly describe the exceptions provided in FSAR Table 1.9-202 inserts.

Please clarify Fermi 3's regulatory guide compliance, results of the conformance evaluation, and list of any exceptions, for the regulatory guides in FSAR Table 1.9-202 and QAPD Part IV provided as part of Attachment 16 to NRC3-10-0036.

Note: This RAI is supplemental to RAI 17.5-23 included in NRC RAI Letter No. 39, dated July 20, 2010.

Response

As part of Attachment 16 to letter Detroit Edison Letter NRC3-10-0036 dated September 2, 2010 (ML102570700), Detroit Edison provided proposed markup to FSAR Table 1.9-202 to show how Fermi 3 complies with Regulatory Guides 1.8, 1.26, 1.28, 1.29, 1.33, 1.37, and 1.54. The description of conformance provided in the proposed markup was consistent with NEI 06-14, Revision 9, Part IV.

In order to clarify Fermi 3 conformance with Regulatory Guides 1.8, 1.26, 1.28, 1.29, 1.33, 1.37, and 1.54, a new markup is provided for Part IV of the QAPD. To be consistent with NEI 06-14A, Revision 7, the discussion of conformance with these regulatory guides is relocated from FSAR Table 1.9-202 to Part IV of the QAPD. FSAR Table 1.9-202 will now include references to Part IV of the QAPD for this discussion.

In addition to relocating this discussion of regulatory guide conformance to Part IV of the QAPD, the following substantive changes are included in the markup:

- A statement has been included for each regulatory guide to clearly describe how Fermi 3 conforms to the regulatory guide as described therein.
- As a result of the response to RAI 17.5-25 in Attachment 2 to this letter, the discussion of conformance to Regulatory Guide 1.33 has been updated to describe that, in lieu of conforming to Regulatory Guide 1.33, Fermi 3 has confirmed that the administrative elements of Regulatory Guide 1.33 are satisfied within the QAPD.
- The description of conformance to Regulatory Guide 1.37 has been updated to provide additional detail consistent with NEI 06-14A, Revision 7.

Proposed COLA Revision

A proposed markup for FSAR Table 1.9-202 and Part IV of the QAPD is attached to reflect the changes described above.

Markup of Detroit Edison COLA
(following 11 pages)

The following markup represents how Detroit Edison intends to reflect this RAI response in a future submittal of the Fermi 3 COLA. However, the same COLA content may be impacted by revisions to the ESBWR DCD, responses to other COLA RAIs, other COLA changes, plant design changes, editorial or typographical corrections, etc. As a result, the final COLA content that appears in a future submittal may be different than presented here.

**Attachment 2
NRC3-10-0054**

**Response to RAI Letter No. 44
(eRAI Tracking No. 5177)**

RAI Question No. 17.5-25

Note: The following markups for the Fermi 3 FSAR Table 1.9-202 supercedes previous Table 1.9-202 markups associated with RAI 17.5-23.

Table 1.9-202 Conformance with Regulatory Guides (Sheet 2 of 25)

See App 17AA,
 QAPD, Part IV

RG Number	Title	Revision	Date	RG Position	Evaluation
1.8	Qualification and Training of Personnel for Nuclear Power Plants	Rev. 3	May-00	C.1 C.2	Conforms. Conforms, with the following exceptions— (1) instead of NQA 1-1983 or NQA-1-1989, NQA-1-1994 is utilized as specified in the QAPD (2) experience requirements cannot be met prior to operations as described in Appendix 13BB.
1.9	Application and Testing of Safety-Related Diesel Generators in Nuclear Power Plants	Rev. 4	Mar-07	General	Not applicable
1.11	Instrument Lines Penetrating Primary Reactor Containment (Safety Guide 11) Supplement to Safety Guide 11, Backfitting Considerations	Rev. 0	Feb-72	C.1, C.2, E	Conforms
1.12	Nuclear Power Plant Instrumentation for Earthquakes	Rev. 2	Mar-97	C.1, C.4 – C.7, C.3, C.8	Conforms Conforms. The seismic monitoring program, including the necessary test and operating procedures, will be implemented prior to receipt of fuel on site.
1.13	Spent Fuel Storage Facility Design Basis	Rev. 2	Mar-07	General	Conforms
1.14	Reactor Coolant Pump Flywheel Integrity	Rev. 1	Aug-75	General	Not applicable
1.16	Reporting of Operating Information—Appendix A Technical Specifications	Rev. 4	Aug-75	General	Conforms with the following exceptions: Reporting per C.1.b(2) and C.1.b(3) is no longer required.
1.20	Comprehensive Vibration Assessment Program for Reactor Internals During Preoperational and Initial Startup Testing	Rev. 3	Mar-07	C.1 C.2 C.3	Conforms. Conforms. Conforms.

Table 1.9-202 Conformance with Regulatory Guides (Sheet 4 of 25)

[EF3 COL 1.9-3-A]

RG Number	Title	Revision	Date	RG Position	Evaluation
1.25	Assumptions Used for Evaluating the Potential Radiological Consequences of a Fuel Handling Accident in the Fuel Handling and Storage Facility for Boiling and Pressurized Water Reactors	Rev. 0	Mar-72	General	Not applicable. RG 1.183 is used.
					See App 17AA, QAPD, Part IV
1.26	Quality Group Classifications and Standards of Water-, Steam-, and Radioactive-Waste-Containing Components of Nuclear Power Plants	Rev. 4	Mar-07	All	Exception: The requirements for quality group classifications and standards are defined by the DCD which implements Rev. 3. Refer to DCD Tables 1.9-21, 1.9-21a, 1.9-21b.
		Rev. 3	Feb-76	All	Conforms. Refer to DCD Tables 1.9-21, 1.9-21a, 1.9-21b.
1.27	Ultimate Heat Sink for Nuclear Power Plants	Rev. 2	Jan-76	General	The UHS is within the scope of the referenced certified design and is addressed in DCD Section 9.2.5.
1.28	Quality Assurance Program Requirements (Design and Construction)	Rev. 3	Aug-85	General	Exception: The QAPD identified in Section 17.5 addresses a QA program based on the newer NQA 1-1994, as provided for in SRP 17.5.
					See App 17AA, QAPD, Part IV
1.29	Seismic Design Classification	Rev. 4	Mar-07	General	Exception: The requirements for seismic design classification are defined by the DCD which implements Rev. 3. Refer to DCD Tables 1.9-21, 1.9-21a, 1.9-21b.
					See App 17AA, QAPD, Part IV
		Rev. 3	Sep-78	All	Conforms. Refer to DCD Tables 1.9-21, 1.9-21a, 1.9-21b.

Table 1.9-202 Conformance with Regulatory Guides (Sheet 5 of 25)

[EF3 COL 1.9-3-A]

RG Number	Title	Revision	Date	RG Position	Evaluation
1.30	Quality Assurance Requirements for the Installation, Inspection, and Testing of Instrumentation and Electric Equipment	Rev. 0	Aug-72	General	Exception: The QAPD identified in Section 17.5 addresses a QA program based on a newer NQA-1-1994, as discussed in SRP 17.5.
1.31	Control of Ferrite Content in Stainless Steel Weld Metal	Rev. 3	Apr-78	General	Conforms. Operational program implementation is described in Section 13.4.
1.32	Criteria for Power Systems for Nuclear Power Plants	Rev. 3	Mar-04	General	Conforms.
1.33	Quality Assurance Program Requirements (Operation)	Rev. 2	Feb-78	General	Exception. The QAPD topical report identified in Section 17.5 follows NQA-1 rather than the older standards referenced in RG 1.33.
		See App 17AA, QAPD, Part IV			
1.34	Control of Electroslag Weld Properties	Rev. 0	Dec-72	General	Conforms. Operational program implementation is described in Section 13.4
1.35	Inservice Inspection of UngROUTED Tendons in Prestressed Concrete Containments	Rev. 3	Jul-90	General	Not applicable
1.35.1	Determining Prestressing for Inspection of Prestressed Concrete Containments	Rev. 0	Jul-90	General	Not applicable
1.36	Nonmetallic Thermal Insulation for Austenitic Stainless Steel	Rev. 0	Feb-73	General	Conforms. Operational program implementation is described in Section 13.4
1.37	Quality Assurance Requirements for Cleaning of Fluid Systems and Associated Components of Water-Cooled Nuclear Power Plants	Rev. 1	Mar-07	General	Conforms
		See App 17AA, QAPD, Part IV			

Table 1.9-202 Conformance with Regulatory Guides (Sheet 7 of 25)

[EF3 COL 1.9-3-A]

RG Number	Title	Revision	Date	RG Position	Evaluation
1.52	Design, Inspection, and Testing Criteria for Air Filtration and Adsorption Units of Post-Accident Engineered-Safety-Feature Atmosphere Cleanup Systems in Light-Water-Cooled Nuclear Power Plants	Rev. 3	Jun-01	General	Conforms
1.53	Application of the Single-Failure Criterion to Safety Systems	Rev. 2	Nov-03	General	Conforms
1.54	Service Level I, II, and III Protective Coatings Applied to Nuclear Power Plants	Rev. 1	Jul-00	General	Conforms
1.56	Maintenance of Water Purity in Boiling Water Reactors	Rev. 1	Jul-78	General	Conforms.
1.57	Design Limits and Loading Combinations for Metal Primary Reactor Containment System Components	Rev. 1	Mar-07	General	Conforms
1.59	Design Basis Floods for Nuclear Power Plants (Errata Published 7/30/80)	Rev. 2	Aug-77	General	Conforms
1.60	Design Response Spectra for Seismic Design of Nuclear Power Plants	Rev. 1	Dec-73	General	Conforms
1.61	Damping Values for Seismic Design of Nuclear Power Plants	Rev. 1	Mar-07	General	Conforms
1.62	Manual Initiation of Protective Actions	Rev. 0	Oct-73	General	Conforms
1.63	Electric Penetration Assemblies in Containment Structures for Nuclear Power Plants	Rev. 3	Feb-87	General	Conforms
1.65	Materials and Inspections for Reactor Vessel Closure Studs	Rev. 0	Oct-73	General	Conforms

See App 17AA,
 QAPD, Part IV

PART IV REGULATORY COMMITMENTS

NRC Regulatory Guides and Quality Assurance Standards

This section identifies the NRC Regulatory Guides and the other quality assurance standards which have been selected to supplement and support the Fermi 3 QAPD. Fermi 3 commits to compliance with these standards to the extent described herein. Commitment to a particular Regulatory Guide or other QA standard does not constitute a commitment to the Regulatory Guides or QA standards that may be referenced therein.

1.1 Regulatory Guides

Regulatory Guide 1.26, Revision 4, March 2007- Quality Group Classifications and Standards for Water-, Steam-, and Radioactive-Waste-Containing Components of Nuclear Power Plants

Regulatory Guide 1.26 defines classification of systems and components.

Fermi 3 commits to the applicable regulatory position guidance provided in this regulatory guide for Fermi 3 components outside the scope of the DCD. The requirements for quality group classifications and standards defined by the DCD meet the regulatory guidance of Revision 3.

Regulatory Guide 1.26, Revision 3, February 1976 - Quality Group Classifications and Standards for Water-, Steam-, and Radioactive-Waste-Containing Components of Nuclear Power Plants

Regulatory Guide 1.26 defines classification of systems and components.

Fermi 3 commits to the applicable regulatory position guidance provided in this regulatory guide for Fermi 3 components within the scope of the DCD with the exceptions described in the ESBWR DCD Table 1.9-21, Table 1.9-21a, and Table 1.9-21b.

Regulatory Guide 1.29, Revision 4, March 2007- Seismic Design Classification.

Regulatory Guide 1.29 defines systems required to withstand a safe shutdown earthquake (SSE).

Fermi 3 commits to the applicable regulatory position guidance provided in this regulatory guide for Fermi 3 systems outside the scope of the DCD. The requirements for seismic design classification defined by the DCD meet the regulatory guidance of Revision 3.

Regulatory Guide 1.29, Revision 3, September 1978 - Seismic Design Classification

Regulatory Guide 1.29 defines systems required to withstand a safe shutdown earthquake (SSE).

Fermi 3 commits to the applicable regulatory position guidance provided in this regulatory guide for Fermi 3 systems within the scope of the DCD with the exceptions described in the ESBWR DCD Table 1.9-21, Table 1.9-21a, and Table 1.9-21b.

~~Regulatory Guide 1.37, Revision 1, March 2007 - Quality Assurance Requirements for Cleaning of Fluid Systems and Associated Components of Water-Cooled Nuclear Power Plants~~

~~Regulatory Guide 1.37 provides guidance on specifying water quality and precautions related to the use of alkaline cleaning solutions and chelating agents.~~

~~Fermi 3 commits to the applicable regulatory position guidance provided in this regulatory guide for Fermi 3 during the construction and preoperational phase of the plant.~~

~~**Standards:**~~

~~**ASME NQA-1-1994 Edition** – Quality Assurance Requirements for Nuclear Facility Applications~~

~~Fermi 3 commits to NQA-1-1994, Parts I and II, as described in the foregoing sections of this document.~~

~~Nuclear Information and Records Management Association, Inc. (NIRMA) Technical Guides (TGs)~~

~~Fermi 3 commits to NIRMA TGs as described in Part II, SECTION 17 of this document.~~

↑
Insert 3 (Note: The following insert for the Fermi 3 QAPD Part IV supercedes previous Part IV markups associated with RAI 17.5-23)

PART IV REGULATORY COMMITMENTS

NRC Regulatory Guides and Quality Assurance Standards

This section identifies the NRC Regulatory Guides (RG) and the other quality assurance standards which have been selected to supplement and support the Fermi 3 QAPD. Fermi 3 complies with these standards to the extent described or referenced. Commitment to a particular Regulatory Guide or other QA standard does not constitute a commitment to the Regulatory Guides or QA standards that may be referenced therein.

Regulatory Guides:

Regulatory Guide 1.8, Rev. 3, May 2000, *Qualification and Training of Personnel for Nuclear Power Plants*

Regulatory Guide 1.8 provides guidance that is acceptable to the NRC staff regarding qualifications and training for nuclear power plant personnel.

Fermi 3 conforms to the applicable regulatory position guidance provided in this regulatory guide as described below:

- This regulatory guide endorses ANSI/ANS-3.1-1993, "Selection, Qualification, and Training of Personnel for Nuclear Power Plants," with certain additions and exceptions that are listed in the Regulatory Position of this guide. Some of the exceptions are endorsements of certain sections of two other standards, ANSI N18.7-1976 (ANS-3.2), "Administrative Controls and Quality Assurance for the Operational Phase of Nuclear Power Plants," and ANSI/ASME NQA-1-1983, "Quality Assurance Program Requirements for Nuclear Power Plants." Rather than to commit to those Standards in the QAPD, appropriate requirements have been directly incorporated into the text if not found in NQA-1-1994. These requirements are consistent with the identified acceptance criteria in SRP Section 17.5. NEI 06-13A as incorporated in FSAR Chapter 13 provides acceptable alternatives for cold licensed operators selection, training and qualification requirements.
- Regulatory positions C.1.1 through C.1.4 and conformance with ANSI/ANS-3.1-1993 are addressed in Chapter 13 of the FSAR.
- Regulatory position C.2.1 addresses alternatives and substitutions for education and experience for quality assurance personnel. Those alternatives and substitutions are reflected in Part II, Section 2.6 of the QAPD.
- Regulatory Positions C.2.2 through C.2.10 are addressed in Chapter 13 of the FSAR.

- Regulatory Position C.2.11 addresses ANSI/ANS-3.1-1993 Section 4.5.5, Quality Control. The QAPD identifies an alternative for this regulatory position in Part II, Section 2.7. As documented in SER ML070510300, the qualification criteria in the QAPD is acceptable and consistent with SRP Section 17.5, paragraph II.T.
- Regulatory Position C.2.12 addresses ANSI/ANS-3.1-1993 Section 4.5.6, Quality Assurance. The QAPD identifies an alternative for this regulatory position in Part II, Section 2.7. As documented in SER ML070510300, the qualification criteria in the QAPD is acceptable and consistent with SRP Section 17.5, paragraph II.S.
- Regulatory Position C.2.13 is addressed in Chapter 13 of the FSAR.
- Regulatory Positions C.2.14 and C.2.15 address ANSI/ANS-3.1-1993 Sections 4.7.1 and 4.7.2 relative to Independent Review qualifications. The QAPD identifies an alternative for this regulatory position in Part V, Section 2.2. As documented in SER ML070510300, the QAPD follows SRP Section 17.5, paragraph II.W for establishing an independent review program for activities occurring during the operational phase.

Regulatory Guide 1.26, Revision 4, March 2007, *Quality Group Classifications and Standards for Water-, Steam-, and Radioactive-Waste-Containing Components of Nuclear Power Plants*

Regulatory Guide 1.26 defines classification of systems and components.

Fermi 3 conforms for site specific SSCs which are not classified by the ESBWR.

Regulatory Guide 1.28, Revision 3, August 1985, *Quality Assurance Program Requirements (Design and Construction)*

Regulatory Guide 1.28 describes a method acceptable to the NRC staff for complying with the provisions of Appendix B with regard to establishing and implementing the requisite quality assurance program for the design and construction of nuclear power plants.

Fermi 3 conforms to the applicable regulatory position guidance provided in this regulatory guide as described below:

- This regulatory guide endorses the basic and supplementary requirements in ANSI/ASME NQA-1-1983, "Quality Assurance Program Requirements for Nuclear Power Plants" and the ANSI/ ASME NQA-1 a-1983 Addenda along with the regulatory positions discussed below for the establishment and

execution of quality assurance programs during the design and construction phases of nuclear power plants. The QAPD provides adequate guidance for establishing a quality assurance program that complies with Appendix B to 10 CFR Part 50 by using ASME NQA standard NQA-1-1994, as supplemented by additional regulatory guidance and industry guidance. Reference approval for Exelon submittal to use NQA-1-1994 as documented in ADAMS Accession number ML023440300.

- Regulatory Position C.1 addresses the qualification of inspection and test personnel. The QAPD identifies an alternative for this regulatory position in Part II, Section 2.7. As documented in SER ML070510300, the qualification criteria in the QAPD is acceptable and consistent with SRP Section 17.5, paragraph II.T. Note that SRP Section 17.5 paragraph II.T.5 and 6 represent alternatives to this regulatory position that were approved in SER ML050700416.
- Regulatory Position C.2 is addressed through Part II, Section 17.1 of the QAPD.
- Regulatory Position C.3 addresses scheduling of audits. In establishing the independent audit program, the Fermi 3 commits to comply with the quality standards described in NQA-1-1994, Basic Requirement 18 and Supplement 18S-1. It follows SRP Section 17.5, paragraph II.R, for establishing the necessary measures to implement audits to verify that activities covered by the QAPD are performed in conformance with the requirements established. The scheduling of Internal Audits is addressed in QAPD Part II Section 18.2 and is consistent with position C.3.1 for the phase prior to placing the facility into operation. External Audits are addressed in QAPD Part II Section 7.1. The requirements are consistent with SRP paragraph II.R.11 and II.R. 12. These requirements address regulatory position C.3.2.

Regulatory Guide 1.29, Revision 4, March 2007, *Seismic Design Classification*

Regulatory Guide 1.29 defines systems required to withstand a safe shutdown earthquake (SSE).

Fermi 3 conforms for site specific SSCs which are not classified by the ESBWR. Regulatory Position C.4 addresses the application of the QA requirements of Appendix B to 10 CFR Part 50 to all activities affecting the safety-related functions of those portions of the SSCs that are covered by Regulatory Positions 2 and 3. Those in Regulatory Position 1 are considered safety-related. This QAPQ addresses the QA program requirements applied to safety-related activities.

Regulatory Guide 1.33, Revision 2, February 1978, *Quality Assurance Program Requirements (Operations)*

Regulatory Guide 1.33 describes a method acceptable to the NRC staff for complying with the Commission's regulations with regard to overall quality assurance program requirements for the operation phase of nuclear power plants. Instead of conforming to RG 1.33, Fermi 3 has confirmed that the administrative elements are satisfied within the QAPD.

Regulatory Guide 1.37, Revision 1, March 2007 -*Quality Assurance Requirements for Cleaning of Fluid Systems and Associated Components of Water-Cooled Nuclear Power Plants*

Regulatory Guide 1.37 provides guidance on specifying water quality and precautions related to the use of alkaline cleaning solutions and chelating agents.

Fermi 3 conforms to the applicable regulatory position guidance provided in this regulatory guide as described below:

- This Regulatory Guide finds that the provisions and recommendations included in ASME NQA-1-1994, Part II, Subpart 2.1 are generally acceptable for onsite cleaning of materials and components, cleanness control, and preoperational cleaning and layup of water-cooled nuclear power plant fluid systems with three regulatory positions. QAPD Part II, Section 13.2 addresses the commitment to NQA-1-1994, Part II, Subpart 2.1
- Regulatory Position C. 1 identifies that the applicability and acceptability of any of the codes, standards, and specifications referenced in the text are or will be addressed through other regulations or NRC guidance. Chapter 1 of the FSAR addresses the codes, standards, and other documents that are used in the COL and any exceptions or alternatives to those documents.
- Regulatory Positions C.2 requires that "the water quality for final flushes of fluid systems and associated components should be at least equivalent to the quality of the operating system water". QAPD Part II Section 13.2 addresses this commitment.
- Regulatory Position C.3 recommends following Sections 8.2.2 and 8.2.3 of ASME NQA-1-1994, Part II, Subpart 2.1 precautions related to the use of alkaline cleaning solutions and chelating agents, respectively, by the use of the guidance in nonmandatory Appendix 2.1 to ASME NQA-1-1994, Part III, Subpart 3.2. In addition, this position recommends that a suitable chloride stress-cracking inhibitor be added to the fresh water used to flush systems containing austenitic stainless steels. QAPD Part II, Section 13.2 addresses the commitment to NQA-1-1994, Part II, Subpart 3.2.

Regulatory Guide 1.54, Revision 1, July 2000 – *Service Level I, II, and III Protective Coatings Applied to Nuclear Power Plants*

Regulatory Guide 1.54 provides guidance for the application of protective coatings within nuclear power plants to protect surfaces from corrosion, contamination from radionuclides, and for wear protection.

Fermi 3 conforms with Regulatory Guide 1.54, Revision 1.

Standards:

ASME NQA-1-1994 Edition -*Quality Assurance Requirements for Nuclear Facility Applications*

Fermi 3 commits to NQA-1-1994, Parts I, II, and III, as described in Parts II and V of this document.

Nuclear Information and Records Management Association, Inc. (NIRMA)
Technical Guides (TGs)

Fermi 3 commits to NIRMA TGs as described in Part II, Section 17 of this document.

NRC RAI 17.5-25

SRP Section 17.5 and the Nuclear Energy Institute (NEI) QAPD template (NEI 06-14A, Revision 7, "Quality Assurance Program Description") are based upon the requirements of ASME standard NQA-1 "Quality Assurance Requirements for Nuclear Facility Applications" (1994 Edition).

The NRC endorsed the NEI QAPD template as a method for providing a QAPD that meets the requirements of 10 CFR Part 50, Appendix B. The NRC's Final Safety Evaluation Report (FSER) dated July 13, 2010 (ML10 1800497) endorsed the generic QAPD template in NEI 06-14, Revision 9. NEI 06-14A, Revision 7, dated August 2010 (ML102370305) published the accepted version of NEI 06-14, Revision 9, and incorporated the NRC's FSER for reference as Appendix 2.

Attachment 16 to NRC3-10-0036, "Detroit Edison Company Response to NRC Request for Additional Information Letter No.39," dated September 2, 2010, states Fermi 3 QAPD Part IV "Regulatory Commitments" and Part V "Additional Quality Assurance and Administrative Controls for the Plant Operational Phase" are being updated to incorporate NEI 06-14 Revision 9.

FSER, section 3.2.3.1, "Alternative for Commitment to RG 1.33," states in order to satisfy Appendix B to Part 50 requirements during the operations phase, an applicant using the template must demonstrate that its QAPD has incorporated all of the administrative controls not included in NQA-1-1994 by either of the following methods:

- 1. Explicitly addressing the provisions in NEI 06-14, Revision 9, Attachment 4 (Ref. 15), while also completing Part V of the QAPD template or,*
- 2. Including an explicit commitment to RG 1.33 in Part IV of the QAPD.*

Staff review did not note an explicit commitment to RG 1.33 in Part IV, nor documentation explicitly addressing the provisions in NEI 06-14, Revision 9, Attachment 4.

Please clearly address the provisions of FSER, section 3.2.3.1, and provide justification for any exceptions to the guidance provided in FSER, section 3.2.3.1.

Note: If Method 1 is selected, please use NEI 06-14A, Revision 7, Appendix 1 (or NEI 06-14, Revision 9, Attachment 4), to verify (block by block) that the Fermi 3 QAPD has incorporated each "American National Standard N 18.7-1 976/ANS-3 .2 Administrative Controls and Quality Assurance for the Operational Phase of Nuclear Power Plants/Regulatory Guide 1.33, Rev. 2 Regulatory Positions" (left column) administrative control. Please also include with your response an annotated version of Appendix 1 which documents the block by block verification.

Note: This RAI is supplemental to RAI 17.5-23 included in NRC RAI Letter No. 39, dated July 20, 2010.

Response

Fermi 3 has selected to use Method 1 in lieu of committing to Regulatory Guide 1.33. As described in the NRC FSER incorporated into NEI 06-14A, Revision 7, an applicant choosing Method 1 and not committing to Regulatory Guide 1.33 must demonstrate that its QAPD has incorporated the administrative controls not included in NQA-1-1994 by explicitly addressing the provisions in NEI 06-14, Revision 9, Attachment 4, while also completing Part V of the QAPD template. It is noted that Appendix 1 of NEI 06-14A, Revision 7, is equivalent to NEI 06-14, Revision 9, Attachment 4.

Attached is a proposed markup to the Fermi 3 QAPD to incorporate NEI 06-14A, Revision 7. The following evaluation in table 1 below is based on this markup of the QAPD, as well as QAPD markups submitted with previous RAI responses. Appendix 1 of NEI 06-14A, Revision 7, provides a roadmap for identifying how Regulatory Guide 1.33, Revision 2, and ANSI N18.7-1976 requirements are addressed by NQA-1-1994 and/or the NEI 06-14 QAPD.

The Fermi 3 QAPD includes Part V consistent with NEI 06-14A, Revision 7. Detroit Edison has verified that the Fermi 3 QAPD has incorporated the administrative controls in ANSI N18.7-1976/ANS-3.2 and Regulatory Guide 1.33, Revision 2, not included in NQA-1-1994. Table 1 below is an annotated version of Appendix 1 which documents this verification.

TABLE 1, Fermi 3 Table of Where Regulatory Guide 1.33, Rev. 2 and ANSI N18.7-1976 Requirements are Addressed by NQA-1-1994 Standards and/or the Fermi 3 QAPD

<p>American National Standard N18.7-1976/ANS-3.2 Administrative Controls and Quality Assurance for the Operational Phase of Nuclear Power Plants / Regulatory Guide 1.33, Rev. 2 Regulatory Positions</p>	<p>Applicable Section of NQA-1-1994 or NEI 06-14 Quality Assurance Program Description (QAPD)</p>	<p>Applicable Section(s) of Fermi 3 QAPD (for those requirements not addressed entirely by NQA-1-1994) [N/A is entered in column if requirements is addressed entirely by NQA-1-1994]</p>	<p>Comments (NEI 06-14A, Revision 7, Appendix 1, Comments adjusted for Fermi 3)</p>
<p>1. Scope</p>			
<p>This Standard provides requirements and recommendations for an administrative controls and quality assurance program necessary to provide assurance that operational phase activities at nuclear power plants are carried out without undue risk to the health and safety of the public. The requirements of this Standard apply to all activities affecting the safety-related functions of nuclear power plant structures, systems, and components. It is not intended to apply to test mobile and experimental reactors nor reactors not subject to U.S. Nuclear Regulatory Commission licensing. However, applicable sections of this Standard should be used as they apply to related activities. Activities included are: design changes, purchasing, fabricating, handling, shipping, storing, cleaning, erecting, installing, inspecting, testing, operating, maintaining, repairing, refueling and modifying.</p>	<p>NQA-1 Introduction to Parts I and II QAPD Part I, Introduction; Part II, Section 2</p>	<p>Fermi 3 QAPD, Part I, Introduction, Fermi 3 QAPD, Part II, Section 2, Quality Assurance Program</p>	
<p>It is recommended that the administrative controls and quality assurance provisions of this Standard be applied to other important plant equipment at a level commensurate with the importance of the equipment to reliable and efficient plant operation. However, it is emphasized that this Standard is directed primarily toward administrative controls and quality assurance associated with safety-related activities, equipment</p>	<p>NQA-1 Introduction to Parts I and II QAPD Part I, Introduction; Part II, Section 2</p>	<p>Fermi 3 QAPD, Part I, Introduction, Fermi 3 QAPD, Part II, Section 2, Quality Assurance Program</p>	

<p>American National Standard N18.7-1976/ANS-3.2 Administrative Controls and Quality Assurance for the Operational Phase of Nuclear Power Plants / Regulatory Guide 1.33, Rev. 2 Regulatory Positions</p>	<p>Applicable Section of NQA-1-1994 or NEI 06-14 Quality Assurance Program Description (QAPD)</p>	<p>Applicable Section(s) of Fermi 3 QAPD (for those requirements not addressed entirely by NQA-1-1994) [N/A is entered in column if requirements is addressed entirely by NQA-1-1994]</p>	<p>Comments (NEI 06-14A, Revision 7, Appendix 1, Comments adjusted for Fermi 3)</p>
<p>This Standard incorporates criteria that permit a degree of flexibility, since administrative practices vary among organizations operating nuclear power plants.</p>			<p>NQA-1 and the NEI 06-14 are similar in allowing some flexibility based on importance to safety.</p>
<p>The Nuclear Regulatory Commission (NRC) promulgates regulations applicable to many aspects of the design, construction and operation of nuclear power reactors. This Standard contains criteria for administrative controls and quality assurance for nuclear power plants during the operational phase of plant life. This phase is generally considered to commence with initial fuel loading, except for certain preoperational activities. Certain operating activities may commence prior to fuel loading and certain initial construction activities may extend past fuel loading. Owner organizations should identify clearly those activities that fall in these overlapping time periods and should specify whether the activities are to be considered as operational or as construction activities.</p>	<p>NQA-1 Introduction to Parts I and II QAPD Part I, Introduction; Part II, Section 2</p>	<p>Fermi 3 QAPD, Part I, Introduction, Fermi 3 QAPD, Part II, Section 2, Quality Assurance Program</p>	
<p>This Standard is intended to be consistent with applicable criteria for quality assurance, including those given in Title 10, Code of Federal Regulations, Part 50, "Licensing of Production and Utilization Facilities," Appendix B. [1]¹ This Standard fully and completely describes the general requirements and guidelines of American National Standard Quality Assurance Program Requirements for Nuclear Power Plants, N45.2-1971, [2] as those requirements and guidelines apply during the operational phase of plant life. Reg. Guide 1.33 – C. Regulatory Position, paragraph 1: The overall quality assurance program requirements for</p>	<p>QAPD Part I, Introduction; Part II, Section 2; Part IV, Commitments</p>	<p>Fermi 3 QAPD, Part I, Introduction, Fermi 3 QAPD, Part II, Section 2, Quality Assurance Program Fermi 3 QAPD, Part IV, Regulatory Commitments</p>	<p>10 CFR 50, Appendix B, for the operational phase is met through a combination of NQA-1 and the QAPD in lieu of a commitment to implement the requirements of ANSI N18.7-1976/ANS-3.2. (Commitment to industry standards is addressed in FSAR Chapter 1. Most of the listed standards are updated and incorporated into NQA1. For the QAPD the following cross-reference is provided:</p>

¹ Footnote from N18.7 – "Numbers in brackets refer to corresponding numbers in Section 6, References."

American National Standard N18.7-1976/ANS-3.2 Administrative Controls and Quality Assurance for the Operational Phase of Nuclear Power Plants / Regulatory Guide 1.33, Rev. 2 Regulatory Positions	Applicable Section of NQA-1- 1994 or NEI 06-14 Quality Assurance Program Description (QAPD)	Applicable Section(s) of Fermi 3 QAPD (for those requirements not addressed entirely by NQA-1-1994) [N/A is entered in column if requirements is addressed entirely by NQA-1-1994]	Comments (NEI 06-14A, Revision 7, Appendix 1, Comments adjusted for Fermi 3)																																
<p>the operation phase that are included in ANSI N18.7-1976/ANS-3.2 are acceptable to the NRC staff and provide an adequate basis for complying with the quality assurance program requirements of Appendix B to 10 CFR Part 50, subject to the following [NOTE: The Regulatory Positions that followed this statement are inserted into the 'best fit' sections of the N18.7-1976/ANS-3.2 text in this column of the table.]:</p> <p>Reg. Guide 1.33 – C. Regulatory Position 2. Throughout ANSI N18.7-1976/ANS-3.2, other documents required to be included as a part of this standard are identified at the point of reference. The specific acceptability of these standards listed in ANSI N18.7-1976/ANS-3.2 has been addressed in the latest revision of the following regulatory guides:</p> <table border="0"> <thead> <tr> <th style="text-align: left;">ANSI Standard</th> <th style="text-align: left;">Regulatory Guide</th> </tr> </thead> <tbody> <tr><td>N45.2 1.28</td><td>1.28</td></tr> <tr><td>N45.2.1</td><td>1.37</td></tr> <tr><td>N45.2.2</td><td>1.38</td></tr> <tr><td>N45.2.3</td><td>1.39</td></tr> <tr><td>N45.2.4</td><td>1.30</td></tr> <tr><td>N45.2.5</td><td>1.94</td></tr> <tr><td>N45.2.6</td><td>1.58</td></tr> <tr><td>N45.2.8</td><td>1.116</td></tr> <tr><td>N45.2.9</td><td>1.88</td></tr> <tr><td>N45.2.10</td><td>1.74</td></tr> <tr><td>N45.2.11</td><td>1.64</td></tr> <tr><td>N45.2.13</td><td>1.123</td></tr> <tr><td>N18.1</td><td>1.8</td></tr> <tr><td>N18.17</td><td>1.17</td></tr> <tr><td>N101.4</td><td>1.54</td></tr> </tbody> </table> <p><i>Note:</i> N45.2.12 is discussed in NRC documents</p>	ANSI Standard	Regulatory Guide	N45.2 1.28	1.28	N45.2.1	1.37	N45.2.2	1.38	N45.2.3	1.39	N45.2.4	1.30	N45.2.5	1.94	N45.2.6	1.58	N45.2.8	1.116	N45.2.9	1.88	N45.2.10	1.74	N45.2.11	1.64	N45.2.13	1.123	N18.1	1.8	N18.17	1.17	N101.4	1.54			<ul style="list-style-type: none"> • N45.2 is replaced by NQA-1-1983 as indicated in Reg. Guide 1.28, Rev. 3 and by the 1994 edition through the NRC approved alternative described in a safety evaluation for Exelon (ref. ADAMS accession no. ML023440300) • N45.2.1 is now NQA-1-1994, Part II, Subpart 2.1 • N45.2.2 is now NQA-1-1994, Part II, Subpart 2.2; NQA-1-1994, Part I, Supplement 8S-1 and Part II, Subpart 2.15 also address certain requirements previously in N45.2.2 • N45.2.3 is now NQA-1-1994, Part II, Subpart 2.3 • N45.2.4 is now NQA-1-1994, Part II, Subpart 2.4 • N45.2.5 is now NQA-1-1994, Part II, Subpart 2.5 • N45.2.6 is now NQA-1-1994, Part I, Supplements 2S-1, 2S-2, and Part III, Nonmandatory Appendix 2A-1; Reg. Guide 1.58 has been withdrawn • N45.2.8 is now NQA-1-1994, Part II, Subpart 2.8 • N45.2.9 is now NQA-1-1994, Part I, Supplement 17S-1 and the list of record types and retention periods is included in Table 1 of Reg. Guide 1.28, Rev. 3; Reg. Guide 1.88 has been withdrawn • N45.2.10 is now NQA-1-1994, Part
ANSI Standard	Regulatory Guide																																		
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American National Standard N18.7-1976/ANS-3.2 Administrative Controls and Quality Assurance for the Operational Phase of Nuclear Power Plants / Regulatory Guide 1.33, Rev. 2 Regulatory Positions	Applicable Section of NQA-1- 1994 or NEI 06-14 Quality Assurance Program Description (QAPD)	Applicable Section(s) of Fermi 3 QAPD (for those requirements not addressed entirely by NQA-1-1994) [N/A is entered in column if requirements is addressed entirely by NQA-1-1994]	Comments (NEI 06-14A, Revision 7, Appendix 1, Comments adjusted for Fermi 3)
<p>WASH-1283, "Guidance on Quality Assurance Requirements During Design and Procurement Phase of Nuclear Power Plants," (Grey Book) and WASH-1309, "Guidance on Quality Assurance Requirements During the Construction Phase of Nuclear Power Plants," (Green Book) and will be endorsed by a regulatory guide upon its approval as an ANSI standard.</p>			<p>I, Introduction; Reg. Guide 1.74 has been withdrawn • N45.2.11 is now NQA-1-1994, Part I, Supplement 3S-1; Reg. Guide 1.64 has been withdrawn • N45.2.12 is now NQA-1-1994, Supplement 18S-1; Reg. Guide 1.144 has been withdrawn • N45.2.13 is now NQA-1-1994, Part I, Supplements 4S-1 and 7S-1; Reg. Guide 1.123 has been withdrawn • N18.1 is now ANS-3.1 • N18.17 and Reg. Guide 1.17 have been withdrawn and the applicable requirements included in 10 CFR Part 73 • N101.4 has been withdrawn and replaced with several other standards as discussed in RG 1.54, Rev. 1)</p>
<p>2. Definitions</p>			
<p>2.1 Limitations.</p>			
<p>The definitions given below are applicable specifically to this Standard. Other terms and their definitions are contained in American National Standard, Quality Assurance Terms and Definitions, N45.2.10 [3].</p>	<p>NQA-1, Introduction to Part I</p>	<p>N/A</p>	<p>NQA-1 replaces N45.2 and daughters, including N45.2.10</p>
<p>2.2 Glossary of Terms</p>			
<p>administrative controls. Rules, orders, instructions, procedures, policies, practices and designations of authority and responsibility.</p>	<p>QAPD, Part V, Section 1</p>	<p>Fermi 3 QAPD, Part V, Section 1</p>	
<p>audit. A formal, independent examination with intent to verify conformance with established requirements.</p>	<p>NQA-1, Introduction to Part I</p>	<p>N/A</p>	<p>NQA-1 provides more clarity</p>

American National Standard N18.7-1976/ANS-3.2 Administrative Controls and Quality Assurance for the Operational Phase of Nuclear Power Plants / Regulatory Guide 1.33, Rev. 2 Regulatory Positions	Applicable Section of NQA-1- 1994 or NEI 06-14 Quality Assurance Program Description (QAPD)	Applicable Section(s) of Fermi 3 QAPD (for those requirements not addressed entirely by NQA-1-1994) [N/A is entered in column if requirements is addressed entirely by NQA-1-1994]	Comments (NEI 06-14A, Revision 7, Appendix 1, Comments adjusted for Fermi 3)
emergency procedures. Written procedures which specify actions, including manipulation of plant controls, to reduce the consequence of an accident or potentially hazardous condition which has already occurred, to implement the emergency plan, or to prepare for possible hazardous natural occurrences.	QAPD, Part V, Section 3	Fermi 3 QAPD, Part V, Section 3	The intent of the definition is met by the description of the Emergency Operating Procedures and Emergency Plan Implementing Procedures in the QAPD.
experiments. Performance of those plant operations carried out under controlled conditions in order to establish characteristics or values not previously known.	QAPD, Part V, Section 1	Fermi 3 QAPD, Part V, Section 1	
independent review. Review completed by personnel not having direct responsibility for the work function under review regardless of whether they operate as a part of an organizational unit or as individual staff members (see review).	QAPD, Part V, Section 1	Fermi 3 QAPD, Part V, Section 1	
inspection. Examination, observation, or measurement to determine the conformance of materials, supplies, components, parts, appurtenances, systems, personnel performance, procedures, processes or structures to predetermined requirements.	NQA-1, Introduction to Part I	N/A	
maintenance and modification procedures. Written procedures defining the policies and practices by which structures; mechanical, electrical and instrumentation and control systems; and components thereof of a nuclear power plant are kept in a condition of good repair or efficiency so that they are capable of performing their intended functions. As used in this Standard, these procedures apply to those activities performed by maintenance or contractor personnel to maintain, repair or modify safety-related equipment. Related activities are those actions taken by operating	NQA-1, Subpart 2.18, Sections 2.2 and 4.4.1 QAPD, Part V, Section 4	Fermi 3 QAPD, Part V, Section 5	

American National Standard N18.7-1976/ANS-3.2 Administrative Controls and Quality Assurance for the Operational Phase of Nuclear Power Plants / Regulatory Guide 1.33, Rev. 2 Regulatory Positions	Applicable Section of NQA-1- 1994 or NEI 06-14 Quality Assurance Program Description (QAPD)	Applicable Section(s) of Fermi 3 QAPD (for those requirements not addressed entirely by NQA-1-1994) [N/A is entered in column if requirements is addressed entirely by NQA-1-1994]	Comments (NEI 06-14A, Revision 7, Appendix 1, Comments adjusted for Fermi 3)
<p>personnel to determine that a planned maintenance activity can be safely performed under the existing plant operating conditions, to authorize the release of equipment to be maintained in accordance with equipment control procedures, and to assure that the equipment has been returned to normal operating status at the completion of the maintenance work including verification of functional acceptability. Procedures for these related activities by operating personnel are considered to be operating procedures, but may be included in maintenance procedures.</p>			
<p>nuclear power plant. Any plant using a nuclear reactor to produce electric power, process steam or space heating.</p>	<p>QAPD, Part V, Section 1</p>	<p>Fermi 3 QAPD, Part V, Section 1</p>	
<p>off-normal condition procedures. Written procedures which specify operator actions for restoring an operating variable to its normal controlled value when it departs from its range or to restore normal operating conditions following a perturbation. Such actions are invoked following an operator observation or an annunciator alarm indicating a condition which, if not corrected, could degenerate into a condition requiring action under an emergency procedure.</p>	<p>QAPD, Part V, Section 3</p>	<p>Fermi 3 QAPD, Part V, Section 3</p>	
<p>onsite operating organization. Onsite personnel concerned with operation, maintenance and certain technical services.</p>	<p>QAPD, Part V, Section 1</p>	<p>Fermi 3 QAPD, Part V, Section 1</p>	
<p>operating activities. Work functions associated with normal operation and maintenance of the plant, and technical services routinely assigned to the onsite operating organization.</p>	<p>QAPD, Part V, Section 1</p>	<p>Fermi 3 QAPD, Part V, Section 1</p>	

American National Standard N18.7-1976/ANS-3.2 Administrative Controls and Quality Assurance for the Operational Phase of Nuclear Power Plants / Regulatory Guide 1.33, Rev. 2 Regulatory Positions	Applicable Section of NQA-1- 1994 or NEI 06-14 Quality Assurance Program Description (QAPD)	Applicable Section(s) of Fermi 3 QAPD (for those requirements not addressed entirely by NQA-1-1994) [N/A is entered in column if requirements is addressed entirely by NQA-1-1994]	Comments (NEI 06-14A, Revision 7, Appendix 1, Comments adjusted for Fermi 3)
operating procedures. Written procedures defining the normal method, means and limits of operation of a nuclear power plant, a plant system or systems, or processes, including actions to be taken by operating personnel for removal from and return to service equipment on which maintenance is to be or has been performed (see also maintenance and modification procedures).	QAPD, Part V, Section 4	Fermi 3 QAPD, Part V, Section 3 and 4	
operational phase. That period of time during which the principal activity is associated with normal operation of the plant. This phase of plant life is considered to begin formally with commencement of fuel loading, and ends with plant decommissioning.	QAPD, Part V, Section 1	Fermi 3 QAPD, Part V, Section 1	
owner organization. The organization, including the onsite operating organization, which has overall legal, financial and technical responsibility for the operation of one or more nuclear power plants.	NQA-1, Basic Requirement 2 QAPD, Part II, Section 1	Fermi 3 QAPD, Part 2, Section 1	This term is also defined in ANS-3.1
quality assurance. All those planned and systematic actions necessary to provide assurance that a structure, system or component will perform satisfactorily in service. It applies to all activities associated with doing a job correctly as well as verifying and documenting the satisfactory completion of the work.	NQA-1, Introduction to Part I	N/A	
review. A deliberately critical examination, including observation of plant operation, evaluation of audit results, procedures, certain contemplated actions, and after-the-fact investigations of abnormal conditions (see independent review).	QAPD, Part V	Fermi 3 QAPD, Part V, Section 1	

American National Standard N18.7-1976/ANS-3.2 Administrative Controls and Quality Assurance for the Operational Phase of Nuclear Power Plants / Regulatory Guide 1.33, Rev. 2 Regulatory Positions	Applicable Section of NQA-1- 1994 or NEI 06-14 Quality Assurance Program Description (QAPD)	Applicable Section(s) of Fermi 3 QAPD (for those requirements not addressed entirely by NQA-1-1994) [N/A is entered in column if requirements is addressed entirely by NQA-1-1994]	Comments (NEI 06-14A, Revision 7, Appendix 1, Comments adjusted for Fermi 3)
shall, should and may. The word “shall” is used to denote a requirement; the word, “should” to denote a recommendation; and the word “may” to denote permission, neither a requirement nor a recommendation.	NQA-1, Introduction to Part I (as part of the definition of guideline)	N/A	The word may is not recognized in NQA-1 or Regulatory Guide 1.33. These words are also defined in ANS3.1.
supervision. Direction of personnel activities or monitoring of plant functions by an individual responsible and accountable for the activities he directs or monitors.	QAPD, Part V	Fermi 3 QAPD, Part V, Section 1	
surveillance testing. Periodic testing to verify that safety-related structures, systems and components continue to function or are in a state of readiness to perform their functions.	QAPD, Part V	Fermi 3 QAPD, Part V, Section 1	
system. An integral part of a nuclear power plant comprising components which may be operated or used as a separate entity to perform a specific function.	QAPD, Part V	Fermi 3 QAPD, Part V, Section 1	
testing. Performance of those steps necessary to determine that systems or components function in accordance with predetermined specifications.	NQA-1, Introduction to Part I	N/A	NQA-1 expounds on the definition.
3. Owner Organization			
3.1 General.			
The owner organization shall establish an administrative controls and quality assurance program which complies with this Standard. The program shall be in effect at all times during the operational phase to assure that operational phase activities are carried out without undue risk to the health and safety of the public. The program shall require that decisions affecting safety are made at the proper level of responsibility and with the necessary technical advice and review. The owner organization may delegate to	NQA-1, Basic Requirement 2 QAPD Policy Statement; QAPD Part II, Sections 1 and 2	Fermi 3 QAPD, Part II, Sections 1 and 2	

American National Standard N18.7-1976/ANS-3.2 Administrative Controls and Quality Assurance for the Operational Phase of Nuclear Power Plants / Regulatory Guide 1.33, Rev. 2 Regulatory Positions	Applicable Section of NQA-1– 1994 or NEI 06-14 Quality Assurance Program Description (QAPD)	Applicable Section(s) of Fermi 3 QAPD (for those requirements not addressed entirely by NQA-1-1994) [N/A is entered in column if requirements is addressed entirely by NQA-1-1994]	Comments (NEI 06-14A, Revision 7, Appendix 1, Comments adjusted for Fermi 3)
<p>other organizations the work of establishing and executing the administrative controls and quality assurance program or an part thereof, in accordance with this Standard, but shall retain responsibility there for.</p>			
<p>It is essential that all members of the organization involved in operation of nuclear power plants, including those at the highest management levels, recognize the necessity that the plants be operated under a well formulated and detailed administrative controls and quality assurance program to assure safety and efficiency. Lines of authority, responsibility and communication shall be established from the highest management level through intermediate levels to and including the onsite operating organization (including those offsite organizational units assigned responsibility for procurement, design and construction, quality assurance, and technical support activities). These relationships shall be documented and updated, as appropriate, in the form of organizational charts, functional descriptions of departmental responsibilities and relationships and job descriptions for key personnel positions or in equivalent forms of documentation. The owner organization shall specify in writing the authority and responsibility assigned to individuals and organizations involved in establishing, executing and measuring the overall effectiveness of the administrative controls and quality assurance program required by this Standard.</p>	<p>NQA-1, Basic Requirement 1 and Supplement 1S-1 QAPD, Part I, Section 1</p>	<p>Fermi 3 QAPD, Part II, Section 1</p>	
<p>The persons or organizations responsible for defining and measuring the overall effectiveness of the program shall be designated, shall be sufficiently independent</p>	<p>NQA-1, Basic Requirement 1</p>	<p>N/A</p>	

American National Standard N18.7-1976/ANS-3.2 Administrative Controls and Quality Assurance for the Operational Phase of Nuclear Power Plants / Regulatory Guide 1.33, Rev. 2 Regulatory Positions	Applicable Section of NQA-1- 1994 or NEI 06-14 Quality Assurance Program Description (QAPD)	Applicable Section(s) of Fermi 3 QAPD (for those requirements not addressed entirely by NQA-1-1994) [N/A is entered in column if requirements is addressed entirely by NQA-1-1994]	Comments (NEI 06-14A, Revision 7, Appendix 1, Comments adjusted for Fermi 3)
<p>from cost and scheduling considerations when opposed to safety considerations, shall have direct access to responsible management at a level where appropriate action can be accomplished, and shall report regularly on the effectiveness of the program to the plant manager and the cognizant offsite management.</p>			
<p>Persons or organizations performing functions of assuring that the administrative controls and quality assurance program is established and implemented or of assuring that an activity has been correctly performed shall have sufficient authority and organizational freedom to: identify quality problems; initiate, recommend or provide solutions, through designated channels; and verify implementation of solutions.</p>	<p>NQA-1, Basic Requirement 1</p>	<p>N/A</p>	
<p>The organizational structure and the functional responsibility assignments shall be such that: (1) Attainment of program objectives is accomplished by those who have been assigned responsibility for performing work. This may include interim examinations, checks, and inspections of the work by the individual performing the work. (2) Verification of conformance to established program requirements is accomplished by a qualified person who does not have responsibility for performing or directly supervising the work. The method and extent of such verification shall be commensurate with the importance of the activity to plant safety and reliability.</p>	<p>NQA-1, 1S-1, Section 2.1</p>	<p>N/A</p>	
<p>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</p>	<p>NQA-1, Supplement 1S-1</p>	<p>N/A</p>	

American National Standard N18.7-1976/ANS-3.2 Administrative Controls and Quality Assurance for the Operational Phase of Nuclear Power Plants / Regulatory Guide 1.33, Rev. 2 Regulatory Positions	Applicable Section of NQA-1– 1994 or NEI 06-14 Quality Assurance Program Description (QAPD)	Applicable Section(s) of Fermi 3 QAPD (for those requirements not addressed entirely by NQA-1-1994) [N/A is entered in column if requirements is addressed entirely by NQA-1-1994]	Comments (NEI 06-14A, Revision 7, Appendix 1, Comments adjusted for Fermi 3)
regarded as the sole domain of a single quality assurance group. For example, it may be more appropriate for nuclear engineers to perform reviews of plant nuclear engineering activities rather than quality assurance engineers because of the special competence required to perform these reviews. Quality assurance encompasses many functions and activities and extends to various levels in all participating organizations, from the top executive to all workers whose activities may influence quality.			
3.3 Indoctrination and Training.			
Provisions shall be made for indoctrination and training of those personnel in the owner organization performing activities affecting quality to assure that suitable proficiency is achieved and maintained. Such personnel also shall be provided training concerning the administrative controls and quality assurance program which, as a minimum, shall include the following areas: overall company policies, procedures, or instructions which establish the program; procedures or instructions which implement the program related to the specific job-related activity.	NQA-1, Basic Requirement 2 NQA-1, Supplement 2S-4 QAPD, Part II, Section 2	QAPD, Part II, Section 2	
3.4 Onsite Operating Organization			
3.4.1 General.			
A number of factors influence management in its decision regarding the establishment of an onsite operating organization. These include the owner organization's established staffing policies, the physical size and complexity of the nuclear power plant, the number of units, the extent of assistance provided by offsite technical support organizations, the extent of	NQA-1, Supplement 1S-1 QAPD, Part II, Section 1	Fermi 3 QAPD, Part II, Section 1	

American National Standard N18.7-1976/ANS-3.2 Administrative Controls and Quality Assurance for the Operational Phase of Nuclear Power Plants / Regulatory Guide 1.33, Rev. 2 Regulatory Positions	Applicable Section of NQA-1- 1994 or NEI 06-14 Quality Assurance Program Description (QAPD)	Applicable Section(s) of Fermi 3 QAPD (for those requirements not addressed entirely by NQA-1-1994) [N/A is entered in column if requirements is addressed entirely by NQA-1-1994]	Comments (NEI 06-14A, Revision 7, Appendix 1, Comments adjusted for Fermi 3)
<p>reliance on consultants and the availability of qualified personnel from other sources to assist in activities, such as initial start-up, refueling, maintenance or modification work. A nuclear power plant onsite operating organization may change with time. For example, the number and qualifications of personnel making up the onsite technical support staff can generally be reduced as a plant progresses through initial operation to operational maturity. Management shall give careful consideration to the timing and extent of such changes.</p>			
<p>3.4.2 Requirements for the Onsite Operating Organization.</p>			
<p>The onsite operating organization shall include one or more individuals knowledgeable in the following fields: nuclear power plant operation; nuclear power plant mechanical, electrical and electronic systems; nuclear engineering; chemistry and radiochemistry; radiation protection; and quality assurance.</p>	<p>QAPD, Part II, Section 1</p>	<p>Fermi 3 QAPD, Part II, Section 1</p>	
<p>Initial incumbents or replacements for members of the onsite operating organization and offsite technical support organizations shall have appropriate experience, training and retraining to assure that necessary competence is maintained in accordance with the provisions of American National Standard for Selection and Training of Nuclear Power Plant Personnel, N18.1-1971. [4] Personnel whose qualifications do not meet those specified in N18.1 and who are performing inspection, examination, and testing activities during the operations phase of the plant, including preoperational and start-up testing,</p>	<p>NQA-1, Supplements 2S-1 and 2S-2 QAPD, Part II, Section 2; Part IV, (by commitment to ANS-3.1)</p>	<p>Fermi 3 QAPD, Part II, Section 2, and Part IV</p>	<p>Technical Specifications also address commitments for training and qualification of the operating staff. Between NQA-1-1994 and the QAPD content, alternative requirements that meet the intent of ANSI N45.2.6 are established.</p>

<p>American National Standard N18.7-1976/ANS-3.2 Administrative Controls and Quality Assurance for the Operational Phase of Nuclear Power Plants / Regulatory Guide 1.33, Rev. 2 Regulatory Positions</p>	<p>Applicable Section of NQA-1-1994 or NEI 06-14 Quality Assurance Program Description (QAPD)</p>	<p>Applicable Section(s) of Fermi 3 QAPD (for those requirements not addressed entirely by NQA-1-1994) [N/A is entered in column if requirements is addressed entirely by NQA-1-1994]</p>	<p>Comments (NEI 06-14A, Revision 7, Appendix 1, Comments adjusted for Fermi 3)</p>
<p>shall be qualified to American National Standard Qualifications of Inspection, Examination, and Testing Personnel for the Construction Phase of Nuclear Power Plants, N45.2.6-1973 [5], except that the QA experience cited for Levels I, II, and III should be interpreted to mean actual experience in carrying out the types of inspection, examination, or testing activity, being performed.</p>			
<p>The owner organization shall designate those positions in the onsite operating organization which shall be filled by personnel holding NRC reactor operator and senior reactor operator licenses. Requirements for the minimum number of personnel holding such licenses who shall be present at the plant under various operating conditions and situations shall be specified.</p>	<p>QAPD, Part II, Section 1; Part IV (by the commitment to ANS-3.1 where it describes functional positions that require an NRC operator license)</p>	<p>Fermi 3 QAPD, Part II, Section 1, and Part IV</p>	<p>Technical Specifications establish specific requirements for numbers of personnel requiring NRC licenses based on operating conditions/situations.</p>
<p>The Plant Manager shall have overall responsibility for the execution of the administrative controls and quality assurance program at the plant to assure safety. An individual or organizational unit knowledgeable and experienced in nuclear power plant operational phase activities and quality assurance practices shall be designated and assigned the responsibility to verify that the program is being effectively implemented. Depending on the organizational structure, the individual or organizational unit may report functionally to onsite plant management or an offsite organization (see also 3.2). Reporting to onsite plant management is preferable since such an arrangement usually results in improved communications in identifying problems and initiating corrective action. The individual or organizational unit in this case may receive technical guidance from offsite support groups.</p>	<p>NQA-1, Basic Requirement 1 and Supplement 1S-1; Basic Requirement 2 and Supplement 2S-3 QAPD, Part II, Section 1 QAPD, Part II, Section 18 for assessing and reporting on the effectiveness of the QA program implementation</p>	<p>Fermi 3 QAPD, Part II, Section 1 and Section 18</p>	

American National Standard N18.7-1976/ANS-3.2 Administrative Controls and Quality Assurance for the Operational Phase of Nuclear Power Plants / Regulatory Guide 1.33, Rev. 2 Regulatory Positions	Applicable Section of NQA-1– 1994 or NEI 06-14 Quality Assurance Program Description (QAPD)	Applicable Section(s) of Fermi 3 QAPD (for those requirements not addressed entirely by NQA-1-1994) [N/A is entered in column if requirements is addressed entirely by NQA-1-1994]	Comments (NEI 06-14A, Revision 7, Appendix 1, Comments adjusted for Fermi 3)
This individual's or organizational unit's duties and responsibilities shall be such that the required attention can be devoted, as required, to verifying that the program is being effectively executed. The individual or organizational unit shall report on the effectiveness of the program to the Plant Manager and to other cognizant management as may be designated. Their activities shall be periodically audited by designated offsite personnel.			
4. Reviews and Audits			
4.1 General.			
Programs for reviews and for audits of activities affecting plant safety during the operational phase shall be established by the owner organization to:	NQA-1, Basic Requirement 18 and Supplement 18S-1 QAPD, Part II, Sections 1, 2, 3, 5, 18, and Part V	Fermi 3 QAPD, Part II, Sections 1, 2, 3, 5 and 18 and Part V	
(1) Verify that these activities are performed in conformance with this Standard and with company policy and rules, approved operating procedures and license provisions.	NQA-1, Basic Requirement 18 and Supplement 18S-1 QAPD, Part II, Sections 1, 2, 3, 5, 18, and Part V	Fermi 3 QAPD, Part II, Sections 1, 2, 3, 5 and 18 and Part V	
(2) Review significant proposed plant changes, tests and procedures	QAPD, Part II, Sections 5, and 18, and Part V, Section 2	Fermi 3 QAPD, Part II, Sections 5 and 18, and Part V, Section 2	
(3) Verify that reportable events, which require reporting to NRC in writing within 24 hours, are promptly investigated and corrected in a manner which reduces the probability of recurrence of such events	QAPD, Part V, Section 2	QAPD, Part V, Section 2	
(4) Detect trends which may not be apparent to a day-to-day observer	QAPD, Part II, Section 18, and Part V, Section 2	Fermi 3 QAPD, Part II, Sections 5 and 18, and Part V, Section 2	
These programs for reviews and audits shall, themselves, be periodically reviewed for effectiveness by management of the owner organization.	QAPD, Part II, Section 18.2	Fermi 3 QAPD, Part II, Section 18.2	

American National Standard N18.7-1976/ANS-3.2 Administrative Controls and Quality Assurance for the Operational Phase of Nuclear Power Plants / Regulatory Guide 1.33, Rev. 2 Regulatory Positions	Applicable Section of NQA-1- 1994 or NEI 06-14 Quality Assurance Program Description (QAPD)	Applicable Section(s) of Fermi 3 QAPD (for those requirements not addressed entirely by NQA-1-1994) [N/A is entered in column if requirements is addressed entirely by NQA-1-1994]	Comments (NEI 06-14A, Revision 7, Appendix 1, Comments adjusted for Fermi 3)
<p>The programs provided for reviews and for audits may take different forms. For example, the owner organization may assign these functions to separate established organizational units independent of the onsite operating organization, or may appoint a standing committee comprised of individuals from within or outside the owner organization to perform reviews and to exercise overview of audits. Historically, a committee approach was used to provide both review and audit capability for early commercial nuclear power plants. This approach was employed to make the most efficient use of personnel with pertinent experience and qualifications. In the ensuing period, the availability of competent personnel has significantly increased as the nuclear power industry has expanded and the sources of trained manpower have responded to the resulting demand. This growing pool of talent in the aggregate, is sufficient to encourage alternative approaches to the review and audit committees commonly used in the past.</p>			<p>This paragraph contains general guidance and historical information, no requirements are specified.</p>
<p>In general, the time required of individuals serving as members of independent review groups is a function of the number of nuclear power plants an owner organization has in operation. For this reason, owner organizations contemplating rapid growth and an expanding commitment to nuclear power should regard the use of committees to meet the independent review functions as an interim approach for effective utilization of available technical expertise. In addition, such owner organizations should include in their expansion planning, provisions for early establishment of organizational units to provide independent review, for</p>			<p>This paragraph provides general guidance information, no requirements are specified.</p>

American National Standard N18.7-1976/ANS-3.2 Administrative Controls and Quality Assurance for the Operational Phase of Nuclear Power Plants / Regulatory Guide 1.33, Rev. 2 Regulatory Positions	Applicable Section of NQA-1- 1994 or NEI 06-14 Quality Assurance Program Description (QAPD)	Applicable Section(s) of Fermi 3 QAPD (for those requirements not addressed entirely by NQA-1-1994) [N/A is entered in column if requirements is addressed entirely by NQA-1-1994]	Comments (NEI 06-14A, Revision 7, Appendix 1, Comments adjusted for Fermi 3)
recruitment of staff, and for an orderly transition to such an organizational structure in the event a committee approach has been used previously to meet the independent review function.			
An independent offsite organizational unit may be assigned review responsibilities including responsibility for reviewing audit reports provided by onsite staff members, or both functions may be assigned to an organizational unit that is independent of line responsibility for operating activities. This Standard does not specify an organizational structure for meeting the review and audit functions, but in lieu thereof delineates essential elements of satisfactorily comprehensive programs for review and for audit in the manner best suited to the owner organization involved.			This paragraph provides general guidance information, no requirements are specified.
4.2 Program Description.			
Written programs for both audits and independent reviews shall be prepared that contain: (1) Subjects to be audited and independently reviewed. (2) Responsibility and authority of those supervising audits and conducting independent reviews. These responsibilities shall include the identification of problems and the verification of corrective action. Additional responsibilities may include recommendations to appropriate management of solutions to problems and the approval or disapproval of contemplated actions. (3) Mechanisms for initiating audit and independent review activities. (4) Provisions for use of specialists or subgroups. (5) Authority to obtain access to the nuclear power	NQA-1, Basic Requirement 18 and Supplement 18S-1 QAPD, Part II, Section 18 and Part V, Section 2	Fermi 3 QAPD, Part II, Section 18, and Part V, Section 2	

American National Standard N18.7-1976/ANS-3.2 Administrative Controls and Quality Assurance for the Operational Phase of Nuclear Power Plants / Regulatory Guide 1.33, Rev. 2 Regulatory Positions	Applicable Section of NQA-1- 1994 or NEI 06-14 Quality Assurance Program Description (QAPD)	Applicable Section(s) of Fermi 3 QAPD (for those requirements not addressed entirely by NQA-1-1994) [N/A is entered in column if requirements is addressed entirely by NQA-1-1994]	Comments (NEI 06-14A, Revision 7, Appendix 1, Comments adjusted for Fermi 3)
<p>plant operating records and operating personnel to perform audits and independent reviews.</p> <p>(6) Requirements, for distribution of reports and other records to appropriate staff members and managers in the owner organization.</p> <p>(7) Identification of the management position (or positions, if auditors and reviewers have different reporting chains) to which auditors and independent reviewers report.</p> <p>(8) Provisions for assuring that personnel responsible for audit and independent review are kept informed on a timely basis of matters within their scope of responsibility.</p> <p>(9) Provisions for follow-up action, including reaudit of deficient areas where indicated.</p> <p>(10) Other provisions required for effective audits and independent reviews.</p>			
<p>4.3 Independent Review Program.</p>			
<p>Activities occurring during the operational phase shall be independently reviewed on a periodic basis. The independent review program shall be functional prior to initial core loading.</p>	<p>QAPD, Part V, Section 2.2</p>	<p>Fermi 3 QAPD, Part V, Section 2.2</p>	
<p>4.3.1 Personnel.</p>			
<p>Personnel assigned responsibility for independent reviews shall be specified, in both number and technical disciplines, and shall collectively have the experience and competence required to review problems in the following areas:</p> <p>(1) Nuclear power plant operations</p> <p>(2) Nuclear engineering</p> <p>(3) Chemistry and radiochemistry</p>	<p>QAPD, Part V, Section 2.2</p>	<p>Fermi 3 QAPD, Part V, Section 2.2</p>	

American National Standard N18.7-1976/ANS-3.2 Administrative Controls and Quality Assurance for the Operational Phase of Nuclear Power Plants / Regulatory Guide 1.33, Rev. 2 Regulatory Positions	Applicable Section of NQA-1- 1994 or NEI 06-14 Quality Assurance Program Description (QAPD)	Applicable Section(s) of Fermi 3 QAPD (for those requirements not addressed entirely by NQA-1-1994) [N/A is entered in column if requirements is addressed entirely by NQA-1-1994]	Comments (NEI 06-14A, Revision 7, Appendix 1, Comments adjusted for Fermi 3)
(4) Metallurgy (5) Nondestructive testing (6) Instrumentation and control (7) Radiological safety (8) Mechanical and electrical engineering (9) Administrative controls and quality assurance practices (10) Other appropriate fields associated with the unique characteristics of the nuclear power plant involved. An individual may possess competence in more than one specialty area. If sufficient expertise is not available from within the owner organization, independent reviews shall be supplemented through outside consultants or organizations. Provisions shall be made to assure that appropriate expertise is brought to bear in reviews of operational phase activities.			
4.3.2 Standing Committees Functioning as Independent Review Bodies			
4.3.2.1 Committee Composition.			
When a standing committee is responsible for the independent review program, it shall be composed of no less than five persons, or whom no more than a minority are members of the onsite operating organization. Competent alternates are permitted if designated in advance. The use of alternates shall be restricted to legitimate absences of principals.	QAPD, Part V, Section 2.2	Fermi 3 QAPD, Part V, Section 2.2	
4.3.2.2 Meeting Frequency.			
Formal meetings of personnel assigned to a standing committee functioning as an independent review group shall be scheduled as needed. During the period of initial operation such meetings should be held no less	QAPD, Part V, Section 2.2	Fermi 3 QAPD, Part V, Section 2.2	

American National Standard N18.7-1976/ANS-3.2 Administrative Controls and Quality Assurance for the Operational Phase of Nuclear Power Plants / Regulatory Guide 1.33, Rev. 2 Regulatory Positions	Applicable Section of NQA-1- 1994 or NEI 06-14 Quality Assurance Program Description (QAPD)	Applicable Section(s) of Fermi 3 QAPD (for those requirements not addressed entirely by NQA-1-1994) [N/A is entered in column if requirements is addressed entirely by NQA-1-1994]	Comments (NEI 06-14A, Revision 7, Appendix 1, Comments adjusted for Fermi 3)
frequently than once per calendar quarter. Subsequently, the meeting frequency shall not be less than twice a year.			
4.3.2.3 Quorum.			
A quorum for formal meetings of the committee held under the provisions of 4.3.2.2 shall consist of not less than a majority of the principals, or duly appointed alternates, and shall be subject to the following constraints: the chairman (or his duly appointed alternate) shall be present for all formal meetings; and no more than a minority of the quorum shall have line responsibility for operation of the plant.	QAPD, Part V, Section 2.2	Fermi 3 QAPD, Part V, Section 2.2	
4.3.2.4 Meeting Records.			
Minutes of all meetings of the committee shall be prepared and retained. All documentary material reviewed should be identified. Decisions and recommendations made by the committee shall be documented. Meeting minutes shall be disseminated promptly to appropriate members of management having responsibility in the area review. (See also Section 5.2.12.)	QAPD, Part V, Section 2.2	Fermi 3 QAPD, Part V, Section 2.2	
4.3.3 Organizational Units Functioning as Independent Review Bodies.			
An organizational unit assigned primary responsibility for review of operational phase activities shall report to a designated management representative who is assigned authority and responsibility for effective functioning of the unit and who is not immediately responsible for the performance of the activities to be reviewed. The supervisor of such an organizational unit should schedule periodic formal meetings of his staff,	QAPD, Part V, Section 2.2	Fermi 3 QAPD, Part V, Section 2.2	

American National Standard N18.7-1976/ANS-3.2 Administrative Controls and Quality Assurance for the Operational Phase of Nuclear Power Plants / Regulatory Guide 1.33, Rev. 2 Regulatory Positions	Applicable Section of NQA-1- 1994 or NEI 06-14 Quality Assurance Program Description (QAPD)	Applicable Section(s) of Fermi 3 QAPD (for those requirements not addressed entirely by NQA-1-1994) [N/A is entered in column if requirements is addressed entirely by NQA-1-1994]	Comments (NEI 06-14A, Revision 7, Appendix 1, Comments adjusted for Fermi 3)
or of appropriate subparts thereof, for the purpose of fostering interaction in reviews of specific operational phase activities.			
4.3.3.1 Documentation of Reviews.			
Written records of reviews shall be prepared and retained. All documentary material reviewed should be identified. Results of reviews conducted by the unit including recommendations and proposed actions shall be subject to approval of the supervisor of the unit, and shall be disseminated promptly to appropriate members of management having responsibility in the area reviewed. (See also Section 5.2.12.)	QAPD, Part V, Section 2.2	Fermi 3 QAPD, Part V, Section 2.2	
4.3.4 Subjects Requiring Independent Review.			
The following subjects shall be reviewed by the independent review body: (1) Written safety evaluations of changes in the facility as described in the Safety Analysis Report, changes in procedures as described in the Safety Analysis Report and tests or experiments not described in the Safety Analysis Report which are completed without prior NRC approval under the provisions of 10 CFR 50.59(a)(1). [1] This review is to verify that such changes, tests or experiments did not involve a change in the technical specifications or an unreviewed safety question as defined in 10 CFR 50.59(a)(2). [1]	QAPD, Part V, Section 2.2	Fermi 3 QAPD, Part V, Section 2.2	
(2) Proposed changes in procedures, proposed changes in the facility, or proposed tests or experiments, any of which involves a change in the technical specifications or an unreviewed safety question as defined in 10 CFR 50.59(c). [1] Matters of this kind shall be referred to the independent review body by the onsite operating	QAPD, Part V, Section 2.2	Fermi 3 QAPD, Part V, Section 2.2	Note – change in 50.59 language (“unreviewed safety question” no longer used) – but otherwise covered in QAPD, Part V, Section 2.2

American National Standard N18.7-1976/ANS-3.2 Administrative Controls and Quality Assurance for the Operational Phase of Nuclear Power Plants / Regulatory Guide 1.33, Rev. 2 Regulatory Positions	Applicable Section of NQA-1- 1994 or NEI 06-14 Quality Assurance Program Description (QAPD)	Applicable Section(s) of Fermi 3 QAPD (for those requirements not addressed entirely by NQA-1-1994) [N/A is entered in column if requirements is addressed entirely by NQA-1-1994]	Comments (NEI 06-14A, Revision 7, Appendix 1, Comments adjusted for Fermi 3)
organization (see 4.4) following its review, or by other functional organizational units within the owner organization, prior to implementation.			
(3) Changes in the technical specifications or license amendments relating to nuclear safety prior to implementation, except in those cases where the change is identical to a previously reviewed proposed change. Reg. Guide 1.33 – C. Regulatory Position 3. Section 4.3.4, "Subjects Requiring Independent Review," Item (3) states, in part, that changes to the technical specifications or license amendments related to nuclear safety are required to be reviewed by the independent review body prior to implementation. It should be noted that proposed changes to technical specifications or license amendments should be reviewed by the independent review body prior to their submittal to the Commission for approval.	QAPD, Part V, Section 2.2	Fermi 3 QAPD, Part V, Section 2.2	
(4) Violations, deviations and reportable events, which require reporting to the NRC in writing within 24 hours, such as:	QAPD, Part V, Section 2.2	Fermi 3 QAPD, Part V, Section 2.2	Regulations for reporting have changed, but the intent of this is addressed in QAPD, Part V, Section 2.2
(a) Violations of applicable codes, regulations, orders, technical specifications, license requirements or internal procedures or instructions having safety significance	QAPD, Part V, Section 2.2	Fermi 3 QAPD, Part V, Section 2.2	
(b) Significant operating abnormalities or deviations from normal or expected performance of plant safety- related structures, systems, or components	QAPD, Part V, Section 2.2	Fermi 3 QAPD, Part V, Section 2.2	
(c) Reportable events, which require reporting to the NRC in writing within 24 hours, as defined in the plant technical specifications Review of events covered under	QAPD, Part V, Section 2.2	Fermi 3 QAPD, Part V, Section 2.2	Regulations for reporting have changed, but the intent of this is addressed in QAPD, Part V, Section

American National Standard N18.7-1976/ANS-3.2 Administrative Controls and Quality Assurance for the Operational Phase of Nuclear Power Plants / Regulatory Guide 1.33, Rev. 2 Regulatory Positions	Applicable Section of NQA-1- 1994 or NEI 06-14 Quality Assurance Program Description (QAPD)	Applicable Section(s) of Fermi 3 QAPD (for those requirements not addressed entirely by NQA-1-1994) [N/A is entered in column if requirements is addressed entirely by NQA-1-1994]	Comments (NEI 06-14A, Revision 7, Appendix 1, Comments adjusted for Fermi 3)
this Section shall include the results of any investigations made and the recommendations resulting from such investigations to prevent or reduce the probability of recurrence of the event.			2.2
(5) Any other matter involving safe operation of the nuclear power plant which an independent reviewer deems appropriate for consideration, or which is referred to the independent reviewers by the onsite operating organization or by other functional organizational units within owner organization.	QAPD, Part V, Section 2.2	Fermi 3 QAPD, Part V, Section 2.2	
4.4 Review Activities of the Onsite Operating Organization.			
The onsite operating organization shall provide, as part of the normal duties of plant supervisory personnel, timely and continuing monitoring of operating activities to assist the Plant Manager in keeping abreast of general plant conditions and to verify that the day-to-day operating activities are conducted safely and in accordance with applicable administrative controls. These continuing monitoring activities are considered to be an integral part of the routine supervisory function and are important to the safety of plant operation.	QAPD, Part V, Section 2.1	Fermi 3 QAPD, Part V, Section 2.1	
The onsite operating organization should perform reviews periodically and as situations demand, to evaluate plant operations and to plan future activities. The important elements of the reviews should be documented. Such reviews serve a useful purpose but shall not take the place of the reviews and audits described in Sections 4.3 and 4.5, respectively. The onsite operating organization should screen subjects of potential concern to independent reviewers and perform	QAPD, Part V, Section 2.1	Fermi 3 QAPD, Part V, Section 2.1	

American National Standard N18.7-1976/ANS-3.2 Administrative Controls and Quality Assurance for the Operational Phase of Nuclear Power Plants / Regulatory Guide 1.33, Rev. 2 Regulatory Positions	Applicable Section of NQA-1- 1994 or NEI 06-14 Quality Assurance Program Description (QAPD)	Applicable Section(s) of Fermi 3 QAPD (for those requirements not addressed entirely by NQA-1-1994) [N/A is entered in column if requirements is addressed entirely by NQA-1-1994]	Comments (NEI 06-14A, Revision 7, Appendix 1, Comments adjusted for Fermi 3)
<pre> preliminary investigations (see 4.3.4). The Plant Manager, in carrying out his responsibility for overall safety of plant operations, shall be responsible for timely referral of appropriate matters to management and independent reviewers. Reg. Guide 1.33 – C. Regulatory Position 5.a. The guidelines (indicated by the verb "should") of ANSI N18.7-1976/ANS-3.2 contained in the following sections have sufficient safety importance to be treated the same as the requirements (indicated by the verb "shall") of the standard: a. Section 4.4–The guidelines concerning review activities of the onsite operating organization, except the guideline that refers to screening subjects of potential concern. [NOTE: The affected “should” words are underlined in the N18.7 excerpt above.] </pre>			
4.5 Audit Program.			
A comprehensive system of planned and documented audits shall be carried out to verify compliance with all aspects of the administrative controls and quality assurance program.	NQA-1, Basic Requirement 18 and Supplement 18S-1 QAPD, Part II, Sections 7 and 18.	Fermi 3 QAPD, Part II, Sections 7 and 18	
Audits of selected aspects of operational phase activities shall be performed with a frequency commensurate with their safety significance and in such a manner as to assure that an audit of all safety-related functions is completed within a period of two years. Audits shall include as a minimum verification of compliance and effectiveness of implementation of internal rules, procedures (for example, operating,	QAPD, Part II, Section 18	Fermi 3 QAPD, Part II, Section 18	Utilities have modified their audit programs over the years to include risk-informed scheduling and controlling the scope of the audits as alternate methods of satisfying the amplified requirements stated in RG 1.33 for specific elements to be audited more frequently than every

<p>American National Standard N18.7-1976/ANS-3.2 Administrative Controls and Quality Assurance for the Operational Phase of Nuclear Power Plants / Regulatory Guide 1.33, Rev. 2 Regulatory Positions</p>	<p>Applicable Section of NQA-1- 1994 or NEI 06-14 Quality Assurance Program Description (QAPD)</p>	<p>Applicable Section(s) of Fermi 3 QAPD (for those requirements not addressed entirely by NQA-1-1994) [N/A is entered in column if requirements is addressed entirely by NQA-1-1994]</p>	<p>Comments (NEI 06-14A, Revision 7, Appendix 1, Comments adjusted for Fermi 3)</p>
<p>design, procurement, maintenance, modification, refueling, surveillance, test, security and radiation control procedures and the emergency plan), regulations and license provisions; programs for training, retraining, qualification and performance of operating staff; corrective actions taken following abnormal occurrences; and observation of performance of operating, refueling, maintenance and modification activities, including associated record keeping.</p> <p>Reg. Guide 1.33 – C. Regulatory Position 4. Section 4.5, "Audit Program," of ANSI N18.7-1976/ANS-3.2 states that audits of selected aspects of operational phase activities shall be performed with a frequency commensurate with their safety significance and in such a manner as to ensure that an audit of all safety-related functions is completed within a period of 2 years. In amplification of this requirement, the following program elements should be audited at the indicated frequencies:</p> <ul style="list-style-type: none"> a. The results of actions taken to correct deficiencies that affect nuclear safety and occur in facility equipment, structures, systems, or method of operation-at least once per 6 months. b. The conformance of facility operation to the provisions contained within the technical specifications and applicable license conditions at least once per 12 months. c. The performance, training, and qualifications of the facility staff-at least once per 12 months. 			<p>two years.</p>

American National Standard N18.7-1976/ANS-3.2 Administrative Controls and Quality Assurance for the Operational Phase of Nuclear Power Plants / Regulatory Guide 1.33, Rev. 2 Regulatory Positions	Applicable Section of NQA-1- 1994 or NEI 06-14 Quality Assurance Program Description (QAPD)	Applicable Section(s) of Fermi 3 QAPD (for those requirements not addressed entirely by NQA-1-1994) [N/A is entered in column if requirements is addressed entirely by NQA-1-1994]	Comments (NEI 06-14A, Revision 7, Appendix 1, Comments adjusted for Fermi 3)
Written reports of such audits shall be reviewed by the independent review body and by appropriate members of management including those having responsibility in the area audited.	NQA-1, Basic Requirement 18 QAPD, Part II, Section 18, and Part V, Section 2.2	Fermi 3 QAPD, Part II, Section 18, and Part V, Section 2.2	
Those performing the audits may be members of the audited organization; however, they shall not audit activities for which they have immediate responsibility. While performing the audit, they shall not report to a management representative who has immediate responsibility for the activity being audited.	NQA-1, Basic Requirement 18	N/A	
Appropriate and timely follow-up action, including reaudit of deficient areas, shall be taken.	NQA-1, Basic Requirement 18	N/A	
Periodic review of the audit program shall be performed by the independent review body or by a management representative at least semiannually to assure that audits are being accomplished in accordance with requirements of technical specifications and of this Standard. Further guidance on requirements for auditing of quality assurance programs for nuclear power plants exists in draft form. ²	QAPD, Part V, Section 2.2	Fermi 3 QAPD, Part V, Section 2.2	Audits are not addressed in Technical Specifications. Based on SRP 17.5, the period for evaluating the audit program is two years rather than every six months.
5. Program, Policies and Procedures			
5.1 Program Description.			
The total program for providing administrative controls and quality assurance during the operational phase may be described in many diverse documents. For example,	QAPD, Part I, Introduction; Part II, Section 6	Fermi 3 QAPD, Part I, and Part II, Section 6	

² Footnote from N18.7 "Requirements for auditing of Quality Assurance Programs for Nuclear Power Plants, Proposed American National Standard N45.2.12, trial use (Draft 4, Revision 2) January 1, 1976; correspondence should be sent to Secretary, American National Standards Committee N45, The American Society for Mechanical Engineers, United Engineering Center, 345 East 47 Street, New York, NY 10017. The provisions of this draft standard shall be used for audits performed under this section except the audit frequency specified herein shall be used."

<p>American National Standard N18.7-1976/ANS-3.2 Administrative Controls and Quality Assurance for the Operational Phase of Nuclear Power Plants / Regulatory Guide 1.33, Rev. 2 Regulatory Positions</p>	<p>Applicable Section of NQA-1-1994 or NEI 06-14 Quality Assurance Program Description (QAPD)</p>	<p>Applicable Section(s) of Fermi 3 QAPD (for those requirements not addressed entirely by NQA-1-1994) [N/A is entered in column if requirements is addressed entirely by NQA-1-1994]</p>	<p>Comments (NEI 06-14A, Revision 7, Appendix 1, Comments adjusted for Fermi 3)</p>
<p>operating procedures may be compiled in one manual, maintenance procedures in a second manual and Quality Assurance procedures in a third. It is not intended that all source documents be compiled in one master document. However, a summary document shall be compiled by each owner organization to identify the sources, to index such source documents to the requirements of this Standard and to provide a consolidated base for description of the program.</p>			
<p>The owner organization shall identify in the program description those structures, systems and components to be covered by the program and the major organizational units and their responsibilities. The program shall provide control over activities affecting the quality of the structures, systems and components to an extent consistent with their importance to safety. The program shall take into account the need for special controls, processes, test, equipment, tools, and skills to attain the required quality and the need for verification of quality by inspections, evaluation or test.</p>	<p>NQA-1, Basic Requirement 2 QAPD, Part II, Section 2</p>	<p>Fermi 3 QAPD, Part II, Section 2</p>	<p>FSAR Section 3.2 provides more detail on the SSCs and their importance to safety. FSAR Section 3.2 incorporates Section 3.2 of the GEH ESBWR DCD by reference.</p>

American National Standard N18.7-1976/ANS-3.2 Administrative Controls and Quality Assurance for the Operational Phase of Nuclear Power Plants / Regulatory Guide 1.33, Rev. 2 Regulatory Positions	Applicable Section of NQA-1- 1994 or NEI 06-14 Quality Assurance Program Description (QAPD)	Applicable Section(s) of Fermi 3 QAPD (for those requirements not addressed entirely by NQA-1-1994) [N/A is entered in column if requirements is addressed entirely by NQA-1-1994]	Comments (NEI 06-14A, Revision 7, Appendix 1, Comments adjusted for Fermi 3)
5.2 Rules of Practice.			
The owner organization shall establish rules and instructions pertaining to personnel conduct and control, including consideration of job-related factors which influence the effectiveness of operating and maintenance personnel, including such factors as number of hours at duty station, availability on call of professional and supervisory personnel, method of conducting operations, and preparing and retaining plant documents. These rules and instructions should provide a clear understanding of operating philosophy and management policies.	QAPD, Policy and Part V	Fermi 3 QAPD, Policy and Part V	
5.2.1 Responsibilities and Authorities of Operating Personnel.			
The responsibilities and authorities of the plant operating personnel shall be delineated. These shall include, as a minimum: (1) The reactor operator's authority and responsibility for shutting the reactor down when he determines that the safety of the reactor is in jeopardy or when operating parameters exceed any of the reactor protection system setpoints and automatic shutdown does not occur. (2) The responsibility to determine the circumstances, analyze the cause, and determine that operations can proceed safely before the reactor is returned to power after a trip or an unscheduled or unexplained power reduction. (3) The senior reactor operator's responsibility to be present at the plant and to provide direction for returning the reactor to power following a trip or an	QAPD, Part I Section 1, and Part V.	Fermi 3 QAPD, Part I, Section 1, and Part V	QAPD provides overall responsibilities in general terms. The specific responsibilities described here are located in the organizational standards and administrative controls, Technical Specifications and reinforced through the systematic training programs.

American National Standard N18.7-1976/ANS-3.2 Administrative Controls and Quality Assurance for the Operational Phase of Nuclear Power Plants / Regulatory Guide 1.33, Rev. 2 Regulatory Positions	Applicable Section of NQA-1- 1994 or NEI 06-14 Quality Assurance Program Description (QAPD)	Applicable Section(s) of Fermi 3 QAPD (for those requirements not addressed entirely by NQA-1-1994) [N/A is entered in column if requirements is addressed entirely by NQA-1-1994]	Comments (NEI 06-14A, Revision 7, Appendix 1, Comments adjusted for Fermi 3)
unscheduled or unexplained power reduction. (4) The responsibility to believe and respond conservatively to instrument indications unless they are proved to be incorrect. (5) The responsibility to adhere to the plant's Technical Specifications. (6) The responsibility to review routine operating data to assure safe operation.			
5.2.2 Procedure Adherence.			
Procedures shall be followed, and the requirements for use of procedures shall be prescribed in writing. Rules shall be established which provide methods by which temporary changes to approved procedures can be made, including the designation of a person or persons authorized to approve such changes.	NQA-1-1994, Basic Requirements 5 and 6, and Supplement 6S-1. QAPD, Part II, Sections 5 and 6	Fermi 3 QAPD, Part II, Sections 5 and 6	
Temporary changes which clearly do not change the intent of the approved procedure, shall as a minimum be approved by two members of the plant staff knowledgeable in the areas affected by the procedures. At least one of these individuals shall be the supervisor in charge of the shift and hold a senior operator's license on the unit affected. Such changes shall be documented and, if appropriate, incorporated in the next revision of the affected procedure. In the event of an emergency not covered by an approved procedure, operations personnel shall be instructed to take action so as to minimize personnel injury and damage to the facility and to protect health and safety.	QAPD, Part II, Sections 5.1 and 6.2	Fermi 3 QAPD, Part II, Sections 5.1 and 6.2	The QAPD requirements only allow temporary changes that do not change the intent of the procedure. All other changes must be done in accordance with the document control program.
Guidance should be provided to identify the manner in which procedures are to be implemented. Examples of such guidance include identification of those tasks that	QAPD, Part II, Section 5.1	Fermi 3 QAPD, Part II, Section 5.1	

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require: (1) The written procedure to be present and followed step by step while the task is being performed (2) The operator to have committed the procedural steps to memory (3) Verification of completion of significant steps, by initials or signatures of check-off lists.			
The types of procedures that shall be present and referred to directly are those developed for extensive or complex jobs where reliance on memory cannot be trusted, e.g., reactor start-up, tasks which are infrequently performed, and tasks in which operations must be performed in a specified sequence. Procedural steps for which actions should be committed to memory include, for example, immediate actions in emergency procedures. Routine procedural actions that are frequently repeated may not require the procedure to be present. Copies of all procedures shall be available to appropriate members of the plant staff. If documentation of an action is required, the necessary data shall be recorded as the task is performed. Examples of procedures requiring verification are furnished in 5.3.4.1 and 5.3.4.2.	QAPD, Part II, Section 5.1	Fermi 3 QAPD, Part II, Section 5.1	
5.2.3 Operating Orders.			
A mechanism shall be provided for dissemination to the plant staff of instructions of general and continuing applicability to the conduct of business. Such instructions, sometimes also referred to as standing orders or standard operating procedures, should deal with job turnover and relief, designation of confines of control room, definition of duties of operators and	QAPD, Part V, Section 3.2	Fermi 3 QAPD, Part V, Section 3.2	

American National Standard N18.7-1976/ANS-3.2 Administrative Controls and Quality Assurance for the Operational Phase of Nuclear Power Plants / Regulatory Guide 1.33, Rev. 2 Regulatory Positions	Applicable Section of NQA-1- 1994 or NEI 06-14 Quality Assurance Program Description (QAPD)	Applicable Section(s) of Fermi 3 QAPD (for those requirements not addressed entirely by NQA-1-1994) [N/A is entered in column if requirements is addressed entirely by NQA-1-1994]	Comments (NEI 06-14A, Revision 7, Appendix 1, Comments adjusted for Fermi 3)
<p>others, transmittal of operating data to management, filing of charts, limitations on access to certain areas and equipment, shipping and receiving instructions, or other such matters. Provisions <u>should</u> be made for periodic review and updating of standing orders.</p> <p>Reg. Guide 1.33 – C. Regulatory Position 5.b. The guidelines (indicated by the verb "should") of ANSI N18.7-1976/ANS-3.2 contained in the following sections have sufficient safety importance to be treated the same as the requirements (indicated by the verb "shall") of the standard:</p> <p>b. Section 5.2.3–The guideline concerning review and updating of standing orders.</p> <p>[NOTE: The affected “should” word is underlined in the N18.7 excerpt above.]</p>			

<p>American National Standard N18.7-1976/ANS-3.2 Administrative Controls and Quality Assurance for the Operational Phase of Nuclear Power Plants / Regulatory Guide 1.33, Rev. 2 Regulatory Positions</p>	<p>Applicable Section of NQA-1- 1994 or NEI 06-14 Quality Assurance Program Description (QAPD)</p>	<p>Applicable Section(s) of Fermi 3 QAPD (for those requirements not addressed entirely by NQA-1-1994) [N/A is entered in column if requirements is addressed entirely by NQA-1-1994]</p>	<p>Comments (NEI 06-14A, Revision 7, Appendix 1, Comments adjusted for Fermi 3)</p>
<p>5.2.4 Special Orders.</p>			
<p>A mechanism shall be provided for issuing management instructions which have short-term applicability and which require dissemination. Such instructions, sometimes referred to as a special orders, should encompass special operations, housekeeping, data taking, publications and their distribution, plotting process parameters, personnel actions, or other similar matters. Provisions <u>should</u> be made for periodic review, updating and cancellation of special orders.</p> <p>Reg. Guide 1.33 – C. Regulatory Position 5.c. The guidelines (indicated by the verb "should") of ANSI N18.7-1976/ANS-3.2 contained in the following sections have sufficient safety importance to be treated the same as the requirements (indicated by the verb "shall") of the standard:</p> <p>c. Section 5.2.4–The guideline concerning review, updating, and cancellation of special orders.</p> <p>[NOTE: The affected “should” word is underlined in the N18.7 excerpt above.]</p>	<p>QAPD, Part V, Section 3.2</p>	<p>Fermi 3 QAPD, Part V, Section 3.2</p>	
<p>5.2.5 Temporary Procedures.</p>			
<p>Temporary procedures may be issued during the operational phase: to direct operations during testing, refueling, maintenance and modifications; to provide guidance in unusual situations not within the scope of the normal procedures; and to insure orderly and uniform operations for short periods when the plant, a system, or a component of a system is performing in a manner not covered by existing detailed procedures or has been modified or extended in such a manner that</p>	<p>QAPD, Part V, Section 3.2 Also, temporary procedures for Maintenance activities are covered under NQA-1-1994, Subpart 2.18, Section 2.2.</p>	<p>Fermi 3 QAPD, Part V, Section 3.2</p>	

American National Standard N18.7-1976/ANS-3.2 Administrative Controls and Quality Assurance for the Operational Phase of Nuclear Power Plants / Regulatory Guide 1.33, Rev. 2 Regulatory Positions	Applicable Section of NQA-1– 1994 or NEI 06-14 Quality Assurance Program Description (QAPD)	Applicable Section(s) of Fermi 3 QAPD (for those requirements not addressed entirely by NQA-1-1994) [N/A is entered in column if requirements is addressed entirely by NQA-1-1994]	Comments (NEI 06-14A, Revision 7, Appendix 1, Comments adjusted for Fermi 3)
portions of existing procedures do not apply. Temporary procedures shall include designation of the period of time during which they may be used and shall be subject to the review process prescribed in 4.3 and 5.2.15 as applicable.			
Temporary procedures shall be approved by the management representative assigned approval authority	QAPD, Part V, Section 3.2	Fermi 3 QAPD, Part V, Section 3.2	
5.2.6 Equipment Control.			
Permission to release equipment or systems for maintenance shall be granted by designated operating personnel. Prior to granting permission, such operating personnel shall verify that the equipment or system can be released, and determine how long it may be out of service. Granting of such permission shall be documented. Attention shall be given to the potentially degraded degree of protection when one subsystem of a redundant safety system has been removed for maintenance.	NQA-1, Basic Requirement 14 and Subpart 2.18, Section 2.5 QAPD, Part V, Section 4	Fermi 3 QAPD, Part V, Section 4	
After permission has been granted to remove the equipment from service, it shall be made safe to work on. Measures shall provide for protection of equipment and workers. Equipment and systems in a controlled status shall be clearly identified. Strict control measures for such equipment shall be enforced.	NQA-1, Basic Requirement 14 QAPD, Part V, Section 4	Fermi 3 QAPD, Part V, Section 4	

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Conditions to be considered in preparing equipment for maintenance include, for example: shutdown margin; method of emergency core cooling; establishment of a path for decay heat removal; temperature and pressure of the system; valves between work and hazardous material; venting, draining and flushing; entry into closed vessels; hazardous atmospheres; handling hazardous materials; and electrical hazards.	NQA-1 Subpart 2.18, Section 2.5 QAPD, Part V, Section 4	Fermi 3 QAPD, Part V, Section 4	
When entry into a closed system is required, control measures shall be established to prevent entry of extraneous material and to assure that foreign material is removed before the system is reclosed.	NQA-1, Subpart 2.3 QAPD, Part II, Section 13.1 and Part V, Section 4	Fermi 3 QAPD, Part II, Section 13.1 and Part V, Section 4	
Procedures shall be provided for control of equipment, as necessary, to maintain personnel and reactor safety and to avoid unauthorized operation of equipment. These procedures shall require control measures such as locking or tagging to secure and identify equipment in a controlled status. The procedures shall require independent verifications, where appropriate, to ensure that necessary measures, such as tagging equipment, have been implemented correctly.	NQA-1, Basic Requirement 14 QAPD, Part V, Section 4	Fermi 3 QAPD, Part V, Section 4	
Temporary modifications, such as temporary bypass lines, electrical jumpers, lifted electrical leads, and temporary trip point settings, shall be controlled by approved procedures which shall include a requirement for independent verification. A log shall be maintained of the current status of such temporary modifications.	QAPD, Part II, Sections 3 and 14	Fermi 3 QAPD, Part II, Sections 3 and 14	
The procedures shall also require that the status of inspections and tests performed upon individual items on the nuclear power plant be indicated by the use of markings such as stamps, tags, labels, routing cards, or	NQA-1, Basic Requirement 14	N/A	

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other suitable means. Suitable means include identification numbers which are traceable to records of the status of inspections and tests.			
Procedures shall also provide for the identification of items which have satisfactorily passed required inspections and tests, where necessary to preclude inadvertent bypassing of such inspections and tests. In cases where required documentary evidence is not available, the associated equipment or materials must be considered nonconforming in accordance with Section 5.2.14. Until suitable documentary evidence is available to show the equipment or material is in conformance, affected systems shall be considered to be inoperable and reliance shall not be placed on such systems to fulfill their intended safety functions.	NQA-1, Basic Requirement 14 QAPD, Part II, Section 14	Fermi 3 QAPD, Part II, Section 14	
When equipment is ready to be returned to service, operating personnel shall place the equipment in operation and verify and document its functional acceptability. Attention shall be given to restoration of normal conditions, such as removal of jumpers or signals used in maintenance or testing or such as returning valves, breakers or switches to proper startup or operating positions from "test" or "manual" positions. When placed into service, the equipment should receive additional surveillance during the run-in period.	NQA-1, Basic Requirement 14, and Subpart 2.18, Section 2.2 QAPD, Part V, Section 4	Fermi 3 QAPD, Part V, Section 4	
5.2.7 Maintenance and Modifications.			
Maintenance or modifications which may affect functioning of safety-related structures, systems, or components shall be performed in a manner to ensure quality at least equivalent to that specified in original	NQA-1, Introduction to Part II, and Subpart 2.18 QAPD, Part V, Section 5	Fermi 3 QAPD, Part V, Section 5	

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<p>design bases and requirements, materials specifications and inspection requirements. A suitable level of confidence in structures, systems, or components on which maintenance or modifications have been performed shall be attained by appropriate inspection and performance testing (see also 5.2.17 and 5.3.5).</p>			
<p>Maintenance or modification of equipment shall be preplanned and performed in accordance with written procedures, documented instructions or drawings appropriate to the circumstances which conform to applicable codes, standards, specifications, and criteria. Skills normally possessed by qualified maintenance personnel may not require detailed step-by-step delineations in a written procedure.</p>	<p>NQA-1, Basic Requirement 5, and Subpart 2.18, Section 2.2 QAPD, Part II, Section 5</p>	<p>Fermi 3 QAPD, Part II, Section 5</p>	
<p>Means for assuring quality of maintenance and modification activities (for example, inspections, measurements, tests, welding, heat treatment, cleaning, nondestructive examination and worker qualifications in accordance with applicable codes and standards) and measures to document the performance thereof shall be established. This documentation shall be retained as specified in Section 5.2.12.</p>	<p>NQA-1, Basic Requirements 2, 3, 9, 10, 11, 17 and associated Supplements, and Subparts 2.1 and 2.3. QAPD, Part II, Sections 2, 3, 9, 10, 11, and 17.</p>	<p>Fermi 3 QAPD, Part II, Sections 2, 3, 9, 10, 11 and 17</p>	
<p>Measures shall be established and documented to identify the inspection and test status of items to be used in maintenance and modification activities. Normally, the point of control for such items should be the plant storage area.</p>	<p>NQA-1, Basic Requirement 14 QAPD, Part II, Section 14</p>	<p>Fermi 3 QAPD, Part II, Section 14</p>	
<p>The following standards contain useful guidance concerning design and construction-related activities associated with modifications and shall be applied to those activities occurring during the operational phase</p>	<p>QAPD, Part IV</p>	<p>Fermi 3 QAPD, Part IV</p>	<p>ANSI N101.4 has been withdrawn and RG 1.54 revised in July 2000 to address the acceptability of the replacement ANSI Standards.</p>

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<p>that are comparable in nature and extent to related activities occurring during initial plant design and construction: American National Standard Installation, Inspection and Testing of Instrumentation and Electric Equipment During the Construction of Nuclear Power Generation Station, N45.2.4-1972 (IEEE 336-1972) [6]; American National Standard Supplementary Quality Assurance Requirements for Installation, Inspection and Testing of Structural Concrete and Structural Steel During the Construction Phase of Nuclear Power Plants, N45.2.5-1974 [7]; American National Standard Qualifications of Inspection, Examination and Testing Personnel for the Construction Phase of Nuclear Power Plants N45.2.61973 [5]; American National Standard Supplementary Quality Assurance Requirements for Installation, Inspection and Testing of Mechanical Equipment and Systems for Construction Phase of Nuclear Power Plants, N45.2.8-1975 [8] American National Standard Quality Assurance Requirements for the Design of Nuclear Power Plants, N45.2.11-1974 [9]; and American National Standard Quality Assurance for Protective Coating Applied to Nuclear Facilities N101.4-1972 [10]. Considerable care is required in assessing which operational phase activities are comparable in nature and extent to activities normally associated with design and construction.</p>			
<p>5.2.7.1 Maintenance Programs. A maintenance program shall be developed to maintain safety-related structures, systems and components at the quality required for them to perform their intended functions.</p>	<p>NQA-1, Subpart 2.18, Section 1</p>	<p>N/A</p>	

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<p>Maintenance shall be scheduled and planned so as not to compromise the safety of the plant. Planning shall consider the possible safety consequences of concurrent or sequential maintenance, testing or operating activities. Equipment required to be operable for the prevailing mode shall be available, and maintenance shall be performed in a manner such that license limits are not violated. Planning for maintenance shall include evaluation of the use of special processes, equipment and materials in performance of the task, including assessment of potential hazards to personnel and equipment.</p>	<p>NQA-1, Introduction to Part II, and Subpart 2.18, Section 2.1</p>	<p>N/A</p>	
<p>General rules for the development of procedures under a maintenance program which is consistent with the provisions of 5.2.7 shall be written before start-up. These general rules shall form the basis for developing the repair or replacement procedures at the time of failure. Procedures required for maintenance of equipment expected to require recurring maintenance should be written prior to plant operation. As experience is gained in operation of the plant, routine maintenance should be altered to improve equipment performance, and procedures for repair of equipment shall be improved as appropriate. Approved procedures shall be available for repair of safety-related equipment prior to the performance of such repairs (see also Sections 5.2.2 and 5.2.7).</p>	<p>NQA-1, Subpart 2.18 QAPD, Part V, Section 3</p>	<p>Fermi 3 QAPD, Part V, Section 3</p>	
<p>A preventive maintenance program including procedures as appropriate for safety-related structures, systems and components shall be established and maintained which prescribes the frequency and type of maintenance to be performed. A preliminary program</p>	<p>NQA-1, Subpart 2.18, Section 3</p>	<p>N/A</p>	

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<p>based on service conditions and experience with comparable equipment should be developed prior to fuel loading. The program should be revised and updated as experience is gained with the equipment.</p>			
<p>The causes of malfunctions shall be promptly determined, evaluated and recorded (see also Sections 4.3 and 4.4). Experience with the malfunctioning equipment and similar components shall be reviewed and evaluated to determine whether a replacement component of the same type can be expected to perform its function reliably. If evidence indicates that common components in safety-related systems have performed unsatisfactorily, corrective measures shall be planned prior to replacement or repair of all such components. Replacement components should have received adequate testing or should be of a design for which experience indicates a high probability of satisfactory performance. Consideration shall be given to phased replacement to permit inservice performance of the new component to be evaluated and thereby minimize the possibility of a hidden deficiency producing a systematic failure. An augmented testing and inspection program <u>should</u> be implemented following a large scale component replacement (or repair) until such time as a suitable level of performance has been demonstrated.</p> <p>Reg. Guide 1.33 – C. Regulatory Position 5.d. The guidelines (indicated by the verb "should") of ANSI N18.7-1976/ANS-3.2 contained in the following sections have sufficient safety importance to be treated the same as the requirements (indicated by the verb "shall") of the standard:</p>	<p>NQA-1, Basic Requirement 16 and Subpart 2.18, Section 4</p>	<p>N/A</p>	

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d. Section 5.2.7.1—The guidelines that address adequate design and testing of replacement parts. [NOTE: The affected “should” words are underlined in the N18.7 excerpt above.]			
5.2.7.2 Modifications.			
Design activities associated with modifications of safety-related structures, systems, and components shall be accomplished in accordance with N45.2.11.1974. [9]	NQA-1, Basic Requirement 3 and Supplement 3S-1 QAPD, Part II, Section 3	Ef3 QAPD, Part II, Section 3	
5.2.8 Surveillance Testing and Inspection Schedule.			
A surveillance testing and inspection program shall be prescribed to insure that safety-related structures, systems, and components will continue to operate, keeping parameters within normal bounds, or will act to put the plant in a safe condition if they exceed normal bounds.	NQA-1, Basic Requirements 10 and 11, and Supplements 10S-1 and 11S-1 QAPD, Part II, Section 11	Fermi 3 QAPD, Part II, Section 11	
Provisions shall be made for performing required surveillance testing and inspections, including inservice inspections. Such provisions shall include the establishment of a master surveillance schedule reflecting the status of all planned in plant surveillance tests and inspections. Frequency of surveillance tests and inspections may be related to the results of reliability analyses, the frequency and type of service, or age of the item or system, as appropriate.	NQA-1, Supplement 10S-1, Section 8, and Basic Requirement 11 QAPD, Part II, Section 11	Fermi 3 QAPD, Part II, Section 11	
Additional control procedures shall be instituted, as necessary, to assure timely conduct of surveillance tests and inspections and appropriate documentation, reporting, and evaluation of the results. Surveillance testing which may increase the probability of plant trips or major transients with accompanying safety concerns	NQA-1, Basic Requirement 11 and Supplement 11S-1	N/A	

<p>American National Standard N18.7-1976/ANS-3.2 Administrative Controls and Quality Assurance for the Operational Phase of Nuclear Power Plants / Regulatory Guide 1.33, Rev. 2 Regulatory Positions</p>	<p>Applicable Section of NQA-1-1994 or NEI 06-14 Quality Assurance Program Description (QAPD)</p>	<p>Applicable Section(s) of Fermi 3 QAPD (for those requirements not addressed entirely by NQA-1-1994) [N/A is entered in column if requirements is addressed entirely by NQA-1-1994]</p>	<p>Comments (NEI 06-14A, Revision 7, Appendix 1, Comments adjusted for Fermi 3)</p>
<p>should be deferred to periods when such plant trips or transients have a minimum impact on safety and reliability.</p>			
<p>5.2.9 Plant Security and Visitor Control.</p>			
<p>Procedures shall be developed to supplement features and physical barriers designed to control access to the plant and, as appropriate, to vital areas within the plant. Information concerning specific design features and administrative provisions of the plant security program shall be confidential and thus accorded limited distribution. The security and visitor control procedures should consider, for example, physical provisions, such as: fences and lighting; lock controls for doors, gates and compartments containing sensitive equipment; and provisions for traffic and access control. Also to be considered are administrative provisions, such as: visitor sign-in and sign-out procedures; escorts and badges for visitors; emphasis on inspection, observation and challenging of strangers by operating crews; and a program of preemployment screening for potential employees. See American National Standard Industrial Security for Nuclear Power Plants, N18.17-1973, for guidance and provisions for security measures adequate to protect nuclear power plants. [11]</p>			<p>Administrative controls are established through the security measures required by regulation (10 CFR 73) and NRC orders. These regulatory requirements have superseded the requirements of ANSI N18.7.</p>
<p>5.2.10 Housekeeping and Cleanliness Control.</p>			
<p>Housekeeping practices shall be utilized recognizing requirements for the control of radiation zones and the control of work activities, conditions and environments that can affect the quality of important parts of the nuclear plant. Housekeeping encompasses all activities related to the control of cleanness of facilities,</p>	<p>NQA-1, Part II, Subpart 2.3 QAPD, Part IV</p>	<p>Fermi 3 QAPD, Part II, Section 13</p>	

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<p>materials, equipment fire prevention and protection including disposal of combustible material and debris and control of access to areas, protection of equipment, radioactive contamination control and storage of solid radioactive waste. Housekeeping practices shall assure that only proper materials, equipment, processes and procedures are utilized and that the quality of items is not degraded as a result of housekeeping practices or techniques.</p>			
<p>Where necessary, procedures and work instructions needed to assure compliance with specific requirements shall be available; e.g., inspection and cleaning of electrical bus and control centers, cleaning of control consoles, radioactive decontamination. Particular attention should be given to housekeeping in work and storage areas where important items are handled and stored to preclude damage or contamination. American National Standard Housekeeping During the Construction Phase of Nuclear Power Plants, N-45.2.3-1973 [12] shall be applied to those activities occurring during the operational phase that are comparable in nature and extent to related activities occurring during construction.</p>	<p>NQA-1, Part I, Basic Requirements 2 and 5; and Part II, Subparts 2.3 and 2.18 QAPD, Part II, Sections 2 and 5.</p>	<p>Fermi 3 QAPD, Part II, Sections 2 and 5</p>	<p>NQA-1, Subpart 2.3 replaces ANSI N45.2.3</p>
<p>During maintenance or modification activities, certain portions of safety-related systems may be subject to potential contamination with foreign materials. To prevent such contamination, control measures, including measures for access control, shall be established. Immediately prior to closure an inspection shall be conducted to assure cleanness and the result of such inspection shall be documented. American National Standard Cleaning of Fluid Systems and</p>	<p>NQA-1-1994, Part II, Subpart 2.1 and Subpart 2.18, Section 2.3</p>	<p>N/A</p>	<p>NQA-1, Subpart 2.1 replaces N45.2.1</p>

American National Standard N18.7-1976/ANS-3.2 Administrative Controls and Quality Assurance for the Operational Phase of Nuclear Power Plants / Regulatory Guide 1.33, Rev. 2 Regulatory Positions	Applicable Section of NQA-1- 1994 or NEI 06-14 Quality Assurance Program Description (QAPD)	Applicable Section(s) of Fermi 3 QAPD (for those requirements not addressed entirely by NQA-1-1994) [N/A is entered in column if requirements is addressed entirely by NQA-1-1994]	Comments (NEI 06-14A, Revision 7, Appendix 1, Comments adjusted for Fermi 3)
Associated Components during Construction Phase of Nuclear Power Plant, N45.2.1-1973 [13] shall be applied to activities occurring during the operational phase that are comparable in nature and extent to related activities occurring during construction. Measures for minimizing the introduction of foreign materials during maintenance or modification, or cleaning following maintenance or modification of radioactively contaminated systems or of equipment of high radiation fields require special consideration.			
5.2.11 Corrective Actions.			
The program shall provide measures to ensure that conditions adverse to plant safety, such as failure, malfunctions, deficiencies, deviations, defective material and equipment, abnormal occurrences, and nonconformances are promptly identified and corrected.	NQA-1, Basic Requirement 16, and Subpart 2.18 QAPD, Section 16	Fermi 3 QAPD, Part II, Section 16	
In the case of significant conditions adverse to safety, the measures shall assure that the cause of the condition is determined and corrective action taken shall be documented and reported to appropriate levels of management and for independent review in accordance with Section 4.3.	NQA-1, Basic Requirement 16, Subpart 2.18, Section 4.3.2 QAPD, Part II, Section 16 and Part V, Section 2	Fermi 3 QAPD, Part II, Section 16 and Part V, Section 2	
5.2.12. Plants Records Management.			
Provisions shall be made for preparation and retention of plant records as appropriate.	NQA-1, Basic Requirement 17 and Supplement 17S-1 QAPD, QAPD Part II, Section 17.1	Fermi 3 QAPD, Part II, Section 17.1	
The responsibility for maintaining records and storing them at a specified location or locations shall be assigned.	NQA-1, Basic Requirement 17	N/A	

<p>American National Standard N18.7-1976/ANS-3.2 Administrative Controls and Quality Assurance for the Operational Phase of Nuclear Power Plants / Regulatory Guide 1.33, Rev. 2 Regulatory Positions</p>	<p>Applicable Section of NQA-1-1994 or NEI 06-14 Quality Assurance Program Description (QAPD)</p>	<p>Applicable Section(s) of Fermi 3 QAPD (for those requirements not addressed entirely by NQA-1-1994) [N/A is entered in column if requirements is addressed entirely by NQA-1-1994]</p>	<p>Comments (NEI 06-14A, Revision 7, Appendix 1, Comments adjusted for Fermi 3)</p>
<p>Retention periods of sufficient duration to assure the ability to reconstruct significant events and satisfy any statutory requirements which apply shall be specified.</p>	<p>NQA-1, Supplement 17S-1, Section 2.8 QAPD, Part II, Section 17.1</p>	<p>Fermi 3 QAPD, Part II, Section 17.1</p>	<p>NQA-1, Supplement 17S-1 with the information in Reg. Guide 1.28, Rev. 3, or NQA-1-1994, Nonmandatory Appendix 17A-1, is equivalent to NSI N45.2.9</p>
<p>American National Standard Requirements for Collection, Storage and Maintenance of Quality Assurance Records for Nuclear Power Plants, N45.2.9-1974, shall be used for management of plant records during the operational phase. [14]</p>	<p>NQA-1 Basic Requirement 17, Supplement 17S-1 QAPD, Part II, Section 17.1</p>	<p>Fermi 3 QAPD, Part II, Section 17.1</p>	<p>NQA-1, Supplement 17S-1 with the information in Reg. Guide 1.28, Rev. 3, or NQA-1-1994, Nonmandatory Appendix 17A-1, is equivalent to ANSI N45.2.9</p>
<p>5.2.13 Procurement and Materials Control.</p>			
<p>Measures shall be provided for procurement, documentation and control of those materials and components including spare and replacement parts necessary for plant operation, refueling, maintenance and modification. These measures shall utilize American National Standard Quality Assurance Requirements for the Control of Procurement of Items and Services for Nuclear Power Plants, N45.2.131976. The Appendix to N45.2.13 is particularly useful in determining the quality assurance requirements depending on the complexity or safety of the item. [15]. Procedures shall be established and implemented to ensure that purchased materials and components associated with safety-related structures or systems are: (1) Purchased to specifications and codes equivalent to those specified for the original equipment, or those specified by a properly reviewed and approved revision. (In those cases where the original item or part is found to be commercially "off the shelf," or without specifically identified quality assurance requirements</p>	<p>NQA-1, Basic Requirements 4, 8, and 15; Supplements 4S-1, 8S-1, and 15S-1; and Subpart 2.2 QAPD, Part II, Sections 4, 8, and 15</p>	<p>Fermi 3 QAPD, Part II, Sections 4, 8 and 15</p>	<p>NQA-1 Basic and Supplemental requirements associated with sections 4 and 7 are equivalent to the requirements of N45.2.13 and replace that standard.</p>

American National Standard N18.7-1976/ANS-3.2 Administrative Controls and Quality Assurance for the Operational Phase of Nuclear Power Plants / Regulatory Guide 1.33, Rev. 2 Regulatory Positions	Applicable Section of NQA-1- 1994 or NEI 06-14 Quality Assurance Program Description (QAPD)	Applicable Section(s) of Fermi 3 QAPD (for those requirements not addressed entirely by NQA-1-1994) [N/A is entered in column if requirements is addressed entirely by NQA-1-1994]	Comments (NEI 06-14A, Revision 7, Appendix 1, Comments adjusted for Fermi 3)
<p>spare and replacement parts may be similarly procured but care shall be exercised to assure at least equivalent performance. In those cases where the QA requirements of the original item cannot be determined, an engineering evaluation shall be conducted by qualified individuals to establish the requirements and controls. This evaluation shall assure that interfaces, interchangeability, safety, fit and function are not adversely affected or contrary to applicable regulatory or code requirements. The results of this evaluation shall be documented);</p> <p>(2) Produced or fabricated under requirements at least equivalent to that of the original equipment, or those specified by a properly reviewed and approved revision;</p> <p>(3) Packaged and transported in a manner that will ensure that the quality is not degraded during transit;</p> <p>(4) Properly documented to show compliance with applicable specifications, codes and standards;</p> <p>(5) Properly inspected, identified and stored to protect against damage, deterioration or misuse;</p> <p>(6) Properly controlled to ensure the identification, segregation and disposition of nonconforming material. Special nuclear material and sources shall be shipped and stored as specified in the U.S. Nuclear Regulatory Commission (NRC) fuel license and other applicable regulatory documents.</p>			
5.2.13.1 Procurement Document Control.			
<p>Measures shall be provided to assure that applicable regulatory requirements, design bases and other requirements which are necessary to assure adequate quality are included or referenced in the procedures for procurement of items and services.</p>	<p>NQA-1, Basic Requirement 4 and Supplement 4S-1, Section 2.2</p>	<p>N/A</p>	

American National Standard N18.7-1976/ANS-3.2 Administrative Controls and Quality Assurance for the Operational Phase of Nuclear Power Plants / Regulatory Guide 1.33, Rev. 2 Regulatory Positions	Applicable Section of NQA-1- 1994 or NEI 06-14 Quality Assurance Program Description (QAPD)	Applicable Section(s) of Fermi 3 QAPD (for those requirements not addressed entirely by NQA-1-1994) [N/A is entered in column if requirements is addressed entirely by NQA-1-1994]	Comments (NEI 06-14A, Revision 7, Appendix 1, Comments adjusted for Fermi 3)
To the extent necessary, procurement documents shall require suppliers to provide a quality assurance program consistent with the pertinent requirements of American National Standard Quality Assurance Program Requirements for Nuclear Power Plants, N45.2-1971. [2]	NQA-1, Basic Requirement 4 and Supplement 4S-1, Section 2.3	N/A	The QA requirements of NQA-1-1994 are equivalent to those of ANSI N45.2-1971.
Where changes are made to procurement documents, they shall be subject to the same degree of control as was used in the preparation of the original documents.	NQA-1, Supplement 4S-1, Section 4	N/A	
Procurement documents shall include provisions for the following, as applicable: (1) Supplier Quality Assurance Program. Identification of quality assurance requirements applicable to the items or services procured.	NQA-1, Supplement 4S-1, Section 2.3	N/A	
(2) Basic Technical Requirements. Where specific technical requirements apply, such as drawings, specifications, and industrial codes and standards, they shall be identified by titles and dates of issue in such a way as to clearly set forth the applicable documents. Where procedural requirement apply, in such areas as test and inspection needs, fabrication, cleaning, erecting, packaging, handling, shipping and storage, they too, shall be identified clearly and in such a way as to avoid uncertainty as to source and need.	NQA-1, Supplement 4S-1, Section 2.2	N/A	
(3) Source Inspection and Audit. Provisions for access to the supplier's facilities and records for source inspection and audit when the need for such inspection or audit has been determined.	NQA-1, Supplement 4S-1, Section 2.4	N/A	
(4) Documentation Requirements. Records to be prepared, maintained, submitted or made available for review, such as drawings, specifications, procedures,	NQA-1, Supplement 4S-1, Section 2.5	N/A	

American National Standard N18.7-1976/ANS-3.2 Administrative Controls and Quality Assurance for the Operational Phase of Nuclear Power Plants / Regulatory Guide 1.33, Rev. 2 Regulatory Positions	Applicable Section of NQA-1- 1994 or NEI 06-14 Quality Assurance Program Description (QAPD)	Applicable Section(s) of Fermi 3 QAPD (for those requirements not addressed entirely by NQA-1-1994) [N/A is entered in column if requirements is addressed entirely by NQA-1-1994]	Comments (NEI 06-14A, Revision 7, Appendix 1, Comments adjusted for Fermi 3)
procurement documents, inspection and test records, personnel and procedure qualifications, and material, chemical, and physical test results. Instruction on record retention and disposition shall be provided.			
(5) Lower Tier Procurement. Provisions for extending applicable requirements to lower tier subcontractors and suppliers, including purchaser's access to facilities and records.	NQA-1, Supplement 4S-1, Sections 2.3 and 2.4	N/A	
5.2.13.2 Control of Purchased Material, Equipment and Services.			
Measures shall be provided to assure that purchased items and services, whether purchased directly or through contractors, conform to the procurement documents.	NQA-1, Basic Requirement 7	N/A	
These measures shall include provisions, as appropriate, for source evaluation and selection, objective evidence of quality furnished by the contractor, inspection and audit at the source and examination of items upon delivery.	NQA-1, Basic Requirement 7	N/A	
Measures for evaluation and selection of procurement sources include the use of historical quality performance data, source surveys or audits, or source qualification programs.	NQA-1, Supplement 7S-1, Section 3.1	N/A	
Source inspection or audit shall be performed as necessary to assure the required quality of an item. Source inspection or audit may not be necessary when the quality of the item can be verified by review of test reports, inspection upon receipt, or other means.	NQA-1, Supplement 7S-1, Section 3.1 and Section 8 QAPD, Part II, Section 7.1	Fermi 3 QAPD, Part II, Section 7.1	
Where required by code, regulation, or contract requirements documentary evidence that items conform to procurement requirements shall be available at the	NQA-1, Supplement 7S-1, Section 8.1	N/A	

American National Standard N18.7-1976/ANS-3.2 Administrative Controls and Quality Assurance for the Operational Phase of Nuclear Power Plants / Regulatory Guide 1.33, Rev. 2 Regulatory Positions	Applicable Section of NQA-1- 1994 or NEI 06-14 Quality Assurance Program Description (QAPD)	Applicable Section(s) of Fermi 3 QAPD (for those requirements not addressed entirely by NQA-1-1994) [N/A is entered in column if requirements is addressed entirely by NQA-1-1994]	Comments (NEI 06-14A, Revision 7, Appendix 1, Comments adjusted for Fermi 3)
nuclear power plant site prior to installation or use of such items.			
This documentary evidence shall be retrievable and shall be sufficient to identify the specific requirements such as codes, standards and specifications met by the purchased item.	NQA-1, Supplement 7S-1, Section 5.2 and Section 6	N/A	
Where not precluded by other requirements, such documentary evidence may take the form of written certifications of conformance which identify the requirements met by the items, provided means are available to verify the validity of such certifications.	NQA-1, Supplement 7S-1, Section 8.2	N/A	
The effectiveness of the control of quality shall be assessed by the purchaser at intervals consistent with the importance, complexity and quality of the item or service.	NQA-1, Supplement 7S-1, Section 5 QAPD, Part II, Section 7.1	Fermi 3 QAPD, Part II, Section 7.1	
5.2.13.3 Identification and Control of Materials, Parts and Components.			
Measures shall be provided for the identification and control of materials, parts, and components including partially fabricated subassemblies.	NQA-1, Basic Requirement 8 and Supplement 8S-1	N/A	
These procedures shall be implemented to provide insurance that only correct and accepted items are used and installed, and relating an item of production (batch, lot, component, part) at any stage, from initial receipt through fabrication, installation, repair or modification, to an applicable drawing, specification, or other pertinent technical document.	NQA-1, Supplement 8S-1, Section 2.1	N/A	

American National Standard N18.7-1976/ANS-3.2 Administrative Controls and Quality Assurance for the Operational Phase of Nuclear Power Plants / Regulatory Guide 1.33, Rev. 2 Regulatory Positions	Applicable Section of NQA-1- 1994 or NEI 06-14 Quality Assurance Program Description (QAPD)	Applicable Section(s) of Fermi 3 QAPD (for those requirements not addressed entirely by NQA-1-1994) [N/A is entered in column if requirements is addressed entirely by NQA-1-1994]	Comments (NEI 06-14A, Revision 7, Appendix 1, Comments adjusted for Fermi 3)
Physical identification shall be used to the maximum extent possible. Where physical identification is either impractical or insufficient, physical separation, procedural control or other appropriate means shall be employed.	NQA-1, Supplement 8S-1, Section 2.2	N/A	
Identification may be either on the item or on records traceable to the item, as appropriate.	NQA-1, Basic Requirement 8	N/A	
Where identification marking is employed, the marking shall be clear, unambiguous and indelible, and shall be applied in such a manner as not to affect the function of the item.	NQA-1, Supplement 8S-1, Section 2.3	N/A	
Markings shall be transferred to each part of an item when subdivided and shall not be obliterated or hidden by surface treatment or coatings unless other means of identification are substituted.	NQA-1, Supplement 8S-1, Section 2.3	N/A	
When codes, standards or specifications require traceability of materials, parts or components to specific inspection or test records, the program shall be designed to provide such traceability.	NQA-1, Supplement 8S-1, Section 3.1	N/A	
5.2.13.4 Handling, Storage and Shipping.			
Measures shall be provided to control handling, storage and shipping, including cleaning, packaging and preservation of material and equipment in accordance with established instructions, procedures or drawings, to prevent damage, deterioration and loss.	NQA-1, Basic Requirement 13, Supplement 13S-1, Section 2	N/A	
When necessary for particular items, special coverings, special equipment and special protective environments, such as inert gas atmosphere, specific moisture content levels and temperature levels shall be specified, provided and their existence verified.	NQA-1, Supplement 13S-1, Section 3.1	N/A	

American National Standard N18.7-1976/ANS-3.2 Administrative Controls and Quality Assurance for the Operational Phase of Nuclear Power Plants / Regulatory Guide 1.33, Rev. 2 Regulatory Positions	Applicable Section of NQA-1- 1994 or NEI 06-14 Quality Assurance Program Description (QAPD)	Applicable Section(s) of Fermi 3 QAPD (for those requirements not addressed entirely by NQA-1-1994) [N/A is entered in column if requirements is addressed entirely by NQA-1-1994]	Comments (NEI 06-14A, Revision 7, Appendix 1, Comments adjusted for Fermi 3)
For critical, sensitive, perishable or high value articles, specific written procedures for handling, storage, packaging, shipping and preservation should be used.	NQA-1, Supplement 13S-1, Section 3.2	N/A	
Special handling tools and equipment <u>should</u> be provided and controlled as necessary to ensure safe and adequate handling. Reg. Guide 1.33 – C. Regulatory Position 5.e. The guidelines (indicated by the verb "should") of ANSI N18.7-1976/ANS-3.2 contained in the following sections have sufficient safety importance to be treated the same as the requirements (indicated by the verb "shall") of the standard: e. Section 5.2.13.4–The guideline concerning special handling tools and equipment. [NOTE: The affected “should” word is underlined in the N18.7 excerpt above.]	NQA-1, Supplement 13S-1, Section 3.3	N/A	
Special handling tools and equipment shall be inspected and tested in accordance with written procedures and at specified times, to verify that the tools and equipment are adequately maintained.	NQA-1, Supplement 13S-1, Section 3.3	N/A	
Attention shall be given to providing adequate instructions for marking and labeling of items for packaging, shipment and storage. Marking shall be adequate to identify, maintain and preserve the shipment, including indication of the presence of special environments or the need for special control.	NQA-1, Supplement 13S-1, Section 4	N/A	
American National Standard for Packaging, Shipping, Receiving, Storage and Handling of Items for Nuclear Power Plants (During the Construction Phase), N45.2.2-1972, shall be applied to those activities	NQA-1, Part II, Subpart 2.2	N/A	NQA-1, Subpart 2.2 is equivalent to the cited ANSI N45.2.2 standard.

American National Standard N18.7-1976/ANS-3.2 Administrative Controls and Quality Assurance for the Operational Phase of Nuclear Power Plants / Regulatory Guide 1.33, Rev. 2 Regulatory Positions	Applicable Section of NQA-1- 1994 or NEI 06-14 Quality Assurance Program Description (QAPD)	Applicable Section(s) of Fermi 3 QAPD (for those requirements not addressed entirely by NQA-1-1994) [N/A is entered in column if requirements is addressed entirely by NQA-1-1994]	Comments (NEI 06-14A, Revision 7, Appendix 1, Comments adjusted for Fermi 3)
occurring during the operational phase that are comparable in nature and extent to related activities occurring during construction. [16]			
5.2.14 Nonconforming Items.			
Measures shall be provided to control items, services or activities which do not conform to requirements (see also Section 5.2.6).	NQA-1, Basic Requirement 15	N/A	
These procedures shall include as appropriate, instructions for identification, documentation, segregation, disposition and notification to affected organizations.	NQA-1, Basic Requirement 15 QAPD, Part II, Section 15	Fermi 3 QAPD, Part II, Section 15	
Nonconforming items shall be reviewed and accepted, rejected, repaired or reworked in accordance with documented procedures.	NQA-1, Supplement 15S-1, Section 4.1	N/A	
The responsibility and authority for the disposition of nonconforming items shall be defined.	NQA-1, Supplement 15S-1, Section 4.2	N/A	
Repaired and reworked items shall be reinspected in accordance with applicable procedures.	NQA-1, Supplement 15S-1, Section 4.5	N/A	
Measures which control further processing, delivery or installation of a nonconforming or defective item pending a decision on its disposition shall be established and maintained. Nonconforming items may be disposed of by acceptance "as is," by scrapping or repairing the defective item, or by rework to complete or correct to a drawing or specification. Such measures shall provide assurance that the item is identified as nonconforming and controlled. The measures shall require documentation verifying the acceptability of nonconforming items which have the disposition of "repair" or "use as is." A description of the change, waiver or deviation that has been accepted shall be	NQA-1, Supplement 15S-1, Sections 2 and 4	N/A	

American National Standard N18.7-1976/ANS-3.2 Administrative Controls and Quality Assurance for the Operational Phase of Nuclear Power Plants / Regulatory Guide 1.33, Rev. 2 Regulatory Positions	Applicable Section of NQA-1– 1994 or NEI 06-14 Quality Assurance Program Description (QAPD)	Applicable Section(s) of Fermi 3 QAPD (for those requirements not addressed entirely by NQA-1-1994) [N/A is entered in column if requirements is addressed entirely by NQA-1-1994]	Comments (NEI 06-14A, Revision 7, Appendix 1, Comments adjusted for Fermi 3)
documented to record the change and denote the as-built condition.			
As a guideline, control of nonconforming items by tagging, marking or other means of identification is acceptable where physical segregation is not practical, although physical segregation and marking are preferred.	NQA-1, Supplement 15S-1, Section 3	N/A	
5.2.15 Review, Approval and Control of Procedures.			
The administrative controls and quality assurance program shall provide measures to control and coordinate the approval and issuance of documents, including changes thereto, which prescribe all activities affecting quality. Such documents include those which describe organizational interfaces, or which prescribe activities affecting safety-related structures, systems, or components. These documents also include operating and special orders, operating procedures, test procedures, equipment control procedures, maintenance or modification procedures, refueling, and material control procedures.	NQA-1, Basic Requirement 6 and Supplement 6S-1 QAPD, Part II, Section 6	Fermi 3 QAPD, Part II, Section 6	
These measures shall assure that documents, including revisions or changes, are reviewed for adequacy by appropriately qualified personnel and approved for release by authorized personnel; and are distributed in accordance with current distribution lists and used by the personnel performing the prescribed activity, and that procedures are provided to avoid the misuse of outdated or inappropriate documents. Procedures for operational phase activities of a nuclear power plant reflect the conditions that exist at the time the procedures are written. These conditions include the	NQA-1, Basic Requirement 6 and Supplement 6S-1 QAPD, Part II, Section 6	Fermi 3 QAPD, Part II, Section 6	

American National Standard N18.7-1976/ANS-3.2 Administrative Controls and Quality Assurance for the Operational Phase of Nuclear Power Plants / Regulatory Guide 1.33, Rev. 2 Regulatory Positions	Applicable Section of NQA-1- 1994 or NEI 06-14 Quality Assurance Program Description (QAPD)	Applicable Section(s) of Fermi 3 QAPD (for those requirements not addressed entirely by NQA-1-1994) [N/A is entered in column if requirements is addressed entirely by NQA-1-1994]	Comments (NEI 06-14A, Revision 7, Appendix 1, Comments adjusted for Fermi 3)
<p>technical information available, industry experience, and in the case of the initial procedures for a new plant, assumptions made regarding the detailed behavior of the plant that may not be fully known prior to operation. In order to ensure that the procedures in current use provide the best possible instructions for performance of the work involved, systematic review and feedback of information based on use is required. Each procedure shall be reviewed and approved prior to initial use. The frequency of subsequent reviews shall be specified and may vary depending on the type and complexity of the activity involved, and may vary with time as a given plant reaches operational maturity. Applicable procedures shall be reviewed following an unusual incident, such as an accident, an unexpected transient, significant operator error, or equipment malfunction. Applicable procedures shall be reviewed following any modification to a system. Plant procedures shall be reviewed by an individual knowledgeable in the area affected by the procedure no less frequently than every two years to determine if changes are necessary or desirable. A revision of a procedure constitutes a procedure review. Procedures shall be approved as designated by the owner organization before initial use. Rules shall be established which clearly delineate the review of procedures by knowledgeable personnel other than the originator and the approval of procedures and procedure changes by authorized individuals.</p>			
<p>Changes to documents shall be reviewed and approved by the same organizations that perform the original review and approval unless the owner organization designates another qualified organization.</p>	<p>NQA-1, Supplement 6S-1, Section 3.1</p>	<p>N/A</p>	

American National Standard N18.7-1976/ANS-3.2 Administrative Controls and Quality Assurance for the Operational Phase of Nuclear Power Plants / Regulatory Guide 1.33, Rev. 2 Regulatory Positions	Applicable Section of NQA-1- 1994 or NEI 06-14 Quality Assurance Program Description (QAPD)	Applicable Section(s) of Fermi 3 QAPD (for those requirements not addressed entirely by NQA-1-1994) [N/A is entered in column if requirements is addressed entirely by NQA-1-1994]	Comments (NEI 06-14A, Revision 7, Appendix 1, Comments adjusted for Fermi 3)
The reviewing organizations shall have access to pertinent background information upon which to base its approval and shall have adequate understanding of requirements and intent of the original document.	NQA-1, Supplement 6S-1, Section 3.1	N/A	
Those participating in any activity shall be made aware of, and use, proper and current instructions, procedures, drawings, and engineering requirements for performing the activity. Participating organizations shall have procedures for control of the document and changes thereto to preclude the possibility of using outdated or inappropriate documents.	QAPD, Part II, Section 6.1	Fermi 3 QAPD, Part II, Section 6.1	
Document control measures shall provide for: (1) Identification of individuals or organizations responsible for preparing, reviewing, approving, and issuing documents and revisions thereto (2) Identifying the proper documents to be used in performing the activity (3) Coordination and control of interface documents (4) Ascertaining that proper documents are being used (5) Establishing current and updated distribution lists	NQA-1, Supplement 6S-1, Section 2 QAPD, Part II, Section 6	Fermi 3 QAPD, Part II, Section 6	
5.2.16 Measuring and Test Equipment.			
The method and interval of calibration for each installed instrument and control device shall be defined and shall be based on the type of equipment, stability and reliability characteristics, required accuracies and other conditions affecting calibration.	NQA-1, Basic Requirement 12, Supplement 12S-1	N/A	
Tools, instruments, testing equipment and measuring devices used for measurements, tests and calibration shall be of the proper range and type and shall be controlled, calibrated and adjusted and maintained at specified intervals or prior to use to assure the	NQA-1, Basic Requirement 12, Supplement 12S-1, Sections 2 and 3	N/A	

American National Standard N18.7-1976/ANS-3.2 Administrative Controls and Quality Assurance for the Operational Phase of Nuclear Power Plants / Regulatory Guide 1.33, Rev. 2 Regulatory Positions	Applicable Section of NQA-1- 1994 or NEI 06-14 Quality Assurance Program Description (QAPD)	Applicable Section(s) of Fermi 3 QAPD (for those requirements not addressed entirely by NQA-1-1994) [N/A is entered in column if requirements is addressed entirely by NQA-1-1994]	Comments (NEI 06-14A, Revision 7, Appendix 1, Comments adjusted for Fermi 3)
necessary accuracy of calibrated devices.			
When calibration, testing, or other measuring devices are found to be out of calibration, an evaluation shall be made and documented concerning the validity of previous test and the acceptability of devices previously tested from the time of the previous calibration.	NQA-1, Supplement 12S-1, Section 3.2	N/A	
If any calibration, testing or measuring device is consistently found to be out of calibration, it shall be repaired or replaced.	NQA-1, Supplement 12S-1, Section 3.2	N/A	
It is not the intent of this Standard to imply a need for special calibration and control measures on rulers, tape measures, levels and other such devices if normal commercial practices provide adequate accuracy.	NQA-1, Supplement 12S-1, Section 3.3	N/A	
Special calibration shall be performed when the accuracy of either installed or calibrating equipment is questionable.	NQA-1, Supplement 12S-1, Section 3.2	N/A	
Records shall be made and equipment suitably marked to indicate calibration status.	NQA-1, Supplement 12S-1, Section 5	N/A	
American National Standard N45.2.4-1972 shall be applied to those activities occurring during the operational phase that are comparable in nature and extent to related activities occurring during construction. [6]	NQA-1, Subpart 2.4	N/A	NQA-1-1994, Subpart 2.4 (ANSI/IEEE Std. 336-1985 IEEE) is equivalent to ANSI N45.2.4. NQA-1-1994, Subpart 2.16 consists of IEEE Std. 498-1985; however, IEEE has withdrawn this standard. The primary requirements from this standard are included in NQA-11994, Basic Requirement 12 and Supplement 12S-1.
5.2.17 Inspections.			
A program for inspection of activities affecting safety shall be established and executed by or for the	NQA-1, Basic Requirement 10 and Supplement 10S-1 establish	Fermi 3 QAPD, Part II, Section 10	

American National Standard N18.7-1976/ANS-3.2 Administrative Controls and Quality Assurance for the Operational Phase of Nuclear Power Plants / Regulatory Guide 1.33, Rev. 2 Regulatory Positions	Applicable Section of NQA-1- 1994 or NEI 06-14 Quality Assurance Program Description (QAPD)	Applicable Section(s) of Fermi 3 QAPD (for those requirements not addressed entirely by NQA-1-1994) [N/A is entered in column if requirements is addressed entirely by NQA-1-1994]	Comments (NEI 06-14A, Revision 7, Appendix 1, Comments adjusted for Fermi 3)
organization performing the activity to verify conformance with applicable documented instructions, procedures and drawings.	program requirements QAPD, Part II, Section 10		
Inspections, examinations, measurements, or tests of material, products, or activities shall be performed for each work operation where necessary to assure quality.	NQA-1, Subparts 2.1, 2.2, 2.3, 2.4, 2.5, 2.8, and 2.15 establish specific inspections to be performed.	N/A	
Such inspections shall be performed by qualified individuals other than those who performed or directly supervised the activity being inspected. Inspection of operating activities (work functions associated with normal operation of the plant, routine maintenance, and certain technical services routinely assigned to the onsite operating organization) may be conducted by second-line supervisory personnel or by other qualified personnel not assigned first-line supervisory responsibility for conduct of the work. These independent inspections, i.e., those performed by individuals not assigned first-line supervisory responsibility for the conduct of the work, are not intended to dilute or replace the clear responsibility of first-line supervisors for the quality of work performed under their supervision.	NQA-1 Basic Requirement 10, and Supplement 10S-1 QAPD, Part II, Section 10 (Note exemption in the QAPD.)	Fermi 3 QAPD, Part II, Section 10 (Note exemption in the QAPD)	
For modifications and nonroutine maintenance, inspections shall be conducted in a manner similar (frequency, type, and personnel performing such inspections) to that associated with construction phase activities (see also Section 5.2.7).	NQA-1, Supplement 10S-1, Section 7.4	N/A	
Inspections of safety-related activities shall be performed in accordance with approved written procedures, which set forth the requirements and	NQA-1, Basic Requirement 10, and Supplement 10S-1, Section 2	N/A	

American National Standard N18.7-1976/ANS-3.2 Administrative Controls and Quality Assurance for the Operational Phase of Nuclear Power Plants / Regulatory Guide 1.33, Rev. 2 Regulatory Positions	Applicable Section of NQA-1- 1994 or NEI 06-14 Quality Assurance Program Description (QAPD)	Applicable Section(s) of Fermi 3 QAPD (for those requirements not addressed entirely by NQA-1-1994) [N/A is entered in column if requirements is addressed entirely by NQA-1-1994]	Comments (NEI 06-14A, Revision 7, Appendix 1, Comments adjusted for Fermi 3)
acceptance limits and specify the inspection responsibilities.			
If mandatory inspection hold points are required, the specific hold points shall be indicated in appropriate documents.	NQA-1, Supplement 10S-1, Section 4	N/A	
Information concerning inspection shall be obtained from the related design drawings, specifications and/or other controlled documents.	NQA-1, Supplement 10S-1, Section 2	N/A	
When inspection techniques require specialized qualifications or skills, personnel performing the inspection shall meet applicable licensing requirements, codes, and standards appropriate to the discipline involved (see also Sections 5.2.7, 5.2.6 and 5.3.10).	NQA-1, Supplement 10S-1, Section 3.2; Supplements 2S-1 and 2S-2	N/A	
If inspection is impossible or disadvantageous, indirect control by monitoring processing methods, equipment and personnel shall be provided.	NQA-1, Supplement 10S-1, Section 6.1	N/A	
Both inspection and process monitoring shall be provided when control is inadequate without both. In cases where documented verification of quality implied by the above requirements is not possible or feasible, the extent of inspection or performance testing to verify adequacy of structures, systems, or components for service should be, in general, greater than otherwise required.	NQA-1, Supplement 10S-1, Section 6.1	N/A	
The owner organization shall evaluate inspection results along with test results (see Section 5.2.19) to determine whether the individual inspection and test programs demonstrate that the plant can be operated safely and as designed.	NQA-1, Supplement 10S-1, Basic Requirement 11 and Supplement 11S-1, and Subpart 2.18, Section 2.2	N/A	
Records shall be kept in sufficient detail to permit adequate confirmation of the inspection program. The	NQA-1, Supplement 10S-1, Section 9 and Supplement 11S-1	N/A	Inspection records under NQA-1, may be a part of the work documents.

American National Standard N18.7-1976/ANS-3.2 Administrative Controls and Quality Assurance for the Operational Phase of Nuclear Power Plants / Regulatory Guide 1.33, Rev. 2 Regulatory Positions	Applicable Section of NQA-1- 1994 or NEI 06-14 Quality Assurance Program Description (QAPD)	Applicable Section(s) of Fermi 3 QAPD (for those requirements not addressed entirely by NQA-1-1994) [N/A is entered in column if requirements is addressed entirely by NQA-1-1994]	Comments (NEI 06-14A, Revision 7, Appendix 1, Comments adjusted for Fermi 3)
person recording the data as well as the person approving the inspection results shall be identified. Deviations, their cause, and any corrective action completed or planned as a result of the deviations shall be documented. Inspection records shall be identified as such and shall be retrievable (see also Section 5.2.12).	Section 5		
5.2.18 Control of Special Processes.			
Measures shall be established and documented to assure that special processes, accomplished under controlled conditions in accordance with applicable codes, standards, specifications, criteria, and other special requirements, use qualified personnel and procedures.	NQA-1, Basic Requirement 9 and Supplement 9S-1, Section 2	N/A	
Qualification of personnel, procedures, and equipment shall comply with the requirements of applicable codes and standards.	NQA-1, Supplement 9S-1, Section 3.1.1	N/A	
Special processes are those that require interim in process controls in addition to final inspection to assure quality including such processes as welding, heat treating, chemical cleaning, and nondestructive examination.	NQA-1, Basic Requirement 9 QAPD, Part II, Section 9	Fermi 3 QAPD, Part II, Section 9	
For special processes not covered by existing codes or standards, or where item quality requirements exceed the requirements of established codes or standards, the necessary qualifications of personnel, procedures, or equipment shall be defined.	NQA-1, Supplement 9S-1, Section 3.4	N/A	
5.2.19 Test Control.			
A test program shall be established to assure that testing required to demonstrate that the item will perform satisfactorily in service is identified and documented, and that the testing is performed in accordance with written test procedures which incorporate or reference	NQA-1, Basic Requirement 11, Supplements 11S-1 and 11S-2, and Subpart 2.18 establish programmatic controls for testing. NQA-1, Subparts 2.1,	N/A	

American National Standard N18.7-1976/ANS-3.2 Administrative Controls and Quality Assurance for the Operational Phase of Nuclear Power Plants / Regulatory Guide 1.33, Rev. 2 Regulatory Positions	Applicable Section of NQA-1- 1994 or NEI 06-14 Quality Assurance Program Description (QAPD)	Applicable Section(s) of Fermi 3 QAPD (for those requirements not addressed entirely by NQA-1-1994) [N/A is entered in column if requirements is addressed entirely by NQA-1-1994]	Comments (NEI 06-14A, Revision 7, Appendix 1, Comments adjusted for Fermi 3)
the requirements and acceptance limits contained in applicable design documents.	2.4, 2.5, and 2.8 establish specific testing requirements that apply to the operational phase.		
<p>The test program shall cover all required tests including:</p> <p>(1) Tests during the preoperational period to demonstrate that performance of plant systems is in accordance with design intent and that the coordinated operation of the plant as a whole is satisfactory, to the extent feasible.</p> <p>(2) Tests during the initial operational phase to demonstrate the performance of systems that could not be tested prior to operation and to confirm those physical parameters, hydraulic or mechanical characteristics that need to be known, but which could not be predicted with the required accuracy, and to confirm that plant behavior conforms to design criteria. The initial start-up test program shall be planned to permit safe fuel loading and start-up; to increase power in safe increments; and to perform major testing at specified power plateaus. If tests require the variation of operating parameters outside of their normal range, the limits within which such variation is permitted shall be prescribed. Prerequisites and record keeping shall be given attention and the scope of the testing shall demonstrate insofar as practicable that the plant is capable of withstanding the design transients and accidents. The suitability of plant operating procedures <u>should</u> be checked to the maximum extent possible during the preoperational and initial start-up test programs.</p> <p>Reg. Guide 1.33 – C. Regulatory Position 5.f. The</p>	NQA-1, Supplement 10S-1, Section 8; Supplement 11S-1, Section 2; Subpart 2.4, Section 7; Subpart 2.8, Section 5; and Subpart 2.18, Section 2.7 QAPD, Part II, Section 11	Fermi 3 QAPD, Part II, Section 11	

<p>American National Standard N18.7-1976/ANS-3.2 Administrative Controls and Quality Assurance for the Operational Phase of Nuclear Power Plants / Regulatory Guide 1.33, Rev. 2 Regulatory Positions</p>	<p>Applicable Section of NQA-1-1994 or NEI 06-14 Quality Assurance Program Description (QAPD)</p>	<p>Applicable Section(s) of Fermi 3 QAPD (for those requirements not addressed entirely by NQA-1-1994) [N/A is entered in column if requirements is addressed entirely by NQA-1-1994]</p>	<p>Comments (NEI 06-14A, Revision 7, Appendix 1, Comments adjusted for Fermi 3)</p>
<p>guidelines (indicated by the verb "should") of ANSI N18.7-1976/ANS-3.2 contained in the following sections have sufficient safety importance to be treated the same as the requirements (indicated by the verb "shall") of the standard: f. Section 5.2.19(2)–The guideline for checking plant operating procedures during the testing program. [NOTE: The affected “should” word is underlined in the N18.7 excerpt above.] (3) Surveillance tests during the operational phase to provide assurance that failures or substandard performance do not remain undetected and that the required reliability of safety-related systems is maintained (see Section 5.2.8). (4) Tests during design, fabrication and construction activities associated with plant maintenance and modifications during the operational phase and the demonstration of satisfactory performance following plant maintenance and modifications or procedural changes (see Section 5.2.7).</p>			
<p>5.2.19.1 Preoperational Tests. Preoperational tests are generally performed sequentially in accordance with written procedures. Procedures should ensure that prerequisite steps for equipment testing, such as completion of necessary construction, prior testing, safety precautions, and measures to preserve equipment status have been or will be performed (see also Sections 5.2.17 and 5.3.10). A detailed prescribed physical inspection of equipment components and facilities should be performed to</p>	<p>NQA-1, Supplement 11S-1, Section 3; Subpart 2.4, Section 7; Subpart 2.8, Section 5 QAPD, Part II, Section 11</p>	<p>Fermi 3 QAPD, Part II, Section 11</p>	<p>NQA-1, Subpart 2.8 is equivalent to the requirements of ANSI N45.2.8</p>

<p>American National Standard N18.7-1976/ANS-3.2 Administrative Controls and Quality Assurance for the Operational Phase of Nuclear Power Plants / Regulatory Guide 1.33, Rev. 2 Regulatory Positions</p>	<p>Applicable Section of NQA-1- 1994 or NEI 06-14 Quality Assurance Program Description (QAPD)</p>	<p>Applicable Section(s) of Fermi 3 QAPD (for those requirements not addressed entirely by NQA-1-1994) [N/A is entered in column if requirements is addressed entirely by NQA-1-1994]</p>	<p>Comments (NEI 06-14A, Revision 7, Appendix 1, Comments adjusted for Fermi 3)</p>
<p>ensure readiness for operation. Typical items to be covered include cleanliness, lubrication, setting of limit switches, calibration of instruments, and presence of safety devices. The test procedure should list the checks to be made and include acceptance criteria and reference sources, such as vendor's literature, engineering drawings or plant specifications. A component test is a functional, operational or performance test of an individual piece of equipment or unit system under prescribed conditions. Typical parameters to be examined are direction of rotation, bearing temperatures, vibration, time delays, and ability to operate with remote and local controls. The procedure should list checks to be made and provide acceptance criteria. Consideration should also be given to providing a run-in period to minimize early failures during operation of the plant. Individual system tests establish the functional adequacy by operation under prescribed conditions. The tests shall be designed to permit evaluation of system performance including, for example, the measurement of flow, temperature, pressure, response time and vibration, transfer of power supply to emergency power and accuracy and response of control devices. The preoperational testing program should demonstrate, as nearly as can be practicably simulated, the overall integrated operation of the plant systems at rated conditions, including simultaneous operation of auxiliary systems. It may be necessary to defer portions of these tests until nuclear heat is available. The procedures used should be similar to those discussed in 5.3.3 and 5.3.4, and they <u>should</u> be modified to require</p>			

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<p>variation in control parameters, such as pump stops and restarts, cycling valves and varying flows so that system performance can be evaluated. For additional requirements in matters relating to preoperational test programs, American National Standard N45.2.8-1975 is generally applicable. [8]</p> <p>Reg. Guide 1.33 – C. Regulatory Position 5.g. The guidelines (indicated by the verb "should") of ANSI N18.7-1976/ANS-3.2 contained in the following sections have sufficient safety importance to be treated the same as the requirements (indicated by the verb "shall") of the standard:</p> <p>g. Section 5.2.19.1–The guidelines for preoperational tests, except the guideline that refers to a run-in period for equipment. In addition to these guidelines, the prerequisite steps for each equipment test should be completed prior to the commencement of the preoperational test.</p> <p>[NOTE: The affected "should" words are underlined in the N18.7 excerpt above.]</p>			
<p>5.2.19.2 Tests Prior to and During initial Plant Operation.</p>			
<p>Prior to placing a nuclear power plant into operation, a preoperational test program shall be performed to demonstrate the functional adequacy of plant components, systems and structures. Following fuel loading an initial start-up test program shall be conducted to evaluate plant performance as the start-up progresses.</p>	<p>NQA-1, Basic Requirement 11, and Subpart 2.8, Section 5 QAPD, Part II, Section 11</p>	<p>Fermi 3 QAPD, Part II, Section 11</p>	

American National Standard N18.7-1976/ANS-3.2 Administrative Controls and Quality Assurance for the Operational Phase of Nuclear Power Plants / Regulatory Guide 1.33, Rev. 2 Regulatory Positions	Applicable Section of NQA-1- 1994 or NEI 06-14 Quality Assurance Program Description (QAPD)	Applicable Section(s) of Fermi 3 QAPD (for those requirements not addressed entirely by NQA-1-1994) [N/A is entered in column if requirements is addressed entirely by NQA-1-1994]	Comments (NEI 06-14A, Revision 7, Appendix 1, Comments adjusted for Fermi 3)
Responsibilities			
The ultimate responsibility for the preparation and execution of adequate preoperational and initial startup test programs rests with the owner organization. If design or construction is performed by other than the owner organization, design organizations involved should participate in definition of the programs, and the construction organization involved may supply manpower or supervision for execution of part or all of the program, but the owner organization shall determine that the program is adequate and that the results are satisfactory.	QAPD, Part II, Section 1	Fermi 3 QAPD, Part II, Section 1	
Scheduling			
A schedule shall be provided and maintained to provide assurance that all necessary tests are performed and properly evaluated on a timely basis. Testing shall be scheduled so that the safety of the plant is never dependent on the performance of an untested system (see also Section 5.2.8).	QAPD, Part II, Section 11	Fermi 3 QAPD, Part II, Section 11	
5.2.19.3 Tests Associated with Plant Maintenance, Modifications or Procedure Changes.			
Tests shall be performed following plant modifications or significant changes in operating procedures to confirm that the modifications or changes reasonably produce expected results and that the change does not reduce safety of operations.	NQA-1, Supplement 11S-1, Section 2 and Subpart 2.18, Section 2 QAPD, Part II, Section 11	Ef3 QAPD, Part II, Section 11	
5.3 Preparation of Instructions and Procedures.			
The administrative controls and quality assurance program shall be carried out throughout plant life in accordance with written procedures. Activities affecting safety at nuclear power plants shall be described by	NQA-1, Basic Requirement 5 QAPD, Part II, Section 5; Part V, Section 3	Fermi 3 QAPD, Part II, Section 5, Part V, Section 3	

American National Standard N18.7-1976/ANS-3.2 Administrative Controls and Quality Assurance for the Operational Phase of Nuclear Power Plants / Regulatory Guide 1.33, Rev. 2 Regulatory Positions	Applicable Section of NQA-1- 1994 or NEI 06-14 Quality Assurance Program Description (QAPD)	Applicable Section(s) of Fermi 3 QAPD (for those requirements not addressed entirely by NQA-1-1994) [N/A is entered in column if requirements is addressed entirely by NQA-1-1994]	Comments (NEI 06-14A, Revision 7, Appendix 1, Comments adjusted for Fermi 3)
<p>written procedures of a type appropriate to the circumstances and shall be accomplished in accordance with these instructions and procedures.</p> <p>Reg. Guide 1.33 – Regulatory Position C, Item 1 ANSI N18.7-1976/ANS-3.2 requires the preparation of many procedures to carry out an effective quality assurance program. Appendix A, "Typical Procedures for Pressurized Water Reactors and Boiling Water Reactors," to this regulatory guide should be used as guidance to ensure minimum procedural coverage for plant operating activities, including related maintenance activities. Appendix A lists typical safety-related activities that should be covered by written procedures but does not provide a complete listing of needed procedures. Many other activities carried out during the operation phase of a nuclear power plant require written procedures not included in Appendix A. Appendix A may also contain procedures that are not applicable to an applicant because of the configuration of the nuclear power plant. The procedures listed in Appendix A may be combined, separated, or deleted to conform to the applicant's procedures plan.</p>			
<p>These procedures shall include appropriate quantitative or qualitative acceptance criteria for determining that important activities have been satisfactorily accomplished. These procedures shall provide an approved preplanned method of conducting operations. Procedures shall be prepared and approved prior to implementation as required by 4.3 and 5.2.15.</p>	<p>NQA-1, Basic Requirement 5</p>	<p>N/A</p>	

American National Standard N18.7-1976/ANS-3.2 Administrative Controls and Quality Assurance for the Operational Phase of Nuclear Power Plants / Regulatory Guide 1.33, Rev. 2 Regulatory Positions	Applicable Section of NQA-1- 1994 or NEI 06-14 Quality Assurance Program Description (QAPD)	Applicable Section(s) of Fermi 3 QAPD (for those requirements not addressed entirely by NQA-1-1994) [N/A is entered in column if requirements is addressed entirely by NQA-1-1994]	Comments (NEI 06-14A, Revision 7, Appendix 1, Comments adjusted for Fermi 3)
5.3.1 Procedure Scope.			
Each procedure shall be sufficiently detailed for a qualified individual to perform the required function without direct supervision, but need not provide a complete description of the system or plant process.	QAPD, Part V, Section 3	Fermi 3 QAPD, Part V, Section 3	
5.3.2 Procedure Content.			
The format of procedures may vary from plant to plant, depending on the policies of the owner organization. However, procedures shall include, as appropriate, the following elements:	QAPD, Part V, Section 3	Fermi 3, QAPD, Part V, Section 3	
(1) Title. Each procedure should contain a title descriptive of the work or system or unit to which it applies, a revision number or date, and an approval status.	QAPD, Part V, Section 3.1	Fermi 3, QAPD, Part V, Section 3.1	
(2) Statement of Applicability. The purpose for which the procedure is intended should be clearly stated; for example, for use during reactor or plant start-up. If the purpose is not clear from the title, a separate statement of applicability should be provided, which may identify the reasons for particular operations.	QAPD, Part V, Section 3.1	Fermi 3, QAPD, Part V, Section 3.1	
(3) References. References, including reference to technical specifications, should be included in procedures as applicable. References should be identified within the body of procedures when the sequence of steps requires other tasks to be performed prior to or concurrent with a particular step within that task.	NQA-1, Introduction to Part II, and Subpart 2.18, Section 2.2 QAPD, Part V, Section 3.1	Fermi 3, QAPD, Part V, Section 3.1	

American National Standard N18.7-1976/ANS-3.2 Administrative Controls and Quality Assurance for the Operational Phase of Nuclear Power Plants / Regulatory Guide 1.33, Rev. 2 Regulatory Positions	Applicable Section of NQA-1- 1994 or NEI 06-14 Quality Assurance Program Description (QAPD)	Applicable Section(s) of Fermi 3 QAPD (for those requirements not addressed entirely by NQA-1-1994) [N/A is entered in column if requirements is addressed entirely by NQA-1-1994]	Comments (NEI 06-14A, Revision 7, Appendix 1, Comments adjusted for Fermi 3)
(4) Prerequisites. Each procedure should identify those independent actions or procedures which shall be completed and plant conditions which shall exist prior to its use. Prerequisites applicable only to certain sections of a procedure should be so identified.	NQA-1, Introduction to Part II, and Subpart 2.18, Section 2.2 QAPD, Part V, Section 3.1	Fermi 3, QAPD, Part V, Section 3.1	
(5) Precautions. Precautions should be established to alert the individual performing the task to those important measures which should be used to protect equipment and personnel, including the public, or to avoid an abnormal or emergency situation. It may be convenient to specify precautions separately. Cautionary notes applicable to specific steps in the procedure should be included in the main body of the procedure and should be identified as such.	NQA-1, Introduction to Part II, and Subpart 2.18, Section 2.2 QAPD, Part V, Section 3.1	Fermi 3, QAPD, Part V, Section 3.1	
(6) Limitations and Actions. Limitations on the parameters being controlled and appropriate corrective measures to return the parameter to the normal control band should be specified. It may be convenient to specify limitations and setpoints in a separate section. Where appropriate, quantitative control guides should be provided; for example, an appropriate step of a procedure should say "Manually adjust the feedwater flow controller to maintain the reactor water level at x feet," rather than "Manually adjust the feedwater flow to maintain water level."	QAPD, Section 5 QAPD, Part V, Section 3.1	Fermi 3 QAPD, Part II, Section 5, and Part V, Section 3.1	
(7) Main Body. The main body of a procedure should contain step-by-step instructions in the degree of detail necessary for performing a required function or task.	NQA-1, Introduction to Part II, and Subpart 2.18, Section 2.2 QAPD, Part V, Section 3.1	Fermi 3, QAPD, Part V, Section 3.1	
(8) Acceptance Criteria. Procedures should contain, where applicable, acceptance criteria against which the success or failure of test-type activity would be judged.	NQA-1, Introduction to Part II, and Subpart 2.18, Section 2.2 QAPD, Part V, Section 3.1	Fermi 3, QAPD, Part V, Section 3.1	

American National Standard N18.7-1976/ANS-3.2 Administrative Controls and Quality Assurance for the Operational Phase of Nuclear Power Plants / Regulatory Guide 1.33, Rev. 2 Regulatory Positions	Applicable Section of NQA-1- 1994 or NEI 06-14 Quality Assurance Program Description (QAPD)	Applicable Section(s) of Fermi 3 QAPD (for those requirements not addressed entirely by NQA-1-1994) [N/A is entered in column if requirements is addressed entirely by NQA-1-1994]	Comments (NEI 06-14A, Revision 7, Appendix 1, Comments adjusted for Fermi 3)
In some cases there would be qualitative criteria, i.e., a given event does or does not occur. In other cases quantitative values would be designated.			
<p>(9) Checkoff Lists. Complex procedures <u>should</u> have checkoff lists. These lists may be included as part of the procedure or may be appended to the procedure.</p> <p>Reg. Guide 1.33 – C. Regulatory Position 5.h. The guidelines (indicated by the verb "should") of ANSI N18.7-1976/ANS-3.2 contained in the following sections have sufficient safety importance to be treated the same as the requirements (indicated by the verb "shall") of the standard:</p> <p>h. Section 5.3.2-The guidelines that describe the content (excluding format) of procedures, except for the guidelines that address (1) a separate statement of applicability in Section 5.3.2(2), (2) inclusion of references in procedures, as applicable, in Section 5.3.2(3), and (3) inclusion of quantitative control guides in Section 5.3.2(6). <u>[NOTE: The affected "should" words are underlined in the N18.7 excerpts above.]</u></p>	NQA-1, Introduction to Part II, and Subpart 2.18, Section 2.2 QAPD, Part V, Section 3.1	Fermi 3, QAPD, Part V, Section 3.1	
5.3.3 System Procedures.			

American National Standard N18.7-1976/ANS-3.2 Administrative Controls and Quality Assurance for the Operational Phase of Nuclear Power Plants / Regulatory Guide 1.33, Rev. 2 Regulatory Positions	Applicable Section of NQA-1- 1994 or NEI 06-14 Quality Assurance Program Description (QAPD)	Applicable Section(s) of Fermi 3 QAPD (for those requirements not addressed entirely by NQA-1-1994) [N/A is entered in column if requirements is addressed entirely by NQA-1-1994]	Comments (NEI 06-14A, Revision 7, Appendix 1, Comments adjusted for Fermi 3)
Instructions for energizing, filling, venting, draining, starting up, shutting down, changing modes of operation and other instructions appropriate for operations of systems related to the safety of the plant shall be delineated in system procedures. Procedures for correcting off-normal conditions shall be developed for those events where system complexity may lead to operator uncertainty. System procedures shall contain checkoff lists where appropriate.	QAPD, Part V, Section 3.2	Fermi 3 QAPD, Part V, Section 3.2	
5.3.4 General Plant Procedures.			
General plant procedures provide instructions for the integrated operations of the plant. In addition to the characteristics of procedures presented in 5.3.1 and 5.3.2, details concerning specific general plant procedures are emphasized in the following sections.	QAPD, Part V, Section 3.2	Fermi 3 QAPD, Part V, Section 3.2	
5.3.4.1 Start-up Procedures.			
Start-up procedures shall be provided that include starting the reactor from cold or hot conditions and establishing power operation, with the generator synchronized to the line. Recovery from reactor trips shall be in accordance with the start-up procedure and shall be subject to the determinations set forth in 5.2.1. (1) Prerequisites. Start-up procedures shall include provisions for documented determination that prerequisites have been met, including confirmation that necessary instruments are operable and properly set; valves are properly aligned; necessary systems procedures, tests and calibrations have been completed; and required approvals have been obtained. Checkoff lists are normally used for this purpose. (2) Main Body. The main body of the start-up	QAPD, Part V, Section 3.2	Fermi 3, Part V, Section 3.2	

American National Standard N18.7-1976/ANS-3.2 Administrative Controls and Quality Assurance for the Operational Phase of Nuclear Power Plants / Regulatory Guide 1.33, Rev. 2 Regulatory Positions	Applicable Section of NQA-1- 1994 or NEI 06-14 Quality Assurance Program Description (QAPD)	Applicable Section(s) of Fermi 3 QAPD (for those requirements not addressed entirely by NQA-1-1994) [N/A is entered in column if requirements is addressed entirely by NQA-1-1994]	Comments (NEI 06-14A, Revision 7, Appendix 1, Comments adjusted for Fermi 3)
<p>procedures shall include the major steps of the start-up sequence, including reference to appropriate system procedures. Such major steps shall include or reference detailed instructions for their performance, for example, minimum instrumentation requirements coverage of control rod withdrawal sequence or soluble poison dilution, manipulation of controls, establishment of feed and steam flow and turbine startup and synchronization. Checkoff lists should be used for the purpose of confirming completion of major steps in proper sequence.</p>			
<p>5.3.4.2 Shutdown Procedures.</p>			
<p>Shutdown procedures shall be provided to guide operations during and following controlled shutdown or reactor trips and shall include instructions for establishing or maintaining hot standby or cold shutdown conditions, as applicable. The major steps involved in shutting down the plant shall be specified, including detailed instructions for the performance of such actions as monitoring and controlling reactivity, load reduction and cooldown rates, sequence of activating or deactivating equipment, requirements for prompt analyses of causes of reactor trips or abnormal conditions requiring unplanned controlled shutdowns, and provisions for decay heat removal. Checkoff lists should be used for the purpose of confirming completion of major steps in proper sequence.</p>	<p>QAPD, Part V, Section 3.2</p>	<p>Fermi 3 QAPD, Part V, Section 3.2</p>	
<p>5.3.4.3 Power Operation and Load Changing Procedures.</p>			
<p>Procedures for steady-state power operation and load changing shall be provided that include, for example,</p>	<p>QAPD, Part V, Section 3.2</p>	<p>Fermi 3 QAPD, Part V, Section 3.2</p>	

American National Standard N18.7-1976/ANS-3.2 Administrative Controls and Quality Assurance for the Operational Phase of Nuclear Power Plants / Regulatory Guide 1.33, Rev. 2 Regulatory Positions	Applicable Section of NQA-1- 1994 or NEI 06-14 Quality Assurance Program Description (QAPD)	Applicable Section(s) of Fermi 3 QAPD (for those requirements not addressed entirely by NQA-1-1994) [N/A is entered in column if requirements is addressed entirely by NQA-1-1994]	Comments (NEI 06-14A, Revision 7, Appendix 1, Comments adjusted for Fermi 3)
provisions for use of control rods, chemical shim, coolant flow control or any other system available for long-or-short term control of reactivity, making deliberate load changes, responding to unanticipated load changes and adjusting operating parameters.			
5.3.4.4 Process Monitoring Procedures.			
Procedures for monitoring performance of plant systems shall be required to assure that core thermal margins and coolant quality are maintained at all times, that integrity of fission product barriers is maintained at all times and that engineered safety features and emergency equipment are in a state of readiness to maintain the plant in a safe condition if needed. The limits (maximum and minimum) for significant process parameters shall be identified. The nature and frequency of this monitoring shall be covered by operating procedures, as appropriate.	QAPD, Part V, Section 3.2	Fermi 3 QAPD, Part V, Section 3.2	
5.3.4.5 Fuel-Handling Procedures.			
Fuel-handling operations shall be performed in accordance with written procedures. These procedures shall specify actions for core alterations, accountability of fuel and partial or complete refueling operations that include, for example, continuous monitoring of the neutron flux throughout core loading, periodic recording of data, audible annunciation of abnormal flux increases and evaluation of core neutron multiplication to verify the safety of loading increments. Provisions shall be made for preparing specific procedures for each refueling outage and for receipt and shipment of fuel. Plant procedures should, nonetheless, prescribe the general preplanning for the	QAPD, Part V, Section 3.2	Fermi 3 QAPD, Part V, Section 3.2	

American National Standard N18.7-1976/ANS-3.2 Administrative Controls and Quality Assurance for the Operational Phase of Nuclear Power Plants / Regulatory Guide 1.33, Rev. 2 Regulatory Positions	Applicable Section of NQA-1- 1994 or NEI 06-14 Quality Assurance Program Description (QAPD)	Applicable Section(s) of Fermi 3 QAPD (for those requirements not addressed entirely by NQA-1-1994) [N/A is entered in column if requirements is addressed entirely by NQA-1-1994]	Comments (NEI 06-14A, Revision 7, Appendix 1, Comments adjusted for Fermi 3)
<p>fuel-handling program and its associated safety measures and should identify those aspects of the program for which procedures are to be prepared for each refueling outage.</p> <p>(1) Prerequisites. Prerequisites shall be provided in the fuel-handling procedures that include, for example, the status of plant systems required for refueling; inspection of replacement fuel, control rods, poison curtains and internals; designation of proper tools; proper conditions for spent fuel movement; proper conditions for fuel cask loading and movement; and status of interlocks, reactor trip circuits and mode switches.</p> <p>(2) Main Body. The main body of fuel handling procedures shall include requirements for refueling; for example, the status of the core, instructions for proper sequence, orientation, and seating of fuel and components, rules for minimum operable instrumentation, actions to be followed in the event of fuel damage, rules for periods when refueling is interrupted, verification of the shutdown margin and the frequency of determination, communications between control room and the fuel loading station, independent verification of fuel and component location, criteria for stopping refueling and for reducing the size of the fuel loading increment, and a containment evacuation plan and its associated safety measures. Documentation of final fuel and component serial numbers and locations shall be maintained.</p>			
<p>5.3.5 Maintenance Procedures. Maintenance procedures shall contain applicable items listed under 5.3.2 and, in addition, measures to cover the features of maintenance described below.</p>	<p>NQA-1, Subpart 2.18, Section 2 QAPD, Part V, Section 3.2</p>	<p>Fermi 3 QAPD, Part V, Section 3.2</p>	

<p>American National Standard N18.7-1976/ANS-3.2 Administrative Controls and Quality Assurance for the Operational Phase of Nuclear Power Plants / Regulatory Guide 1.33, Rev. 2 Regulatory Positions</p>	<p>Applicable Section of NQA-1- 1994 or NEI 06-14 Quality Assurance Program Description (QAPD)</p>	<p>Applicable Section(s) of Fermi 3 QAPD (for those requirements not addressed entirely by NQA-1-1994) [N/A is entered in column if requirements is addressed entirely by NQA-1-1994]</p>	<p>Comments (NEI 06-14A, Revision 7, Appendix 1, Comments adjusted for Fermi 3)</p>
<p>(1) Preparation for Maintenance. Maintenance procedures shall reflect considerations listed under 5.2.6. Adherence to applicable radiation protection measures shall be prescribed. These measures shall specify protective clothing and radiation monitoring needed to assure safety.</p> <p>(2) Performance of Maintenance. The procedures shall contain enough detail to permit the maintenance work to be performed correctly and safely, and shall include provisions for conducting and recording results of required tests and inspections. References should be made to vendor manuals, plant procedures, drawings and other sources as applicable.</p> <p>(3) Post Maintenance Check Out and Return to Service. Instructions shall be included, or referenced, for returning the equipment to its normal operating status.</p> <p>(4) Supporting Maintenance Documents. Where appropriate sections of related documents, such as vendor manuals, equipment operating and maintenance instructions, or approved drawings with acceptance criteria provide adequate instructions to assure the required quality of work, the applicable sections of the related documents shall be referenced in the procedure, or may, in some cases, constitute adequate procedures in themselves. Such procedures shall receive the same level of review and approval as operating procedures.</p>			
<p>5.3.6 Radiation Control Procedures.</p>			
<p>Procedures shall be provided for implementation of a radiation control program to meet applicable program requirements. The radiation control program involves the acquisition of data and provision of equipment to perform necessary radiation surveys, measurements and</p>	<p>QAPD, Part V, Section 3.2</p>	<p>Fermi 3 QAPD, Part V, Section 3.2</p>	

American National Standard N18.7-1976/ANS-3.2 Administrative Controls and Quality Assurance for the Operational Phase of Nuclear Power Plants / Regulatory Guide 1.33, Rev. 2 Regulatory Positions	Applicable Section of NQA-1- 1994 or NEI 06-14 Quality Assurance Program Description (QAPD)	Applicable Section(s) of Fermi 3 QAPD (for those requirements not addressed entirely by NQA-1-1994) [N/A is entered in column if requirements is addressed entirely by NQA-1-1994]	Comments (NEI 06-14A, Revision 7, Appendix 1, Comments adjusted for Fermi 3)
evaluations for the assessment and control of radiation hazards associated with a nuclear power plant. Procedures shall be developed and implemented for: monitoring both external and internal exposures of employees, utilizing accepted techniques; routine radiation surveys of work areas; environmental monitoring in the vicinity of the plant; radiation monitoring of maintenance and special work activities; and for maintaining records demonstrating the adequacy of measures taken to control radiation exposures of employees and others.			
5.3.7 Calibration and Test Procedures. Procedures shall be provided for periodic calibration and testing of safety-related instrumentation and control systems. Procedures shall also be provided for periodic calibration of measuring and test equipment used in activities affecting the quality of these systems. The procedures shall provide for meeting surveillance schedules and for assuring measurement accuracy adequate to keep safety-related parameters within operational and safety limits.	QAPD, Part V, Section 3.2	Fermi 3 QAPD, Part V, Section 3.2	
5.3.8 Chemical-Radiochemical Control Procedures. Procedures shall be provided for chemical and radiochemical control activities. They should include, for example, the nature and frequency of sampling and analyses; instructions for maintaining coolant quality within prescribed limits; and limitations on concentrations of agents that could cause corrosive attack, foul heat transfer surfaces or become sources of radiation hazards due to activation. Procedures shall also be provided for the control, treatment and	QAPD, Part V, Section 3.2	Fermi 3 QAPD, Part V, Section 3.2	

American National Standard N18.7-1976/ANS-3.2 Administrative Controls and Quality Assurance for the Operational Phase of Nuclear Power Plants / Regulatory Guide 1.33, Rev. 2 Regulatory Positions	Applicable Section of NQA-1- 1994 or NEI 06-14 Quality Assurance Program Description (QAPD)	Applicable Section(s) of Fermi 3 QAPD (for those requirements not addressed entirely by NQA-1-1994) [N/A is entered in column if requirements is addressed entirely by NQA-1-1994]	Comments (NEI 06-14A, Revision 7, Appendix 1, Comments adjusted for Fermi 3)
management of radioactive wastes and control of radioactive calibration sources.			
5.3.9 Emergency Procedures.			
<p>Procedures shall be provided to guide operations during potential emergencies. They shall be written so that a trained operator will know in advance the expected course of events that will identify an emergency and the immediate action he should take. Since emergencies may not follow anticipated patterns, the procedures should provide sufficient flexibility to accommodate variations. Emergency procedures that cover actions for manipulations of controls to prevent accidents or lessen their consequences should be based on a general sequence of observations and actions. Emphasis <u>should</u> be placed on operator responses to observations and indications in the control room; that is, when immediate operator actions are required to prevent or mitigate the consequences of a serious condition, procedures <u>should</u> require that those actions be implemented promptly. The emergency procedure format given in 5.3.9.1 provides a basis for coping with emergencies and is an acceptable format for prescribing operator observations and actions. Emergency procedures may contain supplemental background information to further aid operators in taking proper emergency actions, but this information shall be separated from the procedural actions. It is extremely difficult to distinguish between procedures prepared for the purpose of correcting off-normal conditions which in themselves do not constitute actual emergency situations, but which conceivably can degenerate into true emergencies in the absence of positive corrective action, and procedures</p>	QAPD, Part V, Section 3.2	Fermi 3 QAPD, Part V, Section 3.2	Requirements for Emergency Procedures have been updated through the years through industry initiatives and lessons learned.

American National Standard N18.7-1976/ANS-3.2 Administrative Controls and Quality Assurance for the Operational Phase of Nuclear Power Plants / Regulatory Guide 1.33, Rev. 2 Regulatory Positions	Applicable Section of NQA-1- 1994 or NEI 06-14 Quality Assurance Program Description (QAPD)	Applicable Section(s) of Fermi 3 QAPD (for those requirements not addressed entirely by NQA-1-1994) [N/A is entered in column if requirements is addressed entirely by NQA-1-1994]	Comments (NEI 06-14A, Revision 7, Appendix 1, Comments adjusted for Fermi 3)
<p>required for coping with true emergencies that have already occurred. Some owner organizations choose the term "Off-normal Procedures" for the same purpose that others choose "Emergency Procedures." When initially available intelligence provided to operating personnel via instrument readings, physical conditions, and personal observations may not clearly indicate the difference between a simple operational problem and a serious emergency, the actions outlined in the emergency procedures shall be based on a conservative course of action by the operating crew. Considerable judgment on the part of competent personnel is required before departing from the emergency procedure.</p> <p>Reg. Guide 1.33 – C. Regulatory Position 5.i. The guidelines (indicated by the verb "should") of ANSI N18.7-1976/ANS-3.2 contained in the following sections have sufficient safety importance to be treated the same as the requirements (indicated by the verb "shall") of the standard:</p> <p>i. Section 5.3.9--The guideline concerning emergency procedures requiring prompt implementation of immediate operator actions when required to prevent or mitigate the consequences of a serious condition.</p> <p>[NOTE: The affected "should" words are underlined in the N18.7 excerpt above.]</p>			
<p>5.3.9.1 Emergency Procedure Format and Content.</p> <p>Emergency procedures shall include, as appropriate, the following elements:</p> <p>(1) Title. The title should be descriptive of the emergency for which the procedure is provided.</p>	<p>QAPD, Part V, Section 3.2</p>	<p>Fermi 3 QAPD, Part V, Section 3.2</p>	<p>Requirements for Emergency Procedures have been updated through the years through industry initiatives and lessons learned.</p>

<p>American National Standard N18.7-1976/ANS-3.2 Administrative Controls and Quality Assurance for the Operational Phase of Nuclear Power Plants / Regulatory Guide 1.33, Rev. 2 Regulatory Positions</p>	<p>Applicable Section of NQA-1- 1994 or NEI 06-14 Quality Assurance Program Description (QAPD)</p>	<p>Applicable Section(s) of Fermi 3 QAPD (for those requirements not addressed entirely by NQA-1-1994) [N/A is entered in column if requirements is addressed entirely by NQA-1-1994]</p>	<p>Comments (NEI 06-14A, Revision 7, Appendix 1, Comments adjusted for Fermi 3)</p>
<p>(2) Symptoms. Symptoms should be included to aid in the identification of the emergency. They should include alarms, operating conditions and probable magnitudes of parameter changes. If a condition is peculiar only to the emergency under consideration, it should be listed first.</p> <p>(3) Automatic Actions. The automatic actions that will probably occur as a result of the emergency should be identified.</p> <p>(4) Immediate Operator Actions. These steps should specify immediate actions for operation of controls or confirmation of automatic actions that are required to stop the degradation of conditions and mitigate their consequences. Examples include the following:</p> <p>(a) The verification of automatic actions. This step is based on equipment operating as designed and the sequence of events following an expected course. Since variations from the expected course may occur, operators should be prepared to manipulate controls as necessary to cope with the problem. However, the procedure should caution the operator not to place systems in "manual" unless misoperation in "automatic" is apparent, and should require him to make frequent checks for proper operation of systems placed in manual control.</p> <p>(b) Assurance that reactor is in a safe condition. This step usually means shutdown of the reactor with sufficient reactivity margin and establishment of required core cooling.</p> <p>(c) Notification to plant personnel of the nature of the emergency.</p> <p>(d) Determination that the reactor coolant system</p>			

<p>American National Standard N18.7-1976/ANS-3.2 Administrative Controls and Quality Assurance for the Operational Phase of Nuclear Power Plants / Regulatory Guide 1.33, Rev. 2 Regulatory Positions</p>	<p>Applicable Section of NQA-1- 1994 or NEI 06-14 Quality Assurance Program Description (QAPD)</p>	<p>Applicable Section(s) of Fermi 3 QAPD (for those requirements not addressed entirely by NQA-1-1994) [N/A is entered in column if requirements is addressed entirely by NQA-1-1994]</p>	<p>Comments (NEI 06-14A, Revision 7, Appendix 1, Comments adjusted for Fermi 3)</p>
<p>pressure boundary is intact. (e) Confirmation of the availability of adequate power sources. (f) Confirmation that containment and exhaust systems are operating properly in order to prevent uncontrolled release of radioactivity. (5) Subsequent Operator Actions. Steps <u>should</u> be included to return the reactor to a normal condition or to provide for a safe extended shutdown period under abnormal or emergency conditions. Reg. Guide 1.33 – C. Regulatory Position 5.j. The guidelines (indicated by the verb "should") of ANSI N18.7-1976/ANS-3.2 contained in the following sections have sufficient safety importance to be treated the same as the requirements (indicated by the verb "shall") of the standard: j. Section 5.3.9.1–The guidelines that describe the content (excluding format) for: the title in Section 5.3.9.1(1); the inclusion of symptoms to aid in identification in Section 5.3.9.1(2); automatic actions in Section 5.3.9.1(3); immediate operator action, excluding those guidelines contained in the examples, in Section 5.3.9.1(4); and subsequent operator actions in Section 5.3.9.1(5). [NOTE: The affected “should” words are underlined in the N18.7 excerpt above.]</p>			
<p>5.3.9.2 Events of Potential Emergency. Potential emergency conditions shall be identified and procedures for coping with them shall be prepared. The following categories of events may, depending upon the design of the plant, be considered as examples</p>	<p>QAPD, Part V, Section 3.2</p>	<p>Fermi 3 QAPD, Part V, Section 3.2</p>	<p>The list contained in N18.7 is provided as examples and is not stated in the QAPD. NRC regulatory guidance, FSAR/DCD, and</p>

American National Standard N18.7-1976/ANS-3.2 Administrative Controls and Quality Assurance for the Operational Phase of Nuclear Power Plants / Regulatory Guide 1.33, Rev. 2 Regulatory Positions	Applicable Section of NQA-1- 1994 or NEI 06-14 Quality Assurance Program Description (QAPD)	Applicable Section(s) of Fermi 3 QAPD (for those requirements not addressed entirely by NQA-1-1994) [N/A is entered in column if requirements is addressed entirely by NQA-1-1994]	Comments (NEI 06-14A, Revision 7, Appendix 1, Comments adjusted for Fermi 3)
of potential emergencies for which procedures are written and for which immediate action is indicated: (1) Loss of coolant from identified and unidentified sources, from small loss to design-basis-accident loss (2) Reactor transients and excursions (3) Failure of vital equipment (4) Loss or degradation of vital power sources (5) Civil disturbances (6) Abnormally high radiation levels (7) Excessive release of radioactive liquid or gaseous effluent (8) Malfunction of reactivity control system (9) Loss of containment integrity (10) Conditions that require use of standby liquid poison systems (11) Possible natural occurrences (12) Fires			Emergency Plans will provide the basis for what procedures are necessary
5.3.9.3 Procedures for Implementing Emergency Plan.			
Implementing procedures for emergency plan actions shall contain, as appropriate, the following elements: (1) Individual assignment of authorities and responsibilities for performance of specific tasks to specific individuals or staff positions. (2) Protective action levels and protective measures outlined for the emergency identified. (3) Specific actions to be taken by coordinating support groups. (4) Procedures for medical treatment and handling of contaminated individuals. (5) Special equipment requirements for items such as medical treatment, emergency personnel removal,	QAPD, Part V, Section 3.2	Fermi 3 QAPD, Part V, Section 3.2	

American National Standard N18.7-1976/ANS-3.2 Administrative Controls and Quality Assurance for the Operational Phase of Nuclear Power Plants / Regulatory Guide 1.33, Rev. 2 Regulatory Positions	Applicable Section of NQA-1- 1994 or NEI 06-14 Quality Assurance Program Description (QAPD)	Applicable Section(s) of Fermi 3 QAPD (for those requirements not addressed entirely by NQA-1-1994) [N/A is entered in column if requirements is addressed entirely by NQA-1-1994]	Comments (NEI 06-14A, Revision 7, Appendix 1, Comments adjusted for Fermi 3)
<p>specific radiation detection, personnel dosimetry and rescue operations, procedures for making this equipment available, plus operating instructions for such equipment, and provisions for its periodic inspection and maintenance.</p> <p>(6) Identification of emergency communications network, including communications required for personnel identification and effective coordination of all support groups.</p> <p>(7) Description of alarm signals in each facility. At sites with multiple units, alarm signals should be consistent from one unit to another. (Signals for initiating protective measures should be clear and distinct from process or operational alarm system to avoid confusion.)</p> <p>(8) Procedures required to restore the plant to normal conditions following an emergency.</p> <p>(9) Requirements for periodically testing of procedures, communications network and alarm systems to assure that they function properly.</p> <p>See also U.S. Nuclear Regulatory Commission (NRC) "Guide to the Preparation of Emergency Plans for Production and Utilization Facilities." [17]</p>			

American National Standard N18.7-1976/ANS-3.2 Administrative Controls and Quality Assurance for the Operational Phase of Nuclear Power Plants / Regulatory Guide 1.33, Rev. 2 Regulatory Positions	Applicable Section of NQA-1- 1994 or NEI 06-14 Quality Assurance Program Description (QAPD)	Applicable Section(s) of Fermi 3 QAPD (for those requirements not addressed entirely by NQA-1-1994) [N/A is entered in column if requirements is addressed entirely by NQA-1-1994]	Comments (NEI 06-14A, Revision 7, Appendix 1, Comments adjusted for Fermi 3)
5.3.10 Test and Inspection Procedures.			
Test and inspection procedures shall contain a description of objectives; acceptance criteria that will be used to evaluate the results; prerequisites for performing the tests or inspections including any special conditions to be used to simulate normal or abnormal operating conditions; limiting conditions; and the test or inspection procedure. These procedures shall also specify any special equipment or calibrations required to conduct the test or inspection.	NQA-1, Supplement 11S-1, Section 3, and Subpart 2.18, Section 2 QAPD, Part V, Section 3.2	Fermi 3 QAPD, Part V, Section 3.2	
Test and inspection results shall be documented and evaluated by responsible authority to assure that test and inspection requirements have been satisfied.	NQA-1 Basic Requirements 10 and 11, Supplements 10S-1 and 11S-1 QAPD, Section 5.4	Fermi 3 QAPD, Part II, Section 11	
Where tests and inspections are to be witnessed, the procedure shall identify hold points in the testing sequence to permit witnessing. The procedure shall require appropriate approval for the work to continue beyond the designated hold point. The test and inspection procedures shall require recording the date, identification of those performing the test or inspection, as found condition, corrective actions performed, if any, and as-left condition.	NQA-1, Supplement 10S-1, Sections 4 and 9, Supplement 11S-1, Sections 3, 4, and 5, and Subpart 2.18, Section 2 QAPD, Part V, Section 3.2	Fermi 3 QAPD, Part V, Section 3.2	

Proposed COLA Revision

Attached is a proposed markup of the QAPD to incorporate NEI 06-14A, Revision 7.

Markup of Detroit Edison COLA
(following 23 pages)

The following markup represents how Detroit Edison intends to reflect this RAI response in a future submittal of the Fermi 3 COLA. However, the same COLA content may be impacted by revisions to the ESBWR DCD, responses to other COLA RAIs, other COLA changes, plant design changes, editorial or typographical corrections, etc. As a result, the final COLA content that appears in a future submittal may be different than presented here.

Table 1.6-201 Referenced Topical Reports [EF3 SUP 1.6-1]

Report No.	Title	Section No.
NEI 06-13A	Nuclear Energy Institute, "Technical Report on Template for an Industry Training Program Description," NEI 06-13A, Revision 1, March 2008	Appendix 13 BB
NEI 06-14A	Nuclear Energy Institute, "Quality Assurance Program Description," NEI 06-14A, Revision 4, July 2007 ← Revision 7, August, 2010.	17.5
NEI 07-02A	Nuclear Energy Institute, "Generic FSAR Template Guidance for Maintenance Rule Program Description for Plants Licensed under 10 CFR Part 52," NEI 07-02A, March 2008	17.6
NEI 07-03	Nuclear Energy Institute, "Generic FSAR Template Guidance for Radiation Protection Program Description," NEI 07-03, Revision 3, October 2007	Appendix 12 BB
NEI 07-08	Nuclear Energy Institute, "Generic FSAR Template Guidance for Ensuring That Occupational Radiation Exposures Are As Low As Is Reasonably Achievable (ALARA)," NEI 07-08, Revision 0, September 2007	Appendix 12 AA
NEI 07-09A	Nuclear Energy Institute, "Generic FSAR Template Guidance for Offsite Dose Calculation Manual (ODCM) Program Description," NEI 07-09A, Revision 0, March 2009	11.5
NEI 07-10A	Nuclear Energy Institute, "Generic FSAR Template Guidance for Process Control Program (PCP)," NEI 07-10A, Revision 0, March 2009	11.4
NEI 06-12	Nuclear Energy Institute, "B.5.b. Phase 2 & 3 Submittal Guideline," NEI 06-12, Revision 3, September 2009	13.6
NEI 08-09	Nuclear Energy Institute, "Cyber Security Plan for Nuclear Power Reactors", NEI 08-09, Revision 3, September 2009	13.6
ST-56834/P	General Electric Company, "ESBWR Steam Turbine - Low Pressure Rotor Missile Generation Probability Analysis," ST-56834/P, Revision 1, June 17, 2009	10.2

procedures necessary to review and accept the B&V developed COLA products.

The third phase commences with submittal of the Fermi 3 COLA. At this point, the ND QAPD is superseded by the Fermi 3 QAPD submitted as part of the COLA (FSAR Chapter 17, Appendix 17AA). B&V remains the COLA contractor for Detroit Edison and continues to perform delegated quality functions. Detroit Edison retains responsibility via processes and programs necessary to implement the Fermi 3 QAPD, including procurement control and verification of the effectiveness of B&V's 10 CFR 50 Appendix B/NQA-1 QA program. All COLA activities through anticipated COL issuance will be completed in accordance with the Fermi 3 QAPD, this includes delegating responsibilities as described in Part II, Section 2 of the Fermi 3 QAPD.

EF3 COL 17.2-1-A
EF3 COL 17.2-2-A

QA applied to activities to adapt the design to specific plant implementation, construction, and operations is addressed in the Detroit Edison Fermi 3 QAPD (Appendix 17AA). The QAPD is based on NEI 06-014A (Reference 17.5-201).

The implementation milestones for the Operational Quality Assurance Program are provided in Section 13.4

17.5.1 References

17.5-201 Nuclear Energy Institute, "Quality Assurance Program Description." NEI 06-14A, Revision 7, August, 2010.

STD COL 17.4-1-H

17.6 Maintenance Rule Program

NEI 07-02, "Generic FSAR Template Guidance for Maintenance Rule Program Description for Plants Licensed Under 10 CFR Part 52," (Reference 17.6-7) is incorporated by reference with the following supplemental information:

STD SUP 17.6-1

The text of the template provided in NEI 07-02 is generically numbered as "17.X." When the template is incorporated by reference into this section, numbering is changed from "17.X" to "17.6."

STD SUP 17.6-3

17.6.1.1. **Maintenance Rule Scoping per 10 CFR 50.65(b)**

PART I INTRODUCTION

SECTION 1 GENERAL

NOTE: The following markups incorporate changes associated with NEI 06-14A Revision 7 which have not been provided in markups associated with previous RAI responses.

Detroit Edison Company Fermi 3 Quality Assurance Program Description (QAPD) is the top-level policy document that establishes the quality assurance policy and assigns major functional responsibilities for combined construction and operating license (COL) activities conducted by or for Fermi 3. The QAPD describes the methods and establishes Quality Assurance (QA) and administrative control requirements that meet 10 CFR 50, Appendix B and 10 CFR 52. The QAPD is based on the requirements of ASME NQA-1-1994, "Quality Assurance Requirements for Nuclear Facility Applications," Parts I and II as specified in this document. I, II, and III

organizations performing those activities so that the activity is controlled and

The QAPD is defined by the NRC approved regulatory document that describes the Quality Assurance Program (QAP) elements, along with the associated implementing documents. Procedures and instructions that control Fermi 3 activities will be developed prior to commencement of those activities. Detroit Edison policies establish high level responsibilities and authority for carrying out important administrative functions which are outside the scope of the QAPD. Procedures establish practices for certain activities which are common to all Fermi 3 activities carried out in a manner that meets QAPD requirements. Site or organization specific procedures establish detailed implementation requirements and methods, and may be used to implement Policies or be unique to particular functions or work activities.

1.1 Scope / Applicability

This QAPD applies to COL, construction/pre-operation and/or operation activities affecting the quality and performance of safety-related structures, systems, and components, including, but not limited to:

- | | |
|--------------|---|
| Designing | Cleaning |
| Siting | Testing |
| Training | Inspecting |
| Constructing | Preoperational activities (including ITAAC) |
| Procuring | Startup |
| Receiving | Operating |
| Storing | Maintaining |
| Handling | Repairing |
| Shipping | Refueling |
| Erecting | Modifying |
| Installing | Decommissioning |
| Fabricating | |

Safety-related systems, structures, and components, under the control of the QAPD, are identified by design documents. The technical aspects of these items are considered when

determining program applicability, including, as appropriate, the item's design safety function. The QAPD may be applied to certain activities where regulations other than 10 CFR 50 and 10 CFR 52 establish QA requirements for activities within their scope.

The policy of Fermi 3 is to assure a high degree of availability and reliability of its nuclear plant while ensuring the health and safety of its workers and the public. To this end, selected elements of the QAPD are also applied to certain equipment and activities that are not safety-related, but support safe, economic, and reliable plant operations, or where other NRC guidance establishes quality assurance requirements. Implementing documents establish program element applicability.

(insert new paragraph)

The definitions provided in ASME NQA-1-1994, Part 1, Section 1.4, apply to select terms as used in this document.

Site-specific safety-related design basis activities are defined as those activities, including sampling, testing, data collection, and supporting engineering calculations and reports, that will be used to determine the bounding physical parameters of the site. Appropriate quality assurance measures are applied.

are made at the level appropriate for its nature and effect, and with any necessary technical advice or review.

2.3 ~~COL Identification of Site Specific Safety-Related Design Basis Activities~~

~~The development of the Fermi 3 COL application involved site testing, data collection and calculations that may create or bound safety-related design basis data. Site testing and data collection of information pertaining to the physical characteristics of the site that have the potential to affect safety-related design will be considered safety-related. In addition, calculations and other engineering data that bounds or characterizes the site are classified as safety-related. The Fermi 3 COL application was developed by procedurally and/or contractually imposing appropriate quality requirements on those sections where the content is supported by safety-related design basis activities.~~

2.4 Periodic Review of the Quality Assurance Program

Management of those organizations implementing the QA program or portions thereof, assess the adequacy of that part of the program for which they are responsible and assure its effective implementation at least once each year or at least once during the life of the activity, whichever is shorter. However, the period for assessing QA programs during the operations phase may be extended to once every two years.

2.5 Issuance and Revision to Quality Assurance Program

Administrative control of the QAPD will be in accordance with 10 CFR 50.55(f) and 10 CFR 50.54(a), as appropriate. Changes to the QAPD are evaluated by the QA organization to ensure that such changes do not degrade previously approved quality assurance controls specified in the QAPD. This document shall be revised as appropriate to incorporate additional QA commitments that may be established during the COL application development process. New revisions to the document will be reviewed, at a minimum, by the Director, Quality Management and approved by the executive in charge of the MEP organization.

Regulations require that the Final Safety Analysis Report (FSAR) include, among other things, the managerial and administrative controls to be used to assure safe operation, including a discussion of how the applicable requirements of Appendix B will be satisfied. In order to comply with this requirement, the FSAR references this QAPD and, as a result, the requirements of 10 CFR 50.54(a) are satisfied by and apply to the QAPD.

2.6 Personnel Qualifications

Personnel assigned to implement elements of the QAPD shall be capable of performing their assigned tasks. To this end Fermi 3 establishes and maintains formal indoctrination and training programs for personnel performing, verifying, or managing activities within the scope of the QAPD to assure that suitable proficiency is achieved and maintained. Plant and support staff minimum qualification requirements are as delineated in the Technical Specifications. Other

qualification requirements may be established but will not reduce those required by Technical Specifications. Sufficient managerial depth is provided to cover absences of incumbents. When required by code, regulation, or standard, specific qualification and selection of personnel is conducted in accordance with those requirements as established in the applicable Fermi 3 procedures. Indoctrination includes the administrative and technical objectives, requirements of the applicable codes and standards, and the QAPD elements to be employed. Training for positions identified in 10 CFR 50.120 is accomplished according to programs accredited by the National Nuclear Accrediting Board of the National Academy of Nuclear Training that implement a systematic approach to training. Records of personnel training and qualification are maintained.

The minimum qualifications of the Director, Quality Management, and functional QA manager are that each holds an engineering or related science degree and a minimum of four years of related experience including two years of nuclear power plant experience, one year of supervisory or management experience, and one year of the experience is in performing quality verification activities. Special requirements shall include management and supervisory skills and experience or training in leadership, interpersonal communication, management responsibilities, motivation of personnel, problem analysis and decision making, and administrative policies and procedures. Individuals who do not possess these formal education and minimum experience requirements should not be eliminated automatically when other factors provide sufficient demonstration of their abilities. These other factors are evaluated on a case-by-case basis and approved and documented by senior management.

The minimum qualifications of the individuals responsible for planning, implementing and maintaining the programs for the QAPD are that each has a high school diploma or equivalent and has a minimum of one year of related experience. Individuals who do not possess these formal education and minimum experience requirements should not be eliminated automatically when other factors provide sufficient demonstration of their abilities. These other factors are evaluated on a case-by-case basis and approved and documented by senior management.

~~2.7 Independent Review~~

~~Activities occurring during the operational phase shall be independently reviewed on a periodic basis. [START COM 17AA-001] The independent review program shall be functional prior to initial core loading. [END COM 17AA-001] The independent review function performs the following:~~

- ~~a. Reviews proposed changes to the facility as described in the final safety analysis report (FSAR). The Independent Review Body (IRB) also verifies that changes do not adversely affect safety and if a technical specification change or NRC review is required.~~

- b. Reviews proposed tests and experiments not described in the FSAR. Changes to proposed tests and experiments not described in the FSAR that do require a technical specification change must be reviewed by the IRB prior to NRC submittal and implementation.
- c. Reviews proposed technical specification changes and license amendments relating to nuclear safety prior to NRC submittal and implementation, except in those cases where the change is identical to a previously approved change.
- d. Reviews violations, deviations, and reportable events that are required to be reported to the NRC in writing within 24 hours. This review includes the results of investigations and recommendations resulting from such investigations to prevent or reduce the probability of recurrence of the event.
- e. Reviews any matter related to nuclear safety that is requested by the site executive, plant manager, or any IRB member,
- f. Reviews corrective actions for significant conditions adverse to quality.
- g. Reviews the adequacy of the audit program every 24 months.

Independent Review Body

A group may function as an IRB. In discharging its review responsibilities, the IRB keeps safety considerations paramount when opposed to cost or schedule considerations. One or more organizational units may collectively perform this function.

1. IRB reviews are supplemented as follows:
 - a. A qualified person, independent of the preparer, reviews proposed changes in the procedures as described in the FSAR prior to implementation of the change to determine if a technical specification change or NRC approval is required.
 - b. Audits of selected changes in the procedures described in the FSAR are performed to verify that procedure reviews and revision controls are effectively implemented.
 - c. Competent individual(s) or group(s) other than those who performed the original design but who may be from the same organization verify that changes to the facility do not result in a loss of adequate design or safety margins.
2. The results of IRB reviews of matters involving the safe operation of the facility are periodically independently reviewed. This review is intended to support management in identifying and resolving issues potentially affecting safe plant operation. This review supplements the existing corrective action programs and audits.
 - a. The review is performed by a team consisting of personnel with experience and competence in the activities being reviewed, but independent from cost and schedule considerations and from the organizations responsible for those activities.

The IRB supervisor or chairman has a minimum six (6) years combined managerial and technical support experience. The members of the IRB should have a minimum of five years of experience in their own area of responsibility as applicable to the activities being reviewed (i.e., a minimum of five years of experience in one of the twelve areas listed below:

- (1) Nuclear power plant operations
- (2) Nuclear engineering
- (3) Chemistry and radiochemistry
- (4) Metallurgy
- (5) Nondestructive testing
- (6) Instrumentation and control
- (7) Radiological safety
- (8) Mechanical engineering
- (9) Electrical engineering
- (10) Administrative control and quality assurance practices
- (11) Training
- (12) Emergency plans and related procedures and equipment).

- b. The review is supplemented by outside consultants or organizations as necessary to ensure the team has the requisite expertise and competence.
- c. Results of the review are documented and reported to responsible management.
- d. Management periodically consider issues that they determine warrant special attention, such as deficient plant programs, declining performance trends, employee concerns, or other issues related to safe plant operations and determine what issues warrant the review.
- e. Management determines the scheduling and scope of review and the composition of the team performing the review.

~~2.8~~ **NQA-1-1994 Commitment / Exceptions**

2.7

In establishing qualification and training programs, Fermi 3 commits to compliance with NQA-1-1994, Basic Requirement 2 and Supplements 2S-1, 2S-2, 2S-3 and 2S-4, with the following clarifications and exceptions:

- NQA-1-1994, Supplement 2S-1

During the operational phase, where temporary procedures are used, they shall include a designation of the period of time during which it is acceptable to use them.

6.1 Review and Approval of Documents

Documents shall be reviewed for adequacy by qualified persons other than the preparer. During the construction phase, procedures for design, construction, and installation shall also be reviewed by QA organization to ensure quality assurance measures have been appropriately applied. The documented review signifies concurrence.

During the operations phase, documents affecting the configuration or operation of the station as described in the FSAR shall be screened to identify those that require review by the IRB prior to implementation as described in ~~SECTION 2 of this QAPD~~. Part V, Section 2.2.

To ensure effective and accurate procedures during the operational phase, applicable procedures shall be reviewed, and updated as necessary, based on the following conditions:

- (a) following any modification to a system;
- (b) following an unusual incident, such as an accident, significant operator error, or equipment malfunction;
- (c) when procedure discrepancies are found;
- (d) prior to use if not used in the previous two years; or
- (e) results of QA audits conducted in accordance with Part II, Sections 18.1

Prior to issuance or use, documents including revisions thereto, shall be approved by the designated authority. A listing of all controlled documents identifying the current approved revision, or date, is maintained so personnel can readily determine the appropriate document for use.

6.2 Changes to Documents

Changes to documents, other than those defined in implementing procedures as minor changes, 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. Where temporary procedure changes are necessary during the operations phase, changes that clearly do not change the intent of the approved procedure may be implemented provided they are approved by two members of the staff knowledgeable in the areas affected by the procedures. Minor changes to documents, such as inconsequential editorial corrections, do not require that the revised documents receive the same review and approval as the original documents. To avoid a possible omission of a required review, the type of minor changes that do

SECTION 7 CONTROL OF PURCHASED MATERIAL, EQUIPMENT, AND SERVICES

Fermi 3 has established the necessary measures and governing procedures to control the procurement of items and services to assure 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.

7.1 Acceptance of Item or Service

Fermi 3 establishes and implements measures to assess the quality of purchased items and services, whether purchased directly or through contractors, at intervals and to a depth consistent with the item's or service's importance to safety, complexity, quantity and the frequency of procurement. Verification actions include testing, as appropriate, during design, fabrication and ~~construction~~ activities. Verifications occur at the appropriate phases of the procurement process, including, as necessary, verification of activities of suppliers below the first tier.

construction
and operation

Measures to assure the quality of purchased items and services include the following, as applicable:

- Items are inspected, identified, and stored to protect against damage, deterioration, or misuse.
- Prospective suppliers of safety-related items and services are evaluated to assure that only qualified suppliers are used. Qualified suppliers are audited on a triennial basis. In addition, if a subsequent contract or a contract modification significantly enlarges the scope of or changes the methods or controls for activities performed by the same supplier, an audit of the modified requirements is conducted, thus starting a new triennial period. Fermi 3 may utilize audits conducted by outside organizations for supplier qualification provided that the scope and adequacy of the audits meet Fermi 3 requirements. Documented annual evaluations are performed for qualified suppliers to assure they continue to provide acceptable products and services. Industry programs, such as those applied by ASME, Nuclear Procurement Issues Committee (NUPIC), or other established utility groups, are used as input or the basis for supplier qualification whenever appropriate. The results of the reviews are promptly considered for effect on a supplier's continued qualification and adjustments made as necessary (including corrective actions, adjustments of supplier audit plans, and input to third party auditing entities, as warranted). In addition, results are reviewed periodically to determine if, as a whole, they constitute a significant condition adverse to quality requiring additional action.
- Provisions are made for accepting purchased items and services, such as source verification, receipt inspection, pre- and post-installation tests, certificates of conformance, and document reviews (including Certified Material Test Report/Certificate).

Acceptance actions/documents should be established by the Purchaser with appropriate input from the Supplier and be completed to ensure that procurement, inspection, and test requirements, as applicable, have been satisfied before relying on the item to perform its intended safety function.

- Controls are imposed for the selection, determination of suitability for intended use (critical characteristics), evaluation, receipt and acceptance of commercial-grade services or items to assure they will perform satisfactorily in service in safety-related applications.
- If there is insufficient evidence of implementation of a QA program, the initial evaluation is of the existence of a QA program addressing the scope of services to be provided. The initial audit is performed after the supplier has completed sufficient work to demonstrate that its organization is implementing a QA program.

7.2 NQA-1-1994 Commitment

In establishing procurement verification controls, Fermi 3 commits to compliance with NQA-1-1994, Basic Requirement 7 and Supplement 7S-1, with the following clarifications and exceptions:

- NQA-1-1994, Supplement 7S-1
 - Fermi 3 considers that other 10 CFR 50 licensees, Authorized Nuclear Inspection Agencies, National Institute of Standards and Technology, or other State and Federal agencies which may provide items or services to Fermi 3 plants are not required to be evaluated or audited.
 - When purchasing commercial grade calibration services from a calibration laboratory, procurement source evaluation and selection measures need not be performed provided each of the following conditions are met:
 - (1) The purchase documents impose any additional technical and administrative requirements, as necessary, to comply with the Fermi 3 QA program and technical provisions. At a minimum, the purchase document shall require that the calibration certificate/report include identification of the laboratory equipment/standard used.
 - (2) The purchase documents require reporting as-found calibration data when calibrated items are found to be out-of-tolerance.
 - (3) A documented review of the supplier's accreditation shall be performed and shall include a verification of each of the following:
 - ~~The calibration laboratory holds a domestic accreditation by the National Voluntary Laboratory Accreditation Program (NVLAP) or by the American Association for Laboratory Accreditation (A2LA) as recognized by NVLAP through the International Laboratory Accreditation Cooperation (ILAC) Mutual Recognition Arrangement (MRA).~~

Insert 1

Revision 2

Insert 1

The calibration laboratory holds a domestic (United States) accreditation by any one of the following accrediting bodies, which are recognized by the International Laboratory Accreditation Cooperation (ILAC) Mutual Recognition Arrangement (MRA):

- National Voluntary Laboratory Accreditation Program (NVLAP), administered by the National Institute of Standards & Technology;
- American Association for Laboratory Accreditation (A2LA);
- ACLASS Accreditation Services (ACLASS);
- International Accreditation Service (IAS);
- Laboratory Accreditation Bureau (L-A-B);
- Other NRC-approved laboratory accrediting body.

encompasses ANS/ISO/IEC 17025, "General Requirements for the Competence of Testing and Calibration Laboratories."

- The accreditation is based on ANS/ISO/IEC 17025.
 - The published scope of accreditation for the calibration laboratory covers the necessary measurement parameters, ranges, and uncertainties.
- For Section 8.1, Fermi 3 considers documents that may be stored in approved electronic media under Fermi 3 or vendor control and not physically located on the plant site but which are accessible from the respective nuclear facility site as meeting the NQA-1 requirement for documents to be available at the site. Following completion of the construction period, sufficient as-built documentation will be turned over to Fermi 3 to support operations. The Fermi 3 records management system will provide for timely retrieval of necessary records.
 - In lieu of the requirements of Section 10, Commercial Grade Items, controls for commercial grade items and services are established in Fermi 3 documents using 10 CFR 21 and the guidance of EPRI NP-5652 as discussed in Generic Letter 89-02 and Generic Letter 91-05.
 - For commercial grade items, special quality verification requirements are established and described in Fermi 3 documents to provide the necessary assurance an item will perform satisfactorily in service. The Fermi 3 documents address determining the critical characteristics that ensure an item is suitable for its intended use, technical evaluation of the item, receipt requirements, and quality evaluation of the item.
 - Fermi 3 will also use other appropriate approved regulatory means and controls to support Fermi 3 commercial grade dedication activities. ~~One example of this is Electric Power Research Institute (EPRI) Topical Report TR-106439, "Guideline on Evaluation and Acceptance of Commercial Grade Digital Equipment for Nuclear Safety Applications," dated July 17, 1997.~~ Fermi 3 will assume 10 CFR 21 reporting responsibility for all items that Fermi 3 dedicates as safety-related.

SECTION 10 INSPECTION

Fermi 3 has established the necessary measures and governing procedures to implement inspections that assure items, services and activities affecting safety meet established requirements and conform to applicable documented specifications, instructions, procedures, and design documents. Inspection may also be applied to items, services and activities affecting plant reliability and integrity. Types of inspections may include those verifications related to procurement, such as source, in-process, final, and receipt inspection, as well as construction, installation, and operations activities. Inspections are carried out by properly qualified persons independent of those who performed or directly supervised the work. Inspection results shall be documented.

maintenance, modification, inservice

Inspection Program

The inspection program establishes inspections (including surveillance of processes), as necessary to verify quality: (1) at the source of supplied items or services, (2) in-process during fabrication at a supplier's facility or at a company facility, (3) for final acceptance of fabricated and/or installed items during construction, (4) upon receipt of items for a facility, as well as (5) during maintenance, modification, inservice, and operating activities.

The inspection program establishes requirements for planning inspections, such as the group or discipline responsible for performing the inspection, where inspection hold points are to be applied, determining applicable acceptance criteria, the frequency of inspection to be applied, and identification of special tools needed to perform the inspection. Inspection planning is performed by personnel qualified in the discipline related to the inspection and include qualified inspectors or engineers. Inspection plans are based on, as a minimum, the importance of the item to the safety of the facility, the complexity of the item, technical requirements to be met, and design specifications. Where significant changes in inspection activities for the facilities are to occur, management responsible for the inspection programs evaluate the resource and planning requirements to ensure effective implementation of the inspection program.

Inspection program documents establish requirements for performing the planned inspections, and documenting required inspection information such as: reject, acceptance, and reinspection results; and the person(s) performing the inspection.

Inspection results are documented by the inspector, reviewed by authorized personnel qualified to evaluate the technical adequacy of the inspection results, and controlled by instructions, procedures, and drawings.

Inspector Qualification

Fermi 3 has established qualification programs for personnel performing quality inspections. The qualification program requirements are described in SECTION 2 of this QAPD. These

SECTION 12 CONTROL OF MEASURING AND TEST EQUIPMENT

Fermi 3 has established the necessary measures and governing procedures to control the calibration, maintenance, and use of measuring and test equipment (M&TE) that provides information important to safe plant operation. The provisions of such procedures cover equipment such as indicating and actuating instruments and gages, tools, reference and transfer standards, and nondestructive examination equipment. The suppliers of commercial-grade calibration services shall be controlled as described in SECTION 7 of this QAPD.

(insert as
subsection
heading)
12.1

Installed Instrument and Control Devices

For the operations phase of the facilities, Fermi 3 has established and implements procedures for the calibration and adjustment of instrument and control devices installed in the facility. The calibration and adjustment of these devices is accomplished through the facility maintenance programs to ensure the facility is operated within design and technical requirements. Appropriate documentation will be maintained for these devices to indicate the control status, when the next calibration is due, and identify any limitations on use of the device.

12.2

12.1 NQA-1-1994 Commitment / Exceptions

In establishing provisions for control of measuring and test equipment, Fermi 3 commits to compliance with NQA-1-1994, Basic Requirement 12 and Supplement 12S-1 with the following clarification and exception:

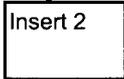
- The out of calibration conditions described in paragraph 3.2 of Supplement 12S-1 refers to when the M&TE is found out of the required accuracy limits (i.e. out of tolerance) during calibration.
- Measuring and test equipment are not required to be marked with the calibration status where it is impossible or impractical due to equipment size or configuration (such as the label will interfere with operation of the device) provided the required information is maintained in suitable documentation traceable to the device. This exception also applies to the calibration labeling requirement stated in NQA-1-1994, Subpart 2.4, Section 7.2.1 (ANSI/IEEE Std. 336-1985).

13.2 NQA-1-1994 Commitment / Exceptions

In establishing provisions for handling, storage and shipping, Fermi 3 commits to compliance with NQA-1-1994, Basic Requirement 13 and Supplement 13S-1. Fermi 3 also commits, during the construction and pre-operational phase of the plant, to compliance with the requirements of NQA-1-1994, Subpart 2.1 (including the guidance of Regulatory Guide 1.37, Rev. 1, March 2007, "Quality Assurance Requirements for Cleaning of Fluid Systems and Associated Components of Water-Cooled Nuclear Power Plants"), and Subpart 2.2, with the clarifications and exceptions shown below:

- NQA -1-1994, Subpart 2.2
 - Subpart 2.2, section 6.6, "Storage Records:" This section requires written records be prepared containing information on personnel access. As an alternative to this requirement, Fermi 3 documents establish controls for storage areas that describe those authorized to access areas and the requirements for recording access of personnel. However, these records of access are not considered quality records and will be retained in accordance with the administrative controls of the applicable plant.
 - Subpart 2.2, section 7.1 refers to Subpart 2.15 for requirements related to handling of items. The scope of Subpart 2.15 includes hoisting, rigging and transporting of items for nuclear power plants during construction.

Insert 2



13.2 NQA-1-1994 Commitment / Exceptions

In establishing provisions for handling, storage and shipping, Fermi 3 commits to compliance with NQA-1-1994, Basic Requirement 13 and Supplement 13S-1. Fermi 3 also commits, during the construction and operational phase of the plant, to compliance with the requirements of NQA-1-1994, Subpart 2.1, Subpart 2.2, Subpart 2.3, and Subpart 3.2, Appendix 2.1, with the following clarifications and exceptions:

NQA-1-1994, Subpart 2.1

- Subpart 2.1, Section 3.1 and 3.2 establish criteria for classifying items into cleanliness classes and requirements for each class. Instead of using the cleanliness level system of Subpart 2.1, Fermi 3 may establish cleanliness requirements on a case-by-case basis, consistent with the other provisions of Subpart 2.1. Fermi 3 establishes appropriate cleanliness controls for work on safety-related equipment to minimize introduction of foreign material and maintain system/component cleanliness throughout maintenance or modification activities, including documented verification of absence of foreign material prior to system closure.

NQA-1-1994, Subpart 2.2

- Subpart 2.2, Section 2.2 establishes criteria for classifying items into protection levels. Instead of classifying items into protection levels during the operational phase, Fermi 3 may establish controls for the packaging, shipping, handling, and storage of such items on a case-by-case basis with due regard for the item's complexity, use, and sensitivity to damage. Prior to installation or use, the items are inspected and serviced as necessary to assure that no damage or deterioration exists which could affect their function.
- Subpart 2.2, Section 6.6, "Storage Records:" This section requires written records be prepared containing information on personnel access. As an alternative to this requirement, Fermi 3 documents establish controls for storage areas that describe those authorized to access areas and the requirements for recording access of personnel. However, these records of access are not considered quality records and will be retained in accordance with the administrative controls of the plant.
- Subpart 2.2, Section 7.1 refers to Subpart 2.15 for requirements related to handling of items. The scope of Subpart 2.15 includes hoisting, rigging and transporting of items for the nuclear power plant during construction.

NQA-1-1994, Subpart 2.3

- Subpart 2.3, Section 2.3 requires the establishment of five zone designations for housekeeping cleanliness controls. Instead of the five-level zone designation, Fermi 3 bases its control over housekeeping activities on a consideration of what is necessary and appropriate for the activity involved. The controls are implemented through procedures or instructions which, in the case of maintenance or modification work, are developed on a case-by-case basis. Factors considered in developing the procedures and instructions include cleanliness control, personnel safety, fire prevention and protection, radiation control and security. The procedures and instructions make use of standard janitorial and work practices to the extent possible.

NQA-1-1994, Subpart 3.2

- Subpart 3.2, Appendix 2.1: Only Section 3 precautions are being committed to in accordance with RG 1.37. In addition, a suitable chloride stress-cracking inhibitor should be added to the fresh water used to flush systems containing austenitic stainless steels.

Instructions require that the individual discovering a nonconformance identify, describe, and document the nonconformance in accordance with the requirements of Part II, Section 16.

SECTION 15 NONCONFORMING MATERIALS, PARTS, OR COMPONENTS

Fermi 3 has established the necessary measures and governing procedures to control items, including services, which do not conform to specified requirements to prevent inadvertent installation or use. Controls provide for identification, documentation, evaluation, segregation when practical, and disposition of nonconforming items, and for notification to affected organizations. Controls are provided to address conditional release of nonconforming items for use on an at risk basis prior to resolution and disposition of the nonconformance, including maintaining identification of the item and documenting the basis for such release. Conditional release of nonconforming items for installation requires the approval of the designated management. Nonconformances are corrected or resolved prior to depending on the item to perform its intended safety function. Nonconformances are evaluated for impact on operability of quality structures, systems, and components to assure that the final condition does not adversely affect safety, operation, or maintenance of the item or service. Nonconformances to design requirements dispositioned repair or use-as-is, shall be subject to design control measures commensurate with those applied to the original design. Nonconformance dispositions are reviewed for adequacy, analysis of quality trends, and reports provided to the designated management. Significant trends are reported to management in accordance with Fermi 3 procedures, regulatory requirements, and industry standards.

15.1 Reporting Program

~~Fermi 3 will establish the necessary measures and governing procedures that implement a reporting program which conforms to the requirements of 10 CFR 52, 10 CFR 50.55(e) and/or 10 CFR 21 during COL and construction and 10 CFR 21 during operations.~~

15.2 NQA-1-1994 Commitment

In establishing measures for nonconforming materials, parts, or components, Fermi 3 commits to compliance with NQA-1-1994, Basic Requirement 15, and Supplement 15S-1.

Fermi 3 has appropriate interfaces between the QAP for identification and control of nonconforming materials, parts, or components and the non-QA Reporting Program to satisfy the requirements of 10 CFR 52, 10 CFR 50.55 and/or 10 CFR 21 during COL design and construction and 10 CFR 21 during operations.

SECTION 16 CORRECTIVE ACTION

Fermi 3 has established the necessary measures and governing procedures to promptly identify, control, document, classify and correct conditions adverse to quality. Fermi 3 procedures assure that corrective actions are documented and initiated following the determination of conditions adverse to quality in accordance with regulatory requirements and applicable quality standards. Fermi 3 procedures require personnel to identify known conditions adverse to quality. When complex issues arise where it cannot be readily determined if a condition adverse to quality exists, Fermi 3 documents establish the requirements for documentation and timely evaluation of the issue. Reports of conditions adverse to quality are analyzed to identify trends. Significant conditions adverse to quality and significant adverse trends are documented and reported to responsible management. In the case of a significant condition adverse to quality, the cause is determined and actions to preclude recurrence are taken.

In the case of suppliers working on safety-related activities, or other similar situations, Fermi 3 may delegate specific responsibilities of the Corrective Action program but Fermi 3 maintains responsibility for the program's effectiveness.

16.1 Reporting Program

~~Fermi 3 has the necessary measures and governing procedures that implement a reporting program that conforms to the requirements of 10 CFR 52, 10 CFR 50.55 and/or 10 CFR Part 21 during COL design and construction, and 10 CFR 21 during operations.~~

16.2 NQA-1-1994 Commitment

In establishing provisions for corrective action, Fermi 3 commits to compliance with NQA-1-1994, Basic Requirement 16.

Fermi 3 has appropriate interfaces between the QAP for corrective actions and the non-QA Reporting Program to satisfy the requirements of 10 CFR 52, 10 CFR 50.55 and/or 10 CFR Part 21 during COL design and construction, and 10 CFR 21 during operations.

through inspections, review, re-audits, or other appropriate means is conducted to verify implementation of assigned corrective action.

Audits of suppliers of safety-related components and/or services are conducted as described in Section 7.1.

Internal Audits

18.2

~~a.~~ Internal audits of organization and facility activities, conducted prior to placing the facility in operation, should be performed in such a manner as to assure that an audit of all applicable QA program elements is completed for each functional area at least once each year or at least once during the life of the activity, whichever is shorter. Internal audits of activities, conducted after placing the facility in operation, should be performed in such a manner as to assure that an audit of all applicable QA program elements is completed for each functional area within a period of two years.

~~b.~~ Internal audit frequencies of well established activities, conducted after placing the facility in operation, may be extended one year at a time beyond the above two-year 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. The evaluation should include a detailed performance analysis of the functional area based upon applicable internal and external source data and due consideration of the impact of any function area changes in responsibility, resources or management. However, the internal audit frequency interval should not exceed a maximum of four years. If an adverse trend is identified in the applicable functional area, the extension of the internal audit frequency interval should be rescinded and an audit scheduled as soon as practicable.

During the operations phase audits are performed at a frequency commensurate with the safety significance of the activities and in such a manner to assure audits of all applicable QA program elements are completed within a period of two years. These audits will include, as a minimum, activities in the following areas:

- (1) The conformance of facility operation to provisions contained within the Technical Specifications and applicable license conditions including administrative controls
- (2) The performance, training, and qualifications of the facility staff
- (3) The performance of activities required by the QAPD to meet the criteria of 10 CFR 50, Appendix B
- (4) The Fire Protection Program and implementing procedures. A fire protection equipment and program implementation inspection and audit utilizing either a qualified offsite licensed fire protection engineer or an outside qualified fire protection consultant.
- (5) Other activities and documents considered appropriate by the CNO

Audits may also be used to meet the periodic review requirements of the code for the Security, Emergency Preparedness, and Radiological Protection programs within the provisions of the applicable code.

Internal audits include verification of compliance and effectiveness of the administrative controls established for implementing the requirements of this QAPD; regulations and license provisions; provisions for training, retraining, qualification, and performance of personnel performing activities covered by this QAPD; corrective actions taken following abnormal occurrences; and, observation of the performance of construction, fabrication, operating, refueling, maintenance and modification activities including associated record keeping.

~~e. Audits of suppliers of safety related components and/or services are conducted as described in Section 7.1.~~

18.2 NQA-1-1994 Commitment

18.3

In establishing the independent audit program, Fermi 3 commits to compliance with NQA-1-1994, Basic Requirement 18 and Supplement 18S-1.

employed shall provide an appropriate degree of guidance to the personnel performing the activity to achieve acceptable functional performance of the SSC.

1.6 Document Control

Fermi 3 shall establish controls for the issuance and change of documents that specify quality requirements or prescribe activities affecting quality to ensure that correct documents are used. These controls include review and approval of documents, identification of the appropriate revision for use, and measures to preclude the use of superseded or obsolete documents.

1.7 Control of Purchased Items and Services

Fermi 3 shall establish measures, such as inspection of items or documents upon receipt or acceptance testing, to ensure that all purchased items and services conform to appropriate procurement documents.

1.8 Identification and Control of Purchased Items

Fermi 3 shall establish measures where necessary, to identify purchased items and preserve their functional performance capability. Storage controls take into account appropriate environmental, maintenance, or shelf life restrictions for the items.

1.9 Control of Special Processes

Fermi 3 shall establish process and procedure controls for special processes, including welding, heat treating, and nondestructive testing. These controls are based on applicable codes, standards, specifications, criteria, or other special requirements for the special process.

1.10 Inspection

Fermi 3 shall establish documented instructions to ensure necessary inspections are performed to verify conformance of an item or activity to specified requirements or to verify that activities are satisfactorily accomplished. These inspections may be performed by ~~personnel in the line organization through the Fermi 3 independent verification (IV)/ simultaneous verification (SV), or similar process that utilizes knowledgeable personnel to perform the verification function.~~

knowledgeable personnel in the line organization.
Knowledgeable personnel are from the same discipline and have experience related to the work being inspected.

1.11 Test Control

Fermi 3 shall establish measures to identify required testing that demonstrates that equipment conforms to design requirements. These tests are performed in accordance with test instructions or procedures. The test results are recorded, and authorized individuals evaluate the results to ensure that test requirements are met.

1.12 Control of Measuring and Test Equipment (M&TE)

Fermi 3 shall establish measures to control M&TE use, and calibration and adjustment at specific intervals or prior to use.

SECTION 2 NONSAFETY-RELATED SSCS CREDITED FOR REGULATORY EVENTS

The following criteria applies to fire protection (10 CFR 50.48), anticipated transients without scram (ATWS) (10 CFR 50.62), and the station blackout (SBO) (10 CFR 50.63) SSCs that are not safety related.

~~Fermi 3 shall implement quality requirements to the fire protection system in accordance with Regulatory Position 1.7, "Quality Assurance," in Regulatory Guide 1.189, "Fire Protection for Operating Nuclear Power Plants."~~

~~Fermi 3 shall implement the quality requirements to ATWS equipment in accordance with Generic Letter 85-06, "Quality Assurance Guidance for ATWS Equipment That Is Not Safety Related."~~

~~Fermi 3 shall implement quality requirements to SBO equipment in accordance with Regulatory Position 3.5, "Quality Assurance and Specific Guidance for SBO Equipment That Is Not Safety Related," and Appendix A, "Quality Assurance Guidance for Non-Safety Systems and Equipment," in Regulatory Guide 1.155, "Station Blackout."~~

Fermi 3 shall implement quality requirements to the fire protection system in accordance with Regulatory Position 1.7, "Quality Assurance," in Regulatory Guide 1.189, "Fire Protection for Operating Nuclear Power Plants" As identified in FSAR Chapter 1.

Fermi 3 shall implement the quality requirements to ATWS equipment in accordance with Part III Section 1.

Fermi 3 shall implement quality requirements to SBO equipment in accordance with Part III Section 1.

**Attachment 3
NRC3-10-0054**

**Response to RAI Letter No. 44
(eRAI Tracking No. 5178)**

RAI Question No. 17.5-26

NRC RAI 17.5-26

SRP Section 17.5 and the Nuclear Energy Institute (NEI) QAPD template (NEI 06-14A, Revision 7, "Quality Assurance Program Description") are based upon the requirements of ASME standard NQA-1 "Quality Assurance Requirements for Nuclear Facility Applications" (1994 Edition).

The NRC endorsed the NEI QAPD template as a method for providing a QAPD that meets the requirements of 10 CFR Part 50, Appendix B. The NRC's Final Safety Evaluation Report (FSER) dated July 13, 2010 (ML10 1800497) endorsed the generic QAPD template in NEI 06-14, Revision 9. NEI 06-14A, Revision 7, dated August 2010 (ML102370305) published the accepted version of NEI 06-14, Revision 9, and incorporated the NRC's FSER for reference as Appendix 2.

NEI 06-14A, Revision 7, Part II, section 13.2, "NQA-1-1994 Commitment / Exceptions," requires commitments to the requirements of NQA-1-1994, Subpart 2.1, Subpart 2.2, Subpart 2.3, and Subpart 3.2, Appendix 2.1, during the construction and operational phase of the plant, and then provides clarifications and exceptions.

The Fermi 3 Combined License Application, Part 2: Final Safety Analysis Report (FSAR), Chapter 17.5, Revision 2, states the QAPD applies to activities to adapt the design to specific plant implementation, construction, and operations is based on NEI 06-014A. Fermi 3 QAPD (FSAR Appendix 17AA) Part II, section 13.2, "NQA-1-1994 Commitment / Exceptions," Revision 2, commits to compliance with the requirements of NQA-1-1994, Subpart 2.1 (including the guidance of Regulatory Guide 1.37, Rev. 1, March 2007, "Quality Assurance Requirements for Cleaning of Fluid Systems and Associated Components of Water-Cooled Nuclear Power Plants"), and Subpart 2.2, during the construction and pre-operational phase of the plant, and then provides clarifications and exceptions.

Staff review of QAPD section 13.2 noted differing plant phases and NQA-1-1994 Subpart commitments when compared with NEI 06-14A, Revision 7.

Please update QAPD section 13.2 to match the requirements of NEI 06-14A, Revision 7, or provide justification for any exceptions to the guidance provided in NEI 06-14A, Revision 7.

Please ensure clarification of the following in your response:

- 1. What NQA-1-1994 Subparts apply,*
- 2. During what phases of the plant does the various Subparts apply, and*
- 3. What clarifications and exceptions apply to each Subpart.*

Additionally, proposed changes to the Fermi 3 FSAR Table 1.9-202, "Insert 1.37," section C.3, provided as part of Attachment 16 to NRC3-10-0036, "Detroit Edison Company Response to NRC Request for Additional Information Letter No.39," dated September 2, 2010, states QAPD

Part II, Section 13.2 addresses the commitment to NQA-1-1994, Part II, Subpart 2.2. Staff review did not note a reference to Subpart 2.2 in Regulatory Position C.3. Please clarify.

Note: This RAI is supplemental to RAI 17.5-23 included in NRC RAI Letter No. 39, dated July 20, 2010.

Response

As part of the response to RAI 17.5-25, a markup for the QAPD is provided to incorporate NEI 06-14A, Revision 7. As part of the markup to the QAPD, Section 13.2 is updated to match the requirements of NEI 06-14A, Revision 7. In addition, as part of the response to RAI 17.5-24, a markup has been provided for Part IV of the QAPD that includes additional description for how Fermi 3 complies with Regulatory Guide 1.37.

The markup for Section 13.2 and Part IV of the QAPD specifically provide the following clarifications:

- Section 13.2 and Part IV clarify which NQA-1-1994 subparts apply consistent with NEI-06-14, Revision 7.
- Section 13.2 clarifies what phases (construction, operation) of the plant that the various NQA-1-1994 subparts apply.
- Section 13.2 and Part IV describe clarifications and exceptions that apply to each subpart of NQA-1-1994.

Consistent with NEI 06-14A, Revision 7, the proposed markup for the Fermi 3 QAPD, Part IV does not include a reference to subpart 2.2 in Regulatory Position C.3. Section 13.2, second bullet, of the markup of the QAPD describes clarifications and exceptions relative to NQA-1-1994, subpart 2.2.

Proposed COLA Revision

The changes described above are included in the markups with the response to RAIs 17.5-24 and 17.5-25, Attachments 1 and 2 respectively.