# CHAPTER 17: QUALITY ASSURANCE

To ensure that the design and construction of the Enrico Fermi Atomic Power Plant Unit 2 (Fermi 2) were in conformance with applicable regulatory requirements and the established design bases, the Detroit Edison Company (Edison), as plant owner, established and implemented a Quality Assurance (QA) program that satisfied the requirements of Appendix B to 10 CFR 50.

Edison, acting as its own Architect-Engineer (A-E), designed major portions of the plant and procured the nuclear steam supply system (NSSS) and the remainder of the plant structures, systems, and components. Edison was assisted in its design effort by the assignment of certain tasks to qualified engineering firms. Administration and control of site erection and construction contractors were assigned to a Construction Manager.

Edison imposed the applicable requirements of Appendix B to 10 CFR 50 on the NSSS vendor, on the engineering firms involved, on the vendors who supplied plant items, and on the contractors who erected and constructed plant structures, systems, and components.

The Edison QA program and its implementation during the plant design, procurement, construction, and testing phases are described in Section 17.1.

The Edison QA program for plant preoperational testing, startup, operation, maintenance, and modification is described in Section 17.2.

## 17.1 DETROIT EDISON QUALITY ASSURANCE DURING DESIGN AND CONSTRUCTION

Edison established a QA program to control the design, procurement, manufacturing, installation, construction, inspection, and testing of the safety-related structures, systems, and components of Fermi 2.

The organization and procedures that implemented the program are described herein. Also included is a brief description of the corporate organization.

### 17.1.1 Organization for Quality Assurance

#### 17.1.1.1 Corporate Organization

That part of Detroit Edison, down to the department level, having corporate responsibilities for quality-related activities for Fermi 2 is shown in Figure 17.1-1. More information on the corporate organization is located in Chapter 13 of the original FSAR.

The President, as chief operating officer, had overall responsibility for engineering, construction, operation, and maintenance of Edison's plants and for system development and interconnection. He was also responsible for establishing corporate policies, goals, and objectives on quality assurance matters. The management functions discussed below reported to him.

A Group Vice President was responsible for those Edison organizational units that provided for the planning, engineering, construction, operation, maintenance, and technical support of the company's power plants and electrical facilities. Vice Presidents of Planning and

Research, Operations, and Engineering and Construction reported to the Group Vice President.

The Vice President - Nuclear Operations, with overall responsibility for the operation, maintenance, and operational quality assurance for the Fermi 2 plant, reported to the President.

A Group Vice President responsible for administrative functions and the division organizations reported to the President.

The Manager - Quality Assurance, who was responsible for quality assurance at the corporate level, reported to the President.

17.1.1.2 Project Organization

The Vice President - Fermi 2 Project reported directly to the President. He had overall responsibility for the completion of construction and startup testing of the Fermi 2 project.

The Manager of the Project was responsible for the design, procurement, and construction activities for the project. He was supported by the Project Management Organization described herein.

The Manager - Startup, who was also Manager - Nuclear Operations, was responsible for the testing activities performed by the Startup Organization, including the checkout and initial operational testing, which was subject to the requirements of the QA program described in this section of the UFSAR.

Project functions were organized into five principal groupings, with the head of each group reporting to the Manager of the Project. The organizational structure of the Project Management Organization is shown in Figure 17.1-2. All groups except Project Engineering were located at the site. Project Engineering maintained an organizational unit at the site.

The Assistant Project Manager - Engineering had overall responsibility for administration and technical direction of the Project Engineering Organization.

The Technical Director provided technical direction to the Fermi 2 project and was assisted by a group of System Engineers and the Project Licensing Engineer in performing his duties, which included

a. Ensuring that safety reviews, safety analyses, and design reviews were conducted
b. Defining and controlling the technical scope of the project
c. Performing licensing activities
d. Ensuring compliance with technical regulatory requirements
e. Ensuring correctness of conceptual design documents and functional system descriptions
f. Ensuring adequacy of test criteria, procedures, and results
g. Identifying safety-related plant structures, systems, and components.

The Director - Project Design had overall responsibility for ensuring the adequacy of design performed by Project Engineering and various design contractors. Among his principal duties were the following:

a. Preparation, review, approval, and control of project design documents, including design instructions, system diagrams, drawings, specifications, design change notices, field modification requests, and purchase requisitions

b. Review and control of design documents produced by design contractors

c. Establishment of requirements and acceptance criteria for testing plant structures, systems, and components

d. Preparation of vendor document lists

e. Technical review of submitted vendor documents.

The Director - Project Engineering Assurance had responsibility for ensuring that the design activities of Project Engineering were adequately controlled and that the design achieved the plant quality objectives. Among his duties were:

a. Ensuring that design control procedures were prepared and implemented

b. Assisting Project QA in audits of Project Engineering activities and design contractors

c. Reviewing design documents for quality criteria

d. Ensuring that Project Engineering personnel were properly trained

e. Ensuring the adequacy of computer codes.

The Director - Project Field Engineering had overall responsibility for design activities performed at the site and for acting as the representative of Project Engineering. His principal duties included:

a. Reviewing and determining disposition of deviation disposition requests, design change requests, and field modification requests

b. Interpreting engineering specifications and drawings

c. Designing electrical conduit, cable trays, and supports

d. Designing small-bore process piping, instrument lines, and supports

e. Verifying or modifying design of large-bore supports

f. Reviewing contractor procedures for technical requirements

g. Providing as-built information for ASME Section III, Class 1, piping systems

h. Reviewing drawings prepared by contractors at the site

i. Interfacing with the Construction Manager's area superintendents through the area engineers.

Project Engineering was assisted by a number of A-Es and engineering consultants, namely:

Sargent & Lundy. Sargent & Lundy (S&L) was contracted to perform the civil, structural, and architectural design of the reactor building, prepare specifications for the primary containment vessel, perform certain electrical design tasks, and conduct piping system analyses. This work was performed as an extension of the Edison design effort and was subject to the same QA procedures and controls as those established for Edison's design efforts, including documented design reviews.

By a second contract, S&L had total responsibility for design of the residual heat removal (RHR) system. This included preparing design documents, procurement documents, and an approved bidders list; reviewing bids received by Edison; recommending contract awards; and reviewing contractor or vendor submittals (e.g., drawings, manufacturing and inspection plans, QA programs, and QA documentation) and recommending that they be approved or revised. S&L's QA program, as described in Topical Report SL-TR-1A, was implemented for this contract.

Stone & Webster. Stone & Webster (S&W) was contracted to assist Edison in the design area. A number of identified tasks were assigned, varying from total engineering responsibility, as in the case of the security system, to supplying personnel to work on Edison premises under direct Edison supervision. Work performed at the S&W offices was in accordance with applicable provisions of the S&W Standard Quality Assurance Program, 1-74A.

Giffels and Associates. Work performed by Giffels and Associates (G&A) was an extension of the Edison design effort. G&A received both design criteria and direction from Edison, and G&A work was subject to review and final approval by Edison.

NUS Corporation. NUS Corporation (NUS) acted as engineering consultant to perform calculations of pressure response in the annular space between the reactor pressure vessel (RPV) and sacrificial shield and for the redesign of the radwaste system. In addition, NUS provided environmental and licensing services for the project. Work was performed under the NUS QA program.

NUTECH. NUTECH acted as engineering consultant and was assigned three tasks: designing torus modifications; performing various tasks associated with the GE Mark I Owners Group; and reviewing the environmental qualifications of electrical equipment. Work was performed in accordance with the requirements of the NUTECH QA program.

The Site Manager, who was also an Assistant Project Manager, had overall responsibility at the site for directing construction activities and for completion and turnover of plant systems to the Startup Organization. Reporting to him were the Project Construction Superintendent; the Daniel International Project Manager; the Bechtel Project Manager; and the Director of System Completion.

The Project Construction Superintendent and his staff assisted the Site Manager in carrying out his duties involving construction activities.

Daniel International Corporation (DIC) was the Construction Manager for the project. The DIC Project Manager reported to the Project Management Organization through the Site

Manager. DIC was responsible for supervision of construction and for administration of the site installation and construction contracts awarded by Edison. In addition, DIC was responsible for construction engineering and implementation of the storage and preservation program for equipment, stored or installed.

Responsibilities of contractors at the site varied from having a complete QA program with an independent QA organization, to providing a work force and a limited-scope QA program.

Contractors providing their own inspection were structured organizationally so as to ensure the independence of inspectors from those directly responsible for the work.

If a contractor was required to provide an individual with responsibility for ensuring effective implementation of its corporate QA program, that individual reported to a responsible offsite corporate management level.

The Bechtel Power Corporation (Bechtel) was contracted as the Maintenance Contractor for the operational phase of the plant but was also assigned certain construction tasks. The Bechtel Project Manager on construction matters reported to the Site Manager. Bechtel's work was performed in accordance with Edison procedures or procedures developed by Bechtel and approved by Edison. Inspection of work was by Project QA.

The Director of Systems Completion was responsible for accomplishing turnover of systems from contractors to Edison, completing punchlist items for each turned-over system, coordinating the checkout and initial operations testing by the Startup Organization of Nuclear Operations, performing system hydros, and finally turning over systems to the Startup Organization for preoperational testing.

The Project Materials Director was the General Purchasing Department's representative on the Project Management Organization. He and his staff were responsible for all contracts, including purchasing and expediting activities for Project Management Organization procurements. Additionally, the Project Materials Director was responsible for purchase of materials for Nuclear Operations and operation of warehousing facilities at the site, including the receipt of materials and equipment purchased by Edison.

The Director of Project Controls was responsible for establishment and administration of project cost and scheduling programs. Activities of his department were not subject to requirements of the QA program.

The Project QA Director reported administratively to the Manager - Quality Assurance, but on project-related matters, he reported to the Manager of the Project. The Project QA Director was responsible for ensuring establishment and effective implementation of the project QA program by Edison and its suppliers and contractors and for coordinating project activities involving the interface with the Region III Office of the NRC. With two Assistant Project QA Directors, he provided administrative and technical direction to Project QA. The Project QA Director had stated authority to initiate action to stop work when significant quality problems existed and to bring about their resolution on a timely basis.

The organizational structure of Project QA is shown in Figure 17.1-3. The organization was located both at the site and at the Engineering Construction Center (ECT) at Troy, Michigan.

The Procurement QA Section of Project QA was responsible for activities associated with procurement of materials and equipment for the project. Included in its activities were the following:

a. Coordination on preparation of source surveillance plans with the General Purchasing Department, Inspection Division

b. Review of Edison procurement documents for items important to safety

c. Acceptance of supplier QA manuals

d. Audit of supplier QA programs

e. Maintenance of the approved suppliers list

f. Receiving inspections and supplier QA records review for procured items

g. Evaluation of vendors'/suppliers' performance

h. Participation in American Society of Mechanical Engineers surveys

i. Surveillance over material control practices in the warehouses.

The Construction QA Section of Project QA was responsible for auditing and surveillance of Edison and contractor activities at the site subject to requirements of the QA program for the project. Among its principal activities were the following:

a. Review and acceptance of contractor QA programs and procedures

b. Audit of onsite contractor QA programs

c. Audit of Edison and Construction Management groups at the site

d. Surveillance of contractor activities for compliance with procedures and quality requirements

e. Coordination of onsite NRC inspections by nonresident inspectors and preparation of responses to inspection reports

f. Reporting 50.55(e) deficiencies to the NRC and coordination and preparation of written reports

g. Review and approval of conditional releases

h. Preparation of management reports

i. Initiation of stop-work action when required

j. Preparation of contractor performance evaluations

k. Audit and surveillance of balance-of-plant construction activities

l. Investigation of significant quality problems and determination of corrective actions

m. Coordination of trend analyses.

The Finish Construction and Maintenance QA Section of Project QA was responsible for the surveillance and inspection of work performed by Bechtel, Plant Maintenance, and contractors who did not furnish inspection personnel. Among its principal activities were

a. Contractor maintenance and construction procedures review

b. Inspection planning

c. Development of inspection procedures and checklists

d. Maintenance and finish construction inspection and surveillance

e. Maintenance nondestructive-examination (NDE) activities

f. System completion and turnover monitoring and documentation review

g. Verification of completion of NRC commitments (hardware)

h. Review of project master punchlist

i. Verification of completion of punchlist items.

Engineering QA, located at Troy, Michigan, was responsible for monitoring and auditing activities associated with Project Engineering. Among its principal activities were the following:

a. Audit and surveillance of Project Engineering activities and support A-Es

b. Review of selected project procedures for offsite activities

c. Review of procurement specifications

d. Review of Edison-ECT procurement documents for QA Level I items

e. Preparation of responses to NRC bulletins, etc.

The Operational Assurance Section of Project QA was responsible for audit, surveillance, and inspection of activities and document review involving systems turned over to the Startup Organization for checkout and initial operations testing, including support activities performed by Nuclear Operations organizations. Among its principal activities were the following:

a. Inspection of startup tests

b. Surveillance of startup activities

c. Review of startup test procedures

d. Review of test results documentation

e. Coordination of nonconformance reports resulting from testing activities

f. Initiation of stop-work action when appropriate

g. Performance of trend analyses.

The Inspection Division of the General Purchasing Department provided qualified personnel to perform vendor surveillance, including inspection of hardware and release of materials and equipment for shipment. They also provided the expertise necessary to perform facilities surveys when potential bidders were being qualified. The participation of Inspection Division personnel in the project was coordinated through Project QA. Certain vendor surveillance and inspection was contracted to qualified outside organizations to augment Edison's vendor surveillance personnel.

Quality Control (QC) and technical specialists, such as metallurgists, NDE specialists, welding engineers, construction inspectors, and others from various Edison departments, were available to the project to participate in evaluation of manufacturing, installation, and construction problems and in audits of vendor and contractor activities. Efforts of QC and technical specialists in the latter role were coordinated through Project QA.

The Startup Organization was responsible for conducting testing of plant equipment and systems, beginning with the checkout and initial operations testing and proceeding through preoperational tests. Managerial and administrative controls for testing programs were prescribed in the Startup Manual.

Nuclear Production was responsible for the tagging of systems and components turned over to Edison jurisdiction from the contractors, for operating such systems and components, and for directing the maintenance and refurbishment programs.

Administration Services of Nuclear Operations was assigned responsibility by the Project Management Organization for the operation of the Document Control Center at the site and the QA records vault.

General Electric Company (GE), as the NSSS supplier, was a major participant in the Fermi 2 project. The official interfaces between the Edison and GE organizations were the GE project managers and Edison's Manager of the Project; at the working level, there were numerous interfaces. Review of designs was coordinated through the Assistant Project Manager - Engineering; audit and surveillance of GE's QA program and related activities were coordinated through the Director of Project QA; GE's involvement with licensing of the plant was coordinated by the Project Licensing Engineer; at the site, GE provided technical consultation and supervision in erection, testing, and operation of the NSSS through its Site Resident Manager and staff of technical and startup specialists and QC representatives. The Site Resident Manager and his staff coordinated their activities through the DIC Project Manager, the Edison Startup Engineer, and Project QA.

### 17.1.2 The Quality Assurance Program

In order to establish the highest degree of functional integrity and reliability for those structures, systems, and components that prevent or mitigate the consequences of postulated accidents that could cause undue risk to the health and safety of the public, Edison implemented a QA program, either directly or through its vendors and contractors, to meet the requirements of Appendix B to 10 CFR 50.

The objectives of this program were to ensure that:

a. Applicable regulatory criteria, codes, standards, and design bases were correctly translated into drawings, specifications, procedures, and instructions

b. Systems, components, and materials fabricated or tested in a manufacturer's facility conformed to drawings, specifications, procedures, and instructions

c. Structures, systems, and components constructed and tested at the Fermi site conformed to drawings, specifications, procedures, and instructions

d. Provisions were made for documenting and retaining information on quality-related activities performed on those structures, systems, and components

whose satisfactory performance was necessary to meet plant safety and availability objectives.

The QA program, as defined in the QA manual, contained established written policies that were intended to (1) aid in achieving the program objectives, and (2) satisfy the requirements of each of the 18 criteria of Appendix B to 10 CFR 50.

In accordance with these policies, written procedures were established and implemented during the design, procurement, manufacturing, installation, construction, inspection, and testing phases of the project to delineate:

a. The structure, responsibilities, and functions of the corporate organization relative to QA

b. The Project Management Organization established by Edison for effective management of the project

c. The project personnel responsible for certain QA functions, and to define the responsibilities, duties, and authorities of persons and organizations performing QA functions

d. The responsibilities and methods to ensure that plant design was appropriately controlled in process and that its adequacy was verified and documented

e. The responsibilities and methods for evaluation and dispositioning of changes, deviations, and incidents affecting the plant configurations as defined in the approved design documents to ensure that such changes, deviations, and incidents were adequately controlled and did not compromise the design intent

f. The responsibilities and methods for receiving, identifying, filing, distributing, maintaining, and reporting status of project documents to ensure that such documents were adequately controlled

g. The control of procurement documents to ensure that requirements referenced or included therein for material, equipment, and services procured by Edison, or by its vendors and contractors, conformed to the requirements of the procurement documents

h. The identification and control of material, parts, and components to ensure the use or installation of only correct and accepted items

i. That the activities affecting quality were prescribed by appropriate written instructions, procedures, or drawings and were accomplished in accordance with these documents

j. That special processes were performed in accordance with qualified procedures and only by qualified personnel

k. That a program for inspection of activities affecting quality was established and executed to verify conformance to the documented instructions, procedures, and drawings prescribing a given activity

l. That a documented test program was established and implemented to demonstrate that structures, systems, and components performed satisfactorily in service

m. The control, calibration, and periodic adjustment of tools, gages, instruments, and other measuring and test equipment used to verify conformance to established requirements

n. Controls for the handling, storage, shipping, cleaning, packaging, and preservation of material and equipment to ensure the maintenance of quality from source through installation or use

o. Requirements, methods, and responsibilities for indicating inspection, test, and operating status of the plant structures, systems, and components

p. Methods of controlling items, services, or activities that do not conform to requirements

q. Methods to ensure that appropriate and prompt corrective action was taken when conditions adverse to quality were identified

r. That sufficient records were provided and maintained to furnish documentary evidence of the quality of items and of those activities affecting quality

s. That a comprehensive system of planned and documented audits was carried out to verify compliance with all aspects of the QA program, and to assess the effectiveness of the program; and further, to require that management review the audit results and take necessary action to correct deficiencies.

Those structures, systems, and components covered by the Edison QA program and the programs of vendors and contractors were indicated in the column titled "Quality Assurance Requirements" in Table 3.2-1 of the original FSAR.

The major organizations participating in the project and involved in the QA program, including their designated functions, are discussed in Subsection 17.1.1 and are summarized in the following paragraphs.

Edison, as plant owner, established and implemented a QA program in accordance with the requirements of Appendix B to 10 CFR 50. Edison performed the major part of the plant design; the preparation of procurement documents; the procurement of systems, materials, equipment, and services exclusive of the scope of supply of the NSSS; source inspection; site receiving inspection; and the site QA and certain QC functions not delegated to contractors.

General Electric, the NSSS supplier, was responsible for the design, procurement, manufacture, inspection, and predelivery testing of the components within its scope of supply and for providing technical direction and instructions for the installation and testing of the NSSS components and systems.

Daniel International Corporation was responsible for construction management at the site.

General Electric Company and the A-Es established and implemented QA programs that satisfied the applicable requirements of Appendix B to 10 CFR 50 as defined in the procurement documents. These programs were reviewed and accepted by Edison. The

proper implementation of these programs was ensured by the performance of planned and periodic audits, with reaudits as necessary, by Edison Project QA.

Materials and components that were not supplied by GE were procured by Edison from qualified vendors. These vendors, with varying responsibilities for design, procurement, assembly, manufacture, inspection, and testing, established and implemented QA programs as required by the procurement documents. The QA programs of these vendors were reviewed and accepted by Edison QA, and their implementation was verified by planned and periodic audits.

Site installation and construction contractors established and implemented QA/QC programs commensurate with responsibilities and in accordance with contract requirements. The programs were reviewed and accepted by Edison QA.

The Fermi 2 QA policies, procedures, and instructions were contained in the project QA manual and in the project procedures manual.

The requirements and practices delineated in these manuals applied to the Project Management Organization, Project QA personnel, the Construction Management Organization, and Edison personnel or organizational groups who had any responsibilities for the project. Controlled copies of the manuals were distributed to these organizations and personnel.

Certain procedures in the manuals concerned work activities that were performed by others rather than Edison. In such cases, the requirements delineated in these procedures were imposed on the vendors, contractors, and A-Es performing the activities. The implementation of these requirements was verified by planned and periodic audits conducted by Project QA.

### 17.1.3 Design Control

Edison established and implemented procedures that delineated the design process from initiation through final approval and release, and determined that design activities were carried out in a planned and controlled manner, and that plant design adequacy was verified and documented.

The established procedures defined for participating design groups were:

a. Responsibilities, authority, reporting paths, and lines and methods of communication

b. Method of identifying and controlling design interfaces, including procedures for review, approval, release, distribution, and revision of documents involving interfaces.

The established procedures also delineated specific requirements and methods to ensure:

a. That applicable regulatory criteria and the design bases including codes and standards, as specified in the Preliminary Safety Analysis Report (PSAR), were correctly translated into design documents

b. That appropriate quality standards were specified and included in design documents. Quality standards include codes and industry standards, and must

include appropriate quantitative or qualitative acceptance criteria for determining that activities were satisfactorily accomplished

c. That selection and review for suitability of application of materials, parts, equipment, and processes that are essential to the safety-related functions of items were accomplished

d. That proper attention was given to constructibility, accessibility for inservice inspection, maintenance, repair, and delineation of acceptance criteria for inspections and tests

e. That adequacy of design was verified and documented

f. That adequacy of a design was verified or checked by the performance of design reviews, by the use of alternate or simplified calculational methods, or by the performance of a suitable testing program

g. That the verifying or checking process was performed by individuals or groups other than those who performed the original design

h. That, as a minimum, verifying or checking consisted of reviewing the design, spot checking the calculations or analyses, and assessing the results against the original design bases and functional requirements

i. That design verification documents identified the verification method utilized

j. That the method and scope of the design verification selected depended upon:

1. Importance and complexity of design
2. Degree of standardization
3. The state of the art
4. Similarity with previously proven designs.

k. That standardized or previously proven designs were carefully reviewed for applicability

l. That formal design reviews, normally consisting of a detailed check of the complete design, were performed. Personnel from Edison engineering, QA, operating, and construction departments or from a consulting engineering organization participated in these design reviews

m. That the adequacy and compatibility of the seismic design performed by vendors were evaluated by a third-party reviewer

n. That where necessary the adequacy of the final design was verified by documented qualification testing of the item or part under the most adverse design conditions

o. That design changes, including field changes, and deviations from design requirements were processed in accordance with established configuration control procedures

p. That design review documentation was filed and maintained with the controlled project QA records

q. That errors and deficiencies in the design process were determined, documented, and dispositioned, and that corrective actions were determined and implemented

r. That the applicable QA requirements of Appendix B to 10 CFR 50 were defined in the procurement documents for the NSSS vendor, and for the design tasks delegated to A-Es

s. That Project QA conducted planned and periodic audits of the Edison design process and of the design processes of others.

### 17.1.4 Configuration Control

Edison established and implemented procedures that delineated the responsibilities and methods for the evaluation and disposition of changes, deviations, and incidents affecting the plant configuration as defined in the approved design documents to ensure that such changes, deviations, and incidents were adequately controlled and did not compromise the design intent.

The established procedures contained provisions to ensure:

a. That Project Engineering was responsible for configuration control and for preparation of the required procedures

b. That changes, deviations, or incidents were classified as Type I or Type II; that configuration control procedures delineated the specific criteria for classifying and the responsibility for processing each type

c. That Type I was assigned to changes, deviations, or incidents that affected a characteristic or process that is essential to the safety-related function of an item. A listing of the systems, structures, and components that have a safety-related function was included in the configuration control procedures

d. That Type I was also assigned to changes, deviations, and incidents that do not involve a safety-related item but would

   1. Involve significant re-engineering of an approved design
   2. Affect a characteristic or process that is essential to the availability of the plant
   3. Have a major impact on plant cost or schedule
   4. Affect in-plant safety of operating personnel.

e. That Type II was assigned to changes, deviations, and incidents that did not meet the criteria for Type I

f. That coordination and implementation of the configuration control procedures at the construction site were the responsibility of Field Engineering

g. That changes to approved design documents initiated within Project Engineering were processed in accordance with the configuration control procedures

h. That changes to Edison-approved design documents by vendors, deviations accepted by vendors, and reported incidents occurring in vendor shops, of the Type I classification, were subject to review and concurrence by Project Engineering in accordance with the configuration control procedures

i. That the dispositioning of Type I changes, deviations, and incidents was by those who approved the original design, or by others to whom the responsibility was delegated; their approval was necessary before the disposition could be implemented. The evaluation and disposition were subject to the same requirements for control and documentation as specified for the original design in the design control procedures

j. That changes, deviations, and incidents occurring at the job site were referred to Field Engineering for review and action

k. That the evaluation and disposition of changes, deviations, and incidents were documented and the records retained in the project file.

### 17.1.5 Procurement Document Control

Edison, acting as its own Architect-Engineer, prepared the technical requirements for the majority of the procurement documents for materials, equipment, and services for the plant. Edison delegated this function to S&L for the RHR complex and the primary containment vessel.

Edison's established procedures were in effect to implement the preparation, review, approval, and control of procurement documents to ensure that the requirements included and/or referenced therein for material, equipment, and services procured for the plant agreed with the design intent and were sufficient to ensure adequate quality.

The established procedures defined the following responsibilities with respect to procurement documents:

a. The Director of Materials Control had the responsibility to coordinate the preparation and administration of procurement document control procedures

b. Project Engineering had the responsibility to prepare, or to delegate the preparation of, the technical content of procurement documents

c. Project QA had the responsibility to prepare, and ensure the inclusion of, the applicable QA requirement

d. Project QA had the responsibility to review the procurement documents to ensure compliance with the requirements of the procedures

e. Changes and/or deviations must have been approved by Project Engineering and Project QA.

The procedures included provisions to ensure that the procurement documents:

a. Were reviewed and that applicable regulatory requirements, design bases, quality requirements, and other requirements were included and/or referenced therein

b. Included requirements for vendors and contractors to provide QA programs in accordance with the identified requirements for QA and the elements of the program applicable to the items or services to be performed, for review and acceptance by Project QA, prior to the initiation of any activity

c. Included, as applicable, basic technical requirements including drawings, specifications, codes, and industrial standards with applicable revision data, test and inspection requirements, and special instructions and requirements such as for designing, fabrication, cleaning, erecting, packaging, handling, shipping, and field storage conditions

d. Included the right of access to vendor and contractor facilities and records for source inspection and audits by Edison and/or its agent

e. Provided for documentation requirements, identifying the documents to be prepared, submitted, maintained, stored, or made available for review, such as drawings, specifications, procedures, procurement documents, manufacturing and testing plans, inspection and test records, personnel and procedures qualifications records, and material, chemical, and physical test results

f. Included instructions for record retention and storage

g. Provided for extending applicable QA requirements to the vendor's or contractor's lower tier suppliers, and including Edison's or its agent's right of access to lower tier suppliers' facilities and records

h. Provided that changes and/or revisions were subject to the same reviews and approvals as the original document.

17.1.6 Instructions, Procedures, and Drawings

The Edison QA program contained provisions to ensure that activities affecting quality were prescribed by appropriate written instructions, procedures, or drawings and that the activities were accomplished in accordance with these documents.

Instructions, procedures, and/or drawings that prescribed quality-affecting activities delineated the method and sequence by which an activity was to be performed, and included appropriate quantitative or qualitative acceptance criteria for determining that the activity had been satisfactorily performed.

Contractors and/or vendors responsible for an activity were required to provide the necessary instructions, procedures, and/or drawings for the accomplishment of the activity.

These documents included as much detail as necessary to properly supplement information given in approved design documents in order that the quality-affecting activity was appropriately described.

The prepared documents were reviewed and approved by responsible personnel in the contractor's or vendor's organization, in accordance with QA program requirements, prior to performing the activity.

Edison may have required contractors or vendors to submit instructions, procedures, and/or drawings to Edison for review and concurrence prior to undertaking the activity. This

requirement was established on the basis of the importance of the activity to plant safety or availability.

Project QA performed audits to ensure that approved and appropriate instructions, procedures, and/or drawings were used by Edison personnel and its vendors and contractors in performing any activity that may have affected quality.

Design control, configuration control, and document control procedures were followed in the preparation, receipt, identification, review, approval, processing of changes and deviations, retention and filing, retrieval, distribution, and control of instructions, procedures, and/or drawings.

### 17.1.7 Document Control

Edison established and implemented procedures to delineate the responsibilities and methods for receiving, identifying, filing, distributing, maintaining, and reporting the status of project documents to determine that such documents were adequately controlled.

The established procedures contained provisions to ensure:

a. That Edison had the overall responsibilities for document control and was responsible for the preparation of the necessary procedures for such control

b. That Edison had the responsibility for site control of documents and was responsible for the preparation of the necessary procedures for such control

c. That Edison had the responsibility for control of documents that recorded evidence of performance of activities affecting quality

d. That an identification system was established and implemented to permit the identification of documents with plant structures, systems, and components. All technical documents were assigned an identification code within the system

e. That documents were received at a central location at both the Edison office and the job site, and that the receipt was recorded

f. That document filing systems were such as to permit ready retrieval of both current and historical documents by reference to the identification system; and that access to the files was controlled to provide security from fire, water, and other hazards

g. That documentation distribution was made in accordance with distribution lists and controlled so that copies of the latest approved documents were available at the place and time needed

h. That documents superseded by revised issues and preliminary or other status drawings not approved for construction or fabrication, were controlled to prevent their inadvertent use

i. That prior to general distribution or release of a document, it had an identification number assigned to it

j. That distribution was accompanied by a transmittal letter, a copy of which, together with a record copy of the document, was maintained in the file

k. That file maintenance procedures established the retention time and final disposition of project documents

l. That a system of document reporting was established and implemented to provide periodic information about the document file; and that this report contained the following information as a minimum:

1. Document control identification number
2. Status
3. Title or description of document
4. Originator of document
5. Status date
6. Originator's identification number
7. Originator's revision number.

m. That a master list of the current revision number of approved design documents was distributed periodically to the authorized distribution list

n. That document review and change and configuration controls were performed in accordance with the established procedures for design control, configuration control, and procurement document control

o. That documents controlled included, but were not limited to, design specifications; design instructions; design calculations; bills of materials; design, manufacturing, construction, and installation drawings; QA program manuals; QA procedures and instructions, checklists, and audits; procurement documents; manufacturing inspection and testing instructions; meeting minutes; accident reports; inspection reports; design change notices; deviation disposition reports; and correspondence

p. That the procurement documents delineated the requirements for document control that vendors and contractors must have met.

### 17.1.8 Control of Purchased Material, Equipment, and Services

Edison established and implemented procedures to ensure that safety-related material, equipment, and services procured by Edison, its vendors, and contractors conformed to the requirements of the approved procurement documents.

The established procedures contained provisions to ensure:

a. That quotations to furnish material, equipment, and services were solicited from qualified bidders

b. That criteria for qualification considered Edison's experience with the bidder, the bidder's reputation and experience in the field and in the nuclear industry, QA capability, and other facts, as appropriate

c. That qualification of bidders not on the approved bidders list was accomplished by a detailed evaluation that included assessment of the bidder's management

capability, financial resources, plant facilities, technical capability, and QA program. To assist in the evaluation process, Edison representatives, including QA personnel, visited the contractor's or vendor's facilities, when deemed necessary and appropriate

d. That bidders proposing to furnish items or services important to plant safety or availability submitted their QA manual or an adequate description of their QA plan and procedures for review and concurrence by Edison

e. That the procurement documents delineated the documentation required to be furnished by the successful bidders as objective evidence of compliance with the procurement document requirements

f. That bids that were not responsive to the QA requirements of the procurement documents were rejected

g. That a source surveillance program was established and that this program required that:

   1. Vendors furnished Edison with sufficient information concerning their manufacturing and inspection plans to permit Edison to plan and implement a source surveillance plan
   2. Project QA coordinated establishment of the surveillance plan with the Inspection Division of the General Purchasing Department
   3. The surveillance plan included inspection of items, witnessing of tests or processes, and audits of vendor's QA program
   4. Material or equipment requiring source inspection in accordance with the surveillance plan was inspected for conformance to the procurement requirements
   5. This inspection verified that quality documentation existed and was complete
   6. An item could not be accepted if it did not conform to the procurement document requirements
   7. An item could not be accepted if the quality documentation did not comply with the procurement document requirements.

h. That site-receiving inspection of items was performed upon receipt in accordance with a documented receiving inspection plan

i. That items that had been inspected and accepted at the source were inspected at the site for shipping damage, correctness of identification, and proper quality documentation

j. That items that had not been inspected at the source had their quality verified by the review of submitted test reports, inspection, user tests, or other means as identified in the inspection plan

k. That documentary evidence that safety-related items conformed to procurement document requirements was available at the site prior to use or installation of such items

l. That documentary evidence was sufficient to identify that specific requirements, such as codes, standards, and specifications were met by the procured item. (This requirement could be satisfied by having available at the site copies of the purchase specification, purchase order, and a written certification of conformance to procurement requirements)

m. That Project QA verified the validity of certifications of conformance by vendor audits.

17.1.9 Identification and Control of Material, Parts, and Components

Edison established and implemented procedures to identify and control safety-related materials, parts, and components to ensure the use or installation of only correct and accepted items.

The procedures contained provisions to ensure:

a. That the procurement documents required that equipment and/or components be identified at the source, prior to shipping, in accordance with the plant identification system

b. That the procurement documents specified when there was a requirement for traceability of materials, parts, or components to their quality documentation

c. That the procurement documents required vendors to identify items in accordance with the plant identification system

d. That the procurement documents stated that the verification of the correct identification of items and their records was a condition for acceptance of the item

e. That source and receiving inspection planning included the verification of the correct identification of items and their records

f. That physical identification was used to the greatest extent possible for relating an item at any stage of work to an applicable drawing, specification, and/or other pertinent technical document

g. That where physical identification was impractical, physical separation, procedural control, or other appropriate means were employed

h. That identification could be either on the item or on records traceable to the item, as appropriate

i. That consideration was given to ensure that the location and method of identification did not affect the function or quality of the item being identified

j. That contractors established and implemented onsite procedures for the identification and control of materials, parts, and components.

## 17.1.10 Control of Special Processes

Edison established and implemented procedures to determine that special processes were performed in accordance with qualified procedures by qualified personnel.

Special processes were defined as those metallurgical, chemical, and other processes where assurance of the process quality was dependent largely on the inherent skill of the operator and on the control of the process parameters, and could not be ensured by direct inspection of the work alone. These included, but were not limited to, welding, heat treating, cadwelding, chemical cleaning, and nondestructive examination.

The established procedures contained provisions to ensure:

a. That Project Engineering, or its agent, established the requirements for special processes and for identifying these processes in drawings, specifications, procedures, and/or instructions, in accordance with applicable codes, standards, specifications, criteria, regulatory requirements, and other special requirements

b. That contractors and vendors, onsite and in manufacturing and production facilities, performed special processes with the use of qualified personnel and procedures that were in accordance with the design documents and applicable codes and standards as defined in the procurement documents

c. That documentation on procedure and personnel qualification was submitted to Edison, or its agent, for review and concurrence when required by the procurement documents

d. That equipment and procedures utilized in the performance, control, and inspection of special processes were qualified prior to use in accordance with approved engineering documents and identified codes and standards

e. That controlled conditions for accomplishing a special process were maintained

f. That personnel performing a special process were qualified by proper training and/or testing prior to performing the task, and that they were certified if so required by code or other requirements

g. That documentation was maintained for currently qualified personnel, processes, or equipment in accordance with the requirements of the design documents, applicable codes and standards, and the procurement documents

h. That the necessary qualifications of personnel, procedures, or equipment were defined in applicable design and procurement documents for special processes not covered by existing codes or standards, or where quality requirements exceeded the requirements of established codes and standards

i. That qualification documentation was made available to Edison, or its agents, and to recognized representatives of regulatory agencies

j. That qualifications documentation was regularly reviewed and audited by Project QA to ensure that personnel qualifications had not expired and that equipment and processes were properly qualified.

### 17.1.11 Inspection

Edison established and executed a program for inspection activities affecting quality to verify conformance to the approved instructions, procedures, and drawings prescribing a given activity.

The established procedures contained provisions that required:

a. That inspection planning included the identification and responsibility for performing and documenting inspections

b. That inspections were performed by individuals other than those who performed an activity and who were appropriately qualified as prescribed by code, specification, or other applicable document

c. That the current status of the qualifications of those who performed inspections was documented and maintained

d. That audits of inspection equipment were conducted to ensure that the equipment was within calibration to perform inspections requiring such equipment

e. That examination, measurement, or tests of items processed were performed after each work operation if deemed necessary to ensure quality

f. That when samples were used to verify the acceptability of a group of items, the documented sampling procedure was based on recognized standard practices and provided justification for the selected procedure

g. That inspection planning prescribed the need for monitoring processing methods and personnel when inspection of the finished product was impractical or inconclusive; and that both inspection and process monitoring were utilized when necessary for adequate control

h. That vendors maintained integrated manufacturing and inspection plans that were reviewed by Edison to establish an agreed-upon set of notification points, including mandatory inspection hold points, beyond which work could not proceed without acceptance by Edison

i. That Edison's General Purchasing Department Inspection Division, or its agent, was responsible for the inspection of vendor's activities in accordance with an inspection plan developed as a part of an overall vendor surveillance program

j. That when mandatory inspection hold points, beyond which work must not proceed until signed off by Edison or its agent, were required, they were indicated in appropriate vendor documents before work was initiated

k. That site contractors having first-level inspection responsibility prepare their inspection plans for review by Project QA and that Project QA establish notification and mandatory inspection hold points beyond which work could not proceed until approved by Project QA

l. That site contractors who furnished only labor prepare limited-scope QA plans and that inspection of their work was performed by Project QA.

## 17.1.12 Test Control

Edison established and implemented a documented test program in accordance with written controlled procedures to demonstrate that safety-related structures, systems, and components performed satisfactorily in service.

The procedures contained provisions to ensure:

a. That tests were performed at vendor facilities or at the job site, in accordance with written test procedures that included or referenced the requirements and acceptance limits contained in applicable design documents

b. That Project Engineering and responsible vendors provided test instructions, requirements, and acceptance criteria

c. That vendors and contractors were required to perform acceptance tests, prototype qualification tests, proof tests prior to installation, and performance tests, when prescribed by applicable design and engineering documents referenced in the procurement documents

d. That when tests were conducted in vendor facilities, the vendor prepared the test procedure for review and approval by Edison

e. That the Startup Organization, or its designated agents, prepared the acceptance, preoperational, and startup testing procedures

f. That the test specification and/or procedure included criteria that had been reviewed and found acceptable by the Project QA Organization, and that the Project QA Organization audited the performance of the testing activity to ensure that the established criteria had been satisfied

g. That test procedures included provisions to ensure that:

    1. Prerequisites for the test had been met
    2. Adequate instrumentation was available and used
    3. Necessary monitoring was performed.

h. That test prerequisites included, but were not limited to:

    1. Appropriate checklists and test report forms
    2. Calibrated instrumentation
    3. Adequate and appropriate equipment
    4. Trained, licensed, and/or certified personnel, as appropriate
    5. Test equipment in good condition
    6. Items to be tested that were in good condition
    7. Suitable environmental conditions

8. Mandatory hold points, as appropriate, for witnessing of tests by Edison personnel, or its agents, for tests performed at vendor facilities and at the site
9. Provisions for data acquisition, evaluation, and storage.

i. That test results were documented, reviewed, and evaluated by responsible personnel to establish that the test requirements and acceptance criteria had been satisfied

j. That nonconformances, when they occurred, were documented and resolved by the responsible organization. The resolutions and corrective actions, if required, were approved by the appropriate Edison personnel and the approval documented

k. That the acceptance status of the component or system tested was identified in accordance with established procedures.

17.1.13 Control of Measuring and Test Equipment

Edison established and implemented procedures for the control, calibration, and periodic adjustment of tools, gages, instruments, and other measuring and test equipment used to verify conformance to established requirements.

The established procedures contained provisions to ensure:

a. That vendors and contractors implemented written procedures for the control and calibration of tools, measuring and test equipment, and devices used in the manufacture, fabrication, assembly, and testing of an item

b. That inspection, test, and work procedures included provisions to ensure that tools, gages, instruments, and other measuring and testing equipment and devices used in activities affecting quality were of the proper range, type, and accuracy to verify conformance to established requirements

c. That inspection, measuring, and test equipment was controlled, calibrated, adjusted, and maintained at prescribed intervals, or prior to use, with calibration performed against acceptable standards

d. That qualified contractors calibrated, adjusted, and maintained measuring and testing equipment and instrumentation used during installation, construction, and acceptance testing

e. That the calibration status, date of calibration, and recall date were displayed prominently on each device, wherever possible, or on records traceable to the device

f. That controls were provided that prevent the use, by unauthorized personnel, of calibrated tools, gages, instruments, and other measuring and test equipment

g. That records of the calibration history were maintained and included such information as:

1. Calibration procedures and standards

2. Identification
3. Calibration data
4. Calibration recall date
5. Instrument characteristics condition at calibration
6. Control measures to prevent unauthorized use.

h. That contractors provided and maintained the calibration status and records of tools, gages, and other measuring and testing devices used by them at the job site

i. That when discrepancies in measuring and test equipment were found, a nonconformance report was issued. The report must include complete identification of the equipment and description of the work or item on which the out-of-calibration equipment was used. The recommended corrective action must include the requirement for a review of the materials, fabricated items, and/or components previously checked with the out-of-calibration equipment to determine if applicable quality standards had been met.

17.1.14 Handling, Storage, and Shipping

Edison established and implemented written work instructions and inspection procedures to control the handling, storage, shipping, cleaning, packaging, and preservation of material and equipment, to establish the maintenance of quality from source through installation or use.

The established procedures contained provisions that ensured that:

a. Project Engineering established and included in procurement documents the requirements for handling, cleaning, preservation, packaging, shipping, and storage of materials and equipment in conjunction with vendors and the Construction Manager at the site

b. Instructions were included in the procurement documents concerning marking and labeling for packaging, shipment, and storage of items. Marking must have been sufficient to identify, maintain, and preserve the shipment, including the indication of the presence of special environments or the need for special control

c. Project QA personnel reviewed the procurement documents for the inclusion of instructions to vendors to provide information on handling, cleaning, preservation, marking and labeling, packaging, shipping, and storage of the product supplied

d. Vendors, in their shops, and contractors at the site, provided and controlled special handling tools and equipment necessary to maintain safe and adequate handling of critical, sensitive, perishable, or high-value items. Special handling tools and equipment, including but not limited to lifting devices, cables, hooks, slings, cranes, and their appurtenances such as brakes and safety devices, were inspected and tested by qualified personnel in accordance with

written procedures at specified times, to verify that the tools and equipment were adequately maintained and were suitable for the intended use

e. Edison Inspection Division personnel, or its agent, verified that the shipping requirements were met prior to release of an item for shipment

f. The Construction Manager prepared and implemented procedures at the job site in accordance with identified requirements for receiving, storing, and preserving materials and equipment

g. When necessary for particular items at the site, special coverings, special equipment, and special protective environments, such as inert gas, and specific moisture-content levels, were specified through Project Engineering, and were provided by the Construction Manager, and their existence and presence were verified by Project QA

h. Project QA established surveillance plans to assess and document onsite compliance with the handling, cleaning, preserving, and storing procedures

i. Nonconformances were reported, corrective actions specified, and monitoring performed to establish compliance with required corrective actions

j. Project QA reviewed the documentation furnished with items received at the site so that the contractor complied with the requirements noted therein.

17.1.15 Inspection, Test, and Operating Status

Edison procedures were in effect to delineate the requirements, methods, and responsibilities for indicating inspection, test, and operating status of the plant structures, systems, and components during manufacturing, installation, testing, and operation.

The established procedures included provisions to ensure that:

a. The inspection and test status of items in vendor shops or at the site was identified, where practicable, by use of stamps, tags, labels, or other suitable means and on records traceable to the item

b. Vendors implemented, in their shops, a system for indicating the inspection, test, and operating status of an item

c. Stamps, tags, labels, or other means of marking were in an approved format and that they conveyed by their color, shape, design, or other characteristic a uniform, unambiguous message

d. Nuclear Production established procedures for the control of test and operating status indicators including the authority for application and removal of tags, markings, labels, and stamps

e. The operating status of systems and components was clearly indicated by suitable means to prevent inadvertent operation and/or hazard to personnel

f. The status indication system did not allow bypassing of inspections, tests, and other critical operations.

### 17.1.16 Nonconforming Materials, Parts, Components, Services, and Activities

Edison established and implemented procedures to delineate the methods of controlling materials, parts, components, services, or activities that did not conform to established requirements.

The established procedures contained provisions to ensure that:

a. Vendors had in effect acceptance procedures for the control of nonconforming items that included delineation of the vendor's method of identification, segregation, documentation, and evaluation of nonconforming items

b. Edison approval was required on vendor dispositions that

   1. Accepted the nonconforming item "as is"

   2. Allowed rework or repair by a procedure that had not received prior approval by Edison.

c. Upon identification of a nonconformance, contractors at the site suspended the affected work until the nonconformance was evaluated if

   1. The continuance of the work would cover up the nonconformance and make its correction difficult

   2. The nonconformance was caused by the work procedure and continuing the procedure would increase the extent or severity of the nonconformance.

d. Nonconforming items, where practical, were segregated from acceptable material in a controlled access location; when this was not practicable, control of the nonconforming item was maintained by tagging, marking, or other clear means of identification

e. Reports of nonconforming items, services, or activities were dispositioned in accordance with configuration control procedures

f. Occurrence of nonconforming items, services, or activities was reported to affected organizations

g. Nonconforming items were repaired or reworked in accordance with documented procedures, and that, before the acceptance of such repaired or reworked items, they were reinspected in accordance with documented applicable inspection plans and procedures

h. Nonconforming items that were rejected were removed from the work location in vendor shops, and from the job location during construction

i. Documentation for items that had been repaired, reworked, or accepted "as is" described the change, waiver, or nonconformance that had been accepted and denoted the as-built condition

j. Reports of onsite nonconforming items or services were filed in the Project QA office, with copies forwarded to Field Engineering for disposition.

### 17.1.17 Corrective Action

Edison established and implemented written procedures to ensure that appropriate and prompt corrective action was taken when conditions adverse to quality were identified.

The established procedures contained provisions to ensure that:

a. QA and QC personnel promptly identified and reported on conditions adverse to quality, such as failures, malfunctions, deficiencies, nonconformances, defective material and/or equipment, and procedural nonconformances

b. The reports on conditions adverse to quality were submitted to Field Engineering for action in accordance with established configuration control procedures

c. Corrective action was taken as soon as practical

d. The technical aspects of conditions adverse to quality were resolved by Project Engineering

e. Project Engineering concurred with or rejected solutions provided by vendors or site contractors

f. Project QA determined the cause of significant conditions adverse to quality and that corrective action was taken to preclude repetition

g. Nonconformances to approved project procedures and instructions were reported to Project QA for action

h. Responsible management of the affected vendor or contractor was promptly notified and made aware of the problem and the required corrective action

i. When conditions adverse to quality existed at the site that required prompt action, and the required corrective measures were not taken by responsible supervision when properly notified, the Project QA Director exercised stop-work authority in the affected area

j. Identification of significant conditions adverse to quality, the cause of the condition, and the corrective action taken were documented and reported to appropriate levels of management by Project QA.

### 17.1.18 Quality Assurance Records

Edison established and implemented requirements that ensured that sufficient records were provided and maintained to furnish documentary evidence of the quality of items and of those activities affecting quality.

Established procedures contained provisions that ensured that:

a. The Document Control Center had the overall responsibility for receiving, filing, and maintaining QA records during and until completion of construction

b. Project QA was responsible for reviewing QA records generated or received at the site

c. QA record requirements, including type and content, were identified in procurement documents

d. Requirements and responsibilities for record transmittal, retention, and maintenance subsequent to the completion of construction were established and documented by written procedures

e. Required QA records included as-built drawings, operating logs, and the results of reviews, inspections, tests, audits, monitoring of work performances, nonconformances, corrective action reports, and materials analyses

f. QA records contained data on the qualification of personnel, procedures, and equipment involved in the quality-related activity

g. The inspection and test reports included identification of the inspector or data recorder, the type of observation made, the test or measurement equipment used, the results, their acceptability, and the disposition of any deviations found

h. Records were identifiable as to structure, system, component, and/or materials, were retrievable, and were secured against loss by theft, fire, or deterioration

i. Vendors or contractors who retained QA records must have met Edison's requirements on retention, and that the records were made available for use by Edison, or its agent, on demand

j. Procurement documents included the requirement that vendors or contractors notify Edison when they intended to dispose of their retained QA records so that Edison could be permitted to take possession of the records

k. Edison was responsible for all QA records, whether retained by Edison or its vendors or contractors

l. Permanent records, such as as-built drawings, and other records required for the operation, maintenance, inservice inspection, or plant maintenance, were retained and maintained for the life of the plant

m. Planned and periodic audits were conducted by Edison and its vendors and contractors to ensure compliance with the requirements for record maintenance and retention.

### 17.1.19 Audits

Edison established a comprehensive system of planned and documented audits to verify compliance with all aspects of the Project QA program and to assess its effectiveness. Responsible management had the responsibility to review the audit results and to take necessary action to correct deficiencies.

Audits of the program were performed to:

a. Provide an objective evaluation of compliance with established requirements, methods, and procedures

b. Assess progress in assigned tasks

c. Determine the adequacy of QA program performance

d. Verify the implementation of recommended corrective action.

The Project QA Director was responsible for ensuring that periodic audits of the project QA program or any portion of it, as deemed necessary, were conducted and the findings reported to responsible management.

Project QA conducted planned and periodic audits of the QA programs of vendors and contractors and reported findings to the Manager of the Project, the Project QA Director, and responsible management of the area audited.

Audits were performed in accordance with written procedures and/or checklists by appropriately trained personnel having no direct responsibilities in the area audited. Audits were scheduled and conducted on the basis of the status and safety importance of the activity being performed.

Audits included an objective evaluation of:

a. Quality assurance practices, procedures, and instructions

b. The effectiveness of program implementation

c. Conformance to policy directives.

Audits also included an evaluation of:

a. Work areas

b. Activities

c. Processes

d. Items

e. Documents and records, and their storage and retrievability.

Audits were initiated early enough to ensure effective implementation of QA programs at the beginning of design, procurement, manufacturing, installation, construction, and testing activities.

Audits were scheduled when one or more of the following conditions existed:

a. When it was necessary to determine the acceptability of a vendor's or contractor's QA program prior to award of a purchase order or contract

b. When, after the award of a purchase order or contract, it was appropriate to determine that a vendor or contractor was implementing his QA program

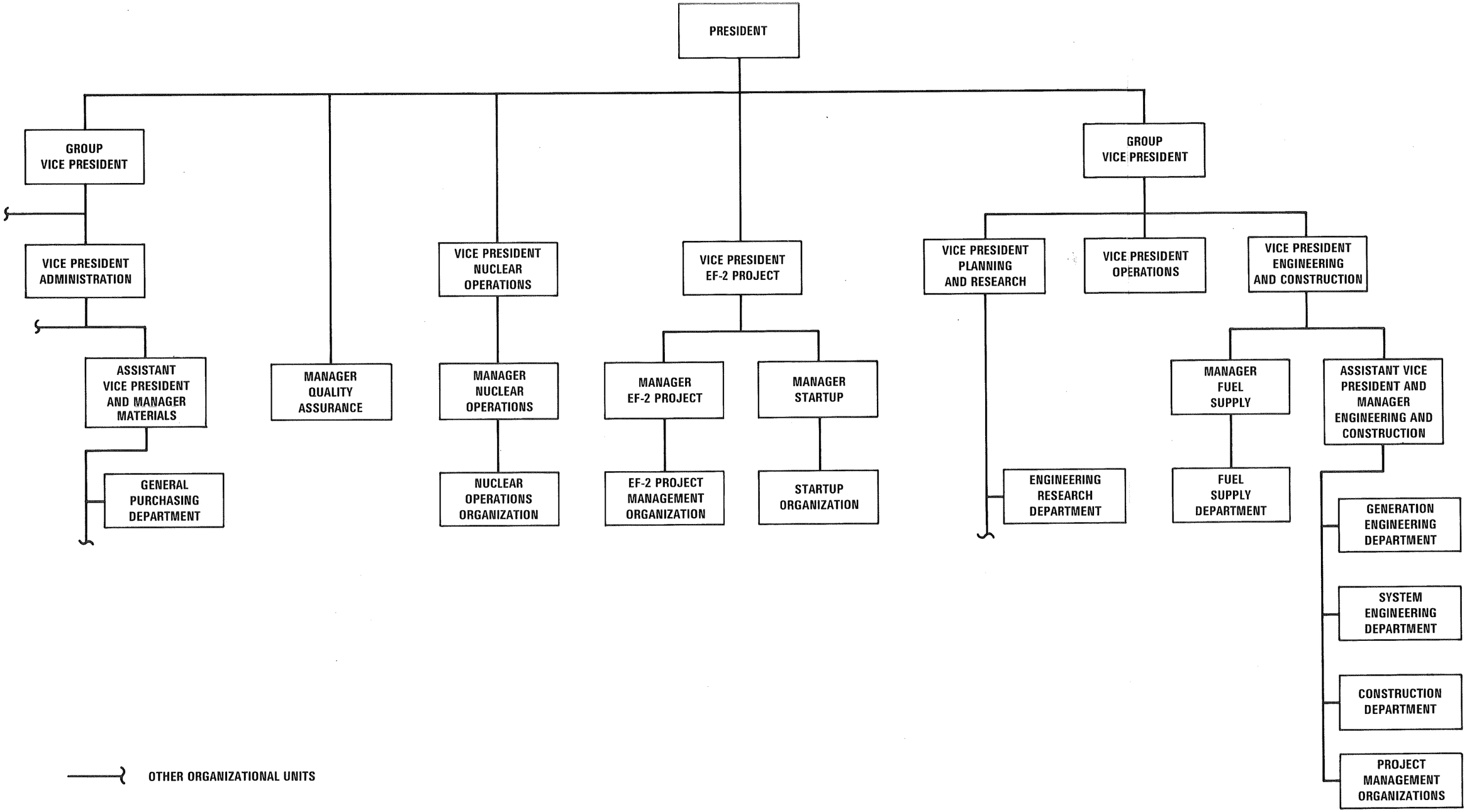
c. When significant changes were made in functional areas of the QA program, including significant organizational changes and/or procedural revisions

d. When it was suspected that safety, performance, or reliability of the item was in jeopardy because of deficiencies and nonconformances in the QA program

e. When a systematic and independent assessment of program effectiveness or item quality, or both, was considered necessary

f. When it was considered necessary to verify the implementation of required corrective actions.

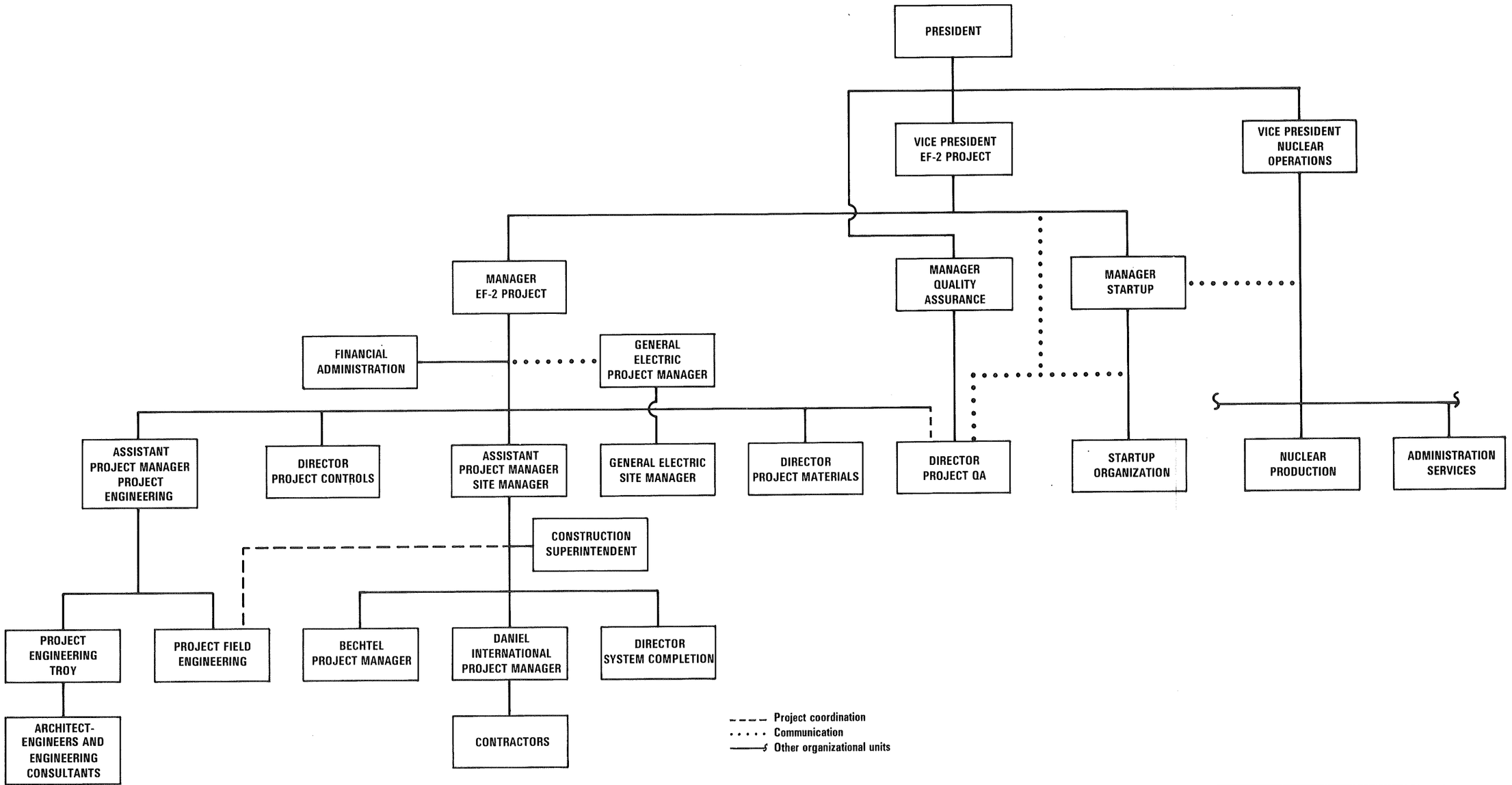
Suppliers, vendors, and contractors who were providing safety-related materials, components, or services were contractually required to conduct audits as part of their QA programs.




**Fermi 2**
UPDATED FINAL SAFETY ANALYSIS REPORT

**FIGURE 17.1-1**

**PORTION OF DETROIT EDISON CORPORATE ORGANIZATION WITH CORPORATE RESPONSIBILITY FOR PROJECT QUALITY-RELATED ACTIVITIES**




**Fermi 2**
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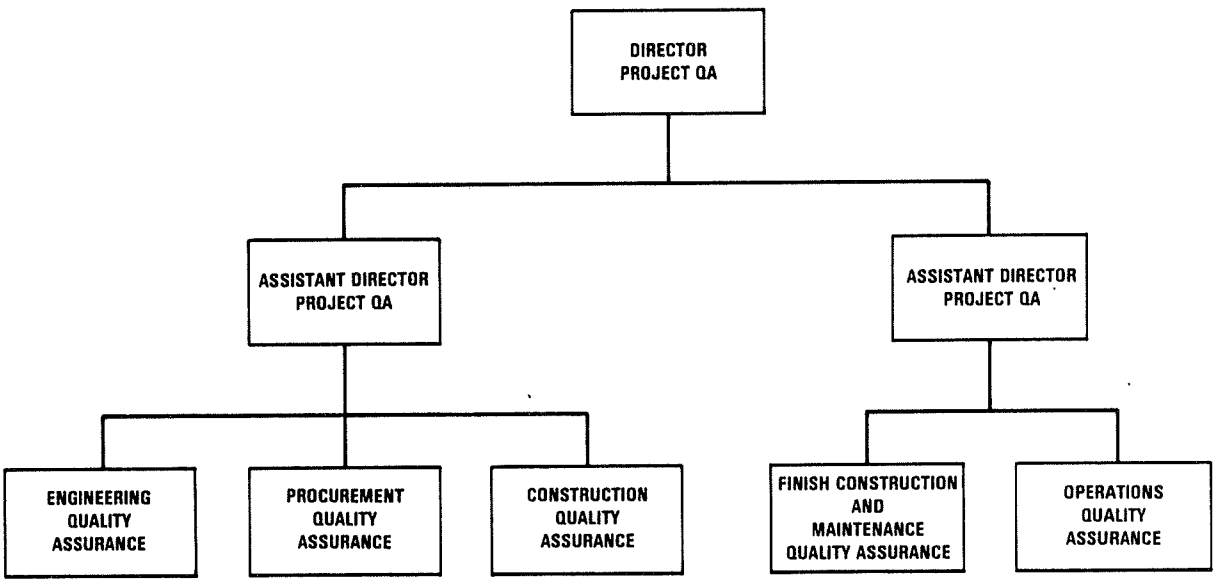
**FIGURE 17.1-2**

**FERMI 2 PROJECT ORGANIZATIONS**




**Fermi 2**
UPDATED FINAL SAFETY ANALYSIS REPORT

**FIGURE 17.1-3**

**PROJECT QUALITY ASSURANCE ORGANIZATION**

## 17.2 QUALITY ASSURANCE PROGRAM FOR PLANT OPERATION

The DTE Electric Company (DTE) operational quality assurance (QA) program is based on American National Standards Institute (ANSI) Standard N18.7-1976, "Administrative Controls and Quality Assurance for the Operational Phase of Nuclear Power Plants," as modified by Regulatory Guide 1.33 as addressed in Appendix A of the UFSAR. The program is structured and implemented in accordance with the guidance of the ANSI standards referenced therein and the associated regulatory guides that endorse them. Compliance with this guidance ensures a comprehensive QA program and an effective implementation of that program for compliance with the requirements of Appendix B to 10 CFR 50 and Appendix A to Branch Technical Position (BTP) APCSB 9.5-1, "Guidelines for Fire Protection for Nuclear Power Plants."

NOTE: When a position is not filled, reporting order will be to the next higher position.

### 17.2.1 Organization

The organizational structure, responsibilities, authorities, and functions of the nuclear organization (Nuclear Generation) are described in this subsection. Those corporate organizational units that support the operation and maintenance of the plant and perform activities subject to the requirements of the QA program are also described. Those organizational units include Supply Chain as discussed in Subsection 17.2.7.

The DTE corporate organization is described in Subsection 13.1.1. That portion of the corporate organization that is involved with activities subject to the QA program is shown in Figure 17.2-1.

#### 17.2.1.1 Senior Vice President and Chief Nuclear Officer (CNO)

The Senior Vice President and Chief Nuclear Officer reports to the President and Chief Executive Officer, DTE Energy. The CNO has responsibility for the overall administration of DTE Nuclear power. The CNO is the ultimate Management Authority for establishing QA Policy and responsibility for the quality assurance function. Reporting to the CNO are the Director – Nuclear Oversight, the Site Vice President – Nuclear Generation, Vice President – Engineering and Technical Support, Director – Strategic Business Operations, and the Nuclear Safety Review Group (NSRG) Chairman. The Senior Vice President and Chief Nuclear Officer is also responsible for the Employee Concerns Program.

##### 17.2.1.1.1 Director – Nuclear Oversight

The Director – Nuclear Oversight is responsible for establishing a sustainable oversight model for Fermi. This includes responsibility for Quality Assurance. Reporting to the Director – Nuclear Oversight is the Manager – Nuclear Quality Assurance.

17.2.1.1.1.1 Manager - Nuclear Quality Assurance

The Manager - Nuclear Quality Assurance is responsible for (1) ensuring the establishment and effective implementation of the Nuclear Generation Quality Assurance Program; (2) monitoring and evaluating the implementation of the Quality Assurance Program within Nuclear Generation by conducting planned and periodic audits; (3) reporting the audit findings to the Site Vice President – Nuclear Generation and Vice President – Engineering and Technical Support; (4) providing direction on Quality Assurance matters to the Executive Director - Nuclear Production; (5) recommending solutions to identified quality problems and verifying implementation of solutions for NQA identified problems which are significant conditions adverse to quality; and (6) issuing action to stop work when appropriate. The Manager - Nuclear Quality Assurance reports to the Director – Nuclear Oversight.

The Manager - Nuclear Quality Assurance has the authority and the responsibility to initiate action to suspend any activity, except reactor operation, if he/she discovers or suspects that a deviation from the QA program has occurred or is developing; nonconformances that appear to warrant suspension of reactor operation, including startup or power generation, will be reported to the Executive Director - Nuclear Production immediately.

The Manager - Nuclear Quality Assurance will meet the following qualifications:

Education: Bachelor Degree in Engineering or related science or the equivalent in practical experience.

Experience: Four years experience in the field of quality assurance, or equivalent number of years of nuclear plant experience in a supervisory or management position preferably at an operating nuclear plant or a combination of the two. At least one year of this four years experience shall be nuclear power plant experience in the implementation of the quality assurance program. Six months of the one year experience shall be obtained within a quality assurance organization.

An additional year of quality assurance program implementation experience may be substituted for six months experience within a quality assurance organization. The equivalent in practical experience to a Bachelor Degree in Engineering or related science is an additional four years experience in the fields of quality assurance, engineering or nuclear plant experience.

The review of implementing QA procedures and the review of nonconformance and corrective action documents covering significant conditions adverse to quality and safety and selected nonsignificant conditions adverse to quality is performed by Nuclear QA.

The NQA organization supports other units within Nuclear Generation to provide the required quality assurance functions.

17.2.1.1.1.1.1 Nuclear Quality Assurance Responsibilities

The Manager - Nuclear Quality Assurance and his/her staff are responsible for the following activities:

a. Performing surveillances of selected plant operations and maintenance and modification activities, Design Engineering, Tactical Engineering and Strategic

Engineering activities, instrument and control activities, transporting of radioactive material, fire protection and other activities which implement the QA program.

b. Review of maintenance and modification procedures, and inspection of maintenance and modification work.

c. Performance of nondestructive testing and examinations or review of its results.

d. Evaluation of inspection and surveillance results.

e. Review of selected engineering related documents.

f. Evaluation of existing and emerging issues and problems having safety significance.

g. Ensuring the content and adequacy of quality program requirements are included in the Fermi Conduct Manuals.

h. Performing audits and surveillances of Nuclear Generation units implementing the QA program.

i. Perform audits and surveillances of the corrective action process.

j. Performing audits and surveillances of onsite and offsite engineering organizations including contractors.

k. Performing supplier audits, source surveillances and commercial grade surveys.

l. Maintenance and issuance of an approved suppliers list.

m. Performing audits and surveillances of the procurement process.

n. Performing special assigned tasks.

17.2.1.1.2 Corporate Support

Corporate Support functions are described in Section 13.1.1.3.2.

17.2.1.1.3 Director – Strategic Business Operations

The functions of the Director – Strategic Business Operations are described in Subsection 13.1.1.3.3.

17.2.1.1.4 Vice President – Engineering and Technical Support

The Vice President – Engineering and Technical Support reports to the Senior Vice President and Chief Nuclear Officer and also has access to the President and Chief Executive Officer, DTE Energy for the reporting of nuclear safety problems. This individual has responsibility for the administration of engineering, including engineering aspects of the fire protection program, and technical support organizations. Reporting to the Vice President – Engineering and Technical Support are the Director – Nuclear Engineering, the Director – Nuclear Technical Support – Project Management, and the Manager – Nuclear Licensing. Supply Chain has a functional relationship to the Vice President – Engineering and Technical

Support. Additional detailed description of those organizations reporting to the Vice President – Engineering and Technical Support is provided in Section 17.2.1.2.

17.2.1.1.5 Site Vice President - Nuclear Generation

The Site Vice President - Nuclear Generation reports to the Senior Vice President and Chief Nuclear Officer and also has access to the President and Chief Executive Officer, DTE Energy for the reporting of nuclear safety problems. The authority and responsibilities of the Site Vice President - Nuclear Generation are discussed in Subsection 13.1.1. He/she has the overall responsibility for the implementation of the QA program and the fire protection program by Nuclear Generation. He/she is assisted by the Executive Director – Nuclear Production, the Manager – Nuclear Security, the Manager – Nuclear Performance Improvement, and the Director – Nuclear Training.

Additional detailed description of those organizations reporting to the Site Vice President – Nuclear Generation is provided in Section 17.2.1.2.

17.2.1.2 Organizations and Positions Reporting to the Site Vice President – Nuclear Generation and the Vice President – Engineering and Technical Support

17.2.1.2.1 Executive Director - Nuclear Production

NOTE: The titles of Plant Manager and Executive Director - Nuclear Production have the same functional responsibility

The Executive Director - Nuclear Production is responsible for the operation, maintenance, and plant administration of Fermi 2 and for the implementation of quality-related procedures and implementing the fire protection program. A detailed description of the Executive Director - Nuclear Production's organization, including responsibilities, authorities, duties, and qualifications for all key staff positions, is given in Subsection 13.1.2.

17.2.1.2.2 Director – Nuclear Technical Support – Project Management

The functions of the Director – Nuclear Technical Support – Project Management are described in Subsection 13.1.2.3.

17.2.1.2.3 Director – Nuclear Engineering

The Director – Nuclear Engineering is responsible for design engineering, including nuclear fuel design and management, strategic engineering, inservice inspection, performance engineering, procurement engineering, and modifications and configuration management in support of plant operations. The Director - Nuclear Engineering is responsible for the formulation and effectiveness of the fire protection program. Reporting to the Director – Nuclear Engineering are Manager – Nuclear Design Engineering, Manager - Nuclear Strategic Engineering, Manager - Nuclear Performance Engineering, and Manager – Nuclear Tactical Engineering.

17.2.1.2.3.1 Manager – Nuclear Design Engineering

The Manager – Nuclear Design Engineering has the overall responsibility for the Fermi 2 plant configuration management program. The Manager – Nuclear Design Engineering is responsible for Engineering Projects and Modifications, and engineering support functions associated with modifications to plant structures, systems and equipment. This responsibility includes the planning and management of the engineering scope and specification, detailed design, procurement, installation and testing phases of the modification. Nuclear Quality Assurance advises the Manager – Nuclear Design Engineering on Quality Assurance matters.

17.2.1.2.3.2 Manager – Nuclear Strategic Engineering

The Manager – Nuclear Strategic Engineering is responsible for strategic engineering.

17.2.1.2.3.3 Manager – Nuclear Performance Engineering

The Manager – Nuclear Performance Engineering is responsible for inservice inspection, including nondestructive examination activities or review of the results, the equipment qualification program, the fire protection program, nuclear fuel, reactor engineering, and probabilistic risk assessment (PSA).

17.2.1.2.3.4 Manager – Nuclear Tactical Engineering

The Manager – Nuclear Tactical Engineering is responsible for Procurement Engineering, including functions of approving procurement documents to ensure that technical and quality requirements are imposed for safety-related or important to safety applications, providing technical support for quality-related supplier oversight, providing evaluations for equivalent part replacements, performing design changes to plant components, and receiving and inspecting safety-related material and supplies.

The Manager – Nuclear Tactical Engineering is also responsible for the Engineering Response Team, including functions of assisting Operations and Maintenance with emergent plant issues, providing technical evaluations for degraded equipment, and performing replacement part evaluations in addition to design changes to plant systems.

The Manager – Nuclear Tactical Engineering has a functional relationship to the Manager – Nuclear Design Engineering, who has overall responsibility for the Fermi 2 plant configuration management program, for the approval of design changes to plant systems and components.

17.2.1.2.4 Director – Nuclear Training

The Director - Nuclear Training is responsible for developing and implementing training programs in support of the safe and efficient operation of the plant. The Director - Nuclear Training also provides the support for licensed operator medical issues.

The training program is described in Section 13.2.

17.2.1.2.5 Other Managers in Figure 17.2-1

17.2.1.2.5.1 Manager – Nuclear Licensing

The Manager - Nuclear Licensing is responsible for nuclear licensing activities, ensuring compliance with regulatory requirements. The Manager or the operating authority is responsible for communications with the NRC regional office on reportable deficiencies for activities covered by the Nuclear QA Program. The Manager – Radiological Emergency Response Preparedness as described in subsection 17.2.1.2.5.4 reports to the Manager – Nuclear Licensing.

17.2.1.2.5.2 Manager – Nuclear Security

The functions of the Manager – Nuclear Security are described in Subsection 13.1.2.5.1.

17.2.1.2.5.3 Manager – Nuclear Performance Improvement

The Manager – Nuclear Performance Improvement is responsible for administration of: 1) the plant Corrective Action Program, including trending and tracking of corrective action documents; 2) the root cause analysis program; 3) benchmarking and self-assessment programs; and 4) internal and external operating experience to provide for early detection of conditions potentially adverse to nuclear safety.

17.2.1.2.5.4 Manager – Radiological Emergency Response Preparedness

The Manager – Radiological Emergency Response Preparedness is responsible for coordinating the activities of Emergency Planning.

17.2.1.3 Review Organizations

The membership, meeting frequency, minutes, quorum, and other details of the NSRG and the OSRO are described in this subsection. These review organizations, which provide a technical review of plant maintenance and operation, have been established in accordance with the criteria listed below. The membership of the NSRG and the OSRO will be supplemented by DTE personnel or consultants as necessary.

17.2.1.3.1 Onsite Review Organization (OSRO)

17.2.1.3.1.1 Function

The OSRO shall function to advise the Executive Director - Nuclear Production on all matters related to nuclear safety as described in Subsection 17.2.1.3.1.6.

17.2.1.3.1.2 Composition

The OSRO membership shall be composed of a minimum of 6 but not more than 11 plant management representatives whose responsibilities include the functional areas of: operations, maintenance, radiation protection, engineering/technical support and quality

assurance. All members shall be appointed in writing by the OSRO chairman. The qualifications of each OSRO member shall meet or exceed the requirements and recommendations of Section 4.2 or 4.3 of ANSI N18.1-1971 and the OSRO chairman shall meet or exceed the requirements of Section 4.2.4 of ANSI N18.1-1971.

17.2.1.3.1.3 Alternates

The Chairman may designate in writing other members who may serve as the Vice Chairman of the OSRO. Alternates may be designated for specific OSRO members. No more than two alternates shall participate as voting members in OSRO activities at any one time. All alternate members shall be appointed in writing by the OSRO Chairman.

17.2.1.3.1.4 Meeting Frequency

The OSRO shall meet periodically and as situations demand as convened by the OSRO Chairman or a Vice Chairman.

17.2.1.3.1.5 Quorum

The quorum of the OSRO necessary for the performance of the OSRO responsibility and authority provisions of this section (17.2.1.3.1) shall consist of the Chairman or Vice Chairman and four members including alternates.

17.2.1.3.1.6 Responsibilities

The OSRO shall be responsible for:

a. Review of Plant Administrative Procedures and changes thereto that could affect nuclear safety;

b. Review of all proposed tests and experiments that affect nuclear safety;

c. Review of all proposed changes to Appendix A Technical Specifications;

d. Review of all proposed changes or modifications to unit systems or equipment that affect nuclear safety. OSRO review of plant modifications which require a 10 CFR 50.59 Evaluation meet the requirements for this review;

e. Review of the 10 CFR 50.59 Evaluations for plant procedures and changes thereto completed under the provisions of 10 CFR 50.59;

f. Review of events reportable under 10 CFR 50.73;

g. Review of unit operations to detect potential hazards to nuclear safety;

h. Performance of special reviews, investigations, or analyses and reports thereon as requested by the Executive Director - Nuclear Production or the Nuclear Safety Review Group;

i. Review of every unplanned onsite release of radioactive material to the environs including the preparation and forwarding of reports covering evaluation, recommendations and disposition of the corrective action to prevent

recurrence to the Site Vice President - Nuclear Generation and to the Nuclear Safety Review Group;

j. Review of changes to the Process Control Program, the Offsite Dose Calculation Manual, and major modifications to the Radwaste Treatment Systems; and

k. Review of all Licensing Change Requests (LCRs) for proposed changes to the Fire Protection Program, Security Plans and the RERP Plan.

17.2.1.3.1.7 Actions for Events Reportable Under 10 CFR 50.73

Each event reportable under 10 CFR 50.73 shall be reviewed by OSRO, and the results of this review shall be submitted to the NSRG and the Site Vice President - Nuclear Generation.

17.2.1.3.1.8 Written Communication

The OSRO shall:

a. Recommend in writing to the Executive Director - Nuclear Production approval or disapproval of items considered under Subsection 17.2.1.3.1.6.a through d prior to their implementation,

b. Render determinations in writing to the Nuclear Safety Review Group with regard to whether or not each item considered under Subsection 17.2.1.3.1.6.a through e requires a License Amendment prior to implementation,

c. Provide written notification within 24 hours to the Site Vice President - Nuclear Generation and the Nuclear Safety Review Group of disagreement between the OSRO and the Executive Director - Nuclear Production; however, the Executive Director - Nuclear Production shall have responsibility for resolution of such disagreements pursuant to Technical Specification 5.2.1b.

17.2.1.3.1.9 Records

The OSRO shall maintain written minutes of each OSRO meeting that, at a minimum, document the results of all OSRO activities performed under the responsibility provisions of this subsection.

Copies shall be provided to the Site Vice President - Nuclear Generation and the Nuclear Safety Review Group.

17.2.1.3.2 Nuclear Safety Review Group (NSRG)

17.2.1.3.2.1 Function

The NSRG shall function to provide independent review of designated activities in the areas of:

a. Nuclear power plant operations,

b. Nuclear engineering,

c. Chemistry and radiochemistry,

d. Metallurgy,

e. Nondestructive testing,

f. Instrumentation and control,

g. Radiological controls,

h. Mechanical and electrical engineering, and

i. Quality assurance practices.

The NSRG shall report to and advise the Senior Vice President and Chief Nuclear Officer on those areas of responsibility in Subsections 17.2.1.3.2.7 and 17.2.1.3.2.8.

17.2.1.3.2.2 Composition

The Senior Vice President and Chief Nuclear Officer shall appoint members to the NSRG and shall designate from this membership a Chairman and at least one Vice Chairman. The membership shall collectively possess experience and competence to provide independent review in the areas listed in Subsection 17.2.1.3.2.1. The Chairman and Vice Chairman shall have nuclear background in engineering or operations and shall be capable of determining when to call in experts to assist the NSRG review of complex problems. All members shall have at least a bachelor's degree in engineering or related sciences or at least 10 years of responsible power plant experience of which a minimum of 3 years shall be nuclear power plant experience. The Chairman shall have at least 10 years of professional level management experience in the power field and each of the members shall have at least 5 years of cumulative professional level experience in one or more of the fields listed in Subsection 17.2.1.3.2.1.

17.2.1.3.2.3 Alternates

All alternate members shall be appointed in writing by the NSRG Chairman to serve on a temporary basis; however, no more than two alternates shall participate as voting members in NSRG activities at any one time.

17.2.1.3.2.4 Consultants

Consultants shall be utilized as determined by the NSRG Chairman to provide expert advice to the NSRG.

17.2.1.3.2.5 Meeting Frequency

The NSRG shall meet at least twice per year.

17.2.1.3.2.6 Quorum

The quorum of the NSRG necessary for the performance of the NSRG review functions of this subsection shall consist of the Chairman or his/her designated alternate and at least one half of the remaining NSRG members, with a minimum of four, of whom two may be

alternates. No more than a minority of the quorum shall have line responsibility for operation of the unit.

17.2.1.3.2.7 Review

The NSRG shall be responsible for the review of Subsection 17.2.1.3.2.7.a through i:

a. Post facto review of 10 CFR 50.59 Evaluations for (1) changes to procedures, equipment, facilities or systems and (2)tests or experiments completed under the provision of 10 CFR 50.59 to verify that such actions did not require a License Amendment prior to implementation;

b. Proposed changes to procedures, equipment, or systems which involve a License Amendment prior to implementation as defined in 10 CFR 50.59;

c. Proposed tests or experiments which involve a License Amendment prior to implementation as defined in 10 CFR 50.59;

d. Proposed changes to Technical Specifications or the Operating License;

e. Violations of codes, regulations, orders, Technical Specifications, license requirements, or of internal procedures or instructions having nuclear safety significance;

f. Significant operating abnormalities or deviations from normal and expected performance of unit equipment that affect nuclear safety;

g. Events reportable under 10 CFR 50.73;

h. All recognized indications of an unanticipated deficiency in some aspect of design or operation of structures, systems, or components that could affect nuclear safety; and

i. Reports and meeting minutes of the OSRO.

17.2.1.3.2.8 Audits

Audits of unit activities shall be performed under the cognizance of the NSRG. These audits shall encompass topics listed in Subsection 17.2.18.5.

17.2.1.3.2.9 Records

Records of NSRG activities shall be prepared, approved, and distributed as indicated below:

a. Minutes of each NSRG meeting shall be prepared, approved, and forwarded to the Senior Vice President and Chief Nuclear Officer promptly following each meeting.

b. Reports of reviews encompassed by Subsection 17.2.1.3.2.7 shall be prepared, approved, and forwarded to the Senior VicePresident and Chief Nuclear Officer promptly following completion of the review.

c. Audit reports encompassed by Subsection 17.2.1.3.2.8 shall be forwarded to the Senior Vice President and Chief Nuclear Officer and to the management

positions responsible for the areas audited within 30 days after completion of the audit by the auditing organization.

### 17.2.2 Nuclear Quality Assurance Program

The Nuclear QA program established for plant operations applies to all quality-related activities associated with the structures, systems, and components identified as safety related. The QA programs for fire protection and the Independent Spent Fuel Storage Installation (ISFSI) are part of the overall QA program. The program is designed to comply with the requirements of Appendix B to 10 CFR 50, NRC regulatory guides, and the endorsed ANSI standards that are used in structuring the program and in developing procedures to implement it. In all cases the required implementation procedures are established before the initiation of a given activity and must comply with the governing QA program.

Application of the 10 CFR 50, Appendix B QA program to activities conducted under 10 CFR 71 is limited to procurement, maintenance, repair and use of transportation packages for shipment of radioactive materials. Design, fabrication, assembly, and modification of shipping casks will not be conducted under this QA program.

#### 17.2.2.1 Corporate QA Policies, Goals, and Objectives

The Senior Vice President and Chief Nuclear Officer has the ultimate authority for establishing QA policy. He/she is assisted by the Manager - Nuclear Quality Assurance in establishing goals and objectives.

##### 17.2.2.1.1 Policies

QA policies are the following:

a. The operation and maintenance of the power plant shall be managed in accordance with a comprehensive QA program

b. The QA program shall be structured to comply with the requirements of regulations, codes, and company policies

c. Mandatory QA program requirements shall be established for all company and contractor personnel who oversee and/or perform activities that may affect safety or plant availability.

##### 17.2.2.1.2 Goals

QA goals are the following:

a. Achieve safe and efficient operation

b. Achieve maximum plant availability within economic and safety limitations.

##### 17.2.2.1.3 Objectives

QA objectives are to provide assurance that:

a. Plant design modifications are performed in accordance with regulatory requirements, codes, and standards to ensure a safe and reliable plant

b. Materials and services for the plant are procured as specified in design documents

c. Plant structures, systems, and components are constructed, maintained, and repaired to design standards

d. Plant structures, systems, and components are inspected to verify compliance with design requirements

e. Plant structures, systems, and components are tested to verify continued performance to design requirements

f. Adequate documentation is provided as objective evidence of quality and as required for plant operation and maintenance

g. No alterations are made to the facility which constitute a change from the current Technical Specifications except as allowed by 10 CFR 50.54(x) and (y) under emergency conditions. Other necessary alterations are made only after formal revision to the Technical Specifications.

The Fermi Conduct Manuals, approved and made mandatory by management, are the chief means of communicating the policies, goals, and objectives stated above to Nuclear Generation. Indoctrination sessions will also aid in furthering understanding. See Subsection 17.2.2.7 for further details.

17.2.2.2 Program Documentation

The Nuclear QA program is described in this section of the UFSAR (17.2) and is supported by Fermi Conduct Manuals and implementing procedures. QA Program elements applied to ISFSI are described in UFSAR Appendix 17.2A. This quality assurance program description (QAPD) and changes thereto shall be approved by the Senior Vice President and Chief Nuclear Officer after review by the Manager - Nuclear Quality Assurance.

17.2.2.2.1 Fermi Conduct Manuals

The Fermi Conduct Manuals address the QA program and other programs associated with the operation, maintenance, and modification of Fermi 2 and the activities of support organizations. These conduct manuals are organized by function and are divided into chapters which represent administrative implementing procedures.

Fermi Conduct Manuals are endorsed by DTE management in the QA management policy statement, and reflect commitments to meet the applicable regulatory requirements for safe operation, as well as provide for ensuring reliability of operation. These Conduct Manuals are approved by Fermi management and are the basis for the overall management program for Nuclear Generation. The Conduct Manuals are also applicable, as appropriate, to other DTE departments, suppliers, and contractors who furnish materials, equipment, or services that can affect the safe and reliable operation of Fermi 2.

Fermi Conduct Manuals identify the requirements and implementing procedures that management has mandated to be followed. Conduct Manuals applicable to the QA program describe responsibilities and principal duties for the performance of specific quality-related activities and the QA requirements applicable to those activities. These Fermi Conduct Manuals are approved by the Executive Director – Nuclear Production after review by the management of affected organizations. The Executive Director – Nuclear Production may delegate approval authority in writing for specific types of procedures to a management representative responsible for the functional area.

Conduct Manuals are controlled documents and are handled as described in Subsection 17.2.6. Revisions will be made, as appropriate, and will be subject to the same review and approval required for the original issue. Controlled copies of the manual are issued to identified personnel. Holders of the manual are required to keep it updated as revisions are issued and to be familiar with its applicable contents.

A matrix showing the 18 criteria of 10 CFR 50, Appendix B, QA Regulatory Guides and endorsed ANSI standards, and the conduct manuals implementing these criteria is shown in The QA Conduct Manual.

17.2.2.3 Program Elements

The Nuclear QA program implemented in the Fermi Conduct Manuals has the following major elements:

a. Definition of responsibility and authority of those involved in the implementation of the QA program during maintenance, modification, and operation of the plant

b. Identification of items and activities covered by the program and the extent of the applicability of the program, based on the safety-related importance of the item or activity

c. Verification and documentation of quality by personnel with sufficient independence and organizational freedom to effectively control quality

d. Performance of activities affecting quality in accordance with written instructions, procedures, or drawings

e. Indoctrination and training of personnel performing activities affecting quality to the extent required to ensure their proficiency

f. Identification and verification of compliance with requirements of applicable codes, standards, design documents, and regulations

g. Performance of activities affecting quality under suitably controlled conditions

h. Documentation of the satisfactory completion of activities and of the quality of an item

i. Regular review by management, outside of Nuclear QA, as directed by the Site Vice President – Nuclear Generation, to assess the status and adequacy of the QA program

j. Review of proposed changes to the QA program to determine if the proposed change requires prior review and acceptance by the NRC.

17.2.2.4 Program Applicability

The requirements of the Nuclear QA program are to be applied to quality-related activities involving safety-related structures, systems, and components. The safety-related structures, systems, and components are identified in Table 3.2-1 of the UFSAR and in the Central Component Computer Data Base (CECO). Procedures describe how changes are made to CECO.

The requirements of the QA program are applicable to the fire protection program and are applied to the extent consistent with safety. Therefore, Sections 17.2.6, 17.2.8, 17.2.9, 17.2.12 and 17.2.13 are not applicable to the fire protection program.

The requirements of the QA program are applicable to the ISFSI program and are applied to the extent consistent with safety. Elements of the QA program applicable to the ISFSI program are delineated in Appendix 17.2.A.

QA program procedures require that the development, control, and use of computer programs are performed in accordance with implementing procedures that incorporate applicable QA requirements to ensure the adequacy of the design and use of these programs.

17.2.2.5 QA Programs of Others

The QA program for Nuclear Generation includes requirements that a contractor providing items, work, or services involving safety-related structures, systems, or components must establish and maintain a prescribed QA program in compliance with the applicable requirements of Appendix B to 10 CFR 50. The specific QA requirements that the contractor program must satisfy are specified in the procurement documents. The program is subject to review and concurrence by Nuclear QA before work is started. The program may be reviewed by another utility provided that an agreement has been established to ensure that DTE's QA requirements have been satisfied. The results of the review will be provided to DTE.

17.2.2.6 Resolution of Disputes

Disputes between Nuclear QA personnel and others are to be referred for resolution to personnel who have the responsibility and authority to make the final decision. On technical matters, the dispute is referred to those in the organization who have the responsibility and expertise to make the decision; e.g., on problems involving the welding process, the Welding Engineer is the arbiter. Disputes involving operating procedures that cannot be resolved with the responsible organization are to be referred to the OSRO for resolution. In the event the OSRO and the Executive Director - Nuclear Production are in disagreement, resolution shall be obtained as described in Subsection 17.2.1.3.1.8.c. Disputes on QA program requirements specified in the Fermi Conduct Manuals are to be referred through the Manager - Nuclear Quality Assurance to the Senior Vice President and CNO as necessary.

17.2.2.7 Indoctrination and Training of Personnel

Personnel whose responsibilities and duties involve quality- related activities will participate in formal indoctrination and training programs conducted by Nuclear Training. These programs, in conjunction with training provided within the plant organizations, are designed to make personnel knowledgeable of the requirements of the Nuclear QA program, including purpose and scope, and the implementing procedures applicable to their work.

Periodic reviews will be scheduled to maintain a high level of understanding and knowledge of the Nuclear QA program. Special training sessions will be established for personnel requiring specialized skills in the performance of their work. The proficiency of such personnel will be established by appropriate examination, reexamination, and certification as required by codes, standards, and regulations. Files for formal training programs will include the objective, the content of training, the list of attendees, the date of attendance, and records of satisfactory completion. See Subsection 13.2.1 for further details.

17.2.2.8 Regulatory Guides and ANSI Standards

The operational QA program is intended to comply with the requirements of 10 CFR 50.55a, Part g; 10 CFR 50, Appendix B; Branch Technical Position (BTP) APCSB 9.5-1, Appendix A; 10CFR72, Subpart G and appropriate regulatory guides as addressed in Appendix A. The program is structured and implemented in accordance with ANSI N18.7-1976, "Administrative Controls and Quality Assurance for the Operational Phase of Nuclear Power Plants," the ANSI standards referenced therein, and the regulatory guides that endorse them as addressed in Appendix A.

Those structures, systems, and components that are addressed by regulatory guides endorsing American Society of Mechanical Engineers (ASME) codes are listed in Section 3.2.

17.2.3 Design Control

Technical Organization is responsible for the engineering scope of modifications to plant structures, systems, and equipment. Design documents (e.g., drawings, calculations, specifications, procedures, and instructions) originating from or released for review by this group will contain the required regulatory requirements, quality standards, and design bases in accordance with NRC licensing requirements. Design activities may include calculations, analysis, materials selection, equipment arrangement and layout, and specification of test and inspection criteria essential to the safety-related functions of structures, systems, and components. Those design activities performed by individuals within DTE organizations are controlled by design control procedures.

Design control procedures satisfy the applicable QA requirements for design activities as specified in ANSI N45.2.11-1974 and as modified by Regulatory Guide 1.64 as addressed in Subsection A.1.64. Any organization performing design work for DTE must have similar requirements in its procedures before its QA program can be accepted.

To ensure that the design is adequate and that the above requirements and procedures are satisfied, designs are internally verified by the originating organization. This internal verification of adequacy may be accomplished either by a design review, by alternative

calculation methods, or by the establishment of a suitable test program. Where a test program is used to verify the adequacy of a specific design feature in lieu of other verification or checking processes, it will include suitable qualification testing of a prototype unit under the most adverse design conditions. Those proposed changes in the facility which involve changes to the Technical Specifications or require a License Amendment prior to implementation as defined in 10 CFR 50.59(c)(2) shall also be reviewed by NSRG. Minutes of each NSRG meeting are prepared and approved.

Design controls have been established to assure that applicable fire protection program guidelines and requirements are included in design and procurement documents and that deviations are controlled. Field changes and design deviations that affect the intent of the modification shall be subject to the same level of controls, reviews, and approvals that were applicable to the original document. Quality standards are specified in the design documents such as appropriate fire protection codes and standards. Deviations or changes from these standards are individually approved. New designs and plant modifications, including fire protection systems, are reviewed by qualified personnel to assure inclusion of appropriate fire protection requirements.

All documentary material reviewed is identified. Copies of minutes are distributed to the originating organization.

During the design reviews, particular attention will be given to ensure that:

a. Appropriate quality standards are contained in the documents and clearly delineated

b. The technical information for the materials, components, equipment, and processes is contained in the documents and is suitable for the intended applications. This information will include, as applicable, the physics, seismic, radiation, hydraulics, thermal, strength, and accident analyses used; the compatibility of design for inservice inspection, maintenance, and repair; and the acceptance criteria for inspections and tests. Performance history and failure data on installed components will be considered when similar components are intended for installation as part of a system or structure modification

c. Design interfaces, when more than one organization has participated in the design, are compatible and consistent with the overall design bases and existing systems

d. In the selection of standard commercial or previously approved items with safety-related functions, a review is performed to determine if the characteristics of the item satisfy the requirements of the application

e. The inspection requirements per Subsection 17.2.10 are included and adequate

f. Errors and deficiencies discovered in the design as a result of the reviews are documented and disposition is assigned. A feedback system of corrective action, by distribution of the review comments to the responsible organization, is used to prevent repetitive errors or deficiencies in the design process.

Changes to the basic documents, including field changes as a result of modifications, which affect the technical adequacy of the design, will receive reviews and approvals comparable to the original basic documents. Editorial changes may be made with the approval of the responsible Nuclear Design Engineering Supervisor or other designated persons. Copies of editorial changes will be routed to the participating design organization and the Information & Procedures organization.

### 17.2.4 Procurement Document Control

#### 17.2.4.1 General

Design documents are used in the procurement of plant materials, equipment, and services to properly define the technical and quality requirements for each procured item. Procurement packages are prepared or initiated by the responsible individual in accordance with established purchase requisition procedures.

The procurement package originator is responsible for ensuring that the applicable specifications, drawings, test requirements, inspection requirements, special process requirements, codes, standards, and regulatory requirements for safety-related items are specified or referenced in the procurement documents. The procurement packages are reviewed by Procurement Engineering to ensure (or provide) inclusion of appropriate technical, QA, and documentation requirements, DTE's right of access, and the control of nonconformances.

The procurement document planning, preparation, review, approval, and control process is performed in accordance with procedures prepared by the responsible organizations. Procurement document control procedures require that changes to procurement documents be subject to the same controls as the original document. Procurement document control procedures satisfy applicable QA requirements described in ANSI N45.2.13-1976 as modified by Regulatory Guide 1.123 as addressed in Subsection A.1.123.

Procurement documents for fire protection materials, equipment, and services are reviewed, approved and documented by qualified personnel to verify the adequacy of fire protection and quality requirements. This review assures that fire protection and quality requirements are correct; that there are adequate acceptance and rejection criteria; and that the procurement document has been properly prepared, reviewed, and approved.

The provisions which ensure that procurement documents contain DTE's right of access to supplier's facilities and records for source inspection and audits are delineated in the Fermi Conduct Manuals.

#### 17.2.4.2 Procurement of Commercial Quality Items

Procurement of safety-related equipment, parts, and materials at Fermi 2 is in compliance with the plant's design requirements and commitments and is consistent with 10 CFR 50, Appendix B. These items may on occasion be procured commercial quality as replacements in safety-related systems. The criteria used for these commercial-quality procurements are consistent with the definition of commercial-grade items for use in safety-related systems contained in 10 CFR 21.

Safety-related items procured as Commercial Quality require specific engineering evaluations to establish engineering criteria and verification requirements prior to hardware acceptance. The development of engineering criteria includes critical performance characteristics and environmental and seismic requirements. Critical performance characteristics evaluate the item's form, fit, and function. Environmental requirements evaluate humidity, temperature, pressure, and radiation fields in which the hardware is expected to function under normal and accident conditions. Seismic requirements necessitate a need to evaluate the items for operation during and after a seismic event. Verification requirements are developed to ensure that established critical performance characteristics and environmental and seismic requirements are met.

Verification of product quality may be accomplished by sampling. The verification process includes visual inspection, analysis/ justification, or testing, either nondestructive or destructive, before release for installation. Other methods that can be used include commercial grade survey of the supplier or source verification. Commercial grade surveys will not be employed as the basis for accepting items from suppliers with undocumented commercial quality control programs or with programs that do not effectively implement their own necessary controls. Commercial grade surveys will not be employed as the basis for accepting items from distributors unless the survey includes the part manufacturer(s) and the survey confirms adequate controls by both the distributor and the part manufacturer (s). Surveys are led by Nuclear QA personnel. Under certain circumstances, equipment, parts, or materials can be verified by post installation testing.

Other verification activities are performed at the direction of Fermi 2 Procurement Engineering and overseen by Nuclear Quality Assurance in accordance with the Fermi 2 Quality Assurance Program with the exception that some source verifications are performed by QA.

Documentation resulting from engineering evaluations and hardware verifications is designed to be auditable and become permanent plant procurement records. It may also be used to replicate generic or specific engineering evaluations during subsequent procurements.

Nuclear QA will ensure that such requirements are included in the detailed procedures. Independent audits by Nuclear QA will ensure compliance with the established procedures.

### 17.2.5 Instructions, Procedures, and Drawings

Activities affecting quality are performed in accordance with approved instructions, procedures, or drawings. These documents include the necessary limits and tolerances on materials, equipment, processes, and procedures for all activities from design through operation. Also included are qualitative or quantitative acceptance criteria to ensure that important operations have been accomplished satisfactorily. The basis for determining the need for procedures and their content is consistent with the requirements of ANSI N18.7-1976 and Regulatory Guide 1.33 as addressed in Subsection A.1.33.

Documents established to ensure that activities affecting quality are accomplished in accordance with applicable codes, standards, specifications, and drawings include the following:

a. Fermi Conduct Manuals, including administrative implementing procedures and NQA procedures

b. Technical procedures, including, but not limited to: Operating procedures, radiation protection procedures, maintenance and modification procedures, periodic calibration and test procedures, special test procedures, and fuel handling procedures

c. Inspections, tests, administrative controls, fire drills and training that govern the fire protection program are prescribed in instructions, procedures or drawings and accomplished in accordance with these documents.

Nuclear Generation unit supervisors are responsible for ensuring compliance to procedures by personnel under their direction. Independent auditing by Nuclear QA will further ensure and verify onsite compliance with the approved procedures. The activities of DTE support organizations and vendors or contractors are also audited by Nuclear QA to verify compliance with requirements.

17.2.5.1 Technical Review and Control

17.2.5.1.1 Activities

Procedures required by Technical Specification 5.4, and other procedures which affect plant nuclear safety, including those governing the fire protection program, as determined by the Plant Manager, and changes thereto, shall be prepared by a qualified individual/organization.

17.2.5.1.2 Review

17.2.5.1.2.1 Procedure Review

Each procedure or procedure change prepared in accordance with 17.2.5.1.1, and each plant administrative procedure and changes thereto, shall be reviewed for technical adequacy by a qualified individual other than the individual that prepared the procedure or change thereto. Each such review shall include a determination of whether or not additional, cross-disciplinary review is necessary. If deemed necessary, such review(s) shall be performed by personnel of the appropriate discipline. Procedures governed by the fire protection program shall be reviewed to assure proper inclusion of fire protection requirements.

17.2.5.1.2.2 Procedures Required by Technical Specification 5.4.1.c and 5.5.1

Each procedure required by Technical Specification 5.4.1.c and 5.5.1, or changes thereto, shall be reviewed by the Manager -Radiation Protection or his/her designee. The Environmental Program Coordinators (an alternate title may be designated for this position) will review any changes pertaining to Technical Specification 5.4.1.c. These reviews may be performed in lieu of, or in addition to, those required by 17.2.5.1.2.1 above.

17.2.5.1.3 10 CFR 50.59 Evaluations

When required by 10 CFR 50.59, a 10 CFR 50.59 Evaluation to determine whether or not a License Amendment is involved shall be included in the review. Pursuant to 10 CFR 50.59, NRC approval of items requiring License Amendments prior to implementation shall be obtained prior to approval of the procedure or procedure change.

17.2.5.1.4 Qualifications

Individuals performing the reviews and evaluations in accordance with 17.2.5.1.2.1 through 17.2.5.1.3 above shall meet or exceed the qualifications stated in Sections 4.2 or 4.4 of ANSI N18.1-1971 for the appropriate discipline, and shall be members of the plant staff previously designated in writing by the Executive Director - Nuclear Production.

17.2.5.1.5 Records

Written records of reviews and evaluations performed in accordance with items 17.2.5.1.2.1 through 17.2.5.1.3 above, including recommendations for approval or disapproval, shall be prepared and maintained.

17.2.5.2 Review and Approval Process and Temporary Change Process

17.2.5.2.1 Plant Administrative Procedures

Each plant administrative procedure, and changes thereto, shall be reviewed in accordance with 17.2.5.1.2 and 17.2.1.3.1.6 and approved by the Executive Director – Nuclear Production prior to implementation, and shall be reviewed periodically thereafter as set forth in administrative procedures. The Executive Director – Nuclear Production may delegate approval authority in writing for specific types of procedures to a management representative responsible for the functional area.

17.2.5.2.2 Plant Procedures Required by Technical Specification 5.4.1

Each plant procedure required by Technical Specification 5.4.1, other than administrative procedures, and changes thereto, shall be reviewed in accordance with 17.2.5.1 and approved by the Executive Director – Nuclear Production prior to implementation and shall be reviewed periodically thereafter as set forth in administrative procedures. The Executive Director – Nuclear Production may delegate approval authority in writing for specific types of procedures to a management representative responsible for the functional area.

17.2.5.2.3 Temporary Changes

Temporary changes to procedures of Technical Specification 5.4.1 may be made provided:

a. The intent of the original procedure is not altered;

b. The change is approved by two members of the unit management staff, at least one of whom holds a Senior Operator license on Fermi 2; and

c. The change is documented, and reviewed and approved in accordance with either 17.2.5.2.1 or 17.2.5.2.2 above, as appropriate, within 14 days of implementation.

17.2.5.3 Process Control Program (PCP)

The PCP shall be approved by the Commission prior to implementation.

17.2.5.3.1 Changes to the PCP

a. Shall be documented and records of reviews performed shall be retained as required by Subsection 17.2.17.4.3n. This documentation shall contain:

1. Sufficient information to support the change together with the appropriate analyses or evaluations justifying the change(s) and

2. A determination that the change will maintain the overall conformance of the solidified waste product to existing requirements of Federal, State, or the applicable regulations.

b. Shall become effective after review and acceptance by the OSRO and the approval of the Executive Director - Nuclear Production.

17.2.6 Document Control

Documents defining the performance of quality-related activities are controlled to ensure that only current and correct information is used at the work location. Such documents include, but are not limited to, the following:

a. Design specifications, calculations, and analyses

b. Design, manufacturing, and construction drawings

c. Procurement documents

d. Fermi Conduct Manuals

e. Technical procedures

f. Nonconformance and design-change documents.

Such documents are drafted, reviewed, and approved by appropriate individuals or groups to ensure that the documents are adequate and that they include appropriate quantitative or qualitative acceptance criteria for determining that prescribed activities have been accomplished satisfactorily. Nuclear QA reviews such documents either directly or by audits and surveillances as appropriate for the type of document to ensure the inclusion of QA program requirements. The appropriate review and approval process is described in administrative procedures. The issuance of approved documents is made in accordance with established distribution lists.

Changes to such documents will meet the same requirements as the original document and will be reviewed and approved by the same organizations that performed the original review and approval, unless this responsibility is specifically delegated by these organizations to another qualified responsible organization.

Supervisors are responsible for ensuring that the correct revisions of necessary documents are being used to accomplish work.

During inspection, surveillance, and audit activities, Nuclear QA will verify that required documents such as drawings, specifications, instructions, or procedures are available at the work location.

The Director – Strategic Business Operations is responsible for maintaining and making available a document control system that identifies the current revision of procedures, specifications, drawings, procurement documents, and other such quality-related documents. The requirements for retaining and storing the quality-related documentation required above and other historical records are described in Subsection 17.2.17.

### 17.2.7 Control of Purchased Material, Equipment, and Services

Individuals designated by procedure approve the placement of contracts based on the analysis and recommendation of the appropriate Nuclear Generation organizational units. The evaluation of the QA capabilities of such vendors and contractors is the responsibility of Nuclear QA.

Supply Chain is responsible for supplier selection and bid evaluations. Requisitions are routed to Nuclear Generation and/or Supply Chain management personnel responsible for the issuance of purchase orders. The technical and quality requirements are transferred from the requisition to the purchase order. Procurement personnel review the purchase order for correctness prior to releasing the order to the vendor.

Three types of QA evaluation of a contractor or vendor are possible. One of these three may be used as appropriate to the level of quality required. They are as follows:

a. Desk Review - Evaluation of contractor or vendor QA capabilities accomplished by the review of pertinent information submitted by the contractor or vendor; quality history records of previous performance; documented review of audit reports by other utilities, or other similar methods. Included are ASME accreditation of an N Stamp, NA, NPT, and NV Stamps and associated Certificates of Authorization accepting the ASME accreditation of holders of the aforementioned in lieu of a separate evaluation of the programmatic adequacy of a supplier's documented QA program.

b. Facility Evaluation - Evaluation of a vendor's QA capabilities conducted at their facility, including

    1. Preaward evaluation of vendor QA system and implementation
    2. Preaward surveillance of vendor products, processing, or service and related documentation in accordance with requirements of the applicable purchase contract
    3. Inprocess evaluations.

c. Commercial grade calibration and/or testing services may be procured from commercial laboratories based on the laboratory’s accreditation to ISO/IEC-17025 by an Accreditation Body (AB) which is a signatory to the International

Laboratory Accreditation Cooperation (ILAC) Mutual Recognition Arrangement (MRA) provided each of the conditions in the following list are met. The ILAC accreditation process cannot be used as part of the commercial grade dedication process of Nondestructive Examination (NDE) or Nondestructive Testing (NDT) services in lieu of performing a commercial grade survey.

1. A documented review of the supplier's accreditation is performed and includes a verification of the following:
   a) The calibration or test laboratory holds accreditation by an accrediting body recognized by the ILAC MRA. The accreditation encompasses ISO/IEC-17025:2017, "General Requirements for the Competence of Testing and Calibration Laboratories."
   b) For procurement of calibration services, the published scope of accreditation for the calibration laboratory covers the needed measurement parameters, ranges, and uncertainties.
   c) For procurement of testing services, the published scope of accreditation for the test laboratory covers the needed testing services including test methodology and tolerances/uncertainties.
   d) The laboratory has achieved accreditation based on an on-site accreditation assessment by the selected AB within the past 48 months. The laboratory's accreditation cannot be based on two consecutive remote accreditation assessments.
2. The purchase documents require that:
   a) The service must be provided in accordance with their accredited ISO/IEC-17025:2017 program and scope of accreditation.
   b) As found calibration data must be reported in the certificate of calibration when calibrated items are found to be out of tolerance (for calibration services only).
   c) The equipment/standards used to perform the calibration must be identified in the certificate of calibration (for calibration services only).
   d) Subcontracting of these accredited services is prohibited.
   e) The customer must be notified of any condition that adversely impacts the laboratory's ability to maintain the scope of accreditation.
   f) Performance of the services listed on this order is contingent on the laboratory's accreditation having been achieved through an on-site accreditation assessment by the AB within the past 48 months.
   g) Additional technical and quality requirements, as necessary, based upon a review of the procured scope of services, which may include,

but are not necessarily limited to, tolerances, accuracies, ranges, and industry standards.

3. It is validated, at receipt inspection, that the laboratory's documentation certifies that:

   a) The contracted calibration or test service has been performed in accordance with their ISO/IEC-17025:2017 program, and has been performed within their scope of accreditation.

   b) The purchase order's requirements are met.

After evaluation, the approved sources are placed on a current list of approved suppliers. Additions and deletions to the list are made by Nuclear QA.

To ensure that material and equipment fabrication is in accordance with procurement requirements, Nuclear Generation or Supply Chain inspection personnel perform source verification of vendor activities, which includes witnessing significant fabrication checkpoints, validity of vendor-supplied documentation, and overall vendor performance as appropriate to the purchased item. The surveillance activities are accomplished in accordance with approved procedures.

Suppliers shall be required, as part of the purchase order, to furnish, as a minimum, a certificate of conformance or compliance that identifies the item provided and specifically itemizes the quality requirements of the procurement documents that it meets. In some instances inspections and audits of records will be used to verify the credibility of the certification.

One of the provisions in the procurement document shall require a supplier to submit to DTE requests for the disposition of all nonconformances to DTE specified requirements. In addition, the supplier shall be required to document the disposition of nonconformances to their own requirements. Those dispositions that resulted in "accept as is" or "repair" shall be described in the submitted documentation. See Subsection 17.2.16 for corrective actions in the case of nonconformances.

After receipt and before the storage of a material, part, or component, inspection is accomplished by qualified personnel as necessary to ensure that the material, equipment, fire protection items, or service is adequately identified and complies with the specifications delineated in the associated procurement documents. These inspections and subsequent identification of status are performed in accordance with material receiving and inspection procedures.

Documentation of the inspection will be prepared. A necessary condition for acceptance is the receipt of the QA records identified in the procurement documents verifying that the specified quality requirements have been met. An item is considered nonconforming until sufficient quality documentation has been provided. Procedures permit the conditional release of material lacking the specified QA records, provided the item can be readily removed if necessary. Functional testing may be performed on materials installed under conditional release; however, these materials are not to be placed in service unless a technical evaluation has been performed and documented in accordance with approved procedures including a 10 CFR 50.59 review.

Following a satisfactory receiving inspection, the receiving inspection report, and required documentation of tests, certificates of conformance or compliance and other specified requirements are retained to provide documentary evidence of compliance. If a nonconforming item is found during the inspection, the item is retained in a hold area or otherwise controlled area pending resolution.

The procurement of spare or replacement parts for structures, systems, and components is subject to QA program controls, codes, and standards and to technical requirements equal to or better than the original technical requirements as necessary to preclude the repetition of defects.

For specific criteria applying to commercial grade items refer to Subsection 17.2.4.2.

### 17.2.8 Identification and Control of Materials, Parts, and Components

Safety-related materials (including consumables), parts, and components (including partially fabricated subassemblies) are identified in a manner that allows traceability to the documentation that verifies the acceptability of the items to the extent specified in the procurement documents. The identification system is used to preclude the use of nonconforming materials, parts, and components. Identification must not adversely affect the function or quality of the item identified. Vendor-supplied items are identified and documented by the manufacturer in a manner consistent with applicable codes and as specified in the procurement documents. Materials, parts, and components manufactured or modified by DTE are identified, documented, and controlled.

When safety-related items are received, the items are inspected according to inspection procedures. Incorrect or defective materials, parts, and components will be identified with a tag or other appropriate means and handled in accordance with Subsection 17.2.15 to preclude inadvertent use before proper disposition. Identification and control of materials, parts, and components at the site is prescribed by, and implemented in accordance with, approved procedures.

### 17.2.9 Control of Special Processes

Special processes used in the course of maintenance, modification, and testing of the plant are controlled to ensure that they are accomplished in a satisfactory manner. Examples of special processes include, but are not necessarily limited to, the following:

a. Chemical cleaning

b. Application of protective coatings

c. Plating

d. Heat treatment

e. Metal joining, such as brazing, soldering, and welding

f. Nondestructive examinations.

Implementing procedures establish the methods for controlling and accomplishing the special processes. These procedures include the following:

a. Training, testing, and qualification requirements of onsite personnel engaged in accomplishing or inspecting special process operations

b. Certification or qualification of equipment and procedures used in the performance of special processes at the site

c. Certification and audit of vendor and contractor special fabrication process equipment, procedures, and personnel

d. Documentation of process results, procedures, personnel qualifications, and equipment certifications.

Implementing procedures define the requirements for the control of special processes to ensure that they are accomplished by qualified personnel in accordance with approved procedures, codes, and specifications. These procedures also require the documentation of personnel qualifications, equipment, special process procedures used, and acceptance/rejection criteria. Supervisors are responsible for ensuring that personnel, equipment, and special processes under their supervision, direction, or use are qualified to accomplish a particular onsite activity. These qualifications are established in accordance with the applicable codes, specifications, and standards.

Offsite special process activities will be performed in accordance with approved procedures and procurement document requirements, and by qualified personnel.

Specific procedures for special processes are prepared by the plant personnel or DTE support organizations. Qualification records of all personnel, procedures, and equipment and copies of procedures for special processes are maintained and controlled in accordance with approved procedures. Personnel performing nondestructive examinations will be qualified and certified in accordance with the requirements of ASNT SNT-TC-1A or ANSI/ASNT-CP-189 (applicable year as specified by the ISI-NDE program) and additional requirements set forth in applicable codes, standards, and specifications.

### 17.2.10 Inspection

Inspections are required to ensure that maintenance, repair, or modification work has been satisfactorily accomplished. Administrative procedures require that maintenance, repair, or modification procedures be submitted for review by Nuclear QA. Nuclear QA, in conjunction with other Nuclear Generation units, establishes the need for inspection, inspection personnel, and documentation and incorporates such information into plans or procedures. Such procedures include criteria for determining which inspections are required and how they are sequenced. Nuclear QA personnel are also required to prepare inspection plans and checklists from information obtained from original design documents to determine which inspections are required and the acceptance and rejection criteria. If the responsible design organization establishes additional requirements or criteria, these must also be included in the inspection checklists. Inspections are accomplished using procedures, instructions, and/or checklists that contain at least the following:

a. Acceptance and rejection criteria

b. Identification of those individuals responsible for performing the inspection activity

c. Description of the method of inspection, examination, measurement, or test of materials or processes necessary to be performed to ensure quality

d. Requirements for inspection equipment and instruments

e. Identification of required witness and/or hold points

f. Results of inspection activity

g. Identification of inspection subject

h. Signoff signature or controlled stamp showing evidence of completion and verification of the inspection

i. Identification of required procedures, drawings, specifications, and revisions.

If inspection of the work is impossible or disadvantageous, indirect control by the monitoring of processing methods, equipment, and personnel is provided. Both inspection and process monitoring are provided when necessary to ensure adequate control.

The inspection program also includes:

a. Periodic inspections of fire protection systems, breathing equipment and emergency lighting to assure the acceptable conditions of these items

b. Periodic inspections of materials subject to degradation such as fire stops, seals and fire retardant coatings to assure that such items have not been damaged or deteriorated.

With the exception of inservice inspection (ISI), receiving inspection, and source inspection inspectors personnel qualified to perform inspections normally will be from Nuclear QA or from onsite support organizations and will be under the control of DTE. Contract inspectors may be used, if required, for special-purpose inspections. Personnel qualified to perform inspections will:

a. Not have performed any of the activities being inspected

b. Have satisfactorily completed the qualification requirements and be certified as specified by procedures that incorporate the requirements of ANSI N45.2.6-1978 as modified by Regulatory Guide 1.58 and Subsection A.1.58 or the requirements of ASNT SNT-TC-1A or ANSI/ASNT CP-189, as applicable per Section 17.2.9

c. Be currently qualified and so designated on a qualified inspectors list approved by management.

If contractors perform special-purpose inspections, such as inservice inspections, they perform such work under the control of onsite supervision. Responsible onsite supervision ensures that contractor personnel, equipment, and procedures are properly qualified and adequate to perform the inspection.

Activities affecting fire protection will be inspected by NQA personnel or other personnel who are independent of the activity being inspected to verify conformance with documented installation drawings and test procedures for accomplishing the activities. Inspection personnel will be knowledgeable in the design and installation requirements for fire protection to the extent necessary to perform the inspection.

If an inspection reveals that a nonconformance has occurred, the inspector has the authority to initiate action to suspend further activity until the nonconformance is resolved. All nonconformances are reported and acted on in accordance with Subsection 17.2.15.

The results of each inspection are documented. The appropriate Nuclear QA Supervisor is responsible for the review of the results following completion of an activity to ensure that inspections were properly performed and documented. Maintenance of inspection records is described in Subsection 17.2.17.

Each vendor is required to establish and implement an inspection program to ensure that requirements of purchase orders are met. DTE personnel perform selective surveillance inspections to evaluate progress, monitor processes, and verify adherence to specifications and codes during fabrication in the vendor's shop. Specific attention is paid to the quality of workmanship, finishes, cleaning procedures and facilities, the interface setup of connections, and the adequacy and cleanliness of shop assembly and test areas. A system of mandatory hold points is established for critical operations and inspections to permit DTE to witness such operations and inspections.

### 17.2.11 Test Control

Preoperational and startup test programs were established and completed in accordance with the guidance provided in Regulatory Guide 1.68, as described in the Startup Manual.

Onsite test activities following plant startup are controlled by the implementation of approved test procedures. These procedures are prepared by the organization responsible for a given test activity, technically reviewed by Nuclear Generation staff, and approved by the Executive Director - Nuclear Production or designee in accordance with approved administrative procedures. Test control at the plant provides assurance that appropriate tests are conducted on structures, components, systems, or parts of systems in accordance with design documents, codes, and Technical Specifications. Tests within the scope of this subsection include periodic tests and those tests required as a result of modification, maintenance, or repair of safety-related items.

Following modification, repair or replacement, sufficient testing is performed to demonstrate that fire protection equipment in support of nuclear safety-related equipment areas will perform satisfactorily in service and that design criteria are met. Written test procedures for installation tests are prepared by the responsible engineering group and incorporate the requirements and acceptance limits contained in applicable design documents.

Implementing procedures describe the criteria used to determine which systems, structures, and components require testing and when such testing should be performed. When systems, structures, and components have been repaired, modified, or replaced, proof tests, operational tests, or other special tests are performed as required by NRC regulations and other applicable codes and standards to demonstrate satisfactory performance of the affected equipment. The responsible supervisor ensures that test procedures are prepared for the required tests and that each test procedure complies with applicable design documents, codes, and specifications. Nuclear QA reviews test procedures through inspections, surveillances, and audits.

Each test procedure includes the following as applicable:

a. Test procedure approval sheet

b. Purpose or objective

c. References

d. Prerequisites and precautions, such as suitable and controlled plant conditions for testing, adequate test equipment and instrumentation (including accuracy and calibration requirements), and completeness of item to be tested

e. Special test equipment and materials

f. The body of the procedure, including the delineation of test requirements and acceptance criteria contained in applicable design and procurement documents

g. Radiological control requirements

h. Data sheets, including provisions for signoff of prerequisites

i. Valve and electrical system lineup sheets for test and return to normal conditions

j. Hold points for inspection and witnessing.

The responsible section head or supervisor is responsible for the overall conduct and review of onsite tests. He/she assigns a qualified lead person and qualified personnel under the lead person to perform tests.

The lead person makes certain that test equipment has the proper accuracy and is properly calibrated and that each test is conducted under proper environmental conditions. Tests are conducted, documented, and results are reviewed by the lead person/qualified personnel. Additionally, the Shift Manager (SM) reviews tests to ensure that the results meet the requirements and acceptance criteria of the applicable test procedures.

Nuclear QA reviews test results through inspections, surveillances, or audits. Test records are maintained as described in Subsection 17.2.17.

Safety-related components and equipment may be tested in the vendor's shop before shipment, as required, to verify that they meet the contract drawings and specifications, and to ensure that the required quality is achieved. Tests are conducted in an environment in which shop conditions and activities do not interfere with test results. DTE requires that vendor-conducted shop tests be conducted in accordance with written test procedures. These procedures define in detail the step-by-step operations for demonstrating each feature of specified performance and provide such information as measuring and test equipment used, specifying range, accuracy, and type. The test data sheet provides space for actual test results and is traceable to the acceptance criteria. Space is provided for the signature and title of the person performing the test.

When appropriate, DTE personnel may witness the testing of items in a vendor's shop to ensure compliance with test procedures and specification requirements. The opportunity to witness will be established and coordinated with the vendor.

### 17.2.12 Control of Measuring and Test Equipment

The control of measuring and test equipment is implemented by specific procedures that describe calibration techniques, frequency requirements, and control of all the instruments and standards used in the measurement, inspection, and monitoring of safety-related components, systems, and structures. Control is used to ensure that tools, gages, instruments, and other measuring and test devices are calibrated to required accuracies against reference and transfer standards traceable to nationally recognized standards. Where national standards do not exist, the basis for calibration is documented in accordance with approved procedures. The DTE organization, supplier, or contractor responsible for testing materials, parts, assemblies, and end products ensures that the specified controls are implemented. Frequently used testing and measuring equipment will be checked for accuracy on a specified routine basis. Testing and measuring equipment used only on an infrequent basis will be checked before use.

Procedures require that testing and measuring equipment be stored in suitable locations and environments and be used only by personnel trained in their proper use and care. The calibration control documentation indicates the source and traceability of calibration, including the date of last calibration. The records also provide identification and traceability for all measuring equipment by a serial number or other suitable means. The responsible supervisor ensures the maintenance of records that indicate the complete status of measuring and test equipment under calibration control. Procedures provide for investigations to be conducted and documented to determine the validity of previously made measurements when measuring or test equipment is found to be out of calibration, and also require the repair or replacement of instruments found to be consistently out of calibration.

The section heads or supervisors of the organizations using measuring and test equipment are responsible for the establishment, implementation, and effectiveness of their calibration program. Procedures describe calibration methods, calibration frequencies, and the use of calibration stickers or tags on equipment indicating the next calibration date.

Calibration frequencies are based on required accuracy, purpose, extent of usage, stability characteristics, and other conditions that affect measurement. Calibrating standards have equal or greater accuracy than the equipment being calibrated. Those standards having equal accuracy must be adequate for the requirements, and such determination is documented and authorized by cognizant staff personnel.

### 17.2.13 Handling, Shipping, and Storage

Requirements for packaging, handling, cleaning, storing, and shipping safety-related materials, components, and systems are specified in procurement, shipping, and design documents in order to prevent damage, loss, or deterioration by environmental conditions such as temperature or humidity. These requirements are in accordance with applicable codes, standards, specifications, and manufacturer's recommendations. The procurement documents include, as applicable, the requirements for the following:

a. Cleaning and preparation of materials

b. Packaging container requirements

c. Identification and cautionary markings

d. Protection against weathering and corrosion

e. Environmental conditions for shipping and storage

f. Safe-handling requirements.

Plant section heads and supervisors are responsible for ensuring that safety-related items are handled, cleaned, stored, preserved, protected, packaged, and shipped by qualified individuals in accordance with specified codes, standards, and procedures. Procedures are established to control the storage (including shelf life) of chemicals, reagents, lubricants, and other consumable materials. Nuclear QA conducts audits to ensure that items are adequately protected and handled.

On receipt of materials and components, special requirements and protective environment, including inert-gas atmospheres, specific moisture content levels, and temperature levels, are verified and documented. During subsequent storage and before installation or use, these special requirements are maintained and will be verified by documented routine inspection in accordance with approved procedures.

Special handling equipment, cranes, and rigging are examined and tested as required by procedures before the handling of important or large items. Detailed handling instructions are prepared for items requiring special handling because of size, weight, susceptibility to shock damage, or importance. Nonconformances concerned with the handling, shipping, and storage of safety-related items will be controlled as described in Subsection 17.2.15.

### 17.2.14 Inspection, Test, and Operating Status

The QA program requires that contractors, suppliers, and onsite organizations indicate the inspection, test, and operating status of structures, components, systems, or parts of systems by a suitable means of identification and in the plant records. This prevents the inadvertent use of nonconforming, inoperative, or malfunctioning systems, structures, or components, and verifies that required inspections or tests have been performed.

Personnel safety and proper equipment operation are paramount in conducting inspections and tests associated with plant maintenance and operation. Written procedures describe the process for tagging and documenting the status of valves, breakers, and related controls for inspection, test, or maintenance.

Procedures describe methods for altering the sequence of required tests, inspections, and other operations important to safety so that appropriate reviews and approvals are performed.

The Technical Specifications establish the requirements for safety-related items necessary for the safe operation of the plant, including provisions for periodic and nonperiodic tests and inspections of various instruments, structures, components, systems, or parts of systems. Periodic tests may be operational tests or tests following maintenance; nonperiodic tests may be tests following repairs or modifications. The Technical Requirements Manual establishes requirements for fire protection items.

Schedules and methods for periodic testing of fire protection systems and components have been developed and documented. Fire protection equipment in support of nuclear safety

related equipment areas is tested periodically to assure that the equipment will properly function and continue to meet the design criteria. Test results are documented, evaluated and reviewed for acceptability.

The Shift Manager is responsible for maintaining sufficient knowledge of the plant status and the status of tests or inspections in progress to ensure safe plant operation. The Shift Manager will ensure that personnel performing onsite tests or inspections keep him/her or the Licensed Nuclear Operator in charge of the main control room advised of the current status of tests or inspections in progress that could affect any safety-related activity.

Supply Chain, assisted by Procurement Engineering as needed, is responsible for correct status indication of equipment and material in storage.

Administrative procedures require that Nuclear QA review maintenance, modification, repair, special tests, and plant technical procedures for performing radwaste processing and shipping as specified by Nuclear QA. Other procedures are reviewed during audits and surveillances as appropriate. Nuclear QA keeps routinely informed of scheduled plant activities to ensure that they can plan to perform and document inspections and be prepared to review, monitor, or audit work and test activities and any critical operations to ensure compliance with specified requirements.

### 17.2.15 Nonconforming Material, Parts, or Components

Written procedures govern the discovery, identification, documentation, segregation, review, notification, and disposition of nonconforming conditions identified during maintenance and operation. Materials and equipment that deviate from approved specifications, codes, drawings, or other applicable documents are considered nonconforming items. Until proper disposition has been made, Supply Chain, assisted by Procurement Engineering as needed, is responsible for such items in storage being clearly identified with appropriate tags or other appropriate measures to indicate unacceptable status and segregated, if possible, to prevent inadvertent use or installation for maintenance or operation of the plant.

When nonconforming items are found or suspected, the items are controlled to preclude further activity pending resolution of the adverse condition. A nonconformance document is originated and processed to the organization responsible for determining cause and recommending corrective action. Nuclear QA is notified of the condition. The nonconformance document has provisions for identifying and describing the nonconforming item, the cause, when appropriate, proposed corrective action, and approval by responsible supervision, actual corrective action taken and acknowledgment by responsible supervisory personnel, and closeout action, including any required inspections or tests and acknowledgment by Nuclear QA.

Corrective action will be proposed by qualified organizations and approved by supervisory personnel having responsibility for dispositioning the nonconforming item.

Copies of completed nonconformance documents are maintained as described in Subsection 17.2.17.

The acceptability of rework, repair, or replacement of materials, parts, components, systems, and structures is verified by inspecting and testing the item for conformance with its original

requirements or acceptable alternatives. The inspection and test records are documented and become part of the QA records for the item.

Nuclear QA periodically analyzes quality data obtained from the review of nonconformance documents including nonconformance documents issued as a result of inspection reports, surveillance reports, and audit reports. This analysis, including the determination of quality trends is reported to appropriate management and supervisory personnel for their review, assessment and appropriate action.

### 17.2.16 Corrective Action

Measures are established to ensure that conditions adverse to quality, such as failures, malfunctions, deficiencies, deviations, defective material and equipment, and nonconformances, are promptly identified and corrected. In the case of a significant condition adverse to quality or safety, procedures require that the cause be determined and corrective action be taken to preclude recurrence, and that the significant condition, its cause, and the corrective action be documented. Significant conditions affecting nuclear safety shall be reported to the Executive Director - Nuclear Production and the NSRG Chairman. Nuclear QA reviews all corrective action documents which delineate significant conditions adverse to quality or safety and some corrective action documents for other conditions adverse to quality to determine, when appropriate, that the root cause of the problem is identified and corrective action is adequate.

The QA requirements in procurement documents or contracts require the vendor or contractor not only to identify material or parts that do not conform to the procurement requirements, but also to determine and correct the causes for the condition adverse to quality.

When vendors furnish products that do not conform to the requirements of the applicable purchase contract, Nuclear QA conducts a reappraisal of the vendor's QA program when appropriate. Results of the reappraisal, together with a request for specific corrective actions, are transmitted to the vendor. If the vendor does not improve their QA program and products as requested, Nuclear QA may remove the vendor from the list of approved suppliers.

Licensing or the operating authority as appropriate is responsible for communications with the NRC Regional Office on reportable deficiencies for activities covered by the Nuclear QA program.

### 17.2.17 Quality Assurance Records

Copies of pertinent documentation, including available design, procurement, fabrication, inspection, deficiencies and corrective action, test, audit, and construction reports; reviews, material analysis, and monitoring of work performance; qualification of personnel, procedures, and equipment; drawings, specifications, calibration procedures, and reports; pertinent operating logs; maintenance and modification procedures and related inspection results; reportable occurrences; and other records required by Subsection 17.2.17.4 are available at the plant. Storage facility environmental conditions will be maintained to protect the records from deterioration. Redundant storage, where practical, is provided offsite to preclude the loss of records through fire, flood, or theft.

17.2.17.1 Plant Records

The Nuclear QA records and documents are filed and maintained by the Director – Strategic Business Operations, who is responsible for maintaining permanent records of the design documents developed during the plant operating, maintenance, and modification phases. These records will provide the historical reference necessary for maintenance, modification, and operation of the plant. Procedures define the necessary practices for the collection, storage, and maintenance of plant Nuclear QA records in accordance with the requirements of ANSI N45.2.9-1974, as endorsed by Regulatory Guide 1.88, and as addressed in Subsection A.1.88.

17.2.17.2 Support Organization Records

Support organizations that perform work for the plant in the areas of design, procurement, maintenance, modification, and testing will document such work and forward records to the Director – Strategic Business Operations for permanent filing and for ensuring that the records are identifiable and retrievable. Records for offsite support organizations are specified in procurement documents.

17.2.17.3 Vendor or Contractor QA Records

Vendors or contractors who exercise the option to retain QA records will comply with the following requirements:

a. Meet DTE's requirements on collection, storage, and maintenance of records

b. Make records available on demand for use by DTE or its agent

c. Inform DTE of any intent to dispose of QA records and permit DTE to take possession of records in accordance with agreed-upon terms.

17.2.17.4 Record Retention

17.2.17.4.1 Minimum Retention Periods

In addition to the applicable record retention requirements of Title 10, Code of Federal Regulations, the following records shall be retained for at least the minimum period indicated.

17.2.17.4.2 Record Retention - Five Years

The following records shall be retained for at least 5 years:

a. Records and logs of unit operation covering time interval at each power level,

b. Records and logs of principal maintenance activities, inspections, repair, and replacement of principal items of equipment related to nuclear safety,

c. All Reportable Events,

d. Records of surveillance activities, inspections, and calibrations required by the Technical Specifications,

e. Records of changes made to the procedures required by Technical Specification 5.4.1,

f. Records of sealed source and fission detector leak tests and results,

g. Records of annual physical inventory of all sealed source material of record.

17.2.17.4.3 Record Retention - Duration of Operating License

The following records shall be retained for the duration of the unit Operating License:

a. Records and drawing changes reflecting unit design modifications made to systems and equipment described in the Final Safety Analysis Report,

b. Records of new and irradiated fuel inventory, fuel transfers, and assembly burnup histories,

c. Records of doses received by all individuals for whom monitoring was required,

d. Records of gaseous and liquid radioactive material released to the environs,

e. Records of transient or operational cycles for those unit components identified in Technical Specification Table 5.5.5,

f. Records of reactor tests and experiments, if applicable.

g. Records of training and qualification for current members of the unit staff,

h. Records of inservice inspections performed pursuant to the Technical Specifications,

i. Records of quality assurance activities required by ANSI N45.2.9-1974.

j. Records of reviews performed for changes made to procedures or equipment or reviews of tests and experiments pursuant to 10 CFR 50.59,

k. Records of meetings of the OSRO and NSRG,

l. Records of the service lives of all hydraulic and mechanical snubbers required by Technical Requirements Manual Sections 3.7.9 and 5.1 including the date at which the service life commences and associated installation and maintenance records,

m. Records of analyses required by the radiological environmental monitoring program that would permit evaluation of the accuracy of the analysis at a later date. This should include procedures effective at specified times and QA records showing that these procedures were followed,

n. Records of reviews performed for changes to the Offsite Dose Calculation Manual and Process Control Program,

o. Records of radioactive shipments.

### 17.2.18 Audits

Within DTE, the implementation of a comprehensive system of planned and periodic audits is the responsibility of Nuclear QA.

Nuclear QA provides a direct audit function of the implementation of the QA program. These audits are performed to verify compliance with all aspects of the QA program, including audits of vendors and service contractors.

#### 17.2.18.1 Audit Personnel

Audit personnel are qualified in accordance with ANSI N45.2.23-1978 and Regulatory Guide 1.146 (August-1980) and are provided appropriate training to ensure that they are competent to perform the required audits. The proficiency of audit personnel is maintained by active participation in the audit process and/or by participation in training or orientation programs.

Audits and evaluations of selected subjects may be conducted by using technical specialists from outside the NQA organization. Technical specialists, who occasionally serve as audit team members, will receive indoctrination and/or training appropriate for the audit function performed.

#### 17.2.18.2 Vendor and Service Contractor Audits

Nuclear QA, supported by technical specialists when appropriate, performs audits, source verification, and commercial grade surveys of vendors and service contractors to verify and evaluate their QA programs, procedures, and/or activities, to ensure that they are meaningful and are effectively complying with all aspects of the QA program and procurement requirements. Nuclear QA also verifies that the vendors and contractors review and audit the QA programs of their suppliers as required.

Nuclear QA performs audits or surveillances of special-purpose inspections, such as inservice inspections, performed by contractors to ensure that the inspection work is being properly performed.

Audits are conducted in accordance with established procedures and by personnel having no direct responsibilities in the areas being audited. Audits, source verifications, and commercial grade surveys performed by other nuclear utilities may be accepted as satisfying DTE's criteria based on a documented evaluation of the report. Evaluation may be performed and documented by another utility provided that an agreement has been established that DTE’s scope of supply will be included. The results of the evaluation will be provided to DTE.

Source verification (surveillance or source surveillance) shall be commensurate with the relative importance, complexity, and quantity of the items or service procured and the vendor’s quality performance. In-process and final surveillance requirements of vendor products shall be determined in advance and performed to assure conformance with procurement document requirements. Remote source surveillance is allowed as an adequate dedication or acceptance process when a pandemic or similar state of emergency has been declared restricting access or travel to and/or from vendor locations affected by the declaration. The remote source surveillance will be in accordance with EPRI’s April 2020

Final Report 3002019436, "Remote Source Verification During a Pandemic or Similar State of Emergency: Screening Criteria and Process Guidance" to screen for eligibility, plan, perform using real time video, and document.

When purchasing commercial grade calibration or testing services from a laboratory holding accreditation by an Accreditation Body (AB) which is a signatory to the International Laboratory Accreditation Cooperation (ILAC) Mutual Recognition Arrangement (MRA), commercial grade surveys need not be performed provided each of the conditions in the following list are met. The ILAC accreditation process cannot be used as part of the commercial grade dedication process of Nondestructive Examination (NDE) or Nondestructive Testing (NDT) services in lieu of performing a commercial grade survey.

1. A documented review of the supplier's accreditation is performed and includes a verification of the following:
    a) The calibration or test laboratory holds accreditation by an accrediting body recognized by the ILAC MRA. The accreditation encompasses ISO/IEC-17025:2017, "General Requirements for the Competence of Testing and Calibration Laboratories."
    b) For procurement of calibration services, the published scope of accreditation for the calibration laboratory covers the needed measurement parameters, ranges, and uncertainties.
    c) For procurement of testing services, the published scope of accreditation for the test laboratory covers the needed testing services including test methodology and tolerances/uncertainties.
    d) The laboratory has achieved accreditation based on an on-site accreditation assessment by the selected AB within the past 48 months. The laboratory's accreditation cannot be based on two consecutive remote accreditation assessments.
2. It is validated, at receipt inspection, that the laboratory's documentation certifies that:
    a) The contracted calibration or test service has been performed in accordance with their ISO/IEC-17025:2017 program, and has been performed within their scope of accreditation.
    b) The purchase order's requirements are met.

Audit results are reported to the Manager - Nuclear Quality Assurance, the management of the organization audited, and the affected DTE organizations. DTE requires written reports from each organization on the measures taken to correct deficiencies and prevent recurrence. Appropriate follow-up, including reaudits, is made to determine that nonconformances are effectively corrected and that the corrective action precludes repetitive occurrences.

17.2.18.3 Nuclear Generation Audits

Nuclear QA is responsible for independent audits of Nuclear Generation unit activities to verify compliance with the QA program and to assess its effectiveness. The activities

audited include those described in the governing procedures that apply to the plant and onsite support organizations.

Copies of the audit report are distributed to appropriate Nuclear Generation management, including the CNO, the Site Vice President - Nuclear Generation, Vice President – Engineering and Technical Support, the Manager - Nuclear Quality Assurance and affected organizations. The NSRG receives a copy of reports of audits for which the NSRG has responsibility to review.

If a condition adverse to quality is discovered that may affect the safe operation of the plant, it will be brought to the attention of the Executive Director - Nuclear Production, in accordance with Subsection 17.2.16. After an audit of an organization has been completed, the appropriate Nuclear Generation manager is responsible for a written report of the corrective action taken in response to any nonconforming conditions identified in the audit report. Appropriate follow-up by Nuclear QA, including reaudits, is made to determine that significant conditions adverse to quality and selected nonsignificant conditions adverse to quality are effectively corrected and that corrective action precludes repetitive occurrences. Other nonsignificant conditions adverse to quality identified during audits are followed up during the next audit of the activity.

Nuclear QA will verify that the correct revisions of procedures, drawings, and other documents are being used when performing an activity affecting quality. This will be accomplished during inspections, surveillances, and audits.

17.2.18.4 Nuclear Safety Review Group

The NSRG is responsible for review as specified in Subsections 17.2.1.3.2.7 and 17.2.1.3.2.8. In addition to these activities, the NSRG will review such other activities as have been established in its charter.

17.2.18.5 Scope and Schedule of Audits

The scope and schedule of audits to be performed will be established by Nuclear QA in coordination with the responsible organizations in accordance with the requirements of the Nuclear QA program. Audit schedules will indicate the activity to be audited and the minimum frequency, and will assign the primary responsibility for the performance of the audit. The audit schedule will be reviewed and revised periodically by Nuclear QA in coordination with the responsible organizations to make certain that coverage and schedule reflect current activities.

A prominent factor in developing and revising audit schedules will be performance in the subject area. The audit schedule will be revised so that weak or declining areas get increased audit or surveillance coverage and strong areas receive less coverage. A maximum interval is set to ensure that all areas receive periodic audit coverage.

Audit schedules shall be based on the month in which the audit starts. For audits scheduled once per 24 months, a 25% grace period beyond the original 24-month completion date may be applied. The maximum time between specific 24-month audits shall not exceed 30 months. Likewise, audits on an annual (12 month) frequency shall not exceed 15 months,

except for audit frequencies defined by regulation such as the Emergency and Security plans where the audit intervals are defined and use of extension periods is not allowed.

When an audit interval extension greater than one month is used, the next audit for that particular audit area will be scheduled from the original anniversary month rather than the month of the extended audit.

The following internal Nuclear generation areas will be audited at least once per 24 months, except where a specific frequency is specified by regulation:

a. The conformance of unit operation to provisions contained within the Technical Specifications and applicable license conditions.

b. The performance, training and qualifications of the entire unit staff.

c. The results of actions taken to correct deficiencies occurring in unit equipment, structures, systems, or method of operation that affect nuclear safety at least once per 12 months.

d. The performance of activities required by the Operational Quality Assurance Program to meet the criteria of Appendix B, 10CFR Part 50.

e. The fire protection programmatic controls including the implementing procedures by qualified licensee QA personnel.

f. The fire protection equipment and program implementation, utilizing either a qualified offsite licensee fire protection engineer(s) or an outside independent fire protection consultant. An outside independent consultant should have the qualification for membership in the Society of Fire Protection Engineers as the grade of member; an equivalency of an experienced Fire Protection Engineer not employed by the licensee. An outside independent fire protection consultant shall be utilized at least every third year.

g. Any other area of unit operation considered appropriate by the Nuclear Safety Review Group, the CNO or the Site Vice President-Nuclear Generation.

h. The radiological environmental monitoring program and the results thereof.

i. The OFFSITE DOSE CALCULATION MANUAL and implementing procedures.

j. The PROCESS CONTROL PROGRAM and implementing procedures for processing and packaging of radioactive wastes.

k. The performance of activities required by the Quality Assurance Program to meet the provisions of Regulatory Guide 1.21, Revision 1, June 1974 and Regulatory Guide 4.1, Revision 1, April 1975. (Radioactive Effluents and Environmental Monitoring)

l. The Safeguards Contingency Plan and Security Program (as specified by regulation, and the 25% grace period does not apply).

m. Access Authorization (as specified by regulation).

n. Fitness for Duty (as specified by regulation).

o. Emergency Preparedness (as specified by regulation, and the 25% grace period does not apply).

p. Radiological Protection (as specified by regulation).

q. Fitness for Duty Laboratory.

r. Station Blackout.

s. Nonradiological Environmental Protection Program.

t. Independent Spent Fuel Storage Installation (ISFSI)

Audits are initiated as early as practicable in the life of the activity, consistent with the schedule for accomplishing the activity, to ensure the timely implementation of QA requirements. Audit scope and schedules are established based on the status and importance of the activities performed to ensure the adequacy of, and conformance with, the Nuclear QA program.

Regularly scheduled audits are supplemented by audits for one or more of the following conditions:

a. When it is necessary to assess the capability of a contractor's QA program before awarding a contract or purchase order

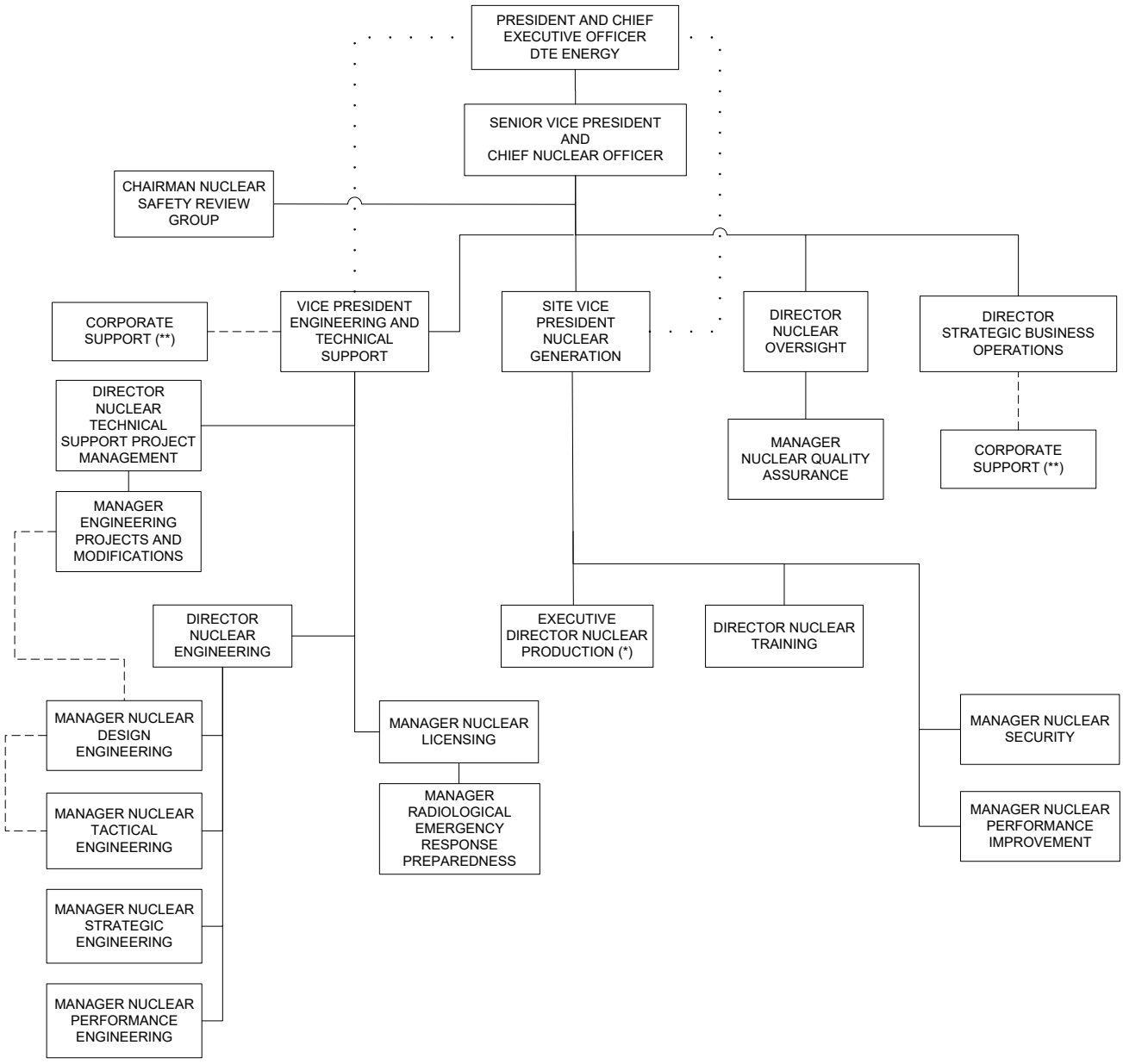
b. When, after the award of a contract, sufficient time has elapsed for implementing the QA program and it is appropriate to determine that the organization is adequately performing the functions as defined in the quality assurance program, codes, standards, and other contract documents

c. When significant changes are made in functional areas of the QA program, such as significant reorganization or procedure revisions

d. When it is suspected that the quality of the item is in jeopardy because of deficiencies in the QA program.

e. When a systematic, independent assessment of program effectiveness is considered necessary

f. When necessary to verify implementation of required corrective action.




. . . . . Signifies Direct Access

- - - - - - - Signifies Functional Relationship

(*) For details of the Nuclear Production organization, see Figures 13.1-2 and 13.1-3.

(**) When corporate support organizations perform quality-related activities for Fermi 2, such activities are performed under the Fermi 2 Quality Assurance Program.

NOTE: When a position is not filled, reporting order will be the next higher position.

**Fermi 2**
UPDATED FINAL SAFETY ANALYSIS REPORT

**FIGURE 17.2-1**
**CORPORATE/NUCLEAR GENERATION ORGANIZATION INVOLVED IN THE QUALITY ASSURANCE PROGRAM FOR OPERATION**

## 17.2A QUALITY ASSURANCE OF THE INDEPENDENT SPENT FUELSTORAGE INSTALLATION

This Appendix describes the administrative controls and the quality assurance (QA) program applied to important-to-safety (ITS) structures, systems and components associated with the Fermi 2 Nuclear Plant Independent Spent Fuel Storage Installation (ISFSI) to assure conformance to regulatory requirements and the design bases. This program is an extension of the quality assurance program described in Section 17.2, modified to address 10 CFR 72 Subpart G items specific to ISFSI and related support activities.

The QA program described in Section 17.2 is applicable to ISFSI items classified as ITS Category A. Specific aspects of the QA program are applied to ITS Categories B and C items as specified in the individual subsections.

The following definitions are applicable to the Fermi 2 Nuclear Plant Quality Assurance Program:

ITS structures, systems, and components are those features of ISFSI whose function is to:

a. Maintain the conditions required to store spent fuel safely,

b. Prevent damage to the spent fuel container during handling, or storage, or

c. Provide reasonable assurance that spent fuel can be received, handled, packaged, stored, and retrieved without undue risk to the health and safety of the public.

The definition of ITS safety categories below are based on NUREG/CR-6407, "Classification of Transportation Packaging and Dry Spent Fuel Storage System Components According to Importance to Safety."

1. Category A – ITS Category A items include structures, components, and systems whose failure could directly result in a condition adversely affecting public health and safety. The failure of a single item could cause loss of primary containment leading to release of radioactive material, loss of shielding, or unsafe geometry compromising criticality control.

2. Category B - ITS Category B items include structures, components, and systems whose failure or malfunction could indirectly result in a condition adversely affecting public health and safety. The failure of a Category B item, in conjunction with failure of an additional item, could result in an unsafe condition.

3. Category C – ITS Category C items include structures, components, and systems whose failure or malfunction would not significantly reduce the packaging effectiveness and would not be likely to create a situation adversely affecting public health and safety.

The QA program, as described in the following identified UFSAR subsections, is applied to ITS Category A, B, and C items unless modified by the description below:

17.2.1 Organization

The corporate organization established to support operation of Fermi 2 Nuclear Plant also functions to support operation of the Fermi 2 Nuclear Plant ISFSI.

Additional offsite support is provided by the storage system vendor.

Some plant personnel who perform 10 CFR 50.59 evaluation reviews also perform the corresponding ISFSI evaluation reviews under 10 CFR 72.48.

17.2.2 Nuclear Quality Assurance Program

QA program requirements are applied to the ISFSI and support structures, systems, and components using a graded approach based on the ISFSI item classification. The program requirements that apply to QA ITS Category A, B and C are identified in table 17.2A-1. Items identified as not important to safety (NITS) are excluded from the QA program.

The plant organization has the same responsibilities as described in paragraph 17.2.1.3 and subsection 17.2.2 for ITS Category A items.

17.2.3 Design Control

Design control measures for ITS Category A and Category B items are applied where appropriate per the controls in subsection 17.2.3. Additional review concerns that are specific to the ISFSI are criticality physics, shielding, and features to facilitate decontamination.

The designs of ITS Category C items specify procurement, inspection, and testing at a level appropriate for the importance of the function performed.

17.2.4 Procurement Document Control

A graded approach is applied through the use of a multi-level procurement classification system based upon the end-use of each item or service. Items procured as ITS Category A items are controlled as described in subsection 17.2.4. ITS Category A items procured as commercial grade are controlled by the existing commercial grade dedication program. ITS Categories B or C items are procured as appropriate for function and safety importance, and are excluded from the provisions of 10 CFR 21.

17.2.5 Instructions, Procedures, and Drawings

17.2.6 Document Control

17.2.7 Control of Purchased Material, Equipment, and Service. (CAT A)

17.2.8 Identification and Control of Materials, Parts, and Components. (CAT A)

17.2.9 Control of Specific Processes. (CAT A & B)

17.2.10 Inspection. (CAT A & B)

17.2.11 Test Control. (CAT A & B)

17.2.12 Control of Measuring and Test Equipment. (CAT A & B)

17.2.13 Handling, Shipping , and Storage, (CAT A)

17.2.14 Inspection, Test, and Operating Status. (CAT A)

17.2.15 Nonconforming Material, Parts, and Components. (CAT A & B)

17.2.16 Corrective Action

17.2.17 QA Records

Records pertaining to design, fabrication, erection, testing, maintenance, and use of ITS items are maintained for the duration of the General License granted under Subpart K of 10 CFR 72 for the specific storage system.

17.2.18 Audits

Audits are performed on a frequency not to exceed 24 months for quality activities related to the operation and maintenance of the ISFSI.

Regarding ISFSI the QA program, as described in the following identified UFSAR subsections, is applied to only ITS Category A and B items as follows.

TABLE 17.2A-1

| | | NUREG/CR-6407 Safety Category | | |
|---|---|---|---|---|
| | 10 CFR 50 Appendix B Criterion | A | B | C |
| I. | Organization | X | X | X |
| II. | Quality Assurance Program | X | X | X |
| III. | Design Control | X | X | X |
| IV. | Procurement Document Control | X | | |
| V. | Instructions, Procedures, and Drawings | X | X | X |
| VI. | Document Control | X | X | X |
| VII. | Control of Purchased Material, Equipment, and Services | X | | |
| VIII. | Identification and Control of Materials, Parts, and Components | X | | |
| IX. | Control of Special Processes | X | X | |
| X. | Inspection | X | X | |
| XI | Test Control | X | X | |
| XII. | Control of Measuring and Test Equipment | X | X | |
| XIII. | Handling, Storage, and Shipping | X | | |
| XIV. | Inspection, Test, and Operating Status | X | X | |
| XV. | Nonconforming Materials, Parts, or Components | X | X | |
| XVI. | Corrective Actions | X | X | X |
| XVII. | Quality Assurance Records | X | X | X |
| XVIII. | Audits | X | X | X |