17.0 QUALITY ASSURANCE

The Quality Assurance (QA) Program, including the following, is discussed in this chapter:

- QA for Design, fabrication, construction, testing, and operation
- The Reliability Assurance Program (RAP)
- The Maintenance Rule (MR) Program

17.0 Introduction

17.0.1 Introduction

The Quality Assurance (QA) Program for design, fabrication, construction, testing, and operation; the Design Reliability Program; and the Maintenance Rule (MR) Program are discussed in this chapter.

17.0.2 Summary of Application

Section 17.0, "Introduction" of the Fermi 3 COL FSAR, Revision 3, incorporates by reference Section 17.0 of the certified ESBWR DCD, Revision 9. In addition, the applicant provides the following:

Supplemental Information

- EF3 SUP 17.0-1

In Section 17.0 of the Fermi 3 COL FSAR, Revision 3, the applicant provides supplemental information that states:

> The QAPD applicable to the COL licensee is described in Section 17.5. The licensee's QAPD describes the basis of the program, its scope of activities, and the control of work performed by suppliers.

17.0.3 Regulatory Basis

The regulatory basis of the information incorporated by reference is in NUREG–1966, the Final Safety Evaluation Report (FSER) related to the certified ESBWR DCD.

In addition, the relevant requirements of the Commission regulations for QA during the design phase, and the associated acceptance criteria, are described in Sections 17.1 and 17.5 of NUREG–0800, "Standard Review Plan for the Review of Safety Analysis Reports for Nuclear Power Plants (LWR Edition)".

17.0.4 Technical Evaluation

As documented in NUREG–1966, NRC staff reviewed and approved Section 17.0 of the certified ESBWR DCD. The staff reviewed Section 17.0 of the Fermi 3 COL FSAR, Revision 3, and checked the referenced ESBWR DCD to ensure that the combination of the information in the ESBWR DCD and the information in the Fermi 3 COL FSAR, Revision 3, appropriately

represents the complete scope of information relating to this review topic.[1] The staff's review confirmed that the information contained in the application and the information incorporated by reference addresses the relevant information related to this section.

The staff reviewed the information in the Fermi 3 COL FSAR as follows:

Supplemental Information

- EF3 SUP 17.0-1

  The QAPD applicable to the COL licensee is described in Section 17.5. The licensee's QAPD describes the basis of the program, its scope of activities, and the control of work performed by suppliers.

The staff's safety evaluation of Fermi 3 COL FSAR Section 17.0 is provided in Section 17.5 of this SER.

The staff reviewed EF3 SUP 17.0-1 and determined that it adequately references Section 17.0 of the Fermi 3 COL FSAR, Revision 3, for a description of the basis of the QA Program, its scope of activities, and the control of work performed by suppliers.

17.0.5 Post Combined License Activities

There are no post COL activities related to this section.

17.0.6 Conclusion

The NRC staff's finding related to information incorporated by reference is in NUREG–1966. NRC staff reviewed the application and checked the referenced DCD. The staff's review confirmed that the applicant has addressed the required information, and no outstanding information is expected to be addressed in the Fermi 3 COL FSAR, Revision 3, related to this section. Pursuant to 10 CFR 52.63(a)(5) and 10 CFR Part 52 Appendix [X] Section VI.B.1, all nuclear safety issues relating to this section that were incorporated by reference have been resolved.

In addition, the staff compared the additional COL supplemental information in the application to the relevant NRC regulations, the guidance in Section 17.1 and 17.5 of NUREG–0800, and other NRC regulatory guides.

17.1 Quality Assurance During Design

17.1.1 *Introduction*

This section of the Fermi 3 COL FSAR, Revision 3, addresses the QA Program related to the design phase, including the preparation of the COL application and site-specific design activities.

[1] See "*Finality of Referenced NRC Approvals*," in SER Section 1.2.2, for a discussion on the staff's review related to verification of the scope of information to be included in a COL application that references a design certification.

17.1.2 *Summary of Application*

Section 17.1 of the Fermi 3 COL FSAR, Revision 3, incorporates by reference Section 17.1 of the certified ESBWR DCD, Revision 9. In addition, in Fermi 3 COL FSAR, Revision 3, Section 17.1, the applicant provides the following:

Supplemental Information

- EF3 SUP 17.1-1

  QA applied during COL application preparation and site specific design activities is addressed in Section 17.5.

17.1.3 *Regulatory Basis*

The regulatory basis of the information incorporated by reference is in NUREG–1966, the Final Safety Evaluation Report (FSER) related to the certified ESBWR DCD.

In addition, the relevant requirements of the Commission regulations for QA during the design phase, and the associated acceptance criteria, are described in Sections 17.1 and 17.5 of NUREG–0800, "Standard Review Plan for the Review of Safety Analysis Reports for Nuclear Power Plants (LWR Edition)."

17.1.4 *Technical Evaluation*

As documented in NUREG–1966, NRC staff reviewed and approved Section 17.1 of the certified ESBWR DCD. The staff reviewed Section 17.1 of the Fermi 3 COL FSAR, Revision 3, and checked the referenced ESBWR DCD to ensure that the combination of the information in the ESBWR DCD and the information in the COL FSAR appropriately represents the complete scope of information relating to this review topic.[1] The staff's review confirmed that the information contained in the application and the information incorporated by reference address the relevant information related to this section.

The staff reviewed the information in the Fermi 3 COL FSAR, Revision 3, as follows:

Supplemental Information

- EF3 SUP 17.1-1

In FSAR Revision 3, Section 17.1, the applicant provides supplemental information that states:

> QA applied during COL application preparation and site specific design activities is addressed in Section 17.5.

The staff reviewed EF3 SUP 17.1-1 and determined that it adequately references Section 17.5 of the Fermi 3 COL FSAR, Revision 3, for a description of the QA Program applied during the design phase, including COL application preparation and site-specific design activities.

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[1] See "*Finality of Referenced NRC Approvals*," in SER Section 1.2.2, for a discussion on the staff's review related to verification of the scope of information to be included in a COL application that references a design certification.

17.1.5 *Post Combined License Activities*

There are no post COL activities related to this section.

17.1.6 *Conclusion*

The NRC staff's finding related to information incorporated by reference is in NUREG–1966. NRC staff reviewed the application and checked the referenced DCD. The staff's review confirmed that the applicant has addressed the required information, and no outstanding information is expected to be addressed in the Fermi 3 COL FSAR, Revision 3, related to this section. Pursuant to 10 CFR 52.63(a)(5) and 10 CFR Part 52 Appendix [X] Section VI.B.1, all nuclear safety issues relating to this section that were incorporated by reference have been resolved.

In addition, the staff compared the additional COL supplemental information in the application to the relevant NRC regulations, the guidance in Section 17.1 of NUREG–0800, and other NRC regulatory guides. The staff's review in Section 17.5 of this SER concluded that the applicant has presented adequate information in the Fermi 3 COL FSAR, Revision 3, to meet the requirements.

17.2 Quality Assurance During Construction and Operations

17.2.1 *Introduction*

This section of the Fermi 3 COL FSAR, Revision 3, addresses the QA Program during the construction and operations phases of the plant, including adapting the design to plant-specific implementation.

17.2.2 *Summary of Application*

Section 17.2 of the Fermi 3 COL FSAR, Revision 3, incorporates by reference Section 17.2 of the certified ESBWR DCD, Revision 9. In addition, in Fermi 3 COL FSAR, Revision 3, Subsection 17.2, the applicant provides the following:

COL Items

- EF3 COL 17.2-1-A QA Program for the Construction and Operations Phases
- EF3 COL 17.2-2-A QA Program for Design Activities

  The licensee's Quality Assurance Program in place during the construction and operations phases, including adapting the design to specific plant implementation, is described in Section 17.5.

17.2.3 *Regulatory Basis*

The regulatory basis of the information incorporated by reference is in NUREG–1966, the Final Safety Evaluation Report (FSER) related to the certified ESBWR DCD.

In addition, the relevant requirements of the Commission regulations for QA during the design phase, and the associated acceptance criteria, are described in Sections 17.2 and 17.5 of

NUREG–0800, “Standard Review Plan for the Review of Safety Analysis Reports for Nuclear Power Plants (LWR Edition)”.

17.2.4 *Technical Evaluation*

As documented in NUREG–1966, NRC staff reviewed and approved Section 17.2 of the certified ESBWR DCD. The staff reviewed Section 17.2 of the Fermi 3 COL FSAR, Revision 3, and checked the referenced ESBWR DCD to ensure that the combination of the information in the ESBWR DCD and the information in the Fermi 3 COL FSAR, Revision 3, appropriately represents the complete scope of information relating to this review topic.[1] The staff’s review confirmed that the information contained in the application and the information incorporated by reference address the relevant information related to this section.

The staff reviewed the information in the Fermi 3 COL FSAR, Revision 3, as follows:

COL Items

- EF3 COL 17.2-1-A QA Program for the Construction and Operations Phases

  The licensee’s Quality Assurance Program in place during the construction and operations phases, including adapting the design to specific plant implementation, is described in Section 17.5. This COL Item is addressed in Section 17.2.

- EF3 COL 17.2-2-A QA Program for Design Activities

  This COL Item is addressed in Section 17.2.

The staff reviewed EF3 COL 17.2-1-A and EF3 COL 17.2-2-A to determine whether they meet NRC regulations by following the guidance in SRP Section 17.5. SRP Section 17.5 provides an outline of a QA Program acceptable to the staff for the design certification, early site permit (ESP), COL, construction permit, and operating license applicants. The staff developed SRP Section 17.5 using ASME NQA-1–1994, “Quality Assurance Requirements for Nuclear Facility Applications,” supplemented by additional regulatory and industry guidance for nuclear operating facilities. SRP 17.5 also addresses additional QA requirements in 10 CFR Part 50, Appendix A, General Design Criterion 1 (GDC 1), and 10 CFR 50.34(f)(3)(ii) and (iii). GDC 1, “Quality Standards and Records,” requires that a QA Program be established and implemented. 10 CFR 50.34(f)(3)(ii) and (iii) specify design and construction QA requirements that must be addressed in a QA Program description. The staff’s safety evaluation of Fermi 3 COL FSAR Section 17.2 is provided in Section 17.5 of this SER. The staff determined EF3 COL 17.2-1-A and EF3 COL 17.2-2-A adequately reference Section 17.5 of the Fermi 3 COL FSAR, Revision 3, for a description of the QA Program applied during the design, construction and operations phases, including adapting the design to specific plant implementation. The Technical Evaluation of EF3 COL 17.2-1-A and EF3 COL 17.2-2-A are addressed in this FSER in Subsection 17.5.4.21, “Additional Quality Assurance and Administrative Controls for the Plant Operational Phase.”

[1] See “*Finality of Referenced NRC Approvals*,” in SER Section 1.2.2, for a discussion on the staff’s review related to verification of the scope of information to be included in a COL application that references a design certification.

17.2.5 *Post Combined License Activities*

There are no post COL activities related to this section.

17.2.6 *Conclusion*

The NRC staff's finding related to information incorporated by reference is in NUREG–1966. NRC staff reviewed the application and checked the referenced DCD. The staff's review confirmed that the applicant has addressed the required information, and no outstanding information is expected to be addressed in the COL FSAR related to this section. Pursuant to 10 CFR 52.63(a)(5) and 10 CFR Part 52 Appendix [X] Section VI.B.1, all nuclear safety issues relating to this section that were incorporated by reference have been resolved.

In addition, the staff compared the additional COL information in the application to the relevant NRC regulations, the guidance in Section 17.2 of NUREG–0800, and other NRC regulatory guides. The staff's safety evaluation of Fermi 3 COL FSAR Section 17.2 is provided in Section 17.5 of this SER, and concluded that Fermi 3 COL FSAR, Revision 3, Section 17.2 is acceptable and meets NRC regulatory requirements.

17.3 Quality Assurance Program Description

17.3.1 *Introduction*

This section of the Fermi 3 COL FSAR, Revision 3, addresses the overall QA Program.

17.3.2 *Summary of Application*

Section 17.3 of the Fermi 3 COL FSAR, Revision 3, incorporates by reference Section 17.3 of the certified ESBWR DCD, Revision 9. In addition, in Fermi 3 COL FSAR, Revision 3, Section 17.3, the applicant provides the following:

COL Item

- EF3 COL 17.3-1-A Quality Assurance Program Document

  The Quality Assurance Program Document applicable to the licensee is described in Section 17.5. The staff's review of this COL item is in Section 17.5 of the Fermi 3 COL FSAR, Revision 3.

17.3.3 *Regulatory Basis*

The regulatory basis of the information incorporated by reference is in NUREG–1966, the Final Safety Evaluation Report (FSER) related to the certified ESBWR DCD.

17.3.4 *Technical Evaluation*

As documented in NUREG–1966, NRC staff reviewed and approved Section 17.3 of the certified ESBWR DCD. The staff reviewed Section 17.3 of the Fermi 3 COL FSAR, Revision 3, and checked the referenced ESBWR DCD to ensure that the combination of the information in the ESBWR DCD and the information in the Fermi 3 COL FSAR, Revision 3, appropriately

represents the complete scope of information relating to this review topic.[1] The staff's review confirmed that the information contained in the application and the information incorporated by reference addresses the relevant information related to the QAPD.

The staff reviewed the information in the Fermi 3 COL FSAR, Revision 3, as follows:

COL Item

- EF3 COL 17.3-1-A Quality Assurance Program Document

  The Quality Assurance Program Document applicable to the licensee is described in Section 17.5.

This COL Item is addressed in Section 17.5.

The staff reviewed EF3 COL 17.3-1-A to determine whether it meets NRC regulations by following the guidance in SRP Section 17.5. SRP Section 17.5 provides an outline of a QA Program acceptable to the staff for the design certification, early site permit (ESP), COL, construction permit, and operating license applicants. The staff developed SRP Section 17.5 using ASME NQA-1–1994, "Quality Assurance Requirements for Nuclear Facility Applications," supplemented by additional regulatory and industry guidance for nuclear operating facilities. SRP 17.5 also addresses additional QA requirements in 10 CFR Part 50, Appendix A, General Design Criterion 1 (GDC 1), and 10 CFR 50.34(f)(3)(ii) and (iii). GDC 1, "Quality Standards and Records," requires that a QA Program be established and implemented. 10 CFR 50.34(f)(3)(ii) and (iii) specify design and construction QA requirements that must be addressed in a QA Program description. The staff determined 17.3-1-A adequately references Section 17.5 of the Fermi 3 COL FSAR, Revision 3, for a description of the Quality Assurance Program Document.

17.3.5 *Post Combined License Activities*

There are no post COL activities related to this section.

17.3.6 *Conclusion*

The NRC staff's finding related to information incorporated by reference is in NUREG–1966. NRC staff reviewed the application and checked the referenced DCD. The staff's review confirmed that the applicant has addressed the required information, and no outstanding information is expected to be addressed in the COL FSAR related to this section. Pursuant to 10 CFR 52.63(a)(5) and 10 CFR Part 52 Appendix [X] Section VI.B.1, all nuclear safety issues relating to the compliance with the 10 CFR 50.55a that were incorporated by reference have been resolved.

In addition, the staff compared the additional COL information in the application to the relevant NRC regulations, the guidance in Section 17.3 of NUREG–0800, and other NRC regulatory guides. The staff's technical evaluation of the QAPD is contained in Section 17.5 of this FSER and concluded that Fermi 3 COL FSAR, Revision 3, Section 17.3 is acceptable and meets NRC regulatory requirements.

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[1] See "*Finality of Referenced NRC Approvals*," in SER Section 1.2.2, for a discussion on the staff's review related to verification of the scope of information to be included in a COL application that references a design certification.

17.4 Reliability Assurance Program During Design Phase

17.4.1 *Introduction*

This section of the Fermi 3 COL FSAR, Revision 3, addresses the Commission's direction in the staff requirements memorandum (SRM) dated June 28, 1995, for Item E, "Reliability Assurance Program," of SECY–95–132, "Policy and Technical Issues Associated with the Regulatory Treatment of Non-Safety Systems (RTNSS) in Passive Plant Designs," dated May 22, 1995. The Reliability Assurance Program (RAP) is implemented using the guidance in Item E of SECY–95–132. The purposes of the RAP are to provide reasonable assurance that:

- A plant is designed, constructed, and operated consistent with the assumptions and risk insights for the structures, systems, and components (SSCs) in the scope of the RAP.
- These SSCs do not degrade to an unacceptable level of reliability, availability, or condition during plant operations.
- The frequency of transients that challenge these SSCs is minimized.
- These SSCs function reliably when challenged.

The purposes of the RAP can be achieved by implementing the program in two stages. The first stage applies to RAP activities that occur before the initial fuel load and is referred to as the Design Reliability Assurance Program (D-RAP). The goal of the D-RAP is to ensure that the plant design meets the considerations identified earlier through the plant design, procurement, fabrication, construction, and preoperational testing activities and programs. The second stage applies to RAP activities for the operations phase of the plant's life cycle. The objective during this stage is to ensure that the reliability for the SSCs within the scope of the RAP is maintained during plant operations. Implementation of the D-RAP by the COL licensee is verified using the inspections, tests, analyses, and acceptance criteria (ITAAC) process, as well as inspections conducted during the detailed design and construction phase, before initial fuel load.

17.4.2 *Summary of Application*

Section 17.4 of the Fermi 3 COL FSAR, Revision 3, incorporates by reference Section 17.4 of the certified ESBWR DCD Tier 2, Revision 9. In addition, in Fermi 3 COL FSAR, Revision 3, Section 17.4, the applicant provides the following:

COL Item

- STD COL 17.4-1-A

  The site-specific SSCs within the scope of the RAP, including a description of the quality elements for developing and implementing the D-RAP (that is, Organization, Design Control, Procedures and Instructions, Records, Corrective Action, and Audit Plans) will be identified prior to the initial fuel load. (COM 17.4-001)

The list of risk-significant SSCs will be confirmed via ITAAC (see DCD Tier 1 Table 3.6-1).

- STD COL 17.4-2-A

  The objectives of reliability assurance during the operations phase are integrated into the Quality Assurance Program (Section 17.5), the MR Program (Section 17.6), and other operational programs. Specific reliability assurance activities are addressed within operational programs (e.g., maintenance rule, surveillance testing, inservice testing, inservice inspection, and quality assurance) and the maintenance programs.

  The MR Program incorporates the following aspects of operational reliability assurance (refer to Section 17.6):

  - Use of probabilistic risk assessment (PRA) importance measures, the expert panel process, and deterministic methods to determine the list of risk-significant SSCs.
  - Evaluation and maintenance of the reliability of SSCs in the scope of the D-RAP
  - Monitoring the effectiveness of maintenance activities needed for operational reliability assurance.
  - Classifying, initially, as high-safety-significant, all SSCs that are in the scope of the D-RAP, or applying expert panel review for any exceptions.
  - Use of historical data and industry operating experience on equipment performance as available.
  - Use of specific criteria to establish the level of performance or condition being maintained for SSCs within the scope of the MR Program; and use of monitoring to identify declining trends between surveillances and to minimize the likelihood of undetected performance or condition degradation to unacceptable levels, to the extent possible.
  - Use of maintenance programs to determine the nature and frequency of maintenance activities to be performed on plant equipment, including SSCs within the scope of the MR Program.

For Fermi 3 COL FSAR, Revision 3, Subsection 17.4.9, “Operational Reliability Assurance Activities,” STD COL 17.4-2-A states:

> Refer to Section 17.4.1 for the implementation of reliability assurance during the operations phase.

For Fermi 3 COL FSAR, Revision 3, Subsection 17.4.10, “Owner/Operator’s Reliability Assurance Program,” STD COL 17.4-2-A states:

> The MR Program is described in Section 17.6. Refer to Section 17.4.1 for the implementation of reliability assurance activities.

17.4.3 *Regulatory Basis*

The regulatory basis of the information incorporated by reference is in NUREG–1966, the Final Safety Evaluation Report (FSER) related to the certified ESBWR DCD.

In particular, the relevant guidance for the RAP, including the associated acceptance criteria, are in the following sources:

- Item E, "Reliability Assurance Program," of SECY-95-132, "Policy and Technical Issues Associated with the Regulatory Treatment of Non-Safety Systems (RTNSS) in Passive Plant Designs," May 22, 1995

- Section 17.4, "Reliability Assurance Program," of NUREG–0800

- Interim Staff Guidance (ISG) DC/COL-ISG-018, "Interim Staff Guidance on Standard Review Plan, Section 17.4, 'Reliability Assurance Program'" (ADAMS Accession Number ML103010113)

17.4.4 *Technical Evaluation*

As documented in NUREG–1966, NRC staff reviewed and approved Section 17.4 of the certified ESBWR DCD Tier 2. The staff reviewed Section 17.4 of the Fermi 3 COL FSAR, Revision 3, and checked the referenced ESBWR DCD to ensure that the combination of the information in the ESBWR DCD and the information in the Fermi 3 COL FSAR, Revision 3, appropriately represents the complete scope of information relating to this review topic.[1] The staff's review confirmed that the information contained in the application and the information incorporated by reference addresses the relevant information related to the RAP.

The staff reviewed the information in the Fermi 3 COL FSAR, Revision 3, as follows:

COL Items

- STD COL 17.4-1-A

In Subsection 17.4.13 of the referenced ESBWR DCD Tier 2, Revision 9, COL Item 17.4-1-A states:

> The COL Applicant will identify the site-specific SSCs within the scope of the RAP, and describe the quality elements for developing and implementing the D-RAP (that is, Organization, Design Control, Procedures and Instructions, Records, Corrective Action, and Audit Plans) that will be applied prior to the initial fuel load (Subsection 17.4.1).

The applicant addresses this COL item in Subsection 17.4.1 of the Fermi 3 COL FSAR, Revision 3, by specifying Commitment (COM 17.4-001) to identify the site-specific SSCs within the scope of the RAP, including a description of the quality elements for developing and implementing the D-RAP before the initial fuel loading.

Based on SECY-95-132 and SRP Section 17.4 (as clarified or changed by ISG DC/COL-ISG-018), the staff found that the applicant did not sufficiently address COL Item 17.4-1-A in the Fermi 3 COL FSAR, Revision 3. ESBWR DCD Tier 2, Revision 9, contains COL Item 17.4-1-A to ensure that COL applications referencing the ESBWR design contain a list of site-specific RAP SSCs (i.e., the RAP SSCs identified in Section 17.4 of the ESBWR DCD Tier 2 and updated, as needed, using COL site- and plant-specific information), and describe the quality elements for developing and implementing the plant-specific D-RAP, which are applied during all plant design and construction activities prior to initial fuel load. It is necessary to identify the

[1] See "*Finality of Referenced NRC Approvals*," in SER Section 1.2.2, for a discussion on the staff's review related to verification of the scope of information to be included in a COL application that references a design certification.

site-specific RAP SSCs prior to the detailed design, procurement, fabrication, construction, inspection, and testing phases of the plant, because the non-safety-related RAP SSCs are subjected to the appropriate QA controls in accordance with SRP Section 17.5, Part V ("Non-safety-Related SSC Quality Controls"). The quality elements of D-RAP are processes and controls that ensure the risk insights and key assumptions from probabilistic, deterministic, and other methods of analysis used to identify and quantify risk are consistent with the designed and constructed plant and that the list of RAP SSCs is appropriately developed, maintained, updated, and communicated to the appropriate organizations. The staff issued RAI 17.04-2 requesting the applicant appropriately address COL Item 17.4-1-A in the Fermi 3 COL FSAR by identifying the site-specific RAP SSCs and describing the quality elements for developing and implementing the D-RAP.

In a letter dated May 25, 2011, the applicant's response to RAI 17.04-2 (ML11151A065) stated that the list of SSCs within the scope of RAP in ESBWR DCD Tier 2 Section 17.4, Revision 9, is incorporated by reference in FSAR Section 17.4, which includes all Regulatory Treatment of Non-safety Systems (RTNSS) SSCs identified in ESBWR DCD Tier 2, Appendix 19A, Revision 9. The applicant added that it has reviewed the list of SSCs within the scope of RAP that were incorporated by reference and concluded that there were no site-specific SSCs that are within the scope of RAP. In addition to the bounding treatment of PRA parameters, there were no departures from the standard design in any systems considered in the PRA model. Therefore, there were no site-specific design features that affect the PRA because the boundary of the certified design covers all of the SSCs necessary for the PRA. Regarding RTNSS SSCs, Appendix 19A of the ESBWR DCD Tier 2, Revision 9, is incorporated by reference in the Fermi 3 COL FSAR, Revision 3, with no departures or supplements. Furthermore, there are no site-specific non-safety-related RTNSS systems beyond the scope of the DCD. Therefore, the applicant concluded that the list of SSCs within the scope of RAP for Fermi 3 is identified in Section 17.4 of the ESBWR DCD Tier 2, Revision 9, which is incorporated by reference in the Fermi 3 COL FSAR, Revision 3.

The applicant also stated that the QA controls for safety-related and non-safety-related SSCs within the scope of RAP are in accordance with the QAPD provided in FSAR Appendix 17AA. QAPD Part II provides the quality assurance controls for safety-related SSCs. QAPD Part III provides the quality assurance controls for non-safety-related SSCs that are a significant contributor to plant safety. In addition, the quality elements are incorporated by reference to Subsection 17.4.5 of the ESBWR DCD Tier 2, Revision 9. The applicant stated that Fermi 3 COL FSAR, Section 17.4, will be revised to remove commitment COM FSAR-17.4-001 and include a statement that there are no site-specific SSCs within the scope of RAP and that the quality elements for all SSCs within the scope of the RAP are in accordance with the QAPD.

The staff found that the applicant's response has sufficiently addressed the issues raised in RAI 17.04-2. Also, the staff independently assessed the COL site- and plant-specific information for its impact on the list of SSCs within the scope of RAP (i.e., additions or deletions to the list of SSCs within the scope of RAP), and concluded that the list of SSCs within the scope of RAP for Fermi 3 is identified in Section 17.4 of ESBWR DCD Tier 2, Revision 9, which is incorporated by reference in the Fermi 3 COL FSAR, Revision 3. Based on the above discussion, RAI 17.04-2 is resolved. The applicant's proposed revision to Fermi 3 COL FSAR, Section 17.4, is being tracked as **Confirmatory Item 17.04-2**.

The COL applicant added the following new paragraph at the end of FSAR Section 17.4.6: "The list of risk-significant SSCs will be confirmed via ITAAC (see DCD Tier 1 Table 3.6-1)." The staff found this statement acceptable since the D-RAP ITAAC in ESBWR DCD Tier 1 Table 3.6-1 will

ensure that the design of SSCs within the scope of the RAP is consistent with the risk insights and key assumptions from the probabilistic, deterministic, and other methods of analysis used to identify and quantify risk. This includes applying the quality elements of D-RAP during design and construction activities that ensure the list of RAP SSCs is appropriately developed, maintained, and communicated to the appropriate organizations.

- STD COL 17.4-2-A

In Section 17.4.13 of the referenced ESBWR DCD Tier 2, Revision 9, COL Item 17.4-2-A requires the applicant to provide a description of operational reliability assurance activities that meet the objectives of the RAP during the operations phase. In FSAR Subsection 17.4.1, the applicant describes an acceptable process for integrating RAP into operational programs to meet the objectives of the RAP during the operations phase. The process involves integrating RAP into the following operational programs: (1) MR Program consistent with RG 1.160, with all RAP SSCs being categorized as having high safety significance; (2) QA Program for safety-related SSCs established through Appendix B to 10 CFR Part 50 requirements; (3) QA controls for non-safety-related RAP SSCs established in accordance with Part V of SRP Section 17.5; and (4) inservice inspection, inservice testing, surveillance testing, and maintenance programs for the RAP SSCs to maintain equipment performance consistent with the risk insights and key assumptions from probabilistic, deterministic, and other methods of analysis used to identify and quantify risk. The applicant also refers to FSAR Section 17.5 for the QA Program and Section 17.6 for the MR Program.

The second paragraph in ESBWR DCD Tier 2, Revision 9, Section 17.4.9 states that the COL holder is responsible for implementation of operational reliability assurance activities. The applicant replaced the second paragraph with the following: “Refer to Section 17.4.1 for the implementation of reliability assurance during the operations phase.” The staff found this replacement acceptable since Fermi 3 COL FSAR Section 17.4.1 describes how the applicant will implement the reliability assurance activities during the operations phase.

The fifth bullet in ESBWR DCD Tier 2, Revision 9, Section 17.4.10 describes the scope of the MR Program and that it is the responsibility of the licensee. The applicant replaced the fifth bullet with the following: “MR Program: The MR Program is described in Section 17.6.” The staff found this replacement acceptable since Fermi 3 COL FSAR Section 17.6 describes the applicant’s MR Program, which meets the scope defined under the fifth bullet in DCD Section 17.4.10. The staff’s safety evaluation of Fermi 3 COL FSAR Section 17.4 is provided in Section 17.5 of this SER.

The last sentence in ESBWR DCD Tier 2, Revision 9, Section 17.4.10 states: “See Subsection 17.4.1 for COL information requirements.” The applicant replaced this sentence with the following: “Refer to Section 17.4.1 for the implementation of reliability assurance activities.” The staff found this replacement appropriate.

The staff reviewed the application and checked the referenced DCD. The staff's review confirmed that the applicant has adequately addressed the required information relating to COL 17.4-2-A consistent with the applicable requirements described in Section 17.4.3 of this SER. Therefore this COL item is closed.

17.4.5 *Post Combined License Activities*

There are no post COL activities related to this section.

17.4.6 *Conclusion*

The NRC staff's finding related to information incorporated by reference is in NUREG–1966. NRC staff reviewed the application and checked the referenced DCD. The staff's review confirmed that the applicant has addressed the required information relating to RAP, and no outstanding information is expected to be addressed in the Fermi 3 COL FSAR related to this section. Pursuant to 10 CFR 52.63(a)(5) and 10 CFR Part 52 Appendix [X] Section VI.B.1, all nuclear safety issues relating to RAP that were incorporated by reference have been resolved.

In addition, the staff compared the information in the Fermi 3 COL FSAR, Revision 3, to the relevant NRC regulations, the guidance in Section 17.4 of NUREG–0800 and DC/COL-ISG-018, and other NRC regulatory guides. The staff's review concluded that, pending the resolution of Confirmatory Item 17.04-2, the applicant has provided sufficient information to address the COL items and to satisfy the NRC requirements in Section 17.4 of this SER.

17.5 Quality Assurance Program Description – Design Certification, Early Site Permits, and New License Applicants

17.5.1 *Introduction*

This section of the Fermi 3 COL FSAR, Revision 3, discusses the overall QA Program, including the QA Program that is applicable during the design, construction, and operations phases of a nuclear power plant.

17.5.2 *Summary of Application*

Section 17.5 of the Fermi 3 COL FSAR, Revision 3, incorporates by reference Section 17.5 of the certified ESBWR DCD, Revision 9. In addition, in Fermi 3 COL FSAR, Revision 3, Section 17.5, the applicant provides the following:

COL Items

- EF3 COL 17.2-1-A QA Program for the Construction and Operations Phases
- EF3 COL 17.2-2-A QA Program for Design Activities

  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.

- EF3 COL 17.3-1-A Quality Assurance Program Document

  QA applied to the DC activities is described in DCD Section 17.1. ESP QA is not applicable to Fermi 3.

Supplemental Information

- EF3 SUP 17.5-2

The applicant provides information to resolve ESBWR DCD COL Items 17.2-1-A, 17.2-2-A, and 17.3-1-A by referencing the Fermi 3 QAPD. The QAPD will be applied to QA activities to adapt the design to plant-specific implementation, construction, and operations.

The applicant provides information to resolve EF3 SUP 17.5-2 by describing QA programs applied to COL application development and support activities from January 2007 through December 2009. The applicant describes the QA controls for each of three phases:

- Development of COLA work products.
- Review and acceptance of COLA work products.
- Application for Combined Operating License.

17.5.3 *Regulatory Basis*

The relevant requirements of the Commission regulations for the QAPD, and the associated acceptance criteria, are in Section 17.5 of NUREG–0800.

The applicable regulatory requirements for the QAPD are as follows:

Appendix B, "Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants," to 10 CFR Part 50, "Domestic Licensing of Production and Utilization Facilities," requires the applicant to include in the application a description of the QA Program that will be applied to the design, fabrication, construction, and testing of the SSCs of the facility and to establish QA requirements for the design, construction, and operation of those SSCs. The pertinent requirements of Appendix B apply to all activities affecting the safety-related functions of the SSCs including designing, purchasing, fabricating, handling, shipping, storing, cleaning, erecting, installing, inspecting, testing, operating, maintaining, repairing, refueling, and modifying these activities.

Section 10 CFR 52.79(a)(17) requires that the application include information with respect to compliance with technically relevant positions of the Three Mile Island requirements of 10 CFR 50.34(f).

Section 10 CFR 52.79(a)(25) requires that the description of the QA Program include a discussion of how the applicable requirements of Appendix B have been and will be satisfied and a discussion of how the QA Program will be implemented.

Furthermore, 10 CFR 52.79(a)(27) requires that the application include information on the managerial and administrative controls to be used for a nuclear power plant and a discussion of how the applicable requirements of Appendix B will be satisfied.

17.5.4 *Technical Evaluation*

The staff reviewed Section 17.5 of the Fermi 3 COL FSAR, Revision 3, and Fermi 3 QAPD information in Appendix 17AA. This information is site-specific and is not part of the certified ESBWR DCD. The applicant discusses in EF3 SUP 17.5-2 the QA programs applied from project inception until 15 months after submitting the license application. The Fermi 3 QAPD addresses the QA Program that will be applied to activities after submitting the license application to adapt the design to plant-specific implementation, construction, and operations.

The staff reviewed and evaluated the Fermi 3 QAPD to determine whether it meets NRC regulations by following the guidance in SRP Section 17.5. SRP Section 17.5 provides an outline of a QA Program acceptable to the staff for the design certification, early site permit

(ESP), COL, construction permit, and operating license applicants. The staff developed SRP Section 17.5 using ASME NQA-1–1994, "Quality Assurance Requirements for Nuclear Facility Applications," supplemented by additional regulatory and industry guidance for nuclear operating facilities. SRP 17.5 also addresses additional QA requirements in 10 CFR Part 50, Appendix A, General Design Criterion 1 (GDC 1), and 10 CFR 50.34(f)(3)(ii) and (iii). GDC 1, "Quality Standards and Records," requires that a QA Program be established and implemented. 10 CFR 50.34(f)(3)(ii) and (iii) specify design and construction QA requirements that must be addressed in a QA Program description.

The Fermi 3 QAPD is the top-level document that establishes the QA measures to be applied to the activities related to the design, construction, and operation of an ESBWR at the Fermi 3 site. The applicant states that the Fermi 3 QAPD is based on NEI 06–14A, Revision 7. The NRC concluded that NEI 06–14A, Revision 7, provides an acceptable format and adequate guidance for establishing a QA program that meets the requirements of 10 CFR Part 50 Appendix B, as documented in the SER, "Quality Assurance Program Description," (ML101800497). Because the applicant claims to have followed an acceptable QA Program format, the following sections provide (1) additional information related to resolving the RAIs; (2) exceptions to industry standard commitments; and (3) cross-references to related SRP acceptance criteria guidance.

The staff conducted a specific comparison of the Fermi 3 QAPD against NEI 06–14A, Revision 7. The following discussion provides details of the staff's review and conclusions for each QAPD section.

17.5.4.1 Organization

The staff noted that the applicant's QAPD refers to Fermi 3 COL FSAR, Chapter 13 for organizational information guiding the transition from the construction to the operating phase, while many sections of Fermi 3 COL FSAR, Chapter 13 refer to FSAR Chapter 17.5 for additional organizational information. A staff review identified inadequate content, inconsistent organizational titles, and differing regulatory change requirements between Fermi 3 COL FSAR, Chapters 13 and 17.5. As a result, the staff issued **RAI 17.5-5** and **RAI 17.5-6** requesting the applicant to clarify change methods for FSAR Chapter 13 content, to further define Fermi 3 organizational responsibilities and structure, to provide organizational flowcharts, and to ensure consistent cross-references between Fermi 3 COL FSAR, Chapters 13 and 17.5. The applicant's response to these RAIs dated September 30, 2009 (ML092790561), provides organizational flowcharts and additional organizational details and amplifies regulatory change requirements for Fermi 3 COL FSAR, Chapter 13 and QAPD Section 1, "Organization." However, a later staff review identified incomplete organizational information in Chapters 13, and in QAPD Section 1, which required additional clarification. As a result, the staff issued seven supplemental organizational RAI questions that are outlined below.

In **RAI 17.5-10** and **RAI 17.5-21**, the staff requested the applicant to address the eight notes of NEI 06–14 (previous version of NEI 06-14A) Part II, Section 1, including identifying each project phase and describing the process for an organizational transition between each phase. The applicant's responses to **RAI 17.5-10** dated April 16, 2010 (ML101190369), and to **RAI 17.5-21** dated August 13, 2010 (ML102290043), address the eight notes of NEI 06–14 Part II, Section 1, by outlining the three project phases and describing the transitional process between each phase. The staff reviewed the applicant's proposed changes to Fermi 3 COL FSAR, Chapter 13 and to the QAPD. The staff determined that the changes are consistent with NEI 06–14A, Revision 7, and are therefore acceptable. The staff verified that the applicant's proposed

changes are included in Fermi 3 COL FSAR, Revision 3. Therefore, the staff determined that RAIs 17.5-10 and 17.5-21 are closed.

In **RAI 17.5-11**, **RAI 17.5-13**, and **RAI 17.5-22**, the staff requested that the applicant provide additional primary contractor details, clarify organization sizing responsibility, clarify transition points, and clarify work locations of the described organization. The applicant's responses to these RAIs, dated April 16, 2010, and August 13, 2010, provide additional organizational details and propose changes to Fermi 3 COL FSAR and the QAPD. The staff reviewed the applicant's proposed changes to Fermi 3 COL FSAR Chapters 1 and 13, and the QAPD, and determined that the changes are consistent with NEI 06–14A, Revision 7, and are therefore acceptable. The staff verified that the applicant's proposed changes are included in the Fermi 3 COL FSAR, Revision 3. Therefore, the staff determined that RAIs 17.5-11, 17.5-13, and 17.5-22 are closed.

In **RAI 17.5-14** and **RAI 17.5-15**, the staff requested the applicant to clarify the sections of the FSAR that describe the design and construction organization and when changes to organizational elements of Fermi 3 COL FSAR, Part II, Chapter 13, will be reviewed under 10 CFR 50.54(a). The applicant's response to these RAIs, dated April 16, 2010 (ML101190369) clarifies the corporate executive, corporate support, and design and construction organizational structure. The applicant also states that design, construction, technical support, and operating organizational changes will be reviewed under the provisions of 10 CFR 50.54(a). The staff reviewed the applicant's proposed changes to Fermi 3 COL FSAR, Chapter 13 and the QAPD. The staff determined that the changes are consistent with NEI 06–14A, Revision 7, and are therefore acceptable. The staff verified that the applicant's proposed changes are included in the Fermi 3 COL FSAR, Revision 3. Therefore, the staff determined that RAIs 17.5-5, 17.5-6, 17.5-14, and 17.5-15 are closed.

The staff concluded that the applicant's QAPD follows the guidance of Section 17.5, SRP Acceptance Criteria Item A, related to the organization, which are based on the following information. The QAPD includes assurance from the applicant that it will comply with the quality standards for QA organizations described by ASME in NQA-1–1994, Basic Requirement 1, and Supplement 1S-1. The QAPD describes and defines the responsibility and authority for planning, establishing, and implementing an effective overall QA program. The QAPD describes an organization's structure, functional responsibilities and levels of authority, and the interfaces for establishing, executing, and verifying the QAPD implementation. The QAPD establishes an independence between the organization responsible for overseeing a function and the organization that performs the function. In addition, the QAPD allows the applicant's management to size the QA organization commensurate with assigned duties and responsibilities.

17.5.4.2 Quality Assurance Program

The staff issued **RAI 17.5-7** requesting the applicant to describe the qualification requirements for the independent review staff, which should meet or exceed those described in Section 4.7 of American National Standard Institute/American Nuclear Society (ANSI/ANS)-3.1–1993, and in RG 1.8, Revision 3. The applicant's response to **RAI 17.5-7** dated September 30, 2009 (ML092790561), revises Section 2.7 of the QAPD to reflect acceptable qualification requirements for the members of the Independent Review Board. The staff reviewed the applicant's response and the proposed changes to Section 2.7 of the QAPD. The staff determined that the changes are consistent with NEI 06–14A, Revision 7, and are therefore acceptable. The staff verified that the applicant's proposed changes are included in Fermi 3 COL FSAR, Revision 3. Therefore, the staff determined that RAI 17.5-7 is closed. The staff

also concluded the QAPD follows the guidance in Section 17.5 of NUREG–0800, SRP Acceptance Criteria Item W, for independent program reviews based on the following. The QAPD provides measures for establishing an independent review program for activities occurring during the operations phase.

Additionally, the staff concluded that the QAPD follows the guidance for training in Section 17.5 of NUREG–0800, SRP Acceptance Criteria Items S and T related to training, which are based on the information that follows. The QAPD describes measures that establish and maintain formal indoctrination and training programs for personnel performing, verifying, or maintaining activities within the scope of the QAPD. The purpose of these measures is to ensure that personnel achieve and maintain suitable levels of proficiency. The plant's technical specifications delineate the minimum qualifications for plant and support staff. Personnel are required to complete the training for positions identified in 10 CFR 50.120, "Training and qualification of nuclear power plant personnel," in accordance with programs accredited by the National Nuclear Accrediting Board of the National Academy for Nuclear Training. The QAPD also establishes minimum training requirements for managers responsible for QAPD implementation, in addition to minimum training requirements for individuals responsible for planning, implementing, and maintaining the QAPD.

In the QAPD, the applicant provides assurance of compliance with the quality standards described in NQA-1–1994 Basic Requirement 2 and Supplements 2S-1, 2S-2, 2S-3, and 2S-4 with the following alternatives:

- NQA-1–1994 Supplement 2S-1 includes NQA-1–1994 Appendix 2A-1. The QAPD proposes the following alternatives to the implementation of Supplement 2S-1 and Appendix 2A-1:

    - NQA-1–1994, Supplement 2S-1, states that the organization designates those activities that require qualified inspectors and test personnel, and establishes written procedures for the qualification of these personnel. As an alternative to this requirement, the QAPD proposes that a qualified engineer may plan inspections, evaluate the capabilities of an inspector, or evaluate the training program for inspectors. For the purposes of these functions, a qualified engineer is one who has a baccalaureate degree in engineering in a discipline related to the inspection or test activity (i.e., electrical, mechanical, or civil engineering) and has at least 5 years of engineering work experience, with at least 2 years of this experience regarding nuclear facilities. The staff evaluated this proposed alternative and determined that the designation of a qualified engineer to plan inspections, evaluate inspectors, or evaluate the inspector qualification programs is consistent with the training and qualification criteria of 10 CFR Part 50, Appendix B, Criterion II, "Quality Assurance Program," and NQA-1–1994, Supplement 2S-1. Therefore, the staff concluded that this alternative is acceptable.

    - NQA-1–1994, Appendix 2A-1, provides guidance for qualifying inspection and test personnel as Level I, II, or III. As an alternative to this guidance, the QAPD proposes that personnel performing independent quality verification inspections, examinations, measurements, or tests will be required to possess qualifications equal to or better than those required for performing the task being verified. In addition, the verification performed must be within the skills of these personnel and addressed by procedures. These personnel will not be responsible for

planning quality verification inspections or tests (i.e., establishing hold points and acceptance criteria in procedures, and determining responsibility for performing the inspection), evaluating inspection training programs, or certifying inspection personnel. The staff evaluated this proposed alternative and determined that it is consistent with inspection and test personnel initial qualification requirements specified in Section 17.5, of NUREG–0800, SRP Acceptance Criteria Item T.5. Therefore, the staff concluded that this alternative is acceptable.

- NQA-1–1994 Supplement 2S-2 states that nondestructive examination personnel must be qualified. As an alternative to this requirement, the QAPD proposes to follow the applicable standard cited in Sections III and XI of the ASME Boiler and Pressure Vessel Code (ASME Code). 10 CFR 50.55a, "Codes and standards," also requires the use of the latest edition and addenda in Sections III and XI of the ASME Code. The staff evaluated this proposed alternative and determined that it is consistent with the regulation in 10 CFR Part 50 Appendix B, Criterion II. Therefore, the staff concluded that this alternative is acceptable.

- NQA-1–1994 Supplement 2S-3 states that the prospective lead auditors must have participated in a minimum of five audits in the previous 3 years. As an alternative to this requirement, the QAPD proposes to follow the guidance of Section 17.5 of NUREG–0800 SRP Acceptance Criteria Item S.4.c, which states that prospective lead auditors shall demonstrate their ability (1) to properly conduct the audit process as implemented by the company; (2) to effectively lead an audit team, and (3) to effectively organize and report results, including participation in at least one nuclear audit within the year preceding the date of qualification. The staff evaluated this proposed alternative and determined that it is consistent with the regulation in 10 CFR Part 50 Appendix B, Criterion II. Therefore, the staff concluded that this alternative is acceptable.

The staff concluded the applicant's QAPD follows the guidance in Section 17.5 of NUREG–0800, SRP Acceptance Criteria Item B for the QA Program based on the information that follows. The QAPD establishes measures to implement a QA Program to ensure that the design, construction, and operation of a nuclear power plant are in accordance with governing regulations and license requirements. The QA Program comprises those planned and systematic actions that are necessary to provide confidence that SSCs will perform their intended safety function, including certain non-safety-related SSCs and activities that are significant contributors to plant safety, as described in the Fermi 3 COL FSAR, Revision 3. The QA Program requires the maintenance of a list or system identifying SSCs and activities applicable to the QAPD.

Further, the staff concluded the applicant's QAPD provides measures to assess the adequacy of the QAPD at least once each year, or at least once during the existence of the activity, whichever is shorter. The program allows the period of time for assessing the QAPD during the operations phase to be extended to once every 2 years. In addition, the staff concluded that the applicant's QAPD is consistent with Section 17.5 of NUREG–0800, SRP Acceptance Criteria Item B.8, because the QAPD applies a grace period of 90 days for activities that must be performed on a periodic basis. The next due date for the performance of an activity that invokes the 90-day grace period remains unchanged (e.g. the next due date is not advanced forward in time). The next due date for an activity performed before the scheduled due date is moved earlier (e.g. the next due date is advanced backward in time), so as not to exceed the interval prescribed for the performance of the activity.

17.5.4.3 Design Control

The staff concluded that the applicant's QAPD follows the guidance of Section 17.5 of NUREG–0800, SRP Acceptance Criteria Item C for design control based on the information that follows. The QAPD establishes the necessary measures to control the design, design changes, and temporary modifications (e.g., temporary bypass lines, electrical jumpers and lifted wires, and temporary setpoints) of items that are subject to the provisions of the QAPD. The QAPD design process includes provisions to control design inputs, outputs, changes, interfaces, records, and organizational interfaces with the applicant and its suppliers. These provisions ensure that the design inputs (i.e., design bases and the performance, regulatory, quality, and quality verification requirements) are correctly translated into design outputs (i.e., analyses, specifications, drawings, procedures, and instructions). The QAPD provides for individuals knowledgeable about QA principles for reviewing design documents to ensure that they contain the necessary QA requirements. Additionally, in the QAPD, the applicant provides assurance of compliance with the quality standards described in NQA-1–1994, Basic Requirement 3 and Supplement 3S-1, Subpart 2.20 for the subsurface investigation requirements, and Subpart 2.7 for the standards for computer software QA controls, to establish its program for design control and verification.

17.5.4.4 Procurement Document Control

The staff determined, in the QAPD, the applicant provides assurance of compliance with the quality standards described in NQA-1–1994, Basic Requirement 4 and Supplement 4S-1, with the following alternatives:

- NQA-1–1994 Supplement 4S-1, Section 2.3, states that procurement documents must require suppliers to have a documented QA program that implements NQA-1–1994 Part I.
    - As an alternative to this requirement, the QAPD proposes that suppliers have a documented QA program that meets the requirements of Appendix B to 10 CFR Part 50, as applicable to the circumstances of the procurement. The staff evaluated this proposed alternative and determined that it is consistent with Appendix B, Criterion IV, "Procurement Document Control." Therefore, the staff concluded that this alternative is acceptable.
    - As an alternative to this requirement, the QAPD proposes that procurement documents could allow suppliers to work under the applicant's QAPD, including its implementation procedures, if suppliers do not have their own QA program. The staff evaluated this proposed alternative and determined that the applicant's QAPD follows the guidance of Section 17.5 of NUREG–0800, SRP Acceptance Criteria Item G, "Control of Purchased Material, Equipment, and Services." Specifically, the QAPD provides measures to evaluate prospective suppliers so that only qualified suppliers are selected, acceptance actions are performed for procuring products and services, and suppliers are periodically audited and evaluated to ensure that qualified suppliers continue to provide acceptable products and services. Therefore, the staff concluded that this alternative is acceptable.
- NQA-1–1994 Supplement 4S-1, Section 3, states that procurement documents are to be reviewed before awarding a contract. As an alternative to this requirement, the QAPD proposes to conduct the QA review of procurement documents through a review of the

applicable procurement specifications, including the technical and quality procurement requirements, before awarding a contract. In addition, procurement document changes (e.g., scope, technical, or quality requirements) will also receive a QA review. The staff evaluated this proposed alternative and determined that it provides an adequate QA review of procurement documents before awarding a contract and after any changes. Therefore, the staff concluded that this alternative is acceptable.

- In the QAPD, the applicant provides assurance that procurement documents prepared for commercial-grade items and procured as safety-related items shall contain technical and QA requirements to which the procured item can be appropriately dedicated. The staff evaluated and determined that it is consistent with staff guidance in Generic Letter (GL) 89–02, "Actions to Improve the Detection of Counterfeit and Fraudulently Marked Products," dated March 21, 1989; and GL 91–05, "Licensee Commercial-Grade Procurement and Dedication Programs," dated April 9, 1991; as delineated in Section 17.5 of NUREG–0800, SRP Acceptance Criteria Items U.1.d and U.1.e. Therefore, the staff concluded that this is acceptable.

The staff concluded that the applicant's QAPD follows the guidance of Section 17.5 of NUREG–0800, SRP Acceptance Criteria Item D for procurement document control based on the following information. The QAPD establishes the necessary administrative controls and processes to ensure that procurement documents include or reference applicable regulatory, technical, and QA Program requirements. As noted in Section 17.5 of NUREG–0800, SRP Acceptance Criteria Item D.1, the applicable technical, regulatory, administrative, quality, and reporting requirements are invoked for the procurement of items and services. These requirements include specifications, codes, standards, tests, inspections, special processes, and the regulation in 10 CFR Part 21, "Reporting of Defects and Noncompliance."

17.5.4.5 Instructions, Procedures, and Drawings

The staff concluded that the applicant's QAPD follows the guidance of Section 17.5 of NUREG–0800, SRP Acceptance Criteria Item E for instructions, procedures, and drawings based on the information that follows. The QAPD establishes the necessary measures and governing procedures to ensure that activities affecting quality are prescribed by, and performed in accordance with documented instructions, procedures, and drawings. Additionally, in the QAPD, the applicant provides assurance of compliance with the quality standards for instructions, procedures, and drawings described in NQA-1–1994, Basic Requirement 5, for establishing procedural controls.

17.5.4.6 Document Control

The staff concluded that the applicant's QAPD follows the guidance of Section 17.5 of NUREG–0800, SRP Acceptance Criteria Item F, for document control based on the information that follows. The QAPD establishes the necessary measures and governing procedures to control the preparation, review, approval, issuance, and change of documents that specify QA requirements or prescribe measures for controlling activities affecting quality, including organizational interfaces. The QAPD provides measures to ensure that the same organization that performed the original review and approval also reviews and approves revisions or changes to documents, unless other organizations are specifically designated.

Furthermore, a listing of all controlled documents that identify the current approved revision or date is maintained so personnel can readily determine the appropriate document for use. To

ensure effective and accurate procedures during the operational phase, applicable procedures are reviewed and updated as necessary, consistent with the staff guidance of Section 17.5 of NUREG–0800, SRP Acceptance Criteria Item F.8. Additionally, in the QAPD, the applicant provides assurance of compliance with the quality standards described in NQA-1–1994 Basic Requirement 6 and Supplement 6S-1, to establish provisions for document control.

17.5.4.7 Control of Purchased Material, Equipment, and Services

The staff evaluated the QAPD and determined that the applicant provides assurance of compliance with the quality standards for the control of purchased material, equipment, and services described in NQA-1–1994, Basic Requirement 7 and Supplement 7S-1, to establish procurement verification controls with the following exceptions and alternatives:

- NQA-1–1994 Basic Requirement 7 and Supplement 7S-1 state that procurement sources and suppliers' performance are to be evaluated. As an exception to these requirements, the QAPD proposes that other 10 CFR Part 50 licensees, authorized nuclear inspection agencies, the National Institute of Standards and Technology (NIST), and other State and Federal agencies that may provide items or services to the applicant are not required to be evaluated or audited.

  The staff acknowledged that 10 CFR Part 50 licensees, authorized nuclear inspection agencies, the National Voluntary Laboratory Accreditation Program (NVLAP) administered by NIST, and other State and Federal agencies perform work under quality programs acceptable to the NRC, and no additional audits or evaluations are required. However, the applicant remains responsible for ensuring that procured items or services conform to Appendix B to 10 CFR Part 50, to applicable ASME Code requirements, and to other regulatory requirements and commitments. The applicant also remains responsible for ensuring that the items or services are suitable for the intended application and for documenting the evaluations that support this conclusion. The staff concluded that this exception is consistent with NEI 06–14A, Revision 7, and therefore acceptable.

- Section 17.5 of NUREG–0800, SRP Acceptance Criteria Item L.8, establishes provisions for the procurement of commercial-grade calibration services for safety-related applications. As an exception to these provisions, the QAPD proposes that procurement source evaluations and selection measures not be required, provided that all of the following conditions are met:

  - Purchase documents impose additional technical and administrative requirements to satisfy any licensee-specific QAPD and technical requirements.
  - Purchase documents require reporting as-found calibration data when calibrated items are found to be out of tolerance.
  - The supplier's accreditation will require a documented review that verifies the following:

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

       a. NVLAP administered by NIST

b. American Association for Laboratory Accreditation (A2LA) as recognized by the NVLAP

c. ACLASS Accreditation Services (ACLASS)

d. International Accreditation Service (IAS)

e. Laboratory Accreditation Bureau (L-A-B)

f. Other NRC-approved laboratory accrediting body

2) The accreditation encompasses the ANS/International Organization for Standardization (ISO)/ International Electrotechnical Commission (IEC) 17025, "General Requirements for the Competence of Testing and Calibration Laboratories."

3) The published scope of accreditation for the calibration laboratory covers the necessary measurement parameters, ranges, and uncertainties.

The staff evaluated and found the ACLASS, IAS, L-A-B, NVLAB and A2LA accreditation programs consistent with NEI 06-14A, Revision 7, and thus acceptable.

- NQA-1–1994 Supplement 7S-1 Section 8.1 states that documented evidence must conform to procurement documents and be available at the nuclear facility site before installation or use. As an alternative to the requirement that documented procurement evidence be available at the nuclear facility site during construction, the QAPD proposes that documented evidence may be stored in physical form or in electronic media, under the control of the applicant or its supplier(s), and at a location(s) other than the nuclear facility site as long as the documents can be accessed at the nuclear facility site during construction. The applicant states that after the completion of construction, sufficient as-built documentation will be available to the licensee to support operations.

  The staff determined that implementation of this alternative would allow access to and review of the necessary procurement documented evidence at the nuclear facility site, both before installation and before use. Therefore, the staff concluded that this alternative is acceptable.

- As an alternative to the requirements that control commercial-grade items and services in NQA-1–1994 Supplement 7S-1, Section 10, the applicant provides assurance in the QAPD to follow NRC guidance discussed in GLs 89–02 and 91–05. In addition, the applicant established and described special quality verification requirements in applicable documents to assure that the commercially procured items will perform satisfactorily and the documents should determine critical characteristics, technical evaluations, receipt requirements, and quality evaluations of the items to ensure that they are suitable for their intended use. In addition, the applicant provides assurance in the QAPD to use other appropriate approved regulatory means and controls to support the applicant's commercial-grade dedication activities, and the applicant will assume 10 CFR Part 21 reporting responsibility for all items that are dedicated as safety related.

The staff determined that this alternative improves the likelihood of detecting counterfeit and fraudulently marked products and improves the commercial-grade dedication programs. This

alternative is consistent with the guidance of Section 17.5 of NUREG–0800, SRP Acceptance Criteria Items U.1.d and U.1.e. Therefore, the staff concluded that this alternative is acceptable.

The staff concluded that the applicant's QAPD follows the guidance of Section 17.5 of NUREG–0800, SRP Acceptance Criteria Item G, for the control of purchased material, equipment, and services based on the following information. The QAPD establishes the necessary measures and governing procedures to control the procurement of items and services and ensure conformance with specified requirements. The program provides measures to evaluate prospective suppliers so that only qualified suppliers are selected. In addition, the program requires that suppliers be periodically audited and evaluated to ensure that qualified suppliers continue to provide acceptable products and services.

Furthermore, the program provides for acceptance actions that include source verification, receipt inspection, pre- and post-installation tests, and the review of documentation such as certificates of conformance to ensure that procurement, inspection, and test requirements have been satisfied before relying on the item to perform its intended safety function. Purchased items (such as components, spares, and replacement parts necessary for plant operation, refueling, maintenance, and modifications) and services are subject to quality and technical requirements at least equivalent to those specified for original equipment, or properly reviewed and approved revisions, to ensure that the items are suitable for the intended service and are of an acceptable quality that is consistent with their effect on safety.

17.5.4.8 Identification and Control of Materials, Parts, and Components

The staff concluded that the applicant's QAPD follows the guidance of Section 17.5 of NUREG–0800 SRP Acceptance Criteria Item H for the identification and control of materials, parts, and components (material traceability) based on the following information. The QAPD establishes the necessary measures for the identification and control of items such as materials, including consumables and items with limited shelf life, parts, components, and partially fabricated subassemblies. The identification of items is maintained throughout fabrication, erection, installation, and use so that the item can be traced to its documentation consistent with the item's effect on safety. Additionally, in the QAPD, the applicant provides assurance to comply with the quality standards for material traceability described in NQA-1–1994 Basic Requirement 8 and Supplement 8S-1, to establish provisions for the identification and control of items.

17.5.4.9 Control of Special Processes

The staff concluded that the applicant's QAPD follows the guidance of Section 17.5 of NUREG–0800, SRP Acceptance Criteria Item I, for the control of special processes based on the information that follows. The QAPD establishes programs, procedures, and processes to ensure that special processes requiring interim controls to maintain quality such as welding, heat treating, chemical cleaning, and nondestructive examinations are implemented and controlled in accordance with applicable codes, specifications, and standards. Additionally, in the QAPD, the applicant provides assurance to comply with the quality standards for the control of special processes described in NQA-1–1994 Basic Requirement 9 and Supplement 9S-1 to establish measures for the control of special processes.

17.5.4.10 Inspection

The Fermi 3 QAPD provides assurances of compliance with QA standards for inspections described in NQA-1–1994 Basic Requirement 10, Supplement 10S-1, and Subparts 2.4, 2.5, and 2.8 to establish inspection requirements with the following:

- NQA-1–1994, Subpart 2.4, requires the use of the Institute of Electrical and Electronics Engineers (IEEE) Standard (Std) 336–1985, "IEEE Standard Installation, Inspection, and Testing Requirements for Power, Instrumentation, and Control Equipment at Nuclear Facilities." IEEE Std 336–1985 refers to IEEE 498–1985, "IEEE Standard Requirements for the Calibration and Control of Measuring and Test Equipment Used in Nuclear Facilities." Each of these standards uses the definition of safety systems equipment from IEEE Std 603–1980, "IEEE Standard Criteria for Safety Systems for Nuclear Power Generating Stations." IEEE Std 603–1980 defines "safety system" as:

  > Those systems (the reactor trip system, an engineered safety feature, or both, including all their auxiliary supporting features and other auxiliary feature) which provide a safety function. A safety system is comprised of more than one safety group of which any one safety group can provide the safety function.

  In the QAPD, the applicant provides information to satisfy the IEEE Standard 603–1980 definition of safety systems equipment to appropriately implement NQA-1–1994, Subpart 2.4. This definition applies only to equipment in the context of NQA-1–1994, Subpart 2.4. The staff evaluated the QAPD and determined that the use of the definition of safety systems equipment is acceptable and is consistent with the requirements in NQA-1–1994, Subpart 2.4.

- NQA-1–1994, Supplement 10S-1, Section 3.1, states that inspection personnel will not report to the immediate supervisor responsible for performing the work being inspected. As an alternative to this requirement, the QAPD proposes that QA inspectors will report to quality control management while performing these inspections. The staff determined that the use of this alternative is consistent with Section 17.5 of NUREG–0800, SRP Acceptance Criteria Item J.1. Therefore, the staff concluded that this alternative is acceptable.

The staff concluded that the applicant's QAPD follows the guidance of Section 17.5 of NUREG–0800, SRP Acceptance Criteria Item J, for inspections based on the following information. The QAPD establishes the necessary measures for implementing inspections to ensure that items, services, and activities affecting safety meet established requirements and conform to applicable documented specifications, instructions, procedures, and design documents. The inspection program establishes requirements for planning inspections, determining applicable acceptance criteria, setting the frequency of inspections, and identifying special tools needed to perform the inspection. Properly qualified personnel independent of those who performed or directly supervised the work are required to perform the inspections

17.5.4.11 Test Control

The staff determined that the Fermi 3 QAPD implements the guidance of Section 17.5 of NUREG–0800, SRP Acceptance Criteria Item K, for test control based on the information that follows. The QAPD establishes the necessary measures and governing provisions to

demonstrate that items subject to the provisions of the QAPD will perform satisfactorily in service, that the plant can be operated safely as designed, and that the operation of the plant as a whole is satisfactory. Additionally, in the QAPD, the applicant provides assurance to comply with the quality standards for test control described in NQA-1–1994, Basic Requirement 11 and Supplement 11S-1, to establish provisions for testing. Furthermore, the applicant also provides assurance in the QAPD to comply with the quality standards for software test control described in NQA-1–1994, Supplements 11S-2 and Subpart 2.7, to establish provisions to ensure that computer software used in applications affecting safety be prepared, documented, verified, tested, and used in a manner that obtains the expected outputs and maintains configuration control.

17.5.4.12 Control of Measuring and Test Equipment

The Fermi 3 QAPD provides assurances of compliance with QA standards for M&TE described in NQA-1–1994, Basic Requirement 12 and Supplement 12S-1 and establishes provisions that control the M&TE with the following clarification and exception:

- The QAPD clarifies that the out-of-calibration conditions described in paragraph 3.2 of Supplement 12S-1 of NQA-1–1994 refer to cases where the M&TE is found to be out of the required accuracy limits (i.e., out of tolerance) during calibration. The staff determined that this clarification for the out-of-calibration conditions is consistent with Supplement 12S-1. Therefore, the staff concluded that this clarification is acceptable.

- As an alternative to NQA-1–1994 Subpart 2.4, Section 7.2.1, "Calibration Labeling Requirements," the QAPD proposes that when it is impossible or impractical to mark equipment with required calibration information because of equipment size or configuration, the required calibration information will be documented and traceable to the equipment. The staff determined that this alternative is consistent with NRC staff guidance provided in Section 17.5 of NUREG–0800, SRP Acceptance Criteria Item L.3. Therefore, the staff concluded that this alternative is acceptable.

The staff evaluated and determined that the applicant's QAPD follows the guidance of Section 17.5 of NUREG–0800, SRP Acceptance Criteria Item L, for the control of measuring and test equipment (M&TE) based on the following. The QAPD establishes the necessary measures to control the calibration, maintenance, and use of the M&TE that provide information important to safe plant operations.

17.5.4.13 Handling, Storage, and Shipping

The staff determined that the Fermi 3 QAPD provides assurances of compliance with QA standards for handling, storage, and shipping described in NQA-1–1994, Basic Requirement 13 and Supplement 13S-1, and to establish provisions for handling, storage, and shipping. In the QAPD, the applicant also provides assurance to comply with the quality standards described in NQA-1–1994 Subpart 2.1, Subpart 2.2, Subpart 2.3, and Subpart 3.2, Appendix 2.1 during the construction and operational phases of the plant, as applicable, with the following clarifications and alternatives:

- NQA-1–1994 Subpart 2.1, Section 3.1 and 3.2 establish criteria for classifying items into cleanness classes and requirements for each class. The QAPD proposes establishing cleanness requirements on a case-by-case basis, consistent with the other provisions of Subpart 2.1. The QAPD clarifies that appropriate cleanliness controls for work on safety-

related equipment will 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. The staff concluded that this alternative and clarification are consistent with NEI 06–14A, Revision 7, and therefore acceptable.

- NQA-1–1994 Subpart 2.2, Section 2.2 establishes criteria for classifying items into protection levels. The QAPD proposes, instead of classifying items into protection levels during the operational phase, establishing 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. The QAPD clarifies that prior to installation or use, the items will be inspected and serviced as necessary to assure that no damage or deterioration exists which could affect their function. The staff concluded that this alternative and clarification are consistent with NEI 06–14A, Revision 7, and therefore acceptable.

- NQA-1–1994 Subpart 2.2, Section 6.6, states that the preparation of records must include information on personnel access to QA records. The QAPD establishes the necessary measures to document personnel authorized to access storage areas and record personnel access. However, the QAPD proposes not to consider these documents as QA records. As an alternative, the applicant will retain these documents in accordance with plant administrative controls. The staff determined that these records did not meet the classification of a QA record as defined in NQA-1–1994, Supplement 17S-1, Section 2.7. Therefore, the staff concluded that this alternative is acceptable.

- NQA-1–1994 Subpart 2.2, Section 7.1, refers to Subpart 2.15 for requirements related to handling items. The QAPD clarifies that the scope of Subpart 2.15 includes hoisting, rigging, and transporting items for nuclear power plants during construction. The staff determined that this clarification is acceptable because it distinguishes between the requirements for construction and operations.

- NQA-1–1994 Subpart 2.3, Section 2.3 requires the establishment of five zone designations for housekeeping cleanliness controls. The QAPD proposes, instead of the five-level zone designation, housekeeping activities are controlled based on consideration of what is necessary and appropriate for the activity involved. The QAPD clarifies the controls are implemented through procedures or instructions. The QAPD states that the factors considered in developing the procedures and instructions include cleanliness control, personnel safety, fire prevention and protection, radiation control and security. The staff concluded that this alternative and clarification are consistent with NEI 06–14A, Revision 7, and therefore acceptable.

- NQA-1–1994 Subpart 3.2, Appendix 2.1 establishes cleaning and cleanness control for fluid systems and associated components. The QAPD clarifies Section 3 precautions in accordance with RG 1.37. The QAPD states a suitable chloride stress-cracking inhibitor should be added to the fresh water used to flush systems containing austenitic stainless steels. The staff concluded that this clarification is consistent with NEI 06–14A, Revision 7, and therefore acceptable.

The staff evaluated and determined that the applicant's QAPD follows the guidance of Section 17.5 of NUREG–0800, SRP Acceptance Criteria Item M, for handling, storage, and shipping based on the following. The QAPD establishes the necessary measures to control the handling,

storage, packaging, shipping, cleaning, and preservation of items to prevent inadvertent damage or loss and to minimize deterioration.

17.5.4.14 Inspection, Test, and Operating Status

The staff evaluated and determined that the applicant's QAPD follows the guidance of Section 17.5 of NUREG–0800, SRP Acceptance Criteria Item N on the inspection, testing, and operating status of items subject to QA oversight based on the following information. The QAPD establishes the necessary measures to identify the inspection, testing, and operating status of items and components subject to the provisions of the QAPD to maintain personnel and reactor safety and to avoid the inadvertent operation of equipment. Additionally, in the QAPD, the applicant provides assurance to comply with the quality standards in this area described in NQA-1–1994, Basic Requirement 14, to establish control over/of activities related to their inspection, testing, and operating status.

17.5.4.15 Nonconforming Materials, Parts, or Components

The staff evaluated and determined that the applicant's QAPD follows the guidance of Section 17.5 of NUREG–0800, SRP Acceptance Criteria Item O for nonconforming materials, parts, or components based on the following information. The QAPD establishes the necessary measures to control items, including services that do not conform to specified requirements, to prevent inadvertent installation or use. Instances of nonconformance are evaluated for their impact on the operability of quality SSCs to ensure that the final condition does not adversely affect the safety, operation, or maintenance of the item or service. The results from evaluations of conditions adverse to quality are analyzed to identify quality trends that are documented and reported to upper management, in accordance with the applicable procedures. In addition, the QAPD provides for establishing the necessary measures to implement the requirements of 10 CFR Part 52, 10 CFR 50.55(e), and/or 10 CFR Part 21 during COL design and construction, and 10 CFR Part 21 during operations. Additionally, in the QAPD, the applicant provides assurance to comply with the quality standards for nonconforming materials, parts, or components described in NQA-1–1994, Basic Requirement 15 and Supplement 15S-1, to establish measures for nonconforming materials.

17.5.4.16 Corrective Action

The staff issued **RAI 17-5.2** requesting the applicant to clarify how the effectiveness of specific reporting programs referenced in the QAPD will be monitored. The applicant's response to **RAI 17.5-2** dated September 30, 2009 (ML092790561), clarifies how the applicant will implement and monitor reporting programs that are applicable to safety-related activities and services. The staff reviewed the applicant's response and proposed changes to Section 16.1 of the QAPD. The staff determined that the changes are consistent with NEI 06–14A, Revision 7, and are therefore acceptable. The staff verified that the applicant has incorporated the proposed changes in the Fermi 3 COL FSAR, Revision 3. Therefore, RAI 17.5-2 is closed.

The staff evaluated and determined that the applicant's QAPD follows the guidance of Section 17.5 of NUREG–0800, SRP Acceptance Criteria Item P, for corrective action programs based on the information that follows. The QAPD establishes the necessary measures to promptly identify, control, document, classify, and correct conditions adverse to quality. The QAPD requires personnel to identify known conditions adverse to quality. Reports of these conditions adverse to quality are analyzed to identify trends. Significant conditions adverse to quality are documented and reported to the responsible management. In the case of suppliers working on

safety-related activities or in similar situations, the applicant may delegate specific responsibility for the Corrective Action Program, but the applicant maintains responsibility for the program's effectiveness. In addition, the QAPD establishes the measures necessary for implementing a reporting program in accordance with the requirements of 10 CFR Part 52, 10 CFR 50.55(e), and/or 10 CFR Part 21 during COL design and construction, and 10 CFR Part 21 during operations. Additionally, in the QAPD, the applicant provides assurance to comply with the quality standards described in NQA-1–1994, Basic Requirement 16, to establish a Corrective Action Program.

17.5.4.17 Quality Assurance Records

The staff evaluated and determined that, in the Fermi 3 QAPD, the applicant provides assurance to comply with the quality standards for QA records described in NQA-1–1994, Basic Requirement 17 and Supplement 17S-1, establishing provisions for records with the following alternative:

- NQA-1–1994 Supplement 17S-1, Section 4.2(b), states that records must be firmly attached in binders or placed in folders or envelopes for storage in steel file cabinets or on shelving in containers. As an alternative to this requirement, the QAPD proposes that hard-copy records be stored in steel cabinets or on shelving in containers, except that methods other than binders, folders, or envelopes may be used to organize records for storage.

  The staff concluded that this alternative is consistent with NEI 06–14A, Revision 7, and therefore acceptable.

The staff evaluated and determined that the applicant’s QAPD follows the guidance of Section 17.5 of NUREG–0800, SRP Acceptance Criteria Item Q for QA records based on the following information. The QAPD establishes the necessary measures to ensure that sufficient records of items and activities affecting quality are generated, identified, retained, maintained, and able to be retrieved. Concerning the use of electronic records storage and retrieval systems, the applicant complies with the NRC guidance in GL 88–18, “Plant Record Storage on Optical Disks,” dated October 20, 1988; and will manage the storage of QA records consistent with Regulatory Issue Summary 2000-18, “Guidance on Managing Quality Assurance Records in Electronic Media,” dated October 23, 2000; and associated Nuclear Information and Records Management Association (NIRMA) Technical Guide (TG) 11-1998, "Authentication of Records and Media," TG 15-1998, "Management of Electronic Records," TG 16-1998, "Software Configuration Management and Quality Assurance," and TG 21-1998, "Electronic Records Protection and Restoration".

17.5.4.18 Quality Assurance Audits

The staff evaluated and determined that the applicant’s QAPD follows the guidance of Section 17.5 of NUREG–0800, SRP Acceptance Criteria Item R for QA audits based on the following information. The QAPD establishes the necessary measures to implement audits to verify that activities covered by the QAPD are performed in conformance with the documented requirements. The audits will be reviewed for effectiveness as part of the overall audit process. Additionally, the QAPD provides for the applicant to conduct periodic internal and external audits. Internal audits are conducted to determine the adequacy of programs and procedures being audited (by representative sampling) and whether they are meaningful and comply with

the overall QAPD. External audits determine the adequacy of supplier and contractor QA programs.

Furthermore, internal audits of organization and facility activities conducted before 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 conducted after placing the facility in operation are performed with a frequency commensurate with the safety significance of the program or activity, and in such a manner as to ensure that an audit of all applicable QA program elements is completed for each functional area within a period of 2 years. 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 on objective evidence that the functional area activities are being satisfactorily accomplished. However, the internal audit frequency interval should not exceed a maximum of 4 years.

Also the applicant ensures that audits are documented and audit results are reviewed. In accordance with the QAPD, the applicant will respond to all audit findings and initiate appropriate corrective actions. In addition, where corrective actions are indicated, the applicant will document the follow-up of applicable areas through inspections, review, repeat audits, or other appropriate means to verify the implementation of assigned corrective actions.

Additionally, in the QAPD, the applicant provides assurance to comply with the quality standards for QA audits described in NQA-1–1994, Basic Requirement 18 and Supplement 18S-1, to establish an independent audit program.

17.5.4.19 Non-safety-Related SSC Quality Assurance Control

17.5.4.19.1 Non-safety-Related SSCs – Significant Contributors to Plant Safety

The staff evaluated and determined that the applicant's QAPD follows the guidance of Section 17.5 of NUREG–0800, SRP Acceptance Criteria Item V.1, on controls related to non-safety-related SSCs based on the following information. The QAPD establishes program controls applied to non-safety-related SSCs that are significant contributors to plant safety and to which Appendix B does not apply. The QAPD applies specific controls to these items in a selected manner targeting the characteristics or critical attributes that render the SSCs significant contributors to plant safety, which are consistent with applicable sections in the QAPD.

17.5.4.19.2 Non-safety-Related SSCs Credited for Regulatory Events

The staff evaluated and determined that the applicant's QAPD follows the guidance of Section 17.5 of NUREG–0800, SRP Acceptance Criteria Item V.2, to establish the quality requirements for non-safety-related SSCs credited for regulatory events based on the following information. In the Fermi 3 QAPD, the applicant provides assurance to comply with the following regulatory guidance:

- The applicant shall implement quality provisions for the fire protection system in accordance with Regulatory Position 1.7, "Quality Assurance," in RG 1.189, "Fire Protection for Operating Nuclear Power Plants," as identified in FSAR Chapter 1.

- The applicant shall implement QA provisions for anticipated transient without scram (ATWS) equipment in accordance with QAPD, Part III, Section 1.

- The applicant shall implement quality provisions for station blackout (SBO) equipment in accordance with QAPD, Part III, Section 1.

17.5.4.20 Regulatory Commitments

To determine how the applicant meets all of the regulatory requirements, the staff identified regulatory commitment information requiring further clarification. The staff issued **RAI 17.5-23** requesting the applicant to clarify (1) the regulatory guide commitments in the QAPD, Part IV, "Regulatory Commitments"; (2) the evaluation of regulatory guide conformance in Fermi 3 COL FSAR Table 1.9-202; and (3) the regulatory commitment change process. The staff also requested additional details on the applicant's regulatory commitments in **RAI 17.5-24**, **RAI 17.5-25**, and **RAI 17.5-26**.

The applicant's response to the **RAI 17.5-23** dated September 2, 2010 (ML102570700), and the applicant's responses to **RAIs 17.5-24** through **17.5-26** dated November 19, 2010 (ML103260455), clarify the regulatory guide commitments; the evaluation of regulatory guide conformance; and the regulatory commitment change process. The applicant states that QAPD Part IV, "Regulatory Commitments," and Part V, "Additional Quality Assurance and Administrative Controls for the Plant Operational Phase," are updated to incorporate NEI 06–14 Revision 9 (which is issued as NEI 06–14A, Revision 7). The updated QAPD, Part IV, includes commitments to RG 1.8 (Revision 3) and RG 1.28 (Revision 3). The applicant also adds the verification that the QAPD incorporates the administrative controls in ANSI N18.7–1976/ANS-3.2 and RG 1.33 Revision 2, "Quality Assurance Program Requirements (Operations)," which are not included in NQA-1–1994, as an alternative to RG 1.33.

The staff reviewed the applicant's proposed changes to Fermi 3 COL FSAR Table 1.9-202 and the QAPD. The staff determined that the changes are consistent with NEI 06–14A, Revision 7, and are therefore acceptable. The staff verified that the applicant's proposed changes are included in the Fermi 3 COL FSAR, Revision 3; therefore, RAIs 17.5-23 through 26 are closed.

The staff evaluated and determined that the applicant's QAPD follows the guidance of SRP Section 17.5 of NUREG–0800, SRP Acceptance Criteria Item U, for describing regulatory commitments based on the following information. The QAPD establishes QA program commitments. In the QAPD, the applicant provides assurance of compliance with the following regulatory guides and other QA standards that are consistent with NEI 06–14A, Revision 7, to supplement and support the QAPD:

- RG 1.8, Revision 3, "Qualification and Training of Personnel for Nuclear Power Plants."

- RG 1.26, Revision 4, "Quality Group Classification and Standards for Water-, Steam-, and Radioactive-Waste-Containing Components of Nuclear Power Plants." In the QAPD, the applicant provides assurance of compliance with the regulatory positions of this guidance for site-specific SSCs not classified by the ESBWR.

- RG 1.28, Revision 3, "Quality Assurance Program Requirements (Design and Construction)."

- RG 1.29, Revision 4, “Seismic Design Classification.” In the QAPD, the applicant provides assurance of compliance with the regulatory positions of this guidance for site-specific SSCs not classified by the ESBWR.

- RG 1.37, Revision 1, “Quality Assurance Requirements for Cleaning of Fluid Systems and Associated Components of Water-Cooled Nuclear Power Plants.”

- RG 1.54, Revision 1, “Service Level I, II, and III Protective Coatings Applied to Nuclear Power Plants.”

- ASME NQA-1–1994, “Quality Assurance Requirements for Nuclear Facility Applications,” Parts I, II, and III.

- NIRMA technical guides as described in Section 17 of the QAPD.

17.5.4.21 Additional Quality Assurance and Administrative Controls for the Plant Operational Phase

The staff evaluated and determined that Part V, “Additional Quality Assurance and Administrative Controls for the Plant Operational Phase,” of the QAPD provides requirements for meeting the regulatory positions of RG 1.33 Revision 2, “Quality Assurance Program Requirements (Operations),” as an alternative to RG 1.33. In a letter dated November 19, 2010 (ML103260455), the applicant verifies that the Fermi 3 QAPD has incorporated the administrative controls in ANSI N18.7–1976/ANS-3.2 and RG 1.33 Revision 2, which are not included in NQA-1–1994. The applicant also provides an annotated version of NEI 06–14A Revision 7, Appendix 1, “Table of Where Regulatory Guide 1.33, Revision 2, and ANSI N18.7-1976 Requirements are Addressed by NQA-1–1994 Standards and/or the NEI 06–14 QAPD,” which documents this verification. The staff reviewed Part V of the QAPD and the annotated version of NEI 06–14A Revision 7, Appendix 1. The staff evaluated and determined that the alternative is consistent with the guidance in SRP Section 3.2.3.1, “Alternative for Commitment to RG 1.33,” (Reference 17.5-7) and is therefore acceptable.

Additionally, the staff verified a sample of the administrative controls included in NEI 06–14A Revision 7, Appendix 1, were incorporated in the Fermi 3 COL FSAR. The staff found the sample to be appropriately incorporated, and therefore accepted the applicant’s verification that all the required administrative controls had been incorporated in the Fermi 3 QAPD.

Based on the preceding information, the staff concluded that the applicant’s QAPD follows the guidance in NEI 06–14A, Revision 7, for describing additional QA and administrative controls during the operational phase and is therefore acceptable.

17.5.4.22 Staff Review of Quality Assurance Program

The staff reviewed and evaluated the applicant’s quality assurance program for attributes outside of the Fermi 3 QAPD, which is discussed above. This section provides the details of the staff review and includes:

- Resolution of COL Items

- Evaluation of supplemental information EF3 SUP 17.5-2

- Resolution of Fermi 3 QA implementation inspection violations
- Resolution of remaining staff quality assurance RAIs

COL Items

- EF3 COL 17.2-1-A QA Program for the Construction and Operations Phases
- EF3 COL 17.2-2-A QA Program for Design Activities
- EF3 COL 17.3-1-A Quality Assurance Program Document

The applicant provides the Fermi 3 QAPD to address and resolve ESBWR DCD COL Items 17.2-1-A, 17.2-2-A, and 17.3-1-A. Appendix 17AA of the Fermi 3 COL FSAR includes the Fermi 3 QAPD applicable to activities that adapt the design to plant-specific implementation, construction, and operations. The applicant states that the B&V 10 CFR 50 Appendix B/NQA-1 QA Program is used for safety-related COL application preparation activities and delegated quality functions. Initially, Detroit Edison controlled these activities contractually; then controlled them under the Nuclear Development Quality Assurance Program Document (ND QAPD) as it was implemented; and finally controlled them under the Fermi 3 QAPD (after September 18, 2008).

The staff evaluated and determined that the Fermi 3 QAPD meets NRC regulatory requirements by adhering to the guidance of SRP Section 17.5. SRP Section 17.5 provides a QA Program outline acceptable to the staff for preparation of DCD, early site permit (ESP), COL, and for applications.

Additionally, the staff concluded that the Fermi 3 QAPD appropriately addresses EF3 COL 17.2-1-A, EF3 COL 17.2-2-A, and EF3 COL 17.3.1-A.

Supplemental information

- EF3 SUP 17.5-2

This supplemental information (EF3 SUP 17.5-2) describes the QA Programs applied to the Fermi 3 COL application and support activities through late 2009. The applicant states that (1) Detroit Edison through contract, delegated the work of establishing and executing the QA Program to Black & Veatch (B&V) for COL application development-related activities, and secured the services of an Owner's Engineer (OE) to support owner-related activities; (2) COL application development commenced under the B&V 10 CFR 50 Appendix B/NQA-1 QA Program; (3) subsequent to contracting with B&V, Detroit Edison developed a Nuclear Development Quality Assurance Program Document (ND QAPD) and implementing procedures for those elements of the ND QAPD associated with the activities planned to be performed by Detroit Edison at the time (e.g., review of B&V COL application work product); (4) the Fermi 3 QAPD (FSAR Chapter 17, Appendix 17AA) superseded the ND QAPD and applies to activities after application to adapt the design to specific plant implementation, construction, and operations; and (5) Detroit Edison continued to delegate the execution of quality- and safety-related services associated with COL application revision and review support to the B&V 10 CFR 50 Appendix B/NQA-1 QA Program under the Fermi 3 QAPD.

RG 1.206, Regulatory Position C.I.17.5.3 states that the FSAR should describe how the applicant will retain responsibility for and maintain control over those portions of the QA Program that are delegated to other organizations. To clarify if the applicant meets the expectations of RG 1.206, the staff used a combination of licensing reviews (RAIs) and inspection activities. For licensing review, the staff issued **RAI 17.5-3** and **RAI 17.5-4** requesting the applicant to provide a description of how the applicant retains responsibility for and maintains control over those portions of the QA Program delegated to B&V. The RAIs also ask for a description of how the applicant will verify the effective implementation of delegated QA functions and the expected scope of work for each QAPD. For inspection, the staff conducted a limited scope inspection at the Detroit Edison facility in Detroit, Michigan, in August 2009. The purpose of the NRC inspection was to verify that the applicant had effectively implemented the QA processes and procedures related to the Fermi 3 COL FSAR.

Inspection report, initial Notice of Violation (NOV), and applicant responses

The staff documented the Fermi 3 inspection and three violations of regulatory requirements in Inspection Report Number 05200033/2009-201 on October 5, 2009 (ML092740064). In the applicant's inspection report response letter dated November 9, 2009 (ML093160318), the applicant contested all violations based on, in part, that (a) Detroit Edison was not an applicant until September 18, 2008, and (b) the cited requirements from the Fermi 3 QAPD and implementing procedures were not enforceable because they had not been accepted by the NRC and incorporated into a condition of a license.

Revised NOV and resolution of applicant responses

The staff reviewed the applicant response to the inspection report and, after consultation with the NRC Office of Enforcement (OE) and Office of the General Counsel (OGC), issued a revised NOV by letter on April 27, 2010 (ML100330687). The staff stated in the revised NOV letter that the applicant must demonstrate compliance with Appendix B in order to receive a COL, and the staff cannot issue a NOV for actions or omissions occurring before the applicant submitted the Fermi 3 COL application to the NRC. As the result of the OE and OGC consultation, the staff modified the initial NOV and issued the revised NOV which identified two violations of NRC requirements for activities performed after the date of the COL application (September 18, 2008). For activities occurring before the date of the COL application, the staff issued a series of RAIs (as outlined below) to evaluate the applicant's control over QA Program elements delegated to other organizations and compliance with Appendix B.

The first violation cited the applicant for failing to perform an evaluation of the B&V QA Program and to adequately document the basis for qualifying B&V to perform safety-related Fermi 3 COL activities. The second violation cited the applicant for failing to complete internal audits of applicable QA programmatic areas and for failing to document any trending evaluations conducted to identify and correct recurring conditions adverse to quality for Fermi 3 COL application activities, in accordance with applicable applicant procedures.

Resolution of inspection violations

The applicant responded to the first violation in a letter dated May 26, 2010 (ML101480046). In that letter, the applicant acknowledges the violation and outlines the corrective steps taken and results achieved to address the concerns noted in the violation. Specifically, the applicant (1) has initiated a plan to establish a more comprehensive vendor qualification review and acceptance program, (2) has conducted an audit of B&V that verified the effective

implementation of the B&V QA Program for Fermi 3 COL application activities, and (3) has confirmed that the safety-related activities performed by B&V before the B&V audit were completed in accordance with the 10 CFR 50 Appendix B requirements.

The staff accepted the applicant response to the second violation based on their original inspection report reply letter dated November 9, 2009 (ML093160318). In that letter, the applicant outlines the corrective steps and results achieved to address the concerns noted in the violation and assures that all COL application activities continue to be conducted at a level of quality necessary to support future safety-related activities. Specifically, the applicant (1) conducted an internal audit, (2) updated the applicable implementation procedures to provide for the review of potential Corrective Action Report (CAR) trends, and (3) documented a trend review of all ND CARs

The staff reviewed the applicant's letters, the reasons for the violations, the corrective steps implemented, and the results achieved. The staff concluded that (a) the letters were responsive to the revised NOV, (b) the implemented corrective actions are appropriate, and (c) the activities cited in the revised NOV are again consistent with the requirements of Appendix B to 10 CFR Part 50. The staff documented the acceptance of the applicant's responses to the revised NOV in a letter dated June 4, 2010 (ML101530596).

Resolution of staff RAIs

The staff received the applicant's responses to RAI 17.5-3 and RAI 17.5-4 in a letter dated September 30, 2009 (ML092790561). In these responses, the applicant separates the Fermi 3 project into three distinct periods and discusses the project for each period beginning with the inception of the project in 2007. The responses also provide additional information on the previous and expected scope of work for the various QAPDs.

The staff reviewed the applicant's letter and determined that the applicant's responses to RAI 17.5-3 and 17.5-4 led to a better understanding of the history of the Fermi 3 project, but did not fully address the four attributes in Regulatory Position C.I.17.5.3 of RG 1.206. As a result, the staff issued **RAI 17.5-19** requesting the applicant to describe how the four attributes in RG 1.206 Regulatory Position C.I.17.5.3 were met for the Fermi 3 project for each of the three distinct project periods. Additionally, to determine whether Fermi 3 safety-related activities are consistent with the requirements of Appendix B to 10 CFR Part 50, the staff issued **RAI 17.5-16, RAI 17.5-17,** and **RAI 17.5-18,** which requested detailed information regarding QA activities that were taking place before the Fermi 3 COL application submittal date of September 18, 2008.

The staff received the applicant's responses to RAI 17.5-16 through RAI 17.5-19 in a letter dated May 10, 2010 (ML101320254). In these responses, the applicant provides amplifying details associated with conduct and development of the safety-related COL application sections for the Fermi 3 project from its inception (January 2007 to the present).

In the response to RAI 17.5-16 through RAI 17.5-18, the applicant provides detailed information outlining QA support for Fermi 3 safety-related activities completed before the Fermi 3 COL application date and outlines proposed changes to the Fermi 3 FSAR. Specifically, the applicant provides (1) a list of safety-related activities and safety-related COL application sections; (2) dates of the activity or section creation; (3) the contracting entity conducting the activity/section creation and governing the QAPD; (4) the QA organization responsible for oversight of the activity/section creation; (5) dates and type of any specific contractor conducting the QA oversight activities (e.g., surveillance, document review, etc.); (6) contractor approval

date; (7) dates of applicant's review and approval; (8) dates and type of any specific applicant QA oversight activities (e.g., surveillance, document review, etc.); (9) background personnel information (including QA qualification types, type of QA support provided, and number of support hours) for both applicant and contractor organizations; and (10) a summary of the various versions of the Fermi 3 QAPD and the implementation procedures.

Additionally, in the response to RAI 17.5-19, the applicant provides detailed information outlining how the Fermi 3 project meets the four attributes in RG 1.206 Regulatory Position C.I.17.5.3 for each of the three distinct project periods. Specially, the applicant's response describes (1) how the applicant retains responsibility for and maintains control over those portions of the QA Program delegated to other organizations, (2) the responsible organization and the process for verifying that delegated QA functions are effectively implemented, (3) the major work interfaces for activities affecting QA, and (4) how clear and effective lines of communication between the applicant and the principal contractors are maintained to assure coordination and control of the QA Program.

The staff evaluated the applicant's RAI response letters, proposed changes to FSAR Table 1.9-203, "Conformance with the FSAR Content Guidance in RG 1.206," changes to FSAR Chapter 17.5, and the various Fermi 3 inspection-related documents mentioned above to determine whether the applicant has maintained control over QA Program elements delegated to other organizations and whether safety-related activities for the Fermi 3 project are in compliance with Appendix B. In the process of the evaluation, the staff determined that Fermi 3 project control (oversight) of QA Program elements delegated to other organizations (contracted activities) may affect compliance with Appendix B for safety-related activities. NRC quality program requirements differ based on when the activities occurred—before or after the date of the COL application.

Staff conclusions for pre-application activities

For activities occurring before the date of the COL application, the staff determined that the applicant had contractually delegated to B&V the work of establishing and executing a QA program satisfying the requirements of 10 CFR 50 Appendix B for COL application development. Furthermore, the staff determined that because B&V had an established 10 CFR 50 Appendix B and American Society of Mechanical Engineers (ASME) NQA-1 Program, internal oversight of safety-related activities was inherent in the B&V program. The staff also determined that the applicant was not required to implement a QA Program in compliance with the criterion of Appendix B. However, the applicant did establish applicable portions of an Appendix B program by creating the ND QAPD and by creating procedures for implementing those elements of the ND QAPD associated with the activities planned in support of the review and acceptance of the B&V COL application work product. Furthermore, the staff determined that the applicant was not required to provide specific quality oversight measures, although the ND QAPD and associated implementation procedures provided additional measures of oversight beyond the applicant's commercial contract oversight.

As a result, the staff concluded that the applicant has provided adequate assurance that the requirements of Appendix B have been met for safety-related activities supporting the Fermi 3 COL application, by appropriately contracting with B&V and by providing satisfactory commercial oversight of contracted activities for activities occurring before the date of the COL application.

Staff conclusions for post-application activities

For activities occurring after the date of the COL application, the staff determined that the applicant has continued to contractually delegate safety-related activities to B&V in support of the Fermi 3 project and these activities continued to be performed under the B&V QA Program. However, the applicant now controlled safety-related activities under the Fermi 3 QAPD. Details of the staff's review of the programmatic aspects of the Fermi 3 QAPD are included above (sections 17.5.4.1 through 17.5.4.21). Implementation of the Fermi 3 QAPD was verified by the staff by inspection.

After reviewing the applicant's response to RAI 17.5-16 through RAI 17.5-19, the proposed changes to the FSAR, and the various Fermi 3 inspection-related documents mentioned above, the staff concluded that for safety-related activities occurring after the date of the COL application, the applicant has provided adequate assurance that the Fermi 3 project has met the requirements of Appendix B by establishing and implementing the Fermi 3 QAPD. The staff also concluded that the applicant has provided satisfactory oversight of the contracted activities by implementing the applicable oversight components of their QA Program.

Furthermore, the staff evaluated and determined that the changes to the FSAR are acceptable and adequately resolve the above RAIs. The staff verified that the applicant's proposed changes are included in the COL application, Revision 3. Therefore, RAI 17.5-3, RAI 17.5-4, and RAIs 17.5-16 through 17.5-19 are closed.

17.5.5 *Post Combined License Activities*

There are no post COL activities related to this section.

17.5.6 *Conclusion*

NRC staff reviewed Section 17.5 of the Fermi 3 COL FSAR and the Fermi 3 QAPD. The staff's review of the Fermi 3 QAPD is based on the review guidance of SRP Section 17.5, and requirements of 10 CFR 52.79(a)(17);10 CFR 52.79(a)(25); 10 CFR 52.79(a)(27); and 10 CFR Part 50, Appendix B, "Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants".

NRC staff reviewed the Fermi 3 COL FSAR and the Fermi 3 QAPD and concluded the following:

- The QAPD provides adequate guidance for Detroit Edison to describe the authority and responsibility of management and supervisory personnel, performance/verification personnel, and self-assessment personnel.

- The QAPD provides adequate guidance for Detroit Edison to provide for organizations and persons to perform verification and self-assessment functions with the authority and independence to conduct their activities without undue influence from those directly responsible for costs and schedules.

- The QAPD provides adequate guidance for Detroit Edison to apply a QAPD to activities and items that are important to safety.

- The QAPD provides adequate guidance for Detroit Edison to establish controls that, when properly implemented, comply with 10 CFR Part 52 Appendix B to 10 CFR Part 50; 10 CFR Part 21; and 10 CFR 50.55(e); with the acceptance criteria associated with

Section 17.5 of NUREG-0800 and with the commitments to the applicable regulatory guidance.

The Detroit Edison Fermi 3 QAPD addresses EF3 COL 17.2-1-A, EF3 COL 17.2-2-A, and EF3 COL 17.3.1-A.

Based on the information provided by the applicant, the staff concluded that Section 17.5 of the Fermi 3 COL FSAR, Revision 3, and the Detroit Edison QAPD meet the requirements of Appendix B to 10 CFR Part 50; 10 CFR 52.79(a)(17); 10 CFR 52.79(a)(25); and 10 CFR 52.79(a)(27), and are therefore acceptable.

17.6 Maintenance Rule Program

17.6.1 *Introduction*

This section of the Fermi 3 COL FSAR, addresses the program for MR implementation based on the requirements of 10 CFR 52.79(a)(15) and 10 CFR 50.65 and on the guidance in RG 1.160, "Monitoring the Effectiveness of Maintenance at Nuclear Power Plants," and RG 1.182, "Assessing and Managing Risk Before Maintenance Activities at Nuclear Power Plants." RG 1.160 endorses Nuclear Management and Resource Council (NUMARC) 93–01, Revision 2, “Industry Guideline for Monitoring the Effectiveness of Maintenance at Nuclear Power Plants,” which provides one acceptable method for implementing the MR. RG 1.182, issued in May 2000, is a companion guide to RG 1.160 and provides guidance on implementing the provisions of 10 CFR 50.65(a)(4) by endorsing the February 22, 2000 revision to Section 11 of NUMARC 93–01, Revision 2 (ML101020415).

17.6.2 *Summary of Application*

In Fermi 3 COL FSAR Section 17.6, Revision 3, the applicant provides the following:

COL Items

- STD COL 17.4-2-A Maintenance Rule Program

  NEI 07-02A, “Generic FSAR Template Guidance for Maintenance Rule Program Description for Plants Licensed Under 10 CFR Part 52," (Reference 17.6-4) is incorporated by reference with the following supplemental information:

Supplemental Information

- STD SUP 17.6-1

  The text of the template provided in NEI 07-02A 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 17.6-2

  Reliability during the operations phase is assured through the implementation of operational programs, i.e., the MR Program (Section 17.6), the Quality Assurance Program (Section 17.5), the Inservice Inspection Program (Subsection 5.2.4, Section

6.6, and Subsection 3.8.1.7.3), and the Inservice Testing Program (Subsection 3.9.6, and Subsection 3.9.3.7.1(3)e), as well as the Technical Specifications Surveillance Requirements (Chapter 16), and maintenance programs.

- STD SUP 17.6-3

  In Paragraph 17.6.1.1.b, replace “(DRAP - see FSAR Section 17.Y)” with the following text “(See Section 17.4)”.

- STD SUP 17.6-4

  Condition monitoring of underground or inaccessible cables is incorporated into the MR Program. The cable condition monitoring program incorporates lessons learned from industry operating experience (e.g., GL 2007-01, NUREG/CR-7000), addresses regulatory guidance, and utilizes information from detailed design and procurement documents to determine the appropriate inspections, tests and monitoring criteria for underground and inaccessible cables within the scope of the maintenance rule (10 CFR 50.65).

17.6.3 *Regulatory Basis*

The regulatory basis of the information incorporated by reference is in NRC final SE, dated January 24, 2008 (ML073650081), for NEI 07–02A, Revision 0, “Generic FSAR Template Guidance for Maintenance Rule Program Description for Plants Licensed Under 10 CFR Part 52.” NEI 07–02A, Revision 0, provides a complete generic program description for use in developing the section of the COL FSAR associated with Section 17.6 ("Maintenance Rule") of NUREG–0800.

The regulatory basis for accepting the MR Program is in 10 CFR 50.65, “Requirements for monitoring the effectiveness of maintenance at nuclear power plants,” and in 10 CFR 52.79(a)(15), which requires a COL FSAR to contain a description of the program and its implementation for monitoring the effectiveness of maintenance necessary to meet the requirements of 10 CFR 50.65.

RG 1.206, Section C.I.17.6, "Description of the Applicant’s Program for Implementation of 10 CFR 50.65, the Maintenance Rule".

17.6.4 *Technical Evaluation*

The staff reviewed Section 17.6 of the Fermi 3 COL FSAR and checked the referenced Topical Report NEI 07-02A template guidance to ensure that the combination of the information in NEI 07-02A and the information in the COL FSAR appropriately represents the complete scope of information relating to this review topic. The staff's review confirmed that the information in the application and the information incorporated by reference address the required information relating to this MR Program.

The staff reviewed the information in the Fermi 3 COL FSAR as follows:

COL Items

- STD COL 17.4-2-A Maintenance Rule Program

NEI 07-02A, “Generic FSAR Template Guidance for Maintenance Rule Program Description for Plants Licensed Under 10 CFR Part 52," (Reference 17.6-4) is incorporated by reference with the following supplemental information:

Supplemental Information

- STD SUP 17.6-1

  The text of the template provided in NEI 07-02A 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 17.6-2

Reliability during the operations phase is assured through the implementation of operational programs, i.e., the MR Program (Section 17.6), the Quality Assurance Program (Section 17.5), the Inservice Inspection Program (Subsection 5.2.4, Section 6.6, and Subsection 3.8.1.7.3), and the Inservice Testing Program (Subsection 3.9.6, and Subsection 3.9.3.7.1(3)e), as well as the Technical Specifications Surveillance Requirements (Chapter 16), and maintenance programs.

- STD SUP 17.6-3

  In Paragraph 17.6.1.1.b, replace “(DRAP - see FSAR Section 17.Y)” with the following text “(See Section 17.4).”

- STD SUP 17.6-4

  Condition monitoring of underground or inaccessible cables is incorporated into the MR Program. The cable condition monitoring program incorporates lessons learned from industry operating experience (e.g., GL 2007-01, NUREG/CR-7000), addresses regulatory guidance, and utilizes information from detailed design and procurement documents to determine the appropriate inspections, tests and monitoring criteria for underground and inaccessible cables within the scope of the maintenance rule (10 CFR 50.65). The staff documented its evaluation of the cable monitoring program in SER Section 8.2.4.

NRC staff reviewed Fermi 3 COL FSAR Table 13.4-201, “Operational Programs Required by NRC Regulations” and determined that the applicant had identified the Maintenance Rule Program and its associated implementation milestone. The License Condition for the operational program implementation schedule, which includes the Maintenance Rule Program, is in Subsection 13.4.4, “Post Combined License Activities” of this SER.

The staff concludes that the information above, meets the requirements, and is thus acceptable.

17.6.5 *Post Combined License Activities*

There are no post COL activities related to this section.

17.6.6 *Conclusion*

NRC staff reviewed and approved NEI 07–02A for use as a generic FSAR template for the development of the MR Program. The staff reviewed the application and checked the referenced NEI 07–02A template guidance. The staff's review confirmed that the applicant has addressed the required information relating to the MR Program, and no outstanding information is expected to be addressed in the COL FSAR related to this section.

In addition, the staff compared the supplemental information in the COL application to the relevant NRC regulations, the guidance in Section 17.6 of NUREG–0800, and other NRC regulatory guides. Based on the discussion in Subsection 17.6.4 of this SER, the staff concluded that the relevant information in the Fermi 3 COL FSAR, Revision 3, is acceptable and meets the requirements of 10 CFR 52.79(a)(15) and 10 CFR 50.65.