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 3 LABORATORY

A surveillance of the Region 3 laboratory was conducted on July 27, 2001. The scope of the surveillance was limited to: (1) evaluating implementation of Region 3'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 August 22, 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 3 has satisfactorily implemented the corrective actions resulting from the annual RESL audit conducted in August 2000. Conclusions regarding implementation of each corrective action do not address the adequacy of the corrective actions, but instead, address implementation of the corrective actions as proposed by Region 3. In some cases, the Region was unable to implement specific corrective actions. If implementation of a specific corrective action could not be verified by the auditor, a conclusion of "Indeterminate" is reported. Minor deviations from the proposed corrective actions were identified during the surveillance. However, since these deviations were administrative in nature and likely did not affect the technical quality of the laboratory results, no findings were generated as a result of this surveillance.

From July 2000, to June 2001, Region 3 analyzed a total of 290 samples. As a result of the RESL audit findings, Region 3 discontinued use of the liquid scintillation counter (LSC) on August 23, 2000. In order to ensure that radiological measurements performed by Region 3 laboratory are of acceptable precision and accuracy and also reflect actual conditions and licensee performance, the Region 3 laboratory participated in the following independent sample analysis programs: (1) RESLs Mixed Analyte Performance Evaluation Program (MAPEP); and (2) NRCs Intercomparison Test Program (ITP). Region 3 produced acceptable results for all test samples analyzed.

The results from this limited scope surveillance indicate that the Region 3 laboratory had adequate controls in place during the past year to produce credible, technically defensible analytical results.

If you have any questions, contact John Buckley at 301-415-6607.

Enclosure: Region 3 Laboratory Surveillance Report

(2) NRCs Intercomparison Test Program (ITP). Region 3 produced acceptable results for all test samples analyzed.

The results from this limited scope surveillance indicate that the Region 3 laboratory had adequate controls in place during the past year to produce credible, technically defensible analytical results.

If you have any questions, contact John Buckley at 301-415-6607.

Enclosure: Region 3 Laboratory Surveillance Report

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ACNW: YES ___ NO ___

# Region 3 Laboratory Surveillance Report

A surveillance of the Region 3 laboratory was conducted on July 27, 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 3'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 August 22, 2000; (2) determining the types and number of samples analyzed since the last audit; and (3) evaluating results from independent test sample analyses.

The auditor did not attempt to determine the adequacy of the corrective actions taken by Region 3. Instead, the auditor evaluated whether Region 3 implemented the corrective actions proposed in the January 22, 2001 letter from C. Pederson to J. Greeves.

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 3 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 3, prior to conduct of the surveillance. The checklist was developed mainly from Region 3's response to the FY2000 RESL audit, dated November 22, 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.

## 3. Surveillance Conclusions

In general, Region 3 has satisfactorily implemented the corrective actions resulting from the annual RESL audit conducted in August 2000. Conclusions regarding implementation of each corrective action are identified as Satisfactory, Indeterminate, or Unsatisfactory. This conclusion does not address the adequacy of the corrective action, but instead, addresses implementation of the corrective action as proposed by Region 3. In some cases, the Region was unable to implement specific corrective actions. If implementation of a specific corrective action could not be verified by the auditor, a conclusion of "Indeterminate" is reported. Minor deviations from the proposed corrective actions 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 June 2001, Region 3 analyzed a total of 290 samples. Of these, 242 were analyzed by gamma spec, 100 by gas flow proportional counting, and 25 were analyzed by liquid scintillation counting. Many samples were counted using two different methods. Liquid scintillation counting was performed before August 23, 2000, when Region 3 suspended use of the liquid scintillation counter (LSC). In order to ensure that radiological measurements performed by Region 3 laboratory are of acceptable precision and accuracy and also reflect actual conditions and licensee performance, the Region 3 laboratory participated in the following independent sample analysis programs: (1) RESLs Mixed Analyte Performance Evaluation Program (MAPEP); and (2) NRCs Intercomparison Test Program (ITP). Region 3 produced acceptable results for all test samples analyzed.

The results from this limited scope surveillance indicate that the Region 3 laboratory had adequate controls in place during the past year to produce credible, technically defensible analytical results.

4. Surveillance Team

John Buckley DWM/DCB/FDS

## REGION 3 LABORATORY CLOSEOUT SURVEILLANCE CHECKLIST

1.0 Evaluate Corrective Actions From FY 2000 RESL Audit

| Requirement | Finding | Corrective Action | Status |
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| 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. | No objective evidence could be identified that documents continued staff retraining to new or modified work practices. | **ACTION 2.2.1: The applicable Lab Procedure will be revised to provide that affected staff will be trained by e-mail with the revised procedure attached. Other available options will also be examined.** | Satisfactory<br><br>Discussion:<br><br>Region 3 revised Procedure 30, "Qualifications and Training for Laboratory Personnel," on 11/21/00. This procedure requires that staff responsible for collecting, transporting, or preparing samples for the laboratory, be trained to Procedures 100, 610, 710, and 810. Training on the new procedures was conducted on December 12, 2000. Staff members unable to attend the training, were notified of the procedural changes by email, and provided copies of the revised procedures. |
| 2.4.9 Corrective steps 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 III to audit findings of the RESL audit conducted on 8-31-99 were not effectively implemented. Evidence of "open" items remaining from the previous audit points to ineffective corrective action, to follow-up and closure. | **ACTION: This item addressed with the resolution of 4.0.1(2).** | Discussion:<br><br>See response to 4.0.1(2). |

| Requirement | Finding | Corrective Action | Status |
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| 3.0.1 Individuals shall be trained and qualified before (they) conduct any activity affecting the quality of sample results.<br><br>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.<br><br>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.<br><br>3.1.8 Personnel qualifications should be documented before work is assigned and reviewed periodically to ensure staff remains qualified as changes in work practices occur. | There is evidence that staff re-training is not provided as work practices change. When implementing procedures are revised or improved, retraining to those new work processes should take place. | **ACTION: When procedures which affect non-lab staff are changed, an e-mail with the revised procedure attached will be distributed to train staff.** | Satisfactory<br><br>Discussion:<br><br>Region 3 revised Procedure 30, "Qualifications and Training for Laboratory Personnel," on 11/21/00. This procedure requires that staff responsible for collecting, transporting, or preparing samples for the laboratory, be trained to Procedures 100, 610, 710, and 810. Training on the new procedures was conducted on December 12, 2000. Staff members unable to attend the training, were notified of the procedural changes by email, and provided copies of the revised procedures.<br><br>Procedure 30 also requires that prior to conducting unsupervised analytical laboratory work, the Laboratory Operations Specialist must demonstrate knowledge and proficiency in implementing the procedures of the NMSS QA Manual, Region 3 Laboratory Procedures Manual. |

| Requirement | Finding | Corrective Action | Status |
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| 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. | Training in quality and procedural requirements was initially provided to NRC lab and field staff in December of 1998. However, no "program" for continued staff training now exists. Apparently there are no developed plans for future staff training in sample collection, laboratory analysis, NRC quality requirements or quality improvements. | **ACTION: This item will be addressed with the resolution of 2.2.1 above.** | Satisfactory<br><br>Discussion:<br><br>Region 3 revised Procedure 30, "Qualifications and Training for Laboratory Personnel," on 11/21/00. This procedure requires that staff responsible for collecting, transporting, or preparing samples for the laboratory, be trained to Procedures 100, 610, 710, and 810. Training on the new procedures was conducted on December 12, 2000. Staff members unable to attend the training, were notified of the procedural changes by email, and provided copies of the revised procedures.<br><br>Procedure 30, Attachment 1 provides the qualification and refresher training requirements for the Laboratory Operations Specialist. |
| 4.0.1Procedures 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. | (1) Analytical measurements for nuclides such as P-32 and I-125 are being performed based on operator knowledge without written procedures or the appropriate chemistry. | **ACTION: None required.** | Satisfactory<br><br>Discussion:<br><br>Use of the LSC was discontinued on August 23, 2000. No samples were analyzed via the LSC since the 2000 RESL audit. |

| Requirement | Finding | Corrective Action | Status |
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| SAME AS ABOVE | (2) The routine practice of analyzing samples by LSC without initial separation chemistry is not consistent with the requirements stated in the *Quality Assurance Policy* and the NRC *Regional Laboratory Mission Statement* found in the NMSS QA Manual. | **ACTION 4.0.1(2): Senior RIII management (jointly wlth the other regions and NMSS) will make a decision regarding uses and limitations on the LSC, and what procedure or practice changes must be made to resolve this finding. Various available options are currently being examined regarding this issue.** (Pederson) | Satisfactory<br><br>Discussion:<br><br>On August 23, 2000, Region 3 discontinued the use of the LSC. No samples were analyzed using the LSC since the 2000 RESL audit.<br><br>NRC management made the decision to discontinue operation of the Regional laboratories before deciding on the uses and limitations of the LSC. Therefore, a procedure for development, use, and revision of control charts for the LSC was not prepared. |
| 4.0.1 SAME AS ABOVE | (3) A procedure that describes the development, use and revision of quality control charts has not been written. | **ACTION 4.0.1(3)-2: Various available options are being examined concerning the operation of the LSC system. If appropriate, based on a final resolution to this issue, a procedure on development, use and revision of control charts for the LSC will be prepared.** (Bonano) | Satisfactory<br><br>Discussion:<br><br>This finding applied to the LSC. On August 23, 2000, Region 3 discontinued the use of the LSC.<br><br>NRC management made the decision to discontinue operation of the Regional laboratories before deciding on the uses and limitations of the LSC. Therefore, a procedure for development, use, and revision of control charts for the LSC was not prepared. |

| Requirement | Finding | Corrective Action | Status |
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| 4.0.1 SAME AS ABOVE | (4) A procedure that describes the calculation and reporting of measurement uncertainty has not been written. This procedure would consider measurement uncertainty factors as described by NIST. | **ACTION 4.0.1(4)-1: The gamma spectroscopy system procedures will be examined and, measurement uncertainty will be incorporated. (Snell)**<br><br>**ACTION 4.0.1(4)-2: Various available options are being examined concerning the operation of the LSC system. If appropriate, based on a final resolution to this issue, a procedure on measurement uncertainty for the LSC will be prepared.** | Satisfactory<br><br>Discussion:<br><br>Region 3 revised Procedures 610, "Logging Sample Receipt and Results," and 710, "Quality Assurance program for Analytical Measurements," to address uncertainty. Procedure 610 now includes a discussion about reporting measurement uncertainties along with NRC Form 304. Procedure 710 states that uncertainties must be reported along with all quantitative data.<br><br>On August 23, 2000, Region 3 discontinued the use of the LSC. NRC management made the decision to discontinue operation of the Regional laboratories before deciding on the uses and limitations of the LSC. Therefore, a procedure for measurement uncertainty for the LSC was not prepared. |
| 4.0.1 SAME AS ABOVE | (5) No procedure has been written that describes the development of Data Quality Objectives or sample collection planning by NRC field personnel. | **ACTION: This item will be addressed with the resolution of 6.5 below.** | Discussion:<br><br>See response to Item 6.5. |

| Requirement | Finding | Corrective Action | Status |
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| 4.0.1 SAME AS ABOVE | (6) Data reduction (calculation) steps or methods have not been incorporated into measurement procedures. | **ACTION 4.0.1(6): Procedure 710 will be clarified to separate laboratory production of analytical data results (subject to the QA Plan) from the interpretation of those results, which is not a lab QA function.** | Satisfactory<br><br>Discussion:<br><br>Procedure 710, "Quality Assurance program for Analytical Measurements," was revised on February 8, 2001, to indicate that data interpretation is not a function of the laboratory. Interpretation of the results of analytical laboratory measurements is the responsibility of the inspection staff. |
| 4.0.1 SAME AS ABOVE | (7) Procedures do not clearly identify specific records that must be kept to document evidence of data quality, or process effectiveness. The gamma spectroscopy procedures do not detail what parameters are relevant to store, such as background and efficiency. | **ACTION 4.0.1(7): The relevant operating procedures will be reviewed and, as appropriate, will be modified to specify document retention or will cross-reference to the quality records procedures (see 5.3 below).** | Satisfactory<br><br>Discussion:<br><br>Procedure 455, "QC Performance Checks of the Gamma Spectrometry System," was revised to state that the spectrum, which includes background and efficiency, must be placed in the QA/QC folder. |
| 4.0.1 SAME AS ABOVE | (8) Chain-of-custody procedures do not exist and are not being used for the mobile laboratory. | **ACTION 4.0.1(8): Various available options are being examined concerning the use of the mobile lab. Specific actions on this issue will be implemented as appropriate.** | Satisfactory<br><br>Discussion:<br><br>Procedure 100, "Sample Collection," is also in effect for the mobile laboratory. Since the last audit, the mobile laboratory was used once, at Lake City Army Ammunition Plant (LAACP) in July 2000. A NRC Form 303, which includes chain-of-custody, was completed for samples taken. |

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| 4.0.1 SAME AS ABOVE | (9) There are no procedures for the method used for the determination of uranium by gamma spectroscopy. | **ACTION: This item will be addressed with the resolution of 4.0.1(6) above.** | Satisfactory<br><br>Discussion:<br><br>Procedure 710, "Quality Assurance program for Analytical Measurements," was revised to state that data interpretation is not a laboratory function. Interpretation of the analytical laboratory measurements is now the responsibility of the inspection staff. |
| 4.0.3 Regional laboratory and sample collection procedures shall provide sufficient detail for persons to be able to perform the activities under controlled conditions. | Measurement procedures do not include step-wise descriptions of the analytical processes, including data reduction and rely heavily on undocumented operator expertise. | **ACTION: This item will be addressed with the resolution of 4.0.1(6) and 4.0.1(9) above.** | Satisfactory<br><br>Discussion:<br><br>Procedure 710, "Quality Assurance program for Analytical Measurements," was revised to state that data interpretation is not a laboratory function. Interpretation of the analytical laboratory measurements is now the responsibility of the inspection staff. |
| 4.0.5 To ensure consistency and completeness, operating procedures should be clear and concise and the procedure format should include the following elements, as required:<br>.<br>.<br>precautions<br>.<br>.<br>reporting/record requirements | Procedures do not contain precautions-limitations, reporting and record requirements. | **REGION 3 DISAGREES WITH THIS FINDING**<br><br>**ACTION: 4.0.1(7) above, specifications or cross-references will be added as deemed necessary to address record requirements.** | Satisfactory<br><br>Discussion:<br><br>Region 3 has revised Procedures 5, "Organizational Structure," and 30, "Training for Laboratory Personnel," by adding sections on reporting and records requirements. |

| Requirement | Finding | Corrective Action | Status |
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| 5.1 Laboratory records will be developed and maintained to: (1) provide traceability of analytical results back to raw data; (2) provide for the control of samples as they are processed through the laboratories; and (3) establish who performed ... work and how it was accomplished. | There was no way to trace the data to the results, or who performed the analysis for any given set of data. For example, the team looked at liquid scintillation results from the analysis of five swipe samples. The count data ... It was also not possible to determine from sample analysis records, what data was reported to the customer, or its associated uncertainty. | **ACTION 5.1: To ensure timely completion of Form 304 in the future, the HPM will conduct a verification check of lab output at least quarterly. Procedure 710 will be revised to reflect this requirement.** | Satisfactory<br><br>Discussion:<br><br>Procedure 100, "Sample Collection," is also in effect for the mobile laboratory. Since the last audit, the mobile laboratory was used once, at LCAAP in July 2000. A NRC Form 303, which includes chain-of-custody, was completed for samples taken. |
| 5.2 All quality affecting activities conducted in the Regional fixed and mobile laboratories will be documented.<br><br>5.4 Sufficient records shall be maintained to furnish evidence of activities affecting the quality of analytical results. | (1) Chain-of-custody requirements are not being implemented for the samples received in the mobile lab.<br><br>(2) Methods used for liquid scintillation determinations and assumptions used when determining alpha-emitting uranium by gamma spectroscopy are not documented.<br><br>(3) The data review process is not documented. It is not possible to determine from current sample analysis records what was reviewed, or by whom. | (1) **ACTION: This item will be addressed with the resolution of 4.0.1(8) above**.<br><br>(2) **ACTION 5.2(2): Various available options are being examined concerning the use of the LSC. Specific actions on this issue will be implemented as appropriate. However, a "draft" protocol for LSC operation is available and may be made final if appropriate.**<br><br>(3) **ACTION: None required.** | Satisfactory<br><br>Discussion:<br><br>1. Procedure 100, "Sample Collection," is also in effect for the mobile laboratory. Since the last audit, the mobile laboratory was used once, at LCAAP in July 2000. A NRC Form 303, which includes chain-of-custody, was completed for samples taken<br><br>2. Use of the LSC was discontinued on August 23, 2001.<br><br>3. Procedure 710, "Quality Assurance Program for Analytical Measurements," was revised on February 8, 2001, to indicate that data interpretation is not a function of the laboratory. Interpretation of the results of analytical laboratory measurements is the responsibility of the inspection staff. |

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| 5.3 Each operating procedure shall identify what records shall be kept for the specific activity involved. | Many procedures do not specify what records or documents will be retained, as an outcome of operating that process. | **ACTION: see item 4.0.1(7) and item 4.0.5 above. Various available options are being examined concerning this issue. Specific actions will be implemented as appropriate.** | Satisfactory<br><br>Discussion:<br><br>Region 3 has revised Procedures 5, "Organizational Structure," and 30, "Training for Laboratory Personnel," by adding sections on reporting and records requirements.<br><br>Procedure 455, "QC Performance Checks of the Gamma Spectrometry System," was revised to state that the spectrum, which includes background and efficiency, must be placed in the QA/QC folder. |

| Requirement | Finding | Corrective Action | Status |
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| 5.5 Records shall be kept that track the receipt and control of samples throughout the collection (i.e., sample collection and chain of custody forms; operating logs; instrumentation printouts and computer data; worksheets; analysis; data reduction and verification; and final recording of results and reporting. | Chain of custody records are not being kept for samples collected using the mobile laboratory. An examination of recent sample analysis records shows that recording and reporting of results is conducted in an informal manner (via e-mail), and that written records are not always kept that documents what data was reported and to whom. | **ACTION: This item will be addressed with the resolution of 4.0.1(8), 4.0.1(9) and 5.1 above.** | Satisfactory<br><br>Discussion:<br><br>Procedure 100, "Sample Collection," is also in effect for the mobile laboratory. Since the last audit, the mobile laboratory was used once, at LCAAP in July 2000. A NRC Form 303, which includes chain-of-custody, was completed for samples taken.<br><br>Procedure 710, "Quality Assurance program for Analytical Measurements,' was revised to state that the Health Physics Manager (HPM) would conduct verification check of laboratory output at least quarterly.<br><br>During the surveillance it was determined that the HPM missed the first quarterly review due to a rotational assignment. However, the second quarter review was conducted on 7/26/01, and included a review of all records back to the revision of this procedure. |

| Requirement | Finding | Corrective Action | Status |
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| 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 dispositioned. | From the data examined, documentation does not always exist to satisfy this requirement. See 5.5. Sample custody upon receipt is not always documented. | **ACTION: This item will be addressed with the resolution of 5.1 and 5.5 above.** | Satisfactory<br><br>Discussion:<br><br>Procedure 100, "Sample Collection," is also in effect for the mobile laboratory. Since the last audit, the mobile laboratory was used once, at LCAAP in July 2000. A NRC Form 303, which includes chain-of-custody, was completed for samples taken. |
| 6.5 The project manager or inspector is responsible for defining the data quality objectives and developing a survey plan to ensure that the collected data will adequately serve their intended purpose.` | Field Sampling Project Data Quality Objectives are not being defined. Survey plans are not being developed to ensure data obtained will adequately serve the intended purpose. Implementing procedures do not address the development of Data Quality Objectives. | **ACTION 6.5: In concert with ACTION 4.0.1(5), various available options are being examined. Specific actions on this issue will be implemented as appropriate.** | Indeterminate<br><br>Discussion:<br><br>Region 3 staff believe that issues regarding the data quality objectives (DQO) process cannot be resolved at the laboratory level. Instead, the DQO process should be examined with regard to the overall inspection program. During a conference call on 12/11/00, Region and Headquarters management decided to explore various options for addressing issues associated with the DQO process. A management decision was made to close the Regional laboratories before this finding could be resolved. |

| Requirement | Finding | Corrective Action | Status |
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| 6.6 On receipt, each sample shall be inspected to ensure integrity has not been compromised. | No formal process for sample receipt inspection exists. NRC Form 304 is not used to document sample condition on arrival. | **ACTION 6.6: Lab Procedure 805, which accomplishes sample receipt inspection, indicates "package" inspection, and does not specifically address each sample within the package, or how any damage will be documented. Procedure 805 will be revised to specify that sample as well as package integrity will be examined, and for any case where sample or package integrity appears compromised, how it will be documented.** | Satisfactory<br><br>Discussion:<br><br>Procedure 805, "Receipt, Handling and Disposal of Radioactive Samples," was revised on 12/11/00 to specify that sample as well as package integrity must be examined. The procedure also describes the process to be followed if sample integrity appears compromised, how it will be documented. |
| 7.6 Criteria shall be given for determining when an instrument is not functioning within the required limits, along with guidance for corrective action. | Procedures should include statements to define the use and limitations of the individual instruments. There are no acceptance criteria established in measurement procedures that define when a measurement process is operating within the required control limits. Procedures do not exist that describe the calculation, use and revision of control limits. | **ACTION: Procedures shall be reviewed and modified as appropriate to address this concern.** | Satisfactory<br><br>Discussion:<br><br>Operating procedures exist for each analytical system in the lab; use and limitations are specified.<br><br>On August 23, 2000, Region 3 discontinued the use of the LSC.<br><br>NRC management made the decision to discontinue operation of the Regional laboratories before deciding on the uses and limitations of the LSC. Therefore, a procedure for development, use, and revision of control charts for the LSC was not . |

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| 7.12 (The) laboratory (must) maintain its capability to meet required data quality objectives and to detect possible instrument contamination, in the event of...increase in background radiation. | Instrument backgrounds are not being collected and retained for the gamma spectroscopy system. | **ACTION 7.12: As an independent check, the gamma spec system QC procedure (Procedure 455) will be revised to specify counting of background samples on a specified frequency, and recording of the data on a Form 304 which will be retained.** | Satisfactory<br><br>Discussion:<br><br>Procedure 455, "QC Performance Checks of the Gamma Spectroscopy System," was revised on 10/12/00. The procedure includes the requirement to save instrument backgrounds in the QA/QC folder for the respective detector.<br><br>Background counts are to be conducted at least once per week.<br><br>The laboratory staff was reminded to retain background counts for the gamma spec system. |
| 8.1 Data...must be properly managed and reviewed to ensure: (1) adequate procedural compliance, (2) valid calculations and/or computations; (3) that transcription errors have been avoided; and (4) consistent and complete reporting of measurement data. | There is no review of the data for transcription errors or consistency and complete reporting of measurement data. The team found that sample data results are informally and frequently sent via e-mail due to a lack of time to finish the data package. There was no evidence of a systematic data review process. | **WE DISAGREE WITH THIS FINDING**<br><br>**ACTION: None required.** | Satisfactory<br><br>Discussion:<br><br>No action taken. |

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| 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. | Plans were not presented to the audit team that described the data quality objectives that were to be satisfied by the data obtained from analysis of the samples. | In many cases, adequate support for Agency decisions does not require data quality objectives. Further, an advance determination of the objectives cannot always be made.<br><br>**ACTION: As stated in ACTION 4.0.1(5) above, various available options are being examined concerning this issue. Specific actions will be implemented as appropriate.** | Indeterminate<br><br>Discussion:<br><br>Procedure 710, "Quality Assurance Program for Analytical Measurements," was revised on February 8, 2001, to indicate that data interpretation is not a function of the laboratory. Interpretation of the results of analytical laboratory measurements is the responsibility of the inspection staff. |

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| 8.4 Procedures for the reduction, review, approval, and reporting of sample data shall be provided. | No formal process exists for the independent review of data or for the reduction of data. In one example, an analytical request was made for H3, C14 and P32. There is no procedure that defines the experimental parameters used for the analysis or to describe the reduction of data to obtain the results. Examples exist for Uranium analyses where many assumptions have to be made, yet these assumptions are not documented. Although NRC Region III Procedure 710,4,7 describes an independent review process, no formal process was implemented for independent review of data. | **ACTION: For the LSC, the current "draft" protocol (providing for H3 and C14 only) may be made "final" , depending on the resolution of the various available options are being examined concerning the use of the LSC. Specific actions on this issue will be implemented as appropriate.** | Indeterminate<br><br>Discussion:<br><br>NRC management made the decision to discontinue operation of the Regional laboratories before deciding on the uses and limitations of the LSC. Therefore, resolution of this issue could not be verified.<br><br>However, the data produced by the gamma spec system is recorded on Form 304 and kept as a QA record.<br><br>Procedure 710, "Quality Assurance Program for Analytical Measurements," was revised on February 8, 2001, to state that data interpretation is not a laboratory function. Interpretation of the results of analytical measurements is the responsibility of the inspection staff.<br><br>Procedure 710 was also revised to state that the Health Physics Manager (HPM) would conduct verification check of laboratory output at least quarterly. During the surveillance it was determined that the HPM missed the first quarterly review. However, the second quarter review was conducted on 7/26/01, and included a review of all records back to the revision of this procedure. |

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| 8.7 A data review program shall be established to verify the data before reporting and shall include the following components...<br>(Several listed) | No objective evidence was found to indicate implementation of a data review program. | **ACTION: None required.** | Satisfactory<br><br>Discussion:<br><br>NRC Form 304 documents the data review process. During the surveillance, NRC Form 304 was reviewed for Samples 01-07 through 01-16. All forms contained the signature of the data reviewer, as required. |
| 8.8 .information reported,,analytical results shall include...:<br>Identification of the lab<br>Identification of the inspector<br>The .. results with error limits assigned; and<br>Signature of person responsible for verification of data quality. | Uncertainties are not being reported for every result; only results from gamma spectrometry analyses that were statistically positive were reported with uncertainties. Results that are statistically zero are ot reported at all, instead a sample specific MDA is calculated and reported. In each case this value was preceded by a "less than" sign. None of the other requirements specified in the NMSS QA Manual concerning the reporting of analysis results were met; signature of person responsible for verification of data quality, identification of the inspector, etc. | **ACTION 8.8: Practices will be modified to ensure statistical uncertainties are recorded on Form 304 as generated by the gamma spec system. Procedure 610 will be revised to reflect this item.** | Satisfactory<br><br>Discussion:<br><br>Procedure 610, "Logging Sample Receipt and Results," was revised to require that NRC Form 304 shall include analytical data of the results of the analysis along with the statistical information affecting overall uncertainty of the result. |

| Requirement | Finding | Corrective Action | Status |
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| 9.3 A non-conformance and corrective action program shall be established and documented in the Regional laboratory procedures. | Internal NRC Region III records do not document that any of the 1999 RESL Audit Findings were actually closed. 1999 RESL Audit Findings were not entered onto Attachment "B," Regional Procedure 770. | **ACTION 9.3: Lab Procedure 770 will be utilized to accomplish applicable corrective actions from the 2000 RESL audit.** | Satisfactory<br><br>Discussion:<br><br>Region 3 implemented Attachment A to Procedure 770, "Corrective Actions for Laboratory Deficiencies," to document the findings from the 2000 RESL audit. All deficiencies were identified in a matrix that was attached to the completed Attachment A.<br><br>When NRC management made the decision to close the laboratories, Region 3 had not yet received management approval on all proposed corrective actions. Region 3 has completed many of the corrective actions. However, since not all deficiencies have been resolved, Attachment B has not been completed. |
| 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. | Previous findings from the RESL 1999 audit were not resolved. There is indication of ineffective closure. | **ACTION: Various available options will be examined concerning the use of the LSC. Specific actions on this issue will be implemented as appropriate.** | Indeterminate<br><br>Discussion:<br><br>NRC management made the decision to discontinue operation of the Regional laboratories before deciding on the uses and limitations of the LSC. Therefore, examination of the corrective action is indeterminate. |

## 2.0 Determine Types and Numbers of Samples Analyzed

From July 2000 to June 2001, the Region 3 Laboratory analyzed a total of 290 samples. Many samples were counted using two different counting methods. The break down is as follows:

Soil by gamma spectrometry (157 samples)
Water by gamma spectrometry (5 samples)
Wipes/filters for gross alpha & beta by gas flow proportional counting (100 samples)
Wipes/filters for LSC counting (25 samples)
Wipes/filters for gamma spectrometry (80 samples)
Other samples for gamma spectrometry (5 samples)

On August 23, 2000, Region 3 discontinued use of the LSC due to concerns raised by RESL during the audit conducted on August 22-23, 2000. The 25 samples counted by the LSC were conducted prior to LSC shutdown.

## 3.0 Evaluate Results of Independent Test Samples

The Region 3 laboratory participated in two independent sample analysis programs; MAPEP, and ITP. Region 3 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.

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 laboratory's performance was acceptable for all test samples analyzed. Since this surveillance was conducted, Region 3 also analyzed ITP Samples 57 and 58. Results for ITP 57 showed that agreement for all isotopes reported were between 11 and 19 percent higher than the known values. Although these results differ from the known values by more than 10 percent, they are still within the 20 percent acceptance range. Region 3 determined that a slight shift in the efficiency curves resulted in the high results. Region 3 took immediate corrective action. Results for ITP 58 show that the corrective actions were adequate, since laboratory results show close agreement with known values.