Wayne H. Jens
Vice President
Nuclear Operations

Detroit Edison

Fermi-2
6400 North Dixie Highway
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(313) 586-4150

March 5, 1985
NE-85-0339

Director of Nuclear Reactor Regulation
Attention: Mr. B. J. Youngblood, Chief
Licensing Branch No. 1
Division of Licensing
U. S. Nuclear Regulatory Commission
Washington, D.C. 20555

Dear Mr. Youngblood:

Reference: (1) Fermi 2
NRC Docket No. 50-341

(2) Detroit Edison letter to NRC-Region III, "FSAR Changes Relative to the Nuclear Safety Review Group", EF2-72792, dated September 12, 1984

Subject: Clarifications of Operational QA Program

This letter documents information discussed with Mr. John W. Gilray of the NRC-NRR staff in telephone conversations on February 27 and March 5, 1985. The conversations addressed the following two issues: 1) status of the NRR review of Reference 2; and 2) operation of equipment under conditional release. Both issues are fully discussed below.

NSRG Review Scope

Reference 2 transmitted to Region III a proposed revision to the Fermi 2 Final Safety Analysis Report which dealt with a the off-site review committee identified as the Nuclear Safety Review Group (NSRG). Edison had transmitted these changes in compliance with 10CFR50.55(f). In the subject telecon, Mr. Gilray indicated that a letter transmitting this information to NRC-NRR for review only (in lieu of review and approval) is all that is required per the regulations for NTOL facilities. Therefore, Edison is providing Reference 2 for your information as Enclosure 1 to this letter. Accordingly, Edison will proceed with implementing the reference (2) change in practice and in the FSAR unless we hear from you to the contrary.

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Conditional Releases

A revision to FSAR Chapter 17.2.7 dealing with the conditional releases of equipment was discussed with Mr. Gilray. As reflected in FSAR Section 17.2.7, the conditional release process allows for the installation and testing of conditionally released items, but does not allow the items to be placed into a system declared operable until the release is cleared (i.e., the documentation lacking is received and accepted from the vendor). As reflected in the draft FSAR change in Enclosure 2, the FSAR is being revisedin a forthcoming amendment to allow an item that has been conditionally released to be placed into a system declared operable if Edison provides a documented technical evaluation including a safety evaluation, in lieu of or supplemental to vendor documents. The safety evaluation criteria which must be satisfied are in accordance with the criteria of 10CFR50.59. This procedure cannot be used for relief from Edison commitments to equipment qualification in accordance with the requirements of 10CFR50.49. Technical evaluations and 10CFR50.59 safety evaluations are performed by Detroit Edison Nuclear Engineering personnel using approved procedures. Support from other internal or external consulting organizations is used when necessary. Detroit Edison has been the architect/engineer for Fermi 2 and its engineers are qualified to perform these evaluations. Personnel performing the evaluation shall be technically competent in the disciplines appropriate to the evaluation. The procedures require the safety evaluations be approved by a cognizant engineering supervisor. The Technical Specifications require, in addition, that if it affects nuclear safety the proposed action be reviewed by the Onsite Review Organization prior to placing the item into a system declared operable and be reviewed independently after-the-fact under the cognizance of the Nuclear Safety Review Group. Included as Enclosure (3) is a copy of the Nuclear Engineering procedure for performing safety evaluations.

For those situations where a conditional release is dispositioned in the manner described above, a nonconformance document will be initiated to track the dispositioning process. The nonconformance document will specifically delineate and reference the technical basis and safety evaluation for allowing the item to be placed into a system declared operable. In addition, nonconformance documents must be approved by Nuclear Quality Assurance prior to implementation of disposition decisions.

Conditional releases and the noncomformance documents (Deviation/Event Reports-DERs) are tracked on status reports which are distributed to Nuclear Operations management. The procedure that will be written to combine together the various parts of the process, i.e., conditional releases, DERs and safety evaluations will be approved by the Manager-Nuclear Operation.

Accordingly, Edison will proceed to implement the above change as per our discussion unless we hear from you to the contrary.

Please direct any questions to Mr. O. K. Earle at (313) 586-4211.

Sincerely,

Wayne H. Jens

cc: (* with enclosures)
Mr. P. M. Byron*
Mr. M. D. Lynch*
Mr. J. W. Gilray*
Mr. F. C. Hawkins (Region III)*
USNRC, Document Control Desk
Washington, DC 20555

Enclosure 1 - Edison to NRC Letter

EF2-72792, Dated September 1?, 1984

Wayne H. Jens
Vice President
Nuclear Operations

Detroit Edison

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6400 North Dixie Highway,
Newport, Michigan 48166
(313) 586-4150

September 12, 1984
EF2-72,792

Mr. James G. Keppler
Regional Administrator
Region III
U. S. Nuclear Regulatory Commission
799 Roosevelt Road
Glen Ellyn, Illinois 60137

Dear Mr. Keppler:

Reference: Fermi 2
NRC Docket No. 50-341

Subject: FSAR Changes Relative to the Nuclear Safety Review Group

Pursuant to 10CFR50.55(ε), approval is requested to make two changes which would reduce stated or implied commitments to the Quallity Assurance program description in the FSAR. Both changes deal with the off-site review committee designated the Nuclear Safety Review Group (NSRG). The changes are as follows:

1. FSAR Section 17.2.15

Description (See attached marked-up)

REMOVE LAST SENTENCE OF FIRST PARAGRAPH

This change removes the implied requirement that the Nuclear Safety Review Group (NSRG) approval of proposed corrective action is required for nonconforming material considered to be a significant condition adverse to quality.

Rationale:

The NSRG is not structured to operate in such an inline fashion. There are no NRC or standards requirements (Fermi 2 Technical Specifications; 10CFR50 Appendix B, ANSI N18.7-1976) that NSRG approval be obtained prior to implementing corrective actions except if an unreviewed safety question or Technical Specification revision is involved. Section 17.2.16 of

the Fermi 2 FSAR, which deals with corrective action, already provides that corrective actions for significant conditions adverse to quality be documented and reported to the NSRG chairman as well as to the Superintendent - Nuclear Production.

2. FSAR Section 17.2.15

Description (See attached mark-up FSAR page 17.2-28):

AT THE END OF THE LAST SENTENCE REPLACE "...and the NSRG for their review and assessment" WITH "for his review and assessment"

This change removes the requirement that NSRG review all trend analysis reports generated by QA.

Rationale:

While the NSRG would likely review any such report of significance, as well as some of the base documents such as audit and inspection reports, it should not be burdened with another all inclusive specific review requirement adding to an already lengthy list. This specific review requirement does not appear in 10CFR50 Appendix B, the Fermi 2 Technical Specifications or in the related standard, ANSI N18.7-1976.

Neither of these changes is considered to reduce the effectiveness of the Quality Assurance program. Your prompt review and approval is requested.

Please direct any questions to Mr. O. Keener Earle at 313-586-4211.

Sincerely,

cc: Mr. P. M. Byron*
Mr. F. Hawkins*
Mr. M. D. Lynch*
USNRC, Document Control Desk*
Washington, D. C. 20555

*With Attachment

Corrective action will be proposed by technically qualified organizations and approved by supervisory personnel having responsibility for the nonconforming item. ~~If the nonconformance is considered to be a significant condition adverse to quality, the proposed corrective action will also be reviewed by the NSRG.~~

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Copies of completed nonconformance documents are maintained in the plant files.

35 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.

The Nuclear QA Department periodically analyzes quality data obtained from various reports, such as nonconformance documents,
56 inspection reports, and audit reports, to determine what quality trends exist. The analysis is reported to the Superintendent - Nuclear Production, ~~and the NSRG for their review and assessment.~~ for his review and assessment.

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, 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 and reported to the Superintendent - Nuclear Production and the NSRG chairman. The Nuclear QA Department reviews all nonconformance
56 documents to determine whether the cause of the problem has been identified and adequate action initiated. The Superintendent - Nuclear Production is notified of conditions requiring further action. 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
35 nonconformances.

When vendors furnish products that do not conform to the requirements of the applicable purchase contract, the Nuclear QA Department 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 his QA program and
56 products as requested, the Nuclear QA Department may have the vendor removed from the list of approved suppliers.

Enclosure 2 - FSAR Revision to

Section 17.2.7

The plant section heads and supervisors are responsible for verifying that the correct revisions of necessary documents are available before work is begun. The Nuclear QA Department will independently conduct surveillance and audits of procedures, drawings, and other documents to verify that only up-to-date revisions are being used. 35

The Supervisor of Information Systems 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 Nuclear QA Department independently conducts the surveillance and audits of procedures, drawings, and other documents to verify that only up-to-date revisions are being used. The requirements for retaining and storing the quality-related documentation required above and other historical records are described in Subsection 17.2.17. 35

17.2.7 Control of Purchased Material, Equipment, and Services

The Vice President - Nuclear Operations approves the placement of contracts based on the analysis and recommendations of the support organizations. The evaluation of the QA capabilities of such vendors and contractors is the responsibility of the Nuclear QA Department. 35

Two types of QA evaluation of a contractor or vendor are possible. Either or both 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; or documented review of audit reports by other utilities, CASE Register, or other similar methods 35

b. Facility Evaluation - Evaluation of a vendor's QA capabilities conducted at his facility, including-- 35

   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

A notice of evaluation results is transmitted to the contractor or vendor by the Nuclear Procurement section of the Nuclear Administration Department. After evaluation, the approved 35 56

FOR INPO ONLY
NO FSAR CHANGE
ON THIS PAGE

sources are placed on a current list of approved suppliers. 56 Additions and deletions to the list are submitted by the Nuclear QA Department.

35 To ensure that material and equipment fabrication is in accordance with procurement requirements, the Nuclear QA Department directs the surveillance of vendor activities, which includes witnessing significant fabrication check points, validity of vendor-supplied documentation, and overall vendor performance as appropriate to the purchased item. The surveillance activities are accomplished in accordance with approved vendor audit and inspection procedures.

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, 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 made using a receiving inspection report. 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. Documentation identifying any other procurement requirements that have not been satisfied must be provided by the supplier. An item is considered nonconforming until sufficient quality documentation has been provided. The receiving inspection procedures permit the conditional release of material lacking the specified QA records, provided the item can be readily removed if necessary. 35 Functional testing may be performed on materials installed under conditional release; however, these materials are not to be placed in service.

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Subsequent to a satisfactory inspection, the receiving inspection report and required documentation of tests, certificates of conformance, 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 pending resolution.

The procurement of spare or replacement parts for structures, systems, and components important to safety 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.

17.2.8 Identification and Control of Materials, Parts, and Components

35 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

INSERT

Unless a technical evaluation has been performed and documented via a safety evaluation request in accordance with both 10 CFR 50.59 and approved procedures.