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GROUP VICE PRESIDENT, NUCLEAR

The Honorable Kenneth M. Carr
Chairman
Nuclear Regulatory Commission
Washington, D.C. 20055

Dear Mr. Chairman:

Recently, the Staff of the House Committee on Energy and Commerce provided the South Texas Project Electric Generating Station (STPEGS) a copy of a letter to you from Chairman Dingell and Representative Bliley which transmitted a Staff report on fitness for duty (FFD) issues. The report discusses at some length an FFD matter which occurred at the STPEGS in the summer of 1989.

This letter furnishes amplifying information regarding the issues raised by the report that may be relevant to the continuing NRC review of Fitness for Duty programs in general. Before addressing these issues, however, the following background information may be helpful.

BACKGROUND

Houston Lighting & Power Company (HL&P) instituted an FFD program at STPEGS, including random testing for substance abuse, in 1986 which generally followed the Edison Electric Institute (EEI) guidelines. The purpose of the program was to deter substance abuse, which HL&P viewed as a potential threat to the health and safety of STPEGS employees and the public. When the events in question occurred, the drug-testing program in effect at STPEGS included features to enhance the accuracy of test results which went beyond the specifications of the EEI guidelines. Before specimens were sent to an off-site laboratory for confirmatory testing, they were first analyzed in the on-site laboratory and determined to be positive in two separate screening tests using the EMIT method. Although not specified by the EEI guidelines, specimens were split into two samples and HL&P retained for one year any sample specimen which was confirmed positive. Confirmation testing was done using the GC/MS technique. This technique is now specified by NRC regulations, but was not required by the EEI guidelines. HL&P required its contractor's Science Director, or designee, to visit the on-site laboratory bi-monthly to verify compliance with laboratory procedures and protocols. HL&P also audited the FFD program periodically with the technical assistance of a consultant whose credentials included a doctorate in Pathology (Clinical Chemistry). There were three such audits in 1989, which covered both on-site and off-site laboratories.

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HL&P initiated this program because the considerations of public health and safety required that, insofar as practical, the STPEGS be a drug-free environment, and the Commission commented positively on this early program. At a meeting of the Commissioners in 1988 to discuss the issuance of a full power authorization for Unit 1 of the STPEGS, former Chairman Zech stated:

"Also, I think your fitness for duty program is an excellent one from all I've heard, and I commend you for your ability to put in place a random testing program."

HL&P has continued to advance the FFD program, most recently in response to requirements of the NRC's regulation, 10 CFR Part 26, effective January 3, 1990. At the same time, testing for substance abuse inevitably requires a balance be developed between the protection of the public health and safety and the rights of the individual. However, as a matter of responsibility to STPEGS employees and the public, HL&P remains absolutely committed to a drug-free work place.

ISSUES RAISED BY COMMITTEE STAFF'S REPORT

The principal criticism that is directly related to the current STPEGS FFD program concerns the qualification of HL&P's current Medical Review Officer (MRO), and the role of an MRO. In addition, the Committee Staff raised various questions about the 1989 FFD program, which we believe have been rendered moot by previously completed changes in the program. These questions include HL&P's use of cut-off levels that were lower than the cut-off levels recommended by the Department of Health and Human Services (HHS), the qualifications of HL&P's confirmatory laboratory, the process utilized to evaluate employee disagreements with positive test results and the utilization of on-site screening. Each of these is discussed in the following paragraphs.

RESPONSE TO THE COMMITTEE STAFF'S ISSUES

Qualifications of MRO: The Committee Staff's criticism that is aimed directly at HL&P's present program is the suggestion that HL&P's MRO is not qualified to perform his duties. We believe this suggestion is premised on an interpretation of the qualifications required for an MRO that can not be supported by the NRC regulations or HHS guidance.

The STPEGS MRO is a physician with 27 years of experience including an extensive background in the recognition and treatment of substance abuse gained as a physician in the United States Navy and in civilian life. He served as a Professor of Pharmacology at the University of Texas Medical and Dental Schools, San Antonio, and is thoroughly familiar with the characterization and effects of pharmaceuticals, including illegal substances. During his naval career, he received formal training in the treatment of alcohol and drug abuse, and was responsible for identifying abusers of drugs and alcohol as part of a physician's regular medical practice and for clinical evaluations of naval personnel suspected of substance abuse problems. He directed the operation of a U.S. Navy Hospital which included an in-patient drug and alcohol rehabilitation program, and routinely visited with and interviewed patients. In civilian life, he supervised a large occupational clinic which performed drug screening for private companies, and, as such, he is familiar with the equipment, procedures and analyses employed in such activities. He operates a clinic involved in the collection of specimens for urinalysis, and is, therefore, knowledgeable about, and sensitive to, chain of custody requirements and the documentation required in FFD programs. In addition to serving as HL&P's MRO, he is also MRO for the Federal Aviation Administration (FAA) and has attended the FAA's MRO training program.

In summary, HL&P's MRO is a person proven by training and experience to have, in the words of 10 CFR Part 26.3, a "...knowledge of substance abuse disorders and has appropriate medical training to interpret and evaluate an individual's positive test result together with his or her medical history and any other relevant biomedical information."

Role of MRO: The Committee Staff's report questions the qualifications of the STPEGS MRO because he is not qualified as a forensic toxicologist. Such qualifications are not required by 10 CFR Part 26, nor should they be required. HL&P does not believe it is appropriate to fragment responsibility for performing reviews of printouts from gas chromatograph and mass spectrometer tests which are now assigned to a certified laboratory with appropriate review and audit controls. Addition of a routine review by the MRO is inappropriate.

For purposes of forensic toxicology, under current HHS guidelines, it is clearly appropriate for the licensee to rely on the expertise of the confirmatory laboratory as suggested by 10 CFR Part 26, Appendix A, Section 2.9(g). Rigorous standards have been established which the certified laboratories must meet to obtain and retain their certifications. These measures provide adequate assurance of the quality of laboratory performance. The NRC regulations thus appropriately reflect the judgement that an employer should not be responsible for independent technical verification of the accuracy of each laboratory test result.

This does not mean that the utility must or should accept without question the result reported by a NIDA-certified laboratory. Laboratories do err and there may be alternative explanations of test results. It is here that the MRO brings to bear his skills, not as a forensic toxicologist, but as a physician schooled in clinical observation, perhaps pharmacology, knowledgeable of the indicia of substance abuse, to explore alternative explanations and when, in doubt, to order reanalysis. He does not assume, however, the role performed by the laboratory and, indeed, 10 CFR Part 26, Appendix A, Section 2.9(g) suggests the opposite. If questions arise which require application of special expertise in forensic toxicology, the regulations suggest that he can consult with the laboratory manager, "...or other individuals who are forensic toxicologists or who have equivalent forensic experience in urine drug testing...".

Plainly stated, this system makes sense and also ensures that the Commission's regulations fulfill the important safety objectives of an FFD program which includes due regard for individual rights.

1990 FFD Program Changes: In accordance with NRC regulation, 10 CFR Part 26, changes were made, effective in January of this year, to HL&P's FFD program which are particularly relevant to criticisms in the Staff's report:

Cut off Levels: HL&P now uses cut-off levels which are the same as the HHS levels except that 50 ng/ml is the screening cut-off for marijuana while HHS specifies 100 ng/ml. The NIDA Consensus Conference last year recommended reducing the HHS screening cut-off level to 50 ng/ml for marijuana.

Laboratory Certification: HL&P now uses an HHS certified confirmatory laboratory to analyze the samples which have screened positive in the laboratory at STPEGS. The measures in effect in 1989 to assure the quality of the testing activities, which are described above in the Background discussion, also remain in effect.

Review of Test Results: All positive results reported by the confirmatory laboratory are now reviewed by the MRO who offers the individual an opportunity to discuss the test result. In 1989 the STPEGS FFD administrative staff received test results and discussed them with employees.

Appeal Process: HL&P has established a formal process through which persons may appeal test results verified to be positive.

Use of Preliminary Screening Results: The FFD program has been modified to assure that no action is taken on the basis of an unconfirmed positive test result. Previously, the program provided for site access to be suspended for persons whose specimen screened positive for an illegal drug, pending completion of confirmatory testing.

CONCLUSION

The HL&P FFD program meets current NRC requirements, including the requirements regarding the qualifications and role of the MRO. The changes to the FFD program completed in January 1990 render moot the Committee Staff's concerns. As noted in the Staff's report, the individual involved in the case under discussion is now back at work at the STPEGS.

HL&P's commitment to a rigorous and effective FFD program remains a vital element of our long-range plan for success at STPEGS and the discharge of our responsibility for the safety of all employees and the South Texas community.

Sincerely,



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Nuclear

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