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PART I INTRODUCTION

SECTION 1 GENERAL

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

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

1.1 Scope / Applicability

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

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

Safety-related systems, structures, and components, under the control of the QAPD, are identified by design documents. The technical aspects of these items are considered when determining program applicability, including, as appropriate, the item's design safety function. The QAPD may be applied to certain activities where regulations other than 10 CFR 50 and 10 CFR 52 establish QA requirements for activities within their scope.

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

PART II QAPD DETAILS

SECTION 1 ORGANIZATION

This Section describes the Detroit Edison Fermi 3 organizational structure, functional responsibilities, levels of authority and interfaces for establishing, executing, and verifying QAPD implementation. The organizational structure includes corporate support and onsite functions for Fermi 3 including interface responsibilities for multiple organizations performing quality-related functions. Implementing documents assign more specific responsibilities and duties, and define the organizational interfaces involved in conducting activities and duties within the scope of this QAPD. Management gives careful consideration to the timing, extent and effects of organizational structure changes.

Detroit Edison Fermi 3 management is responsible to size the Quality Assurance organization commensurate with the duties and responsibilities assigned.

The following sections describe the reporting relationships, functional responsibilities and authorities for organizations implementing and supporting the QA Program. The titles used herein are generic functional descriptions. Administrative documents are maintained to relate the generic titles to the Detroit Edison Fermi 3 organization.

1.1 Chief Nuclear Officer (CNO)

The CNO is responsible for all aspects of design, construction and operation of Detroit Edison's nuclear plants. The CNO is also responsible for all technical and administrative support activities provided by Detroit Edison and contractors. The CNO establishes the Fermi 3 quality assurance policy and provides guidance regarding its implementation. The CNO has delegated the responsibility and authority for approval of the QAPD to the executive in charge of the major enterprise projects (MEP) organization. The CNO has the authority to resolve disputes related to implementation of this QAPD for which resolution is not achieved at lower levels with the organization.

1.2 Technical Services and New Plant Development

The Fermi 3 MEP organization is responsible for implementing QAP requirements for activities involved with new nuclear plant engineering, design, procurement, construction, startup and operational development activities. These responsibilities include establishing appropriate interface controls with agents and contractors and the operating units. The Fermi 3 MEP organization is also responsible for implementing QAP requirements applicable to design engineering, technical support for programs such as fire protection, in-service inspection and testing, PRA, and configuration management and records managements activities. This organization is also responsible for surveillance and inspection of nuclear fuel suppliers and receipt inspection of nuclear fuel. The executive in charge of MEP reports to the CNO. The

organizational transition from the construction phase to the operating phase is addressed in the Fermi 3 FSAR, Chapter 13.

1.3 Site Executive

The site executive reports to the CNO and is responsible for the overall safe and efficient operation of the Fermi 3 plant, and for the implementation of quality assurance requirements in the areas specified by the operations QAPD.

For the purposes of this program, the description of the duties of the site executive and staff will be limited to those site activities that support Fermi 3 plant activities.

1.3.1 Technical Support and Services

The Fermi 3 technical support and services organizations are responsible for implementing the QAP requirements related to nuclear facility operation, including maintenance, refueling, and modification activities, and support functions such as training, procurement (supply chain), security and emergency preparedness. The transition from the construction to operations phases of the plant as well as a more detailed description of the operation organization is described in the Fermi 3 FSAR, Chapter 13. The Fermi 3 technical support and services organizations report to the site executive.

1.3.2 Operations and Maintenance

The operations and maintenance organization is responsible for implementing the QAP requirements for facility operation. The responsibilities include operating the facility in accordance with the license, regulatory requirements and the provision of the Technical Specifications. This organization is also responsible for the scheduling and conduct of maintenance and refueling activities, and performing modifications to the facility.

1.4 Quality Assurance

The Detroit Edison quality assurance (QA) organization is responsible for independently planning and performing activities to verify the development and effective implementation of the Fermi 3 QAPD including but not limited to engineering, document control, corrective action program and procurement that support new nuclear plant generation.

1.4.1 New Plant Oversight Manager

The new plant oversight manager is responsible for developing and maintaining the Fermi 3 QAPD, evaluating compliance to the programs, and managing QA resources. The new plant oversight manager is responsible for assuring compliance with regulatory requirements and procedures through audits and technical reviews; for monitoring organization processes to ensure conformance to commitments and licensing document requirements; for ensuring that vendors providing quality services, parts and materials to Fermi 3 are meeting the requirements of 10 CFR 50, Appendix B through NUPIC or Fermi 3 vendor audits.

The new plant oversight manager has sufficient independence from other department priorities to bring forward issues affecting safety and quality and makes judgments regarding quality in all areas necessary regarding Fermi 3 nuclear activities. The new plant oversight manager may make recommendations to management regarding improving the quality of work processes. If the new plant oversight manager disagrees with any actions taken by other Fermi 3 organizations and is unable to obtain resolution, the new plant oversight manager shall bring the matter to the attention of the executive in charge of the MEP organization who will determine the final disposition.

1.5 Agents and Contractors

The initial design of Fermi 3 for the COL application is the responsibility of GEH with a primary contract to Black & Veatch for site specific features.

For the construction phase of Fermi 3, Detroit Edison will establish an Engineering, Procurement and Construction (EPC) contract that identifies the Engineer and Constructor for the unit. This contract shall extend the quality program requirements described in this document to all applicable supplier, contractor and subcontractors. The executive in charge of the MEP organization is responsible for implementation of the QAP requirements of this document assigned to the EPC contractor and subcontractors.

1.6 Authority to Stop Work

The QA organization and inspection personnel have the authority, and the responsibility, to stop work in progress, which is not being done in accordance with approved procedures or where safety or SSC integrity may be jeopardized. This extends to off-site work performed by suppliers furnishing safety-related materials and services to Fermi 3.

1.7 Quality Assurance Organizational Independence

For the COL, independence shall be maintained between the organization or organizations performing the checking (quality assurance and control) functions and the organizations performing the functions. This provision is not applicable to design review/verification.

1.8 NQA-1-1994 Commitment

In establishing its organizational structure, Detroit Edison commits to compliance with NQA-1-1994, Basic Requirement 1 and Supplement 1S-1.

SECTION 2 QUALITY ASSURANCE PROGRAM

Fermi 3 has established the necessary measures and governing procedures to implement the QAP as described in the QAPD. Fermi 3 is committed to implementing the Quality Assurance Program in all aspects of work that are important to the safety of the nuclear plants as described and to the extent delineated in this QAPD. Further, Fermi 3 ensures through the systematic process described herein that its suppliers of safety-related equipment or services meet the applicable requirements of 10 CFR 50, Appendix B. This QAPD also applies to certain nonsafety-related structures, systems, components and activities to a degree consistent with their importance to safety. Senior management is regularly apprised of audit results evaluating the adequacy of implementation of the QAP through the audit functions described in the Audit Section of this QAPD.

The objective of the QAP is to assure that Fermi 3 nuclear generating plant is designed constructed and operated in accordance with governing regulations and license requirements. The program is based on the requirements of ASME NQA-1-1994, “Quality Assurance Requirements for Nuclear Facility Applications,” as further described in this document. The QAPD applies to those quality-related activities that involve the functions of safety-related structures, systems, and components (SSCs) associated with the design, licensing, construction and operation of new nuclear power plants as described in the COL Final Safety Analysis Report. Examples of COL safety-related activities include, but are not limited to, site specific engineering related to safety-related SSCs, site geotechnical investigations, site engineering analysis, seismic analysis, and meteorological analysis. A list or system identifying SSCs and activities to which this program applies is maintained at the appropriate facility. The Design Certification Document is used as the basis for this list. Cost and scheduling functions do not prevent proper implementation of the QAP.

Specific program controls are applied to non-safety related SSCs, for which 10CFR50, Appendix B is not applicable, that are significant contributors to plant safety. The specific program controls consistent with applicable sections of the QAPD are applied to those items in a selected manner, targeted at those characteristics or critical attributes that render the SSC a significant contributor to plant safety.

Delegated responsibilities may be performed under a supplier’s or principal contractor’s QA, Program provided that the supplier or principal contractor has been approved as a supplier in accordance with the QAP. Periodic audits and assessments of supplier QA programs are performed to assure compliance with the supplier’s or principal contractor’s QAPD and implementing procedures. In addition, routine interfaces with project personnel assure that quality expectations are met.

For the COL application, this QAPD applies to those Fermi 3 activities that can affect either directly or indirectly the safety-related site characteristics or analysis of those characteristics. In

addition, this QAPD applies to engineering activities that are used to characterize the site or analyze that characterization.

New nuclear plant construction will be the responsibility of Detroit Edison's Fermi 3 organization. Detailed engineering specifications and construction procedures will be developed to implement the QAPD and supplier QA programs prior to commencement of construction (COL) activities and subsequent operations. Examples of Limited Work Authorization (LWA) activities that could impact safety-related SSCs would include impacts of construction to existing facilities and for construction of new plants, the design interface between nonsafety-related and safety-related SSCs and the placement of seismically designed backfill.

In general, the program requirements specified herein are detailed in implementing procedures that are either Detroit Edison/Fermi 3 implementing procedures, or supplier implementing procedures governed by a supplier quality program.

A grace period of 90 days may be applied to provisions that are required to be performed on a periodic basis unless otherwise noted. Annual evaluations and audits that must be performed on a triennial basis are examples where the 90 day grace period could be applied. The grace period does not allow the "clock" for a particular activity to be reset forward. The "clock" for an activity is reset backwards by performing the activity early. Audits schedules are based on the month in which the audit starts.

2.1 Responsibilities

Personnel who work directly or indirectly for Fermi 3 are responsible for the achievement of acceptable quality in the work covered by this QAPD. This includes those activities delineated in Part I, Section 1.1 of this QAPD. Fermi 3 personnel performing verification activities are responsible for verifying the achievement of acceptable quality. Activities governed by the QAPD are performed as directed by documented instructions, procedures and drawings that are of a detail appropriate for the activity's complexity and effect on safety. Instructions, procedures and drawings specify quantitative or qualitative acceptance criteria as applicable or appropriate for the activity, and verification is against these criteria. Provisions are established to designate or identify the proper documents to be used in an activity, and to ascertain that such documents are being used. The QA organization is responsible to verify that processes and procedures comply with QAPD and other applicable requirements, that such processes or procedures are implemented, and that management appropriately ensures compliance.

2.2 Delegation of Work

Fermi 3 retains and exercises the responsibility for the scope and implementation of an effective QAP. Positions identified in the Organization Section of this QAPD may delegate all or part of the activities of planning, establishing, and implementing the program for which they are responsible to others, but retain the responsibility for the program's effectiveness. Decisions affecting safety

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

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

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

2.4 Periodic Review of the Quality Assurance Program

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

2.5 Issuance and Revision to Quality Assurance Program

Administrative control of the QAPD will be in accordance with 10 CFR 50.55(f) and 10 CFR 50.54(a), as appropriate. Changes to the QAPD are evaluated by the QA organization to ensure that such changes do not degrade previously approved quality assurance controls specified in the QAPD. This document shall be revised as appropriate to incorporate additional QA commitments that may be established during the COL application development process. New revisions to the document will be reviewed, at a minimum, by the Fermi 3 new plant oversight manager and approved by the executive in charge of the MEP organization.

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

2.6 Personnel Qualifications

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

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

The minimum qualifications of the Fermi 3 new plant oversight manager are to hold an engineering or related science degree and have a minimum of four years of related experience (3 of the 4 years must include 2 years of nuclear power plant experience and 1 year of supervisory or management experience). One year of experience performing quality verification activities. Special requirements shall include management and supervisory skills and experience or training in leadership, interpersonal communication, management responsibilities, motivation of personnel, problem analysis and decision making, and administrative policies and procedures. Individuals who do not possess these formal education and minimum experience requirements should not be eliminated automatically when other factors provide sufficient demonstration of their abilities. These other factors are evaluated on a case-by-case basis and approved and documented by senior management.

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

2.7 Independent Review

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

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

b. Reviews proposed tests and experiments not described in the FSAR. Changes to proposed tests and experiments not described in the FSAR that do require a technical specification change must be reviewed by the IRB prior to NRC submittal and implementation.

c. Reviews proposed technical specification changes and license amendments relating to nuclear safety prior to NRC submittal and implementation, except in those cases where the change is identical to a previously approved change.

d. Reviews violations, deviations, and reportable events that are required to be reported to the NRC in writing within 24 hours. This review includes the results of investigations and recommendations resulting from such investigations to prevent or reduce the probability of recurrence of the event.

e. Reviews any matter related to nuclear safety that is requested by the site executive, plant manager, or any IRB member,

f. Reviews corrective actions for significant conditions adverse to quality.

g. Reviews the adequacy of the audit program every 24 months.

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

1. IRB reviews are supplemented as follows:

   a. A qualified person, independent of the preparer, reviews proposed changes in the procedures as described in the FSAR prior to implementation of the change to determine if a technical specification change or NRC approval is required.

   b. Audits of selected changes in the procedures described in the FSAR are performed to verify that procedure reviews and revision controls are effectively implemented.

   c. Competent individual(s) or group(s) other than those who performed the original design but who may be from the same organization verify that changes to the facility do not result in a loss of adequate design or safety margins.

2. The results of IRB reviews of matters involving the safe operation of the facility are periodically independently reviewed. This review is intended to support management in identifying and resolving issues potentially affecting safe plant operation. This review supplements the existing corrective action programs and audits.

   a. The review is performed by a team consisting of personnel with experience and competence in the activities being reviewed, but independent from cost and schedule considerations and from the organizations responsible for those activities.

b. The review is supplemented by outside consultants or organizations as necessary to ensure the team has the requisite expertise and competence.

c. Results of the review are documented and reported to responsible management.

d. Management periodically consider issues that they determine warrant special attention, such as deficient plant programs, declining performance trends, employee concerns, or other issues related to safe plant operations and determine what issues warrant the review.

e. Management determines the scheduling and scope of review and the composition of the team performing the review.

2.8 NQA-1-1994 Commitment / Exceptions

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

- NQA-1-1994, Supplement 2S-1
  - Supplement 2S-1 will include use of the guidance provided in Appendix 2A-1 the same as if it were part of the Supplement. The following two alternatives may be applied to the implementation of this Supplement and Appendix:

    (1) In lieu of being certified as Level I, II, or III in accordance with NQA-1-1994, personnel performing independent quality verification inspections, examinations, measurements, or tests of material, products, or activities will be required to possess qualifications equal to or better than those required for performing the task being verified; and the verification is within the skills of these personnel and/or is addressed by procedures. These individuals will not be responsible for the planning of quality verification inspections and tests (i.e., establishing hold points and acceptance criteria in procedures, and determining who will be responsible for performing the inspections), evaluating inspection training programs, nor certifying inspection personnel.

    (2) A qualified engineer may be used to plan inspections, evaluate the capabilities of an inspector, or evaluate the training program for inspectors. For the purpose of these functions, a qualified engineer is one who has a baccalaureate in engineering in a discipline related to the inspection activity (such as electrical, mechanical, civil) and has a minimum of five years engineering work experience with at least two years of this experience related to nuclear facilities.

- NQA-1-1994, Supplement 2S-2
  - In lieu of Supplement 2S-2, for qualification of nondestructive examination personnel, Fermi 3 will follow the applicable standard cited in the version(s) of

Section III and Section XI of the ASME Boiler and Pressure Vessel Code approved by the NRC for use at Fermi 3.

- NQA-1-1994, Supplement 2S-3
  - The requirement that prospective Lead Auditors have participated in a minimum of five (5) audits in the previous three (3) years is replaced by the following, “The prospective lead auditor shall demonstrate his/her ability to properly implement the audit process, as implemented by Fermi 3, to effectively lead an audit team, and to effectively organize and report results, including participation in at least one nuclear audit within the year preceding the date of qualification.”

SECTION 3 DESIGN CONTROL

Fermi 3 has established and implements a process 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 this QAPD. The design process includes provisions to control design inputs, outputs, changes, interfaces, records and organizational interfaces within Fermi 3 and with suppliers. These provisions assure that design inputs (such as design bases and the performance, regulatory, quality, and quality verification requirements) are correctly translated into design outputs (such as analyses, specifications, drawings, procedures, and instructions) so that the final design output can be related to the design input in sufficient detail to permit verification. Design change processes and the division of responsibilities for design-related activities are detailed in Fermi 3 and supplier procedures. The design control program includes interface controls necessary to control the development, verification, approval, release, status, distribution and revision of design inputs and outputs. Design changes and disposition of nonconforming items as “use as is” or “repair” are reviewed and approved by the Fermi 3 design organization or by other organizations so authorized by Fermi 3.

Design documents are reviewed by individuals knowledgeable in QA to ensure the documents contain the necessary QA requirements.

3.1 Design Verification

Fermi 3 design processes provide for design verification to ensure that items and activities subject to the provisions of this QAPD are suitable for their intended application, consistent with their effect on safety. Design changes are subjected to these controls, which include verification measures commensurate with those applied to original plant design.

Design verifications are performed by competent individuals or groups other than those who performed the original design but who may be from the same organization. The verifier shall not have taken part in the selection of design inputs, the selection of design considerations, or the selection of a singular design approach, as applicable. This verification may be performed by the originator’s supervisor provided the supervisor did not specify a singular design approach, rule out certain design considerations, and did not establish the design inputs used in the design, or if the supervisor is the only individual in the organization competent to perform the verification. If the verification is performed by the originator’s supervisor, the justification of the need is documented and approved in advance by management.

The extent of the design verification required is a function of the importance to safety of the item under consideration, the complexity of the design, the degree of standardization, the state-of-the-art, and the similarity with previously proven designs. This includes design inputs, design outputs and design changes. Design verification procedures are established and implemented to assure that an appropriate verification method is used, the appropriate design

parameters to be verified are chosen, the acceptance criteria are identified, and the verification is satisfactorily accomplished and documented. Verification methods may include, but are not limited to, design reviews, alternative calculations and qualification testing. Testing used to verify the acceptability of a specific design feature demonstrates acceptable performance under conditions that simulate the most adverse design conditions expected for the item's intended use.

Fermi 3 normally completes design verification activities before the design outputs are used by other organizations for design work, and before they are used to support other activities such as procurement, manufacture or construction. When such timing cannot be achieved, the design verification is completed before relying on the item to perform its intended design or safety function.

3.2 Design Records

Fermi 3 maintains records sufficient to provide evidence that the design was properly accomplished. These records include the final design output and any revisions thereto, as well as record of the important design steps (e.g., calculations, analyses and computer programs) and the sources of input that support the final output.

Plant design drawings reflect the properly reviewed and approved configuration of the plant.

3.3 Computer Application and Digital Equipment Software

The QAPD shall govern the development, procurement, testing, maintenance, and use of computer application and digital equipment software when used in safety-related applications and designated nonsafety-related applications. Fermi 3 and suppliers shall be responsible for developing, approving, and issuing procedures, as necessary, to control the use of such computer application and digital equipment software. The procedures shall require that the application software be assigned a proper quality classification and that the associated quality requirements be consistent with this classification. Each application software and revision thereto shall be documented and approved by authorized personnel. This QAPD shall also be applicable to the administrative functions associated with the maintenance and security of computer hardware where such functions are considered essential in order to comply with other QAPD requirements such as QA records.

3.4 Setpoint Control

Instrument and equipment setpoints that could affect nuclear safety shall be controlled in accordance with written instructions. As a minimum, these procedures shall:

(1) Identify responsibilities and processes for reviewing, approving, and revising setpoints and setpoint changes originally supplied by the NSSS supplier, the A/E, and the plant's technical staff.

(2) Ensure that setpoints and setpoint changes are consistent with design and accident analysis requirements and assumptions.

(3) Provide for documentation of setpoints, including those determined operationally.

(4) Provide for access to necessary setpoint information for personnel who write or revise plant procedures, operate or maintain plant equipment, develop or revise design documents, or develop or revise accident analyses.

3.5 NQA-1-1994 Commitment

In establishing its program for design control and verification, Fermi 3 commits to compliance with NQA-1-1994, Basic Requirement 3, and Supplement 3S-1, the subsurface investigations requirements contained in Subpart 2.20 and the standards for computer software contained in Subpart 2.7.

SECTION 4 PROCUREMENT DOCUMENT CONTROL

Fermi 3 has established the necessary measures and governing procedures to assure that purchased items and services are subject to appropriate quality and technical requirements. Procurement document changes shall be subject to the same degree of control as utilized in the preparation of the original documents. These controls include provisions such that:

- Where original technical or quality assurance requirements cannot be determined, an engineering evaluation is conducted and documented by qualified staff to establish appropriate requirements and controls to assure that interfaces, interchangeability, safety, fit and function, as applicable, are not adversely affected or contrary to applicable regulatory requirements.
- Applicable technical, regulatory, administrative, quality and reporting requirements (such as specifications, codes, standards, tests, inspections, special processes, and 10 CFR 21) are invoked for procurement of items and services. 10 CFR 21 requirements for posting, evaluating and reporting will be followed and imposed on suppliers when applicable. Applicable design bases and other requirements necessary to assure adequate quality shall be included or referenced in documents for procurement of items and services. To the extent necessary, procurement documents shall require suppliers to have a documented QA program that is determined to meet the applicable requirements of 10 CFR 50, Appendix B, as appropriate to the circumstances of procurements (or the supplier may work under the licensees approved QA program).

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

4.1 NQA-1-1994 Commitment

In establishing controls for procurement, Fermi 3 commits to compliance with NQA-1-1994, Basic Requirement 4 and Supplement 4S-1, with the following clarifications and exceptions:

- NQA-1-1994, Supplement 4S-1
  - Section 2.3 of this Supplement 4S-1 includes a requirement that procurement documents require suppliers to have a documented QAP that implements NQA-1-1994, Part 1. In lieu of this requirement, Fermi 3 may require suppliers to have a documented supplier QAP that is determined to meet the applicable requirements of 10 CFR 50, Appendix B, as appropriate to the circumstances of the procurement.
  - With regard to service performed by a supplier, Fermi 3 procurement documents may allow the supplier to work under the Fermi 3 QAP, including implementing procedures, in lieu of the supplier having its own QAP.

- Section 3 of this supplement 4S-1 requires procurement documents to be reviewed prior to bid or award of contract. The quality assurance review of procurement documents is satisfied through review of the applicable procurement specification, including the technical and quality procurement requirements, prior to bid or award of contract. Procurement document changes (e.g., scope, technical or quality requirements) will also receive the quality assurance review.
- Procurement documents for Commercial Grade Items that will be procured by Fermi 3 for use as safety-related items shall contain technical and quality requirements such that the procured item can be appropriately dedicated.

SECTION 5 INSTRUCTIONS, PROCEDURES, AND DRAWINGS

Fermi 3 has established the necessary measures and governing procedures to ensure that activities affecting quality are prescribed by and performed in accordance with instructions, procedures or drawings of a type appropriate to the circumstances and which, where applicable, include quantitative or qualitative acceptance criteria to implement the QAP as described in the QAPD. Such documents are prepared and controlled according to Part II, SECTION 6 of this QAPD. In addition, means are provided for dissemination to the staff of instructions of both general and continuing applicability, as well as those of short-term applicability. Provisions are included for reviewing, updating, and canceling such procedures.

5.1 Procedure Adherence

The Fermi 3 policy is that procedures are followed, and the requirements for use of procedures have been established in administrative procedures. Where procedures cannot be followed as written, provisions are established for making changes in accordance with Part II, SECTION 6 of this QAPD. Requirements are established to identify the manner in which procedures are to be implemented, including identification of those tasks that require (1) the written procedure to be present and followed step-by-step while the task is being performed, (2) the user to have committed the procedure steps to memory, (3) verification of completion of significant steps, by initials or signatures or use of check-off lists. Procedures that are required to be present and referred to directly are those developed for extensive or complex jobs where reliance on memory cannot be trusted, tasks that are infrequently performed, and tasks where steps must be performed in a specified sequence.

In cases of emergency, personnel are authorized to depart from approved procedures when necessary to prevent injury to personnel or damage to the plant. Such departures are recorded describing the prevailing conditions and reasons for the action taken.

5.2 Procedure Content

The established measures address the applicable content of procedures as described in the introduction to Part II of NQA-1-1994. In addition, procedures governing tests, inspections, operational activities and maintenance will include as applicable, initial conditions and prerequisites for the performance of the activity.

5.3 NQA-1-1994 Commitment

In establishing procedural controls, Fermi 3 commits to compliance with NQA-1-1994, Basic Requirement 5.

SECTION 6 DOCUMENT CONTROL

Fermi 3 has established the necessary measures and governing procedures to control the preparation of, issuance of, and changes to documents that specify quality requirements or prescribe how activities affecting quality, including organizational interfaces, are controlled to assure that correct documents are being employed. The control system (including electronic systems used to make documents available) shall be documented and shall provide for (a) through (f) below:

(a) identification of documents to be controlled and their specified distribution;

(b) a method to identify the correct document (including revision) to be used and control of superseded documents;

(c) identification of assignment of responsibility for preparing, reviewing, approving, and issuing documents;

(d) review of documents for adequacy, completeness, and correctness prior to approval and issuance.

(e) a method for providing feedback from users to continually improve procedures and work instructions.

(f) coordinating and controlling interface documents and procedures.

The types of documents to be controlled include:

(a) drawings such as design, construction, installation, and as-built drawings;

(b) engineering calculations

(c) design specifications

(d) purchase orders and related documents

(e) vendor-supplied documents

(f) audit, surveillance, and quality verification/inspection procedures

(g) inspection and test reports

(h) instructions and procedures for activities covered by this QAPD including design, construction, installation, operating (including normal and emergency operations), maintenance, calibration, and routine testing

(i) Technical Specifications

(j) nonconformance reports and corrective action reports

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

6.1 Review and Approval of Documents

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

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

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

(a) following any modification to a system

(b) following an unusual incident, such as an accident, significant operator error, or equipment malfunction

(c) when procedure discrepancies are found

(d) prior to use if not used in the previous two years

(e) QA audits are conducted in accordance with Sections 18.1 of this QAPD

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

6.2 Changes to Documents

Changes to documents, other than those defined in implementing procedures as minor changes, shall be reviewed and approved by the same organizations that performed the original review and approval unless other organizations are specifically designated. The reviewing organization shall have access to pertinent background data or information upon which to base their approval. Where temporary procedure changes are necessary during the operations phase, changes that clearly do not change the intent of the approved procedure may be implemented provided they are approved by two members of the staff knowledgeable in the areas affected by the procedures. Minor changes to documents, such as inconsequential editorial corrections, do not require that the revised documents receive the same review and approval as the original documents. To avoid a possible omission of a required review, the type of minor changes that do

not require such a review and approval and the persons who can authorize such a classification shall be clearly delineated in implementing procedures.

6.3 NQA-1-1994 Commitment

In establishing provisions for document control, Fermi 3 commits to compliance with NQA-1-1994, Basic Requirement 6 and Supplement 6S-1.

SECTION 7 CONTROL OF PURCHASED MATERIAL, EQUIPMENT, AND SERVICES

Fermi 3 has established the necessary measures and governing procedures to control the procurement of items and services to assure conformance with specified requirements. Such control shall provide for the following as appropriate: source evaluation and selection, evaluation of objective evidence of quality furnished by the supplier, source inspection, audit, and examination of items or services.

7.1 Acceptance of Item or Service

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

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

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

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

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

7.2 NQA-1-1994 Commitment

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

- NQA-1-1994, Supplement 7S-1
  - Fermi 3 considers that other 10 CFR 50 licensees, Authorized Nuclear Inspection Agencies, National Institute of Standards and Technology, or other State and Federal agencies which may provide items or services to Fermi 3 plants are not required to be evaluated or audited.
  - When purchasing commercial grade calibration services from a calibration laboratory, procurement source evaluation and selection measures need not be performed provided each of the following conditions are met:

    (1) The purchase documents impose any additional technical and administrative requirements, as necessary, to comply with the Fermi 3 QA program and technical provisions. At a minimum, the purchase document shall require that the calibration certificate/report include identification of the laboratory equipment/standard used.

    (2) The purchase documents require reporting as-found calibration data when calibrated items are found to be out-of-tolerance.

    (3) A documented review of the supplier's accreditation shall be performed and shall include a verification of each of the following:

    - The calibration laboratory holds a domestic accreditation by the National Voluntary Laboratory Accreditation Program (NVLAP) or by the American Association for Laboratory Accreditation (A2LA) as recognized by NVLAP through the International Laboratory Accreditation Cooperation (ILAC) Mutual Recognition Arrangement (MRA).

  - The accreditation is based on ANS/ISO/IEC 17025.
  - The published scope of accreditation for the calibration laboratory covers the necessary measurement parameters, ranges, and uncertainties.

- For Section 8.1, Fermi 3 considers documents that may be stored in approved electronic media under Fermi 3 or vendor control and not physically located on the plant site but which are accessible from the respective nuclear facility site as meeting the NQA-1 requirement for documents to be available at the site. Following completion of the construction period, sufficient as-built documentation will be turned over to Fermi 3 to support operations. The Fermi 3 records management system will provide for timely retrieval of necessary records.
- In lieu of the requirements of Section 10, Commercial Grade Items, controls for commercial grade items and services are established in Fermi 3 documents using 10 CFR 21 and the guidance of EPRI NP-5652 as discussed in Generic Letter 89-02 and Generic Letter 91-05.
- For commercial grade items, special quality verification requirements are established and described in Fermi 3 documents to provide the necessary assurance an item will perform satisfactorily in service. The Fermi 3 documents address determining the critical characteristics that ensure an item is suitable for its intended use, technical evaluation of the item, receipt requirements, and quality evaluation of the item.
- Fermi 3 will also use other appropriate approved regulatory means and controls to support Fermi 3 commercial grade dedication activities. One example of this is NRC Regulatory Issue Summary 2002-22. Fermi 3 will assume 10 CFR 21 reporting responsibility for all items that Fermi 3 dedicates as safety-related.

SECTION 8 IDENTIFICATION AND CONTROL OF MATERIALS, PARTS, AND COMPONENTS

Fermi 3 has established the necessary measures and governing procedures to identify and control items to prevent the use of incorrect or defective items. This includes controls for consumable materials and items with limited shelf life. 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. Identification locations and methods are selected so as not to affect the function or quality of the item.

8.1 NQA-1-1994 Commitment

In establishing provisions for identification and control of items, Fermi 3 commits to compliance with NQA-1-1994, Basic Requirement 8 and Supplement 8S-1.

SECTION 9 CONTROL OF SPECIAL PROCESSES

Fermi 3 has established the necessary measures and governing procedures to assure that special processes that require interim process controls to assure quality, such as welding, heat treating, and nondestructive examination, are controlled. These provisions include assuring that special processes are accomplished by qualified personnel using qualified procedures and equipment. Personnel are qualified and special processes are performed in accordance with applicable codes, standards, specifications, criteria or other specially established requirements. Special processes are those where the results are highly dependent on the control of the process or the skill of the operator, or both, and for which the specified quality cannot be fully and readily determined by inspection or test of the final product.

9.1 NQA-1-1994 Commitment

In establishing measures for the control of special processes, Fermi 3 commits to compliance with NQA-1-1994, Basic Requirement 9 and Supplement 9S-1.

SECTION 10 INSPECTION

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

Inspection Program

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

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

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

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

Inspector Qualification

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

qualification programs are applied to individuals performing quality inspections regardless of the functional group where they are assigned.

10.1 NQA-1-1994 Commitment / Exceptions

- In establishing inspection requirements, Fermi 3 commits to compliance with NQA-1-1994, Basic Requirement 10, Supplement 10S-1 and Subpart 2.4, with the clarification that follows below. In addition, Fermi 3 commits to compliance with the requirements of Subparts 2.5 and 2.8 for establishing appropriate inspection requirements.
    - Subpart 2.4 commits Fermi 3 to IEEE 336-1985. IEEE 336-1985 refers to IEEE 498-1985. Both IEEE 336 -1985 and IEEE 498-1985 use the definition of “Safety Systems Equipment” from IEEE 603-1980. Fermi 3 commits to the definition of Safety Systems Equipment in IEEE 603-1980, but does not commit to the balance of that standard. This definition is only applicable to equipment in the context of Subpart 2.4.
    - An additional exception to Subpart 2.4 is contained in SECTION 12 of this QAPD.
    - Where inspections at the operating facility are performed by persons within the same organization (e.g. Maintenance group), Fermi 3 takes exception to the requirements of NQA-1-1994, Supplement 10S-1, Section 3.1, the inspectors report to the QA organization while performing those inspections.

SECTION 11 TEST CONTROL

Fermi 3 has established the necessary measures and governing procedures to demonstrate that items subject to the provisions of this QAPD will perform satisfactorily in service, that the plant can be operated safely and as designed, and that the coordinated operation of the plant as a whole is satisfactory. These programs include criteria for determining when testing is required, such as proof tests before installation, pre-operational tests, post-maintenance tests, post-modification tests, in-service tests, and operational tests (such as surveillance tests required by Technical Specifications), to demonstrate that performance of plant systems is in accordance with design. Programs also include provisions for establishing and adjusting test schedules and maintaining status for periodic or recurring tests. Tests are performed according to applicable procedures that include, consistent with the effect on safety, (1) instructions and prerequisites to perform the test, (2) use of proper test equipment, (3) acceptance criteria, and (4) mandatory verification points as necessary to confirm satisfactory test completion. Test results are documented and evaluated by the organization performing the test and reviewed by a responsible authority to assure that the test requirements have been satisfied. If acceptance criteria are not met, retesting is performed as needed to confirm acceptability following correction of the system or equipment deficiencies that caused the failure.

The initial start-up test program is planned and scheduled to permit safe fuel loading and start-up; to increase power in safe increments; and to perform major testing at specified power levels. If tests require the variation of operating parameters outside of their normal range, the limits within which such variation is permitted will be prescribed. The scope of the testing demonstrates, insofar as practicable, that the plant is capable of withstanding the design transients and accidents. For new facility construction, the suitability of facility operating procedures is checked to the maximum extent possible during the preoperational and initial start-up test programs.

The tests are performed and results documented in accordance with applicable technical and regulatory requirements including those described in the Technical Specifications and FSAR. The test programs ensure appropriate retention of test data in accordance with the records requirements of this QAPD. The personnel performing or evaluating tests are qualified in accordance with the requirements established in SECTION 2 of this QAPD.

11.1 NQA-1-1994 Commitment

In establishing provisions for testing, Fermi 3 commits to compliance with NQA-1-1994, Basic Requirement 11 and Supplement 11S-1.

11.2 NQA-1-1994 Commitment for Computer Program Testing

Fermi 3 establishes and implements provisions to assure that computer software used in applications affecting safety is prepared, documented, verified and tested, and used such that

the expected output is obtained and configuration control maintained. To this end, Fermi 3 commits to compliance with the requirements of NQA-1-1994, Supplement 11S-2 and Subpart 2.7 to establish the appropriate provisions.

SECTION 12 CONTROL OF MEASURING AND TEST EQUIPMENT

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

Installed Instrument and Control Devices

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

12.1 NQA-1-1994 Commitment / Exceptions

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

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

SECTION 13 HANDLING, STORAGE, AND SHIPPING

Fermi 3 has established the necessary measures and governing procedures to control the handling, storage, packaging, shipping, cleaning, and preservation of items to prevent inadvertent damage or loss, and to minimize deterioration. These provisions include specific procedures, when required to maintain acceptable quality of the items important to the safe operations of the plant. Items are appropriately marked and labeled during packaging, shipping, handling and storage to identify, maintain, and preserve the item's integrity and indicate the need for special controls. Special controls (such as containers, shock absorbers, accelerometers, inert gas atmospheres, specific moisture content levels and temperature levels) are provided when required to maintain acceptable quality.

Special or additional handling, storage, shipping, cleaning and preservation requirements are identified and implemented as specified in procurement documents and applicable procedures. Where special requirements are specified, the items and containers (where used) are suitably marked.

Special handling tools and equipment shall be used and controlled as necessary to ensure safe and adequate handling. Special handling tools and equipment shall be inspected and tested at specified time intervals and in accordance with procedures to verify that the tools and equipment are adequately maintained.

Operators of special handling and lifting equipment shall be experienced or trained in the use of the equipment. During the operational phase, Fermi 3 establishes and implements controls over hoisting, rigging and transport activities to the extent necessary to protect the integrity of the items involved, as well as potentially affected nearby structures and components. Where required, Fermi 3 complies with applicable hoisting, rigging and transportation regulations and codes.

13.1 Housekeeping

Housekeeping practices are established to account for conditions or environments that could affect the quality of structures, systems and components within the plant. This includes control of cleanness of facilities and materials, fire prevention and protection, disposal of combustible material and debris, control of access to work areas, protection of equipment, radioactive contamination control and storage of solid radioactive waste. Housekeeping practices help assure that only proper materials, equipment, processes and procedures are used and that the quality of items is not degraded. Necessary procedures or work instructions, such as for electrical bus and control center cleaning, cleaning of control consoles, and radioactive decontamination are developed and used.

13.2 NQA-1-1994 Commitment / Exceptions

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

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

SECTION 14 INSPECTION, TEST, AND OPERATING STATUS

Fermi 3 has established the necessary measures and governing procedures to identify the inspection, test, and operating status of items and components subject to the provisions of this QAPD in order to maintain personnel and reactor safety and avoid inadvertent operation of equipment. Where necessary to preclude inadvertent bypassing of inspections or tests, or to preclude inadvertent operation, these measures require the inspection, test or operating status be verified before release, fabrication, receipt, installation, test or use. These measures also establish the necessary authorities and controls for the application and removal of status indicators or labels.

In addition, temporary design changes (temporary modifications), such as temporary bypass lines, electrical jumpers and lifted wires, and temporary trip-point settings, are controlled by procedures that include requirements for appropriate installation and removal, independent/concurrent verifications and status tracking.

The administrative procedures also describe the measures taken to control altering the sequence of required tests, inspections, and other operations. The review and approval for these actions is subject to the same control as taken during the original review and approval of tests, inspections, and other operations.

14.1 NQA-1-1994 Commitment

In establishing measures for control of inspection, test and operating status, Fermi 3 commits to compliance with NQA-1-1994, Basic Requirement 14.

SECTION 15 NONCONFORMING MATERIALS, PARTS, OR COMPONENTS

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

15.1 Reporting Program

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

15.2 NQA-1-1994 Commitment

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

SECTION 16 CORRECTIVE ACTION

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

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

16.1 Reporting Program

Fermi 3 has in-place the necessary measures and governing procedures that implement a program to identify, evaluate and report defects and noncompliances in accordance with 10 CFR 50.55(e) and/or 10 CFR Part 21, as applicable. Such a reporting program applies to safety-related activities and services performed by Fermi 3 and/or Fermi 3 suppliers / sub-suppliers providing input to the COL application development.

16.2 NQA-1-1994 Commitment

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

SECTION 17 QUALITY ASSURANCE RECORDS

Fermi 3 shall establish the necessary measures and governing procedures to ensure that sufficient records of items and activities affecting quality are developed, reviewed, approved, issued, used, and revised to reflect completed work. The provisions of such procedures establish the scope of the records retention program for Fermi 3 and include requirements for records administration, including receipt, preservation, retention, storage, safekeeping, retrieval, access controls, user privileges, and final disposition.

17.1 Record Retention

Measures are required to be established that ensure that sufficient records of completed items and activities affecting quality are appropriately stored. Such records and their retention times are defined in appropriate procedures. In all cases where state, local, or other agencies have more restrictive requirements for record retention, those requirements will be met.

17.2 Electronic Records

When using electronic records storage and retrieval systems, Fermi 3 complies with NRC guidance in Generic Letter 88-18, “Plant Record Storage on Optical Disks.” Fermi 3 will manage the storage of QA Records in electronic media consistent with the intent of RIS 2000-18 and associated NIRMA Guidelines TG 11-1998, TG15-1998, TG16-1998, and TG21-1998.

17.3 NQA-1-1994 Commitment / Exceptions

In establishing provisions for records, Fermi 3 commits to compliance with NQA-1-1994, Basic Requirement 17 and Supplement 17S-1, with the following clarifications and exceptions:

- NQA-1-1994, Supplement 17S-1
  - Supplement 17S-1, section 4.2(b) requires records to be firmly attached in binders or placed in folders or envelopes for storage in steel file cabinets or on shelving in containers. For hard-copy records maintained by Fermi 3, the records are suitably stored in steel file cabinets or on shelving in containers, except that methods other than binders, folders or envelopes may be used to organize the records for storage.

SECTION 18 AUDITS

Fermi 3 has established the necessary measures and governing procedures to implement audits to verify that activities covered by this QAPD are performed in conformance with the requirements established. The audit programs are themselves reviewed for effectiveness as a part of the overall audit process.

18.1 Performance of Audits

Internal audits of selected aspects of licensing, design, construction phase and operating activities are performed with a frequency commensurate with safety significance and in a manner which assures that audits of safety-related activities are completed. During the early portions of Fermi 3 COL activities, audits will focus on areas including, but not limited to, site investigation, procurement, and corrective action. Functional areas of an organization's QA program for auditing include at a minimum verification of compliance and effectiveness of implementation of internal rules, procedures (e.g., operating, design, procurement, maintenance, modification, refueling, surveillance, test, security, radiation control procedures, and the emergency plan), Technical Specifications, regulations and license conditions, programs for training, retraining, qualification and performance of operating staff, corrective actions, and observation of performance of operating, refueling, maintenance and modification activities, including associated record keeping.

The audits are scheduled on a formal preplanned audit schedule. The audit system is reviewed periodically and revised as necessary to assure coverage commensurate with current and planned activities. Additional audits may be performed as deemed necessary by management. The scope of the audit is determined by the quality status and safety importance of the activities being performed. These audits are conducted by trained personnel not having direct responsibilities in the area being audited and in accordance with preplanned and approved audit plans or checklists, under the direction of a qualified lead auditor and the cognizance of the new plant oversight manager.

Fermi 3 is responsible for conducting periodic internal and external audits. Internal audits are conducted to determine the adequacy of programs and procedures (by representative sampling), and to determine if they are meaningful and comply with the overall QAPD. External audits determine the adequacy of supplier and contractor quality assurance program.

The results of each audit are reported in writing to the responsible executive, or designee, as appropriate. Additional internal distribution is made to other concerned management levels in accordance with approved procedures.

Management responds to all audit findings and initiates corrective action where indicated. Where corrective action measures are indicated, documented follow-up of applicable areas

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

Internal Audits

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

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

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

(1) The conformance of facility operation to provisions contained within the Technical Specifications and applicable license conditions including administrative controls

(2) The performance, training, and qualifications of the facility staff

(3) The performance of activities required by the QAPD to meet the criteria of 10 CFR 50, Appendix B

(4) The Fire Protection Program and implementing procedures. A fire protection equipment and program implementation inspection and audit utilizing either a qualified offsite licensed fire protection engineer or an outside qualified fire protection consultant.

(5) Other activities and documents considered appropriate by the CNO

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

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

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

18.2 NQA-1-1994 Commitment

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

PART III NONSAFETY-RELATED SSC QUALITY CONTROL

SECTION 1 NONSAFETY RELATED SSCS - SIGNIFICANT CONTRIBUTORS TO PLANT SAFETY

Specific program controls are applied to non-safety related SSCs, for which 10 CFR 50, Appendix B is not applicable, that are significant contributors to plant safety. The specific program controls consistent with applicable sections of the QAPD are applied to those items in a selected manner, targeted at those characteristics or critical attributes that render the SSC a significant contributor to plant safety.

The following clarify the applicability of the QA Program to the nonsafety-related SSCs and related activities, including the identification of exceptions to the QA Program described in Part II, Sections 1 through 18 taken for nonsafety-related SSCs.

1.1 Organization

The verification activities described in this part may be performed by the Fermi 3 line organization, the QA organization described in Part II is not required to perform these functions.

1.2 QA Program

Fermi 3 QA requirements for nonsafety-related SSCs are contained in this QAPD and appropriate procedures. Suppliers of these SSCs or related services describe the quality controls applied in appropriate procedures, a new or separate QA program is not required.

1.3 Design Control

Fermi 3 shall establish design control measures to ensure that the contractually established design requirements are included in the design. These measures ensure that applicable design inputs are included or correctly translated into the design documents, and deviations from those requirements are controlled. Design verification is provided through the normal supervisory review of the designer’s work.

1.4 Procurement Document Control

Procurement documents for items and services obtained by or for Fermi 3 shall include or reference documents describing applicable design bases, design requirements, and other requirements necessary to ensure component performance. The procurement documents are controlled to address deviations from the specified requirements.

1.5 Instructions, Procedures, and Drawings

Fermi 3 shall provide documents such as, but not limited to, written instructions, plant procedures, drawings, vendor technical manuals, and special instructions in work orders, to direct the performance of activities affecting quality. The method of instruction

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

1.6 Document Control

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

1.7 Control of Purchased Items and Services

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

1.8 Identification and Control of Purchased Items

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

1.9 Control of Special Processes

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

1.10 Inspection

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

1.11 Test Control

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

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

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

1.13 Handling, Storage, and Shipping

Fermi 3 shall establish measures to control the handling, storage, cleaning, packaging, shipping, and preservation of items to prevent damage or loss and to minimize deterioration. These measures include appropriate marking or labels, and identification of any special storage or handling requirements.

1.14 Inspection, Test, and Operating Status

Fermi 3 shall establish measures to identify items that have satisfactorily passed required tests and inspections and to indicate the status of inspection, test, and operability as appropriate.

1.15 Control of Nonconforming Items

Fermi 3 shall establish measures to identify and control items that do not conform to specified requirements to prevent their inadvertent installation or use.

1.16 Corrective Action

Fermi 3 shall establish measures to ensure that failures, malfunctions, deficiencies, deviations, defective components, and nonconformances are properly identified, reported, and corrected.

1.17 Records

Fermi 3 shall establish measures to ensure records are prepared and maintained to furnish evidence that the above requirements for design, procurement, document control, inspection, and test activities have been met.

1.18 Audits

Fermi 3 shall establish measures for line management to periodically review and document the adequacy of the process and take any necessary corrective action, audits independent of line management are not required. Line management is responsible for determining whether reviews conducted by line management or audits conducted by any organization independent of line management are appropriate. If performed, audits are conducted and documented to verify compliance with design and procurement documents, instructions, procedures, drawings, and inspection and test activities. Where the measures of this part (Part III) are implemented by the same programs, processes, or procedures as the comparable activities of Part II, the audits performed under the provisions of Part II may be used to satisfy the review requirements of this Section (Part III, Section 1.18).

SECTION 2 NONSAFETY-RELATED SSCS CREDITED FOR REGULATORY EVENTS

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

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

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

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

PART IV REGULATORY COMMITMENTS

NRC Regulatory Guides and Quality Assurance Standards

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

1.1 Regulatory Guides

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

Regulatory Guide 1.26 defines classification of systems and components.

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

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

Regulatory Guide 1.26 defines classification of systems and components.

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

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

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

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

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

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

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

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

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

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

Standards:

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

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

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

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