UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION III
2443 WARRENVILLE ROAD, SUITE 210
LISLE, IL 60532-4352

November 12, 2009

EA-09--267

Mr. Jack M. Davis
Senior Vice President and
Chief Nuclear Officer
Detroit Edison Company
Fermi 2 - 210 NOC
6400 North Dixie Highway
Newport, MI 48166

SUBJECT: FERMI POWER PLANT, UNIT 2
NRC INSPECTION REPORT NO. 05000341/2009010(DRS)

Dear Mr. Davis:

On October 23, 2009, the U. S. Nuclear Regulatory Commission (NRC) completed a review of your identification of incomplete medical testing of licensed operators at the Fermi 2 Power Plant. The enclosed report documents our findings which were discussed with J. Plona and other members of your staff on October 23, 2009.

This inspection was conducted between August 14, 2009, and October 23, 2009, and examined activities conducted under your license as they relate to safety and compliance with the Commission's rules and regulations and with the conditions of your operator licenses.

Based on the results of this review, one apparent violation involving 10 CFR 50.9, "Completeness and Accuracy of Information" was identified. This violation is being considered for escalated enforcement action in accordance with the NRC's Enforcement Policy. The current Enforcement Policy is included on the NRC's Web site at http://www.nrc.gov/about-nrc/regulatory/enforcement/enforc-pol.pdf.

On August 13, 2009, you identified that since 1999, licensed operators had not received olfactory and tactile testing as required by American National Standards Institute/American Nuclear Society (ANSI/ANS) 3.4-1976. We renewed and issued numerous senior reactor operator and reactor operator licenses since May 1999 without knowledge of the incomplete medical testing, relying on incomplete and inaccurate information you provided in licensing documentations. Your review determined Detroit Edison had changed their medical implementation procedure in May 1999, inadvertently deleting olfactory and tactile testing.

The circumstances surrounding the apparent violation, the significance of the issues, and the need for lasting and effective corrective actions were discussed with members of your staff during an exit meeting on October 23, 2009. As a result, it may not be necessary to conduct a Pre-decisional Enforcement Conference (PEC) in order to enable the NRC to make an enforcement decision. In addition, since your facility has not been the subject of escalated enforcement actions within the last two years, and based on our understanding of your corrective actions, a civil penalty may not be warranted in accordance with Section VI.C.2 of the Enforcement Policy. The final decision will be based on your confirming on the license docket that the corrective actions previously described to the staff have been or are being taken.

Before the NRC makes its enforcement decision, we are providing you an opportunity to either: (1) respond to the apparent violation addressed in this inspection report within 30 days of the date of this letter; or (2) request a PEC. If a PEC is held, it will be open for public observation. The NRC will also issue a press release to announce the conference. Please contact Mr. Hironori Peterson at (630) 829-9707 within seven days of the receipt of this letter to notify the NRC of your intended response.

If you choose to provide a written response, it should be clearly marked as a "Response to an Apparent Violation in Inspection Report No 050000341/2009010(DRS); EA-09-267" and should include for the apparent violation: (1) the reason for the apparent violation, or if contested, the basis for disputing the apparent violation; (2) the corrective steps that have been taken and the results achieved; (3) the corrective steps that will be taken to avoid further violations; and (4) the date when full compliance will be achieved. Your response may reference or include previously docketed correspondence, if the correspondence adequately addressed the required response. If an adequate response is not received within the time specified or an extension of time has not been granted by the NRC, the NRC will proceed with its enforcement decision or schedule a pre-decisional enforcement conference.

In addition, please be advised that the characterization of the apparent violation described in the enclosed inspection report may change as a result of further NRC review. You will be advised by separate correspondence of the results of our deliberations on this matter.

In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice," a copy of this letter, its enclosure, and your response, if you choose to provide one, will be available electronically for public inspection in the NRC Public Document Room or from the Publicly Available Records System (PARS) component of NRC's Agencywide Documents Access and Management System (ADAMS), accessible from the NRC Web site at http://www.nrc.gov/reading-rm/adams.html (the Public Electronic Reading Room).

To the extent possible, your response should not include any personal privacy, proprietary, or safeguards information so that it can be made available to the Public without redaction.

Sincerely,

/RA/

Anne T. Boland, Director
Division of Reactor Safety

Docket No. 50-341
License No. NPF 43

Enclosure: Inspection Report 050000341/2009010(DRS);
w/attachment: Supplemental Information

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U. S. NUCLEAR REGULATORY COMMISSION

REGION III

Docket No:	50-341
License No.	NPF 43
Report No:	05000341/2009010(DRS);
Licensee:	Detroit Edison Company
Facility:	Fermi 2 Nuclear Generating Station
Location:	Monroe, Michigan
Dates:	August 14, 2009 through October 23, 2009
Inspector:	R. K. Walton, Operations Engineer
Approved by:	H. Peterson, Chief Operations Branch Division of Reactor Safety

Enclosure

SUMMARY OF FINDINGS

IR 05000341/2009010(DRS); 08/14/2009 – 10/23/2009 (in-office review); Fermi 2 Power Plant, Licensed Operator Requalification.

This report covers an approximate two-month period of in-office review of licensee and NRC documents in the area of Operator Licensing. The review was conducted by one regional specialist inspector. One apparent violation was identified during the review. The significance of most findings is indicated by their color (Green, White, Yellow, Red) using Inspection Manual Chapter (IMC) 0609, "Significance Determination Process." Findings for which the Significance Determination Process does not apply may be "Green" or be assigned a severity level after NRC management review. The NRC's program for overseeing the safe operation of commercial nuclear power reactors is described in NUREG-1649, "Reactor Oversight Process," Revision 3, dated July 2000.

A. Inspector-Identified and Self-Revealed Findings

Cornerstone: Mitigating Systems

No violations of significance were identified.

B. Licensee-Identified Violations

Apparent Violation: On August 13, 2009, during performance of a self-assessment, the licensee identified that two American National Standards Institute (ANSI) Standard requirements for physical examinations of licensed operators were no longer being administered by Fermi medical personnel. Specifically, olfactory and tactile testing were deleted by a procedure change that was implemented in May 1999. Because the issue affected the NRC's ability to perform its regulatory function, it was evaluated using the traditional enforcement process. Although licensed operators were subsequently tested and found to have passed the olfactory and tactile tests, this failure had regulatory significance because the incomplete and inaccurate information was provided under a signed statement to the NRC and impacted numerous licensing decisions. This was preliminarily determined to be an apparent violation of 10 CFR 50.9, "Completeness and Accuracy of Information." No cross cutting aspect was identified for the finding due to the age of the performance deficiency (e.g., 1999).

REPORT DETAILS

1. REACTOR SAFETY

Cornerstone: Initiating Events, Mitigating Systems, and Barrier Integrity

1R11 Licensed Operator Requalification Program (71111.11)

.1 Conformance with Operator License Conditions

a. Inspection Scope

The inspector reviewed licensee records and related NRC regulations. The inspectors verified licensee actions to comply with the medical standards delineated in American National Standards Institute/American Nuclear Society (ANSI/ANS) 3.4-1976, "American National Standard Medical Certification and Monitoring of Personnel Requiring Operator Licenses for Nuclear Power Plants," and with 10 CFR 55.21, "Medical examination," 10 CFR 55.23, "Certification," 10 CFR 55.33, "Disposition of an initial application," and 10 CFR 55.53, "Conditions of licenses." The inspector reviewed Condition Assessment Resolution Document (CARD) 09-26243 and its associated root cause evaluation.

b. Findings

Introduction: On August 13, 2009, during performance of a self-assessment, the licensee identified that two ANSI Standard requirements for physical examinations of licensed operators were no longer being administered by Fermi medical personnel. Specifically, olfactory and tactile testing were deleted by a procedure change that was implemented in May 1999. Although licensed operators were subsequently tested and passed the testing, the issue was considered to be of regulatory significance because the information was provided to the NRC under a signed statement and resulted in numerous licensing actions that were taken based on incomplete and inaccurate information being provided to the NRC. This was an apparent violation of 10 CFR 50.9, "Completeness and Accuracy of Information."

Description: Applicants for licensed reactor operator and senior reactor operator positions are required to be medically examined as part of the licensee's initial operator license program. Similarly, previously qualified operator licenses expire every six years and must be renewed to allow the operator to continue to perform license duties. When a license renewal occurs, the licensee must submit an NRC Form 398, "Personal Qualification Statement – Licensee," and an NRC Form 396, "Certification of Medical Examination by Facility Licensee," (required by 10 CFR 55.21) to the NRC. The NRC Form 396 certifies, when signed by a senior facility licensee official, that the operator has been examined by a doctor and meets the medical standards in the ANS/ANSI 3.4, edition specified.

On August 13, 2009, while performing a self-assessment, the licensee identified that two ANSI Standard requirements for physical examinations were no longer being administered by Fermi medical personnel. Specifically, ANS/ANSI 3.4-1976 Sections 5.4.2 required operators be able to detect odor of products of combustion and

Section 5.4.14 required tactile discrimination sufficient to distinguish among various shapes of control knobs and handles by touch. The licensee documented this condition on CARD 09-26243.

On August 14, the licensee ordered medical equipment to perform both olfactory and tactile testing of all licensed operators. On August 18, all licensed operators assigned to the control room were subjected to olfactory and tactile testing prior to assuming shift responsibilities. Eventually, all licensed operators submitted to, and passed, olfactory and tactile testing.

The licensee root cause report determined that the licensee changed their Medical Certification program contained in MGA10, "Fitness-for-Duty," to MGA13, "Licensed Operator Medical Certification" in December 1997. Associated forms for MGA13 did not contain testing requirements for products of combustion (olfactory testing) nor did the form contain testing requirements for neurological discrimination (tactile testing). The medical examinations included use of this form beginning in May 1999.

Since May 1999, NRC Region III issued and renewed numerous operator licenses based on the NRC Form 396 signed by the facility licensee stating that licensed operators (and operator license applicants) had received a medical examination following the criteria provided by ANS/ANSI 3.4-1976. The information provided to the NRC in the various license renewal applications (and initial license applications) was material to the NRC licensing action. Because the license applications inappropriately certified on NRC Form 396 that the requirements of ANS/ANSI 3.4-1976 were met, licensing actions were taken by NRC Region III that were incorrect. Because the licensee failed to provide complete and accurate information to the NRC in the license renewal applications (and initial license applications), this was identified as an apparent violation of 10 CFR 50.9. This apparent violation, due to its age, did not have any cross-cutting aspects.

Analysis: Because a violation of 10 CFR 50.9 is considered to be a violation that potentially impedes or impacts the regulatory process, it was dispositioned using the NRC traditional enforcement instead of the Reactor Oversight Process. The finding was determined to be more than minor because the information associated with the numerous operator license renewals and initial license applications was provided to the NRC under a signed statement by the Site Vice President and impacted NRC licensing decisions. Licensed operators did not have a complete physical hence there was potential for the operators to possess medical conditions that could disallow control room operations. In addition, the failure to conduct all medical tests required by ANS/ANSI 3.4–1976, per 10 CFR 55.21, invalidated all initial and renewed operator licenses issued during the period May 1999, until August 2009. The licensed operators were subsequently tested and passed the missed examinations; however, the issue has regulatory significance because the information was material to NRC-licensing decisions and NRC-operating licenses were issued without the proper medical testing being completed.

Enforcement: Title 10 CFR 50.9 requires, in part, that information provided to the Commission by an applicant for a license or by a licensee or information required by statute or by the Commission's regulations, orders, or license conditions to be maintained by the applicant or the licensee shall be complete and accurate in all material respects.

Title 10 CFR 55.21 requires, in part, that an applicant for a license shall have a medical examination by a physician and the licensee shall have a medical examination by a physician every two years. The physician shall determine that the applicant or licensee meets requirements of Section 55.33(a)(1).

Title 10 CFR 55.33(a)(1) requires, in part, that applicants medical condition and general health will not adversely affect the performance of assigned operator job duties or cause operational errors endangering public health and safety.

Title 10 CFR 55.23 requires, in part, that to certify the medical fitness of the applicant, an authorized representative of the facility licensee shall complete and sign NRC Form-396, "Certification of Medical Examination by Facility Licensee."

NRC Form-396, when signed by an authorized representative of the facility licensee, certifies that a physician conducted a medical examination of the applicant and that the guidance contained in the specified edition of ANSI/ANS 3.4, "Medical Certification and Monitoring of Personnel Requiring Operator Licenses for Nuclear Power Plants" was followed in conducting the examination and making the determination of medical qualification. The licensee certified that ANS/ANSI 3.4-1976 would be followed.

American National Standards Institute/American Nuclear Society 3.4-1976, Section 5.4 provides specific minimum capacities required for medical qualifications. Section 5.4.2, requires, "Ability to detect odor of products of combustion and tracer or marker gases." Section 5.14 requires, "Tactile discrimination sufficient to distinguish among various shapes of control knobs and handles by touch."

From May 1999 until August 13, 2009, the facility licensee had not completed physical examinations of licensed operators in accordance with ANSI/ANS 3.4-1976. The licensee submitted numerous NRC Form-396s for renewal of senior reactor operator and reactor operator licenses and for initial license applicants that certified that the applicant met the medical requirements of ANSI/ANS 3.4-1976 when, in fact, adequate olfactory and tactile testing had not been completed. This information was material to the NRC because it formed the basis for licensing decisions for plant operators. Submitting incomplete or inaccurate information to the NRC that would have resulted in a reconsideration of a regulatory position was considered an Apparent Violation (**AV 05000341/2009010-01**) of 10 CFR 50.9. This issue was entered in the licensee's corrective action program as CARD 09-26243.

The licensee performed a root cause evaluation for this condition. The licensee took or plans to take a number of corrective actions including: (1) immediately performing tactile and olfactory testing of licensed operators assigned control room responsibilities; (2) revising procedure MGA13 to conform with ANSI 3.4-1976 requirements for tactile and olfactory testing; (3) revising Nuclear Quality Assurance audit planning guides for

compliance to ANSI/ANS 3.4-1976 in lieu of complying with the MGA13 procedure; and (4) providing just-in-time training to medical staff prior to conducting yearly physicals.

4OA6 Management Meetings

.1 Exit Meeting Summary

On October 23, 2009, the inspector presented the inspection results to Mr. J. Plona and other members of the Fermi staff. Mr. Plona and the staff acknowledged the issue presented. The inspector confirmed that none of the potential report input discussed was considered proprietary.

ATTACHMENT: SUPPLEMENTAL INFORMATION

SUPPLEMENTAL INFORMATION

KEY POINTS OF CONTACT

Licensee
J. Plona, Site Vice President
T. Conner, Plant Manager
C. Walker, Director, Organizational Effectiveness
G. Strobel, Operations Manager
D. Coseo, Operations Training General Supervisor
R. Johnson, Licensing Manager
G. Ohlemacher, Supervisor, Licensing
J. Flint, Senior Licensing Specialist

Nuclear Regulatory Commission
J. Giessner, Chief, Reactor Projects, Branch 4, Region III
R. Walton, Operations Engineer, Region III
R. Lerch, Project Engineer, Branch 4, Region III
B. Jones, Resident Inspector, Fermi Power Plant

LIST OF ITEMS OPENED, CLOSED, AND DISCUSSED

Opened

05000341/2009010-01	AV	Failure to Provide Complete Information to the NRC which Impacted Licensing Decisions. (Section 1R11)

Closed

None

Discussed

None

LIST OF DOCUMENTS REVIEWED

The following is a list of documents reviewed during the inspection. Inclusion on this list does not imply that the NRC inspectors reviewed the documents in their entirety, but rather, that selected sections of portions of the documents were evaluated as part of the overall inspection effort. Inclusion of a document on this list does not imply NRC acceptance of the document or any part of it, unless this is stated in the body of the inspection report.

1R11 Licensed Operator Requalification

CARD 09-26243, Fermi Licensed Operator Exam does not meet ANSI Standard; September 2009

Root Cause Report for CARD 09-26243; October 13, 2009

ANS/ANSI-3.4-1976; Medical Certification and Monitoring of Personnel Requiring Operator Licenses for Nuclear Power Plants.

LIST OF ACRONYMS USED

ANS	American Nuclear Society
ANSI	American National Standards Institute
CARD	Condition Assessment Resolution Document
CFR	Code of Federal Regulations
IMC	Inspection Manual Chapter
NRC	U. S. Nuclear Regulatory Commission
NRR	Nuclear Reactor Regulation
PEC	Pre-decisional Enforcement Conference

To the extent possible, your response should not include any personal privacy, proprietary, or safeguards information so that it can be made available to the Public without redaction.

Sincerely,

/RA/

Anne T. Boland, Director
Division of Reactor Safety

Docket No. 50-341
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Letter to Jack M. Davis from Anne T. Boland dated November 12, 2009

SUBJECT: FERMI POWER PLANT, UNIT 2
NRC INSPECTION REPORT NO. 05000341/2009010(DRS)

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