

Detroit
Edison

Douglas R. Gipson
Senior Vice President
Nuclear Generation

Fermi 2
6400 North Dixie Highway
Newport, Michigan 48166
(313) 586-5249

May 10, 1996
NRC-96-0048

U. S. Nuclear Regulatory Commission
Attn: Document Control Desk
Washington, D. C. 20555

Reference: Fermi 2
NRC Docket No. 50-341
NRC License No. NPF-43

Subject: Proposed Quality Assurance Program Change for Audit Program

In accordance with 10 CFR 50.54(a), Detroit Edison Company requests NRC review and approval of a change to the Fermi 2 Quality Assurance Program as contained in Section 17.2 of the Updated Final Safety Analysis Report. This change revises Section 17.2.18.5, "Scope and Schedule of Audits" of the UFSAR to delete frequencies from audits specified by regulations and deletes the requirement to perform an annual audit of the fitness for duty laboratory.

Deletion of frequencies from audits presently specified in the Quality Assurance program is a reduction in commitment in that audit frequencies specified by regulations will not be listed. This change will preclude additional Quality Assurance program changes in the future should the frequencies specified by regulations be changed, such as, with the fitness for duty laboratory audit.

The removal of the requirement to perform an annual audit of the fitness for duty laboratory is a reduction in commitment based on 10 CFR Part 26 interpretation from a previous Fermi submittal to the NRC for a Quality Assurance Program change. However, the NRC Office of General Council has determined an annual audit is not required as documented in a letter from the NRC to Union Electric Company, dated June 22, 1994, addressing an unresolved item from Inspection Report No. 50-483/93021 pertaining to regulatory requirements to audit HHS certified laboratories on an annual basis. This letter states "The OGC has concluded that 10 CFR Part 26, as currently written, does not require a licensee to conduct an annual audit of HHS certified laboratories used to perform fitness for duty confirmatory

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testing." The audit will be conducted as specified in the Quality Assurance Program, i.e., at least once per 24 months or as necessary based on program performance or changes in the program.

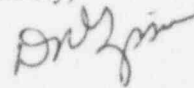
Editorial revision has also been made in reordering the sequence of audits to separate audits with frequencies specified by regulation from those not specified by regulation.

The compliance of Detroit Edison with the requirements of 10 CFR 50, Appendix B is not adversely affected by this proposed change in the Quality Assurance Program.

The marked up pages of Section 17.2.18.5 of the UFSAR are attached.

Please contact Mr. Hari O. Arora at (313) 586-4213 with any questions. Prompt review and approval of this request will be appreciated.

Sincerely,



Enclosure

cc: T. G. Colburn
M. J. Jordan
H. J. Miller
A. Vogel

QA PROGRAM MARKED UP PAGES

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.

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The following internal Nuclear Generation areas will be audited at least once per 24 months, except where a specific frequency is listed.

- 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, 10 CFR 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 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 or the Senior 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 at least once every 12 months (specified by regulation).
- m. Access Authorization at least once per 24 months (specified by regulation).
- n. Fitness for Duty at least once every 12 months (specified by regulation).
- o. Fitness for Duty Laboratory at least once every 12 months (specified by regulation).
- p. Emergency Preparedness at least once per 12 months (specified by regulation).
- q. Radiological Protection at least once per 12 months (specified by regulation).
- r. Station Blackout.
- s. Nonradiological Environmental Protection Program.

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.

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The following internal Nuclear Generation areas will be audited at least once per 24 months, except where a specific frequency is listed or a 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, 10 CFR Part 20.
- 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 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 or the Senior 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).
- m. Access Authorization (as specified by regulation).
- n. Fitness for Duty (as specified by regulation).
- o. Emergency Preparedness (as specified by regulation).
- p. Radiological Protection (as specified by regulation).

- q. Fitness for Duty Laboratory
- r. Station Blackout.
- s. Nonradiological Environmental Protection Program.