U. S. NUCLEAR REGULATORY COMMISSION
REGION II

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Facility Name:	General Electric Company Nuclear Energy Production
Location:	Wilmington, N.C. 28402
Dates:	September 30 - October 3, 1996
Inspector:	T. Decker, Technical Assistant
Approved By:	E. J. McAlpine, Chief Fuel Facilities Branch Division of Nuclear Materials Safety

Enclosure 2

EXECUTIVE SUMMARY

G. E. Wilmington
NRC Inspection Report 70-1113/96-10

The inspection was conducted to review elements of the internal dose monitoring and controls program including activities in the urinalysis bioassay and associated air sampling program. The inspection included review of an investigation performed by the licensee to determine whether certain samples had been analyzed properly in October of 1994 and whether associated data was accurate.

RADIOLOGICAL CONTROLS

The licensee was conducting an effective program to provide bioassay analytical services with the program generally providing accurate, timely results. These results were used in conjunction with air sampling and lung counting to determine internal doses to workers and were used to initiate corrective actions where appropriate. The licensee had performed a comprehensive investigation to determine whether certain bioassay laboratory procedures were being properly implemented. The licensee's review of this issue determined that during October 1994, the urinalysis sample analysis procedure had not been properly performed. The licensee concluded that, despite this, other data was sufficient to document worker doses during the period in question. Based on independent review of the data, records, and interviews with cognizant laboratory personnel, the NRC concluded that the procedure had not been properly implemented. However, the NRC review of other data showed that worker doses would not have been affected. The NRC identified one Violation for failure to properly follow procedures.

DETAILS

1.0 Bioassay Analyses (83822)

a. Inspection Scope

The inspection focused on operations in the Chemet Laboratory specifically, analyses conducted in the environmental section of the laboratory which were used to determine the concentrations of uranium in urine. The review was to determine whether bioassay analysis procedures were being effectively implemented and in accordance with requirements. Nuclear Safety Instruction (NSI) 0-2.0, Bioassay (Excreta)-Program Rev. 32, dated March 13, 1996, requires the licensee (Radiation Protection) to calculate an intake should a urinalysis result from someone working in areas where the potential exposure to uranyl nitrate is greater than 20 ug U/l (uranyl nitrate) or 15 ug U/l (uranium hexafluoride). Laboratory Procedure 1.2.21.10, Revision 4, dated March 15, 1995, titled "Measurement of Trace Uranium in Urine Using the Scintrex UA-3 Analyzer" defines the laboratory process for analyzing urine samples.

The inspection included review of a report of an investigation conducted by the licensee to determine whether in October 1994, the procedures had been properly implemented.

b. Observations and Findings

The inspector reviewed pertinent procedures and records, interviewed licensee personnel concerning laboratory operations, and observed a production analysis of daily urinalysis samples.

The Radiation Protection staff was responsible for routinely collecting samples of urine in the change rooms and transporting them to the Environmental Laboratory. These samples were collected for individuals assigned to work in areas where soluble uranium compounds were processed. Once per day, when bioassays were analyzed, a percent recovery was run. The percent recovery was an analysis of samples previously prepared (spiked) with a specific quantity of uranium. The licensee intended that the actual uranium content of such samples not be known by analysts processing the samples. These "blind" samples were used to validate the sample preparation. This sample is analyzed along with the other operational samples and was processed in the same manner. If the analysis results for one of these percent recovery samples was not within an acceptable range from the known value, the system would "alarm" and would not allow further data entry of the routine samples.

On December 12, 1994, the licensee instituted an investigation based on information that they had received indicating that certain bioassay analyses may have not been properly performed and that the resulting data may not have been accurate. This information was provided to licensee management following a manager's discussion of GE's integrity policy with staff members including duties of individual workers with respect to the integrity program. The licensee established an investigation team and began interviews that evening. The licensee's investigation included consideration of whether there might have been any record falsification, such as whether data may

have been recorded without the analyses being performed or whether the data recorded may not have been the actual data that resulted from the sample analysis. The following day, licensee representatives notified the NRC of the investigation. Previously, on or about October 24, 1994, licensee management (laboratory supervisor) had been informed by licensee staff of the issue concerning out of sequence samples. Further, on or around December 8, 1994, licensee management had been informed by licensee staff that the NRC had shown some interest in the issue.

The issue centered around the percent recovery analysis in the urinalysis laboratory. On October 20 and 21, 1994, two unknown percent recovery samples were discovered to have been analyzed out of sequence. Each of these samples, as well as the samples that should have been analyzed, had been spiked with different quantities of uranium. The computer was set to compare the results of the analysis of the samples which had been next in sequence to corresponding values in the computer. This reversal of samples would be expected to provide inaccurate results due to their different concentrations. At the time of occurrence, it was theoretically possible to manipulate the input data to cause agreement, within statistically acceptable limits, such that the percent recovery values would not be out of control boundaries, even if no samples were analyzed. Shortly following this review, the licensee made a change to the computer program so that the true value was unavailable to the analyst.

The licensee investigation documentation was reviewed and found to be thorough and included interviews with staff and management. As part of the review, the licensee evaluated several scenarios to determine if there were ways the samples could have been properly analyzed and documented and still have the reported results which were not consistent with the expected values. One possibility considered whether standard laboratory procedural errors by the analyst or individual preparing the standards could have caused the results. This assumption was tested in the laboratory by the licensee and the results indicated that contaminated equipment or improper pH control could have perturbed the data enough to cause the observed results even though the staff indicated that these are not common or expected occurrences. The licensee's investigation determined that there had been a violation of NRC requirements in that laboratory procedures had not been adhered to. The investigation concluded that the question of whether records had been falsified could not be absolutely determined.

During the licensee investigation, a failure to document a percent recovery sample was identified. This analysis is required by CM&S Analytical Method 1.2.21.10, Revision 3 (active procedure at the time of the event). The record for October 19, 1994, did not indicate that the required analysis had been performed even though bioassays had been run on that date. Similarly, on October 20 and 21, 1994, the analyst failed to follow procedures in that he did not analyze the percent recovery samples in sequence. The investigation also determined that a supervisor had been informed of the issue and had not reported the issue to the laboratory manager. The

licensee evaluation concluded that a violation had occurred. Since licensee management had been made aware of the issue and failed to take prompt, corrective action, credit for licensee identification is not appropriate.

Through discussions with members of the investigation team, laboratory personnel at the facility, and review of the investigation record, the inspector concluded that the procedure had not been properly implemented on October 19, 20, and 21, in that either the sample analysis documentation was not recorded as required or the samples were analyzed out of sequence. Either of the possible actions resulted in inaccurate data being recorded. The inspector noted that there were several potential reasons for this inaccuracy, including inadequate procedure implementation or recording of data without analyzing the blind percent recovery samples. Following the investigation, the licensee took disciplinary actions against the individual responsible for analyzing the samples in question and the supervisor, and the licensee reiterated the company integrity policy to all laboratory workers.

The failure to follow CM&S Analytical Method 1.2.21.10 was identified as a violation (70-1113/96010-1).

Urinalysis was used in conjunction with other methods such as airborne radioactivity sampling, dosimeter badging, and whole body counting to monitor occupational radiation dose exposure at the facility. The inspector reviewed air sampling results during the time in question and noted no abnormal measured concentrations that workers might have been exposed to. The actual bioassay results appeared to be consistent with airborne uranium concentrations in the facility as determined from review of air sampling results for the time in question.

c. Conclusions

The licensee was conducting an effective program to provide bioassay analytical services. Analysts performing urinalysis performed well during observation of work in progress. The licensee performed a comprehensive investigation to follow up on an issue regarding implementation of laboratory procedures for bioassay analyses. The bioassay procedure had not been adequately implemented on October 19, 20, and 21, 1994. There was insufficient information to conclude that the bioassay data had been falsified. The licensee's corrective actions to assure that analyses were properly performed were effective.

d. Exit Interview

The inspection scope and results were summarized on October 3, 1996. The inspector discussed the program areas inspected as well as the findings and observations. On November 4, 1996, during a telephone conversation, the licensee was informed that the failure to adequately implement the bioassay sample analysis procedure was identified as a violation of License Condition No. S-1. There were no dissenting comments by the licensee.

ATTACHMENT

PARTIAL LIST OF PERSONS CONTACTED

Licensee Personnel

R. Foleck, Senior Licensing Specialist
T. Hauser, Manager, GE-NE QA
P. Hann, Analyst, Chemet Laboratory
D. McCaughey, Manager, Fuel and Chemet Lab Quality
R. Robinson, Principal Engineer-Nuclear Safety

INSPECTION PROCEDURES USED

IP 83822 Radiation Protection

LIST OF ITEMS OPENED, CLOSED, AND DISCUSSED

Opened

Item Number	Type	Description and Discussion
70-1113	V!O	Failure to follow procedures in Chemet Laboratory

Closed

Item Number	Type	Description and Discussion
N/A	N/A	N/A