U.S. Department of Energy
Office of River Protection
P.O. Box 450, MSIN H6-60
Richland, Washington 99352

SEP 2 2 2006

06-ESQ-045

Dr. J. G. Hwang, Project Manager
Advanced Technologies
and Laboratories International, Inc.
P.O. Box 250
Richland, Washington 99352

Dear Dr. Hwang:

CONTRACT NO. DE-AC27-05RV14548 – ASSESSMENT REPORT A-06-ESQ-ATL-001 – ADVANCED TECHNOLOGIES AND LABORABORIES INTERNATIONAL, INC. (ATL) QUALITY ASSURANCE (QA) PROGRAM REVIEW, APRIL 10 THROUGH 19, 2006

The U.S. Department of Energy (DOE), Office of River Protection assessed the ATL QA Program and its implementation during the period of April 10 through 19, 2006. The assessment reviewed the ATL QA Program to the requirements of DOE O 414.1C and 10 CFR 830, Subpart A, as described in ATL-MP-1002, "Quality Assurance Program Description (QAPD)."

The Team found that ATL had implemented its QA Program but had not effectively established and/or implemented all processes required by its QAPD. Processes identified as not fully meeting requirements (Finding A-06-ESQ-ATL-001-F01) included lessons learned, Suspect/Counterfeit Items, documents and records, graded approach, and control of nonconforming items. These process deficiencies were considered latent organization defects because the Team identified no instances where the deficiencies resulted in an unacceptable quality product. The Team noted the skill and training of the staff and limited need to use the processes significantly contributed to providing acceptable quality products. The Team also identified a large number of procedure errors (Finding A-06-ESQ-ATL-001-F02) none of which were safety significant but collectively suggest ATL should carefully examine its process for procedure review and validation. The Team also considered the procedure errors latent defects and error precursors. The Team found the ATL independent assessment program did not meet established requirements because it did not identify and schedule sufficient self-assessments to periodically evaluate the areas required by the QAPD.

The Team identified two Findings and two Observations. One Finding described quality processes that did not adequately implement requirements and the other identified a high number of errors in quality procedures. The Observations dealt with weaknesses in the ATL independent assessment process and deficiencies resulting from use of different versions of NQA-1 by ATL and CH2M HILL Hanford Group, Inc.

SEP 22 2006

Within 30 days of receipt of this letter, ATL should respond to the assessment Finding. The response should include:

- The cause of the Findings;
- The corrective steps that have been taken to control or remove any adverse impact to identified noncompliance situation(s) (remedial actions), and the results achieved;
- The corrective steps that will be taken to prevent similar Findings; and
- The date when all corrective actions are completed, verified, and compliance to applicable requirements is achieved.

If you have any questions, please contact me, or your staff may call Robert C. Barr, Director, Office of Environmental Safety and Quality, (509) 376-7851.

Sincerely,

Roy J. Schepens, Manager
Office of River Protection

ESQ:SAV

Attachment

cc w/attach:
H. L. Anastos, ATL
P. H. Bruce, ATL

Attachment
06-ESQ-045
A-06-ESQ-ATL-001

U.S. DEPARTMENT OF ENERGY
Office of River Protection
Environmental Safety and Quality

ASSESSMENT: Quality Assurance Program Review

REPORT: A-06-ESQ-ATL-001

FACILITY: Advanced Technologies and Laboratories International, Inc.

LOCATION: Hanford Site, 222-S Laboratory

DATES: April 10 through 19, 2006

ASSESSORS: Samuel A. Vega, Lead Assessor
Dennis Carson, Assessor
Tino Maciuca, Assessor

APPROVED BY: Patrick P. Carier, Team Lead
Verification and Confirmation

Executive Summary

The U.S. Department of Energy (DOE), Office of River Protection assessed the Advanced Technologies and Laboratories International, Inc. (ATL) Quality Assurance (QA) Program and its implementation during the period of April 10 through 19, 2006. The assessment reviewed the ATL QA Program to the requirements of DOE O 414.1C and 10 CFR 830, Subpart A, as described in ATL-MP-1002, "Quality Assurance Program Description (QAPD)."

The Team found that ATL had implemented its QA Program but had not effectively established and/or implemented all processes required by its QAPD. Processes identified as not fully meeting requirements (Finding A-06-ESQ-ATL-001-F01) included lessons learned, Suspect/Counterfeit Items, documents and records, graded approach, and control of nonconforming items. These process deficiencies were considered latent organization defects because the Team identified no instances where the deficiencies resulted in an unacceptable quality product. The Team noted the skill and training of the staff and limited need to use the processes significantly contributed to providing acceptable quality products. The Team also identified a large number of procedure errors (Finding A-06-ESQ-ATL-001-F02) none of which were safety significant but collectively suggest ATL should carefully examine its process for procedure review and validation. The Team also considered the procedure errors latent defects and error precursors. The Team found the ATL independent assessment program did not meet established requirements because it did not identify and schedule sufficient self-assessments to periodically evaluate the areas required by the QAPD.

The Team identified two Findings and two Observations. One Finding described quality processes that did not adequately implement requirements and the other identified a high number of errors in quality procedures. The Observations dealt with weaknesses in the ATL independent assessment process and deficiencies resulting from use of different versions of NQA-1 by ATL and CH2M HILL Hanford Group, Inc.

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List of Acronyms

AFI	Assessment Follow-Up Item
ATL	Advanced Technologies and Laboratories International, Inc.
CH2M HILL	CH2M HILL Hanford Group, Inc.
DOE	U.S. Department of Energy
IIF	Issue Identification Form
OIG	Office of Inspector General
ORP	Office of River Protection
QA	Quality Assurance
QAPD	Quality Assurance Program Description
S/CI	Suspect/Counterfeit Item

Advanced Technologies and Laboratories International, Inc. (ATL)

Quality Assurance (QA) Program Review

1.0 Details

This assessment evaluated the ATL QA Program and its implementation of requirements which were found in ATL-MP-1002, "Quality Assurance Program Description (QAPD)." The Team evaluated the following program elements found in the ATL QAPD: Personnel Training and Qualifications, Quality Improvement, Document and Records, Document Control, Records Management, Work Processes, Design, Procurement, Inspection and Acceptance Testing, Management Assessments, Independent Assessments, Suspect/Counterfeit Items, and Software Quality Assurance. The Team focused on assuring the requirements identified in the QAPD were adequately translated to implementing procedures and interfaces established between the operator, ATL, and the facility owner, CH2M HILL Hanford Group, Inc. (CH2M HILL) were adequate.

1.1 Personnel Training and Qualifications

The Team evaluated the personnel training and qualifications process for compliance with the requirements of ATL-MP-1002, "Quality Assurance Program Description." The Team reviewed implementing procedures and training records to verify adequate implementation of the process. Procedures reviewed included ATL-MP-1024, "ATL Training and Qualification Plan," ATL-MP-1025, "ATL Training Implementation Matrix," ATL-MP-1027, "Qualification Requirements for Analytical Field Work Supervisors," ATL-310-Section 5.7, "Procedure On-the-Job Training," ATL-312-Section 1.12, "Qualification of Assessment Personnel," and ATL-312-Section 5.01, "ATL Training Records, Scheduling, and Interfaces." Documents reviewed included training and qualification records, and electronic training completion records maintained in the Integrated Training Electronic Matrix for the following ATL positions: management and independent assessors, lead assessors, chemist, project coordinator, QA/Quality Control, manager, chemist technician, and field work supervisor.

The Team determined that the ATL personnel training and qualifications processes were adequate because the procedures associated with personnel training and qualifications met QAPD requirements, and the documentation examined indicated the procedures were implemented adequately. The Team found some procedure did not identify specific training requirements, as required by the QAPD. This is included in Finding A-06-ESQ-ATL-001-F02.

1.2 Quality Improvement

The Team evaluated the ATL quality improvement processes to assess compliance with the requirements of the ATL QAPD. The Team reviewed the following implementing procedures: ATL-312, Section 1.04, "ATL Corrective Action Management," ATL-312, Section 9.02, "ATL

Causal Analysis Process," ATL-312, Section 1.11, "ATL Corrective Action Data Analysis and trending," and ATL-312, Section 1.05, "Lessons Learned." The Team also interviewed ATL staff and reviewed related documentation of activities involving corrective action management, trending, and lessons learned to assess adequate process implementation.

The Team identified 15 instances where ATL-312 did not adequately implement QAPD requirements. The trending and lessons learned procedures did not adequately implement the requirements of the QAPD. These procedure deficiencies were captured in Finding A-06-ESQ-ATL-001-F02. This large number of deficiencies calls into question the ATL procedure approval and validation process.

With respect to process, the Team found ATL did not always perform "extent of condition determinations" when resolving deficiencies classified in NQA-1 as "conditions adverse to quality." This issue was captured in Finding A-06-ESQ-ATL-001-F01.

1.3 Document and Records

1.3.1 Document Control

The Team evaluated the document control process for compliance with the requirements of ATL-MP-1002, "Quality Assurance Program Description." The Team reviewed procedures and ATL management plans and processes for developing, issuing, revising, and controlling documents to verify adequate implementation. Procedures reviewed included ATL-MP-1016, "Interface Control Document between ATL and CH2M HILL," ATL-312, Section 1.41, Revision 0, "Review and Approval of ATL Documents," ATL-MP-1001, "Procedures Acceptable for Use by the ATL 222-S Analytical Production Contractor," ATL-MP-1005, "Technical records Management Plan," and ATL-312, Section 1.01, Administrative Procedure Control Process."

The Team concluded ATL-312, Section 1.41, Revision 0, "Review and Approval of ATL Documents," did not provide validation process for procedures furnished by CH2M HILL. This represents a latent organization weakness in that procedure furnished by a different organization may never be validated and found defective during first use. Section 2.4 of the ATL QAPD states: "The TFC Laboratory Support Services (LSS) organization will provide central management and control services for ASPC documents under an Interim Interface Management Plan signed by authorized representatives of both companies on May 16, 2005… The procedures governing document control processes are provided by the TFC and shall be reviewed by the ASPC to ensure adequacy for the ASPC work scope." The Team determined procedure ATL-312, Section 1.41 lacked a process necessary for receiving and validating CH2M HILL provided procedures; which would include the reviewing of procedures, providing comments, and resolving comments. Procedures ATL-312, Section 1.01, "Administrative Procedure Control Process," and Procedure ATL-312, Section 11.16, "Technical Procedure Control Process," provided some direction, but was incomplete. Procedures ATL-312, Section 1.01 referred to ATL-312, Section 1.41 as the source of the procedure validation process, but procedure ATL-312, Section 1.41 only provided attachments with tables indicating review

criteria with no substantial process or reference to the direction found in ATL-312, Section 1.01 and ATL-312, Section 11.16. The Team's review of related activities revealed there were activities performed by ATL that required interfacing with CH2M HILL, but interface activities were not addressed in ATL or CH2M HILL procedures. The interface was performed by ATL staff on an ad hoc basis. Good process knowledge of ATL staff performing these activities resulted in no notable deficiencies. This issue is documented in Finding A-06-ESQ-ATL-001-F01.

The Team identified the Management Plan ATL-MP-1001, "Procedures Acceptable for Use by the ATL 222-S Analytical Production Contractor" did not list some procedures being used (adopted) by ATL. This issue is addressed in Finding A-06-ESQ-ATL-001-F02.

1.3.2 Records Management

The Team evaluated the records management process for compliance with the requirements of ATL-MP-1002, "Quality Assurance Program Description." The Team reviewed procedures for controlling technical records, in-process documents, and maintaining the Records Inventory and Disposition Schedule. The Team interviewed ATL personnel responsible for records management, and reviewed several records to verify records were generated and maintained in accordance with procedures. The Team noted ATL performed records management in collaboration with CH2M HILL. CH2M HILL maintained and stored the procedures record files, facility training records, and analytical data packages ATL provided.

The Team identified one procedure and one process deficiencies associated with records management. The Team found ATL records were not maintained in fire rated cabinets, as required in the QAPD. The Team inspected the facilities where CH2M HILL maintained ATL records for long term storage and found the required had not been provided the CH2M HILL records custodian. This issue is identified in Finding A-06-ESQ-ATL-001-F01. The Team also noted there was no flow down of QAPD requirements for QA record authentication into ATL implementing procedures. This issue is addressed in Finding A-06-ESQ-ATL-001-F01.

1.4 Work Processes

The Team evaluated ATL work processes to assess compliance with requirements of ATL-MP-1002, "Quality Assurance Program Description." The Team reviewed procedures governing the ATL analytical project process flow and the interfaces between ATL and CH2M HILL. The Team found many daily interfaces and shared roles and responsibilities existed because ATL operations were embedded within the CH2M HILL 222-S Laboratory Complex. Activities were performed in accordance with documented, management-approved procedures and instructions that were developed to meet the applicable regulations, U.S. Department of Energy (DOE) Orders, technical standards, and client work instructions. The Team noted that workers and supervisors were held accountable to comply with their procedures.

The Team reviewed several analytical procedures and verified compliance with instrument calibration requirements. The Team determined the procedures contained adequately defined

processes that were properly implemented and controlled. The Team noted special processes defined in NQA-1-1989 were not part of the ATL work scope.

The Team noted identification and control of items for analytical work activities was CH2M HILL's responsibility and sample control, including chain-of-custody, was a shared function adequately integrated within the 222-S Laboratory work processes.

The Team identified no issues related to work processes associated with ATL's analytical work activities.

1.5 Design

ATL-MP-1002, Revision 4, "Advanced Technologies and Laboratories International, Inc. (ATL) Quality Assurance Program Description (QAPD)," Section 2.6 – Design, describes the requirements and responsibilities for planning, controlling, and verifying design activities. ATL developed this section to satisfy the requirements of 10 CFR 830.122, Criterion (f) and DOE O 414.1C, Attachment 2, Criterion 6. However, ATL's work scope does not include design activities. Interviews with responsible management indicated the design criteria had been included in the QAPD for possible future work scope. The Team reviewed the QAPD design requirements and found the QAPD adequately addressed the elements of NQA-1 for Design Control except for QAPD Section 2.6.2.2, Paragraph 2.c. This paragraph did not reflect NQA-1 requirements and should be removed. This deficiency is included in Finding A-06-ESQ-ATL-001-F02.

1.6 Procurement

The Team evaluated the procurement process to the requirements of ATL-MP-1002, "Quality Assurance Program Description." The Team reviewed implementing procedures and reviewed procurement records. Procedures reviewed included ATL-MP-1016, "Interface Control Document between ATL and CH2M HILL," ATS-310-Section 1.46, "Procurement of Analytical Technical Services Equipment," ATL-312-Section 1.16, "Procurement Process Interfaces," and LO-150-063, "Chemical Management." The Team examined documentation associated with four procurements.

The Team noted ATL procurements were limited to initiation of material requisitions through the Tank Farm Material Services System and receipt inspection of hazardous chemicals. CH2M HILL performed the procurement of items and services for ATL, as a government provided service. CH2M HILL used its own procurement processes when performing this service. The Team reviewed four material requisitions and associated documentation and found that the material requisitions were properly completed; including item description, flow down of quality requirements, and acceptance criteria.

The Team concluded the ATL implementation of procurement requirements was adequate. The Team noted improvement was needed in procedures controlling receipt inspection records to

ensure that these records were properly authenticated. There was no evidence of proper record authentication in the four requisitions reviewed. The issue of authentication of QA records is incorporated in Finding A-06-ESQ-ATL-001-F01. ATL initiated Issue Identification Form (IIF) ATL-2006-014 to change procedure LO-150-063, "Chemical Management," to add steps to the receipt inspection process and the receipt inspection record to ensure proper authentication is achieved.

1.7 Inspection and Acceptance Testing

The Team evaluated the inspection and acceptance testing processes for compliance with the requirements of the ATL-MP-1002, "Quality Assurance Program Description." Procedures reviewed included: ATS-310-Section 1.46, "Procurement of Analytical Technical Services Equipment," ATS-310-Section 3.18, "Instrument Calibration," ATL-312-Section 1.04, "Corrective Action Management," ATL-312-Section 1.16, "Procurement Process Interfaces," ATL-312-Section 9.03, "ATL Control of Nonconformances," LO-140-008, "Routine Use and Quality Assurance for Analytical Balances at 222-S Laboratory Complex," LO-150-063, "Chemical Management," LO-190-101, "222-S Laboratory Sample Receiving and Custodianship," LO-190-102, "222-S/222-SA ABCASH and Surveillance Technologist Sample Receiving and Custodianship," and "Organization Charts for 222-S Laboratory Analytical Services and Testing."

The Team assessed only receipt inspection of chemicals, as there was no activity performed related to inspection and acceptance testing. The Team concluded that ATL had procedures in place that implement the requirements of the QAPD with the exception of control of nonconforming items. ATL did not have a process in place that adequately implemented the requirements to ensure the proper identification, control, and resolution of nonconforming items.

Procedure ATL-312, Section 9.03, "Control of Nonconforming Items," did not provide a process that met the criteria in QAPD, Section 2.3.1.3. The procedure scope indicated: "The items, materials and equipment that the Analytical Services Production Contractor (ASPC) handles are not intended to be installed in a nuclear facility and the typical report with justifications for dispositions such as 'repair,' 'use-as-is,' and 're-work' are not applicable to work performed by the ASPC. The potential for procured items, samples, equipment, and data to be nonconforming to requirements is, however, possible. Controls for nonconforming procured items, samples, equipment and data, are described in other procedures. This procedure will provide direction to those procedures." The resolution of nonconformances was anticipated and the resolution addressed in individual procedures that focus only on correcting the discrepancy (usually involve nonconformance samples, data, or equipment calibration). The Team identified one nonconformance related to a gas standard (an Item) that was not an anticipated nonconformance addressed in ATL procedures. This deficiency was documented in an IIF. The resolution of the IIF was not completed at the time of the assessment, but a review of work already done and discussions with individuals involved did not indicate QAPD requirements for nonconforming items would be satisfied. ATL's approach did not provide a process for addressing nonconforming items that meets QAPD requirements.

Related work was based on the Contractor's employee process knowledge of CH2M HILL procedures, but that work was not always adequate. ATL had documented deficiencies related to the inadequate control of nonconforming chemicals prior to this DOE Office of River Protection (ORP) assessment. This issue is captured in Finding A-06-ESQ-ATL-001-F01.

1.8 Management Assessments

The Team evaluated the ATL management assessment process to assess compliance with the requirements of ATL-MP-1002, "Quality Assurance Program Description." The Team reviewed the following implementing procedures: ATL-312, Section 1.14, "Performance of Management Assessments," and ATL-312, Section 1.12, "Qualification of Assessment Personnel." The Team interviewed responsible ATL staff and reviewed the assessment schedule, management assessment reports, Issue Identification Reports, and training records to assess adequate implementation of the process.

The Team noted ATL had conducted a management assessment to assess QA requirement implementation in March 2006. The ATL assessment identified deficiencies with the Suspect/Counterfeit Item (S/CI) process, the maintenance of training records, records management, and the control of nonconforming items. ATL staff wrote IIFs to capture these deficiencies. The Team noted ATL was in the process of correcting these deficiencies at the time of this assessment. The DOE ORP will track completion of these corrective actions as an Assessment Follow-up Item (AFI) and verify corrective action completion.

The Team concluded ATL had implemented the management assessment process in accordance with the aforementioned procedures. ATL had scheduled and performed Management Assessments; these assessments were conducted by trained personnel; assessments were conducted and documented per the procedures; and issues were adequately documented in the contractor's corrective action management process.

The Team identified a deficiency in procedure ATL-312, Section 1.14. The procedure did not capture the QAPD requirement for managers to perform regular management assessments of the QA program elements they were responsible to implement. This issue is contained in Finding A-06-ESQ-ATL-001-F02.

1.9 Independent Assessments

The Team evaluated the ATL independent assessment process to assess compliance with the requirements of ATL-MP-1002, "Quality Assurance Program Description." The Team reviewed the following implementing procedures: ATL-312, Section 1.13, Revision 0, "Performance of Independent Assessments," and ATL-312, Section 1.12, "Qualification of Assessment Personnel,"ATL-312, Section 1.06. The Team interviewed responsible ATL staff and reviewed the assessment schedule. At the time of this assessment, ATL has performed no independent assessments.

The Team concluded the independent assessment procedures adequately implemented QAPD requirements. The Team identified procedures deficiencies that required correction. These deficiencies are captured in Finding A-06-ESQ-ATL-001-F02.

Because ATL had not scheduled any independent assessment for the year, the Team concluded ATL had not effectively implemented an independent assessment program to assure proper independent oversight of QA and other Integrated Safety Management System related program requirements. The Team noted the following weaknesses: ATL had not performed any independent assessments; ATL had not scheduled or performed any assessments of the services provided by CH2M HILL; and ATL had not established a planning process for assuring assessment activities were scheduled or conducted in a manner and frequency commensurate with the importance and complexity of ATL work activities. This issue is included in Finding A-06-ESQ-ATL-001-F02.

1.10 Suspect/Counterfeit Items

The Team evaluated the ATL S/CI process to assess compliance with the requirements of ATL-MP-1002, "Quality Assurance Program Description." The Team reviewed implementing procedure ATL-312, Section 1.06, "Suspect/Counterfeit Control," interviewed responsible ATL staff and reviewed process documents.

The Team found ATL had not effectively implemented the S/CI process required by QAPD, Section 2.11 requirements. The QAPD stated: "Work control processes shall be developed using the DOE Guide G 414.1-3, Suspect/Counterfeit Items Guide for Use with Requirements of 10 CFR 830 Subpart A; Quality Assurance Requirements, and DOE O 414.C, Quality Assurance." The procedure did not fully address the processes prescribed in the mentioned guide (which is evoked in DOE O 414.1C). For example, the procedure did not fully capture the evaluation of potential S/CI, the methods of identifying or segregating S/CI, the allowable limited use of S/CI, or how to contact and the Office of Inspector General (OIG) and what minimum information is required to be communicated to the OIG. The procedure did not identify specific training requirements; the procedure merely stated training would be provided. The Team found that the S/CI Coordinator was not aware of and had not read the guide discussed in the QAPD. This issue is captured in Finding A-06-ESQ-ATL-001-F01.

1.11 Software Quality Assurance

The Team evaluated the ATL software QA processes to assess compliance with the requirements of ATL-MP-1002, "Quality Assurance Program Description." The Team reviewed relevant documentation, interviewed key personnel responsible for the maintenance, control, and operation of software, assessed activities for computer use and software verification, and reviewed spreadsheet software used to evaluate analytical data.

The Team found ATL used computer software to perform quality-affecting activities such as control of analytical measurement equipment and calculation of analytical results from raw data. Much of this software was provided by CH2M HILL as a government-furnished service. This

resulted in the need for a limited software QA program where the only software life cycle phases that applied to ATL was installation and operation. The ATL scope of work did not include the procurement, development, or use of safety software. The Team reviewed spreadsheet software used to evaluate analytical data.

The Team concluded Software QA processes were adequately described in ATL procedures. The Team also concluded implementation of software QA process procedures was adequate because software was properly installed, tested, and maintained. The Team did note that the ATL QAPD, Section 2.13, described CH2M HILL's computer software processes, and not processes applied by ATL. Additionally, Section 2.6.2 of the ATL QAPD incorrectly indicated that operation is the only applicable software life cycle phase. This issue is captured in assessment Finding A-06-ESQ-ATL-001-F02.

2.0 Findings and Observations

Finding: A-06-ESQ-ATL-001-F01 - Processes were not compliant with ATL QAPD requirements

ATL-MP-1002, Revision 4, "Quality Assurance Program Description," Section 2.5.2., stated: "ATL regards all work as a process. Each work process consists of a series of actions planned and carried out by qualified workers using specified work steps… Procedures, work instructions, or other documents with scope and detail commensurate with the importance, complexity of the work, and hazards associated with the work are used to implement work processes."

The Team identified several QA processes that were not adequately established within the Contractor's procedures, and/or were not implemented adequately. These included the following:

- Lessons Learned (ATL-312, Section 1.05) – This procedure did not implement QAPD, Section 2.1.2.3, Item 3, which stated: "A lessons learned program shall be adopted or developed that facilitates promulgation of good practices learned from experience and for precluding repetition of undesirable events. The program shall provide for identification and documentation of lessons learned, and for dissemination of lessons learned information to ASPC organizations for their use, as applicable, in improving system quality."

  The procedure did not provide "specified work steps" for the identification and documentation of lessons learned and for dissemination and use of lessons learned information. The procedure did not clearly indicate what type information constituted a lessons learned, the sources for potential lessons learned, how to submit potential lessons learned, and what to do with lessons learned information when received. The procedure did not provide administrative direction for documenting the receipt, review, and distribution of lessons learned information;

- S/CI (ATL-312, Section 1.06) - The ATL S/CI process did not adequately implement QAPD, Section 2.11 requirements. The QAPD stated: "Work control processes shall be developed using the DOE Guide G 414.1-3, Suspect/Counterfeit Items Guide for Use with

Requirements of 10 CFR 830 Subpart A; Quality Assurance Requirements, and DOE O 414.C, Quality Assurance."

The procedure did not fully address the processes prescribed in the mentioned guide (which is evoked in DOE O 414.1C). For example, the procedure does not fully capture the evaluation of potential S/CI, the methods of identifying or segregating S/CI, the allowable limited use of S/CI, or how to contact the OIG and what minimum information is required to be communicated to the OIG. The procedure did not identify specific training requirements. The procedure stated: "training will be provided." Through interview, the Team noted that the S/CI Coordinator was not aware and had not read the guide discussed in the QAPD;

- ATL-312, Section 1.41, "Review and Approval of ATL Documents," did not adequately implement QAPD Section 2.4, which states: "The TFC Laboratory Support Services (LSS) organization will provide central management and control services for ASPC documents under an Interim Interface Management Plan signed by authorized representatives of both companies on May 16, 2005… The procedures governing document control processes are provided by the TFC and shall be reviewed by the ASPC to ensure adequacy for the ASPC work scope."

  Procedure ATL-312, Section 1.41, "Review and Approval of ATL Documents," lacked a process for receiving and validating CH2M HILL provided procedures; which would include the reviewing of procedures, providing comments, and resolving comments;

- QAPD, Section 2.4.2.2, establishes QA record storage requirements with respect to fire rating of cabinets, which ATL was not implementing.

  Fire rated cabinets required by the ATL QAPD were not used by the CH2M HILL Records Custodian. This deficiency resulted from both companies operating to different versions of NQA-1 which apply different criteria for assuring the safety of records;

- ATL-312, Section 9.03, "Control of Nonconforming Items" - Did not provide a process that met the criteria in QAPD, Section 2.3.1.3. ATL-312 states: "The items, materials and equipment that the Analytical Services Production Contractor (ASPC) handles are not intended to be installed in a nuclear facility and the typical report with justifications for dispositions such as 'repair,' 'use-as-is,' and 're-work' are not applicable to work performed by the ASPC. The potential for procured items, samples, equipment, and data to be nonconforming to requirements is, however, possible. Controls for nonconforming procured items, samples, equipment and data, are described in other procedures. This procedure will provide direction to those procedures." The resolution of nonconformances was anticipated and the resolution addressed in individual procedures that focus only on correcting the discrepancy (usually involve nonconformance samples, data, or equipment calibration).

  The Team identified one nonconformance related to a gas standard (an Item) that was not anticipated in ATL procedures. This deficiency was documented in an IIF. The resolution of the IIF had not been completed at the time of the assessment, but a review of the work that

was completed, and discussions with individuals involved did not indicate QAPD requirements for nonconforming items would be satisfied;

- ATL-312, Section 1.04 requires assessing the extent of condition for conditions adverse to quality, which implements the QAPD Section 2.3 requirement.

  The Team found that resolution of Issue Identification Reports for conditions adverse to quality did not require extent of condition reviews. The Team identified a number of IIFs that had not extent of condition reviews performed;

- QAPD, Section 2.4 states: "Records shall be authenticated, as required. This may include a dated handwritten signature or initials, a stamp or other control means to ensure that only authorized personnel authenticate records."

  The Team identified several record types that were not authenticated. This requirement was not captured in the ATL procedures governing the handling and control of records; and

- QAPD, Section 2.10, did not implement an independent assessment program adequately.

The Team found an inadequate number of assessments had been scheduled, current and past, to assure adequate coverage of program activities. Just two assessments had been scheduled for 2006.

Finding: A-06-ESQ-ATL-001-F02 - Procedure Deficiencies

Errors were identified in the QAPD and QA procedures did not capture QA requirements specified in the ATL QAPD. The following list these errors:

- ATL-MP-1002, Revision 4, "Advanced Technologies and Laboratories International, Inc. (ATL) Quality Assurance Program Description (QAPD)," Section 2.6 – Design; Captured NQA-1-1989 design requirements incorrectly. [ATL does not perform design, therefore, should consider removing design requirements from the QAPD.]

- ATL QAPD, Figure 1, "Organizational Structure of Analytical Services Production Contractor." The organization chart did not provide evidence of independent reporting of the QA Manager to the Program Manager. [Section 1.1, Paragraph 3 stated the quality manager reported directly to the project manager. Section 2.1.2.1, Item 3 stated the quality assurance manager reported directly to the program manager. This is not consistent.]

- ATL QAPD, Section 2.3.2, "Implementing Responsibilities," in 2.3.2.3 referred to "Quality Management" which is a function and not a position. This term should be replaced with "Quality Assurance Manager."

- QAPD Section 2.6.2.2, Paragraph 2.c. was not based on any NQA-1 requirement and should be removed.

- The ATL QAPD, Section 2.8.2.3, "Inspection Requirements," Item 5, included an inspection type called "In-Service Inspection." This type inspection is not an acceptable NQA-1 method and should be removed.

- The ATL QAPD, Section 2.13 described a process appropriate for CH2M HILL's computer software control activities, but not necessarily appropriate for ATL to control the acquisition, development, operation, maintenance, and retirement of computer software purchased and controlled by ATL.

- The ATL QAPD, Section 1.2.2 was inconsistent in that it stated the 222-S laboratory was a Category III Nuclear Facility, but Item 2 in the same section referred to complying with "Enforcement of 10 CFR 830.120 (Quality Assurance Rule) for Facilities Below Hazard Category III."

- ATL-312, Section 1.04, Revision 2, "ATL Corrective Action Management," was inconsistent with QAPD requirements:

  a. Section 5.1.1, fifth bullet referred to Nonconformance item reports, but ATL had no process in place that issued such a report.
  b. Section 5.1.4 and 5.2 did not require a justification be documented when an IIF was invalidated or screened out.
  c. Section 5.2, the entire section was unclear and the assessor could not determine what needed to be done as a result of Section 5.2.
  d. Section 5.3, Item 1 required a statement of expected actions be provided for performance improvements documented on an IIF, but the procedure did not indicate where this statement was documented and what information was required to be included (the actionee's name, completion date, etc.).
  e. Section 5.3, Item 3, required submittal of issues to the "Performance Enhancement Team," but did not indicate how the submittal was done and what the team was suppose to do with the submittal.
  f. Section 5.3, Item 5 did not require a determination of remedial actions.
  g. The IIF forms did not require recording the extent of condition, the causes (root or apparent, direct, and contributing), results of closure verification, or a signature and date when the issue was closed to validate the QA record.
  h. The procedure did not require corrective action completion verification for significant conditions adverse to quality.
  i. Section 5, Item 3 indicated the root cause analysis trained individual assigned to the causal analysis team was to function as a facilitator. A trained individual should lead the team.
  j. Section 5.5 did not require the determination of extent of condition for significant issues. The procedure also did not provide direction on what to do if the extent of condition review identified similar conditions elsewhere.
  k. Section 5.5.3 had several "should" statements that need to be changed to "shall."
  l. Section 5.5.3 needs a forth item that indicates corrective actions are entered into the Action tracking form.

m. Section 5.5.4 was missing a step directing the Corrective Action Program Manager to sign the IIF.
n. Section 7.0 was inadequate because it did not indicate the specific records generated from this process.
o. Definitions provided for "Corrective action," and "Resolution Required," were incorrect and need to be replaced with definitions consistent with NQA-1.

- ATL-312, Section 9.02, Revision 0, "ATL Casual Analysis Process;"
  a. Contained a philosophy regarding the relationship between causes (root cause, direct cause, and contributing causes) and corrective actions that does not conform with DOE O 414.C.
  b. The Training Section did not identify who was required to be trained.

- ATL-312, Section 1.11, Revision 0, "ATL Corrective Action Data Analysis and Trending;" Several deficiencies were noted that need correcting:
  a. Section 4.1 was missing the title of one of the referenced procedure.
  b. 4.3.2, Item c. indicated actions to address adverse trend data could be elicited, but did not indicate how and what conditions warrant it.
  c. Section 4.5 indicated all IIF generated as a result of adverse trends were to be designated as Significant. One trend IIF was issued since the procedure was initiated, and it was not designated as significant.
  d. The process was lacking the establishment and reporting of performance indicators.
  e. Attachment A, the section on programmatic deficiencies (Item 3) indicated reporting was needed, but the procedure did not indicate how and where, or to who.

- ATL-312, Section 1.12, Revision 0, Qualification of Assessment Personnel;"
  a. Qualification of Lead Assessors was missing training requirements (see NQA-1 Supplement 2S-3, Section 3.2).
  b. Qualification of Lead Assessors was missing the requirement to participate in five QA assessments (one nuclear) within three years.
  c. Qualification of Lead Assessors was missing the requirement to administer a qualification examination.
  d. Qualification of Lead Assessors did not clearly indicate that qualification was to be assessed annually and documented.

- ATL-312, Section 1.14, Revision 0, "Performance of Management Assessments" did not capture the QAPD, Section 2.9.2.1, Item 5, requirement to regularly assess the adequacy of the QA program.

- ATL-MP-1001, "Procedures Acceptable for Use by the ATL 222-S Analytical Production Contractor," Appendix A, identified documents maintained by other Hanford contractors and implemented by ATL. The assessor noted instances where ATL procedure referenced other contractor procedures used by ATL that were not listed in the Appendix A (example: HNF-PRO procedures indicated in ATL-312, Section 1.01 as being requirements documents).

Observation: ATL QA staff was not sufficiently independent to conduct independent assessments

The Team found the QA staff was involved substantially in program development, procedure writing, and in coaching other contractor staff on process development. The Team was concerned this level of involvement in these type activities would not allow the QA staff to have the independence and objectivity required by the QAPD to perform independent assessments. The only qualified assessor was a member of the QA staff. Discussions with the Contractor indicated they were aware of this potential problem, and indicated they were considering bringing in outside contractors to perform independent assessments.

Observation: Disconnect between the ATL application of NQA-1-1989 and the CH2M HILL implementation of NQA-1-2000

The Team identified one case where disconnects existed between ATL requirements and the CH2M HILL provided services. This resulted in discrepancies with the storage of QA records where the ATL QAPD required the use of 1- and 2-hour fire rated cabinets, but the CH2M HILL QAPD did not have that same requirement and CH2M HILL was not using fire rated cabinets. The Team determined this disconnect resulted because ATL used NQA-1-1989 as its implementing standard and CH2M HILL used NQA-1-2000. The Team felt theses two revisions of NQA-1 were sufficiently different in their specified rigor and approach that it was possible that more than the one noted case existed where CH2M HILL provided services did not comply with ATL QAPD requirements. ATL had not verified CH2M HILL procedures met ATL requirements, or had conducted any oversight of CH2M HILL provided services. The Team considered this an Observation because ATL had previously committed to ORP to implement NQA-1-2000 by the end of Fiscal Year 2006.

3.0 Conclusion

The Team found while ATL had implemented its QA Program it had not effectively established and/or implemented all processes required by its QAPD. The Team identified requirements missing from some procedures and some procedures that lacked detail to assure consistent performance of quality activities. Processes identified as inadequate included lessons learned, S/CI, documents and records, graded approach, and control of nonconforming items. The Team also concluded the ATL independent assessment program did not meet established requirements. No one of the procedure deficiencies by itself reached the threshold of a Finding; however, due to the large number of procedure deficiencies a Finding was issued. The Findings suggests ATL should carefully examine its procedure review and validation process to understand why these deficiencies were not identified before this assessment.

4.0 Items Opened, Closed, and Discussed

Opened

A-06-ESQ-ATL-001-F01: Finding	Several ATL processes were not in compliance with QAPD requirements.
A-06-ESQ-ATL-001-F02: Finding	Procedure deficiencies were noted.
A-06-ESQ-ATL-001-A01: AFI	Perform Closure Verification and effectiveness review of corrective actions for ATL Management Assessment 5 conducted March 2006.

Closed

None.

Signatures

Samuel Vega,
Assessment Team Leader

ASSESSMENT NOTE

Assessment Note Number: A-06-ESQ-ATL-001-01

Assessor Name: Samuel Vega

Date of Assessment: April 10-19, 2006

Item Assessed: Quality improvement, Management Assessments, Independent Assessments, and Suspect/Counterfeit Items

The assessor reviewed the Contractor's procedures for compliance to the "Quality Assurance Program Description," ATL-MP-1002, Rev. 4. The assessor reviewed assessment reports, Issue Identification Forms (IIRs), training records, and other relevant records associated with Quality improvement, Management Assessments, Independent Assessments, and Suspect/Counterfeit Items. The assessor also interviewed ATL staff and management about responsibilities and activities performed in relation to assessed activities. From these activities, the assessor was able to assess the effectiveness of program implementation.

Documents Reviewed

- 222-S Laboratory Analytical Services and testing organization Chart
- ATL-MP-1002, Rev. 4, "Quality Assurance Program Description"
- ATL-MP-1020, Rev. 0, "Assessment Program Plan"
- ATL-MP-1016, rev.2, "Interface Control Document Between ATL and CH2M HILL
- ATL-MP-1015, Rev. 0, "Quality Assurance Implementation Matrix"
- ATL-MP-1001, Rev. 6, "Procedure Acceptable for Use by the ATL 222-S Analytical Services Production Contractor"
- TFC-ENG-DEIGN-P-26, rev. B-6, "Determination of Equipment Safety Classification and Quality Assurance Levels"
- Causal Analysis Tree, Rev. 0) (DOE G 231.1-2)
- ATL-312, Section 1.04, Rev. 2, "ATL Corrective Action management"
- ATL-312, Section 9.02, Rev. 0, "ATL Causal Analysis Process"
- ATL-312, Section 1.11, Rev. 0, "ATL Corrective Action Data Analysis and trending"
- ATL-312, Section 1.12, Rev. 0, "Qualification of Assessment Personnel"
- ATL-312, Section 1.05, Rev. 0, "Lessons Learned"
- ATL-312, Section 1.13, Rev. 0, "Performance of Independent Assessments"
- ATL-312, Section 1.14, "Performance of Management Assessments"
- ATL-312, Section 9.03, "ATL Control of Nonconformances"

- ATL-312, Section 8.01, Rev. 0, “Graded Application of Quality Assurance”
- ATL-312, Section 1.06, Rev. 1, “Suspect/Counterfeit Control”
- ATL-312, Section 1.41, Rev. 1, “Review and Approval of ATL Documents”
- ATL-312, Section 1.01, Rev. 0, “Administrative Procedure Control Process
- Issue Identification Form, ATL-2006-065
- Issue Identification Form, ATL-2006-067
- Issue Identification Form, ATL-2006-068
- Issue Identification Form, ATL-2006-069
- Issue Identification Form, ATL-2006-070
- Issue Identification Form, ATL-2006-075
- Issue Identification Form, ATL-2006-0002
- Issue Identification Form, ATL-2006-004
- Issue Identification Form, ATL-2006-020
- Issue Identification Form, ATL-2005-008
- Issue Identification Form, ATL-2005-010
- Issue Identification Form, ATL-2005-030
- Issue Identification Form, ATL-2005-031
- Issue Identification Form, ATL-2005-036
- Issue Identification Form, ATL-2005-037
- Issue Identification Form, ATL-2005-038
- Issue Identification Form, ATL-2005-039
- Issue Identification Form, ATL-2005-040
- Issue Identification Form, ATL-2005-043
- Issue Identification Form, ATL-2005-046
- Issue Identification Form, ATL-2005-050
- Issue Identification Form, ATL-2005-075
- Issue Identification Form, ATL-2005-076
- Action Tracking Form ATL-2006-038
- Action Tracking Form ATL-2006-039
- Action Tracking Form ATL-2006-040
- Action Tracking Form ATL-2006-043
- Action Tracking Form ATL-2006-059
- Action Tracking Form ATL-2006-075
- Action Tracking Form ATL-2006-002
- Action Tracking Form ATL-2006-004
- Action Tracking Form ATL-2006-020
- Action Tracking Form ATL-2006-030
- Action Tracking Form ATL-2006-031
- Document/Issue Tracking Form ATL-2006-062
- Action Tracking Form ATL-2006-036
- Action Tracking Form ATL-2006-037
- Action Tracking Form ATL-2006-038
- Action Tracking Form ATL-2006-046
- Action Tracking Form ATL-2006-050

- Action Tracking Form ATL-2006-075
- Action Tracking Form ATL-2006-076
- Letter Number 05-ATL-049, 'Contract No. DE-AC27-05RV14548 – Quality Assurance program Plan Under the analytical Services Production Contract"
- Letter 05-ATL-102, "Audit of Advanced technologies and Laboratories International, Inc. Quality Program at Richland, Washington"
- Management Assessment 6, "Integrated Environmental, Safety and Health Management System Implementation
- ATL Lead Assessor Qualification Record
- Required Reading List, "Lessons Learned: Flash Fire in Building 773-A"
- Lessons Learned 2006-SR-WSRC-0002, "Flash Fire in Building 773-A – DOE type B investigation Initiated"
- Required reading List, "2408 Working Safely With Acids'
- Lessons Learned Report, 08/15/05, "Working Safe With Acids"
- Required Reading List, "Caution Bulletin – Finger Injury While Checking Air Lock Door Switch"
- PHMC Lessons Learned 2006-RL-HNF-0010, "Finger Injury While Checking Air Lock Door Switch"
- Implementation Plan, "Areas Identified a Non-Implemented in Audit FH-AVS-05-17," 1/23/06
- FY2006 ATL Assessment Schedule

Observations and Assessments:

The assessment resulted in two findings that captured common problems with several of the QA program elements assessed. The findings in this assessment note are a consolidation of the deficiencies identified during this entire assessment.

A-06-ESQ-ATL-001-F01: Several ATL processes were not in compliance with QAPD requirements due to inadequate procedures, and/or inadequate implementation of processes

Requirements:

ATL-MP-1002, Rev. 4, "Quality Assurance program Description," Section 2.5.2.1 states:

> "All Activities that can affect the quality, safety, or environment of ASPC product and services shall be prescribed by and performed in accordance with documented, management approved procedures and instructions that meet the requirements of applicable regulations, DOE orders, technical standards, administrative controls, and client work instructions."

ATL-MP-1002, Rev. 4, "Quality Assurance program Description," Section 2.5.2. states:

> "ATL regards all work as a process… Procedures, work instructions, or other documents with scope and detail commensurate with the importance, complexity of the work, and hazards associated with the work are used to implement work processes."

ATL-MP-1009, Rev. 0, "Integrated Environmental, Safety, and Health Management System Description for the 222-S Analytical Services Production Contractor," Section 11, states in part:

> "ASPC personnel are responsible/accountable for the performance of work within the established controls, and the safety controls are a discernible part of ASPC procedures, plans, and work packages."

Discussion:

The QAPD requires all work is to be conducted per approved procedures, work instructions, or other documentation commensurate with the importance, complexity, and hazards associated with the work. The assessors identified several QA processes that were not adequately established within the Contractor's procedures, and/or were not adequately implemented. Process inadequacies included the following:

- ATL did not comply with QAPD, Section 2.1.2.3, Lessons Learned requirements because the established process was incomplete and lacked sufficient detail to adequately perform required activities. The work performed was ad hoc, not part of the formal process, but the assessors found it to be adequate. This was due to the process knowledge of the individual performing the activity, but much of the activity was not adequately documented. Specific process deficiencies included:

    1. The procedure lacked sufficient detail for someone to adequately performing the activity consistently

    2. The procedure did not identify sources of information required to be reviewed for lessons learned applicability

    3. The procedure did not require a record be maintained lessons learned information reviewed; what was looked at and the final disposition

    4. A record of any actions taken as a result of a lessons learned was not maintained or required

    5. The process did not provide sufficient instruction on what to do if action was required to address a lesson learned bulletin

6. The process did not provide direction on what to do with a lessons learned bulletin distributed to individuals who receive lessons learned information to review

7. the process did not require entering ATL LL into DOE system or distributing lessons learned information to other site contractors

- The ATL Suspect/Counterfeit Item process was inadequate and did not meet QAPD, Section 2.11 requirements.

  1. The procedure lacked sufficient detail to implement, the implementation of the process was inadequate

  2. the procedure did not comply with the QAPD or with DOE Guide 440.1-6, "Implementation Guide for use with Suspect/Counterfeit Items Requirements of DOE O 440.1, Worker Protection Management; 10 CFR 830.120; and DOE 5700.6C, Quality Assurance"

- ATL had not established a process for applying a Graded Approach that meets QAPD, Section 2.1.2.3 requirements; the procedure did not provide a process that can be implemented

- ATL failed to provide a process for procedure validation activities that satisfies QAPD, Section 2.4 requirements. Procedure, ATL-312, Section 1.41, "Review and Approval of ATL Documents," lacked a process for interfacing with the CH2M HILL document control provided service. Work performed was adequate, but was based on the ATL and CH2M HILL Contractor employees' process knowledge, and on ATL-312, Section 1.01 and ATL-312, Section 11.16 procedures which provided incomplete direction.

- Storage requirements for QA records did not meet QAPD, Section 2.4.2.2. Fire rated cabinets required by the ATL QAPD were not used by the CH2M HILL Records Custodian.

- The resolution of Issue Identification Form did not include assessing the extent of condition for conditions adverse to quality as required in ATL implementing procedures. This applied to the majority of the IFFs reviewed classified as "Resolution Required."

- QAPD, Section 2.4 requirements for records authentication were not met for some QA records, and the requirement to authenticate QA records was not captured in ATL procedures. Two examples were identified:

  1. Corrective action management process records (Issue Identification Form, Action tracking Form, and Action tracking/Issue Review Request)

2. Receipt inspection documentation

- The ATL Process for Control of Nonconforming Items (NCR) was inadequate and did not meet QAPD, Section 2.3.1.3 requirements. The NCR procedure did not contain sufficient detail to assure issues with nonconforming items will be adequately and consistently addressed. Work performed was ad hoc and not always adequate.

- The ATL independent assessment program was not been implemented as required by the QAPD, Section 10.2; only two assessments had been scheduled, insufficiently trained staff, an inadequate amount of assessment had been schedule, and lack of assessment planning.

A-06-ESQ-ATL-001-F02: Procedure deficiencies were noted

The assessors noted seven key QA process procedures inadequately capture QA requirements specified in the QAPD. The assessors determined the deficiencies noted in this finding were minor due to the fact that they had not adversely impacted any work performed. This was because these procedures had only been in place for five months or less, and the work activities related to the deficiencies had not been encountered, or the activity was done correctly because of the process knowledge of the individuals performing the activities. Specific procedure deficiencies include:

1. ATL-MP-1002, Rev. 4, "Advanced Technologies and Laboratories International, Inc. (ATL) Quality Assurance Program Description (QAPD)," Section 2.6 – Design; Captured NQA-1-1989 design requirements (some incorrectly), but ATL work scope did not include any design work; Design was N/A for ATL and the requirements should be removed from the QAPD.
2. The ATL QAPD, Section 2.4 "Documents and Records", Subsection 2.4.2.2, paragraph 13 contained requirements for long term storage of records, but ATL work scope did not require any long term storage of records; should be N/A.
3. The ATL QAPD, Figure 1, "Organizational Structure of Analytical Services Production Contractor." The organization chart did not provide evidence of independent reporting of the QA Manager to the Program Manager. Section 1.1, 3rd paragraph stated the quality manager reported directly to the project manager. Section 2.1.2.1, Item 3 stated the quality assurance manager reported directly to the program manager. This is not consistent.
4. The ATL QAPD, Section 2.3.2, "Implementing Responsibilities," in 2.3.2.3 referred to "Quality Management" which is a function and not a position. There were no responsibilities assigned to the Quality Assurance Manager.
5. QAPD Section 2.6.2.2, paragraph 2.c. was not based on any NQA-1 requirement and should be removed.
6. The ATL QAPD, Section 2.8.2.3, "Inspection requirements," Item 5, included an inspection type called "In-Service Inspection." These type inspection is not an acceptable NQA-1 method and needs to be removed.

7. The ATL QAPD, Section 2.13 described a process appropriate for CH2M HILL's computer software control activities, but not necessarily appropriate for ATL to control the acquisition, development, operation, maintenance, and retirement of computer software purchased and controlled by ATL.
8. The ATL QAPD, Section 1.2.2 contained an inconsistency where it stated the 222-S laboratory was a Category III Nuclear Facility, but item 2 in the same section referred to complying with *Enforcement of 10 CFR 830.120 (Quality Assurance Rule) for Facilities Below Hazard Category III.*
9. ATL-312, Section 1.04, Revision 2, "ATL Corrective Action Management," contained several deficiencies noted that need correcting:

    a. Section 5.1.1, fifth bullet referred to Nonconformance item reports, but ATL had no process in place that issued such a report.
    b. Section 5.1.4 and 5.2 did not require a justification be documented when an Issue Identification Form was invalidated or screened out.
    c. Section 5.2, the entire section did not flow well, and was unclear as to what was to be dome.
    d. Section 5.3, item 1 required a statement of expected actions to be provided for performance improvements documented on an IIF, but the procedure failed to indicate where this statement was to be documented and what information was required to be included (the actionee's name, completion date, etc.).
    e. Section 5.3, item 3, required issues to be submitted to the "Performance Enhance Team," but failed to indicate how the submittal was done and what the team was suppose to do with the submittal.
    f. Section 5.3, item 5 failed to indicate require a determination of remedial actions.
    g. The IIF forms did not require recording the extent of condition, the causes (root or apparent, direct, and contributing), results of closure verification, or a signature and date when the issue was closed to validate the QA record.
    h. The procedure did not require corrective action completion verification for significant conditions adverse to quality.
    i. Section 5, item 3 indicated the root cause analysis trained individual assigned to the causal analysis team was to function as a facilitator. A trained individual should lead the team.
    j. Section 5.5 failed to require the determination of extent of condition for significant issues. The procedure also failed to provide direction on what to do if the extent of condition review identified similar conditions elsewhere
    k. Section 5.5.3 had several "should" statements that need to be changed to "shalls"
    l. Section 5.5.3 needs a forth item that indicates corrective actions are entered into the Action tracking form.
    m. Section 5.5.4 was missing a step directing the CAM Program Manager to sign the IIF.
    n. Section 7.0 was inadequate because it failed to indicate the specific records generated from this process.

    o. Definitions provided for ‘Corrective action,” and “Resolution Required,” were incorrect and need to be replaced with definitions consistent with NQA-1

10. ATL-312, Section 9.02, Rev. 0, “ATL Casual Analysis Process;”
    a. Contained an inadequate philosophy regarding the relationship between causes (root cause, direct cause, and contributing causes) and corrective actions.
    b. Training section failed to identify who was required to be trained
11. ATL-312, Section 1.11, Rev. 0, “ATL Corrective Action Data Analysis and Trending;” Several deficiencies were noted that need correcting:
    a. Section 4.1 was missing the title of one of the referenced procedure
    b. 4.3.2, item c. indicated actions to address adverse trend data could be elicited, but failed to indicate how and what conditions warrant it.
    c. Section 4.5 indicated all IIF generated as a result of adverse trends were to be designated as Significant. One trend IFF was issued since the procedure was initiated, and it was not designated as significant. This is not a QA requirement.
    d. The process was lacking the establishment and reporting of performance indicators.
    e. Attachment A, the section on programmatic deficiencies (item 3) indicated reporting was needed, but the procedure failed to indicate how and where, or to who.
12. ATL-312, Section 1.12, Rev. 0, Qualification of Assessment Personnel;”
    a. Qualification of Lead Assessors was missing training requirements (see NQA-1 Supplement 2S-3, Section 3.2)
    b. Qualification of Lead Assessors was missing the requirement to participate in 5 QA assessments (one nuclear) within 3 years
    c. Qualification of Lead Assessors was missing the requirement to administer a qualification examination
    d. Qualification of Lead Assessors did not clearly indicate that qualification was to be assessed annually and documented
13. ATL-312, Section 1.14, rev. 0, “Performance of Management Assessments” did not capture the QAPD, Section 2.9.2.1, item 5, requirement to regularly assess the adequacy of the QA program
14. ATL-MP-1001, “Procedures Acceptable for Use by the ATL 222-S Analytical Production Contractor,” Appendix A, identified documents maintained by other Hanford contractors and implemented by ATL. The assessor noted instances where ATL procedure referenced other contractor procedures used by ATL that were not listed in the Appendix A (example: HNF-PRO procedures indicated in ATL-312, Section 1.01 as being requirements documents).

Quality improvement

The assessors evaluated the ATL quality improvement processes to assess compliance with the requirements of ATL-MP-1002, “Quality Assurance Program Description.” This was done by reviewing the implementing procedures ATL-312, Section 1.04, “ATL

Corrective Action management," ATL-312, Section 9.02, "ATL Causal Analysis Process," ATL-312, Section 1.11, "ATL Corrective Action Data Analysis and trending," and ATL-312, Section 1.05, "Lessons Learned," to verify they adequately captured QAPD requirements. The assessors also interviewed responsible ATL staff and reviewed related documentation of activities involving corrective action management, trending, and lessons learned to assess adequate implementation of the process.

The assessors determined the adequacy of the corrective action management procedure, ATL-312, Section 1.04, was marginal because it failed to adequately implement all the QAPD requirements. The assessors identified 15 instances where the procedure required correcting. The assessors considered each individual instance to be minor, so the issue was captured in Finding A-06-ESQ-ATL-001-F02. The assessors determined the implementation of corrective action management requirements was adequate except that ATL did not always perform an extent of condition determination required when resolving deficiencies classified in NQA-1 as "conditions adverse to quality." This issue was captured in Finding A-06-ESQ-ATL-001-F01.

The assessors found the procedures for trending to be adequate except for some minor discrepancies. These have been captured in Finding A-06-ESQ-ATL-001-F02. Trending reports had been generated since February 2006, but the trending process was not fully implemented. This was because trending data sufficient to perform meaningful trending had not been collected. Trending data collection capabilities had only been in place for approximately four months at the time of the assessment, and less than 50 deficiency data points existed. The assessors determined the implementation of the trending process was indeterminate due to insufficient data.

The assessors determined the lessons learned process was inadequate because the related procedure failed to provide sufficient details to adequately conduct the required activities. The work performed was ad hoc, not part of the formal process, but the assessors found it to be adequate. This was due to the process knowledge of the individual performing the activity, but much of the activity was not adequately documented. This issue is captured in Finding A-06-ESQ-ATL-001-F01.

Management Assessments

The assessors evaluated the ATL management assessment process to assess compliance with the requirements of ATL-MP-1002, "Quality Assurance Program Description," by reviewing the implementing procedures ATL-312, Section 1.14, "Performance of Management Assessments," and ATL-312, Section 1.12, "Qualification of Assessment Personnel," to verify they adequately captured QAPD requirements. The assessors also interviewed responsible ATL staff and reviewed the assessment schedule, management assessment reports, Issue Identification Reports, and training records to assess adequate implementation of the process.

The assessors concluded the management assessment process was adequate because procedures adequate established processes that met QAPD requirements, management assessments were scheduled and performed as scheduled, assessment were conducted by trained personnel, assessments were conducted and documented per the procedures, and issues were adequately documented in the contractor's corrective action management process. The assessors noted one minor deficiency in procedure ATL-312, Section 1.14. The procedure failed to capture the QAPD requirement for managers to perform regular management assessments of the QA program elements they were responsible to implement. This issue is captured in Finding A-06-ESQ-ATL-001-F02. ATL had conducted a company level QA program management assessment in March of 2006

Independent Assessments

The assessors evaluated the ATL independent assessment process to assess compliance with the requirements of ATL-MP-1002, "Quality Assurance Program Description," by reviewing the implementing procedures ATL-312, Section 1.13, rev. 0, "Performance of Independent Assessments," and ATL-312, Section 1.12, "Qualification of Assessment Personnel,"ATL-312, Section 1.06, to verify they adequately captured QAPD requirements. The assessors also interviewed responsible ATL staff and reviewed the assessment schedule. At the time of the assessment, there had been no independent assessments conducted by ATL.

The assessors concluded the independent assessment procedures adequately implemented QAPD requirements. The assessors did identify several minor procedures deficiencies that required correction. These deficiencies are captured in Finding A-06-ESQ-ATL-001-F02.

The assessors concluded ATL had not adequately implemented its independent assessment program because assessments had not been sufficiently scheduled to assure proper independent oversight of QA and other ISMS related program requirements, ATL had not performed any independent assessments, ATL had not scheduled or performed any assessments of the services provided by CH2M HILL, and ATL had not established a planning process for assuring assessment activities are scheduled and conducted in a manner and frequency commensurate with the importance and complexity of ATL work activities. This issue is captured in Finding A-06-ESQ-ATL-001-F02

Suspect/Counterfeit Items

The assessors evaluated the ATL suspect/counterfeit Items (S/CI) process to assess compliance with the requirements of ATL-MP-1002, "Quality Assurance Program Description," by reviewing the implementing procedure ATL-312, Section 1.06, "Suspect/Counterfeit Control," to verify it adequately captured QAPD requirements. The assessors also interviewed responsible ATL staff and reviewed process documentation to assess adequate implementation of the process.

The assessors determined the S/CI process procedure did not contain sufficient detail to adequately perform the activity, did not adequately capture QAPD requirements, and did not implement the processes described in DOE Guide 440.1-6, "Implementation Guide for use with Suspect/Counterfeit Items Requirements of DOE O 440.1, Worker Protection Management; 10 CFR 830.120; and DOE 5700.6C, Quality Assurance," which were necessary to successfully interface with the Office of Inspector General (OIG) and other DOE sites. The assessors also determined implementation of the process was not adequate; process steps were not properly documented, and required process activities were not performed. This issue is captured in Finding A-06-ESQ-ATL-001-F01.

Conclusions:

The assessors concluded ATL had not adequately established and implemented processes for all QA program elements as specified in the Contractor's QAPD. The assessors found procedures with missing requirements, procedures that lacked sufficient detail to adequately perform required activities, procedure with processes not in compliance with the QAPD, or the procedures were not implemented. QA processes identified by the assessors as being inadequate included lessons learned, suspect/counterfeit items, documents and records, graded approach, and control of nonconforming items. The assessors concluded the independent assessment program was not adequately implemented, and the implementation of trending was indeterminate. Minor procedure deficiencies were noted in the procedures related to corrective action management, qualification of assessment personnel, casual analysis, management assessments, and trending. The assessors also identified some minor deficiencies with the QAPD where requirements were not adequately captured or did not relate to ATL work scope.

The deficiencies noted by the assessors impacted QA processes necessary to successfully integrate the ATL ISMS. The ISMS Core function most significantly impacted was Core function 5, "Feedback and Continuous Improvement." ATL will need to adequately implement the following QA processes before this core function can be effective; independent assessments, corrective action management, trending, lessons learned, and suspect counterfeit items. Core Function 4, "Perform Work," was also impacted in that ISMS requires work to be defined and conducted in accordance to structured processes documented in procedures.

The assessors also noted that the Contractor's March 2006 management assessment program also identified QA program deficiencies. The assessors consider the deficiencies identified during that assessment as additional indicators that the ATL program was not adequate. These deficiencies will also need to be corrected before ORP can consider ATL's QA program to be adequate.

Key Personnel Interviewed:

Phyllis Bruce, ATL
Heather Anastos, ATL
Larry Penfold, ATL
Ray Akita, ATL

Signed/date: _____ Signed/date: _____
Assessor Lead Assessor (author of this rewrite)

Assessment Note Number: A-06-ESQ-ATL-001-02

Assessor Name: Dennis Carson

Date of Assessment: April 10 through 20, 2006+

Item Assessed: Personnel Training and Qualifications, Quality Assurance Program, Procurement, Inspection and Acceptance Testing

The assessor reviewed the Contractor's procedures for compliance to the "Quality Assurance Program Description," ATL-MP-1002, Rev. 4. The assessor also reviewed relevant records and reports, and interviewed ATL staff and management about responsibilities and activities performed in relation to assessed activities. From these activities, the assessor was able to assess the effectiveness of program implementation. Two findings were identified during this assessment which contained issues common to many of the areas assessed. These common findings are captured in detailed in Assessment Notes No. A-06-ESQ-ATL-001-01

Observations and Assessments

Documents Reviewed

- ATL-MP-1001, Rev. 6, "Procedures Acceptable for Use by the ATL 222-S Analytical Services Production Contractor"
- ATL-MP-1002, Rev. 4, "Quality Assurance Program Description"
- ATL-MP-1015, Rev. 0, "Quality Assurance Program Implementation Matrix"
- ATL-MP-1016, Rev. 2, "Interface Control Document Between ATL and CH2M HILL"
- ATL-MP-1024. Rev. 0, "ATL Training and Qualification Plan"
- ATL-MP-1025, Rev. 0, "ATL Training Implementation Matrix"
- ATL-MP-1027, Rev. 0, "Qualification Requirements for Analytical Field Work Supervisors"
- ATL Letter 05-ATL-049, "Contract No. DE-AC27-05RV14548- Quality Assurance Program Plan Under The Analytical Services Production Contract", Dated June 17, 2005
- ATL Assessments FY2006 Schedule, Status as of 06-Apr-06
- Chart of "NQA-1 Training Status" Generated 04/05/2006
- ATL Qualification Record for 222-S Laboratory Field Work Supervisors, Dated 03/07/06
- ATL-310, Administration
    - Section 1.46, Rev. 1, "Procurement of Analytical Technical Services Equipment"
    - Section 3.18, Rev. 1, "Instrument Calibration"
    - Section 5.7, Rev. 2, "Procedure On-the-Job Training"
- ATL-312, Administration
    - Section 1.04, Rev. 2, "Corrective Action Management"
    - Section 1.12, Rev. 0, "Qualification of Assessment Personnel"
    - Section 1.16, Rev. 0, "Procurement Process Interfaces"
    - Section 2.04, Rev. 0, "Employment"
    - Section 4.26, Rev. 1, "ATL Analytical Project Process Flow"

    - Section 5.01, Rev. 0, “ATL Training Records, Scheduling, and Interfaces”
    - Section 9.03, Rev. 0, ``“ATL Control of Nonconformances”
- MA-QA-06-1, “Management Assessment 5 Quality Assurance Plan Implementation Report”
- LO-140-008, Rev. C-0, “Routine Use and Quality Assurance for Analytical Balances at 222-S Laboratory Complex”
- LO-150-063, Rev. D-0, “Chemical Management”
- LO-150-063, Rev. E-0 (DRAFT), “Chemical Management”
- LO-190-101, Rev. Z-1, “222-S Laboratory Sample Receiving and Custodianship”
- LO-190-102, Rev. F-0, “222-S/222-SA ABCASH and Surveillance Technologist Sample Receiving and Custodianship”
- Organization Charts for 222-S Laboratory Analytical Services and Testing, dated 02/28/06
- ATL-CATRAX (Corrective Action Tracking) form, number ATL-2005-014
- ATL Training Records:
    - Procedure OJT Checklist for Laboratory Technical Procedures
    - Integrated Training Electronic Matrix (ITEM) Reports
- ATL Initiated “CH2M Material Request” forms:
    - MR-06-00133
    - MR-06-00316
    - MR-06-00334
    - MR-06-00645

Discussion:

Personnel Training and Qualifications

The assessor reviewed training plans and personnel training and qualifications procedures to assess the adequacy in implementing the requirements of the ATL Quality Assurance Program Description (QAPD), Section 2.2, Personnel Training and Qualification. The assessor’s review determined ATL procedures and plans adequately implement QAPD requirements.

The assessor evaluated the adequacy of procedure implementation by reviewing qualification records, and the training reports maintained in the Integrated Training Electronic Matrix (ITEM) for the following positions: chemist, project coordinator, QA/QC, manager, chemist technician, and a field work supervisor. The assessor also reviewed on-the-job training records completed since ATL took over the laboratory operations. The assessor found implementation of training and qualification procedures to be adequate because the training processes were followed, and the assessor did not find any instance where established training was inadequate, or where training/qualification records were out of date or lapsed.

Use of the Integrated Training Electronic Matrix (ITEM) for scheduling and tracking of required and completed training should be considered a positive asset to the personnel training and qualification program.

Quality Assurance Program

The assessors evaluated the overall adequacy of the quality assurance program and the interface established with CH2M HILL by reviewing documents and implementing procedures that established the Contractor's overall QA policy and implementing philosophy. This review included ATL-MP-1001, "Procedures Acceptable for Use by the ATL 222-S Analytical Services Production Contractor," ATL-MP-1002, "Quality Assurance Program Description," "ATL-MP-1016, "Interface Control Document between ATL and CH2M HILL," and ATL letter 05-ATL-049, "Contract No. DE-AC27-05RV14548 – Quality Assurance Program Plan under the Analytical Services Production Contract." Management assessment report MA-QA-06-1, "Management Assessment 5 Quality Assurance Plan Implementation Report," was also reviewed.

The assessors concluded that The Contractor interfaces with CH2M HILL had been adequately established and documented, but the QA program as described in the Contractor's QAPD was not completely implemented. Several important processes had not been adequately established or implemented. These are discussed in more details throughout this report. Some minor discrepancies were identified with the QAPD. These are captured in Finding A-06-ESQ-ATL-001-F02.

Two observations resulted from the assessors' QA program review:

ATL QA staff was not sufficiently independent to conduct independent Assessments:

The assessors found the QA staff was heavily involved in program development, procedure writing, and in coaching other contractor staff on process development. The assessors were concerned this level of involvement in these type activities would not allow the QA staff to have the independence and objectivity required by the QAPD to perform independent assessments. Discussions with the Contractor indicated they were aware of this potential problem, and indicated they were considering bring in outside contractors to perform their independent assessments.

Disconnect exists between ATL's application of NQA-1-1989 and CH2M HILL's implementation of NQA-1-2000:

The assessors identified one cases where disconnects existed between ATL requirements and the CH2M HILL provided services. This resulted in discrepancies with the storage of QA records where the ATL QAPD required the use of 1 and 2 hour fire rated cabinets, but the CH2M HILL QAPD did not have that requirement and CH2M HILL was not using fire rated cabinets. The assessors determined this disconnect resulted because ATL used NQA-1-1989 as its implementing standard and CH2M HILL used NQA-1-2000. Theses two revisions of NQA-1 were sufficiently different in their specified rigor that at least one case existed where CH2M HILL provided services did not comply with ATL QAPD requirements. ATL was not aware of this possibility or the extent of any discrepancies because ATL had not conducted any oversight of CH2M HILL provided services. The assessors consider this situation as an observation because only one such case was identified, because ATL had previously committed to ORP to implement NQA-1-2000 by the end of FY-06, and the lack of oversight was captured as part of Finding A-06-ESQ-ATL-001-F01.

<u>Procurement</u>

The assessor found the ATL procurement process was contained in the following procedures, ATS-310, Section 1.46, Rev. 1, *Procurement of Analytical Technical Services Equipment*, and ATL LO-150-063, Rev. D-0, *Chemical Management.* The assessor reviewed these procedures and interviewed key ATL staff involved in the procurement process. The assessor found ATL procurement activities were limited to the initiation of material requisitions and the receipt of chemicals and reagents used in the laboratory. Procurement services, after ATL's initiation of a material request, were provide by CH2M HILL through the PassPort system. Source and Receiving inspection was performed for ATL by the Fluor Hanford Acquisition Verification Services (AVS). The procurement of facility equipment, including analytical instrumentation and any required calibration, was provided as government furnished services by CH2M HILL. According to the ATL point of contact, there has been no procurement of services by ATL prior to the audit.

The assessor reviewed a number of material requisitions to ensure they were properly completed; that they adequately described the items to be procured; they contained adequate acceptance criteria to ensure the correct items were ordered; the appropriate quality requirements were flowed down to the supplier; and inspections were performed to verify the received items were acceptable. The assessor did not identify any problems with the initiation of the material requests, and determined the activity was adequately implemented in accordance with established procedures.

The assessor determined through interviews that ATL performs some receipt inspection of procured chemicals. The majority of these chemicals were ordered as commercial grade items, but because of their associated hazards, they were received by ATL who employed staff trained to properly handle such chemicals. The material requisition was used by ATL as the receiving inspection record; a quality record. The receiving inspection process included a physical inspection of the item, and an inspection of the accompanying documentation, such as a Certificate of Conformance and/or Certificate of Analysis, to assure they complied with the material requisition specifications. The assessor reviewed a sample of material requisitions documentation to assess the adequacy of the receiving inspection process. The assessor found the process failed to document the name of the individual who performs the receipt inspection, either in the material requisition or accompanying requisition documentation. The process also failed to comply with the QA record authentication requirements found in the ATL QAPD, Section 2.4.2.2, item 3, which required QA records to be authenticated. Authentication is accomplished by signing and dating a record. This issue is captured in assessment finding A-06-ESQ-ATL-001-F01.

The authentication problem was brought to the attention of ATL personnel (C. Neff and L. Penfold). According to ATL, this problem had already been identified and corrective action was initiated to revise ATL procedure LO-150-063. The assessor reviewed the draft revision of the procedure and found the proposed changes failed to completely correct the problem. The proposed correction was to have the individual performing the inspection sign or initial the vendor invoice and certificate of analyses to validate all of the required information was present. Authentication requires both a signature and date. This was brought to the attention of ATL personnel who promptly initiated an amendment to the procedure (Section 6.2.13, item h) to require that the individual performing the receipt inspection of laboratory-use chemicals "sign and date both the vendor invoice and certificate of analyses to validate that all of the required information was present." ATL showed responsiveness to this issue and was tracking corrective actions for this specific issue in ATL-CATRAX (Corrective Action Tracking) form, number ATL-2005-014. However, another example was identified in another area assessed, so the issue remained as part of finding A-06-ESQ-ATL-001-F01 to allow ATL to determine and address the extend of condition.

The assessor evaluated the ATL process for the control of nonconforming items, and was told by ATL personnel the control of nonconformances was described in ATL procedure, ATL-312, Section 9.03, Revision 0, *ATL Control of Nonconformances*. The assessor reviewed this procedure and found several deficiencies. First, the purpose and scope incorrectly defined the application of controls for nonconforming items. It states that the use of a Nonconformance Report (NCR) typical to a traditional nuclear quality assurance programs generally applied to structures, systems, and components to be installed in a nuclear facility. The assessor did not agree; NQA-1, 1989 basic requirement 15 did not refer to installed structures, systems, and components. It referred to items that did not conform to specified requirements, and indicated these items "shall be controlled to prevent inadvertent installation or use." The procedure application was to limiting and would exclude some applicable conditions. Second, the purpose and scope statement stated that nonconformance reporting that would result in dispositions of "repair", "use-as-is" and "rework" did not apply to work performed by ASPC. The assessor determined this logic also did not comply with the NQA-1 requirement basic requirement 15 which would be applicable to procured items, equipment, and consumables (such as chemicals and reagents used in the laboratory). Third, the process provided in the procedure failed to comply with the process described in the ATL QAPD. The QAPD correctly captured NQA-1-1989 requirements, and committed to implementation of a traditional process that would control nonconforming items. The assessor determined that the reviewed procedure was not adequate in capturing QAPD requirements, and the process implemented not adequate or effective in assuring nonconforming items would be sufficiently identified, controlled, and corrected. This issue is captured in assessment finding A-06-ESQ-ATL-001-F01.

The assessor attended several discussions on nonconformance reporting with ATL personnel (P. Bruce, C. Neff, and L. Penfold). The ATL QA Manager presented a position statement to the assessment team. This stated in part that indicated the following:

1. The laboratory does not procure engineered items, items procured to unique drawings or specifications.

2. The potential for nonconforming characteristics is limited and known. Thus the actions for the disposition such characteristics (should they be encountered) can be defined in the procedure.

3. The laboratory does not utilize the dispositions of "rework" or "repair".

The first statement was incorrect in that it inferd the application of nonconforming items was limited only to engineered items, items procured to unique drawings or specifications. That assumption was not supported by the QAPD or NQA-1-1989. Also, ATL procured items such as chemicals using material requisitions which specified requirements derived from engineered operational specifications.

The second statement was incorrect because it inferred that all possible nonconformances had been identified and dispositions for each of them accounted for in individual process procedures. The assessment team identified an Issue Identification Forms where just prior to this assessment ATL had documented nonconforming characteristics in an Argon gas shipment. This was a new situation

encountered by ATL, and was not anticipated in operating procedures. ATL chose to address this issue by using the corrective action management process. The assessors felt the use of the corrective action process was not a good fit for addressing a nonconforming items because the process required a causal analysis and extent of condition evaluation (activities which ATL did not do for this IIF) when all that was needed was to determine how to disposition the item. The assessors communicated to ATL they had not performed all required activities. The assessor also felt adding specific processes to procedures for addressing every specific nonconforming condition was not practical, and this approach did not allow ATL the flexibility to change mission and work scope. The assessor suggested to ATL that a more traditional, general procedure for nonconformance reporting be developed.

NQA-1 (1989) definition of nonconformance states that a nonconformance "is a deficiency in characteristic, documentation, or procedure that renders the quality of an item or activity unacceptable or indeterminate." Missing or incomplete documentation that is necessary to determine the quality of the chemical being received would be a nonconformance. The NQA-1 definition of rework is the process by which an item is made to conform to original requirements by completion or correction. The requesting of missing or incomplete documentation required by the original requirements of the procurement would meet the definition of "rework". ATL did not agree with this interpretation and requested missing documentation regularly without documenting the nonconformance.

It was the prerogative of the QA management to interpret and direct the implementation of quality requirements. However, the assessor was concerned with the position presented but the ATL QA Manager, and felt interpretation and direction for complying with the NQA-1 requirements for controlling nonconformances from ORP may be warranted to ensure adequate compliance with the requirements. This issue is captured in assessment finding A-06-ESQ-ATL-001-F01. The assessor's final determination was that ATL did not have in place a process for addressing nonconformance items that met the requirements in the ATL QAPD.

The review of ATL procedure LO-150-063, "Chemical Management" found that the procedure appeared to be used to implement a multitude of quality, environmental, and safety requirements. The assessor felt it may be too complex to be effective. ATL should consider reviewing the procedure ensure that it focuses on "chemical management" tasks and consider moving some of the other implementing steps to other more appropriate procedures.

Inspection and Acceptance Testing

ATL inspection and acceptance testing is limited to the receipt inspection activity which is discussed in the procurement section.

Conclusions:

The assessor determined ATL had procured materials (services excluded because there was no evidence of such procurement), and planned and performed limited receiving inspection using adequate procedures and qualified and certified QC inspectors. Improvement in the receipt inspection process is needed in the areas of inspection records (captured in finding A-06-ESQ-ATL-001-F01). The inspector determined the

process for control of nonconforming items was inadequate (captured in finding A-06-ESQ-ATL-001-F01). Procedures used to implement the procurement process need improvement by clarifying and specifying steps in the procedures and if appropriate, reducing the complexity of the procedures.

ATL has in place adequate procedures to ensure that inspection and testing are performed in accordance with the requirements of ATL-MP-1002, Rev. 4, “Quality Assurance Program Description”, Section 2.2, Personnel Training and Qualifications. The assessor found that training and qualification of personnel was being adequately performed and documented. This area appeared to be well managed and well documented.

ATL has in place adequate procedures to ensure that inspection and testing awere performed in accordance with the requirements of ATL-MP-1002, Rev. 4, “Quality Assurance Program Description”, Section 2.8, Inspection and Acceptance Testing. Evidence reviewed found that laboratory personnel are complying with those procedures.

ATL had in place plans and procedures for implementing their quality assurance program. However, in general, improvement to implementing procedures is needed. Procedures need clarification and greater specificity to directions included in them to ensure that personnel can understand and follow the procedure (captured in finding A-06-ESQ-ATL-001-F01 and (captured in finding A-06-ESQ-ATL-001-F02).

Personnel Interviewed:

H. L. Anastos, Chief Operating Officer
P. H. Bruce, Quality Assurance/PAAA/Assessments
C. R. Neff, Field Work Supervisor
L. E. Penfold, Quality Assurance/Quality Control

Signed/date: _____ Signed/date: _____
Assessor Lead Assessor (author of this rewrite)

Assessment Note Number: A-06-ESQ-ATL-001-03

Assessor Name: Constantin Maciuca

Date of Assessment: April 10 through 20, 2006

Item Assessed: Work Processes

Documents Reviewed

- ATL-MP-1002, Rev. 4, "Quality Assurance Program Description"
- ATL-MP-1015, Rev. 0, "Quality Assurance Program Implementation Matrix"
- ATL-MP-1001, Rev. 6, "Procedures Acceptable for Use by the ATL 222-S Analytical Services Production Contractor"
- ATL-MP-1016, Rev. 2, "Interface Control Document Between ATL and CH2M HILL"
- ATL-MP-1012, Rev. 0, "ATL Procedure Compliance Expectations"
- ATL-312, Section 4.26, Rev. 1, "ATL Analytical Project Process Flow"
- ATL-MP-1024. Rev. 0, "ATL Training and Qualification Plan"
- ATL-312, Section 1.01, Rev. 0, "Administrative Procedure Control Process"
- ATL-312, Section 11.16, Rev. 0, "Technical Procedure Control Process"
- Fluor Hanford, M2310-06-001, 01/30/2006, "Letter of instruction for analysis of paint, liquid, and concrete samples from PFP building 232-Z"
- DOE/RL-2004-22, Rev. 0, "Sampling and Analysis Plan for the Contaminated Waste Recovery Process Facility, Building 232-Z"
- 222-S Analytical Workload Status by Doe Date, as of 04/17/06
- ATL Analytical Project Schedules, status as of 04/17/06
- Fluor Hanford, M2100-06-010.R1, 01/25/2006, "Reissuance of NDA results for 232-Z scrubber cell samples"
- ATL, TSCA Regulated PCB Status Chart, 03/23/2006
- ATL, Project Coordinator Checklist, PFP 232-Z, 03/01/06
- LABCORE Completed Batch Report for Batch#00001590, 02/01/06
- ATL Final Report for Tank 241-S-102 Grab Samples in Support of Tank Retrieval Operations, 03/27/06
- ATL Issue Identification Form, 02/13/06
- ATL Work Location/Coverage Requirements for Alpha Work at 222-S, 01/26/06
- LO-140-008, Rev. C-0, 06/01/2005, "Analytical Technical Services 222-S Laboratory Operating Procedure"
- ATL Balances Calibration Status Report, printed 04/19/06
- Energy Northwest Standards Laboratory Calibration Certificate, Report Number 1129709237, 10/19/05
- Energy Northwest Standards Laboratory Calibration Report – Mass Calibration, Calibration Code: 702-86-02-022, Serial Number: 79161, 10/10/05
- LA-523-140, Rev. E-0, 01/31/06, "ATL 222-S Laboratory Analytical Procedure: Polychlorinated Biphenyls (PCBs) by SW-846 Method 8082, Using Gas Chromatography With Electron Detection"
- WSCF/222-S Initial Calibration Data Report, 02/16/06

- WSCF/222-S Initial Calibration Data Report, 01/21/06
- WHC-N-487, Laboratory Notebook – Pesticide/PCB Standard Preparation Logbook, Issued 02/12/1991
- LA-325-106, Rev. D-0, 12/06/05, "ATL 222-S Laboratory Analytical Procedure: Mercury Analysis by Cold Vapor Atomic Absorption Using the FIAS-400"
- ATL FIAS Hg Runlog, 3/23/06, Worksheet #1968 Rerun
- ATL FIAS Hg Runlog, 3/13/06, Worksheet # 241Z Swipe
- LQ-150-115, Rev. A-1, 02/14/05, "ATS 222-S Laboratory Quality Control Procedure: Instrument Standards Counting Frequency – 222-S Counting Room"
- 222-S Counting Room, Detector Efficiency Update Form, 06/29/05
- LA-508-104, Rev. D-0, 03/02/06 "ATL 222-S Laboratory Analytical Procedure: Total Alpha Counting by Alpha Proportional Counters"
- LQ-508-002, Rev. C-0, 08/25/05, "222-S Laboratory Quality Control Procedure: Calibration Guidelines for Window-Type Gas Flow Alpha/Beta Proportional Counters"
- LQ-508-102, Rev. A-0, 01/31/05, "ATS 222-S Laboratory Quality Control Procedure: Detection Limits and Uncertainty Calculations for Radioisotopic Counting"
- LO-140-008, Rev. C-0, "Routine Use and Quality Assurance for Analytical Balances at 222-S Laboratory Complex"

Observations and Assessments:

Work Processes

The assessor conducted a review of the work processes used by ATL to assess the adequacy in complying with applicable QAPD requirements. The assessor accomplished this by reviewed the procedures governing the ATL analytical project work processes, and the documents which describe the interfaces between ATL and CH2M HILL. The assessor noted there were many daily interfaces and shared roles and responsibilities between ATL and CH2M HILL. This was because ATL operations were embedded within the CH2M HILL 222-S Laboratory Complex. The assessor determined the analytical work activities, specifically those affecting quality, safety, or the environment of the ATL products and services, were performed in accordance with documented, management-approved procedures and instructions that were developed to meet the applicable regulations, DOE orders, technical standards, and client work instructions. The assessor took notice that workers and their supervisors were held accountable for working in compliance with their procedures, whether they were administrative or technical.

Special processes, as defined and usually applied in the context of NQA-1-1989, had not been identified in the ATL's scope of work, and were determined to be not applicable.

Identification and control of items was indicated as being a CH2M HILL's responsibility, while sample control, including chain-of-custody, was determined to be a shared function integrated with the 222-S Laboratory work processes.

Calibration Requirements for ATL Analytical Instruments and Balances

The assessor made a random selection of analytical procedures and performed a walked-down at various work locations in the laboratory to verify compliance with prescribed calibration requirements. Calibration requirements were evaluated for the following areas:

Organic Chemistry – The assessor tracked compliance to PCB procedure LA-523-140, Rev E-0, "ATL 222-S Laboratory Analytical Procedure: Polychlorinated Biphenyls (PCBs) by SW-846 Method 8082, Using Gas Chromatography With Electron Detection," for one instrument (ECD-1) by comparing the calibration records to the stock standard certification record that were stored at 222-SA (Standards Laboratory). This verification included reviewing page entries from calibration log book WHC-N-487 for the calibration standards used and tracing them back to the initial stock standard certification and lot number records provided by the initial supplier. The assessor determined the procedure clearly documented the calibration/verification process within the procedure's quality control protocol section. The protocol adequately incorporated acceptance criteria as defined by the referenced Environmental Protection Agency (EPA) method and the ATL Quality Assurance Project Plan for the 222-S Laboratory, ATL-MP-1011.

Radiochemistry – The assessor reviewed the Total Alpha Counting procedure LA-508-104, rev D-0, "ATL 222-S Laboratory Analytical Procedure: Total Alpha Counting by Alpha Proportional Counters," to assess the adequacy of calibration techniques. The assessor determined the procedure adequately provided guidelines for choosing the appropriate standard sources (for calibrating of both radionuclide and activity), and provided an adequate step by step procedure (with flow diagrams) for performing the required calibrations. The assessor also reviewed detector efficiency reports, and the methods used for checking counting systems at specific frequencies to verify system performance complied with criteria established in ATL Quality Assurance Project Plan for 222-S Laboratory, ATL-MP-1011 and the calibration procedures.

Inorganic Chemistry – The assessor evaluated the adequacy of the calibration process provided in procedure LA-325-106, rev D-0, "ATL 222-S Laboratory Analytical Procedure: Mercury Analysis by Cold Vapor Atomic Absorption Using the FIAS-400." The procedure required the instrument be calibrated using 5 different concentrations of mercury standards. The assessor reviewed the run logs containing data for two analytical batches (dated 3/13/06 and 3/23/06). The assessor determined the instrument calibration was adequate and in accordance to the quality control protocol documented in the procedure, which provided acceptance criteria as defined by the EPA method referenced in the procedure, and the ATL Quality Assurance Project Plan for the 222-S Laboratory, ATL-MP-1011.

Balances – The assessor reviewed procedure LO-140-008 Rev C-0, "Routine Use and Quality Assurance for Analytical Balances at 222-S Laboratory Complex" to evaluate the adequacy of the provided calibration practices. The assessor also checked a number of balances to verify they contained the required calibration stickers, and reviewed calibration records to verify they were documenting routine calibration checks and linearity checks. The assessor also reviewed maintenance schedules and preventive maintenance activities.

Conclusions:

The assessor determined ATL has in place adequate procedures to ensure that work process were performed in accordance with the requirements of ATL-MP-1002, Rev. 4, "Quality Assurance Program Description", Section 2.5, Work Process. The assessor determined through interviews performed and the

documentation reviewed that ATL work processes were adequately defined, implemented, and controlled to ensure the quality of ATL's products and services.

The assessor concluded that there were no items of concern associated with calibration processes within the PCB, Mercury, Total Alpha or Analytical Balance procedures.

Personnel Interviewed:

H. L. Anastos, Chief Operating Officer
P. H. Bruce, Quality Assurance
L. E. Penfold, Quality Assurance/Quality Control
K. A. Keltner, Chemist – Organic Chemistry
B. V. Dang, Chemist – Inorganic Chemistry
R. W. Schroeder, Radiochemistry Manager
J. L. Heinemann, Maintenance Manager
S. R. Longoria, Preventive Maintenance Planner
R. Akita, Laboratory Standards Manager

Open Findings:

None

Open Observations:

None

Signed/Date_____/_____Signed/Date_____/_____
Assessor Lead Assessor

Assessment Note Number: A-06-ESQ-ATL-001-04

Assessor Name: Constantin Maciuca

Date of Assessment: April 10 through 20, 2006

Item Assessed: Design and Software Quality Assurance

Documents Reviewed

- ATL-MP-1002, Rev. 4, "Quality Assurance Program Description"
- ATL-MP-1015, Rev. 0, "Quality Assurance Program Implementation Matrix"
- ATL-MP-1011, Rev. 2, "ATL Quality Assurance Project Plan for 222-S Laboratory"
- ATL-MP-1001, Rev. 6, "Procedures Acceptable for Use by the ATL 222-S Analytical Services Production Contractor"
- ATL-MP-1016, Rev. 2, "Interface Control Document Between ATL and CH2M HILL"
- ATL-MP-1012, Rev. 0, "ATL Procedure Compliance Expectations"
- ATS-310, Section 8.14, Rev. 4, 08/04/05, "Analytical Technical Services 222-S Laboratory Administration, Computer Software Management"
- ATS-310, Section 8.15, Rev. 3, 04/03/06, "Laboratory Information Management System (LIMS) Change Request Procedure"
- LCCB Configuration Database Data Retrieval, printed 04/13/2006
- ATL SVF-1019, Rev. 0, October 2005, "Spreadsheet Description Document for CLEANUPICPMS.XLS"
- RPP-28553, Rev. 0, March 2006, "Spreadsheet Description Document for Tank Farms Double-Shell Tank Waste Chemistry Limits Check"
- RPP-PLAN-24784, Rev. 1, January 2006, "Total Inorganic Carbon/Total Organic Carbon (TIC/TOC) Software Upgrade Software Quality Assurance Plan"
- RPP-25648, Rev. 1, January 2006, "TIC/TOC Software Design Document"
- RPP-27687, Rev. 1, October 2005, "TIC/TOC Version Description Document"
- RPP-RPT-28629, Rev. 0, January 2006, "TIC/TOC Revision 3.0.1 Test Report"

Observations and Assessments:

The assessor reviewed the ATL Quality Assurance Program Description (QAPD), documented quality assurance program, design and software process procedures, related process documentation, and interviewed key personnel to evaluate ATL procedure adequacy in meeting requirements, and to evaluate the adequacy in implementing established procedures.

Design

The requirements and responsibilities for planning, controlling, and verifying design activities were described in the ATL QAPD, ATL-MP-1002, Rev. 4, in Section 2.6 – Design. This section of the QAPD was developed to satisfy the requirements of 10 CFR 830.122, Criterion (f) and DOE Order 414.1C, Attachment 2, Criterion 6 – Design. The ATL used NQA-1-1989 as the implementing standard. The

assessor determined the QAPD adequately addressed NQA-1 design requirements except for QAPD Subsection 2.6.2.2, paragraph 2.c. This assessor found this portion of the QAPD was incorrect, not based on any NQA-1 requirement, and should be removed or rewritten. This issue is captured in finding A-06-ESQ-ATL-001-F02. The assessor also noted the ATL work scope did not include any design activities, and the design requirements were not applicable to current ATL work.

Software Quality Assurance

The assessor's review of ATL software QA related activities found that ATL used computer software to perform quality-affecting activities such as control of analytical measurement equipment, and the calculations of analytical results from raw data. Much of the software used by ATL was provided by CH2M HILL as government-furnished services. The software life cycle phases associated with ATL's software applications were installation and operation because ATL work scope does not include the procurement, development, or use of software, including safety software. For applications used by 222-S Laboratories Complex (CH2M HILL ATS and ATL), such as Laboratory Information Management System (LIMS) and Total Inorganic Carbon/Total Organic Carbon (TIC/TOC), the software documentation was developed by LMIT for CH2M HILL, and the computer programs were controlled by CH2M HILL.

The assessor reviewed relevant documentation and interviewed key personnel responsible for the maintenance and operation of software to evaluate the adequacy in meeting QAPD requirements. The software application selected by the assessor for review included spreadsheet used to evaluate analytical data. Software quality assurance activities and practices for computer use and verification were also evaluated to assess the adequacy of process implementation.

The ATL system software configuration control was governed by several ATS and CH2M HILL procedures approved for use by ATL. The assessor found these processes to be adequate and properly implemented.

Configuration change control at ATL was found by the assessor to be a mature process with formal problem reports and software change request being controlled by the Laboratory Configuration Control Board (LCCB). The LCCB was composed of representatives from both ATL and CH2M HILL Analytical Technical Services (ATS). The LCCB was responsible for tracking, reviewing, and approving configuration changes for ATL systems and instruments software. The assessor found this process to be adequate and fully implemented.

The assessor found the ATL QAPD, Section 2.13 described a process appropriate for CH2M HILL's computer software control activities, but not necessarily appropriate for ATL to control the acquisition, development, operation, maintenance, and retirement of computer software purchased and controlled by ATL. The assessor also found Section 2.6.2 of the ATL QAPD incorrectly indicated that "operation" was the only applicable phase of the software life cycle. These issues are captured in finding A-06-ESQ-ATL-001-F02.

Conclusions:

The assessor concluded ATL procedures used to implement design and software QA requirements were adequate and implemented ATL-MP-1002, "Quality Assurance Program Description," requirements. The

assessor found design and software controls activities were adequately performed in accordance with established procedures. The also assessor noted the requirements described in the ATL QAPD were more extensive than those applicable for the ATL scope of work. The assessor concluded found that the control of software was adequate for the ATL scope of work.

Personnel Interviewed:

H. L. Anastos, Chief Operating Officer
P. H. Bruce, Quality Assurance
L. E. Penfold, Quality Assurance/Quality Control
T. H. Bushaw, Analytical Service Manager
R. W. Schroeder, Radiochemistry Manager

Open Findings:

None

Open Observations:

Observation A-06-ESQ-ATL-001-OXX.

Signed/Date_____/_____Signed/Date_____/_____
Assessor Lead Assessor

Assessment Note Number: A-06-ESQ-ATL-001-05

Assessor Name: Constantin Maciuca

Date of Assessment: April 10 through 20, 2006

Item Assessed: Document Control and Records Management

Documents Reviewed

- ATL-MP-1002, Rev. 4, "Quality Assurance Program Description"
- ATL-MP-1011, Rev. 2, "ATL Quality Assurance Project Plan for 222-S Laboratory"
- ATL-MP-1015, Rev. 0, "Quality Assurance Program Implementation Matrix"
- ATL-MP-1001, Rev. 6, "Procedures Acceptable for Use by the ATL 222-S Analytical Services Production Contractor"
- ATL-MP-1016, Rev. 2, "Interface Control Document Between ATL and CH2M HILL"
- ATL-MP-1005, Rev. 1, Technical Records Management Plan"
- ATL-MP-1012, Rev. 0, "ATL Procedure Compliance Expectations"
- ATL-312, Section 1.01, Rev. 0, "Administrative Procedure Control Process"
- ATL-312, Section 11.16, Rev. 0, "Technical Procedure Control Process"
- ATL-312, Section 1.41, "Review and Approval of ATL Documents"
- ATL-312, Section 5.01, Rev. 0, "ASPC Training Records, Scheduling, and Interfaces"

Data packages:

- Final Report for the semi-volatile organic analysis of a complex sampling, September 7, 2005
- Final Report for the Ammonia and Mercury samples from C-Farm COPC sampling, February 2006
- Final Report for Tank 241-AZ-102 Cores 316 and 317 in support of corrosion mitigation and criticality program, August 1, 2005 (re-issued)
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Records Inventory and Disposition Schedule (RIDS):

- RIDS No. 1/Rev. 0, Organization: Performance Assurance
- RIDS No. 2/Rev. 0, Organization: COO – Hot Cell Operations
- RIDS No. 3/Rev. 0, Organization: COO – Standards Laboratory
- Training records for seven ATL's employees (Managers, Chemists, and Technicians)

Observations and Assessments:

Document Control

The assessor reviewed the process procedures used by ATL for developing, issuing, revising, and controlling documents that specify technical requirements, quality requirements, or prescribe activities affecting quality to assess the adequacy of process implementation. The assessor reviewed the ATL plans and procedures within the document control program to assess compliance with the quality assurance requirements of the ATL Quality Assurance Program Description (QAPD), ATL-MP-1002. The assessor also examined the ATL management plan, ATL-MP-1001, Rev. 6, "Procedures Acceptable for Use by the

ATL 222-S Analytical Services Production Contractor," describing the procedures that were developed and maintained by other Hanford contractors and used by ATL to facilitate interfacing work activities in a facility managed by CH2M HILL. The assessor found ATL maintained multiple processes for controlling the different document types, these included technical procedures, administrative procedures, operating procedures, safeguards and security procedures.

The assessor identified procedural inadequacies related to the review and approval of ATL documents:

Procedure ATL-312, Section 1.41, Revision 0, "Review and Approval of ATL Documents" was incomplete and failed to provide a process:

- Section 2.0 Requirements was noted as being not applicable (N/A)
- Section 4.0 Procedure was noted as being N/A and provided no process for performing this activity or for interfacing with CH2m HILL provided services.

This issue is captured in assessment finding A-06-ESQ-ATL-001-F01.

The assessor also identified other procedural inconsistencies with regard to procedure validation activity and procedures adopted by ATL that were not listed the management plan:

- Management Plan ATL-MP-1001, "Procedures Acceptable for Use by the ATL 222-S Analytical Production Contractor," Appendix A, listed documents owned by other Hanford contractors used by ATL. The assessor identified procedures that were not listed in Appendix A (example: several HNF-PRO procedures were identified in ATL-312, Section 1.01 as being requirements documents, but these documents were not listed in Appendix A).
- Procedure ATL-312, Section 1.01, Revision 0, Administrative Procedure Control Process", made reference to a "procedure validation" activity (paragraph 1.2.3), but the assessor could not find a procedure validation process, or a definition, in any of the ATL procedures.

These issues are captured in assessment finding A-06-ESQ-ATL-001-F02.

Records Management

The assessor reviewed records management process implementing procedures and associated documentation documents describing the system for controlling the technical records, in-process documents, and maintaining the Records Inventory and Disposition Schedule (RIDS) to assess the adequacy of these processes in incorporating QAPD requirements. The assessor also reviewed a sample of several records to verify that records generation and maintenance were being performed in compliance with the established processes. The assessor interviewed responsible ATL personnel and found the records management process was performed in collaboration with CH2M HILL who providing records management support to ATL. CH2M HILL was responsible for records maintenance and records storage, and maintained procedure record files, facility training records, and analytical data packages.

The assessor observed that ATL did not use fire rated cabinets for the long term storage of records, as required by the QAPD.

1. The QAPD, Section 2.4 "Documents and Records", Subsection 2.4.2.2, paragraph 14, states: "When procedures require that records be available for processing, review, or use, the records may

be stored temporarily in a 1-hr fire rated container". Management Plan ATL-MP-1005, Revision 1, "Technical Records Management Plan", Section 2.1, "Quality Assurance Records" requires that "Fire-resistant cabinets bearing an Underwriters Laboratory label, or equivalent, certifying one-hour fire protection or better shall be used to store quality assurance (QA) records".

Contrary to this requirement, no fire-resistant containers were used by CH2M HILL to store the QA records. This issue is identified in finding A-06-ESQ-ATL-001-F01.

2. The QAPD, Section 2.4 "Documents and Records", Subsection 2.4.2.2, paragraph 13 reads: "Long-term storage of records shall meet one of the following requirements:
    a. Records shall be stored in 2-hr fire-rated Class B file containers meeting any of the following National Fire Protection Association standards: NFPA 232-1986, NFPA 232AM-1986, NFPA-232-1975, or NFPA-232-1980. Records shall be maintained in duplicate at two storage locations sufficiently remote from each other to eliminate the chance of exposure to a simultaneous hazard.

    b. Records not required for long-term reference shall be transferred to the Hanford Centralized Site Records Management Service, in accordance with Contract DE-AC27-05RV14548, Sec. H.6."

Paragraph 13 a. is the requirement for long-term storage, and activity not part of ATL work scope and is therefore not applicable to ATL. The long term storage requirements need to be removed from the QAPD. This issue is identified in finding A-06-ESQ-ATL-001-F02.

The assessor visited the facilities where the records were maintained by CH2M HILL and determined that ATL QAPD requirements for long term storage of records were not passed on to the CH2M HILL records custodians. The ATL QAPD applied NQA-1-1989 as the national consensus standard to implement the criteria of 10 CFR 830.122. CH2M HILL applied NQA-1-2000 which, for record storage, contains requirements less rigorous then the 1989 version. The application of these two versions of NQA-1 had created a disconnect that resulted in a situations of noncompliance for ATL, but not for CH2M HILL. The assessor found ATL was not aware that CH2M HILL provided services may not always meet ATL requirements. ATL had not performed any oversight of CH2M HILL to assure provided services meet requirements. The issue with program disconnects is captured in observation A-06-ESQ-ATL-001-O02. The issues with lack oversight and the deficient record storage are captured in finding A-06-ESQ-ATL-001-F02.

Conclusions:

The assessor concluded that the ATL plans and procedures that were in place adequately implemented the requirements of ATL-MP-1002, Rev. 4, "Quality Assurance Program Description", Section 2.4, Documents and Records, but the ATL document control process was determined to be inadequate because it was missing a key process for the review and approval of documents. The assessor concluded that records management processes were adequately implemented because the procedures associated with the generation, control, and maintenance of records met applicable requirements. The assessor concluded ATL was adequately implementing procedure established processes. The assessor also concluded ATL

record storage requirements were not adequately implemented by CH2M HILL because ATL records were mot maintained in fire rated cabinets as required by the ATL QAPD.

Personnel Interviewed:

H. L. Anastos, Chief Operating Officer
P. H. Bruce, Quality Assurance
L. E. Penfold, Quality Assurance/Quality Control
K. R. Fuller, CH2M HILL Analytical Projects
T. Y. Reavis, Records Management
K. K. Brey, CH2M HILL Laboratory Support Services

Open Findings:

A-06-ESQ-ATL-001-FXX

Open Observations:

Observation A-06-ESQ-ATL-001-OXX.

Signed/Date_____/_____Signed/Date_____/_____
Assessor Lead Assessor