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

NOV 2 0 2007

07-ESQ-214

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

Dear Dr. Hwang:

CONTRACT NO. DE-AC27-05RV14548 – ASSESSMENT REPORT A-07-ESQ-ATL-002 – ADVANCED TECHNOLOGIES AND LABORATORIES INTERNATIONAL, INC. (ATL) QUALITY ASSURANCE (QA) PROGRAM REVIEW - SEPTEMBER 24 THROUGH SEPTEMBER 28, 2007

This letter transmits the results of the U.S. Department of Energy (DOE), Office of River Protection (ORP) assessment of the ATL implementation of its QA Program for the operation of the 222-S Laboratory (attached). The assessment was performed from September 24 through 28, 2007. The purpose of the assessment was to determine effective implementation of selected elements from 10 CFR 830, Subpart A, "Quality Assurance," DOE O 414.1, "Quality Assurance," and ATL MP-1002, "ATL Quality Assurance Program Description" (QAPD). In addition, the assessment was to perform closure verification of corrective actions associated with DOE ORP Assessment A-06-ESQ-ATL-001 conducted in April 2006.

The Assessment Team determined The ATL QAPD adequately captured DOE O 414.1C requirements, but the ATL QA Program implementation and effectiveness was marginal. Improvement was noted from the DOE ORP Assessment conducted in April 2006 and corrective actions had been completed. However, the Assessment Team noted some key QA program processes require significant improvement, and ATL needs to improve on its implementation of established processes. The Assessment Team identified five findings and two Non-cited findings:

A-07-ESQ-ATL-002-F01: ATL Records Management Processes/Procedures are inadequate.

A-07-ESQ-ATL-002-F02: Implementation of the ATL Corrective Action Management Process does not meet requirements.

A-07-ESQ-ATL-002-F03: Implementation of the Independent Assessment Program does not meet QA requirements.

A-07-ESQ-ATL-002-F04: Implementation of the Management Assessment Program does not meet QA requirements.

A-07-ESQ-ATL-002-F05: Completed On-the-Job Training Checklists are incorrectly designated as an in-process record.

A-07-ESQ-ATL-002-NCF01: ATL Organization Roles and Responsibilities for the QA Organization do not fully meet requirements.

A-07-ESQ-ATL-002-NCF02: Nonconformance report procedure deficiencies identified (due to self-imposed non Nuclear Quality Assurance [NQA-1] process requirements).

In addition, the Assessment Team identified one observation and one Recommendation.

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

- The causes of the findings;
- The corrective actions taken to control or remove any adverse impact to identified noncompliance situations (remedial action) and the results achieved;
- The corrective actions that will be taken to identify the extent of condition, correct the cause(s), and prevent further findings; and
- The date when all corrective actions will be completed, verified, and compliance to applicable requirements achieved.

If you have any questions, please contact me, or your staff may contact Sam A. Vega, (509) 373-1240.

Sincerely,

William J. Taylor, Assistant Manager
Office of Environmental Safety and Quality

ESQ:SAV

Attachment

cc w/attach:
P. H. Bruce, ATL
K. J. Kuhl-Klinger, ATL

Attachment
07-ESQ-214
A-07-ESQ-ATL-002

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

ASSESSMENT:	Advanced Technologies and Laboratories International, Inc. Quality Assurance Program Assessment
REPORT:	A-07-ESQ-ATL-002
FACILITY:	222-S Laboratory
LOCATION:	Richland, Washington
DATES:	September 24 through 28, 2007
ASSESSORS	Sam A. Vega, Assessment Team Leader Jeff D. May, Assessor Mary A. Ryan, Assessor (in training) Leigh A. Gouveia, Assessor
APPROVED BY:	Patrick P. Carier, Team Lead Verification and Confirmation Official

EXECUTIVE SUMMARY

The U.S. Department of Energy (DOE), Office of River Protection (ORP), conducted an assessment of the Advanced Technologies and Laboratories International, Inc. (ATL) Quality Assurance (QA) Program from September 24 through 28, 2007. The purpose of the assessment was to determine effective implementation of selected elements of DOE O 414.1, "Quality Assurance," as specified in ATL MP-1002, "ATL Quality Assurance Program Description (QAPD)." In addition, the assessment was to perform closure verification of corrective actions associated with DOE ORP Assessment A-06-ESQ-ATL-001 conducted in April 2006.

The scope of the assessment was to evaluate if the ATL QA program elements and implementing procedures adequately address the DOE QA program requirements in the areas of organization, graded approach, personnel training and qualification, quality improvement, records management, work processes, management assessments, independent assessments, and suspect/counterfeit items. The assessment was also to determine if the assessed work activities were effective in meeting program requirements as established the ATL QAPD.

The Assessment Team determined The ATL QAPD adequately captured DOE O 414.1C requirements, but the ATL QA Program implementation and effectiveness was marginal. Improvement was noted from the DOE ORP Assessment conducted in April 2006 and corrective actions had been completed. However, the Assessment Team noted some key QA program processes require significant improvement, and ATL needs to improve on its implementation of established processes. The Assessment Team identified five findings and two Non-cited findings:

A-07-ESQ-222S-002-F01: ATL Records Management Processes/Procedures were inadequate and do not meet DOE requirements.

A-07-ESQ-222S-002-F02: Implementation of the ATL Corrective Action Management Process did not meet requirements.

A-07-ESQ-222S-002-F03: Implementation of the Independent Assessment Program did not meet QA requirements.

A-07-ESQ-222S-002-F04: Implementation of the Management Assessment Program did not meet QA requirements.

A-07-ESQ-222S-002-F05: Completed On-the-Job Training Checklists were incorrectly designated as an in-process record and are not maintained in accordance with requirements.

A-07-ESQ-222S-002-NCF01: ATL Organization Roles and Responsibilities for the QA Organization do not fully meet requirements.

A-07-ESQ-222S-002-NCF02: Nonconformance Report procedure deficiencies identified (due to self-imposed non Nuclear Quality Assurance [NQA-1] process requirements).

In addition, the Team identified one observation and one Recommendation.

Table of Contents

List of Acronyms

ATL	Advanced Technologies and Laboratories International, Inc.
CAMPATS	Corrective Action Management/Price-Anderson Amendments Act Tracking System
CFR	Code of Federal Regulations
CH2M HILL	CH2M HILL Hanford Group, Inc.
DOE	U.S. Department of Energy
FY	Fiscal Year
IA	Independent Assessment
ICPMS	Inductively Coupled Plasma Mass Spectrometer
IIF	Issue Identification Form
ITEM	Integrated Training Electronic Matrix
NCF	Non-Cited Findings
NCR	Nonconformance Report
NQA	Nuclear Quality Assurance
OJT	On-the-Job Training
ORP	Office of River Protection
PER	Problem Evaluation Report
PI	Performance Improvement
QA	Quality Assurance
QA Rule	10 CFR 830, Subpart A, "Quality Assurance"
QAPD	Quality Assurance Program Description
RIDS	Records Inventory and Disposal System
S/CI	Suspect/Counterfeit Items

1.0 DETAILS

This assessment evaluated ATL's QA program elements and implementing procedures to determine that they adequately address the U.S. Department of Energy (DOE) QA program requirements in the areas of organization and reporting chain, graded approach, personnel training and qualification, quality improvement, documents and records, work processes, management assessments, independent assessments, and Suspect/Counterfeit Items (S/CI) prevention. The assessment also evaluated procedure implementation and the effectiveness of the assessed work activities in meeting program requirements in 10 Code of Federal Regulations (CFR) 830, Subpart A, "Quality Assurance," DOE O 414.1, "Quality Assurance," as established in their Quality Assurance Program Description (QAPD).

Following is a brief discussion of the assessment results. For more details of the discussed findings, Non-Cited Findings (NCF), observations, and recommendations, see the discussion in Section 3 of this report titled "Findings and Observations."

2.0 PROGRAM OVERVIEW

Organization

The Team reviewed the ATL procedures describing the ATL organization and responsibilities, the ATL QAPD, and organization charts. The team also interviewed ATL management.

The Team determined that ATL had not adequately assigned responsibility for development, implementation, assessment, and improvement of the QA program to a senior level manager as required in DOE O 414.1C. Procedure ATL-MP-1007, "ATL Job and Organizational Descriptions," assigned these responsibilities to an ATL staff position titled "Quality Assurance Program Manager." The ATL Organization chart contained a senior level organizational manager (Senior Quality Assurance Manager), who the QA Program Manager reported to, but according to ATL-MP-1007, the Senior QA Manager was not responsible for development, implementation, assessment, and improvement of the QA program. In addition, the position was vacant. The ATL Deputy Manager was functioning as both the Deputy and the QA Manager, which was a potential issue with the independence required in Nuclear Quality Assurance (NQA) NQA-1-2000 because the Deputy Manager had cost and schedule responsibilities. The Team did not identify any evidence indicating there existed issue with independence.

At the time of the assessment, ATL was in the process of revising ATL-MP-1007. Discussions with the ATL Deputy Manager indicated that the intended changes would address the issue with the QA organization and the roles and responsibilities. ATL also indicated they were hiring more QA personnel and had plans to staff the Senior Quality Assurance Manager position. ATL initiated Issue Identification Form (IIF) ATL-2007-0270 to address the deficiencies with ATL-MP-1007 and the organization (completion date is November 29, 2007). DOE Office of River Protection (ORP) will perform closure verification of this IIF when actions are completed. NCF A-07-ESQ-222S-002- NCF01 was issued to document this discrepancy.

Conclusions:

The Assessment Team determined ATL established roles and responsibilities were not adequate and implementation did not meet DOE O 414.1C. The organizational structure established did not assure the independence of the QA function would be maintained as required by NQA-1-2000.

Graded Approach

The Team reviewed the ATL procedures that describe implementation of the graded approach to determine if they adequately reflected the graded approach requirements; reviewed a sample of documents associated with the application of the graded approach; and interviewed personnel who were involved in application of the graded approach.

The Team determined the ATL procedures adequately implemented the requirements. The procedures had been adequately revised to resolve the deficiencies identified by DOE ORP during the assessment conducted in April 2006.

The Team found that QA controls were an integral part of the analytical work process, and because of the nature and scope of analytical work and contract requirements, grading was not applied to analytical activities. The Team found that appropriate emphasis was placed on determining risks associated with hazards (such as radiological, chemical properties, toxic wastes, operational, reactivity, etc.), and the development of appropriate work controls to minimize the risks associated with the identified hazards was adequate.

For administrative purposes, the grading of QA requirements was based on the nature of the work and risk involved. The grading process was accomplished by deliberate planning and was based on activity or facility specific factors such as those described in DOE O 414.1C and more specifically in DOE G 414.1-2A.

Conclusion:

The Team did not identify any issues in this area. Grading activities were satisfactorily implemented and effective.

Personnel Training and Qualification

The Team reviewed a sample of individual position descriptions, and training information contained in the Integrated Training Electronic Matrix (ITEM). In addition, the Team evaluated five individual training packages for four ATL positions. On-The-Job Training (OJT) records for two Chemists were also evaluated, and the Team observed the storage methods and procedures for the OJT records.

The Team did not identify any issues with procedures or the implementation of the training processes. However, the Team noted that the ATL record documenting completion of OJT of analytical chemists and technicians also contains additional signature blocks to document completion of continuing training activities such as completion of OJT on subsequent revisions to the procedure. Through interview and reviewing record management procedures, the Team discovered that ATL maintained these original OJT records as in-process records until all the continuing training signature blocks were completed. ATL Procedure ATL-312, Section 8.09, "Records Management Process," states that OJT records are maintained as in-process documents for as long as necessary to monitor employee-training status. Some of these original OJT records dated back to August 1999. The Team determined that these records of completed OJT met the NQA-1 definition of a completed QA record, not an in-process record, and that the storage practices applied by ATL did not satisfy records storage requirements of QA records. Finding A-07-ESQ-222S-002-F05 was issued to document this discrepancy with the classification of OJT records.

Storage of these OJT records was identified as a problem during the April 2006 DOE ORP Assessment of ATL. It was also an issue in the previous 2005 assessment of the laboratory conducted jointly by CH2M HILL Hanford Group, Inc. (CH2M HILL) and ORP (before ATL assumed responsibility of the analytical work). Past ATL corrective actions applied were not effective.

Conclusion:

The Team determined that the area of Personnel Training and Qualification was adequate, satisfactorily implemented, and effective except for the storage of OJT records as discussed above.

Quality Improvement

The Team reviewed the following ATL quality improvement processes; Lessons Learned, Corrective Action Management, and Nonconformance Reporting. The Team reviewed the ATL procedures related to these processes; reviewed two lessons learned reports and 17 deficiency report, and interviewed ATL staff and management responsible for these activities. The Team verified procedures addressing Lessons Learned, Corrective Action Management, and Nonconformance Reporting for were adequately revised to resolve the deficiencies identified by DOE ORP during the assessment conducted in April 2006.

Lessons Learned:

The team determined ATL Procedure ATL-312, Section 10.05, "Lessons Learned," adequately described the lessons learned program and addressed the requirements established by DOE Orders. In addition, the procedure adequately addressed the deficiencies identified by DOE ORP during its April 2006 assessment (A-06-ESQ-ATL-001).

The Team found that the current Lessons Learned Coordinator has been on the job for only a short time (less than two weeks).

The Team reviewed the Lessons Learned Review Log, which commenced on August 1, 2006, and was developed in response to the April 2006 DOE ORP assessment. The log contained over 650 entries from numerous external sources. The team determined ATL was doing an adequate job of reviewing external sources for potential lessons learned. However, the log did not record the review of the two internal lessons learned reports generated in 2007 as required by ATL-312, Section 10.05. The log did not reflect the status of recommended actions resulting from the performed reviews.

The Team reviewed two examples of recent lesson learned reports issued in June and July of 2007. The team identified a number of procedure discrepancies with the handling of these reports, and the Team also noted that ATL had not established performance metrics as required by the procedure. However, because the Lessons Learned Coordinator was new, because the governing procedure was adequate but in place for only four months, and because there was only two lessons learned reports issued since the procedure was changed, Recommendation A-07-ESQ-222S-002-R01 was issued to recommend that ATL apply a concerted effort to improve implementation of its Lessons Learned Program.

Conclusions:

The Team determined the procedure adequately captured requirements. However, the Lessons Learned Program had undergone recent staff changes, the controlling procedure went through a major revision in May 2007, and only two lessons learned reports were issued since the procedure was revised. As a result, the Team could not determine current program effectiveness, but recommends the Lessons Learned Program receives appropriate management attention to assure its future effectiveness.

Nonconformance Reporting:

The Team determined procedure ATL Procedure ATL-312, Section 8.03, "Nonconforming Item Reporting and Control," adequately implemented NQA-1-2000 requirements for identifying, reporting, controlling, evaluating, and the disposition of nonconforming items. The procedure was adequately revised to resolve the deficiencies identified by DOE ORP during the assessment conducted in April 2006.

The Team noted that the procedure was cumbersome and required activities beyond what NQA-1-2000 stipulated. The Team determined that ATL adequately implemented the activities required by NQA-1. However, activities required by the procedure that went beyond NQA-1 were not always adequately performed. For example, ATL procedures require for nonconforming items significance classification, causal analysis, extent of condition, and corrective actions; activities which were not required by NQA-1-2000 or the ATL QAPD. ATL initiated IIF ATL-2007-0269 to revise ATL-312, Section 8.03 to remove self-imposed activities that go beyond requirements and render the process too cumbersome. ORP will perform closure verification of this IIF when actions are completed. NCF A-07-ESQ-222S-002-NCF02 was issued to document this discrepancy.

Conclusion:

The Team determined Procedure ATL-312, Section 8.03 adequately captured requirements, and that process implementation satisfied NQA-1 requirements. However, ATL was not implementing cumbersome procedure activities that went beyond what NQA-1 required. Because ATL was not implementing all required activities prescribed in their procedure, the Team determined implementation of the ATL nonconformance reporting process was not effective.

Corrective Action Management:

The team reviewed Procedure ATL-312, Section 9.04, "ATL Corrective Action Management," and determined it was adequate in capturing requirements. The Team did identify minor improvements or needed clarifications to the procedure, but these did not affect the overall determination that the procedure was adequate. Procedure improvements were discussed with the contractor.

The Team also assessed procedure implementation by reviewing 17 IIF forms. The Team identified several instances where required activities were not implemented as specified in the procedure for IIF with deficiencies that met the NQA-1 definition of "conditions adverse to quality." Examples include inadequate or missing cause determination; inadequate or missing extent of condition; corrective actions not sufficient to address investigation results or cause analysis; and the description of the issues was not adequate. Finding A-07-ESQ-222S-002-F02 was issued to document this discrepancy.

Conclusion:

The team determined that ATL-312, Section 9.04 adequately captured QAPD requirements. However, the Team determined implementation of procedures was not adequate or effective. Because procedures were not followed, deficient conditions were not adequately documented, the full impact of a deficiency was not determined because extent of condition evaluations were inadequate or not performed, established corrective actions were incomplete or not adequate to preventing recurrence of the noted deficiency.

Records

The Team reviewed ATL records management Procedure ATL-312, Section 8.09, and their Records Management Plan, ATL-1005. The team also reviewed record storage locations and determined procedures did not establish adequate records management processes, and ATL was not managing its records in a sufficient manner to meet the intent of the ATL QAPD and NQA-1 requirements that require records to be "protected from damage or loss." The Team determined the following:

- ATL procedures did not contain a process for managing and storing records; ATL procedures primarily address the Records Inventory and Disposal System (RIDS) and related activities. They did not adequately address the records storage stations maintained at manager's offices and at MO-409.

- ATL was not managing its records station(s); CH2M HILL, by contract, maintained a records station for ATL in MO-409, but ATL was not managing the station, and was not performing oversight of that activity.

- ATL's process for classification of QA records (lifetime and non-permanent) was not adequate; procedures inappropriately claimed ATL does not have lifetime QA records.

- ATL did not have a record transmittal process for transferring analytical records to CH2M HILL.

Finding A-07-ESQ-222S-002-F01 was issued to document this discrepancy with records management.

ATL conducted an internal assessment, 2007-IA-003, "Records Management," which identified four IIFs. However, that assessment only identified process improvements and not the program deficiencies noted in this assessment.

Conclusions:

The team determined ATL had not adequately implemented records management requirements, had not developed adequate processes and controls for managing their record stations, had not established formal processes for transmitting records to CH2M HILL. The team determined established records management processes were not effective in meeting requirements.

Work Processes

The Team observed the labeling methods employed to identify reagents formulated in the lab and the methods utilized to maintain these chemicals to prevent their damage, loss, or deterioration. The Team also reviewed a sample of calibration records for the Inductively Coupled Plasma Mass Spectrometer (ICPMS) and interviews were conducted with an

ATL chemist and a project coordinator to evaluate implementation of the laboratory work processes. No issues with work process activities reviewed were identified.

Conclusion:

No Findings or Observation were noted and the Team determined that the area of Work Processes were satisfactorily implemented, and effective.

Management Assessment

The Team reviewed the ATL procedures that describe the management assessment program, five management assessments reports, and documents related to the reviewed assessments. The Team also reviewed training records and resumes of the lead assessors who conducted the management assessments, evaluated the lesson plan for assessment technique training, and the Fiscal Year (FY) 2006 and FY 2007 assessment schedules. The Team interviewed the personnel who were involved in the administration of the program and who performed management assessments.

The Team determined ATL procedures adequately addressed ATL QAPD requirements established by the 10 Code of Federal Regulations (CFR) 830, Subpart A, "Quality Assurance," (QA Rule) and various DOE Orders. The procedures were adequately revised to resolve the deficiencies identified by DOE ORP during the April 2006 assessment.

The team reviewed the assessment schedules for FY 2006 and FY 2007. Two of four FY 2006 scheduled assessments were completed. Three additional management assessments were conducted in FY 2007. At the time of the assessment, three management assessments were scheduled for FY 2008. The Team determined ATL was not adequately managing the schedule to assure scheduled assessments were performed or that assessment topics satisfied requirements. The Team did note that additional managements assessments (not originally scheduled) were conducted, but the majority of the management assessments performed were focused on programmatic and/or requirement-based topics, rather than focusing on organizational level reviews required by DOE O 414.1C. In addition, no management assessments were conducted in FY 2007 to verify effective implementation of the QA program within each organization. Also, the Team noted that all ATL staff designated as a "managers" in the organization chart had not performed management assessments.

Assessment schedule development does not appear to occur annually as procedures indicated, rather the schedule is a rolling schedule that is revised periodically. According to the Deputy Project Manager, the schedule was reviewed by a committee quarterly. However, ATL did not maintain documentation to support the basis for changes in the schedule, and the Team could not find evidence that the committee is focused on assuring assessment requirements are met. There was also no documentation of review and approval on the original schedules. The Team determined procedures do no provide adequate detail to address the schedule management activities applied by ATL.

The Team determined the reports and plans of the management assessments conducted during FY 2007 adequately implemented procedure requirements for format, content, and review and approval requirements. Assessment findings, except for one instance, were processed into the corrective action management system as required by procedures. Also required signatures were missing from completed management assessment reports.

The Team determined training and qualification requirements were adequate and all but one of the four ATL leads reviewed were adequately trained. One Lead assessor had not taken the required examination. The required examination was completed satisfactorily during the assessment and no finding was issued to document this discrepancy. The computer based training lesson plan used for training ATL personnel in assessment techniques was reviewed and found to be satisfactory. In addition, the resumes of the lead assessors were reviewed and it was determined that the personnel were experienced in the areas they assessed.

The team identified a discrepancy between MP-1020 and ATL-312, Section 9.12, because they are not consistent in specifying training requirements. All the issues discussed in this section were captured in Finding A-07-ESQ-222S-002-F04.

Conclusions:

The Team determined that implementation of the ATL Management Assessment Program was not yet fully effective; not all scheduled assessments were performed; schedule changes were not formal (process was not in procedures and justification for changes were not documented); all managers were not conducting or participating in management assessments; management assessments conducted did not meet the intent of DOE requirements; and deficiencies were noted in the completeness of the resulting documentation.

Independent Assessments

The Team reviewed the ATL procedures that describe the independent assessment program, and reviewed three FY 2007 independent assessments reports and related documents. The team also reviewed training and qualification records and resume of the lead assessor for each of the assessments reviewed, reviewed the lesson plan for assessment technique training, reviewed the FY 2006 and FY 2007 assessment schedules, and interviewed the personnel responsible for the administering the program and for performing independent assessments.

The Team determined ATL procedures adequately addressed the independent assessment requirements in the QAPD established by the QA Rule and DOE Orders. The procedures were adequately revised to resolve the deficiencies identified by DOE ORP during the April 2006 assessment.

The Team reviewed the assessment schedules for FY 2006 through FY 2007. In FY 2006, when the independent assessment program was first implemented, no assessments were conducted. Nine assessments were scheduled since the last DOE ORP Assessment of ATL in April 2006. Only two of the nine were performed. At the time of this assessment, there were no assessments scheduled for FY 2008.

The Team determined ATL management was not adequately managing assessment commitments. According to the Deputy Project Manager, the schedule was a rolling schedule that was reviewed at quarterly meetings where commitments were assessed and schedule changes were managed. However, there was no documented evidence to support the basis for schedule changes, nor was there documented evidence that the original annual schedule was review and approval. ATL procedures did not contain the process for managing the assessment schedule discussed by the Deputy Project Manager. The Team also could not find evidence that ATL was actively managing the QAPD requirement to assess all QA program elements within a three year cycle. Past performance, discussions with ATL management, and staffing levels indicated to the team that ATL could not meet that commitment. In addition, ATL had not scheduled or performed any assessments of the services provided by CH2M HILL.

The Team's review of three assessment reports resulted in identifying several deficiencies with procedure implementation that included missing or unsigned assessment plans, missing checklists, no statement of assessed program effectiveness, and findings and observations not entered into Corrective Action Management/Price-Anderson Amendment Act Tracking System (CAMPATS). All the discrepancies noted in this section were included in Finding A-07-ESQ-222S-002-F03.

The team determined procedure requirements for education, experience, training, qualification, certification of Lead Assessors were adequately implemented. However, one minor problem was noted with the requalification one lead assessor. The requalification date on the qualification record was May 2006 instead of May 2007. This was corrected during the assessment.

Conclusions:

The team determined implementing procedures adequately captured QAPD requirements. ATL implementation of the Independent Assessment Program was not effective; the number of assessments performed over the last two years was not adequate to ensure that all QA program elements will be evaluated over a three-year period; Implementation of assessment documentation requirements was not always adequate; and assessment scheduled commitments were not adequately managed.

S/CI Prevention

The Team reviewed the ATL procedure that governs the S/CI prevention program and interviewed the ATL person who manages the S/CI.

The team determined ATL procedures were adequate in meeting QAPD requirements, which implement DOE O 414.1C requirements for S/CI. The Team found no issues with the methods applied by ATL to screen for S/CIs at receipt inspection, and for evaluating other reported noncompliances. The Team did note that evaluation/screening results were documented via e-mails and maintained informally. This documentation should be maintained in a more formal manner. Observation A-07-ESQ-222S-002-O01 was issued to identify the need to formalize documentation methods applied to S/CI evaluation/screening.

Conclusion:

Aside from the observation noted, the team determined that ATL's procedures were adequate and that the S/CI prevention program implementation was adequate, satisfactorily implemented, and effective. However, the implementation of this program continues to mature as the ATL knowledge base regarding S/CI control continues to increase.

3.0 FINDINGS AND OBSERVATIONS:

Finding A-07-ESQ-222S-002-F01: ATL Records Management Processes/Procedures are inadequate.

Requirements:

ATL-MP-1002, "Quality Assurance Program Description," Section 17.2.1, states, "Records shall furnish documentary evidence that items or activities meet specified quality requirements. Records shall be identified, generated, authenticated, maintained, and their final disposition specified. Requirements and responsibilities for these activities shall be documented. A records system shall be maintained in accordance with written procedures, instructions, or other documentation. Requirements and responsibilities for record transmittal, distribution, retention, maintenance, and disposition shall be established and documented. Records shall be distributed, handled, and controlled in accordance with written procedures."

ATL-MP-1002, "Quality Assurance Program Description," Section 17.2.4 states, "Lifetime records are those that meet one or more of the following criteria: Those which would be of significant value in demonstrating capability for safe operation; Those which would be of significant value in maintaining, reworking, repairing, replacing, or modifying an item; Those which would be of significant value in determining the cause of an accident or malfunction of an item; Those which would provide required baseline data for in service inspections; and project personnel exposure records."

ATL-MP-1002, "Quality Assurance Program Description," Section 17.2.5, states, "The organization responsible for the receipt of records shall designate a person or position responsible for receiving records. The designee shall be responsible for organizing and

implementing a system of receipt control of records for permanent and temporary storage."

ATL-MP-1002, "Quality Assurance Program Description," Section 17.2.6, states, "Records shall be stored in facilities, containers, or a combination thereof, constructed and maintained in a manner which minimizes the risk of damage or destruction from the following: Natural disasters such as winds, floods, or fires; Environmental conditions such as high and low temperatures and humidity; Infestation of insects, mold, or rodents."

Discussion:

The Team determined ATL Procedure ATL-312, Section 8.09, and the records management plan, ATL-1005, mainly provided a process for managing RIDS. Procedures provided some dialogue about managing records and direction to protect records but these procedures lacked actual processes for managing and storing records and for maintaining records stations. Interviews with ATL responsible staff and management indicated ATL managed only in-process records and therefore did not require a records storage process. The Team did not agree with ATL's assumption that they only manage in-process records. The Team found that ATL managers maintained OJT training records in their offices, and analytical records were maintained in building MO-409. Training and analytical records are QA records definition in the QAPD.

The Team interviewed CH2M HILL management responsible for maintaining the ATL records in building MO-409 and found that CH2M HILL was managing ATL's analytical records for ATL as an activity contracted by ATL. As such, ATL was considered the owners of those records. However, ATL was not aware they were responsible and had never assumed responsibility for those records. ATL procedures did not provide sufficient direction for establishing and maintaining a records station (lacked direction for records receipt control, indexing, access control, etc.), and ATL had never performed oversight of the contracted activities performed at the MO-409 records station. The CH2M HILL records coordinator maintained analytical records in accordance to CH2M HILL processes, which was what he was used to doing.

ATL records management Procedure ATL-312, Section 8.09, indicated that "None of ATL quality assurance records meet NQA-1-2000 Criteria of "lifetime" or "permanent" records and are therefore maintained as "nonpermanent" records." When discussed with ATL, the Contractor indicated the determination was made by comparing ATL generated records with the sample list of lifetime records provided in NQA-1-2000, Appendix 17A-1, "Nonmandatory Guidance on Quality Assurance Records." Because none of the examples included records associated with analytical activities, and because QA manuals and nonconformance reports were listed as operational records (ATL does not do facility operation activities), ATL determined none of their records were lifetime QA records. The Team did not agree with ATL. The lifetime record determination was to be made by using the criteria provided in NQA-1-2000, Part 1, Requirement 17, which the ATL QAPD had incorporated. The team determined ATL had several record types that were lifetime records (for example the QAPD, nonconformance reports, etc.).

The Team determined that ATL procedures did not assign a person/organization responsible for receiving records. Procedures did not provide a system of receipt control of records for temporary storage (RIDS processes provided receipt control for permanent storage). Records were just given to the records station in MO-409, and there was no evidence that the records coordinator at MO-409 verified records received were adequate and complete, or that any other receipt control activities were performed. The assessment Team also noted that there was no formal process for transmitting records between ATL and CH2M HILL. ATL does not keep track of records submitted to CH2M HILL and CH2M HILL does not perform receipt control activities of ALT records received. From interviews with ATL and CH2M HILL, the Team determined that because both contractors use the same records station, this transfer of records was very informal, and it was confusing to determine when ownership of a record is actually transferred. CH2M HILL generated a Problem Evaluation Report (PER) to address deficiencies within their processes.

ATL had self-identified some problems with the records management process in Independent Assessment (IA) IA-2007-003, and were in the process of revising procedures, but ATL did not identify the programmatic issues noted in this finding.

Finding A-07-ESQ-222S-002-F02: Implementation of the ATL Corrective Action Management Process does not meet requirements.

Requirements:

DOE O 414.1C, "Quality Assurance," Attachment 2, Section 3, Item c. (3), "Identify the cause of problems, and include prevention of recurrence as a part of corrective action planning."

DOE O 226.1, Attachment A, "Contractors Assurance System," 1.(4) states the contractor is to have a system for "issues management, including causal analysis, identification of corrective actions and recurrence controls, corrective action tracking and monitoring, closure of corrective actions and verification of effectiveness, trend analysis, and identification of continuous improvement opportunities."

ATL-MP-1002, "Quality Assurance Program Description," Section 16.2.1, states "Conditions adverse to quality shall be identified promptly and corrected as soon as practicable. In the case of a significant condition adverse to quality, the cause of the condition shall be determined and corrective action taken to preclude recurrence."

ATL-312, Section 9.04, "ATL Corrective Action Management," Section 5.0 requires deficiencies to be entered into CAMPATS with a description that provides sufficient information to allow the reader to understand the issue; a cause analysis, an extent of condition, and corrective actions (including remedial actions) to prevent repetition.

Discussion:

The Team reviewed 17 IIFs. Five of these met the NQA-1-2000 definition for "conditions adverse to quality." Of these five, the Team determined that the resolution of four of these was not in accordance with ATL procedures, and did not meet the intent of the ATL QAPD, NQA-1, or DOE requirements. Following are some examples of what the Team noted:

- ATL-2007-0224:
  1. The description indicated that the IIF addresses three deficiencies identified in an annual IH audit; no actual description of the individual deficiencies was provided in the description block.

  2. The apparent cause discussion was inadequate; it did not provide a cause but an opinion; "ISO 17025 remains a relatively new standard for ATL. It is not surprising that there remain some requirements where compliance is lacking."

  3. Corrective actions only addressed the condition reported in the IH audit report and did not attempt to fix the cause, which, based on the cause analysis provided, appeared to be a problem with ATL implementing new requirements.

- ATL-2006-0087:
  1. The required "Apparent Cause" was not provided. Only generic cause codes were included with no explanation of what they mean.

  2. There was no extent of condition provided.

  3. There were only two corrective actions established; the first corrective action required a "feasibility review" be conducted, and the second corrective action requires a lessons learned be generated of the "feasibility review" results. There were no corrective actions established to fix anything.

  4. ATL conducted an event investigation of the deficiency described in this IIF, but ATL failed to incorporate the results of the investigations or the corrective actions prescribed in the investigation report into the IIF.

- ATL-2006-0285:
  1. The issue description provided was a two-page dissertation describing a process for purchasing compresses gas, which mentioned problems with that process, evaluation needs, laboratory impact, etc. The description did not provide a clear statement of what the actual deficiency was. The Team could only determine the actual deficiency through interviews and by reading the violated requirement referenced in the "Requirement" block of the IIF which indicated compressed gas bottles were required to be labeled; the issue was inadequate or missing labeling of compressed gas bottles.

2. The extent of condition provides more discussion about problems with inadequate tracking of compressed gasses. However, this discussion did not explain what was done to evaluate extent of condition nor does it discuss the results of the extent of condition evaluation. It was also not clear how the provided discussion was a result of an extent of condition evaluation, and it did not relate the lack of tracking to the IIF issue description that compressed gases were not labeled.

3. The three corrective actions established were set to be completed 12 months after the issue was identified. No immediate or compensatory measures were put in place. The described issue was related to inadequate labeling of compressed gas bottles and inadequate control of compressed gases; situations with a potential to significantly impact safety and product quality if not controlled.

4. The significance level of the IIF was Requires Resolution instead of significant. The ATL procedure indicated that issues that were "worker safety issues" received a classification of "significant." NQA-1 required deficiencies with a potential to impact worker safety were significant. The Team felt that lack of labeling and tracking of compressed gas bottles had the potential to impact worker safety if not promptly addressed.

- ATL-2006-0316;
  1. The significance of this deficiency was designated as "Track to Completion." The procedure indicated that this significance classification was applied to only minor issues needing only correcting. This IIF identified a maintenance process noncompliances that was not minor, and the Team determined the significance assigned to this IIF was incorrect. When this was discussed with ATL, the Contractor responded that this was a CH2M HILL process but corrective actions on ATL's part were required, thus the "Track to Completion" designation. This application of the process was not discussed in the ATL procedure.

In addition to the above examples, ATL conducted an assessment of their records management program (2007-IA-003, "Records Management") which identified four IIFs (ATL-2007-0233, ATL-2007-0234, ATL-220-0235, and ATL-2007-0236) that were classified as Performance Improvement (PI) or Track to Completion. These IIFs identified requirement deficiencies and were improperly classified. Each of the three IIFs designated a PI included the following explanation; "Even though a noncompliance exists, the assessor determined that unless the critical or safety-related issue was found, all issues would be designated a PI to allow actions necessary to raise the baseline in a timely manner." This is not in accordance to ATL procedures, the QAPD, or DOE requirements. By designating these noncompliances as PIs there is no causal analysis, extent of condition, etc.

ATL management indicated they encouraged some of the above mentioned activities because closure of the deficiency was expedited.

A-07-ESQ-222S-002-F03: Implementation of the Independent Assessment Program does not meet QA requirements.

Requirements:

ATL-MP-1002, Section 18.1, "Independent Assessments," provide requirements for the performance of independent assessments as follows:

- Assessments shall be scheduled in a manner to provide coverage and coordination with ongoing work process activities and at a frequency commensurate with the status and importance of the activity and the schedule shall be periodically reviewed and revised, as necessary, to ensure coverage is current. (18.1.2.1)

- Assessment plans shall be developed and documented for each assessment and the plan shall identify the assessment scope, requirements, assessment personnel, activities to be assessed, organizations to be notified, applicable documents, schedule, and written implementing documents/checklists to be used. (18.1.2.2)

- The assessment report shall, among other things, include a statement on the effectiveness of the elements assessed. (18.1.2.6)

- Each finding or observation shall be processed in accordance with the Corrective Action Management System. (18.1.2.6)

- Independent assessment records shall include assessment plans, assessment reports, written replies, and the record of completion of corrective action. (18.1.2.9)

ATL-MP-1011, Section 13.1, "Quality Assurance Program Audits," provides requirements for the performance of independent assessments as follows:

- QA audits are scheduled in a manner to provide coverage and coordination with ongoing QA program activities starting as early in the activity as practical.

- The audit schedule is reviewed annually and revised as necessary.

- Preparation of a documented audit plan to identify the audit scope, requirements, audit personnel, activities to be audited, organizations to be notified, applicable documents, schedule, and written procedures/checklists to be used.

- Development of an audit report to include, among other things, a statement on effectiveness of the areas audited.

ATL-MP-1020, Section 4.1, "Independent Assessments," requires:

- QA Program Assessments to be scheduled such that a complete QA Program assessment is accomplished every three years.

- The training and qualification program be scheduled once every two years.

ATL-312, Section 9.13, "Performance of Independent Assessments," provides requirements for conducting independent assessments as follows:

- Schedule independent assessment at a frequency commensurate with the status of ongoing program activities. (4.1)

- Develop an assessment plan to identify the assessment scope, assessment personnel, activities to be assessed, organizations to be notified, applicable documents and requirements, and duration of the assessment. (4.2.2)

Discussion:

The Team determined ATL management was not adequately managing assessment commitments. Review of the assessment schedules for FY 2005 through FY 2007 revealed that nine assessments had been scheduled since the last DOE ORP Assessment of ATL in April 2006, but only two of the nine scheduled assessments were conducted. In FY 2006, when the independent assessment program was initially implemented, ATL did not conduct any independent assessments. At the time of the assessment, there were no assessments scheduled for FY 2008. According to the Deputy Project Manager, the schedule was a rolling schedule that was reviewed at quarterly meetings where commitments were assessed and schedule changes were managed. However, there was no documented evidence to support the basis for schedule changes, nor was there documented evidence that the original annual schedule was review and approval. ATL procedures did not contain the process for managing the assessment schedule discussed by the Deputy Project Manager.

The Team could not find evidence that ATL was actively managing the QAPD requirement to assess all QA program elements within a three year cycle. Past performance, discussions with ATL management, and staffing levels indicated to the team that ATL could not meet that commitment. Also, ATL had not scheduled or performed any assessments of the contracted services provided by CH2M HILL.

The Team reviewed three assessment reports and identified the following deficiencies:

- An assessment plan is not available for Independent Assessment IA-2007-003.

- The assessment plans were not signed by the lead assessor for IA-2007-001 & IA-2007-002.

- Assessment checklists/annotated procedures are not included in assessment plans for IA-2007-001 & IA-2007-002.

- A statement of effectiveness of the elements assessed is not included in the report for IA-2007-003.

- Findings and observations were not entered into CAMPATS for IA-2007-001 (procedure revisions were planned to resolve the issue, therefore, no CAMPAT was issued to track the procedure revisions to ensure completion).

Finding A-07-ESQ-222S-002-F04: Implementation of the Management Assessment Program does not meet QA requirements.

Requirements:
MP-1002, "Quality Assurance Program Description," Section 18.2, "Management Assessments," provided requirements for the management assessment program and required:

- All levels of management are to plan and conduct assessments to evaluate their organizations performance. (18.2.1)

- Management shall regularly assess the adequacy and implementation of the QA program. (18.2.2)

- Management assessments shall be conducted according to an assessment schedule and shall be focused on management systems and processes that are important to achieving organizational success. (18.2.2)

- Findings and observations must be documented and processed in accordance with the corrective action management system. (18.2.2)

MP-1011, "ATL Quality Assurance Project Plan for 222-S Laboratory," Section 13.2, "Management System Assessments," required managers to schedule assessments annually.

MP-1020, Section 4.2, "Management Assessments," required:

- Formal scheduling of management assessments and that they be integrated with other scheduled assessments.

- Management assessments are conducted by all levels of management in accordance with approved procedures.

- Management assessments are conducted by managers knowledgeable in the areas they assess and that they are trained in assessment techniques and are knowledgeable of assessment program requirements.

ATL 312, Section 9.14, "Performance of Management Assessments," provides requirements for:

- The performance of an annual planning meeting and resultant management assessment schedule. (4.1.1)

- The signatures of the assessment team leader and manager of the area being assessed documented on the management assessment plan. (4.2.1)

- Documenting findings and observations in accordance with the ATL Corrective Action Management System. (4.2.3)

Discussion:

Contrary to the above requirements, the Team identified the following discrepancies: The team reviewed the assessment schedules for FY 2006 and FY 2007. Two of four FY 2006 scheduled assessments were completed. Three additional management assessments were conducted in FY 2007. At the time of the assessment, three management assessments were scheduled for FY 2008. The Team determined ATL was not adequately managing the schedule to assure scheduled assessments were performed or that assessment topics satisfied requirements. The Team did note that additional managements assessments (not originally scheduled) were conducted, but the majority of the management assessments performed were focused on programmatic and/or requirement-based topics, rather than focusing on organizational level reviews required by DOE O 414.1C. In addition, no management assessments were conducted in FY 2007 to verify effective implementation of the QA program within each organization. Also, the Team noted that all ATL staff designated as a "managers" in the organization chart had not performed management assessments.

Assessment schedule development does not appear to occur annually as procedures indicated, rather the schedule is a rolling schedule that is revised periodically. According to the Deputy Project Manager, the schedule was reviewed by a committee quarterly. However, ATL did not maintain documentation to support the basis for changes in the schedule, and the Team could not find evidence that the committee is focused on assuring assessment requirements are met. There was also no documentation of review and approval on the original schedules. The Team determined procedures do not provide adequate detail to address the schedule management activities applied by ATL.

The following deficiencies with the management assessment reports issued were identified:

- All four of the management assessment plans reviewed did not contain the required signatures of the assessment team leader and the manager of the organization being assessed.

- Two observations from Management Assessment MA-MU-06-05, "Training at 222-S Laboratory," were not entered into CAMPATS.

In addition, The Team identified discrepancies between MP-1020 and ATL-312, Section 9.12, regarding the training and qualification of lead assessors:

- MP-1020 requires lead assessors to be knowledgeable in the area to be assessed ***and*** that they are trained in assessment techniques and the assessment program.

- ATL-312, Section 9.12, requires lead assessors meet ***one*** or more of the following:
  - 1 year experience in the area to be assessed;
  - Orientation to ATL-312, Section 9.14;
  - OJT under the guidance of a manager experienced in performing management assessments.

- ATL-312, Section 9.12, would allow a person with one year of experience in the area to be assessed to conduct an assessment without training in assessment techniques and the assessment program.

Finding A-07-ESQ-222S-002-F05: Completed OJT Checklists are incorrectly designated as an in-process record.

Requirements:

ASME NQA-1-2000, "Quality Assurance Requirements for Nuclear Facility Applications," Part I, "Requirements for Quality Assurance Programs for Nuclear Facilities," Section 400, "Terms and Definitions," defines a QA record as a completed document that furnishes evidence of the quality of items and/or activities affecting quality. ..."

ATL-MP-1002, "Quality Assurance Program Description," Section 17.2.1 indicated that QA records "shall furnish documentary evidence that items or activities meet specified quality requirements."

ATL-312, Section 8.09, "Records Management Process," Section 4.1.2, Item 5, states, "Documents that represent the completion, verification, or acceptance of work or activity, or that documents compliance to requirements are considered valid records after they are stamped, initialed, or signed and dated by authorized personnel or otherwise authenticated."

Discussion:

ATL has developed a checklist to record completion of OJT titled, "ATS/ATL On-The-Job Training Checklist." Signatures from the training instructor, the training evaluator, the trainee, the trainee's immediate manager, and the Laboratory Training System database administration documented completion of OJT. The reverse side of the

"ATS/ATL On-The-Job Training Checklist" contains eight additional blocks that identifies the revision, effective date, method, and the applicable signatures. These were used to document that the employee had completed OJT on later revisions to the procedure. Through interview and by reviewing the record management procedures, the Team discovered that ATL maintained these original OJT record as in-process records until all the continuing training signature blocks were completed. ATL procedure, ATL-312, Section 8.09, "Records Management Process," states that OJT records are maintained as in-process documents for as long as necessary to monitor employee-training status." The Team also noted that these records were maintained at each supervisors work location, and some of these original OJT records dated back to August 1999. The Team determined that these records of completed OJT met the NQA-1 definition of a QA record because they document the completion of a QA activity when completion of the initial OJT was documented. At that moment when the original signatures were applied, the OJT checklist became a completed QA record, not an in-process record. Because ATL understood these records were in-processes records, that the storage practices applied by ATL did not satisfy records storage requirements of QA records.

Storage of these OJT records was identified as a problem during the April 2006 DOE ORP Assessment of ATL. It was also an issue in the previous 2005 assessment of the laboratory conducted jointly by CH2M HILL and ORP (before ATL assumed responsibility of the analytical work).

Non-cited Finding A-07-ESQ-222S-002-NCF01: ATL Organization Roles and Responsibilities for the QA Organization do not fully meet requirements.

Requirements:

DOE O 414.1C, "Quality Assurance," Attachment 2, Section 2, Item a. required: "A contractor must assign and identify a senior management position responsible for the development, implementation, assessment, and improvement of the QAP..."

ASME NQA-1-2000, "Quality Assurance Requirements for Nuclear Facility Applications," Part 1, Requirement 1, in 201 (d) it stated, "those responsible for the verifying quality achievement have sufficient authority, direct access to management, organizational freedom, and access to perform their function."

Discussion:

The Team determined that ATL had not adequately assigned responsibility for development, implementation, assessment, and improvement of the QA program to a senior level manager. Procedure ATL-MP-1007, "ATL Job and Organizational Descriptions," assigned these responsibilities to an ATL staff position titled "Quality Assurance Program Manager." The ATL Organization chart contained a senior level organizational manager (Senior Quality Assurance Manager), but, according to ATL-MP-1007, that manager "directs and manages the QA/QC organization." There was no

specific assignment of responsibility for the development, implementation, assessment, and improvement of the QA program. In addition, the position was vacant.

The ATL Deputy Manager was functioning as both the Deputy and the QA Manager, which could be an issue with the independence (organizational freedom) required in NQA-1-2000 because the Deputy Manager had cost and schedule responsibilities, which could create a conflict of interest. The Team did not identify any evidence indicating there was an independence issue but did express concern to ATL.

At the time of the assessment, ATL was in the process of revising ATL-MP-1007. Discussions with the ATL Deputy Manager indicated that the intended changes would address the issue with the QA organization and the roles and responsibilities. ATL also indicated they were hiring more QA personnel and had plans to staff the Senior Quality Assurance Manager position. ATL initiated IIF ATL-2007-0270 to address the deficiencies with ATL-MP-1007 and the organization. The Team reviewed the proposed corrective actions, which included correctly assigning QA responsibilities to the Senior QA Manager, and revising the organization structure so that the Senior QA Manager has direct access to the Project Manager (completion date of corrective action was November 29, 2007). After the assessment field work, ORP Office of Environmental Safety and Quality management met with the ATL Deputy Manager and stressed DOE's concern with the potential conflict of interest, and discussed acceptable management structures. At that time, ATL committed to establish an organization where the Senior QA Manager reported directly to the ATL Project Manager.

ORP will perform closure verification of this IIF when actions are completed. NCF A-07-ESQ-222S-002-NCF01 was issued to document this discrepancy.

Non-cited Finding A-07-ESQ-222S-002-NCF02: Nonconformance Report (NCR) Procedure deficiencies identified (due to self-imposed non NQA-1 process requirements).

Requirements:

DOE O 414.1C, "Quality Assurance," Attachment 2, Section 3, Item e (1) states, "Perform work consistent with technical standards, administrative controls, and hazard controls adopted to meet regulatory or contractual requirements using approved instructions, procedures, etc."

ATL-312, Section 8.03, "Nonconforming Item Reporting and Control," Section 4.2; "The ASPC utilizes the Corrective Action Management system, which is governed by procedure ATL-312, Section 9.04, 'ATL Corrective Action Management.' The ATL Issue Identification System (a part of the CAMPATS database) is accessible by general staff. After a staff member documents the issue in CAMPATS following the process outlined in ATL-312, Section 9.04..."

ATL-MP-1002, "Quality Assurance Program Description," Section 15.0 states, "Items that do not conform to specified requirements shall be controlled to prevent inadvertent installation or use of the item. Controls shall provide for identification, documentation, evaluation, segregation when practical, and disposition of nonconforming items, and for notification to relevant organizations." (same as NQA-1-2000, Requirement 15). The section continues with specific criteria for the identification, documentation, evaluation, segregation, and disposition of nonconforming items.

Discussion:

The Team determined ATL was not adequately implementing Procedure ATL-312, Section 8.03, "Nonconforming Item Reporting and Control." This procedure required that nonconforming items be reported in CAMPATS and the process in procedure ATL-312, Section 9.04, be followed. ATL-312, Section 9.04, required significance classification, causal analysis, extent of condition, and corrective actions. The ATL QAPD does not require nonconforming items be addressed within the corrective action management system. NQA-1-2000 deliberately separates the processes for correcting nonconforming items and the corrective action management process for conditions adverse to quality (Findings). The focus of NQA-1 nonconforming item criteria is to get the item back in service or replaced. The focus of the corrective action management process is to correct conditions adverse to quality and correct or remove the programmatic or process conditions. By requiring nonconforming items to be addressed as findings, ATL had self-imposed additional requirements that encumber the process. The Team reviewed three nonconforming item reports and determined implementation of the procedure was attempted in that information was placed in the fields of the electronic form for significance classification, causal analysis, extent of condition, and established corrective actions, but that implementation had not been adequate to meet corrective action management process requirements. For example, extent of condition information provided discussed things like the nonconforming condition, or the actions taken to notify the vendor; corrective actions only addressed disposition of the item and not the identified causes; identified causes described the condition and not the actual cause. Discussion with ATL staff indicated an understanding that the procedure was cumbersome and that the procedure needed to be corrected in some future day. The Team determined that ATL adequately implemented activities required by NQA-1.

ATL initiated IIF ATL-2007-0269 to revise ATL-312, Section 8.03 to remove self-imposed activities that go beyond requirements and render the process too cumbersome (completion date of November 30, 2007). ORP will perform closure verification of this IIF when actions are completed.

Observation A-07-ESQ-222S-002-O01: The Documentation for S/CI applicability evaluation/screening should be formally maintained.

Discussion:

ATL evaluated/screened for S/CIs at receipt inspection, and screened other reported noncompliances for potential S/CIs. The Team noted that ATL conducted these evaluations of potential S/CIs through meetings and discussing with counterparts. The results of these meetings/discussions are documented on e-mails that were informally maintained by the ATL S/CI coordinator. This practice resulted in much of the rationale for determining if an item met the S/CI criteria for reporting to the Inspector General was maintained informally and could be lost with time. The ATL S/CI coordinator does maintain the e-mails on his computer, but a more formal method for keeping this information should be developed to assure supporting information is not lost, and the method applied is standardized.

Recommendation A-07-ESQ-222S-002-R01: Implementation of the lessons learned process needs improvement.

Discussion:

The Team found that portions of the ATL Lessons Learned Program were not implemented in accordance with the governing procedure. However, the Team noted that the Lessons Learned Program had undergone recent staff changes, the controlling procedure went through a major revision in May 2007, and only two lessons learned reports were issued since the procedure was revised. As a result, the Team could not determine current program effectiveness, but recommends the Lessons Learned Program receive appropriate management attention to assure its future effectiveness.

The following requirements are identified in order to highlight the requirement source for the discrepancies noted for use by ATL in improving the Lessons Learned Program:

ATL-312, Section 10.05, "Lessons Learned," Section 4.1, "Develop the Lessons Learned;" Section 4.2, "Screen External Sources for Applicable Lessons Learned;" Section 4.3, "Distribute the Lessons Learned;" and Section 4.5, "Monitor Program Performance," required the following actions that were not performed:

- The Lessons Learned Forms were not properly completed.
- There was no documented evidence that the lessons learned forms received the required reviews and approvals.
- There was no evidence the lessons learned reports were distributed for review.

- The Lessons Learned Review Log only documented review of external sources; the two internal lessons learned issued in 2007 were not logged as receiving a review for possible distribution.

- Metrics to measure performance and evaluate the effectiveness of the lessons learned program were not developed.

The Team also recommends the Lessons Learned Review Log document the status and completion of recommended actions resulting from evaluation of lessons learned information. The Lessons Learned Review Log does not reflect the completion status of recommended actions; some actions appear to be open since August 2006.

4.0 ITEMS CLOSED:

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

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

The repeated record storage issue will be addressed in A-07-ESQ-ATL-002-F05

The repeated issues with management assessment issues will be addressed in A-07-ESQ-ATL-002-F03

5.0 DOCUMENTS ASSESSED:

- DOE O 414.1C, "Quality Assurance," Section 4.a(1), "Quality Assurance Program Requirements."

- DOE G 414.1-2A, "Quality Assurance Management System Guide," Section 4.1.3, "Graded Approach."

- DOE O 210.2, "DOE Corporate Operating Experience Program."

- DOE O 151.1C, "Comprehensive Emergency Management System."

- DOE O 226.1, "Implementation of DOE Oversight Policy."

- 10 CFR 830.122, "Quality Assurance Criteria," Section (j) Criterion 10, "Independent Assessment."

- DOE ORP Assessment Report A-06-ESQ-ATL-001, "ATL QA Program Review," April 2006.

- ATL-MP-1009, "Integrated ES&H Management System Description for the 222-S Analytical Services Production Contractor."
- ATL-MP-1001, Procedures Acceptable for Use by the ATL 222-S Analytical Services Production Contractor, August 29, 2007.
- ATL-MP-1002, "Quality Assurance Program Description," Revision 6, March 1, 2007.
- ATL-MP-1005, "Records Management Plan," Revision 2, June 28, 2007.
- ATL-MP-1011, "ATL Quality Assurance Project Plan for 222-S Laboratory."
- ATL-MP-1015, "Quality Assurance Program Implementation Matrix."
- ATL-MP-1020, "Assessment Program Plan."
- ATL-MP-1034, "ATL Work Control."
- ATL-MP-1007, Revision 6, "ATL Job and Organizational Descriptions."
- ATL-MP-1024, Revision 3, "ATL Training and Qualification Plan."
- ATL-MP-1025, Revision 2, "ATL Training Implementation Matrix."
- ATL-MP-1036, Revision 1, "ATL Training Program Description."
- ATL-312, Section 10.05, "Lessons Learned," Revision 2, May 21, 2007.
- ATL-312, Section 5.04, Revision 0, "Conduct of Qualification Cards."
- ATL-312, Section 5.01, Revision 1, "ASPC Training Records Scheduling and Administration."
- ATL-312, Section 5.07, Revision 2, "On-the-Job Training (OJT)."
- ATL-312, Section 8.03, "Nonconforming Item Reporting and Control," Revision 0, February 15. 2007.
- ATL-312, Section 8.09, Revision 1, "Records Management Process," Revision 0, June 28, 2007.
- ATL-312, Section 9.02, "ATL Causal Analysis Process," Revision 1, August 30, 2006.

- ATL-312, Section 9.04, "ATL Corrective Action Management," Revision 1, May 30, 2007.
- ATL-312, Section 4.26, "ATL Analytical Project Process Flow."
- ATL-312, Section 9.14, "Performance of Management Assessments."
- ATL-312, Section 9.12, "Qualification of Assessment Personnel."
- ATL-312, Section 9.13, "Performance of Independent Assessments."
- ATL-312, Section 8.06, Revision 0, "Suspect/Counterfeit Control."
- ATL-2006-0224, "Compressed gases used as Laboratory Chemicals," October 26, 2006.
- ATL-2007-0224, "IH Internal Audit Deficiencies," July 17, 2007.
- ATL-2006-0087, "Faulty Syringe," April 18, 2002.
- ATL-2006-0240, "Inadequate Implementation of QA processes," September 28, 2006.
- ATL-2006-0241, "QA Procedures LTA," September 28, 2006.
- ATL-2006-0330, "Client Compliant Reissue RPP-PRT-29745- AW105," December 21, 2006.
- ATL-2006-0316, "Possible Arc/Spark During Instrument Housekeeping."
- ATL-2007-0018, "Lessons Learned- Animal Sample Prep," January 19, 2007.
- ATL-2007-0039, "Corrective Action for ATL-2007-0038," February 2, 2007.
- ATL-2006-0295, "Aloha Work W/O Pre-Job Meeting," November 8, 2006.
- ATL-2007-0269, "Problem with NCR Process," September 27, 2007.
- ATL-2007-0270, "Roles and Responsibilities for QA Position," September 27, 2007.
- ATL-2006-0218, "Corrective Action Process," September 12, 2006.
- ATL-2006-0213, "Graded Approach," September 12, 2006.

- ATL-2007-0116, "NCR- Tissue Homogenizer," April 12, 2007.
- ATL-2007-0085, "Suspected Leaking Containers Nitric Acid Received," March 14, 2007.
- ATL-2007-0114, "Aroclor 1254 Suspect Standard," April 10, 2007.
- ATL-HLA-06-009, "Event Investigation Report ATL-2006-087, Unexpected Discharge of Spring-Loaded Syringe," April 28, 2007.
- RPP-PLAN-31719, "Tank Grab Sampling and Analysis Plan in Support of Evaporator Campaigns for FY2007," July 2007.
- FY 2006 Statement of Work, "Radiological Sample Analysis for Hanford Site Emergencies by ATL Analytical Services," August 2006.
- ITEM.
- Individual training packages.
- OJT records for two Chemists.
- ATL ASPC Lessons Learned Review Log, August 1, 2006, to present.
- ATL Lesson Learned Form, June 28, 2007, "Issues With Movement of Refrigerator."
- ATL Lesson Learned Form, July 31, 2007, "Heating Element Failure on Gas Chromatograph/Mass Spectrometer."
- CAMPAT ATL-2006-0316, 12/6/06, "Possible Arc/spark During Instrument Housekeeping."
- ATS LO-120-001, Revision I-0, Labeling of Standards and Reagents by Standards Laboratory Personnel.
- ATS LO-150-063, Revision G-0, "Chemical Management."
- Calibration records for the ICPMS including the Instrument Tuning Record, the 10 replicate stability run printout, a Standard Preparation Log page, ICPMS Bench Sheet File, Fully Quantified Calibration Curves, and Semi Quantified calibration Curves.
- FY 2006 ATL Assessment Schedules, dated November 17, 2005, April 17, 2006, June 1, 2006, and August 1, 2006.
- ATL/ORP Assessment & Surveillances FY 2007 Schedule, dated April 12, 2007.

- ASPC Assessment & Surveillance Schedule, dated August 20, 2007.
- Management Assessment Report MA-MU-06-05, "Training at 222-S Laboratory," November 2006.
- Management Assessment Report MA-MU-07-03, "Industrial Hygiene Annual Audit," July 2007.
- Management Assessment Report MA-MU-07-04, "Radiation Protection," July 2007.
- Management Assessment Report MA-OT-(SAS)-07-01, "Safeguards and Security," March 2007.
- Management Assessment Report ATL-RRL-06-038, "Voluntary Protection Program," November 2006.
- Assessment Technique Training Records for 7 Lead Assessors.
- Computer Based Training Module CN 172029, "ATL Assessment Techniques."
- Independent Assessment Report IA-2007-001, "ATL Procurement Process for Chemicals," March 2007.
- Independent Assessment Report, IA-2007-002, "Verification of Corrective Action for Lapse in Training Qualification," May 2007.
- Independent Assessment Report IA-2007-003, "Records Management," August 2007.
- Resume of 1 Lead Auditor.

6.0 PERSONNEL INTERVIEWED:

- ATL Project Manager.
- S/CI Coordinator.
- Inorganic Chemistry Manager.
- QA Program Manager.
- Training Lead.
- Lessons Learned Coordinator.

- Safety and Support Services Manager.
- QA/Quality Control Scientists.
- Project Coordinator.
- Chemical Technologist.
- Deputy Project Manager.
- Facility Security Officer.
- Analytical Chemistry Scientist.
- Chemistry Manager.
- Chemists.

Task# ORP-ESQ-2007-0224

E-STARS[R] Report
Task Detail Report
11/20/2007 0418

TASK INFORMATION			
Task#	ORP-ESQ-2007-0224		
Subject	CONCUR:07-ESQ-214; ASSESSMENT REPORT A-07-ESQ-ATL-002 - ATL QA PROGRAM REVIEW - SEPTEMBER 24 - 28, 2007		
Parent Task#		**Status**	CLOSED 11/20/2007
Reference	07-ESQ-214	**Due**	
Originator	Gano, Becky (Gano, Becky)	**Priority**	High
Originator Phone	(509) 376-6004	**Category**	None
Origination Date	11/15/2007 1344	**Generic1**	
Remote Task#		**Generic2**	
Deliverable	None	**Generic3**	
Class	Long Term	**View Permissions**	Normal
Instructions	Correspondence is being routed for concurrence via hard copy instead of electronically. Once you receive the correspondence, please approve or disapprove electronically via E-STARS and route to next person on the routing/concurrence list. BCC: ESQ OFF FILE ESQ RDG FILE MGR RDG FILE S.C.JOHNSON, AMD C.B.REID, AMD P.P.CARIER, ESQ W.J.TAYLOR, ESQ S.A.VEGA, ESQ RECORD NOTE:		

ROUTING LISTS

1	Route List	Inactive
	• Vega, Samuel A - Review - Concur - 11/19/2007 0713 *Instructions:*	
	• Carier, Patrick P - Review - Concur - 11/19/2007 0709 *Instructions:*	
	• Taylor, William - Review - Concur - 11/19/2007 0709 *Instructions:*	
	• Noyes, Delmar L - Review - Cancelled - 11/20/2007 1618 *Instructions:*	
	• Olinger, Shirley J - Approve - Approved with comments - 11/20/2007 1352 *Instructions:*	

ATTACHMENTS

Attachments	1. 07-ESQ-214 ATL LTR Assessment Report A-07-222S-002 ATL QA Program Review.doc 2. 07-ESQ-214 att 2007 ATL QA Program Assessment Report A-07-222S-002.doc

COLLABORATION

Task# ORP-ESQ-2007-0224

COMMENTS

Poster	Olinger, Shirley J (Mendoza, Stella) - 11/20/2007 0111
	Approve
	Steve W. reviewed for Shirley, gave back to change signature block to Bill Taylor.
Poster	Gano, Becky (Gano, Becky) - 11/20/2007 0411
	CLOSED
	Signature Block changed to Bill Taylor per Shirley Olinger.

TASK DUE DATE HISTORY

No Due Date History

SUB TASK HISTORY

No Subtasks

-- end of report --

Task# ORP-ESQ-2007-0224

E-STARS[R] Report
Task Detail Report
11/15/2007 0151

TASK INFORMATION			
Task#	ORP-ESQ-2007-0224		
Subject	CONCUR:07-ESQ-214; ASSESSMENT REPORT A-07-ESQ-ATL-002 - ATL QA PROGRAM REVIEW - SEPTEMBER 24 - 28, 2007		
Parent Task#		**Status**	Open
Reference	07-ESQ-214	**Due**	
Originator	Gano, Becky (Gano, Becky)	**Priority**	High
Originator Phone	(509) 376-6004	**Category**	None
Origination Date	11/15/2007 1344	**Generic1**	
Remote Task#		**Generic2**	
Deliverable	None	**Generic3**	
Class	Long Term	**View Permissions**	Normal
Instructions	Correspondence is being routed for concurrence via hard copy instead of electronically. Once you receive the correspondence, please approve or disapprove electronically via E-STARS and route to next person on the routing/concurrence list. BCC: ESQ OFF FILE ESQ RDG FILE MGR RDG FILE S.C.JOHNSON, AMD C.B.REID, AMD P.P.CARIER, ESQ W.J.TAYLOR, ESQ S.A.VEGA, ESQ RECORD NOTE:		

ROUTING LISTS

1	Route List	Active
	• Vega, Samuel A - Review - Awaiting Response - Due Date SV 11/15/07 *Instructions:*	
SV	• Carier, Patrick P - Review - Awaiting Response - Due Date WQT 11/18/07 *Instructions:*	
	• Taylor, William - Review - Awaiting Response - Due Date WQT 11/18/07 *Instructions:*	
DLN	• Noyes, Delmar L - Review - Awaiting Response - Due Date DLN 11/19/07 *Instructions:*	
	• Olinger, Shirley J - Approve - Awaiting Response - Due Date *Instructions:*	

ATTACHMENTS

Attachments	1. 07-ESQ-214 ATL LTR Assessment Report A-07-222S-002 ATL QA Program Review.doc 2. 07-ESQ-214 att 2007 ATL QA Program Assessment Report A-07-222S-002.doc

COLLABORATION