October 1, 2001

MEMORANDUM TO: Larry W. Camper, Chief
Decommissioning Branch
Division of Waste Management

THRU: Claudia M. Craig, Chief **/RA/**
Facilities Decommissioning Section
Decommissioning Branch
Division of Waste Management

FROM: John T. Buckley **/RA/**
Facilities Decommissioning Section
Decommissioning Branch
Division of Waste Management

SUBJECT: SURVEILLANCE REPORT FOR REGION 1 LABORATORY

A surveillance of the Region 1 laboratory was conducted on July 19, 2001. The scope of the surveillance was limited to: (1) evaluating implementation of Region 1's corrective actions resulting from the annual audit conducted by the U.S. Department of Energy's (DOE's) Radiological and Environmental Sciences Laboratory (RESL) on July 18, 2000; (2) determining the types and number of samples analyzed since the last audit; and (3) evaluating results from independent test sample analyses. Enclosed is the surveillance report.

In general, Region 1 has satisfactorily implemented the corrective actions resulting from the annual RESL audit conducted in July 2000. Corrective actions were generally implemented on a schedule consistent with Region 1's commitments dated October 11, 2000. Minor deviations from procedural requirements were identified during the surveillance. However, since these deviations were administrative in nature and did not affect the technical quality of the laboratory results, no findings were generated as a result of this surveillance.

From July 2000, to July 2001, Region 1 analyzed a total of 373 samples. The Region 1 laboratory participated in the following three independent sample analysis programs: (1) RESL's Mixed Analyte Performance Evaluation Program (MAPEP); (2) DOE's Environmental Measurements Laboratory (EML) Quality Assurance Program (QAP); and (3) NRC's Intercomparison Test Program (ITP). Region 1 produced acceptable results for all test samples analyzed.

The results from this limited scope surveillance indicate that the Region 1 laboratory had adequate controls in place during FY01 to produce credible, technically defensible analytical results.

If you have any questions, contact John Buckley at 301-415-6607.
Enclosure: Region 1 Laboratory Surveillance Report

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A surveillance of the Region 1 laboratory was conducted on July 19, 2001. This surveillance was conducted in place of the annual independent audit required by the "Quality Assurance Manual for Office of Nuclear Material Safety and Safeguards," (QAM) Rev. 1, dated May 12, 1998. The surveillance was conducted by John Buckley, Project Manager, Decommissioning Branch (DCB), Division of Waste Management (DWM).

1. Surveillance Purpose and Scope

The scope of the surveillance was limited to: (1) evaluating implementation of Region 1's corrective actions resulting from the annual audit conducted by the U.S. Department of Energy's (DOE's) Radiological and Environmental Sciences Laboratory (RESL) on July 18, 2000; (2) determining the types and number of samples analyzed since the last audit; and (3) evaluating results from independent test sample analyses.

The QAM requires an annual external independent audit of the Regional laboratories. However, given that the Regional laboratories will cease operations in September 2001, DWM, in agreement with the Regions, decided it would be more cost effective to conduct a limited scope surveillance to determine if Region 1 effectively implemented the corrective actions from the FY2000 RESL audit, rather than an independent audit of the entire QA program.

2. Surveillance Checklist

A surveillance checklist was prepared, and provided to Region 1, prior to conduct of the surveillance. The checklist was developed mainly from Region 1's response to the FY2000 RESL audit, dated October 11, 2000. The checklist includes: (1) audit findings; (2) identification of the requirements which were not met; and (3) the proposed corrective actions. A completed surveillance checklist is attached. The condition of each item evaluated was determined to be either satisfactory, or unsatisfactory.

3. Surveillance Conclusions

In general, Region 1 has satisfactorily implemented the corrective actions resulting from the annual RESL audit conducted in July 2000. Corrective actions were generally implemented on a schedule consistent with Region 1's commitments dated October 11, 2000. Minor deviations from procedural requirements were identified during the surveillance. However, since these deviations were administrative in nature and did not affect the technical quality of the laboratory results, no findings were generated as a result of this surveillance.

From July 2000, to July 2001, Region 1 analyzed a total of 373 samples. Of these, 109 were analyzed by gamma spec, 31 by gas flow proportional counting, and 233 were analyzed by liquid scintillation counting. In order to ensure that radiological measurements performed by Region 1 laboratory are of acceptable precision and accuracy and also reflect actual conditions and licensee performance, the Region 1 laboratory participated in the following three

independent sample analysis programs: (1) RESL's Mixed Analyte Performance Evaluation Program (MAPEP); (2) DOE's Environmental Measurements Laboratory (EML) Quality Assurance Program (QAP); and (3) NRC's Intercomparison Test Program (ITP). Region 1 produced acceptable results for all test samples analyzed.

The results from this limited scope surveillance indicate that the Region 1 laboratory had adequate controls in place during FY01 to produce credible, technically defensible analytical results.

4. Surveillance Team

John Buckley DWM/DCB/FDS

REGION 1 LABORATORY CLOSEOUT SURVEILLANCE CHECKLIST

1.0 Evaluate Corrective Actions From FY 2000 RESL Audit

Requirement	Finding	Corrective Action	Status
2.2.1 Once the QA Program documentation has been prepared, reviewed and approved, new or modified practices shall be implemented by training personnel in their use. 2.2.2 Personnel shall receive general instruction in the overall content of the QA program.	NRC Region I Inspectors have not been indoctrinated and trained in applying requirements of the NMSS Quality Assurance Manual. Ineffective completion of the Sample Chain-of-Custody forms and failure to prepare data quality objectives and survey plans point to this weakness.	We agree with these findings. Although training was provided to the staff in November 1999, and the list of people trained was made available to the auditor, the training did not include the requirements of the NMSS QA Manual. Training will be given to the Division staff in December 2000 as part of the regional training seminar. The Division will develop a read and sign manual in conjunction with this training and will maintain this record for future audits, and for training of staff not available in December. This action will be completed by 12/15/00 (Kottan and Shaffer).	Satisfactory Discussion: Mr. Kottan provided training to DNMS staff on December 7, 2000. This training included discussions on completion of sample chain-of-custody forms and the importance of identifying data quality objectives. In addition, Region 1 prepared a “Read and Sign” manual, dated December 1, 2000, to ensure that staff read and understand the requirements of the NMSS QA manual. Further, the laboratory did not analyze samples submitted by staff who did not complete the “read and sign.”

Requirement	Finding	Corrective Action	Status
2.4.1 Internal assessments of sample collection and laboratory operations shall be conducted periodically. 2.4.6 Reports of internal assessments and audits shall be written. Reports will include assessment or audit results and recommendations for corrective actions to be taken to resolve deficiencies identified.	NRC Region I has no policy or procedures to conduct and document internal assessments of sample collection and laboratory operations. Internal assessments of these operations are not being conducted. Documentation of internal assessments is not being performed.	We agree with these findings. The Division will prepare a Directive that establishes an internal assessment program that meets the requirements of the NMSS QA Manual. Internal assessments will be conducted at least once a year. This Division Directive will be prepared by 12/31/00 and an internal assessment will be conducted in accordance with the Directive by 4/31/01. (Shaffer)	Satisfactory Discussion: DNMS prepared a Policy Directive entitled, “Internal Assessment of Sample Collection and Laboratory Operations” dated January 18, 2001. DNMS conducted an internal audit in accordance with this Policy Directive on May 14, 2001. An audit report was published on June 11, 2001.

Requirement	Finding	Corrective Action	Status
2.4.9 Corrective actions shall be taken as indicated by the assessment or audit report, and follow-up actions shall be taken, including a reassessment or re-audit, whenever appropriate.	Corrective actions proposed by NRC Region I to audit findings of RESL audit conducted on 7/27/1999 were not communicated to the NMSS Technical Monitor. Evidence of "open" items remaining from the previous audit points to ineffective corrective action, follow-up and closure.	We agree that the corrective actions were not provided to NMSS. The three findings of the 1999 audit provided at the time of the exit–preparation of additional procedures, review and revision of procedures, and technical enhancements--were assigned as a DNMS action item and corrective actions were taken. Additional procedural requirements were not fully implemented as specified in the NMSS QA Manual. This memo documents our planned corrective actions. Individual DNMS action items will be assigned to each audit finding and tracked to completion. We will provide a monthly status report on implementation of these corrective actions to NMSS beginning on 12/31/00.	Satisfactory Discussion: On October 11, 2000, Region 1 provided NMSS a response to RESLs audit findings. The response included proposed corrective actions and schedule for completion. In addition, Region 1 provided monthly status reports to NMSS on implementation of the corrective actions.

Requirement	Finding	Corrective Action	Status
3.0.1 Individuals shall be trained and qualified before they conduct any activity affecting the quality of sample results. 3.0.2 The extent of training required will depend on the work being performed, the staffs' education ... demonstrated level of competence and previous work experience. 3.1.2 Individuals must be trained in accordance with a documented training/qualification program to ensure that individuals are adequately trained, and that they remain trained as changes in work practices occur. 3.2.1 A documented training program ... shall be established, to ensure that ... personnel performing quality related activities are trained in...principles and techniques of ... activities being performed. 3.2.4 Training and qualifications shall be documented ...	Audit finding RI-0799-F-2 from the previous audit concluded that "The training/qualification program does not ensure documentation that laboratory staff and inspectors are adequately trained and that they remain trained as changes in work practices occur." In response to the above audit finding, a new procedure–712, dated April 3, 2000 entitled "Qualification and Training" was prepared. However, based on discussions with inspectors, the auditors concluded that the inspectors need training in completion of chain-of-custody forms, maintaining sample integrity, sample plan development and development of data quality objectives.	We agree with these findings. Chain of custody forms have not been completed by the inspection staff, and DQOs and sample plans are not being developed. As noted in the response to 2.2.1 and 2.2.2, the Division will provide training to the inspectors in these areas and will assure that documentation of that training is prepared and kept for future audits. The completion date for this item will be 12/15/00 (Kottan and Shaffer).	Satisfactory Discussion: Region 1 addressed this finding, in part, by providing training to DNMS staff on December 7, 2000. This training included discussions on completion of sample chain-of-custody forms and the importance of identifying data quality objectives. In addition, Region 1 prepared a "Read and Sign" manual, dated December 1, 2000, to ensure that staff read and understand the requirements of the NMSS QA manual. Objective evidence showed that the laboratory did not analyze samples submitted by staff who did not complete the "read and sign." Further, qualification letters were on file for laboratory personnel.

Requirement	Finding	Corrective Action	Status
4.0.1 Procedures shall be prescribed, developed, and maintained for all activities that affect the quality of sample data and shall accurately reflect all phases of survey and analytical operations. 4.0.2 Procedures used in the Regions that govern sample collection and analytical activities shall be maintained in the Regional Laboratory and sample collection procedures.	Analytical measurements for nuclides such as I-125, P-32, and S-35 are being performed based on operator knowledge without written procedures.	We agree with these findings. These findings relate to a Liquid Scintillation Counting (LSC) procedure for the analysis of I-125, P-32, and S-35. An LSC procedure will be written and implemented by 1/31/01. (Kottan)	Satisfactory Discussion: This finding was addressed by development and implementation of Procedure 431, "Liquid Scintillation Sample Counting," dated January 5, 2001.
5.3 Each operating procedure shall identify what records shall be kept for the specific activity involved.	Procedures do not define which records should be kept for the activity involved.	We agree with this finding. The appropriate procedures will be modified by 12/31/00 to identify what records shall be generated by that specific procedure. (Gordon)	Satisfactory Discussion: Region 1 issued a revised Laboratory Manual on March 22, 2001. Procedures were revised to include a "Reporting and Records Requirements" section in applicable procedures. This section identifies which records must be kept as QA records.

Requirement	Finding	Corrective Action	Status
5.5 Records shall be kept that track the receipt and control of samples throughout the collection process.	Chain of custody requirements have not been effectively implemented.	We agree with this finding. We are implementing this requirement within the Decommissioning and Laboratory Branch, and in specific instances with other technical staff, using documented Procedure 110. After training is given to the remainder of the Division staff, then the entire division will be complying with this requirement. Completion date: 12/15/00. (Kottan and Shaffer)	Satisfactory Discussion: DNMS staff were trained on chain-of-custody requirements on December 7, 2000. This training included discussions on completion of sample chain-of-custody forms. Chain-of-custody forms are present in the sample receipt and storage room.
5.11 Records shall be kept that document training and qualification of staff.	There were no records presented to the audit team that documented the training or qualifications of the staff.	We agree with this finding. Once the training is complete, records will be generated and kept. Completion date: 1/31/01.	Satisfactory Discussion: Laboratory staff produced a training log to document which DNMS staff had attended the December 7, 2000, training on the NMSS QA requirements. In addition, qualification letters for laboratory personnel are kept as QA records.

Requirement	Finding	Corrective Action	Status
5.13-5.16 Record storage.	Records are not being transferred to and stored in the NRC Archival Facility	We agree with this finding. We will transfer all records 3 years old or greater to the NRC Archives in accordance with the requirements of the NMSS QA Manual. This transfer will be completed by 12/31/00. (Kottan and Perkins)	Satisfactory Discussion: Region 1 transferred all QA records dated before 4/98, to NRC archives. Document transfer was demonstrated by a completed NRC Form 35, "Records Transfer."
6.4 Documentation of sample custody is initiated on collection and continues until such time that the samples are analyzed, data reported and samples are properly disposed.	Documentation does not exist to satisfy this requirement. See response to item 5.5. Sample custody upon receipt is not always maintained.	We agree with this finding. Documentation of sample disposal will be implemented after 1/31/01. This will require a procedure change which will be completed by 1/31/01. (Kottan and Shaffer) See response to item 5.5 for resolution of sample custody upon receipt (chain of custody).	Satisfactory Discussion: Region 1 revised Procedure 110, "Sample Handling and Flow" on March 20, 2001. This procedure includes a discussion on sample disposal. Implementation of a sample receipt and disposal log book began on January 1, 2001.

Requirement	Finding	Corrective Action	Status
6.5 The project manager or inspector is responsible for defining the Data Quality Objectives (DQOs) and developing a survey plan to ensure that the collected data will adequately serve their intended purpose.	Evaluation of data quality objectives and survey plans are not being used to ensure data obtained will adequately serve the intended purpose.	We agree with this finding. The inspectors need to be trained in this area and this will be covered in the training scheduled to be given by 12/15/00.	Satisfactory Discussion: DNMS received training on December 7, 2000. This training included discussions on the importance of identifying data quality objectives. Personnel attending the training were required to sign an attendance form. The training sign-in form is kept as a permanent QA record. In addition, Region 1 prepared a "Read and Sign" manual, dated December 1, 2000, to ensure that inspectors read and understand the requirements of the NMSS QA manual.

Requirement	Finding	Corrective Action	Status
6.6 On receipt, each sample shall be inspected to ensure sample integrity has not been compromised.	No formal process for receipt of samples exists. Samples are often brought in and placed in the laboratory without being stored by laboratory staff. The key to the locked sample storage room is not being controlled.	We agree with this finding. We have assigned additional resources to the lab, and will have laboratory staff available to receive samples at all normal business hours. Inspection staff will be trained so that samples are properly transferred to the lab. Training will be given by 12/15/00 (Kottan). The sample storage room has a combination lock, and the regional building is secure, therefore we believe the sample storage room is adequately controlled.	Satisfactory Discussion: Region 1 has revised its sample receipt process. Additional resources have been assigned to the laboratory. Therefore laboratory staff are now available during business hours to receive samples. DNMS staff was trained on sample receipt procedures during training provided on December 7, 2000. Sample receipt is now conducted in a secured sample receipt and storage room. DNMS staff is required to complete a chain-of-custody form before samples are received by laboratory personnel.

Requirement	Finding	Corrective Action	Status
6.14 (Sample) integrity shall be maintained for samples to be returned to the project manager or inspector and the method of sample disposal should be documented.	Disposition of samples are not being documented	We agree with this finding. Sample disposition will be noted in our sample receipt log book. (The Division does keep an inventory of samples that have been disposed of as radwaste, but the log book will address all samples.) Training to inspectors will also be given by 12/15/00. (Kottan)	Satisfactory Discussion: Laboratory personnel now track samples from receipt to disposal in a sample receipt log book.
8.3 It is the responsibility of the project manager or inspector to define the objectives and develop a plan for survey and data collection to ensure that the collected data will adequately support Agency decisions.	There are no plans to define the objectives and develop a plan for survey and data collection to ensure that the collected data will adequately support Agency decisions.	See response to Item 6.5 above.	Satisfactory Discussion: DNMS received training on December 7, 2000. This training included discussions on the importance of identifying data quality objectives. Personnel attending the training were required to sign an attendance form. The training sign-in form is kept as a permanent QA record. In addition, Region 1 prepared a “Read and Sign” manual, dated December 1, 2000, to ensure that DNMS staff read and understand the requirements of the NMSS QA manual.

Requirement	Finding	Corrective Action	Status
8.4 Procedures for the reduction, review and reporting of sample data shall be provided... 8.5 ...computation of the concentration of radioactive material shall include...independent verification of 5 percent of the results...by a person other than...one performing original computation. 8.7 A data review program shall be established to verify the data before reporting and shall include the following components....	No formal process exists for the independent review of data.	We agree with these findings. This was/is a staffing issue. Now that we have additional support in the lab, this issue has been addressed and we are independently reviewing the data. NRC Form 304 data sheets have two signature blocks, which are now being signed. This item is closed.	Satisfactory Discussion: Additional resources were assigned to the laboratory making it possible to independently review data sheets. Laboratory personnel began independent reveiw of all sample data on January 23, 2001. NRC Form 304, “Sample Record Sheet” now includes the signatures of the person conducting the analysis, and the independent data reviewer.

Requirement	Finding	Corrective Action	Status
9.4 The non-conformance and corrective action program...should include procedures for: (1) documentation of non-conformance items and deficiencies; (2) evaluation of...; and (3) corrective action and final disposition. 9.5 As a minimum, non-conformance and corrective action reports or documentation should include....	Previous findings from the RESL 1999 audit were not resolved. There is indication of ineffective closure.	See response to Item 2.4.9 above.	Satisfactory Discussion: On October 11, 2000, Region 1 provided NMSS a written response to RESLs audit findings. The response included proposed corrective actions and schedule for completion. In addition, Region 1 provided monthly status reports to NMSS on implementation of the corrective actions. In addition, Region 1 revised Procedure 750, "Corrective Action program" on March 14, 2001.

2.0 Determine Types and Numbers of Samples Analyzed

From July 1, 2000 to July 19, 2001, the Region I Laboratory analyzed a total of 373 samples. The break down is as follows:

Soil by gamma spectrometry (94 samples)
Water by gamma spectrometry (4 samples)
Wipes/filters for gross alpha & beta by gas flow proportional counting (31 samples)
Wipes/filters for LSC counting (233 samples)
Sediment for gamma spectrometry (3 samples)
Other samples for gamma spectrometry (8 samples (1 brick dust, 6 glass, and 1 paint))

3.0 Evaluate Results of Independent Test Samples

The Region 1 laboratory participated in three independent sample analysis programs; MAPEP, QAP, and ITP. Region 1 produced acceptable results for all test samples analyzed.

The laboratory receives MAPEP samples two times a year. One sample is a soil sample, and the other is a water sample. Results for Sample No. MAPEP-00-S7 and MAPEP-00-W8 show that the laboratory had acceptable performance for analyzing gamma emitters in soil and water, respectively.

The laboratory also receives QAP samples twice each year. Each set of samples includes filters, soil samples and water samples for analysis The filters are analyzed for gamma, gross alpha and gross beta. The soil samples are analyzed for gamma emitters, and the water samples are analyzed for gamma emitters and tritium. The results for QAP-53 and QAP-54 are all acceptable.

During the past year, the laboratory received ITP Samples 52, 53, 54, 55, and 56. Each test sample was a soil sample containing mixed gamma emitters. Results indicate that the laboratories performance was acceptable for all test samples analyzed.