Final Audit Report
of the ENV-MAQ Rad-NESHAP Program

Audit conducted in December 2004
Report delivered January 13, 2005

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This cover sheet added by D. Fuehne, ENV-MAQ
Page 6 of the audit report has additional comments added by Fuehne on 4/21/2005

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2.0 AUDITED ORGANIZATION

Los Alamos National Laboratory (LANL), Environmental Stewardship (ENV) Division, Meteorology and Air Quality Group (MAQ), Rad-NESHAP team.

3.0 DATE

November 19, 2004 through January 13, 2005.

Site Visit: December 14 through December 17, 2004

4.0 AUDITORS

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5.0 SCOPE

The Audit encompassed site-wide activities and associated documents of the LANL ENV-MAQ, Rad-NESHAP team. The audit methodology included personal interviews, document/record review, and electronic media review.

6.0 AUDITED ACTIVITIES

The Audit ensured demonstrated compliance of Rad-NESHAP activities to the following:

- Compliance with Department of Energy (DOE) Order (O) 414.1B, DOE O 414.1B
- Compliance with 40 Code of Federal Regulations (CFR) 61, Subpart H, 40 CFR 61 Subpart H, 2003 Revision
  - Identification of point sources that require monitoring
  - Maintenance of Laboratory's Rad-NESHAP quality assurance program as required by 40 CFR 61, Appendix B, Method 114 and ANSI N13.1-1999, 40 CFR 61 Appendix B, Method 114, 2003 Revision
  - Monitoring the Laboratory's airborne emissions of radioactive materials and assessing impact on the 10-mrem/yr standard
  - Tracking Laboratory emissions to ensure they remain below the 10-mrem/yr standard
  - Implementation of ANSI N13.1-1999, e.g., inspections & new stack design/testing
  - "Follow the data" from sample change-out to final EPA report
  - Generating an annual compliance report that meets the requirements of 40 CFR 61.94 (http://www.access.gpo.gov/nara/cfr/waisidx_04/40cfr61_04.html)
- Compliance with the Rad-NESHAP Federal Facility Compliance Agreement (FFCA)
  - Tracking operations exhausted by unmonitored point sources to confirm and verify low emissions
- Working with facility management and program personnel to identify and mitigate compliance concerns (e.g., needed sampling equipment)
- Follow-up to RAC/John Till's 2002 audit, Final Report

7.0 KEY PERSONNEL CONTACTED

- Jean Dewart, Group Leader
- Dianne Wilburn, Deputy Group Leader

- Dave Fuehne, Project Leader
- Terry Morgan, Quality Assurance Officer
- Linda Nelson
- Debra Archuleta
- Keith Jacobson
- Carolyn Macdonell
- Harold Martinez
- Libby Jones
- Kevin Anderson
- Susan Terp
- Richard Sturgeon

8.0 AUDIT SUMMARY

The ENV-MAQ group, Rad-NESHAP team, complies with DOE O 414.1B, Quality Assurance; 10 CFR 830 Subpart A, Nuclear Safety Management; the Rad-NESHAP Federal Facility Compliance Agreement (FFCA); 40 CFR 61.94, annual compliance report generation; and maintains a quality assurance program according to 40 CFR 61, Appendix B, Method 114, and ANSI N13.1-1999. The following findings that require corrective-action responses do not represent major noncompliance to these requirements, but, for the most part, noncompliance to the ENV-MAQ Quality Management Program (QMP) and/or the Rad-NESHAP Quality Assurance Project Plan (QAPP).

The Rad-NESHAP team complies with 40 CFR 61, Subpart H. The audit methodology included "following the data." The auditor interviewed sample-collection staff, reviewed procedures, and observed sample collecting activities and field data entry. The auditor reviewed analytical laboratory procedures and electronic and hard-copy analytical reports, as well as observing data validation and verification. The auditor interviewed database personnel and reviewed RADAIR database reports to assess compliance with quality assurance requirements for laboratory data. The auditor also interviewed dose-assessment personnel and reviewed dose assessment procedures, as well as interviewing staff who prepare the data annual report, examining report preparation files, and reviewing report preparation procedures.

The audit team reviewed the implementation of the monitoring and sampling design and inspection criteria as outlined in 40 CFR 61 Subpart H, ANSI N13.1- 1999 and the Method 114 Table 2 inspection criteria by the Rad NESHAP Team. The following findings that require corrective-action responses do not represent noncompliance with the regulations, but provide more defensible documentation that the facility meets the requirements.

The "Observations" noted below do not require a formal corrective-action response. However, each "Finding" below requires a response that includes a proposed corrective action and a compliance date. Return responses to Jeanne_HQC@msn.com. The lead auditor verifies compliance to the corrective actions.

9.0 PROGRAM RESULTS

9.1 Noteworthy Practices

9.1.1 Rad-NESHAP Team

The Rad-NESHAP project team demonstrated exceptional project knowledge, personal motivation, team morale, and emphasis on teamwork. The auditors commend this organization for providing the work environment that promotes these qualities so necessary for successful work activities.

9.1.2 Databases

The auditor commends ENV-MAQ for the development and maintenance of the quality record control and training documentation databases. In addition, the RADAIR stack sample database is exemplary in its capacity to minimize data entry and allow quality assurance reviews.

9.1.3 Safety Team

The auditor commends the group for the organization and performance of the Safety Team, which weekly addresses critical group activities, e.g., procedural needs/requirements, IWD reviews, safety issue follow-up, problem solving, team representation, etc.

9.2 Observations

9.2.1 MAQ QMP

Although the QMP states " . . . develop, measure, track, and communicate MAQ performance metrics related to ES&H," the auditor found no documented compliance evidence. The auditor recommends following this requirement or eliminating it from the QMP.

9.2.2 Procedural Training Requirements

Although MAQ-026, Deficiencies, documents required actions for personnel, the procedure does not require MAQ Rad-NESHAP team personnel to formally train to MAQ-026, Deficiencies. This procedure documents critical quality processes, e.g., root cause analysis, corrective action, lessons learned, future prevention, etc., to which personnel should train. Although the Rad-NESHAP team places this procedure on the required training list, the auditor recommends changing the procedure to document the requirement for all personnel to train to the procedure.

9.2.3 MAQ-024, Personnel Training

Although the Training Coordinator requires documenting "required training changes" via e-mail, the procedure allows "verbal" communication of required training changes. The auditor recommends removing this wording in the procedure, requiring only documented training change requests.

Although the procedure states, "Establish and document job descriptions for each position, including education and skills, knowledge, and abilities required," it is not clear "how" this is accomplished. The auditor recommends documenting this process.

The auditor recommends adding an "Organization" blank on training documentation forms; the Training Coordinator receives the form, but cannot identify a person's organization. Thus sorting by organization to ensure training compliance, especially of subcontractors, is not possible.

MAQ-024 and MAQ-032 allow the Training Coordinator a month to enter documented training into EDS. Thus, it is not clear how the Team Leader knows that project personnel complete all required training before work commencement. The auditor recommends clarifying and documenting this important process.

9.2.4 QAPP (RRES-MAQ-RN, R3, page 9) Requirement

Although the project requires personnel ". . . with knowledge of the following:

- Point source monitoring requirements as stated in 40 CFR 61, Subpart H, and the FFCA
- Unmonitored point source requirements as stated in 40 CFR 61, Subpart H, and the FFCA
- Ambient monitoring technology
- Dose assessment methods from the air pathway
- Radionuclide airborne emissions estimation principles
- Ventilation systems
- Data management principles, including databases, web development, validation and verification, and legal defensibility
- Radiochemical procedures, as described in Method 114 of Appendix B to 40 CFR 61
- ANSI Standards N13.1-1969 and N13.1-1999
- Quality assurance requirements in 40 CFR 61, App. B, Method 114
- ANSI N13.1-1999, Section 7"

it is not clear "how" the team leader measures and documents this required "knowledge." The auditor recommends changing the QAPP language from "required" to "should possess the knowledge of" or similar language.

9.3 Findings

9.3.1 Approved Suppliers' Evaluation

DOE O 414.1B (10 CFR 830, Subpart A) Criterion 7, Procurement, states, "Establish and implement processes to ensure that approved suppliers continue to provide acceptable items and services." The auditor found no evidence of documentation of these processes. The auditor recommends that the ENV-MAQ Rad-NESHAP project document these required processes.

9.3.2 Annual Rad-NESHAP Reports

The Rad-NESHAP QAPP requires that the annual Rad-NESHAP reports ". . . address items such as:

- Audit/assessment activities relating to quality assurance of Rad-NESHAP activities.
- Problems or deficiencies identified during assessment activities or during routine performance of work.
- Deficiency report trending and analysis."

The auditor found no evidence that the 2001, 2002, and 2003 Annual Project Reports included

- subcontractors, organizations providing services, and internal assessments;
- included problems or deficiencies identified during assessment activities or during routine performance of work; nor
- reported deficiency report trending and analysis.

The auditor recommends including these topics in the 2004 Annual Rad-NESHAP Report and all following reports.

9.3.3 Rad-NESHAP Deficiencies

The QAPP states the following:

1) "At least once a year, the Rad-NESHAP Team Leader will review the deficiency reports to look for trends in the occurrence of deficiencies. Trending is intended to determine the existence of systematic design or implementation problems. The trending analysis results will be documented in a memo or report, forwarded to the MAQ Group Leader, and copied to the MAQ records management system."

2) "Rad-NESHAP activities will adhere to the policy for continuous improvement as given in the MAQ QMP. The MAQ Group Leader, the Rad-NESHAP Team Leader, and the MAQ Quality Assurance Officer will use performance reports and deficiency trending results to improve project processes."

Although ENV-MAQ reports deficiencies according to established procedures, the Rad-NESHAP project cannot comply with these requirements because the

Quality Officer performed and documented the last deficiency trending analysis in 2001, and the auditor found no documented deficiency report review and trending by the Team Leader. Also, since April 2002, the project Team Leader closed only 14% of project-related deficiencies, thus putting the continuous improvement process, especially relating to the existence of systematic design or implementation problems, in jeopardy. This also indicates the lack of importance management places on the deficiency closeout process, which enables continuous process improvement. The auditor recommends immediate attention to closing out all overdue deficiencies as soon as possible.

In addition, the record center did not contain deficiency #491, 08/26/2004, concerning the incomplete radionuclide emissions source term for calendar year 2003, occurring because after acquiring a "new" (10/01/2003) analytical laboratory, new "positive hits" from gamma spectroscopy were not included in the weekly emissions reports or source term summaries. Although the Team Leader wrote a memo to file, ENV-MAQ:04-382, which discussed the deficiency, the memo did not indicate "how" this occurrence is prevented in the future as a deficiency report does. The auditor recommends closing out this deficiency, i.e., date for completion 10/30/2004, and ensuring that the record center receives a copy.

10.0 DATA RESULTS

10.1 Noteworthy Practices

10.1.1 Analytical Data Validation and Verification Process

The sample-collection staff checks data received from Paragon Analytics, the analytical laboratory that analyzes stack samples collected on glass-fiber filters and charcoal cartridges. Using the validation and verification checklist produced by the RADAIR database, the staff ensures that data reporting includes all samples and that the quality-control results remain within the specified limits. The staff then validates and verifies at least 10% of the electronic copy results against the hard-copy results.

The detailed validation and verification checklist ensures a methodical review of the data. In fact, the checklist requires three levels of review, which ensures that no errors go undetected. The RADAIR quality-control reports provide excellent information that allows the staff to identify data trends and to follow-up on problem samples if further investigation is needed.

10.1.2 Annual Source Term Documentation

The Rad-NESHAP Team Leader maintains complete and easily auditable, 2003 source-term documentation. The documentation process allows the identification

of potential errors in the annual source term calculation before preparing reports. For example, while preparing the 2003 source-term documentation, the team leader recognized the lack of update of stack flow data for 2003. The Team Leader corrected the error and input the correct flow data before calculating annual doses.

The documentation includes a complete record of revisions to the source term enabling the reproduction of the source term, if necessary. The auditor recommends completing the process by preparing a formal procedure detailing how source-term documentation production and maintenance is accomplished.

10.2 Observations

10.2.1 Analytical Laboratory Duplicate Results

The auditor reviewed and compared the hard-copy analytical laboratory results, the RADAIR database report, and the procedure for performing duplicate analyses as a quality control measure. The Rad-NESHAP program uses the following three different metrics for duplicates (also called "replicates" in various documents):

- The analytical laboratory reports the duplicate error ratio (DER) and provides an acceptable range of values, although it is not clear how the ratio is calculated and who determined the acceptable range, the analytical lab or LANL.
- The RADAIR database reports the ratio of the original result to the repeated result but provides no acceptable range of values for staff reviewing the RADAIR reports.
- The Rad-NESHAP Quality Assurance Program Plan requires the calculation of the relative percent difference (RPD) (without explaining how) and stipulates that the RPD must be less than 10%.

The auditor observed that choosing one metric and using it exclusively to assess the quality of duplicates seems most useful. During discussions the Rad-NESHAP Team Leader suggested that the DER represents the most useful metric. If this is the metric chosen, then the QMP and the RADAIR database require an update to reflect the correct metric, its calculation method, and the acceptable ranges. In addition, the analytical lab's statement of work requires an update to specify the calculation method and acceptable ranges.

10.2.2 Trip Blanks

The auditor noted that although trip blanks are sent with glass-fiber filter samples (as required by procedure RRES-MAQ-109), trip blanks are neither required nor sent along with charcoal cartridge or ethylene glycol samples. Although the purpose of trip blanks is to identify transport-related contamination, they also

serve to identify contamination that occurs during storage. Charcoal can adsorb ambient gases during transport or storage. Although it is less likely, the possibility exists that ethylene glycol could also become contaminated during transport or storage. Ideally, the trip blank analysis occurs for each sample-collection medium to provide valuable information about sample integrity.

10.2.3 Sample Flow-Direction Markings

The auditor observed the sample-collection staff during sample change-outs and noted that at some locations, the air sample flow lacks clear marking at a location near the sample holder. Procedure MAQ-109 requires placement of glass-fiber filters with the fibrous side toward the vacuum source and alignment of the arrow on charcoal cartridges with the sample air flow. For these media, it is critical that the staff knows the sample air-flow direction in order to position collection media correctly.

Many sampling locations' exposure to the weather makes sample change-outs challenging. Although the sample-collection staff is knowledgeable about the systems and able to trace the expected air-flow direction, the process takes a deliberate effort under the best conditions. Under the worst, the likelihood increases that the field staff hurries, misjudges the air-flow direction, and installs a filter or cartridge backward. The potential for error reduces greatly by indelibly and clearly marking the direction of air flow at a location near the sample holder, thus increasing visibility to the person changing out a sample.

10.2.4 Laboratory Calibration Procedures and Frequency

The auditor requested copies of the analytical procedures used by both the on- and off-site laboratories to analyze samples. Although the Rad-NESHAP staff obtained the procedures, the procedures were not on file.

To meet the quality assurance requirements of 40 CFR 61, Method 114, the Rad-NESHAP program must describe the "laboratory analysis procedures used for each radionuclide measured, including frequency of analysis, ***calibration procedures and frequency of calibration***"(emphasis added). The Rad-NESHAP QAPP states that the analytical laboratory will maintain the frequency and supporting documentation for laboratory equipment. There is no evidence, however, that Rad-NESHAP project staff checked to ensure that the analytical procedures include information about calibration methods and frequency. The fact that the procedures are not on file with the Rad-NESHAP project suggests the lack of analytical procedure review for compliance with 40 CFR 61, Method 114.

10.2.5 Analytical Laboratory Audit

The auditor reviewed the final report, "LANL MAQ Assessment of Paragon Analytics Quality Program." The report documented a July 2004, visit by ENV division personnel to Paragon Analytics in Fort Collins, Colorado, to perform a two-day assessment of Paragon's quality program. Paragon Analytics analyzes stack and ambient air samples for the ENV division.

Paragon Analytics participates in the Department of Energy's Consolidated Audit Program (DOECAP), which is an organization that conducts audits of analytical laboratories contracted to perform services for DOE programs. DOECAP uses a formalized multi-checklist audit process with trained and qualified auditors to perform audit functions. These audit teams are composed of auditors from various contractor facilities across the DOE complex. There are approximately 33 laboratories certified by DOECAP, including Paragon Analytics.

DOECAP audits support the implementation of environmental management systems required to integrate into Integrated Safety Management Systems. DOECAP audits also satisfy the requirements of the following DOE Orders:

- DOE Order 414.1, Quality Assurance
- DOE Order 435.1, Radioactive Waste Management
- DOE Order 450.1, Environmental Protection Program

If the LANL Rad-NESHAP Program participated in DOECAP, LANL could improve the quality and consistency of data received from Paragon Analytics and reduce auditing costs. Other DOE labs find that participation in DOECAP allows sample-analysis management through contracted analytical laboratories without impact to schedule or mission, with greater confidence in analytical data's legal defensibility.

10.3 Findings

10.3.1 Response Factor for Tritiated Water Emissions

The auditor reviewed memo RRES-MAQ:04-089, "Change in Tritium Emissions Calculation Processes for 2003 and Beyond," from the Rad-NESHAP Team Leader to program staff. The memo states that for 2003 and subsequent years, emissions of tritiated water vapor must be corrected by the bubbler response (efficiency) factor, measured by periodic performance tests of the sampling system. The auditor also reviewed procedure RRES-MAQ-112, which discusses how tritium emissions are calculated.

The RADAIR database calculates emissions of tritiated water vapor using the response factor. Although the memo RRES-MAQ:04-089 was distributed in March 2004, the procedure RRES-MAQ-112 is not yet updated to reflect the new calculation method.

The auditor recommends that the ENV-MAQ Rad-NESHAP project update procedure MAQ-112 to require the use of a response or efficiency factor when calculating the activity of tritiated water emissions.

10.3.2 Efficiency Factor for Charcoal Cartridges

The auditor reviewed approved procedures for quantifying radioactive air emissions from sampled stacks. Recognizing that charcoal cartridges are not 100% efficient at adsorbing the gaseous radionuclides that pass through the cartridges, Rad-NESHAP staff applies an efficiency correction to the activity measured by the analytical laboratory.

Testing at LANL suggests that the efficiency ranges from 87% to 100%. Rad-NESHAP staff assumes that charcoal cartridges are even less efficient, but the documentation of the efficiency factor is conflicting. While procedure ESH-17-114 provides an efficiency factor of 75%, the Rad-NESHAP QAPP provides an efficiency factor of 65%. In practice, Rad-NESHAP staff uses the 65% value, which is more conservative and less likely to underestimate radionuclide quantities in air emissions.

The auditor recommends the update of procedure ESH-17-114 to standardize the efficiency factor at 65%.

10.3.3 Alpha/Beta Matrix Spikes

The auditor reviewed the statement of work (SOW-09) that governs the work performed by Paragon Analytics to analyze particulate samples collected on glass-fiber filters. The statement of work requires that for each group of glass-fiber filters, the analytical laboratory must spike a blank filter with known quantities of alpha and beta activity and report the results.

Paragon Analytics never prepared and reported such matrix spikes. The Rad-NESHAP staff discussed this subject with Paragon Analytics and in October 2004, thus eliminating the matrix-spike requirement.

The auditor recommends the update of SOW-09 to eliminate the requirement for analyzing matrix spikes and to include the requirement for laboratory control samples.

10.3.4 Department of Transportation Requirements

The auditor reviewed MAQ-109, the procedure documenting sample transport processes. The procedure states that Department of Transportation (DOT) regulations do not require special handling for material with a specific activity less than 2 nCi/g; however, the DOT regulations changed and the new quantities for determining whether a material requires special handling depends on the amount of radionuclide in the sample. Shipping personnel should be familiar with and

comply with the new regulations. The auditor recommends the update of MAQ-109 to incorporate the latest DOT regulations for shipping stack samples.

11.0 DESIGN RESULTS

11.1 Noteworthy Practices

11.1.1 Radioactive Material Usage Survey

This very detailed process provides extremely useful data. The process, although somewhat labor intensive, does provide an excellent avenue for MAQ personnel's continued contact with the facilities. The facilities generally welcome MAQ assistance, thus the relationship between MAQ and the facilities remains open and strengthened while maintaining compliance.

11.1.2 TA-55 Monitoring Upgrade Plan

After reviewing this plan and visually inspecting the site and drawings, the auditor concludes that the well thought out plan satisfies the monitoring needs of the facility. The plan does not require any extra monitoring or testing beyond the minimum to ensure regulatory compliance while balancing facility needs. The plan demonstrates a cost-effective approach in a difficult sampling environment.

11.1.3 In-house Design and Testing

This practice provides a consistent approach to sampling at the LANL. In-house design by MAQ personnel avoids the problems associated with one or more external organizations providing design engineers and testing personnel to perform design and testing in order to demonstrate compliance with a regulation for which the non-MAQ organization is not responsible. The current in-house approach provides similar sampling systems, procedures, and maintenance practices among LANL facilities.

11.2 Observations

Define Start of Construction in PR-ID Process

PHC-ID 18 addresses pre-construction activities and approvals for new or modified Rad-NESHAP sources. The guidance section identifies the requirement for a pre-construction approval prior to construction of the new source or modification. The PHC should include guidance on the regulatory definition of start of construction.

Subpart A of 40 CFR 61 prohibits construction or modification at any stationary source without obtaining written approval from the administrator [§61.05]. In fact, the subpart goes on to require application submission before commencement of the construction or modification [§61.07]. The key word in this phase is commenced. Commenced is defined, "… an owner or operator has undertaken continuous program of construction or modification or that an owner or operator has entered into a contractual obligation to

undertake and complete, within a reasonable time, continuous program of construction or modification" [§61.02]. EPA in other regions uses the contractual portion of this definition along with the definition of construction, "… fabrication, erection, or installation of an affected facility" [§61.02], and defines "start of construction" as either

- physical commencement of construction activities, or
- entering into a contract to procure any item used as part of the physical construction.

The EPA assumes that once one enters into a contract one commences construction or fabrication. The fabrication does not have to occur at the site, but can occur at the vendor location.

The auditor recommends that MAQ ensure that the understanding of "start of construction" matches that of the regulator and then document that in the PHC. (Please note that in Part 63 the definition of construction is limited to on-site activities.)

11.3 Findings

11.3.1 Method 114 Table 2 Inspections Not Formalized

The criteria of Table 2 of 40 CFR 61 Method 114 are a regulatory compliance requirement. To ensure that adequate documentation exists to demonstrate compliance with the inspection criteria exists, Rad-NESHAP needs to formalize the requirements. Procedures need modification to address routine requirements such as inspection of rotameters for foreign material at every sample change-out. Currently a work order and a letter to file that documents work performance deals with the visual inspection criteria compliance. ENV-MAQ Rad-NESHAP needs a procedure or other formal mechanism that addresses the visual inspection criteria. The auditor also suggests that the Rad-NESHAP team completes a formal report for each source that documents the compliance status of that emission point according to each criterion in Table 2. The auditor recommends that ENV-MAQ Rad-NESHAP peer review this report and make it available for future audits.

Although at this time LANL possesses no sources that must comply with ANSI N13.1 – 1999, there are similar inspection criteria in the ANSI standard. The procedure should address the ANSI criteria as well.

11.3.2 Visual Inspection of Nozzle External Surfaces

The Rad-NESHAP inspection team limited visual inspections to a borescope inspection of the internal surfaces of the probe, nozzles, and limited sections of the transport line. The team initiated probe cleaning for several sampling systems based on this information. The inspection worksheet asks if the nozzle inlets are smooth and free of burrs and debris. A visual inspection cannot totally answer this question. For a sharp-edged nozzle any debris on the external surface can

cause significant degradation of nozzle performance. Without an external inspection of the probe and nozzle, the inspection staff misses any debris or depositional buildup on the external surfaces of the nozzles, unless the debris occluded a portion of the nozzle opening. An internal inspection allows visibility of such an occlusion.

A visual internal inspection of the nozzles can find certain types of nozzle damage, such as damage that creates an irregular noncircular opening. Internal inspections cannot detect other types of damage, such as loss of the nozzle's sharp-edge.

The auditor recommends that the MAQ Rad-NESHAP project develop the methods and procedures to perform external inspections of the sampling nozzles and probes. MAQ should not base these methods on removing the probe, as damage to the nozzles can occur upon reinsertion of the probe. Other DOE facilities perform external surface inspection by inserting a camera into the stack.

12.0 RAC/J. TILL'S 2002 AUDIT FOLLOW-UP

The auditor reviewed the responses to the observations raised by RAC to ensure that

- the responses proved adequate to address the observations, and
- response implementation occurred per the MAQ commitment.

In all cases, the auditor deemed MAQ responses and proposed corrective actions adequate to address the observation. MAQ satisfactorily completed all corrective actions with due dates that occurred before the current audit date.

Submitted by Leader Auditor

E. Jeanne Hamilton 01/13/05

E. Jeanne Hamilton Date