SAND2007-1493C

Radiological Sample Analysis Laboratory Management (Quality Assurance)

Presented at the 3rd RMCC Workshop Held at The Food and Environment Monitoring Centre

April 2-4, 2007

Ministry of Regional Municipalities, Environment & Water Resources (MRMEWR), Muscat, Oman

Dr. Faraj Ghanbari
Sandia National Laboratories
USA

Sandia is a multiprogram laboratory operated by Sandia Corporation, a Lockheed Martin Company for the United States Department of Energy's National Nuclear Security Administration under contract DE-AC04-94AL85000.

Preparing for Development of QA Plan

Need to Identify or Describe the Followings (a partial list):

- Objectives of the Program
- Identify Sample Types/media (Air, Water, soil, Veg., etc)
- Identify Customer / Standards / Compliance Requirements
- Identify Types of Analysis for each Sample Type
- Identify Sample Preparation Methods
- Identify Analysis Methods (Gamma Spect, Alpha Spect, Gross Alpha/Beta, Liquid Scint, ICP/Mass Spect)
- Identify Equipment/Instrumentation
- Identify Facility/Laboratory
- Identify Human Resources/Skills and Training Needs
- Identify Intercomparison / Proficiency Programs

A Typical QA Program: Brief Description

A QA program:

- is laboratory's specific policies and requirements, plans and procedures, and their implementation and maintenance;
- is established to ensure achievement of established performance criteria;
- shall provide for the planning and accomplishment of activities affecting quality.
- shall provide for indoctrination and training of personnel performing activities affecting quality to assure that suitable proficiency is achieved and maintained.

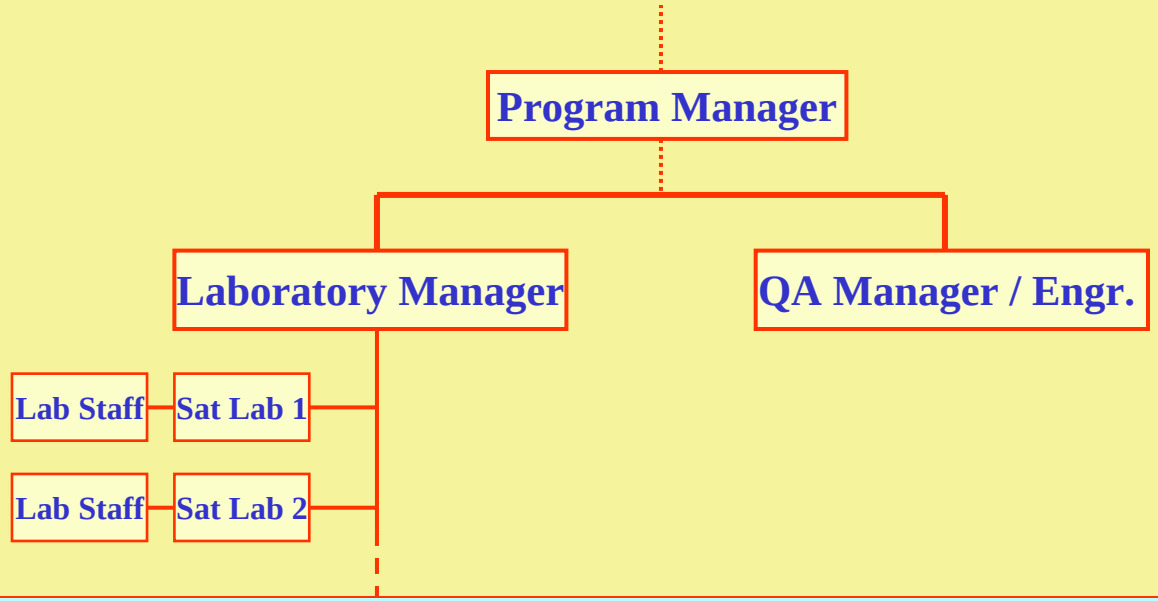
Management shall regularly assess the adequacy of the program to assure its effective implementation.

Elements of a Typical QA Program

- Organization
- Design Control
- Procurement Control
- Instruction and Procedures
- Document Control
- Identification and Control
- Validation and Verification
- Control of Instruments, Measuring, and Test Equipment
- Corrective Actions
- QA Records
- Assessments

Brief Description of QA Program Elements: Organization (1)

- This Element documents organizational structure
  - defines the specific lines of authority and communication for laboratory management, and job descriptions outlining the responsibilities of management and staff:



Organization (2)
Program Manager Responsibility

Program Manager is responsible for the development, implementation, and operation of the Radiological Sample Analysis Program; including:

- Interpreting regulations
- Managing program resources to:
  - provide the necessary staff, facilities, equipment, and supplies for continued operation during both normal and emergency conditions.

The Program Manager delegates day-to-day process management and technical oversight to the Laboratory Manager.

Organization (3)
Laboratory Manager Responsibilities (1)

The Laboratory Manager is responsible for the day-to-day process management and technical oversight of activities including: meeting schedules, assigning tasks, interacting with customers, reviewing staff work and product quality.

Organization (3)
Laboratory Manager Responsibilities (2)

Responsibilities also include:

- Developing and implementing technical processes;
- Developing and approving routine implementing procedures and appropriate staff training;
- Keeping the Program Manager informed of unusual or non-routine issues affecting the project or the RP Program;
- Providing agreed upon project metrics reports;
- Maintaining and revising the Quality Implementation Plan.

Organization (4)
Laboratory Staff Responsibilities

- The Laboratory Staff has the responsibility of implementation of approved processes, methods, and procedures for analyses of samples and data per QA Plan.

Responsibilities include:

- day-to-day set-up, calibration, and operations of instrumentation and equipment, performing sample preparation and counting, test performance, data analysis, reporting results, and records management;
- maintenance of instrumentation and reference standards.

Organization (5)
QA Manager/Engr Responsibilities (1)

- The QA Manager/Engr reports directly to the Program Manager.

- The QA Manager/Engr shall perform internal audits and review project corrective actions and review the program documents and quality procedures to ensure quality and adherence to the established regulatory, national, or international standards.

Organization (5)
QA Manager/Engr Authorities (2)

QA Manager/Engr is authorized to:

- Perform assessments to assure compliance;
- Initiate corrective action requests;
- Assure that further analyses are not performed until the proper disposition of all non-conformances, deficiencies, or unsatisfactory conditions have occurred;
- Verify implementation of corrective actions.
- Have direct access to responsible management at a level where appropriate action can be effected.

Shall report to management level such that required authority and organizational freedom are provided, including independence from financial and schedule considerations.

Brief Description of QA Program Elements: Design Control

- Describe the flow path of the operational function of the laboratory organization.
- Document applicable operational functions and their relationship to other functions within the laboratory environment including, but not limited to,the definition, description, documentation, and performance of the following:
  - Sample receipt, storage, preservation, and control,
  - Sample log-in,
  - Sample analysis within specified holding times and measurement,
  - Data verification and processing (including data deficiency reports),
  - Reporting,
  - Records management.

Brief Description of QA Program Elements: Procurement Control (1)

- Written instructions and/or procedures shall be prepared for documenting and controlling procurement of equipment, supplies, and services that have an impact on quality. Examples:
  - Reference material (radioactive standards)
  - Reagents and supplies
  - Analytical instruments
  - Measurement and test equipment (e.g., volumetric labware, analytical pipettes, balances, thermometers, pH meters)
  - Computer software

Brief Description of QA Program Elements: Procurement Control (2)

- Upon receipt of a quality-related order item, it shall be inspected to verify that the item received satisfies the description and requirements provided on the purchase order. If any requirement is not satisfied, the item shall be marked as nonconforming and segregated to prevent inadvertent use of the item.

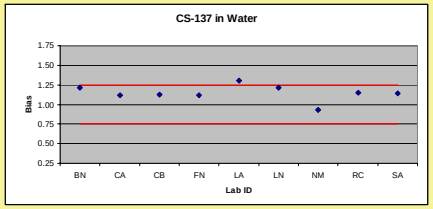
- Provisions for subcontracting of services that may have an impact on quality shall include:
  - Transmittal (flow down) of applicable QA requirements to subcontractor(s)
  - Right of access for assessment/surveillance purposes
  - Notification to client that subcontracting is being performed as part of processing client work.

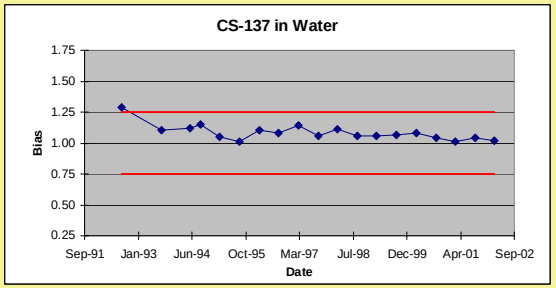
Brief Description of QA Program Elements: Instruction and Procedures (1)

- Written instructions and/or procedures covering the administrative, operational, and quality activities of the laboratory shall be established and implemented. Standard operating procedures include but are not limited to:
  - Calibration and operation of laboratory instruments and equipment;
  - Analytical methods and methods validation;
  - Data verification;
  - Implementation of interlaboratory and intralaboratory QC programs;
  - Software quality assurance (verification and validation);
  - Preventative maintenance program for instruments and equipment;
  - Training and qualification of laboratory personnel;

Brief Description of QA Program Elements: Instruction and Procedures (2)

- Nonconformance (deficiencies) and corrective actions;
- Procurement of quality-related items;
- Sample receipt and control;
- Radioactive material handling and waste disposal;
- QA procedures;
- Instructions relative to the chain-of-custody of samples during laboratory processing [including as a minimum the signature or cross-referenced initials of the analysts (handwritten or electronic) at each stage of the sample process];
- Sample preparation and storage;
- Disposal of sample extracts;
- Records retention;
- Document control.





Brief Description of QA Program Elements: Document Control (1)

- The preparation, issue, and change of documents that specify quality requirements or prescribe activities affecting quality shall be controlled to assure that appropriate documents are being employed.

- Such documents, including changes thereto, shall be reviewed for adequacy and approved for release by authorized personnel.

Brief Description of QA Program Elements: Document Control (2)

- The control system shall be documented and shall provide for:
  - Identification of documents to be controlled, including revision level and their specified distribution;
  - Identification of assignment of responsibility for preparing, reviewing, approving, and issuing documents;
  - Review of documents for adequacy, completeness, and correctness prior to approval and issuance;

- Major changes shall be subject to the same level of review and approval as the original level of review and approval. Minor changes may receive less rigorous review prior to approval.

Brief Description of QA Program Elements: Identification and Control

- Controls shall be established to assure that only correct and accepted items (including computer software) are used or installed.
- Where specified, items having a limited shelf life shall be identified and controlled to preclude use of any item whose shelf life has expired.
- Provisions shall be made for the control of item identification consistent with the planned duration and conditions of use. Identification and control measures shall be used to assure that samples are identifiable at all steps of the analytical process and are traceable from their source to the resultant report.

Brief Description of QA Program Elements: Validation and Verification

- Conformance of an item or activity to specified requirements shall be planned and executed.
- Procedure or method validation shall be performed with matrix spikes prior to the commencement of processing samples in order to ensure that the analyte of interest is properly measured without significant interferences and to within pre-established, acceptable quality performance levels.
- Software verification and validation shall be performed with known results to ensure that calculational and data manipulation programs perform properly.
- Data verification begins with the processing of data and continues through the review of the data and reporting of analytical results. Data review begins with a reviewer, who is independent of the data acquisition and processing, verifying that data has been correctly calculated and that appropriate and complete entries have been made.
- The review continues through the review and approval and verification that reported analytical results correspond to the data acquired and processed.

Brief Description of QA Program Elements:
Control of Instruments, Measuring, and Test Equipment (1)

- Performance criteria and controls shall be established for instruments or test equipment.
- Performance of the measurement equipment shall be checked and evaluated at regular intervals while the equipment is in use. These checks shall be sufficient to demonstrate that the measurement equipment is properly calibrated and that all components are functioning properly.
- Measurements shall include instrument background and response to known sources of activity. The number of instrument QC measurements shall represent at least 5% of the total number of measurements by analyte.
- Items that do not conform to specified requirements shall be managed to prevent inadvertent use. Procedures shall provide for identification, documentation, evaluation, and segregation and disposition of a nonconforming item.

Brief Description of QA Program Elements:
Control of Instruments, Measuring, and Test Equipment (2)

Instrument control records shall, as a minimum, identify:

- Item tested, including model and serial numbers;
- Date of last calibration and next calibration due date;
- Applicable calibration certificates;
- Tester (person performing the calibration or test) and data recorder if applicable;
- Type of observation;
- Results and acceptability;
- Acceptable control or tolerance limits;
- Action taken when any deviations are noted.

Brief Description of QA Program Elements: Corrective Actions (1)

- Shall include provisions to identify promptly and to correct conditions out of compliance with the established performance criteria of the laboratory. Corrective actions shall be documented and reported to appropriate levels of management. Results for samples processed using out-of-compliance processes or system(s) since the last verified condition of compliance shall be considered potentially deficient. Appropriate deficiency report forms shall be issued and notifications provided.
- 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. The identification, cause, and corrective action for significant conditions adverse to quality shall be documented and reported to appropriate levels of management; follow-up action shall be taken to verify implementation of this corrective action.

Brief Description of QA Program Elements: Corrective Actions (2)

- Management of the organization or activity shall provide for investigations of adverse findings, including notification of the appropriate organization in writing of action taken or planned.
- Nonconforming items will be managed to prevent their inadvertent use.
- Conditions adverse to quality shall be tracked with the proposed and actual dates that the corrective actions are completed and verified. Proposed dates for completion of corrective/prevention action may be extended with the approval of the QA Manager/Engr.

Brief Description of QA Program Elements: QA Records

- Records (hard copy and/or electronic) that furnish documentary evidence of quality shall be specified, prepared, and maintained. Records shall be legible, identifiable, and retrievable. Records shall be protected against damage, deterioration, or loss. Requirements and responsibilities for record transmittal, distribution, retention, and maintenance shall be established and documented.
- The records shall be stored in predetermined locations that meet the requirements of applicable standards, codes, and regulatory agencies.
- Measures shall be established to preclude the entry of unauthorized personnel into the storage area. These measures shall guard against larceny and vandalism.
- Prior to record destruction, the records shall be reviewed to determine if the retention time should be extended.

Brief Description of QA Program Elements: Assessments (1)

- Management self-assessments are to be established and implemented:
  - Periodic assessments shall focus on the integrated QA program and shall identify management barriers that hinder the organization from achieving its objectives
  - Results shall be documented.
  - Management shall take prompt action on the recommendations resulting from the assessment process. Follow-up assessments shall include an evaluation of the effectiveness of management actions.
- Internal audits and surveillance shall be planned, scheduled, and performed to:
  - Verify compliance with all aspects of the QA program and to determine its effectiveness.
  - Audits shall be performed in accordance with written procedures or checklists by personnel who do not have direct responsibility for performing the activities being audited.
  - Results shall be documented and reported to and reviewed by responsible management.
  - Follow-up action shall be taken where indicated.

Brief Description of QA Program Elements: Assessments (2)

- QA audits or surveillance shall be scheduled in a manner to provide coverage and coordination with ongoing QA program activities.
- QA audits or surveillance shall be scheduled at a frequency commensurate with the status and importance of the activity.
- The audit/surveillance schedule shall be reviewed periodically and revised as necessary to assure that coverage is maintained to remain current.
- Regularly scheduled audits/surveillance shall be supplemented when necessary to provide adequate coverage.

Brief Description of QA Program Elements: Assessments (3)

- The auditing organization shall develop and document an audit/surveillance plan. This plan shall identify the scope, requirements, personnel, applicable documents, schedule, and written procedures or checklists.
- The report shall be signed and issued by the team leader, and it shall include the following information, as appropriate:
  - Description of the scope;
  - Identification of the auditor(s);
  - Identification of person(s) contacted during audit/surveillance activities;
  - Summary of results, including a statement on the effectiveness of the QA program elements;
  - Description of each reported adverse audit or surveillance finding in sufficient detail to enable corrective action to be taken by the audited organization.

Brief Description of QA Program Elements: Assessments (4)

- Participation in Intercomparison / Proficiency Programs
  - Help determine the proficiency of the sampling and analyses;
  - Is the most efficient process for assessing the effectiveness of the QA program;
  - Can help identify the deficiency (ies) in each element of the operation;
  - Will add confidence that the reported results are reliable and can be used to take remedial action where needed;
  - Is an excellent platform for the exchange of information, experience, and knowledge among participant and laboratories

Summary and Conclusions

- Briefly Discussed Approach to Developing a QA Program
- Briefly Described Elements (11) of a Typical QA Program
- Briefly Discussed the Importance of Participation the Intercomparison / Proficiency Programs

References

- ANSI N42.23-1996, "INSTRUMENTATION QUALITY ASSURANCE FOR RADIOASSAY LABORATORIES."
- For Example: SOFTWARE VERIFICATION AND VALIDATION CAN BE FOUND IN IEEE SANDARD 1012-1986.