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Workshop Training
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Workshop Training

1. Organization and Management

- Quality Assurance (QA) Plan includes organizational chart
- QA Officer designated, including trained backup
  - Laboratory organization includes quality-related key positions (Health & Safety Officer, Radiation Safety Officer) and backups for both positions
- QA responsibilities:
  - Nonconformance reports
  - Oversight of corrective actions
  - Performance evaluation analyses
  - Reviews of standard operating procedures (SOPs)
  - Internal audits
  - Logbooks reviews
  - Control charts reviews

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2. Quality Systems – Establishment, Audits, Essential Quality Control (QC), and Data Verification

- QA Plan consistent of all requirements
- QA Plan defines laboratory policies and commitment to the following:
  - -- Ethical standards
  - -- Providing accurate, defensible data
  - -- Client confidentiality
  - -- Good laboratory practices
- QA Plan includes a list of certifications/accreditations
- Laboratory has established a minimum frequency for review of control documents/procedures (e.g., all SOPs)
- Internal audit program
- Effectiveness review of corrective actions – causal effects to prevent reoccurrences
- Participation a minimum of 1 year in an internationally/ nationally recognized performance evaluation program for radiochemistry, inorganic materials, and organic materials

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3. Personnel

- Laboratory maintains records of indoctrination/training in the form of:
  - Attendance sheets
  - Training logs
  - Personnel training records
- Training includes:
  - Technical skills – demonstration of capability
  - Laboratory analytical methods
  - QC procedures
  - Safety policies
  - Waste management practices
  - Radiation materials control/radiation worker training

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3. Personnel (continued)

Employee/Analyst Considerations:

- Monitoring for radiological/chemical exposure (e.g., lead, mercury, asbestos, polychlorinated biphenyls, etc.)
- Adherence to personnel protective equipment (PPE) requirements
  - Remove PPE in eating areas
- Testing of eye wash stations
- Emergency preparedness drills
  - No blockage of ingress/egress routes

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4. Equipment

- Laboratory maintains a current list of available major equipment type, date of purchase, repair history, and operational status
- Schedule for preventative maintenance
- Program in place to ensure that balances are calibrated before initial use and annually thereafter
- Class I (formerly Class S) certified check weights must be calibrated every 5 years
- SOP to identify equipment taken out of service
- Documentation of initial and verification checks

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5. Measurement, Traceability, and Calibration

- Measurements made are traceable to recognized standards of measurement (e.g., National Institute of Standards and Technology)
- Records of all calibration certificates traceable to international/national standards
- Program of calibration and verification for reference standards
- SOPs for reagents and deionized water production
- Procedures are defined for ensuring that balances, refrigerators, ovens, thermometers, and other laboratory equipment are accurate and that performance is monitored and documented

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6. Test Methods and Standard Operating Procedures

- SOPs are in place for (but not limited to):
  - -- Sample management
  - -- Reagent/standard preparation
  - -- General laboratory techniques
  - -- Test methods
  - -- Equipment calibration/maintenance
  - -- QC
  - -- Corrective actions
  - -- Each accredited analysis or test method
  - -- Reporting
  - -- Records management
  - -- Information management
  - -- Health and safety
  - -- Radioactive materials mgmt
  - -- Waste disposal
  - -- Data reduction and validation
- Laboratory has procedure to track the expiration date of standards and to remove expired standards from use
- When sub-sampling (obtaining sample aliquots) is carried out as part of the test method, the laboratory uses documented SOPs and appropriate techniques to obtain representative sub-samples
- SOP to ensure that all QC measures are reviewed and evaluated before data is reported to client

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7. Sample Handling, Sample Acceptance Policy, and Sample Receipt

- Laboratory has SOPs to address the following:
  - Checking sample preservation
  - Proper containers
  - Notifying clients of shipping or sample anomalies
  - Checking holding times, and notifying laboratory personnel of short holding times
  - Use of fume hoods for opening shipping containers/ samples
  - Radiation screening of samples, and laboratory notification and labeling requirements for radioactive samples

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7. Sample Handling, Sample Acceptance Policy, and Sample Receipt (continued)

- Prior to performing radiological surveys for potential fixed contamination of all external surfaces, the radiological survey instrumentation must be checked for operational performance using a radiological source and a battery check
- Sample receiving logbook is used to record the chronology of sample entry into the laboratory, including time, date, customer, sample identification numbers, and signature or initials of person making the entry
- Internal chain-of-custody procedure
- Laboratory procedure to ensure radioactivity levels comply with regulatory levels (radiological controls per individual analyte/ cumulative activity)

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8. Records

- Documents must be retained for 5 years
- System in place to ensure that records are legible, accurate, and complete (e.g., independent review of records, logbooks)
- Records of analytical data, administrative records, and other technical information are maintained in environmentally secure, controlled-access storage
- Transfer of samples, sub-samples, digesettives, or extracts to another party is subject to chain-of-custody legal requirements
- Record of annual documented review of waste disposal vendor to check the following:
  - Operational status (e.g., upset conditions)
  - Notices of Violations
- Records indicating the date of sample disposal at hazardous waste facility and the name of the individual that performed the task

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8. Records (continued)

- Hardcopy laboratory logbooks comply with the following:
  - Permanent binding – loose-leaf binders are not permitted
  - Controlled through documented system
  - Sequentially numbered pages
  - Unique serial numbers clearly displayed on each notebook
  - Reviewed on a regular frequency
  - Documentation of reviews must be maintained

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9. Laboratory Report Format and Content

- SOP for notification of affected organizations/client of nonconforming items
- SOP for reviewing and documenting changes made to data after report preparation that ensures traceability of updates

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10. Subcontracting Analytical Samples

- Laboratory has records to indicate that it advised the client in writing of its intention to subcontract any portion of the testing to another party

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11. Outside Support Services and Supplies

- Contracted items and services that have the potential to affect the quality of analytical tests are controlled to ensure conformance with contractual requirements:
  - Source evaluation and selection
  - Source verification
  - Audit
  - Examination of items or services before use
  - Vendor supplier list with all supply items (bottles, pipettes, beakers, etc.)

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12. Complaints

- Laboratory has a documented policy and SOP for resolution of complaints received from clients or other parties about the laboratory's activities

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13. Laboratory Information Management System (LIMS)

- Software change control documentation identifies:
  - Persons requesting/authorizing software changes
  - Measures for testing and QA
  - Approving changes
- Systems backups occur on a regular basis
- LIMS is protected from computer viruses
- Individual user names and passwords have been implemented
  - Passwords changed at 6-month or 1-year intervals
- Users are trained in computer awareness security, and the training is documented
- Fire extinguishers that are designed to avoid damage to the computer equipment must be available and mounted in visible, accessible areas