Implementation of a DOD ELAP Conforming Quality System at a FUSRAP Site Field Temporary Radiological Screening Laboratory – 13500

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ABSTRACT

A case study is presented on specific program elements that supported the transition of a temporary field radiological screening lab to an accredited operation capable of meeting client quality objectives for definitive results data. The temporary field lab is located at the Formerly Utilized Sites Remedial Action Program Linde Site in Tonawanda, NY. The site is undergoing remediation under the direction of the United States Army Corps of Engineers – Buffalo District, with Cabrera Services Inc. as the remediation contractor and operator of the on-site lab. Analysis methods employed in the on-site lab include gross counting of alpha and beta particle activity on swipes and air filters and gamma spectroscopy of soils and other solid samples. A discussion of key program elements and lessons learned may help other organizations considering pursuit of accreditation for on-site screening laboratories.

INTRODUCTION

Clean-up of radiologically-contaminated sites requires rapid turn-around of sample analysis to aid in decision making, both day to day and for final site disposition. In order to be most useful to a given project, supporting environmental labs must be able to deliver timely and defensible data. Both the results turn-around time and level of data defensibility (i.e., the data/measurement quality objectives) are established in coordination between the lab, the remediation contractor, the client, and other stakeholders.

The measurement quality objectives for individual sample types are based on how the data will be used (i.e., screening vs. definitive) in consideration of stakeholder interests and will eventually dictate:

- where a sample will be analyzed,
- what methods will be employed,
- how sensitive, accurate, and precise the measurements must be,
- how quality-indicator samples will be evaluated,
- how soon results are expected,
- what interim-final data deliverables will look like, and
- how much the entire analytical and reporting process will cost.

As defined in the Uniform Federal Policy for Quality Assurance Project Plans, March 2005 [1], "definitive" data are of sufficient quality to support final decision-making. "Screening" data are of sufficient quality to support an intermediate or preliminary decision, but must eventually be supported by definitive data. These definitive data are to be provided by a laboratory accredited under the Department of Defense Environmental Laboratory Accreditation Program (DoD-ELAP) for the specific parameter to be measured.

Screening-level samples (e.g., used for remedial support) are typically evaluated on-site in a temporary lab established by a Contractor to support a specific site on a finite schedule. On-site screening labs provide both the Contractor and Customer a very good estimate of the radiological activity concentrations present. Data quality requirements for "screening" data are typically less rigorous and limited to project-specific client requirements.

Final Status Survey and other select project activities typically require a higher level of data defensibility than those data used to make day-to-day remedial support decisions. These "definitive" samples are typically analyzed in an off-site commercial lab, independently accredited/certified to meet specific project data quality objectives/requirements.

After a thorough assessment of project data needs and quality criteria, it will often prove beneficial to have an on-site lab to provide timely remedial support sample results. It may even be determined that pursuing formal accreditation of an on-site screening lab will provide greater benefit to the project long-term, via suitability for on-site sample results that meet the quality objectives for "definitive" data.

Presented is a case-study in the development and implementation of a quality system for the Linde On-Site Lab which resulted in formal accreditation under the umbrella of the DOD ELAP. The on-site lab's quality system is based on the Department of Defense Quality Systems Manual, Version 4.2 [2], and ISO-17025 (2005), General Requirements for the Competence of Testing and Calibration Laboratories [3]. The focus of this case-study is the specific elements of the Linde On-Site Lab Quality System which have helped guide the transition from an on-site screening lab to an accredited operation producing definitive results for selected radiological parameters.

FACILITY DISCUSSION

The Formerly Utilized Sites Remedial Action Program (FUSRAP) Linde On-Site Lab is made up of two temporary structures located at 175 E. Park Drive, Tonawanda, New York. The Gamma Spectroscopy Lab (Fig. 1) consists of a trailer with two distinct laboratory rooms. The laboratory rooms include a sample receiving/preparation room and a gamma spectrometry counting room.

Fig. 1 Linde Lab Trailer (Sample Preparation & Gamma Spectrometry)

The Gross Alpha-Beta Lab consists of a trailer with two separate areas. One half is used for other project-related storage. The other half is used for gross counting of swipes/filters as well as radiation protection field instrument maintenance and storage.

The trailers are locked when not occupied by laboratory personnel; in addition, the computer for the gamma spectroscopy equipment is password protected to prevent unauthorized modifications to analysis software. All data is maintained in the laboratory areas or in lockable office areas. Lab waste is stored in a designated section of the sample-receiving room.

The Lab accommodates the equipment and personnel needed to perform the required tasks at this location. Electricity is provided to the Lab via direct line service from a local electrical utility. The test area environment is regulated, to the extent practicable, to assure that the instrumentation and the analytical results will not be affected by wide differences in temperature, pressure, or humidity. The lab has no water or natural gas service and utilizes pressurized cylinders for storage and supply of P-10 gas (for gas-flow proportional counters) and liquid nitrogen (for gamma spectroscopy detector cooling).

A HEPA–filtered down-draft table is utilized in the Sample Prep Area for worker protection during sample drying and homogenization activities. (Fig. 2) The down-draft table effectively minimizes occupational exposures from inhaled radionuclides for lab staff to levels below Project ALARA thresholds.

Fig. 2 Sample Preparation Room

Routine housekeeping and periodic radiological surveys are performed by trained technicians in all lab areas to ensure radioactive contamination is effectively controlled and worker radiation exposures are maintained As Low As Reasonably Achievable.

QUALITY SYSTEM DISCUSSION

An effective quality system is made up of many individual elements with each contributing to the robustness of reported results and overall success of the analytical program. Key elements of the Linde quality system are based on DOD and ISO guidance and are discussed in the following sections:

Clear Scope of Accreditation

A clearly defined scope-of-accreditation is critical for communicating capabilities to clients and stakeholders. The USACE Linde Site On-Site Lab was granted DOD ELAP accreditation by Laboratory Accreditation Bureau (L-A-B) on April 26, 2012. The Scope of Accreditation is valid for an initial period of three years and is presented in Table I:

TABLE I. Laboratory Scope of Accreditation

Testing - Environmental (Solid and Chemical Materials)		
Technology	**Method**	**Analyte**
Gamma Spectroscopy	HASL-300 Method Ga-01-R [4]	Ra-226 (daughter in-growth) and U-238 (Th-234)
Gas Proportional Counter	Cabrera OP-069 (based on EPA 900.0 MOD) [5]	Gross Alpha and Gross Beta on filter paper and wipes

Other non-accredited parameters, when reported, are noted as “screening” results.

Well-Defined Organizational Structure

The Buffalo District USACE office has primary authority over the laboratory location and is managing the remediation of the FUSRAP Linde Site. To support the USACE mission at the Linde Site, Cabrera Services has been contracted to complete the remediation scope. A component of this mission is establishment and maintenance of an on-site laboratory to support site investigation and remediation activities using gamma spectrometry and gross alpha-beta counting systems. Lab operations and quality are the responsibility of Cabrera Services management. The Cabrera organizational structure for the Linde Lab is presented in Figure 1.

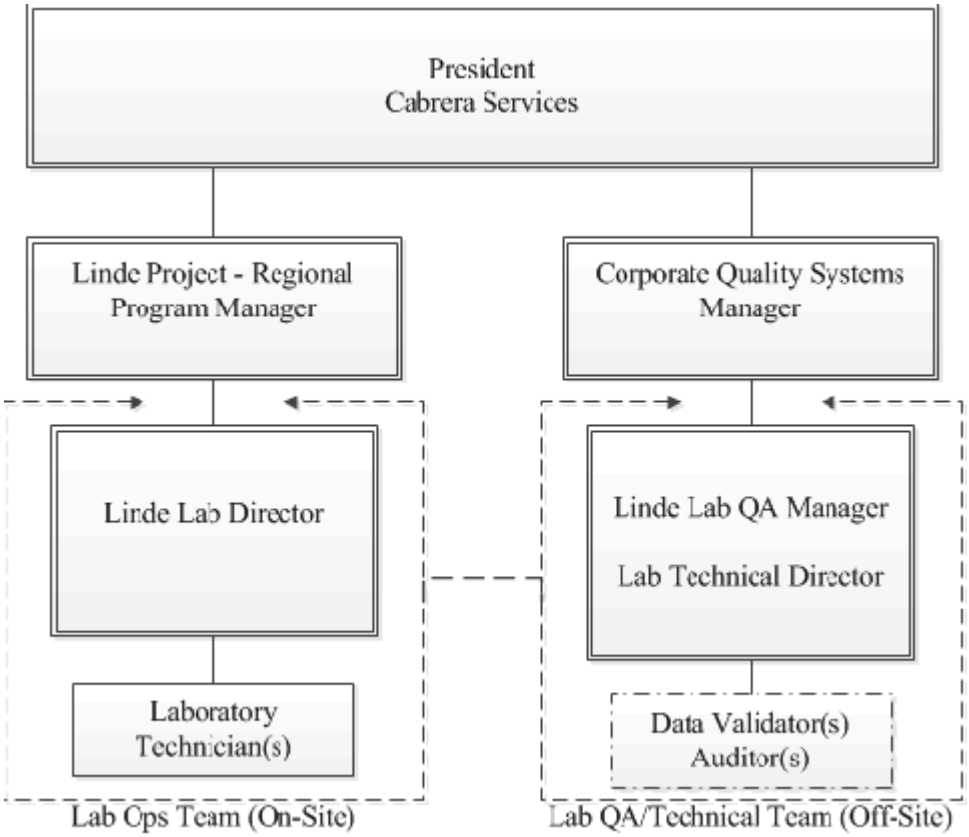

Fig. 3 Cabrera Linde On-Site Lab Organizational Structure

Overall responsibility for Cabrera Field Operations lies with the Company President. For Lab operations and oversight there are two distinct and independent lines-of-authority. Operationally, the Lab day-to-day operations are the responsibility of the Lab Director and Technician(s). These personnel directly support the Cabrera Linde Project Manager, ensuring that lab operations are aligned with the critical path needs of the remediation field team.

On-Site Lab Operations Team

The Laboratory Director (LD) has direct responsibility for implementation of the Lab Quality Systems Manual (LQSM) via direct oversight of day-to-day lab operations, management of the laboratory staff/resources, and maintenance of lab programs and procurements. The LD is also specifically responsible for:

- Training laboratory personnel to assure that suitable proficiency is achieved and maintained and that they perform their duties in accordance with specified plans, procedures and protocols.
- Initial development, implementation, and periodic review of laboratory procedures.
- Coordination with the PM, Lab QA Manager (LQM), and the client to resolve problems related to operation of the laboratory that could prevent completion of required analysis.
- Implementation of the Lab's corrective action processes.
- Reviewing final data generated to assure completeness and adherence to contractual requirements.
- Communicating data quality concerns or lab operational issues to the LQM and PM.
- Providing technical and operational direction to the Lab Technician(s)
- Monitoring standards of performance in quality control and quality assurance and monitoring the validity of the analyses performed and data generated in the laboratory to assure reliable data.
- Ensure there is adequate supervision of personnel, especially for trainees with limited experience.

Laboratory Technicians (LT) are responsible for the quality of their work and for implementing the requirements of Lab's quality system and applicable procedures on a daily basis. With appropriate technique training and the consent of the LD, the LT performs the following tasks:

- Calibrate, operate, and maintain lab analytical equipment.
- Maintain the lab working databases/spreadsheets
- Ensure that adequate laboratory supplies are available for daily operation.
- Conduct sample preparation and analyses as outlined in this LQSM.
- Coordinate with laboratory management to resolve abnormalities, deficiencies, inefficiencies, and resource requirements.
- Assist in the assembly and delivery of lab data deliverables
- Perform sample custodian functions for samples stored in the lab for processing and analysis

Lab/QA Technical Team

The Laboratory Technical Director (LTD) is a corporate-level subject matter expert providing analytical systems technical and operational support to Cabrera field projects. The LTD performs frequent reviews of routine instrument performance checks and batch-based quality indicator sample results. The LTD participates in the corrective action process and provides overall technical guidance for analytical systems. The LTD meets all of the requirements to act as the LD and can fill-in during extended absences to maintain seamless supervision of accredited methods.

The LQM is responsible for the overall quality assurance (QA) of Lab operations. The LQM performs the following QA and operational support functions:

- Conducting management reviews of lab operations
- Providing technical guidance on best lab practices and radio-analytical principals
- Providing oversight and technical guidance to the lab corrective actions processes
- Provide technical support to clients related to results interpretation or data quality concerns
- Maintain the current quality manual and ensure its annual review
- Performing QA-level reviews of completed data deliverables
- Implementing, maintaining, and improving the quality system
- Ensuring that all personnel understand their contributions to the quality system
- Ensuring communication takes place at all levels within the laboratory regarding the effectiveness of the quality system
- Evaluating the effectiveness of training
- Using available tools, such as audit and surveillance results, control charts, proficiency testing results, data analysis, corrective and preventive actions, customer feedback, and management reviews in efforts to monitor trends and continually improve the quality system

Unique to the Linde Lab operation is the inclusion of an independent Data Validator (DV) as part of the established QA process. Working from a single client's expectations, the DV supports the data evaluation process by reviewing final data and the results of quality indicator samples. The DV also performs a QC check of the electronic deliverable. The DV reviews any non-conformance issues with the LD, LTD, and LQM, assigns final data qualifiers based on client specifications, and prepares a summary narrative of findings that accompanies each Lab deliverable from both the on-site Lab and any DOD ELAP-accredited subcontractor environmental labs.

The LQM performs a final QA-level review of all deliverables prior to release. The focus of this final review is to ensure that the Lab's quality system was effectively implemented and is reflected in a defensible data deliverable. LQM comments are addressed prior to the release of any final results data.

This overall structure maintains operational focus for the Lab and; ensures the on-site team receives the necessary technical support, and quality feedback to promote principles of continuous improvement. The independent nature of the Off-Site Technical Team ensures that project operational pressures have minimal effect on Quality System implementation.

Establishing Achievable Measurement Quality Objectives

Quality assurance objectives for measurement data will be based on evaluation methods for the following parameters:

- Precision via batch analysis and comparison of laboratory replicates
- Accuracy and Bias via analysis and periodic evaluation of check sources and batch laboratory control standards
- Sensitivity via calculation of detection limits and effective control of counting times and background radioactivity
- Completeness via monitoring of rejected or incomplete results data against project-specific criteria (90% for the Linde data).
- Comparability via the use of industry-accepted methodologies, traceable standards, training, and participation in external quality control/proficiency testing (i.e., blind) studies.

Samples are analyzed in batches of up to twenty (20) regular samples with required quality indicator sample analyses performed for each batch of samples processed. Use of Batch QC is common to commercial environmental labs. On-site screening labs typically rely on daily QA to track method performance.

Addressing Non-Conformances & Customer Feedback

Conditions adverse to the quality affect the integrity of laboratory data and need to be corrected upon identification. In the event there is a noted non-conformance of the analytical data, a non-conformance report (NCR) is initiated to resolve and track the problem. The NCR includes: identifying the non-conforming work; what actions are being taken to correct issue; the individual responsible to complete actions; the significance of the issue and whether data quality is or may be effected; and if client notification is necessary. When an issue is identified, a NCR is initiated to begin the resolution and tracking process. A tracking number is generated and the type of issue is documented (i.e., non-conforming work, customer feedback, or audit/review

finding). Issues significant enough to stop or suspend operations are documented with the date and time work was suspended. Restart of suspended analytical work requires approval of the LD and LQM.

NCRs are reviewed by management to determine any trending or quality improvement achieved as a result of the corrective actions. Issues that result in noticeable quality impact to final delivered data quality are communicated to the client at the time of data reporting to allow opportunity for feedback. Root cause(s) and associated corrective actions are recorded on the NCR. Follow-up steps are performed by the laboratory staff to verify implementation of an effective corrective action and determine the need for any additional action(s)

USACE is the sole client of the Linde FUSRAP On-Site Lab. USACE provides formal feedback to the Lab in the form of comments to data deliverables and through weekly project meetings. The LD or LQM typically attends these meetings to obtain first-hand feedback from USACE. Feedback to data deliverables is resolved through the project's comment resolution process. Other feedback and associated response(s) are captured in meeting minutes or e-mail records.

In the event a formal complaint about the performance of the laboratory in producing measurement data is received from the USACE, the NCR reporting process is used to document, evaluate, and resolve the issue, as well as solicit final feedback from the client regarding resolution of the concern. Feedback is used and analyzed to improve the quality system, testing activities, and service to the client.

Conducting Management Reviews and Audits

Lab Management conducts periodic reviews of the laboratory's quality system and environmental testing activities to ensure their continuing suitability and effectiveness, and to introduce necessary changes or improvements. The review considers the suitability of existing policies and procedures, reports from managerial and supervisory personnel, the outcome of recent internal audits, corrective and preventive actions, assessments by external bodies, the results of inter-laboratory comparisons or proficiency tests, changes in the volume and type of the work, client feedback, complaints, and other relevant factors, such as quality control activities, resources, and staff training. Findings from management reviews and the actions that arise from them are documented and tracked until resolution.

The Corporate QA Manager (QAM), or appropriately qualified designee, conducts a formal audit of on-site Lab operations a minimum of once per calendar year. At a minimum, each annual audit has to include the following scope:

- Suitability of policies and procedures
- Reports and feedback from Lab Operations Staff and clients

- Outcome of recent internal audits
- Corrective and preventative actions taken by the Lab Staff to improve/maintain data quality
- Outcome of recent external assessments
- Results of inter-laboratory comparisons and proficiency tests
- Workload and staffing
- Staff training

Ad-hoc audits may be initiated by clients at any time. The Lab staff shall support client audits by providing requested lab documents/records, facilitating lab visits, answering auditor questions, and prompt resolution of identified concerns via the NCR process.

Subcontracting Laboratory Services

When Cabrera subcontracts analytical work, whether because of unforeseen reasons (e.g., surge capacity or need for special analysis) or on a continuing basis (e.g., through permanent subcontracting, agency or franchising arrangements), the work is placed with an NELAP-accredited laboratory for the tests to be performed or, with a laboratory that meets applicable statutory and regulatory requirements for performing and submitting the results of tests performed. The laboratory performing the subcontracted work and any screening parameters are identified in the final report. To preserve confidentiality, subcontracted analysis results are communicated electronically to the LD. Each validation report prepared by the DV includes a table of reported parameters and associated accreditation traceability for the results data.

The PM notifies the client if subcontract services are required to meet project needs. Prior to using a subcontractor, the LQM or LD verifies that the lab possesses accreditation for the methods to be performed and provides accreditation details to USACE for approval PRIOR to the start of analyses by the subcontractor. Documentation of accreditation by subcontracted laboratories is maintained as a quality record in laboratory files.

LESSONS LEARNED

When trying to decide on pursuit of formal accreditation of an on-site lab, Project Stakeholders have to consider how long the overall process will take. In the case of the Linde Lab, there were several issues which extended the accreditation schedule.

Adequacy of Utilities and Facility

During project start-up there were issues obtaining precise and accurate results from the gamma spectroscopy system. These had little effect on the usability of screening results supporting low-risk decision making on the project. With implementation of an ELAP-compliant quality system

came a higher level of expectation for performance in quality indicator samples, specifically laboratory control standards and replicate analyses. After several rounds of system testing and maintenance, temperature cycling, and component swapping, the root causes were determined to be detector condition, electrical service quality, and outside environmental conditions affecting the lab instrumentation quality indicator sample results. Key corrective actions included the procurement of a high-quality commercial line conditioning universal power supply with under/over-voltage management and administrative practices instituted in the lab to reduce foot traffic to help maintain temperatures, particularly in the Count Room. An additional recommendation for future projects is to ensure that on-site facilities designated for lab use can handle large and heavy analysis equipment and maintain controlled environmental conditions regardless of ambient weather changes.

Accreditor's Schedule vs. Project Schedule

The applicant lab has little control over the schedule of the accrediting body's assessment effort. If a project is considering accreditation, it is critical to identify and meet with the accrediting body's point-of-contact to establish reasonable schedules for the receipt and review of the quality systems manual, lab procedures, training files, and other accreditation related records, as well as for the initial on-site assessment.

Required Performance Evaluation Study Participation

When initially establishing a lab's accreditation schedule, one specific element to make note of is the availability, frequency, and timing of performance evaluation (PE) peer studies. The Linde Lab was required to provide evidence of successful participation in two blind study programs for the media and parameters to be accredited prior to scheduling the initial assessment by the accrediting body. Given the specific sample volume needs for gamma spectroscopy at Linde and the need for a filter-swipe PE program for gross alpha-beta; study participation options were limited to those conducted twice per calendar year (March and November). The candidate lab should consider the PE Study schedules or identify ad-hoc PE sample providers when establishing a realistic accreditation schedule.

CONCLUSION

Adopting a DoD ELAP/ISO-17025-compliant quality system changes the way samples and the resulting data are handled at temporary field labs with limited client-specified work scopes. The quality system established for the Linde On-Site Lab resulted in the accreditation of an on-site remediation support laboratory. The use of accredited methods on-site provides additional value to project stakeholders through higher confidence in the quality of data used to make field remedial/FSS decisions.

Inevitably, sites undergoing long-term remediation will generate thousands of sample data points that could be potentially useful for additional characterization, remedial design, risk assessment, and final disposition of the site. Data provided from labs accredited by recognized organizations/programs can be trusted to have met the standards of quality established at the beginning of projects between the remediation contractor, the client, regulators, and stakeholders.

These specific experiences may assist other FUSRAP project stakeholders as they decide if their current/future on-site screening labs and overall quality systems would benefit from undergoing accreditation under DoD-ELAP. Even if decisions are made to continue analyzing definitive samples at a third-party off-site accredited laboratory, adopting the critical "grey-box" requirements of the DoD Quality Systems Manual will generally improve the quality of data used to support day-to-day project decision-making without the added rigors and costs associated with maintaining a formally accredited program.

REFERENCES

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