U.S. NUCLEAR REGULATORY COMMISSION

REGION III

Report No. 50-341/92003(DRSS)

Docket No. 50-341 License No. NPF-43

Licensee: Detroit Edison Company
2200 Second Avenue
Detroit, MI 48226

Facility Name: Fermi 2 Atomic Power Plant

Inspection At: Plant Site and NRC Region III Headquarters, Glen Ellyn, Illinois

Inspection Dates: January 30 - February 25, 1992

Inspector: James Belanger for
Gary L. Pirtle
Plant Protection Analyst
3/17/92
Date

Reviewed By: James Belanger for
James R. Creed, Chief
Safeguards Section
3/17/92
Date

Approved By: R Greger
L. Robert Greger, Chief
Reactor Programs Branch
3/19/92
Date

Inspection Summary

Inspection between January 30 and February 25, 1992 (Report No. 50-341/92003 (DRSS))
Areas Inspected: Reactive, announced fitness-for-duty (FFD) inspection involving management actions and sanctions; chemical testing; FFD procedure guidance; audits; protection of information; and followup on previous inspection findings.
Results: The licensee was found to be in compliance with NRC requirements within the areas examined except as noted below:

1. In one case, the unescorted access for an individual with a positive drug test result was not removed in a timely manner.

2. In twelve cases, confirmatory tests for alcohol were not conducted.

3. In four cases, urine specimens were not collected during for-cause tests.

4. In one case, a blood sample was analyzed by a laboratory not certified by the Department of Health and Human Services (HHS) to perform drug abuse analysis in accordance with 10 CFR Part 26 requirements.

5. In one case, a urine split sample was sent for analysis to the same laboratory that performed the initial analysis. Additionally, for approximately a five month period, the contracted laboratory arrangements precluded split samples being processed by a different laboratory than the one that performed the initial analysis.

Some sections of the FFD procedure required clarification to assure that the procedure did not conflict with the requirements of 10 CFR Part 26.

Strengths were noted in reference to the Quality Assurance audits, the progress in consolidating FFD functions under one department, the FFD Administrator's knowledge of FFD requirements, and the observed sensitivity to protecting the privacy of FFD-related records and information.

The inspection results, coupled with the licensee's audit findings, indicate multiple past failures by the Medical Department to adequately comply with certain provisions of the licensee's FFD program. Continued failures could reduce the overall effectiveness of meeting FFD program objectives. Management implemented corrective actions, to include consolidation of FFD responsibilities under the security department, warrant closely monitored and aggressive oversight.

Three previous FFD-related open inspection findings were reviewed and closed.

DETAILS

1. Key Persons Contacted

*D. Gipson, Assistant Vice President and Manager, Nuclear Production
*R. McKeon, Plant Manager
*A. Settles, Director Licensing
*J. Korte, Director, Nuclear Security/Fitness-For-Duty Program Manager
*L. Goodman, Director, Quality Assurance
W. Duncan, Director, Health and Safety
*J. Tibai, Supervisor, Compliance
*M. Candela, Supervisor, Personnel Security
*J. Joy, Senior Compliance Engineer
*L. Edwards, Security Compliance Supervisor
*R. Fitzsimmons, Fitness-For-Duty Administrator
*J. Louweis, Quality Assurance Specialist

*K. Riemer, Resident Inspector, NRC Region III

The asterisk (*) denotes those present during the February 20, 1992 exit interview conducted at the end of the onsite portion of the inspection.

2. Followup on Previous Inspection Findings (IP 92701, 92702, 92703)

a. (Closed) Open Item (Report No. 50-341/89022-01): This open item was discussed in Section 3 (page 8) of the above referenced report and noted that a conflict existed between the Plant Manager's policy and the Fitness-For-Duty (FFD) procedure in reference to who was responsible (the employee or the supervisor) for obtaining medical referral when prescribed medication which could warrant duty restrictions was used while on duty. The licensee was requested to resolve the conflict in guidance.

Section 6.8 of procedure FIP AD4-02 "Drug and Alcohol Testing" was revised to require the supervisor to coordinate with the Medical Department if clarification regarding restricted duties is needed because of an employee's use of prescription or non-prescription medication. This item is considered closed.

b. (Closed) Open Item (Report No. 50-341/89022-02): This open item was discussed in Section 3 (page 8) of the above referenced report and pertained to inadequate procedure guidance for the Employee Assistance Program (EAP) in reference to non-drug related fitness-for-duty issues.

The licensee's Medical Department prepared a document entitled "Operational Procedures for the Employee Assistance Program" dated March 21, 1990. The document provides adequate guidance in reference to reporting responsibility; record-keeping; communication with persons outside of the medical department on case-related material; EAP followup; status of personnel using the EAP Program; and other appropriate areas. The Medical Department procedure clarifies that the procedure requirements apply to all Fermi 2 FFD cases whether the problem involves substance abuse or is a non-drug FFD issue. This item is considered closed.

c. (Closed) Open Item (Report No. 50-341/89022-03): This open item was discussed in Section 3 (page 8) of the above referenced report and pertained to lack of aggressiveness and timeliness by the Medical Department in resolving an identified non-drug FFD issue in that plant management was not advised of a potential FFD concern involving one of the plant's employees.

Section 6.3.3 of FFD procedures FIP-AD4-01, Section 6.9.2 of FFD procedure FIP-AD4-02, and Section III of the Medical Department's "Operational Procedures for the Employee Assistance Program" have been revised to require the FFD Program Manager to be advised if an employee may constitute a hazard to himself/herself or others (even if the employee is self-referred), and if the Medical Department determines that an individual should not continue working at the site. This item is considered closed.

3. Entrance and Exit Interviews

a. At the beginning of the onsite portion of the inspection, Mr. R. Stafford, General Director, Nuclear Assurance, and other members of the licensee's staff were informed of the purpose of the visit and the functional areas to be examined.

b. The inspector met with the licensee representatives denoted in Section 1 at the conclusion of the onsite inspection on February 20, 1992. A general description of the scope of the inspection was provided. The licensee representatives were informed that the inspection findings would be reviewed by NRC Region III management and that they would be advised if the management review results were significantly different from the results discussed during the exit interview. Briefly listed below are the findings discussed during the exit interview and a statement provided by or describing licensee management's response to the findings.

(1) Personnel were advised that three previous open inspection findings were reviewed and will be recommended for closure (see Section 2 for details).

(2) A potential violation was noted in reference to chemical testing. Confirmatory testing for alcohol abuse was not conducted in 12 cases between October 1990 and May 1991. Between January and December 1991, there were four occasions whereby a urine sample was not collected for analysis during for-cause testing.

Additionally, on January 23, 1991, a blood sample collected for a blood alcohol level test was analyzed at a local hospital laboratory that was not certified under the U.S. Department of Health and Human Services (HHS) for drug testing in accordance with mandatory guidelines (see Section 4.b(3) for details).

(3) A potential violation was also noted because of delay in removing protected area access for a person identified as

having a confirmed positive test result for drugs (see Section 4.c for details).

(4) A weakness was noted in reference to the urine split sample program. In one case, a split sample was sent for analysis to the same laboratory that performed the initial analysis. For a five month period in 1991, a backup laboratory was not contracted with the licensee to analyze split samples (see Sections 4.b.(3) and (4) for details).

(5) The personnel present were advised that we would monitor closure of the Quality Assurance FFD findings contained in an August 1991 report and a January 7, 1992 audit report (see Section 4.e for details).

(6) The FFD procedure (FIP-AD4-02) required clarification in some sections to prevent potential conflicts with the requirements of 10 CFR Part 26. (See Section 4.d for details).

(7) Four strengths were noted. The strengths pertained to the quality of the program audits; the FFD Administrator's knowledge of program requirements; measures to protect the privacy and confidentiality of FFD related records; and progress in reorganizing FFD program responsibilities (see Sections 4.a, e, and f for details).

c. The senior management representatives acknowledged the inspector's comments and noted that the findings were being addressed by the FFD staff as soon as they were noted. The Assistant to the Vice President noted that the problems which have not already been fixed will be corrected as soon as possible. The inspector noted the licensee's progress in reorganizing FFD program responsibilities under one department (security) with only Employee Assistance Program (EAP) functions being provided by the Medical Department.

d. On March 6, 1992, the FFD Program Manager was advised that the NRC Management review resulted in three cited violations being identified. The violations pertained to the delay in removing access for a person with a confirmed positive drug test result; the failure to complete a confirmatory test for positive initial breath analysis; and the failures to collect urine specimens during for-cause testing. A noncited violation was noted for sending a blood sample to a non-HHS certified laboratory for analysis and sending a urine split sample to the same laboratory that performed the initial urine analysis.

4. Fitness-For-Duty (FFD) Program (IP 81502): Three violations were noted during the inspection, and are described in Sections b and c below. A noncited violation was also noted and is described in Section b(3) below. Some weaknesses were noted in the FFD procedure. Additionally, for a five month period, a laboratory was not contracted to perform analysis of urine split samples.

Strengths were noted in reference to the Quality Assurance (QA) audits, the progress in consolidating FFD functions under one department, the FFD Administrator's knowledge of FFD requirements, and the observed sensitivity to protecting the privacy of FFD-related records.

a. Management Actions: No violations were noted in this functional area.

The inspection results and the licensee's self audit findings identified some programmatic weaknesses and multiple violations of licensee procedures and 10 CFR Part 26 requirements within the FFD program. The vast majority of the inspection and audit findings involved the licensee's Medical Department. The licensee's audit reports concluded that Corporate Medical was not sensitive to a regulatory environment. Our inspection findings support that perspective. The audit reports also noted that the separation of program responsibilities between Corporate Medical and Nuclear Security contributed to the problems identified. Our inspection findings also support that perspective (refer to Section 4.e for related information).

The licensee's management actions in reference to their audit findings and our inspection findings were short range (immediate) and longer term. An FFD Action Plan was provided to the inspector on February 12, 1992, which described the purpose of the action plan as to identify elements required to ensure an effective and efficient assumption of FFD program responsibilities by Nuclear Security from the Health and Safety Services Organization. The action plan's tentative schedule called for completion of the reorganization of FFD responsibilities from medical to security by the end of March 1992. The Corporate Medical Department's FFD support would be limited to Employee Assistance Program support and an alternate Medical Review Officer.

Discussions with the FFD Program Manager and the Director, Health and Safety Services showed that both managers: supported the action plan objectives, had met target date objectives for February 1992, and were progressing toward overall goal attainment in a cooperative manner. The program in attaining action plan objectives was considered a strength.

A supplemental action plan was provided to the inspector subsequent to the onsite inspection. The action items included:

(1) Independently verify that information provided by the Medical Department concerning all positive drug and alcohol certifications was complete and accurate. (Item completed, no additional deficiencies, except as in these report details, were noted.)

(2) Identify elements of the FFD program requiring evaluation. (Item completed)

(3) Prepare audit checklists for FFD program elements identified in action item 2. (Due March 31, 1992)

(4) Initiate Security Compliance Section evaluation of the FFD program using the audit checklists developed. (To begin April 1, 1992)

(5) Review findings and observations of the evaluation with Security, Nuclear Assurance, Nuclear Quality Assurance (NQA), and Licensing Management. Initiate DERs as appropriate. (Due May 15, 1992)

(6) Assistance from the NQA organization may be requested if needed.

The action plan items appear appropriate. If the goals can be attained is still an open issue which will be monitored during future inspections.

The FFD Administrator (FFDA) was very knowledgeable of the licensee's program and 10 CFR Part 26 requirements. The majority of the licensee's audits and our inspection findings were discovered by reviewing medical department documents which the FFDA normally does not have routine access to. Corrective actions for inspection findings were initiated by the FFDA at the time the deficiencies were noted. The FFDA's knowledge of program requirements is considered a strength

b. Chemical Testing: Two violations were noted in this functional area. A non-cited violation was also noted, and a program weakness was identified in reference to the urine split sample analysis program.

(1) During interviews and record reviews, it was noted that between October 1990 and May 1991, there were 12 instances when a person with an initial positive breath analysis was not given a confirmatory test (either a blood test or breath analysis on another breath analysis device) prior to sanctions being imposed.

This is a violation of 10 CFR 26.24(g) which requires, in part, that tests for alcohol must be administered by breath analysis, and a breath alcohol content indicating a blood concentration of 0.04 percent or greater must be considered a positive test. 10 CFR 26.24(g) further provides that a confirmatory test for alcohol shall be done with another breath measurement device (blood analysis may be performed upon request by the individual). (314/92003-01)

The root cause for this violation appears to be a conflict in procedures. The FFD procedure (FIP-AD4-02) describes the correct actions to take for an initial positive breath analysis result. A Medical Work Instruction did not require confirmatory testing after an initial positive breath analysis. The personnel conducting the tests followed the work instruction guidance rather than the FFD procedure.

The licensee discovered the potential for this deficiency in July of 1991 and initated Deviation Event Report (DER) 91-0630 to document the discrepancies between the Medical Department's internal work instruction and FIP-AD4-02. The DER was closed based upon a memorandum, dated March 2, 1991, from the Medical Review Officer (MRO) which advised the medical staff to conduct confirmatory breath analysis tests in accordance with the FFD procedure for drug and alcohol testing.

During the inspector's review of another FFD-related DER, the inspector requested some information which disclosed that in 12 instances between October 1990 and May 1991, a person with a positive breath analysis was not given a confirmatory test prior to sanctions being imposed under the criteria of 10 CFR Part 26.

The safety significant of this violation is low because the same sanctions were imposed on the basis of a single breath analysis as would have been imposed if two positive tests had been performed as required. Therefore, a person potentially not fit for duty was not allowed unescorted access to the plant. The violation however does indicate that the Medical Department did not fully understand the testing requirements for alcohol breath analysis.

The licensee's corrective actions consisted of:

(a) Placing a letter in the background screening files of the affected individuals which identified that a previously recorded positive alcohol breath test was not performed in accordance with 10 CFR 26.24, and that any suitable inquiry received would reflect this information.

(b) The background screening files were reviewed by the licensee and it was verified that no suitable inquiries were requested for the individuals involved.

(c) The computerized FFD screens were updated to correct the Suitable Inquiry questions inputs.

(d) The affected employees and their employers were advised that the positive test results were based upon a single breath analysis test, rather than on two analysis tests as required by 10 CFR Part 26.24. It should be noted that future suitable inquiries will be responded to by advising the inquirer that the person was positive on a breath analysis test, but that a second test on a different instrument was not performed. The utility or agency conducing the suitable inquiry can use the information for unescorted access determination as required by their individual FFD programs.

(e) Verifying that all specimen collectors have been informed of the incident and are aware of the correct procedure in the event of an initial positive alcohol test.

(2) Interviews and record reviews disclosed that between January and December 1991, there were four instances whereby a urine sample was not collected for drug abuse analysis during for-cause testing. Breath analysis tests were conducted however.

This is a violation of Section 2.1(a) of Appendix A to 10 CFR Part 26 which requires licensees to test, as a minimum, for marijuana, cocaine, opiates, amphetamines, phencyclidine, and alcohol for pre-access, for-cause, random, and followup tests (341/92003-02).

The root cause appears to be noncompliance with procedures. Section 6.6.3 of the FFD procedure (FIP-AD4-02) requires drug/alcohol testing during for-cause tests unless the individual refuses to be tested.

The safety significance of this violation is low because those persons with a positive breath analysis had the same level of sanctions imposed as if they had positive test results for drugs. The level of sanctions would have been no greater if they were also positive for drug abuse. The lack of testing for drugs however could have resulted in drug abuse not being detected and therefore, not addressed in any type of employee assistance program followup that may be initiated. The violation also demonstrates a lack of detailed knowledge of chemical testing requirements.

The licensee's corrective actions consisted of advising all specimen collection personnel of the substances that must be tested for during pre-access, for-cause, random, and followup tests. Future surveillances and audits will also periodically review this issue.

(3) Interviews and record reviews showed that on January 23, 1991, a blood specimen for confirmatory test purposes was analyzed by a local hospital whose laboratory was not HHS certified to perform drug abuse analysis. Additionally, an immunoassay analysis, rather than a gas chromatography analysis, was performed on the blood specimen.

This is a violation of Section 4.1(a) of Appendix A to Part 26 which requires licensees to use only laboratories certified under DHHS "Mandatory Guidelines for Federal Workplace Drug Testing Programs," Subpart C- "Certification of Laboratories Engaged in Urine Drug Testing for Federal Agencies" (53FR11970, 11986-11989) dated April 11, 1988), and subsequent amendments thereafter. This incident also violated 10 CFR 26.24(g) which requires gas chromatography analysis of blood for a confirmatory alcohol analysis test if the person tested

requests a blood specimen for confirmatory test purposes. The safety significance is low since the blood analysis showed that the individual was not positive for alcohol abuse.

Additionally, interviews and record reviews showed that on April 2, 1991, the laboratory that performed the original analysis on the first specimen and a reanalysis on the aliquot was also requested to perform an analysis on a urine split sample.

This is a violation of Section 2.7(j) of Appendix A to Part 26, which requires split samples (urine specimens retained by the licensee) to be forwarded to another HHS-certified laboratory that did not test the original aliquot if a person requests a reanalysis.

The safety significance is low because, if requested by the individual, a urine sample is analyzed at least twice for contractors, and possibly three times for licensee employees, even if by the same laboratory. The matter is primarily a compliance issue.

The root cause for the two above noted incidents appears to be inadequate procedure guidance. The FFD procedure (FIP-AD4-02) does not specifically address the unique analysis requirements for blood samples or urine split sample processing at another HHS certified laboratory. The two examples noted above also indicate that the Medical Department does not fully understand when use of different HHS certified laboratories is appropriate.

Although the two above incidents constitute a violation, this violation is categorized at Severity Level V and is not being cited because the criteria specified in Section V.A of the "General Statement of Policy and Procedure for NRC Enforcement Actions," (Enforcement Policy, 10 CFR Part 2, Appendix C, 1992), were satisfied. Immediate corrective actions consisted of advising the Director, Health and Safety of the circumstances when an alternate HHS laboratory use is appropriate. The FFD procedure (FIP-AD4-02) will be revised to address the unique analysis requirements for blood samples and urine split sample processing at another HHS certified laboratory (341/92003-03).

(4) Although the split sample program for licensee employees has been in effect since February 7, 1991, the capability to send split samples to a second HHS-certified laboratory did not exist between June 20 and November 12, 1991, because only one laboratory was contracted with and had a precontract audit performed. Therefore, any split samples that were to be analyzed, would have to be analyzed at the laboratory that performed the initial analysis.

Interviews with the FFD Administrator confirmed that no licensee personnel had a positive drug test between June 20 and November 12, 1991. Therefore, there was no need to analyze a urine split sample during this time period.

By memorandum dated March 2, 1992, the Director, Health and Safety reminded the medical staff that split samples for urine analysis must be sent to the alternate (back-up) HHS certified laboratory contracted for such purposes.

c. Management Actions and Sanctions: One violation was noted in this functional area.

Interviews and record reviews disclosed that on March 23, 1990, the Medical Department advised the Security Department that an individual had a positive drug screen. However, the individual's unescorted access to the Protected Area was not terminated until March 25, 1990. The individual was within the Protected Area on the day the unescorted access was terminated (March 26, 1990).

This is a violation of 10 CFR 26.27(b)(2) which states in part that a confirmed positive drug test must result in immediate removal from activities within the scope of Part 26. (341/92003-04)

The root cause of this violation appears to be personnel error. The incident report (No. 90-075), dated March 27, 1990, indicated that the security representative that received the March 23, 1990 report from the Medical Department thought the positive drug screen report was from a previous occurrence involving the same individual, and took no action on March 23, 1990.

The safety significance of this violation was high because a person who was identified as not qualified for continued unescorted access was allowed continued unescorted access to the protected area.

The licensee's initial corrective actions consisted of briefing all personnel in the Personnel Security Section on the incident report prepared in reference to the delay in removing the unescorted access for a person who had a positive drug test. The licensee reviewed the work performance of the subject individual for the period of March 23-26, 1990 and found no problems. Although the corrective action may not have been extensive, it appears to have been effective. There was no evidence that a repeat incident has occurred since March 1990.

Based on discussions with the FFD Program Manager on February 27, 1992, timely removal of unescorted access for personnel with a positive drug or alcohol test result will be periodically reviewed by the Security Compliance Section during future surveillances of the FFD program.

d. FFD Procedures: No violations were noted. However, the FFD procedure pertaining to drug and alcohol testing requires clarification in some areas.

Licensee procedure FIP-AD4-02, "Drug/Alcohol Testing" Revision 4, describes actions to take in reference to testing for drug and alcohol abuse. The procedure in general is well written and provides sufficient guidance to meet program objectives in reference to drug and alcohol testing. However, clarification is warranted in the following sections of procedure FIP-AD4-02. (431/92003-05)

(1) Section 6.3.1f.1 of the procedure allows the MRO to deny a request for reanalysis of a specimen. This conflicts with Section 2.9(e) of Appendix A to 10 CFR Part 26 which states that the MRO "shall" authorize a reanalysis of the original aliquot on timely request of the individual tested, and "shall" also authorize an analysis of any samples stored by the licensee.

Neither the FFD Program Manager (PM), the FFD Administrator, nor the Director, Health and Safety were aware of any occasion when a request for reanalysis was denied by the MRO. The previous MRO has been on a leave-of-absence since about August 1991 and was out of the country and therefore unavailable to be interviewed.

The FFD PM stated that the above change would be made to FFD procedure FIP-AD4-02.

(2) Section 6.1.9.3 of the procedure implies that the MRO has ten days from receipt of laboratory results to complete the review for positive drug tests. This section should be changed to clarify that the MRO's review of positive test result must be completed within 10 days of the initial presumptive positive screening test as required by 10 CFR 26.24(e).

The FFD PM stated that the above change would be made to FFD procedure FIP-AD4-02.

(3) Procedure FIP-AD4-02 does not clearly describe the licensee's urine split sample program. The procedure only requires split samples to be obtained and stored, "if appropriate." The licensee's program utilized split samples for licensee personnel but not contractor personnel. The procedure should clarify that split urine samples will be obtained from licensee personnel.

The FFD PM stated that the above change would be made to FFD procedure FIP-AD4-02.

e. Audits: No violations were noted in this functional area. The licensee's audits were considered to be a program strength. NRC Region III will monitor closure of surveillance findings noted during August 1991, and closure of audit findings noted during December 1991 (341/92003-06).

The 1990 annual audit of the licensee's FFD program was conducted between July 26 and October 25, 1990, with audit team member from American Electric Service Company, Detroit Edison, Boston Edison, and Comfort Care Laboratory. The audit report (date January 22, 1991) noted that adequate policies, procedures, and practices to ensure compliance had been established, and were effective in meeting the objectives stated in 10 CFR 26.10(a)(b) and (c).

A licensee's Quality Assurance Surveillance (No. 91-0158) of the FFD Program was completed between August 12-16, 1991. The surveillance report was dated August 23, 1991, and noted adverse performance indicators for the Corporate Medical Department. The surveillance report cover letter noted that deficiencies identified clearly indicate that Corporate Medical was not sensitive to a regulatory environment which had resulted in a lack of timely corrective action to potential and actual deficiencies. The report also noted that the identified problems appeared to be the direct result of the separation of program responsibilities between Corporate Medical and Nuclear Security. The surveillance report identified three Deviation Event Reports (DERs) and four observations. Some of the DERs were written for licensee requirements which exceed 10 CFR Part 26 requirements.

Another annual audit by QA conducted in December 1991 concluded that the FFD program was "Less Than Satisfactory." Four Deviation Reports and five observations were noted. Deficiencies were noted in reference to safety related work reviews; calibration of alcohol testing devices; the blind performance test program; internal chain of custody documentation; medical file documentation on positive drug and alcohol screening test results; review of negative tests results; and verifications of the accuracy of alcohol test results. Again, some of the audit findings exceed basic 10 CFR Part 26 requirements. All audit findings were in the process of being closed.

The inspector also confirmed by interview and record reviews that the required audits of the HHS certified laboratories used by the licensee had been performed and were adequate. Additionally, the inspector reviewed the annual audits for the only contractor approved program accepted by the licensee (INPO). The audits were adequate.

f. Protection of Information: No violations were noted in this functional area. Protection of information was considered a program strength.

All department and personnel involved in the inspection activities were sensitive to the need to protect the personal and private information within the FFD-related files and records. Whenever practical, individuals names were deleted on listings developed to consolidate inspection findings and identifiers or control numbers were used in place of individual names. FFD records and forms of a sensitive nature were stored in a large envelope with a confidential

marking on the envelope. Such material was routinely accounted for at the end of each day and was not left unattended in office areas during the day. Most licensee forms and laboratory records within the FFD file had the persons names marked through prior to release to the inspector for review. During the inspection of the Medical Department, FFD-related documents were removed from the persons medical file and presented in a separate file for FFD inspection purposes. The above actions to protect personal and private information did not hinder the inspection effort.