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Docket Number 50-346

License Number NPF-3

Serial Number 1-1098

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United States Nuclear Regulatory Commission  
Document Control Desk  
Washington, D. C. 20555

Subject: Response to Inspection Report 50-346/95010

Gentlemen:

Toledo Edison (TE) has received Inspection Report 95010 (Log Number 1-3688) and the enclosed Notice of Violation; the response to which is provided below.

Reply to a Notice of Violation (346/95010-04)

Alleged Violation

10 CFR 26.2(a) states, in part, that the regulations in 10 CFR Part 26 apply to licensees authorized to operate a nuclear power reactor. The section also states that each licensee shall implement a fitness-for-duty (FFD) program which complies with 10 CFR Part 26 and the provisions of the program must apply to all persons granted unescorted access to nuclear power plant protected areas.

10 CFR 26.20 requires licensees to establish written FFD program policies and procedures to implement the general performance objectives, including testing procedures and quality controls, and to describe the immediate and follow-on actions when an individual is determined to have used illegal drugs.

10 CFR 26.21 requires licensees, in part, to provide training to personnel prior to assignment to activities within the scope to 10 CFR Part 26. The training must include the licensee's FFD policy and procedures and what consequences may result from lack of adherence to the policy.

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Contrary to these requirements, the licensee imposed sanctions not included in its written policies or procedures, nor did they provide prior training on these matters. Specifically, when a specimen was suspected of dilution as evidenced by low specific gravity and creatinine, the laboratory tested the specimen to its limit of detection (LOD) as requested by the licensee. The laboratory determined that the specimen contained a concentration of a prohibited drug above the LOD but below the cutoff level established by 10 CFR Part 26 and the licensee's testing procedure. The medical review officer (MRO) on October 7, 1994, considered these results to be a positive test result and the licensee imposed sanctions consistent with a positive test result. The licensee's written policy, procedures, and training did not address the sanctions for suspect specimens.

This is a Severity Level IV violation (Supplement VII).

#### Toledo Edison Response

##### 1. Reason for the Violation

In early 1992, TE reviewed Nuclear Regulatory Commission (NRC) Fitness For Duty (FFD) inspection reports for other licensees and noted an identified program strength for programs that had specified actions for low creatinine and specific gravity levels. The actions consisted of testing to the LOD to confirm the presence of drugs in a suspected adulterated specimen. After reviewing these inspection reports, TE revised its FFD program on September 21, 1992, and its purchase order (PO) with the testing laboratory to require performance of Gas Chromatography/Mass Spectrometry (GC/MS) for urine specimens with creatinine or specific gravity levels below the criteria specified by 10CFR26 Appendix A, 2.4 (f) (2) indicating an adulterated specimen.

This revision was made to enhance TE's FFD policy of zero tolerance of prohibited drugs at the Davis-Besse Nuclear Power Station. Under the revision of the program, the Medical Review Officer (MRO) was still required to review the laboratory test results and conduct a personal interview with the individual before determining that the test results were positive. However, TE did not revise the FFD program implementing procedures to reflect these additional positive test criteria and corresponding sanctions associated with positive test result under these circumstances.

##### 2. Corrective Actions Taken and Results Achieved

Toledo Edison has revised Procedure IS-AC-00018, Drug and Alcohol Testing Process, effective October 13, 1995, to identify sanctions for positive test resulting from specimens with low creatinine or

specific gravity, which are confirmed at the LOD of the prohibited substances. On March 19, 1996, Nuclear Group procedure NG-IS-00004, Fitness For Duty Program, was revised to specify sanctions applicable in these circumstances. Prior to implementation of this procedure site personnel were required to read and acknowledge having read this procedure change. Toledo Edison purchase orders for contractors working on site include the FFD procedures to identify TE's FFD program.

3. Corrective Actions to Prevent Recurrence

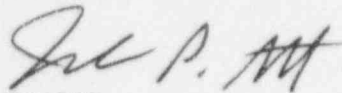
The procedures revision identified above are sufficient to prevent recurrence.

4. Date When Full Compliance Will Be Achieved

Full compliance was achieved on March 19, 1996, with the implementation of the revisions to NG-IS-00004, Fitness For Duty Program, as described above.

Should you have any questions or require additional information please contact Mr. James L. Freels, Manager - Regulatory Affairs, at (419) 321-8466.

Sincerely yours,



GAB/11h

cc: L. L. Gundrum, NRC Project Manager  
H. J. Miller, Regional Administrator, NRC Region III  
S. Stasek, DB-1 NRC Senior Resident Inspector  
Utility Radiological Safety Board