

APPENDIX H

AUDIT CHECKLISTS
FOR THE
NEVADA BROWNFIELDS PROGRAM

APPENDIX H -- AUDIT CHECKLISTS FOR THE NEVADA BROWNFIELDS PROGRAM

General Audit Procedures

1. Scope and Application

- 1.1. The following procedures describe the process of examination applied to laboratory-generated analytical results and outside laboratory results after the final data packages are available.
- 1.2. These procedures are intended to detect issues with sampling design and implementation, laboratory analytical procedures, quality control (QC) results, and conformance to the needs of the project
- 1.3. This standard operating procedure (SOP) describes the process to be taken and the responsibility of the Nevada Brownfields Program (NBP) Quality Coordinator and U.S. Environmental Protection Agency (EPA) Quality Assurance Officer (QA Officer), primarily.

2. Summary of procedure

- 2.1. During sampling events, the QA Officer or designee will fill out Field Audit Checklist.
- 2.2. The QA Officer or designee will prepare Field Audit Reports within two weeks for the Project Manager.
- 2.3. Samples analyzed by the laboratory will be subjected to three levels of review, involving the Laboratory Manager, the QA Officer and Laboratory Director.
- 2.4. Upon completion of analysis of samples and receipt of final data package, the QA Officer will go through the Data Audit Checklist, noting any deficiencies.
- 2.5. The QA Officer will prepare a Data Audit Report within two weeks for the Project Manager (Laboratory Director).
- 2.6. The Project Manager will have the responsibility of instituting corrective action and applying supplied reports to program needs and data quality objectives for final decision making.

3. Comments

- 3.1. This procedure is applicable to all activities of the EPA and all federally funded programs carried out by the NBP.
- 3.2. This procedure coincides with Option 3 of the tiered validation approach summarized in the table, "Region 9 QA Office's General Guidelines for Superfund Data Validation/Review".
- 3.3. Qualifiers/flags used by the Laboratory are as follows:
 - 3.3.1. Green flag (g): note issue, but accept result as valid unless other problem indicators arise
 - 3.3.2. Yellow flag (y): note issue, results suspect and/or data inclusion requires caution
 - 3.3.3. Red flag (r): note issue, results invalid or unacceptable for inclusion in decision-making

4. Procedure

4.1. In the field, during sampling, the QA Officer has the responsibility of overseeing activities of sampling staff and documenting deficiencies through the use of the Field Audit Checklist (see attached).

4.2. The QA Officer must stop sampling activities that may compromise sample quality and, therefore, data quality.

4.3. Based on observations in the field, the QA Officer will prepare a Field Audit Report within two weeks to keep the Project Manager informed.

4.4. The Field Audit Report will summarize the event, including a table of samples collected, a description of any deviations from procedures, and notes of all issues surrounding samples that could lead to data quality issues (from Field Audit Checklist):

4.4.1. If data is recorded in pencil, the author will be requested to rerecord data and initial the correction.

4.4.2. Any deviation from SOPs will be flagged appropriately depending on the gravity of the issue and noted in the Field Audit Report.

4.4.3. Lack of trained personnel or QA oversight will be noted in report and data will be assigned a yellow flag.

4.4.4. Sample containers that are not certified clean will not be used. If they are mistakenly used to collect samples, a red flag will be assigned to resulting data.

4.4.5. Lack of preservative in samples will be noted in report and data assigned a yellow flag.

4.4.6. Samples collected from incorrect locations are assigned red flags and this is noted in report.

4.4.7. If not all samples are collected; a green flag is assigned so that the issue of completeness can be examined.

4.4.8. If expired standards are used this will be noted in the Field Audit Report. The field analysis is invalid (adequate purge questionable) and data resulting from collected samples will be assigned a yellow flag.

4.4.9. Field calibration and documentation issues raise the same question as 4.4.8 and if uncorrected, data will be assigned a yellow flag.

4.4.10. If samples are kept cold by sampling personnel, the mistake will be corrected in the field or the time elapsed will be noted and the Project Manager will make a decision concerning level of concern.

4.4.11. Chain-of-custody issues will be resolved prior to sample shipment. If uncorrected, flags will be assigned to data based on the seriousness of the mistake.

4.4.12. Samples not delivered within holding times will be noted in Field Audit Report and data will be assigned red flags.

4.5. Samples submitted to laboratory should be subjected to three levels of review that include recalculation and a check of transcription from logbooks to electronic form.

4.6. After the Laboratory performs the analysis and submits a final report or final results are received from an outside laboratory, the QA Officer will use the Data Audit Checklist (see attached) as a guide to examine whether the measurement quality objectives, as well as all other requirements of the QAPP, have been met.

4.7. The QA Officer will prepare, within two weeks, a Data Audit Report based on the checklist, deliverable to the Project and Laboratory Managers.

4.8. The Data Audit Report will include, in addition to details from the Data Audit Checklist, information from the Field Audit Report that has relevance to sample results and possible data quality (e.g. all flagged samples will be noted and described or referenced back to field documentation, corrective actions at any stage of sampling or analysis).

4.8.1. If Chain-of-custody forms are not included, the lab is contacted. If forms are lost, unsigned or unavailable, this will be noted in the Data Audit Report and the sampling data will be assigned a red flag.

4.8.2. If custody seals are broken in transit, this will be noted in the Data Audit Report and the sampling data will be assigned a red flag.

4.8.3. If samples are not received cold by the laboratory, the time elapsed in transit will be noted and the Project Manager will make a decision what level of concern is appropriate.

4.8.4. QA/QC reports are required in the final data package, if not received, the lab will be contacted and a note will be included in the report. If no QA/QC info is supplied, the data will be assigned a red flag.

4.8.5. Method blank information is not required of outside laboratories, but is required in Laboratory final data package.

4.8.6. Calibration curves are not required of outside laboratories, but are required in Laboratory final data package.

4.8.7. Calibration curves containing less than 5 points will be noted and data assigned a green flag (use spikes as accuracy indicators). If curve does not bracket samples, data will be assigned a red flag.

4.8.8. If calibration checks differ by more than 15%, this will be noted and the data will be assigned a red flag.

4.8.9. If QC samples are not included in each batch, this will be noted and the data will be assigned a yellow flag.

4.8.10. If blanks show contamination, this will be noted and the data will be assigned a red flag.

4.8.11. For surrogate and matrix spike recoveries:

4.8.11.1. If there is no detection, a red flag is warranted.

4.8.11.2. If the compounds are detected, but below ranges, a yellow flag is assigned (quantitation suspect).

4.8.11.3. If the compounds are recovered above the specified ranges, a green flag will be given.

4.8.12. If the matrix spike duplicate differs by more than 15%, this will be noted and the data will be assigned a yellow flag.

4.8.13. If not all target analytes are included, the lab will be contacted and requested to reanalyze if the holding time has not expired (no flag). If the holding time has expired, this issue will be noted in reference to completeness of monitoring (green flag).

4.8.14. If methods used by the laboratory were inappropriate, the lab will be contacted and reanalyzed requested if holding times have not expired (no flag). A yellow flag will be assigned if samples cannot be reanalyzed.

4.8.15. Samples analyzed outside of holding times will be assigned a red flag.

4.8.16. The lab will be contacted to describe report flags and detection limits if not included in analytical report. This information will be included in Data Audit Report.

4.8.17. If the results are not reported in agreement with listed detection limits, the lab will be contacted for clarification or the result will be recalculated. If results are less than the limits provided by the lab, the data will be assigned a red flag.

4.8.18. A yellow flag will be given to all data that differs by more than 15% from data from another lab.

4.9. Annually, the Project Manager will compile the reports for federally funded projects for decisions on sample design and collection, choice of laboratory and overall program execution.

4.10. The QA Officer will resolve issues (with Project Manager oversight) encountered in the field or with laboratories if the problem pertains to quality assurance/quality control.

4.11. The Project Manager confirms the proper resolution of issues in the field, resolves administrative problems uncovered in Field or Data Audits or in the annual review, and decides what data to use for decision-making based on professional judgment and all available information.

5. Bibliography

5.1. EPA Guidance for Quality Assurance Project Plans, EPA QA/G-5, February 1998.

5.2. Region 9 Tiered Approach to Validation

Checklists Attached Below

Appendix H - Field Audit Checklist

See also, the NELAC Quality System Checklist (99 pages) at:

<http://www.nelac-institute.org/qscheck2009-access.php>

Sampling Project: _____

Date of Sampling: _____

- _____ All relevant information recorded in bound logbooks using ink
- _____ Sampling personnel are in possession of relevant, current SOPs
- _____ SOPs are followed or deviations are noted in logbooks with appropriate flags for the samples involved
- _____ All samplers are trained or supervised by trained personnel
- _____ QA oversight is provided during sampling activities
- _____ Sample containers are appropriate for the intended analyses and certified clean, either by laboratory or manufacturer
- _____ Sample containers have preservatives if needed for the intended analyses
- _____ The sampled are collected from the proper sites
- _____ All required QC samples are collected
- _____ Standards for field analyses are fitting for the intended use and are not expired
- _____ Field calibrations performed were performed successfully within QC limits
- _____ Field calibration and calibration verification data appropriately recorded in bound logbook
- _____ Results of field sample analysis appropriately recorded in bound logbook
- _____ Samples are stored at 4 degrees C
- _____ All chain-of-custody documentation is complete and included in sample delivery
- _____ Custody seals are present and intact at time of delivery
- _____ Samples are delivered within prescribed holding times

Printed name of auditor: _____

Signature of auditor: _____

Title of auditor: _____

Address and phone number of auditor: _____

Date of audit: _____

Appendix H - Data Audit Checklist

See also, the NELAC Quality System Checklist (99 pages) at:

<http://www.nelac-institute.org/qscheck2009-access.php>

Sampling Project: _____

Date of Sampling: _____

Analytical Laboratory: _____

- _____ Copies of the chain-of-custody forms are included in the final data package
- _____ Chain-of-custody forms are signed by all parties involved in sample transit
- _____ Custody seals were listed as intact upon receipt by the laboratory
- _____ Sample conditions was listed as cold upon receipt by the laboratory
- _____ The final data package includes a QA/QC report. Check the following:
 - _____ Method blank information is included and results are acceptable
 - _____ Calibration curve is supplied
 - _____ Calibration curve contains at least five points and brackets concentrations of samples unless impractical for method.
 - _____ Calibration checks are listed and relative differences are within 15%
 - _____ Calibration checks, matrix spikes and duplicates are analyzed with each batch of 20 samples
 - _____ Field and equipment blanks show no contamination with analytes of interest or with contaminants that interfere with target analytes
 - _____ Surrogate recoveries are listed and are within the ranges specified by the QA Program Plan or project-specific SAP
 - _____ Results of matrix spike samples are listed and are within the ranges specified by the QA Program Plan or project-specify SAP
 - _____ Results of matrix spike duplicates are within 15% of matrix spike results
 - _____ All target compounds are included in laboratory analytical reports as stated in the QA Program Plan or project-specify SAP
 - _____ Proper analytical methods were employed by the laboratory to analyze samples as stated in the QA Program Plan or project-specify SAP
 - _____ Samples were extracted and analyzed within holding times
 - _____ Descriptions of qualifiers and flags are provided in the report
 - _____ Method detection limits or practical quantitation limits are listed in the report
 - _____ Reported results agree with listed MDLs or PQLs
 - _____ If two or more laboratories analyzed the same sample, results are within 15%

Printed name of auditor: _____

Signature of auditor: _____

Title of auditor: _____

Address and phone number of auditor: _____

Date of audit: _____

The Nevada Laboratory Certification Program (LCP) is administered through the Bureau of Water Quality Planning, Nevada Division of Environmental Protection (NDEP). Nevada is not an accrediting authority for the National Environmental Laboratory Accreditation Conference (NELAC); however, the state does assess laboratories to NELAC standards. Assessment forms from the LCP are attached below.

| Laboratory: | | Audit Date: | Assessor: |
|--------------------|---|--------------------|--|
| Item | Line of Inquiry | Status | Summary of Observations/Objective Evidence Reviewed |
| 1.1 | Quality Assurance Documents | | |
| 1.1.1 | The laboratory has developed a Laboratory Quality Assurance Plan (QAP) consistent with NELAC 5.5.2 that is issued and maintained as a controlled document. | | |
| 1.1.2 | The QAP defines the laboratories policies and its commitment to: <ul style="list-style-type: none"> • ethical standards • client confidentiality • good laboratory practices • client service | | |
| 1.1.3 | The QAP includes a listing of certifications and accreditations or a reference to the location of such a list if not part of the QAP. | | |
| 1.1.4 | The QAP describes the: <ul style="list-style-type: none"> • organizational structure • functional responsibilities • levels of authority • interfaces for those managing, performing and assessing work. | | |
| 1.1.5 | The QAP is accessible to all laboratory personnel and they are aware of its location. | | |
| 1.1.6 | The QAP includes an organizational chart showing that QA personnel: <ul style="list-style-type: none"> • operate independently from line management • are not directly involved with cost, schedule or production functional areas • report directly to the highest level of laboratory management | | |

| Laboratory: | | Audit Date: | | Assessor: | |
|--------------------|--|--------------------|--|------------------|--|
| Item | Line of Inquiry | Status | Summary of Observations/Objective Evidence Reviewed | | |
| 1.2 | Quality Assurance Management | | | | |
| 1.2.1 | General Quality Assurance responsibilities include: <ul style="list-style-type: none"> • Oversight of corrective actions • Oversight of PT analysis • Reports directly to management • Internal audits • Review of SOPs | | | | |
| 1.2.2 | A quality assurance officer has been designated in writing who is empowered to: <ul style="list-style-type: none"> • stop unsatisfactory work • prevent reporting results from an out of control measurement system • initiate and monitor corrective action procedures • revise, control and distribute the QAP | | | | |
| 1.3 | Performance Evaluation Programs | | | | |
| 1.3.1 | The laboratory demonstrates successful participation for two of the last three NIST recognized PT programs conducted at six month intervals | | | | |
| 1.3.2 | The laboratory documents the root cause and corrective action for failed PT samples. | | | | |

| Laboratory: | | Audit Date: | Assessor: |
|--------------------|--|--------------------|--|
| Item | Line of Inquiry | Status | Summary of Observations/Objective Evidence Reviewed |
| 1.4 | Personnel Training and Qualification | | |
| 1.4.1 | The laboratory organization possesses well-defined and documented roles and responsibilities for each position. | | |
| 1.4.2 | The laboratory maintains records of indoctrination and training in the form of: <ul style="list-style-type: none"> • attendance sheets • training logs • personnel training records • a description of the training and indoctrination | | |
| 1.4.3 | Documentation is maintained indicating training in: <ul style="list-style-type: none"> • technical skills • laboratory analytical methods • QC Procedures • safety policies • waste management practices • radiation worker training | | |
| 1.4.4 | The laboratory has a written analyst proficiency evaluation policy that provides a means to gauge and document the continuing competence of experienced individuals, as well as specifying additional training and documentation practices applicable to all personnel. | | |
| 1.4.5 | The following personnel criteria have been satisfied: <ul style="list-style-type: none"> • management and supervisory personnel possess a BS or BA in chemistry or related science and 2 years directly related experience • laboratory manager/director with at least a BS or BA in chemistry or related science and 5 years directly related experience • written documentation to support qualifications of staff consisting of listing personnel, their assignments, responsibilities, degrees of education and years of applicable experience. | | |

| Laboratory: | | Audit Date: | Assessor: |
|--------------------|---|--------------------|--|
| Item | Line of Inquiry | Status | Summary of Observations/Objective Evidence Reviewed |
| 1.5 | Quality Control Systems | | |
| 1.5.1 | The laboratory has established a system to identify, document, correct, and prevent quality problems. | | |
| 1.5.2 | There has been documented review by management to assess the effectiveness of the quality improvement system. | | |
| 1.5.3 | The laboratory has established a "Non-Conformance System" to identify problems, out-of-control events and issues that are not part of scheduled assessments. | | |
| 1.5.4 | A corrective action process has been implemented which determines: <ul style="list-style-type: none"> • events leading to the adverse condition • technical activities associated with the problem • generic implications of the problem • extent to which similar problems have occurred • assignment of personnel to corrective action • documentation of corrective action plan • effectiveness of corrective actions • actions taken to preclude recurrence • review of regulatory requirements • client notification | | |
| 1.5.5 | Written procedures are in place for the notification to affected organizations of nonconforming items. | | |
| 1.5.6 | The laboratory has a system that tracks corrective actions to completion. | | |

| Laboratory: | | Audit Date: | Assessor: |
|--------------------|--|--------------------|--|
| Item | Line of Inquiry | Status | Summary of Observations/Objective Evidence Reviewed |
| 1.6 | Documents and Records | | |
| 1.6.1 | Laboratory activities affecting quality are defined in documented instructions or procedures which are: <ul style="list-style-type: none"> • distributed in a controlled manner • periodically reviewed and updated • available to all laboratory personnel • retained in the laboratory's archives | | |
| 1.6.2 | The laboratory has established a minimum frequency for review of controlled documents and procedures | | |
| 1.6.3 | Documents are retained for a minimum of 5 years | | |
| 1.6.4 | Standard Operating Procedures are in place for (but not limited to) the following areas: <ul style="list-style-type: none"> • Analytical tests • Sample tracking and COC (from receipt to disposition) • Sample preparation (including subsampling) • Sample storage and security • Prevention of sample contamination • Facility security • Data reduction, verification, and reporting • Acceptance criteria (e.g., QC limits, calibrations, etc.) • Document control • Data packages review prior to submittal • Shipment of deliverables • Records disposition • Preparation and traceability of standards • Catastrophic failure of a refrigerator, incubator, etc. • Glassware cleaning • Equipment maintenance • Qualification of personnel and training | | |

| Laboratory: | | Audit Date: | Assessor: |
|--------------------|--|--------------------|--|
| Item | Line of Inquiry | Status | Summary of Observations/Objective Evidence Reviewed |
| 1.6.5 | <p>At a minimum the SOPs define, establish and implement the following:</p> <ul style="list-style-type: none"> • identification of the test method • applicable matrix or matrices • detection limit • scope and application, including components to be analyzed • summary of the test method • definitions • interferences • safety • equipment and supplies • reagents and standards • sample collection, preservation, shipment, storage • quality control • calibration and standardization • procedure • calculations • method performance • pollution prevention • data assessment and acceptance criteria for quality control measures • corrective actions for out-of-control or unacceptable data • waste management • references • any tables, diagrams, flowcharts and validation data | | |
| 1.6.6 | A system is in place to ensure that quality records are legible, accurate, and complete, e.g., independent review of records, logbooks, etc. | | |
| 1.6.7 | Corrections to documents that will become quality records are made by drawing a single line through the error, initialing and dating the error, and justifying the correction (if not self-explanatory). | | |

| Laboratory: | | Audit Date: | Assessor: |
|--------------------|---|--------------------|--|
| Item | Line of Inquiry | Status | Summary of Observations/Objective Evidence Reviewed |
| 1.6.8 | <p>The laboratory has a procedure delineating the records control system that includes:</p> <ul style="list-style-type: none"> • Specifications of items, data, and processes of which records are to be controlled • Requirements for the preparation, review, approval, and maintenance of records to accurately reflect completed work and to fulfill statutory requirements • Requirements and responsibilities for record transmittal distribution, change, retention, protection, preservation, traceability, archival, retrieval, and disposal • Verification that records received are legible and are in agreement with the transmittal document • Requirements for access to and control of the files • Procedures for the control, client confidentiality, and accountability of records removed from the storage location • Procedures for filing of supplemental information and disposition of superseded records • Storage of records in a manner approved by the organizations responsible for the records • Replacement, restoration, or substitution of lost or damaged records • Procedures for data correction, which include how corrections are to be made and establish who is authorized to change or correct data. | | |

| Laboratory: | | Audit Date: | Assessor: |
|--------------------|---|--------------------|--|
| Item | Line of Inquiry | Status | Summary of Observations/Objective Evidence Reviewed |
| 1.6.9 | <p>The laboratory has procedures in place to validate non-standardized methods, laboratory designed/developed methods, standardized methods used outside their intended range and amplifications of standardized methods to confirm that the methods are fit for the intended use. The procedures include:</p> <ul style="list-style-type: none"> • scope • description of the type of item to be tested or calibrated • parameters or quantities to be determined • apparatus, equipment, reference standards and reference materials required • environmental conditions required and any stabilization period needed • description of the procedure, including affixing identification marks, handling, transporting, storing and preparing of items, checks to be made before the work is started, checking that the equipment is working properly and, where required, calibrations and adjusting the equipment before each use, method of recording the observations and results, any safety measures to be observed • criteria and/or requirements for approval/rejection • data to be recorded and method of analysis and presentation • uncertainty or procedure for estimating uncertainty | | |
| 1.6.10 | The laboratory has procedures for reviewing and documenting changes made to data after report preparation that ensure traceability of updates | | |
| 1.6.11 | Records of data and other technical information are maintained in environmentally secure controlled access storage which shall protect the records from unauthorized access or damage. Alternatively, the laboratory stores duplicate records at a different location. | | |

| Laboratory: | | Audit Date: | | Assessor: | |
|--------------------|--|--------------------|--|------------------|--|
| Item | Line of Inquiry | Status | Summary of Observations/Objective Evidence Reviewed | | |
| 1.7 | Work Process | | | | |
| 1.7.1 | The laboratory maintains: <ul style="list-style-type: none"> • a list of typical method detection limits, achieved for water, soil and other matrices commonly analyzed • procedures for determining limits of detection and frequency of verification | | | | |
| 1.7.2 | A standard Operating Procedure is in place for reagent and deionized water production which includes (at a minimum): <ul style="list-style-type: none"> • preventative maintenance of water purification equipment • control criteria • corrective action process for out-of-spec water | | | | |
| 1.7.3 | The laboratory has a water system capable of meeting the ASTM specifications of "Type II" water | | | | |
| 1.7.4 | The conductivity and/or resistivity of the water from the purification system is monitored daily and the results are recorded in a logbook. | | | | |
| 1.7.5 | Sample glassware and containers are either designated as disposable or cleaned according to recommended procedures that are listed in the individual Analytical Master Specifications. | | | | |
| 1.7.6 | A copy of the laboratory-specified Standard Operating Procedure (SOP) for glassware is posted in the glassware cleaning area. The sample preparation area is kept clean to avoid contamination or cross-contamination. | | | | |

| Laboratory: | | Audit Date: | | Assessor: | |
|--------------------|---|--------------------|--|------------------|--|
| Item | Line of Inquiry | Status | Summary of Observations/Objective Evidence Reviewed | | |
| 1.7.7 | A refrigerator storage blank is present for the storage of all volatile organic samples. Specific procedures for assessing the adequacy of these storage blank data and taking action for nonconforming conditions is established. The refrigerator storage is analyzed every 14 days when samples are being stored in the laboratory. The data from the analysis of the refrigerator storage blanks is available for review. | | | | |
| 1.7.8 | The laboratory maintains hard copy laboratory notebooks that detail: <ul style="list-style-type: none"> • the sample bottle preparation and analytical work, including the analyses being performed • samples being analyzed • procedures used • reading taken • calculations performed • analytical results • any observations during analysis | | | | |
| 1.7.9 | Standards and reference materials shall be stored separately from samples and standards protected in a controlled cabinet or refrigerator. | | | | |
| 1.7.10 | Reagent grade or higher purity chemicals are used. Reagents are checked prior to use and the supporting documentation of the checks shall be filed in a manner that can be easily retrieved. | | | | |

| Laboratory: | | Audit Date: | Assessor: |
|--------------------|--|--------------------|--|
| Item | Line of Inquiry | Status | Summary of Observations/Objective Evidence Reviewed |
| 1.8 | Statistical Control Methods | | |
| 1.8.1 | The laboratory Quality Control manager or his/her designee periodically reviews control charts at a specified frequency for out of control conditions and initiates appropriate corrective action procedures. | | |
| 1.8.2 | Control methods are accessible to the individual performing the analyses, data reviewers, and the quality assurance staff. | | |
| 1.9 | Procurement | | |
| 1.9.1 | A process is established and implemented to control purchased items and services. This process is subject to ongoing review by management to assess its effectiveness. | | |
| 1.9.2 | Contracted items and services that have the potential to affect the quality of analytical tests are controlled to ensure conformance with contractual requirements. Such control includes one or more of the following: <ul style="list-style-type: none"> • Source evaluation and selection (pre-performance/pre-award survey) • Source verification • Audit • Examination of items or services before use | | |
| 1.9.3 | Procurement system controls makes provision for the following: <ul style="list-style-type: none"> • Identify applicable technical and administrative requirements from the Statement of Work for contracted services and items including acceptance criteria • The process for selecting and qualifying subcontractors • Establishing processes to ensure that qualified subcontractors continue to provide acceptable products and/or services • Accepting purchased item and/or services • Receiving and maintaining procurement records, including evidence of conformance • Documenting nonconforming items and services | | |

| Laboratory: | | Audit Date: | | Assessor: | |
|--------------------|---|--------------------|--|------------------|--|
| Item | Line of Inquiry | Status | Summary of Observations/Objective Evidence Reviewed | | |
| 1.9.4 | When there are indications that subcontractors knowingly supplied items or services of substandard quality, this information is forwarded to appropriate management for action. | | | | |
| 1.10 | Internal Audit Procedures | | | | |
| 1.10.1 | The laboratory has established an internal audit program which includes: <ul style="list-style-type: none"> • Independent assessments by technically qualified personnel • Maintenance of an audit schedule • Audit procedures • Standard formats for reporting findings to laboratory management • Methods for implementing and verifying corrective actions | | | | |
| 1.10.2 | Personnel conducting independent assessments have sufficient authority, access to work areas, and organizational freedom necessary to observe all activities affecting quality and to report the results of such assessments to laboratory management. | | | | |
| 1.10.3 | Assessment results are documented, reported to and reviewed by the level of management with authority to affect any necessary corrective actions. | | | | |
| 1.11 | Sample Receiving | | | | |
| 1.11.1 | The laboratory has procedures in place to address the following: <ul style="list-style-type: none"> • Checking sample preservation (pH, temperature) • Proper containers • Preserving samples when required • Notifying clients of shipping or sample anomalies • Checking holding times and notification of lab personnel of short holding times • Use of fume hoods for opening samples and shipping containers • Radiation screening of samples, lab notification and labeling requirements for radioactive samples | | | | |
| 1.11.2 | Sample custodians document anomalies encountered in the sample receiving process. | | | | |

| Laboratory: | | Audit Date: | | Assessor: | |
|--------------------|--|--------------------|--|------------------|--|
| Item | Line of Inquiry | Status | Summary of Observations/Objective Evidence Reviewed | | |
| 1.12 | Sample Control and Building Security | | | | |
| 1.12.1 | Physical or administrative controls exist to ensure that: <ul style="list-style-type: none"> Chain of Custody (COC) is not broken during times that laboratory staff are present or not present. Visitor access is controlled by positive administrative controls and strict escort rules developed for all visitors The facility has controlled entrance and egress points | | | | |
| 1.12.2 | A sample receiving logbook or equivalent system is used to record the chronology of sample entry into the laboratory including time, date, customer, sample identification numbers, etc. | | | | |
| 1.12.3 | When samples are received by the laboratory, an internal chain of custody procedure is initiated. | | | | |
| 1.12.4 | Internal custody is maintained until final disposition or return of the sample to the client. | | | | |
| 1.12.5 | The laboratory maintains an indexed sample storage system which facilitates sample retrieval. | | | | |
| 1.12.6 | The laboratory has established, implemented and documented procedures to ensure the sample's radioactivity levels are consistent with the accompanying documentation and that laboratory regulatory levels are not exceeded. | | | | |
| 1.13 | Inspection and Acceptance Testing | | | | |
| 1.13.1 | The laboratory maintains a current list of available (on hand) equipment types, models, and years and a general description of the facility. | | | | |

| Laboratory: | | Audit Date: | | Assessor: | |
|--------------------|--|--------------------|--|------------------|--|
| Item | Line of Inquiry | Status | Summary of Observations/Objective Evidence Reviewed | | |
| 1.13.2 | A schedule of preventative maintenance activities is developed and the performance of preventive maintenance is documented. | | | | |
| 1.13.3 | Procedures are defined for ensuring that balances, refrigerators, ovens, and other laboratory equipment are accurate and that their performance is monitored and documented. | | | | |
| 1.13.4 | Balances are checked each day that they are used and are calibrated at least annually by an independent company or source. | | | | |
| 1.13.5 | Refrigerator temperatures shall be monitored daily. | | | | |