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August 11, 1995  
NRC-95-0067

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

- References: 1) Fermi 2  
NRC Docket No. 50-341  
NRC License No. NPF-43
- 2) NRC Inspection Report 50-341/95008,  
dated July 12, 1995

Subject: Reply to a Notice of Violation (95008-03)

Enclosed is Detroit Edison's response to the Notice of Violation (NOV) contained in Reference 2. The NOV concerns failure to follow procedure which contributed to inadequate Quality Assurance followup of the Measuring and Test Equipment Program.

The following commitments, as noted in the response to the NOV, are being made in this letter:

1. All 1993 and 1994 audits will be reviewed to ensure that the post-audit reviews of checklists were properly completed. For any checklists that are found to be improperly completed, then an evaluation will be conducted to determine the impact of the incomplete checklist item. This review and evaluation will be completed by November 15, 1995.
2. The next session of QA Audit Team Leader refresher training will be modified to include emphasis on the importance of procedural requirements for completing audit documentation and to perform self-checking when performing audit activities.

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U.S. Nuclear Regulatory Commission  
August 11, 1995  
NRC-95-0067  
Page 2

If there are any questions related to this response, please contact Ken Riches,  
Compliance Engineer at (313) 586-5529.

Sincerely,

*Robert McKeon*

Enclosure

cc: T. G. Colburn  
H. Miller  
M. P. Phillips  
A. Vogel  
Region III

**Response to Notice of Violation 50-341/95008-03**

**Statement of Notice of Violation**

10 CFR Part 50, Appendix B, Criterion V, requires, in part, that activities affecting quality be accomplished in accordance with prescribed procedures. Fermi Interfacing Procedure FIP-AS1-01, Revision 10, "Internal Audits and Surveillances," Steps 6.6.1 and 6.6.2, require, in part, that the team leader review the completed audit checklist before writing the audit report, to ensure that all checklist items have been addressed and to acknowledge this post-audit review by signing and dating the checklist.

Contrary to the above, Quality Assurance Audit 93-0122, of the Measuring and Test Equipment Program, July 14, 1993, an activity affecting quality, was not accomplished in accordance with prescribed Procedure FIP-AS1-01 in that the team leader did not review the checklists until October 1993, approximately three months after the audit report was issued. This resulted in a failure to recognize that Checklist Area 4.1.5, evaluations of out-of-tolerance measuring & test equipment (M&TE) was not addressed, even though this area was found deficient during the previous audit.

**Reason for the Violation**

Audit team members did not perform self-checking to confirm that the checklist accurately documented all activities. During the post-audit review, the Audit Team Leader did not verify that all checklist items had been observed and documented. Additionally, the Audit Team Leader failed to sign for review of the audit checklist items prior to writing the audit report.

**Corrective Actions Taken and the Results Achieved**

To ensure that programmatic guidance is adequate and clearly stated, FIP-AS1-01, "Internal Audits and Surveillances," was reviewed. This review confirmed that FIP-AS1-01 clearly describes the Audit Team Leaders responsibility associated with review and dating of checklist prior to issuance of the audit report.

A sampling of other audits performed in 1993 and 1994 has been conducted and additional occurrences of incorrectly completed checklists were identified. In addition, lessons learned meetings were conducted with all QA auditors to emphasize the importance of reviewing completed checklists prior to issuing the final audit report and to perform self-checking when performing audit activities.

The M&TE program was audited by QA during the period of June 5 through June 23, 1995. This audit addressed the out-of-tolerance evaluations that were not addressed in the 1993 audit.

**Corrective Actions Taken to Prevent Recurrence**

The remaining 1993 and 1994 audits that were not reviewed as part of the above sample will be reviewed to ensure that the post-audit review checklists were properly completed. For any checklists that are found to be improperly completed, then an evaluation will be conducted to determine the impact of the incomplete checklist item. This review and evaluation will be completed by November 15, 1995.

The next session of QA Audit Team Leader refresher training will be modified to include emphasis on the importance of procedural requirements for completing audit documentation and to perform self-checking when performing audit activities.

**Date When Full Compliance Will Be Achieved**

Full compliance was achieved in June, 1995, when the lessons learned meetings were conducted with QA audit personnel and the 1995 M&TE audit was conducted, which covered the area not addressed in 1993.