UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION III
801 WARRENVILLE ROAD
LISLE, ILLINOIS 60532-4351

November 3, 1999

Mr. R. Douglas Carlson, Director
Radiological Environmental Sciences Laboratory
Mail Stop 4149
850 Energy Drive
Idaho Falls, ID 83401

SUBJECT: AUDIT REPORT FOR THE NRC REGION III DIVISION OF NUCLEAR MATERIALS SAFETY LABORATORY (OARM-RESL-99-171)

Dear Mr. Carlson:

This is in response to your letter of September 29, 1999, which transmitted the subject audit report.

Your letter did not specify actions or request a response concerning five observations noted in the report. We intend, however, to evaluate each observation and to implement appropriate actions in response, such that we would anticipate favorable results should these items be revisited in future audits.

Your letter did request written notification concerning our investigation, corrective action and action to prevent recurrence for three findings. Our response follows.

RIII-0899-F-1: Technical Enhancements

Finding: Current procedures for the liquid scintillation counter include precautions against quantification of positive samples. However, samples with detectable activity are routinely quantified and reported in spite of this stated precaution. . . .statistically positive samples. . . .should be submitted to a qualified laboratory for quantitative analysis that includes chemical separations. (Cff. Item II.E, NMSS 7.0, 430.4, 432.4, 435.2)

Discussion: Region III agrees with the finding. Some samples were quantified despite a procedural precaution to the contrary, though we would not have characterized these occurrences as "routine."

In the absence of chemical preparation, the laboratory analyst can not be completely certain of the identity of any isotope present in the sample, and can not be certain that any scintillation effects are not the result of some chemical phenomenon. Thus, the analyst should not be held solely accountable to quantify any specific isotope. The procedural precaution was intended to limit accountability of the laboratory to screening only.

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On the other hand, Laboratory Procedure 010, "Laboratory Procedure Documentation and Control," does allow for temporary changes to analytical procedures as long as such changes are documented, with justification. This provides needed flexibility, for example, to test new methods before they are codified into approved procedures.

In the case of the liquid scintillation analyses, laboratory personnel worked with the system vendor during 1999 on software upgrades, including Y2K, and learned that the system could be used, with proper controls, to support a quantitative determination for some samples. These controls include QA/QC activities in the lab, and determining there is no likelihood of chemical effects, multiple isotopes, or unknown isotopes.

Some analyses were performed and the results were quantified using the vendor's principles; however, the controls and conditions under which this was done were not documented and no temporary changes were made to the applicable laboratory procedures. This failure to follow lab procedures was apparently due to a mis-communication among lab staff, and it created the circumstances which resulted in the finding.

Actions: Laboratory practices and procedures for the liquid scintillation system will be brought into conformance. Procedures will address and control the application of a QA/QC process, as specified by the vendor, using reference standards for H-3 and C-14. The analyst will be accountable to screen all samples and to report any "positive" samples for further specific evaluation to determine the following:

- no nuclides other than H-3 or C-14 are present
- chemically-induced scintillation is extremely unlikely

If these conditions are satisfied, the H-3 and/or C-14 present in the sample may be quantified. Otherwise, including all cases where the spectrum does not match either H-3 or C-14, a decision will be made concerning the need to send the sample to another laboratory for processing and quantitative analysis.

These actions will be completed before any sample is quantified and in any event by November 30, 1999. Adherence to the modified procedures will prevent recurrence of this finding.

RIII-0799-F-2: Uncertainty Reporting

Finding: Uncertainties are not being reported with all analytical results (as) required by Procedure 710.4.9. Current reporting includes only the counting uncertainty. . . .the team recommends that. . . .total propagated uncertainty. . . .be reported with each result (Cff. Item II.E, NMSS 8.0, 710.4.9).

Discussion: Region III agrees with the finding, and agrees in principle with the action recommended by the Audit Team.

Procedure 710.4.9 does not explicitly state that total propagated uncertainty must be determined, but it is our intent that it should be determined and verified to be acceptable. The data for which total propagated uncertainties were lacking were analytical results from the gross α and gross β proportional counting system, and analytical results from the liquid scintillation counting system.

Action: Procedures for each counting system will be reviewed and the precision needed to meet Agency requirements will be determined and specified. Depending on the nature and purpose of the analysis, the specified relative standard deviation may be determined on a case basis. The counts obtained for each measurement will be sufficient to ensure that the specified relative standard deviation is achieved.

This action will be taken by November 30, 1999. Adherence to the revised procedure will prevent recurrence of this finding.

RIII-0799-F-3: Software Verification

Finding: Verification of in-house automated calculations has not been documented. (Cff. Item II.E, NMSS 8.0, 710.4.8)

Discussion: Region III agrees with the finding. The computer program calculations in question were verified as required, by using the programs to analyze traceable calibration standards and determining that they gave the correct results. However, the verifications were not documented as such. The problem could recur if a computer program were to be changed and not re-verified.

Action: A document will be prepared identifying the technique and results described above and it will be filed as required. This action will be completed by November 30, 1999.

To prevent recurrence, a procedure change will be made to specify that any time a subject computer program is revised, it will be re-verified and the results will be documented. This action will be completed by November 30, 1999.

Sincerely,

/s/ C. D.Pederson

Cynthia D. Pederson, Director
Division of Nuclear Materials Safety

cc: D. Sill, RESL

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R. Caniano, RIII
W. Snell, RIII

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