

GENERAL ELECTRIC

NUCLEAR FUEL MANUFACTURING DEPARTMENT

GENERAL ELECTRIC COMPANY - P. O. BOX 780 - WILMINGTON, NORTH CAROLINA 28402

September 20, 1985

Gary G. Zech, Chief
Vendor Program Branch
Division of Quality Assurance, Vendor
and Technical Training Center Programs
Office of Inspection and Enforcement
United States Nuclear Regulatory Commission
Washington, D.C. 20555

Dear Mr. Zech:

This letter is in response to Inspection Report No. 99900003/85-01 as documented in your letter of August 26, 1985. General Electric's Nuclear Fuel Manufacturing Department submits the attached responses to the seven (7) nonconformances (B-1 through B-7) identified by R. L. Cilimberg and approved by J. W. Craig of your office as a result of their June 24-28 inspection.

We have reviewed the referenced report and found nothing considered proprietary about the information provided therein. We are, however, very concerned about the following statements which appear in the third paragraph of your letter - quote

"We (the NRC Inspection Team) are concerned that technicians routinely do not follow procedures and, in some instances, cannot follow the procedures as written. The use of inadequate procedures and the established practice of not following procedures was known by personnel at the Wilmington facility and corrective action was not initiated."

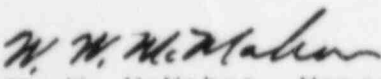
These statements appear generic in nature and we question whether sufficient justification exists to draw such general conclusions - especially in view that:

- 1) The referenced inspections focused principally on one laboratory test (wet iron), and
- 2) None of the seven specific nonconformances reflected upon product quality.

Even so, we have initiated some generic-type corrective actions beyond those described in the attached responses, which we will gladly review with your inspector during the next scheduled inspection.

Should you or your staff have any questions regarding this letter, please contact either this office or C. W. Doyle, NFMD's organizational contact (telephone #919-343-5874).

Sincerely,


W. W. McMahon, Manager
Quality Assurance

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B-1 NONCONFORMANCE:

Contrary to Section 10, "Inspection," and Section 12, "Control of Measuring And Test Equipment," of NEDO 11209-04A, Revision 4, dated December 31, 1982, and GE SCP No. 208, Revision 3, dated May 24, 1983, analyses conducted during the time period October 12, 1984, to November 1, 1984, were not conducted in accordance with established procedures in that wet iron test results were calculated using outdated calibration values.

GE RESPONSE:

1. On October 12, 1984, a new calibration curve was issued and placed in the Station Control Document Book W-24 for Wet Iron. Since no formal notification was made to off shift laboratory analysts, some continued to input the February 8, 1984 calibration constants into the computer for the calculation of wet iron. However, as noted by the NRC, the test results obtained using the previous February 8, 1984 calibration data were within the specified accuracy of the test method and therefore the test results are acceptable. As a result of this nonconformance, all lab analysts were instructed by lab supervision during the NRC inspection to check the calibration curves posted in the Station Control Document Book for the latest calibration curve data prior to conducting analyses.
2. To preclude use of outdated calibrations in the future, two actions have been taken. First, new software has been implemented which restricts access to change calibration constants. A database is maintained on the system which identifies specific employees as authorized to make calibration constant changes. Second, Station Control Plan 202 for wet iron analysis was revised to formally include the current calibration constants. In the future, recalibration data will be formally communicated to the analysts using SCP's rather than informally placing the information in the Station Document Books.
3. Item 1 was completed June 28, 1985.
Item 2 - Both actions were completed August 16, 1985.

B-2 NONCONFORMANCE:

Contrary to Section 12, "Control of Measuring and Test Equipment," of NEDO 11209-04A, Revision 5, dated March 1, 1985, items of measuring and test equipment are not suitably, nor uniquely identified to provide traceability to calibration test data in that both Beckman instruments in the Chemet laboratory were labeled 201, and all wet iron test results entered in the computerized data system were identified as having been performed using instrument 201.

GE RESPONSE:

1. Although test data was not uniquely identified to the instrument, all measurements were performed using control standards which were evaluated against established quality control limits thus assuring that only acceptable test results were released.

The software system for the wet iron program "WETFEO" was immediately modified during the NRC inspection (June 28, 1985) to identify measurements conducted on the Brinkman versus those conducted on the two Beckman instruments. In addition, the two Beckmans were separately identified with a unique number and the software modified to insure that each measurement will be traceable to the specific Beckman instrument.

2. To ensure that test data in the future is uniquely identified to the test equipment, the following requirements have been established: a) each lab instrument used to perform measurements shall be uniquely identified with a lab computer system analyzer number; and, b) each measurement result issued shall be checked by the analyst to assure that the correct analyzer number is present on the lab result report. These requirements are being formally documented in lab operation procedures.
3. Item 1 was completed August 16, 1985.
Item 2 - COI #027 and identification of all lab instruments is scheduled for completion by October 25, 1985.

B-3 NONCONFORMANCE:

Contrary to Section 12, "Control of Measuring and Testing Equipment," NEDO-11209-04A, Revision 5, and GE SCP No. 202, "Wet Iron," Revision 5, dated May 3, 1984, the calibration curves contained in the yellow work station book for the Beckman instrument were dated January 7, 1981, based upon calibration tests performed using a Beckman Model 25 instrument. The Beckman instruments currently used in the Chemet laboratory are both model DU-5.

GE RESPONSE:

1. New calibration curves were established for iron and nitrogen based on data traceable to each Beckman DU-5 instrument. An evaluation of the new calibration curves versus those in use indicates analytical results were within the measurement accuracy established for each method.
2. The steps which will be taken to assure applicable calibration curves are established for each unique instrument include:
 - a. Each instrument which performs analytical measurements shall be uniquely identified with a lab computer analyzer number.
 - b. Each analyzer number will be traceable to a serial number or other identification to uniquely identify the instrument.
 - c. For all methods requiring a calibration curve, the method's station Control Procedure will be revised to require that the calibration curve be identified with the unique analyzer or instrument identification, analyst and date performed. For infrequent calibrations (annual basis), the calibration data will be issued as a formal part of the station documentation with an expiration date the same as the date of the calibration expiration.
3. Item 1 was completed August 8, 1985.
Item 2a & b will be completed October 25, 1985.
Item 2c will be completed by November 27, 1985.

B-4 NONCONFORMANCE:

Contrary to Section 10, "Inspection," NEDO-11209-04A, Revision 5, procedures for examinations and measurements were not adequately defined, in that, GE Analytical Test Method No. 1.2.9.4, Revision 4, dated July 12, 1984, Step 7.7 requires sample volumes to be 200 ml, and COI 203, Revision 1, dated June 3, 1985, Step 4.3 contains references to nonexistent steps 4.5.1.2 through 4.5.1.5.

GE RESPONSE:

1. As indicated by the inspection report, Analytical Test Method No. 1.2.9.4 Revision 4 requires in Step 7.7 that samples be diluted to 200 ml.

Step 7.8 states:

"Wait 30-45 minutes and measure absorbance in 2 cm cell at 509 nm versus water. (See Note 10.1)".

Note 10.1 states:

"Laboratory has an option. Develop colored iron complex in 200 ml and read absorbance using a 2 cm cell or develop color in 100 ml and use a 1 cm cell. CAUTION: Parameters used in construction of the calibration curve should be used in the PROCEDURE section, Steps 7.7 and 7.8.

If the spectrophotometer uses nominal wave length settings as opposed to specific settings, choose the nominal setting that most closely approximates 509 nm".

Step 3.1 states:

"Spectrophotometer, type optional".

Together Steps 3.1 and note 10.1 would indicate that when using the Beckman DU-5, which only accepts a 1 cm cell, one would dilute to a 100 ml volume at Step 7.7 rather than 200 ml. Based upon these allowances in the procedure, technicians were instructed by their supervisors to use the Beckman DU-5 and a 100 ml dilution volume.

Although NFMD feels that CM&S 1.2.9.4, Revision 4 was adequate, the procedure was revised to provide primary dilution instructions based upon a 1 cm cell spectrophotometer. In addition, COI #215 was issued which provides technician instructions which are specifically directed for wet iron analyses using the Beckman DU-5 instrument.

COI #203 Revision 1, "Waste Water Analyses", contains a typographical paragraph numbering error in Section 4.3, i.e., Paragraph 4.3.2.2 which referenced 4.5.1.2 - 4.5.1.5 should have referenced 4.3.1.2 - 4.3.1.5. COI #203 was revised to correct the typographical errors.

B-4 GE RESPONSE: (continued)

2. All product quality related laboratory test procedures will be reviewed for clarity and ease of implementation by at least two laboratory analysts. The procedures will be revised as necessary.

To prevent procedural errors and inadequacies in the future staff personnel will review and edit more thoroughly each procedure prior to issuance. Also, technicians and analysts were counseled by lab supervision regarding total compliance to written procedures and the need to inform supervision when planning errors and inconsistencies were detected.

3. Item 1 - Revision 5(A) to CM&S 1.2.9.4 was issued August 8, 1985.
 - COI #215 was issued August 16, 1985.
 - COI #203 was issued September 20, 1985.

Item 2 - Review and revision of all lab procedures is scheduled for completion by December 31, 1985. Communication to lab personnel was completed on August 12, 1985.

B-5 NONCONFORMANCE:

Contrary to Section 5, "Instructions, Procedures and Drawings," NEDO-11209-04A, Revision 5, and Step 7.8 of GE Analytical Test Method No. 1.2.9.4, Revision 4, technicians did not wait 30-45 minutes prior to measuring absorbance of samples.

GE RESPONSE:

1. As identified by the NRC inspection, some technicians and some supervisors incorrectly interpreted Step 7.8 of the analytical test procedure CM&S 1.2.9.4 Revision 4. Rather than wait the 30-45 minutes after the dilution step, samples were measured without waiting. By not waiting for sufficient time after addition of the complex reagents, the iron color could be under developed. Under developed iron color would result in analytical values biased low.

CM&S 1.2.9.4 Revision 4 pertaining to the measurement of iron in a uranium matrix called for the following sequence in operational steps.

- a) Add complex reagents.
- b) Adjust pH.
- c) Dilute to volume. Mix.
- d) Wait 30-45 minutes.
- e) Measure absorbance of the solution.

The foregoing presentation of procedural steps followed recognized technical publications. See ASTM C699 and C759, Volume 12.01. Although the wait time is called for after the dilution step, the color development begins after the addition of the complex reagents.

The lab normally processes wet iron samples and standards in groups of 7 to 17. This would result in a minimum waiting time of approximately 20 minutes for the group of 7 samples and a maximum waiting time of approximately 60 minutes for the group of 17 samples with times approximated from the complex reagent addition. No immediate action was taken to change the technician's routine for processing wet iron analyses until the time effects were more thoroughly understood.

A test was performed, "Color Stability of the Iron Ortho Phenanthroline Complex", and documented in Quality Notice F-Q-1618. Test data supports the following:

- Color development is essentially complete within seven minutes following addition of the complex reagent. Between 7 and 90 minutes the difference is less than 5 ugFe/gU when the sample weight approximates 0.5 grams.

B-5 GE RESPONSE: (continued)

- The iron complex is relatively stable up to 90 minutes. During the time interval 90 to 180 minutes, absorbance reading increases approximately 0.009 units. This absorbance increase translates in a false elevation of the iron measurement by 11 ug/gU (sample size 0.5 grams).

Testing color development at time intervals less than 7 minutes is not practical. One cannot realistically handle multiple samples (at least 3), add reagent, adjust pH, dilute to volume, mix, and set up a spectrophotometer for the absorbance measurement in a shorter time span.

Failure to adhere to the minimum "wait time" (30 minutes) specified in CM&S 1.2.9.4 Revision 4 did not lead to the issuance of iron values having a significant low bias.

Maximum time for the iron matrix color stability is 90 minutes. Between 90 and 180 minutes a positive bias of all ugFe/gU occurs. The bias becomes progressively more positive if the "wait time" is extended. Failure to adhere to a maximum "wait time" can lead to the rejection of acceptable uranium oxide but not to the acceptance of "out of specification" powder.

In an effort to clarify "wait time", CM&S 1.2.9.4 Revision 5(A) and COI #215 was issued to define "wait time" in considerable detail based upon the QN F-Q-1618 test.

2. To prevent recurrence, roundtable sessions were held with all lab shifts to stress the need and responsibility for a total commitment to follow all documented instructions. Personnel were instructed to not follow conflicting or unclear instructions and to document requests to have inadequate procedural requirements corrected.
3. Item 1 - QN F-Q-1618 and Revision 5(A) of CM&S 1.2.9.4 were issued on August 9, 1985. COI #215 was issued August 16, 1985.
Item 2 was completed August 12, 1985.

B-6 NONCONFORMANCE:

Contrary to Section 5, "Instructions, Procedures and Drawings," NEDO-11209-04A, Revision 5, Step 7.7 of GE Analytical Test Method No. 1.2.9.4, Revision 4, and Step 4.3.1.2 of GE COI No. 203, Revision 1, (1) technicians diluted to a 100 ml volume of mix solution instead of the 200 ml specified, and (2) technicians did not prepare a 25 ml blank.

GE RESPONSE:

1. See GE response for nonconformance Item B-4 for corrective actions relative to CM&S 1.2.9.4.

COI #203, Revision 1, "Waste Water Analyses" does not apply to samples for quality, environmental or safeguards measurements. Currently, only composite waste stream samples are measured for nitrates per Section 4.3 to monitor nitrate trends entering the waste process lagoons.

Based upon the relative accuracy required for general monitoring versus required analytical time, the nitrate method was established without the use of a blank for sample analysis. By establishing a calibration curve with a blank and omitting the blank for samples, an intentional conservative bias was built into the method. Since the sample analysis steps cross-referenced certain calibration steps, a possible inference exists that a blank should be prepared with samples. However, the equation for calculating results does not include a variable for the blank. Technicians and supervisors routinely and correctly interpreted the instructions as not requiring a blank.

2. However, to correct any future misinterpretation of the blank correction requirements, COI #203 was revised to provide a completely separate set of instructions for the calibration and sample analysis activities. An explanation was also included to provide the basis for omitting the blank correction and to quantize the inherent resulting conservative bias.
3. COI #203 was issued September 20, 1985.

B-7 NONCONFORMANCE:

Contrary to Section 5, "Instructions, Procedures and Drawings," NEDO-11209-04A, Revision 5, and Section 4.4.5 of GE Practices and Procedures No. 30-33, Revision 6, dated April 22, 1985, Chemet Laboratory personnel used white-out on data forms rather than drawing a single line through incorrect data entries.

GE RESPONSE:

1. All laboratory personnel were advised immediately to discontinue the use of white-out for correction of errors on data forms. All bottles of white-out were collected and removed from the lab.

For entries in the "Rad Safety Book for PRM-4B", the 1300 hours entry quoted by the NRC Inspection Report as being for 1/28/85 was actually dated 1/24/85. The actual entries are 1300 hours for 1/24/85, 1000 hours and 1700 hours for 1/28/85. With these dates the entries are appropriately sequenced. The "Rad Safety Book for PRM-4B" is maintained by Radiation Safety Personnel to record verification checks for survey monitors assigned to lab supervisors. These survey monitors are not a part of the Radiation Protection Program's requirements and are not subject to NEDO-11209-4A requirements.

2. To prevent recurrence of white-out on lab data forms, all laboratory personnel attended a formal training session regarding the proper technique for correction of quality records per Practices & Procedure 30-33. In addition, the quality records requirements of P/P 30-33 will be incorporated into a formal procedure, "Chemet Lab Records Completion".
3. Item 1 was completed June 27, 1985.
Item 2 - Training was completed August 7, 1985. "Chemet Lab Records Completion" is scheduled for issuance by October 25, 1985.