

QUALITY ASSURANCE PROGRAM MANUAL

**QAM**, Rev. 16 Effective: 08-22-08

Section: 6.0 – Procurement Document Control

provided. Documentary evidence that products and services conform to procurement requirements will be provided and retained. A list of Richmond laboratory approved vendors will be provided the Albuquerque Procurement Office.

- 6.5.2 The effectiveness of the control of quality by contractors and subcontractors will be assessed at intervals consistent with the importance, complexity, and quantity of the product or services.
- 6.5.3 The purchasing department is responsible for maintaining a record of quality related materials received from vendors including any reports for non-conforming material.

#### 6.6 QUALITY RELATED SERVICES

Q.A. personnel will review the purchase requisitions for quality related services. Those services that are determined to be quality related will include, as applicable, the following statement, or similar wording, in the body of the purchase order or by attachment: "The pieces of equipment and/or services to be furnished under this purchase order are subject to the applicable requirements of NQA-1-1994 or ANSI/NCSL-Z540-1-1994."

#### 6.7 NUCLEAR SAFETY RELATED SERVICES

Not applicable to the services provided to clients by Eberline Services.



QUALITY ASSURANCE PROGRAM MANUAL

QAM, Rev. 16 Effective: 08-22-08

Section: 7.0 - Material Receipt and Control

Page 34 of 54

# SECTION 7.0

#### MATERIAL RECEIPT AND CONTROL

#### 7.1 **POLICY**

Only material with acceptable quality characteristics will be allowed into the laboratory.

#### 7.2 **RESPONSIBILITY**

Receipt and initial verification of all materials and equipment received by the Richmond laboratory, either purchased or contract (client) supplied, is the responsibility of the Facilities Support Superintendent or designated individual. Technical verification for materials and equipment will be by the requisitioner or Q.A. personnel, whichever is applicable. Quality related purchase order items will be receipt inspected by Q.A. personnel or the requisitioner.

#### 7.3 MATERIAL CONTROL

Purchased material is controlled by the Facilities Support Superintendent or designated individual.

- 7.3.1 The Facilities Support Superintendent, or designated individual, is responsible for the expedient and correct routing of all initially accepted received materials to general laboratory material storage, or to the requisitioner.
- 7.3.2 Purchasing department personnel are responsible for maintaining a record of materials received from vendors, including Rejected Material Report (RMR), or equivalent form, for any non-conforming material.

#### 7.4 NON-CONFORMING MATERIAL

When received material, affecting quality, has been determined to be non-conforming, the requisitioner or the Q.A. Manager will work with the Purchasing Agent for proper disposition.

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"over 55 years of quality nuclear services"



QUALITY ASSURANCE PROGRAM MANUAL

QAM, Rev. 16 Effective: 08-22-08

Section: 8.0 – Material Storage and Control

Page 35 of 54

SECTION 8.0

#### MATERIAL STORAGE AND CONTROL

#### 8.1 **POLICY**

All materials and supplies in storage will have the necessary protection to preclude deterioration, corrosion, or damage during storage life and will carry identification sufficiently clear to ensure that only those materials specified by process instructions will be withdrawn from material storage and issued for processing.

#### 8.2 **RESPONSIBILITY**

Only authorized personnel will have access to, and the responsibility for, control and issue of materials or supplies. Materials and supplies will be stored to allow for ready identification. Care will be taken to preclude mixing of rejected material and supplies with those that are qualified for issue.



QUALITY ASSURANCE PROGRAM MANUAL

QAM, Rev. 16 Effective: 08-22-08

Section: 9.0 – Control of Process

### SECTION 9.0 CONTROL OF PROCESS

#### 9.1 STANDARD PRACTICES

Standard practices applicable to services provided by the Richmond laboratory are contained in documented procedures and this Q.A. Program Manual. Every effort is made to fulfill the requirements of the following laws, rules, guidance(s), and directives as may be applicable to the operational practices within the laboratory.

- 9.1.1 Federal and State rules and regulations.
- 9.1.2 Consensus standards related to the services performed (e.g., American National Standards Institute).
- 9.1.3 Regulatory Guides published by the Nuclear Regulatory Commission, Department of Energy, or the Environmental Protection Agency.
- 9.1.4 Specific contractual agreements with clients.
- 9.1.5 Where conflict occurs among the above four items, or other appropriate authority, the client will be notified and requested to specify the policy to be followed.

#### 9.2 DOCUMENTED PROCEDURES

- 9.2.1 The laboratory has developed, promulgated, and implemented procedures for the operations performed in the laboratory *including all test methods under which accredited testing is performed. These procedures are documented in the following controlled manuals:* 
  - 9.2.1.1 Bioassay Procedures Manual
  - 9.2.1.2 Calculations Procedures Manual
  - 9.2.1.3 Carriers and Tracers Procedures Manual
  - 9.2.1.4 Commercial Procedures Manual
  - 9.2.1.5 Drinking Water Procedures Manual
  - 9.2.1.6 Hazardous Waste Procedures Manual
  - 9.2.1.7 Quality Assurance Procedures Manual
  - 9.2.1.8 Quality Control Laboratory Procedures Manual
  - 9.2.1.9 Radioactivity Measurements Instrument Procedures Manual
  - 9.2.1.10 Radiochemistry Calibration Procedures Manual
  - 9.2.1.11 Radiometrics Quality Control Procedures Manual
  - 9.2.1.12 Reactor Procedures Manual
  - 9.2.1.13 Reagents Preparation Manual
  - 9.2.1.14 Sample Control Procedures Manual
  - 9.2.1.15 Sample Preparation Procedures Manual
  - 9.2.1.16 Waste Water Procedures Manual



QUALITY ASSURANCE PROGRAM MANUAL

QAM, Rev. 16 Effective: 08-22-08

Section: 9.0 - Control of Process

Page 37 of 54

- 9.2.2 Additionally, the *laboratory has developed* general procedures *that are documented in the following controlled manuals:* 
  - 9.2.2.1 Chemical Hygiene Plan
  - 9.2.2.2 Client Services Procedures Manual
  - 9.2.2.3 Environmental Compliance Procedures Manual
  - 9.2.2.4 Facilities Maintenance Procedures Manual
  - 9.2.2.5 Health & Safety Manual
  - 9.2.2.6 Laboratory Safety Procedures Manual
  - 9.2.2.7 Radiation Safety Manual
  - 9.2.2.8 Radiation Safety Procedures Manual

#### 9.3 **RESPONSIBILITY**

The Operations Manager, or designated representative, determines which instructions or procedures require quantitative or qualitative acceptance criteria and specifies the appropriate criteria on special contracts or projects.

#### 9.4 WORK POLICY

All work to be performed by the Richmond Laboratory on client samples is authorized by the client and controlled through a Laboratory Information Management System (LIMS) work order process, or other document deemed necessary by the Program Manager, which incorporates the client's requirements. Field sampling operations are not performed by laboratory personnel.

- 9.4.1 The work order specifies those analyses necessary to assure compliance with contractual obligations.
- 9.4.2 The Program Manager, or designated individual, is responsible for notifying the Q.A. Manager and performing laboratory departments, through the appropriate supervisor, of all contract requirements including reporting format and quality control criteria. This may be done by reference to other documents (e.g., Purchase Order, statement of work, technical specifications, etc.) that delineates the contract requirements.
- 9.4.3 The Program Manager, Operations Manager, or designee, will ensure planning, scheduling, and resources are considered when contracting for or accepting work.
- 9.4.4 When subcontracting analytical services, the Program Manager, or designated individual, will assure that the requirements for subcontractor laboratories, as specified in Section 6.4 of this manual, are met and that the client is notified in writing of the intention to subcontract any portion of the testing to another party.



QUALITY ASSURANCE PROGRAM MANUAL

QAM, Rev. 16 Effective: 08-22-08

Section: 10.0 – Preventive Maintenance

#### SECTION 10.0 PREVENTIVE MAINTENANCE

#### 10.1 **POLICY**

Preventive maintenance is performed as required on instrumentation and equipment to prevent down time and to ensure reliable performance. The laboratory maintains instrument redundancy which precludes the requirement for a repair and maintenance capability for instrumentation. Maintenance and/or repair of equipment is performed by the equipment manufacturer or authorized representative under contract or purchase order.

#### 10.2 MAINTENANCE

Preventive maintenance procedures will be developed for use where instructions are not provided in the manufacturer supplied operator's manual. As applicable, each department will maintain a major equipment and measurement standards list. A record of instrument maintenance, calibration, and repair, if applicable, will also be maintained. The supervisors and operating personnel are responsible for complying with the department maintenance schedule.

#### 10.3 SPARE PARTS

Supervisors will ensure that an adequate inventory of spare parts and consumables is requisitioned and maintained for instrumentation in their area in order to prevent down time or compromised operating conditions.

#### 10.4 FACILITIES MAINTENANCE

Procedures have been developed for management, operation, and maintenance of the facility to include systems maintenance and repair and building security.



QUALITY ASSURANCE PROGRAM MANUAL

QAM, Rev. 16 Effective: 08-22-08

Section: 11.0 – Control of Measurement and Test Equipment

#### SECTION 11.0

#### CONTROL OF MEASUREMENT AND TEST EQUIPMENT

#### 11.1 MEASUREMENT AND TEST EQUIPMENT CALIBRATION POLICY

This section establishes the controls and calibration requirements for all analytical and nuclear measurement equipment. An equipment list will be maintained indicating calibration status.

- 11.1.1 All equipment, whose operation and function directly affect the quality of service, will be inspected/calibrated at established intervals. As applicable, equipment will be suitably identified to reflect calibration status. If an instrument is determined to be out-of-tolerance, it will be segregated, or otherwise clearly identified as inoperable. Records of each calibration will be kept in appropriate logbooks or files. Instruments whose calibrations are performed during method operations are calibrated and controlled in accordance with the method requirements. Run logs will be maintained for this category of instrumentation.
- 11.1.2 The equipment used to determine the quality characteristics and accuracy of instruments will be checked and verified either internally (dependent upon capability), or by qualified calibration services.
- 11.1.3 Frequency of inspection/calibration will be based on use of the equipment or instrument, environmental conditions in which it is used, its inherent stability, manufacturer's recommendation, and the wear or deterioration resulting from its use.
- 11.1.4 Certified standards are used for all primary calibrations. National Institute of Standards and Technology (NIST) or NIST traceable, Environmental Protection Agency (EPA), New Brunswick Laboratory (NBL), or Department of Energy (DOE) standards are used, when available, for the primary calibrations or verification of primary calibrations.
- 11.1.5 All preparations of standard solutions are recorded in a standards preparation logbook or file. Identities of standards are such that a secondary standard or dilution can be traced, through subsequent actions, back to the initial certification.
- 11.1.6 Quality control check standards are used to record instrument sensitivity and linearity and to verify proper response. Methods and calibration entries are dated, initialed, and documented by the analyst.



QUALITY ASSURANCE PROGRAM MANUAL

QAM, Rev. 16 Effective: 08-22-08

Page 40 of 54

#### Section: 11.0 – Control of Measurement and Test Equipment

11.1.7 Measuring and test equipment are tagged as to calibration or operating status for periodic processes performed on a scheduled interval of greater than one month. For processes performed more frequently, separate documentation will be available for verification of operational status. Instruments that are too small to be tagged or are subject to a wide variety of calibrations shall have separate documentation of status available.

#### 11.2 **RESPONSIBILITY**

Testing and/or calibration of equipment and instruments will be performed under the direction of the supervisor, the department manager, or the operations manager and performed under suitable environmental conditions.

#### 11.3 PROCEDURES

Tests and calibrations will be performed in accordance with written procedures which contain provisions for ensuring that all prerequisites for the given test have been met, including appropriate equipment to be used.

#### 11.4 CERTIFICATION AND CERTIFICATES OF CALIBRATION

- 11.4.1 To the extent possible, calibration will be traceable to NIST. Records of traceability will be maintained along with records of routine calibrations of each instrument or measurement system. Where no NIST traceability exists, the basis used for calibration will be documented.
- 11.4.2 Equipment records will be maintained to indicate past and current status, and to provide reproducibility and traceability of results.

#### 11.5 RADIOACTIVE SOURCE CALIBRATION

Radioactive sources used as calibration standards will be periodically calibrated and controlled. Current calibration certificates will be kept on file.

#### 11.6 CALIBRATION RECORDS

Supervisors will ensure that calibration data for instruments and radioactive sources is recorded in the instrument logbook, on data work sheets, on computer files and/or control charts. Supervisors will also ensure that field/portable survey instruments are identified with the individual calibration labels. When required, new calibration charts will be prepared when there is measurable change in calibration effect on instruments that have been calibrated. If an instrument is determined to be out of tolerance, it will be segregated or otherwise clearly tagged as inoperable and not used until repaired.



QUALITY ASSURANCE PROGRAM MANUAL

QAM, Rev. 16 Effective: 08-22-08

Section: 11.0 – Control of Measurement and Test Equipment

Page 41 of 54

#### 11.7 REPORTS GENERATED FROM USE OF A DEFICIENT INSTRUMENT

If a major deficiency in an instrument or device is detected during periodic calibration procedures, the technician will immediately notify his/her supervisor who will notify the Operations Manager, and the Q.A. Manager. A conference will immediately be scheduled to investigate and decide corrective actions to be taken for past data and reports resulting from the use of the deficient instrument or device. A record of corrective actions will be maintained.

#### 11.8 PERFORMANCE CHECKS OF RADIATION SCREENING INSTRUMENTS

Performance checks will be made to ensure the continuing capability of radiation screening instruments. Procedures will include efficiency checks and background determinations. The procedure and frequency of each check is optimized for each detector system to provide assurance of the detector's performance. Documentation of the checks and the results are kept for all operations.

QUALITY ASSURANCE PROGRAM MANUAL

QAM, Rev. 16 Effective: 08-22-08

Section: 12.0 - Data Reduction and Reporting

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SECTION 12.0

#### DATA REDUCTION, VERIFICATION, AND REPORTING

#### 12.1 USE OF COMPUTER HARDWARE AND SOFTWARE

Computer programs used in the production or support of client data are either purchased, or developed using approved development methodology. Such programs are independently validated, verified, and documented. Changes are controlled to assess the potential impact of the change on the performance of the program.

#### 12.2 DATA REDUCTION AND VERIFICATION

- 12.2.1 Results of analyses are generated by computer and are reviewed initially by the Radiometrics staff. The Program Manager, Operations Manager, or designated individual, performs the final review and approves the data.
- 12.2.2 Calculation methods, transcriptions, and data flow, plus times and locations of the various tiers of review are detailed in the specific procedure manual.

#### 12.3 **REPORTING**

The Program Manager or designated individual is responsible for providing the client with the required analytical results. Reports to clients will be reviewed for accuracy and completeness and, where required, analytical methods and minimum/method detection limits (MDL) will be reported. Laboratory reports of analyses will be signed by an authorized individual who, along with the person who signed the data sheets, can attest to the fact that the data was generated in accordance with established procedures.



QUALITY ASSURANCE PROGRAM MANUAL

QAM, Rev. 16 Effective: 08-22-08

Section: 13.0 – Document Control

### SECTION 13.0 DOCUMENT CONTROL

#### 13.1 **POLICY**

The primary formal communication methods within the Richmond laboratory departments are documents that inform or direct activities affecting purchasing, sample analyses and reporting, instrument calibration and/or testing, proper handling of wastes, and Health and Safety. These documents are controlled by the Q.A. Program Manual, Operating Procedure Manuals, other documented procedures, or by interoffice memoranda. Drawings and specifications are not controlled as separate documents but are included in controlled procedures where applicable.

#### 13.2 **RESPONSIBILITY**

- 13.2.1 The Document Control Custodian is primarily responsible for maintaining files of all controlled documents and will:
  - 13.2.1.1 Ensure all holders of controlled documents receive copies of revisions to the documents.
  - 13.2.1.2 Maintain files of controlled document distribution indicating document title, number, revision number, assigned date, and the name of the individual to whom the document is assigned.
  - 13.2.1.3 Forward revisions of controlled documents to assigned individuals. An acknowledgment form will accompany each document revision for verification of receipt and to provide disposition instructions for the superseded pages.
- 13.2.2 Uncontrolled copies of controlled documents will be distributed only if marked "Uncontrolled."
- 13.2.3 Superseded and/or obsolete documents are isolated from use or destroyed.
- 13.2.4 Supervisors are responsible for revisions or changes to operating procedures for their area of responsibility.
- 13.2.5 The Q.A. Manager will be advised of any changes in procedures required to satisfy specifications of the client.
- 13.2.6 Clients will be queried for disposition instructions for their related documentation if the laboratory transfers ownership, is decommissioned, or goes out of business.



QUALITY ASSURANCE PROGRAM MANUAL

QAM, Rev. 16 Effective: 08-22-08

Section: 14.0 – Internal Quality Control

SECTION 14.0

#### INTERNAL QUALITY CONTROL

#### 14.1 LABORATORY ANALYTICAL SERVICES

Precautions are taken in the chemistry laboratories to avoid cross-contamination of samples and to ensure the reporting of accurate results. Quality control samples are analyzed along with routine samples to indicate when results may be in error due to improper operation or calibration of equipment, inadequate training of personnel, a deficiency in the procedure, or cross-contamination from other samples. The Q.C. Coordinator will have oversight of PE analysis.

- 14.1.1 Laboratory Precision Laboratory management personnel are responsible to ensure that analytical results are reproduced internally within acceptable limits.
- 14.1.2 Precision and Accuracy Replicate standards and/or samples are used to estimate the precision of each analytical test procedure for a known matrix. Data control limits are established to satisfy the requirements of specific measurement projects based on prior knowledge of the measurement system and method validation studies. Certified standards and/or spiked samples are used to estimate chemical recovery and accuracy for these procedures for known matrices.
- 14.1.3 Calibration and Performance Checks of Nuclear Measurement Systems Reference standards are used for calibrating nuclear measurement systems. In addition to calibration of all instrumentation, routine monitoring is performed to ensure the continuing integrity of the instrument performance. The monitoring parameters performed include efficiency checks, background determinations, and energy calibrations. The procedure and frequency of each check is optimized for each detector system to provide assurance of the detector's performance. Documentation of the checks and the results are kept for all systems. The supervisor is responsible for these calibration and performance checks.
- 14.1.4 Duplicate Analysis Duplicate aliquots of randomly selected samples will be processed on a routine basis. The analyst will always process samples in accordance with approved operating procedures. The evaluation of the duplicate analysis will be based on examination of the difference between the duplicates. A statistical analysis of the data may be performed when a cursory evaluation indicates problems with the results. If the two results agree with the three standard deviation limits, more detailed evaluation will generally not be necessary. Results of duplicate analyses will be included in the monthly Q.C./Q.A. report.



QUALITY ASSURANCE PROGRAM MANUAL

QAM, Rev. 16 Effective: 08-22-08

Section: 14.0 – Internal Quality Control

- 14.1.5 Detection and Elimination of Bias Where possible, calibration will be with standards that are traceable to NIST. However, traceability to NIST is not always possible and reliance on other suppliers may be necessary (e.g., International Atomic Energy Agency, U.S. Department of Energy, U.S. Environmental Protection Agency, or commercial suppliers such as Analytics, Amersham Biosciences, AEA Technology, etc.). Standards in the appropriate geometry or form will be used to determine efficiency of instruments on a periodic basis. In the calibration process, the ideal standard will be a known quantity of the radionuclide to be measured, prepared in exactly the same geometry as the samples and counted under the same conditions. In this way, factors such as self-absorption, back-scattering, sample geometry, and detector efficiency will be accounted for empirically.
  - 14.1.5.1 Spiked Samples A known quantity of calibrated radioactive standard solution will be added to an aliquot of the sample or to a "blank" sample for replicate analysis. When the entire analytical system is operating properly, the laboratory record will demonstrate the accuracy and precision of the data. Divergent data from the spiked sample will point out problem areas. If the data is consistently higher or lower than the known value, bias in the analytical procedure is indicated. This may require a search for personnel errors, re-standardization of carriers or tracers, and/or recalibration of counting equipment.
- 14.1.6 Background Determination The type of equipment and environmental factors contribute to variation in the counting rate of instrument background. The background of each system instrument will be determined and recorded with sufficient frequency to provide a firm statistical basis for that measurement and also to ensure response to potential instrument problems or other artifacts such as controlled contamination.
  - 14.1.6.1 These background determinations will include use of the items that most closely duplicate the analytical configuration in type, geometry, and with any associated fixtures. In some cases, true blanks are not available, but the closest practicable analog is used.
  - 14.1.6.2 Some systems are sufficiently stable to require no change in backgrounds used for data reduction (e.g., uranium daughter gamma-rays found in gamma spectra due to adjacent building materials and earth). In this case, backgrounds will be compared to historical data to insure sufficient stability. Other systems experience enough variability to require computed backgrounds based upon running averages.
  - 14.1.6.3 Background data will be recorded in the logbook or computer file for that specific instrument along with calibration data and instrument maintenance records.
- 14.1.7 Blanks Blank samples are routinely analyzed to verify control of contamination and process. Results of processed blanks will be included in the monthly Q.C./Q.A. report.



QUALITY ASSURANCE PROGRAM MANUAL

QAM, Rev. 16 Effective: 08-22-08

Page 46 of 54

#### Section: 14.0 – Internal Quality Control

14.1.8 Collaborative Testing - The Richmond Laboratory participates in collaborative testing or interlaboratory comparison programs. Natural or synthetic samples prepared to contain known concentrations of certain radionuclides are sent to participating laboratories by an independent referee group such as the Radiological and Environmental Sciences Laboratory, DOE, Idaho Falls, Idaho (MAPEP) and by a NELAC approved provider or by client(s).

These programs enable Richmond Laboratory personnel to document the precision and accuracy of radioactivity measurements, identify instrumental and procedural problems, and compare performance with other laboratories.

#### 14.2 QUALITY CONTROL AND DATA REPORTS

#### 14.2.1 Quality Control Reports

Quality control results will be summarized monthly with distribution to management and others upon request.

#### 14.2.2 Data Reports

Routine performance requires documentation of all pertinent information with the basic documents dated and initialed or signed. Required documentation will be the initial work order, Chain-of-Custody (CoC), or document, that records all pertinent information such as the identity of the sample and analyses to be performed. Technical analysis notes, logbooks, and work sheets, utilized during the analytical procedure are other major documents that include all raw data and other information used in performing the analysis. The report of analysis will be the final report of the data to the client and is issued in accordance with the laboratory's procedure for review and processing.

#### 14.3 DATA VERIFICATION

Routine performance requires inclusion of all pertinent information with basic documents dated and initialed or signed. The work order has recorded such information as the identity of the samples and analyses to be performed. All raw data and other information used in performing the analyses is documented.

14.3.1 Electronic Deliverables Verification - Program managers, or designated individuals, are responsible for ensuring that electronic deliverables are complete and accurate.



QUALITY ASSURANCE PROGRAM MANUAL

QAM, Rev. 16 Effective: 08-22-08

Section: 14.0 – Internal Quality Control

Page 47 of 54

#### 14.4 SAMPLE CUSTODY

Samples are assigned a unique laboratory identification number, marked on a label which is applied directly to the container and which identifies the work order set number and the laboratory sample number. Sample control personnel are designated sample custodians for strict (legally defensible) CoC samples. Locked buildings, rooms, refrigerators, freezers, and cabinets are available for storage of CoC samples. Sample custody forms or technician analysis notes are used for tracking all samples through the analytical process. Details for radiological survey of samples, sample security, sample disposal, etc. are outlined in approved Sample Control Procedures. Sample chemistry and nuclear counting requirements are assigned by the program manager, or designated individuals, after consultation with the operations manager, if necessary.



QUALITY ASSURANCE PROGRAM MANUAL

QAM, Rev. 16 Effective: 08-22-08

Page 48 of 54

## SECTION 15.0 AUDITS

#### 15.1 **POLICY**

The Richmond laboratory has established a comprehensive system of planned and documented audits to verify compliance with all aspects of the Q.A. Program. An audit is defined as a documented activity performed in accordance with written procedures or checklists to verify, by examination and evaluation of objective evidence, that applicable elements of the Q.A. Program have been developed and effectively implemented in accordance with specific requirements. Audits will be performed by persons not having direct responsibility for the areas being audited.

- 15.1.1 Client Access to the Richmond Laboratory Facilities and Personnel The client is frequently responsible for auditing the Richmond Laboratory's performance relative to contractual requirements. The exact nature of this responsibility is relative to the nature of the regulatory or licensing requirements, the significance of the services, and the technical expertise available or inherent within the client's organization. The need for, and frequency of, client audits is dependent upon the above factors. A client may authorize an independent agency to perform an audit on his behalf. When possible, the facilities, equipment, and records (proprietary information excluded) of the Richmond laboratory will be made available for client inspection along with the necessary personnel to permit verification of quality characteristics.
  - 15.1.1.1 The Q.A. Manager will coordinate and participate in audits conducted by the client or the client's representative.
- 15.1.2 Internal Audits The Q.A. Manager will schedule and ensure audits the laboratory operations are conducted to verify compliance with established procedures and requirements set forth in the Q.A. Program Manual. Use of a check list will insure items in compliance are noted as well as any requirements for improvement.
- 15.1.3 External Audits External audits of organizations providing services to the Richmond laboratory are scheduled at a frequency commensurate with the status and importance of the activity.

#### 15.2 **RESPONSIBILITY**

Audits will be directed by the Q.A. Manager with assistance from designated personnel or the Operations Manager.

15.2.1 The Q.A. Manager will be responsible for an independent quality assurance audit of each department.



QUALITY ASSURANCE PROGRAM MANUAL

*QAM, Rev. 16 Effective: 08-22-08* 

Section: 15.0 - Audits

Page 49 of 54

- 15.2.2 The Q.A. Manager will be responsible for assuring that audits are performed by knowledgeable professionals.
- 15.2.3 An independent qualified auditor will audit areas of responsibility assigned to the Q.A. Manager.
- 15.2.4 The individual assigned the responsibility of conducting an audit will be certified to ASME NQA-1 requirements.

#### 15.3 DOCUMENTATION

Audit results will be documented by the Q.A. Manager.

- 15.3.1 The Laboratory Manager and the responsible Manager or Supervisor will be provided a copy of the audit report.
- 15.3.2 Recipients will review the audit report to determine responsibility and any corrective actions required.

#### 15.4 **DEFICIENT AREAS**

- 15.4.1 The responsible Manager will ensure correction of the identified deficiencies.
- 15.4.2 The Q.A. Manager will verify that action is taken to correct any deficiency and will take follow-up action to ensure that corrections have been completed.
- 15.4.3 The Q.A. Manager will ensure close out, with documentation, of the audit after corrective actions have been completed.
- 15.4.4 For uncorrected or unresolved deficiencies and after due diligence, the Q.A. Manager will petition the Laboratory Manager to impose his authority for resolution of the deficiencies.

#### 15.5 FREQUENCY OF AUDITS

The Q.A. Manager will ensure internal audits are conducted on an annual basis. Additional selective audits will be conducted when one or more of the following conditions exists:

- 15.5.1 When significant changes are made in functional areas of the Q.A. Program, including significant reorganization or procedure revisions.
- 15.5.2 When assessment of the Program's effectiveness is considered necessary.



QUALITY ASSURANCE PROGRAM MANUAL

QAM, Rev. 16 Effective: 08-22-08

Section: 16.0 – Quality Assurance and Inspection Records

#### SECTION 16.0 QUALITY ASSURANCE AND INSPECTION RECORDS

#### 16.1 **POLICY**

Records that provide objective evidence of the quality of work and of associated activities conducted in all phases of project work are generated and maintained. These records include controlled logbooks, customer instructions, sample analyses data sheets, the results of reviews, inspections, tests, audits, corrective actions, reports, and training records. Also included are related data such as personnel qualifications, procedures, and equipment records.

#### 16.2 **RESPONSIBILITY**

Responsibility for initiation, completeness, and reliability of Q.A. records is vested in the appropriate supervisor with periodic verification checks by the Q.A. Manager. All Richmond laboratory personnel performing processes or services for which controlling documentation is an associated part of the work being performed will assist in the efforts.

#### 16.3 **RECORDS**

- 16.3.1 Inspection and test records will, as a minimum, identify the inspector or data recorder, the type of observation, the results, the action taken in connection with any deficiencies noted, and the date of the inspection or test.
- 16.3.2 All required records will be legible and of a quality that can be copied. Records shall be completed using reproducible ink. Errors or incorrect entries, will be lined through with a single line, dated, and initialed by the recorder.
- 16.3.3 Correspondence from clients may be made available for inspection at the discretion of client representatives and authorization from the originating organization.
- 16.3.4 Q.A. records will be identified and controlled by customer number and/or client identification as applicable.

#### 16.4 STORAGE OF RECORDS

Quality assurance records will be firmly attached in binders, or placed in folders or envelopes, and, if applicable, cross referenced by client identification and stored in a secure area.



# **RICHMOND, CA LABORATORY** QUALITY ASSURANCE PROGRAM MANUAL

QAM, Rev. 16 Effective: 08-22-08

<u>يع</u> <u>Section: 16.0 – Qua</u>	ality Assurance and Inspection Records	Page 51 of 54
16.4.1	Q.A. records will be properly stored and may be made available to the cli	ent upon request.
16.4.2	Records will be maintained in a secured and protective storage area.	
16.4.3	Records will be identified so as to be retrievable at a later date.	
16.4.4	CoC records are included with the sample set records.	
16.4.5	Specific arrangements will be made by the client for longer retention or dup	blication of records.
16.4.6	The <i>Facilities Support Superintendent</i> will be responsible for governing acc of these records.	cess to, and control
16.4.7	Analytical reports and source calibration data will be retained for a minimur results are reported to the client.	n of five years after
16.4.8	Procurement records will be retained for a minimum of five years or a contract.	is required by the



QUALITY ASSURANCE PROGRAM MANUAL

QAM, Rev. 16 Effective: 08-22-08

Section: 17.0 – Corrective Action

Page 52 of 54

### SECTION 17.0 CORRECTIVE ACTION

#### 17.1 **POLICY**

The Richmond laboratory policy is to ensure continuous acceptable quality levels for services provided. Conditions adverse to quality will be identified and corrected as soon as practical.

#### 17.2 CORRECTIONS

#### 17.2.1 CORRECTIVE ACTION REQUEST (CAR)

In the case of a <u>significant</u> 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 shall be documented and reported to appropriate levels of management. Follow-up action shall be taken to verify implementation of this corrective action. The Corrective Action Request (CAR) Form shall be used to document this condition. Typically the Q.A. Manager/Q.C. Coordinator will initiate investigation and corrective action by issuing a Corrective Action Request (CAR) in any of the following situations:

- 17.2.1.1 When an audit reveals circumstances that will adversely affect quality (Audit Finding) as determined by the Q.A. Manager.
- 17.2.1.2 When any results of an inter-comparison study are out of control, or for nonparticipation.
- 17.2.1.3 When procedural or technical problems arise and the Q.A. Manager or Q.C. Coordinator determine that they will significantly affect quality.

#### 17.2.2 NON-CONFORMANCE REPORT (NCR)

A non-conformance is a deficiency in a characteristic, procedure, or documentation that renders the quality of an item unacceptable, however, is not considered to be a significant condition that would require an investigation by use of a CAR. In the laboratory non-conformances can include physical defects, incorrect or inadequate documentation, and deviations from an established protocol, plan, or documented technical requirement. This condition is documented using a Non-Conformance Report (NCR) Form.

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QUALITY ASSURANCE PROGRAM MANUAL

#### Section: 17.0 - Corrective Action

#### 17.3 **RESPONSIBILITY**

All laboratory personnel are responsible to communicate any evidence of unacceptable quality performance to their supervisor, the responsible manager, and/or the Q.A. Manager.

- 17.3.1 The responsible manager will ensure investigation of a condition adverse to quality, determine assignable cause, and provide recommendation(s) for corrective action.
- 17.3.2 The responsible manager will ensure action is initiated to correct the assignable cause of the adverse condition and to determine and initiate the specific corrective action(s) necessary to preclude recurrence.
- 17.3.3 The Q.A. Manager/Q.C. Coordinator will review CARs, NCRs, and routine Q.C. reports for evidence of unacceptable quality.
- 17.3.4 Copies of the completed CARs and NCRs will be kept on file by the Q.A. staff.

#### 17.4 CLIENT NOTIFICATION

The client will be notified when any Corrective Action is initiated due to evidence of unacceptable quality that is related to their contract. The client will be kept abreast of progress in correcting the adverse condition and will be provided a copy of the signed CAR and all related closure documentation when the CAR is closed.

#### 17.5 RESUMPTION OF WORK

In the event that non-conforming work is identified, the Operations Manager will confer with the Technical Director, the Program Manager, and the applicable supervisor to evaluate the significance of the non-conformance, the corrective action(s) to be taken, and client notification requirements prior to authorizing resumption of that portion of the work process.



QUALITY ASSURANCE PROGRAM MANUAL

QAM, Rev. 16 Effective: 08-22-08

Section: 18.0 – Quality Assurance Reports to Management

Page 54 of 54

#### SECTION 18.0

#### QUALITY ASSURANCE REPORTS TO MANAGEMENT

#### 18.1 **POLICY**

The policy at the Richmond laboratory is to keep management apprised of all quality assurance problems, actions taken to correct them, and any actions taken to prevent recurrence.

#### 18.2 QUALITY ASSURANCE REPORTS

- 18.2.1 The Q.A. Manager will provide the Laboratory Manager with a monthly report detailing the quality related activities and performance summaries for the laboratory.
- 18.2.2 Special reports to management will be provided whenever results of inter-comparison studies or tests are received and whenever CARs are initiated.
- 18.2.3 The Q.A. Manager will also report all general or system audit results, problems, corrective actions, and replies.



Title: Eberline Services' Corporate Positions

#### Eberline Services' Corporate Positions

Position	Employee
President	Dr. Wm. Shelton Clark
Human Resources Manager	Lori Jordan
Finance Manager	Carl Lloyd
Laboratory Manager, Oak Ridge, TN Lab	Mike McDougall
Lionville Laboraotory, Exton, PA	Carter Nulton
Laboratory Manager, Richmond, CA Lab	Rodney Melgard

Сору No. \_\_\_\_\_



#### Title: Richmond, CA Laboratory Positions

#### Richmond, CA Laboratory Positions

Laboratory Director Rodney Melgard Laboratory Manager Rodney Melgard Deputy Laboratory Manager Michael W. Thorn	
Deputy Laboratory Manager Michael W. Thorn	
Facilities Support Superintendent Roger J. Mitchell	
Deputy Facilities Support Superintendent Rodney Melgard	
Technical Director Marvin E. Clague	
Technical Director Rodney Melgard	
Technical Director Cesar S. Sangalang	
Operations Manager Michael W. Thorn	
Deputy Operations Manager Cesar S. Sangalang	
Program Manager Melissa C. Mannion	
Deputy Program Manager Norbert J. Verville	
Supervisor, Sample Programs Alex B. Kelenson	
Supervisor, Chemistry Programs Teresita S. Cruz	
Quality Assurance Manager Katsumi Yamamoto	
Deputy Quality Assurance Manager Melissa C. Mannion	
Quality Control Coordinator Katsumi Yamamoto	
Environmental Compliance Officer Fredelino F. Sarao	
Deputy Environmental Compliance Officer Ted McKay	
Health and Safety Officer Fredelino F. Sarao	
Deputy Health and Safety Officer Roger J. Mitchell	
Radiation Safety Officer Melissa C. Mannion	
Deputy Radiation Safety Officer Katsumi Yamamoto	
Document Control Custodian Janine R. Gutierrez	
Deputy Document Control Custodian Katsumi Yamamoto	
Information Technology Specialist Roc L. Smith	
Purchasing Agent Roger J. Mitchell	



# **Cover Page:**

# **Quality Assurance Manual**

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# **Title Page:**

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Quality Manager - David Dawes

Technical Director, Semivolatiles – Gerardo Muñoz

Technical Director, Volatiles - Valerie Sierzchula

Denny

Technical Director, Metals - Denny Tran

Wet Chemistry - Tung Nguyen hical Director.

Technical Director, Inorganic Prep - Jim Blustein

Technical Director, Organic Prep - Michelle Castro

Date

Date

1/30/08

Date

Date

130/08 Date

Date

Date

Date

#### **SECTION 2**

## TABLE OF CONTENTS

Section No.	Title	Page No.	Effective Date
-	COVER PAGE	COVER	01/31/2008
1.0	TITLE PAGE	1-1	01/31/2008
2.0	SECTION 2	2-1	01/31/2008
3.0	INTRODUCTION	3-1	01/31/2008
3.1	Introduction And Compliance References	3-1	01/31/2008
3.2	Terms And Definitions	3-1	01/31/2008
3.3	Scope / Fields Of Testing	3-1	01/31/2008
3.4	Management Of The Manual	3-2	01/31/2008
4.0	ORGANIZATION AND MANAGEMENT (NELAC 5.4.1)	4-1	01/31/2008
4.1	Overview	4-1	01/31/2008
4.2	Roles And Responsibilities	4-2	01/31/2008
4.3	Deputies	4-13	01/31/2008
5.0	QUALITY SYSTEM (NELAC 5.4.2)	5-1	01/31/2008
5.1	Quality Policy Statement	5-1	01/31/2008
5.2	Ethics And Data Integrity	5-1	01/31/2008
5.3	Quality System Supporting Documentation	5-2	01/31/2008
5.4	Qa/Qc Objectives For The Measurement Of Data	5-3	01/31/2008
5.5	Criteria For Quality Indicators	5-5	01/31/2008
5.6	Statistical Quality Control	5-5	01/31/2008
5.7	Quality System Metrics	5-6	01/31/2008
6.0	DOCUMENT CONTROL (NELAC 5.4.3)	6-1	01/31/2008
6.1	Overview	6-1	01/31/2008
6.2	Document Approval And Issue	6-1	01/31/2008
6.3	Procedures For Document Control Policy	6-2	01/31/2008
6.4	Obsolete Documents	6-3	01/31/2008
7.0	REVIEW OF WORK REQUEST	7-1	01/31/2008
7.1	Overview	7-1	01/31/2008
7.2	Review Sequence And Key Personnel	7-2	01/31/2008
7.3	Documentation	7-3	01/31/2008
8.0	SUBCONTRACTING OF TESTS (NELAC 5.4.5)	8-1	01/31/2008
8.1	Overview	8-1	01/31/2008
8.2	Qualifying And Monitoring Subcontractors	8-1	01/31/2008
8.3	Oversight And Reporting	8-4	01/31/2008
8.4	Contingency Planning	8-5	01/31/2008
9.0	PURCHASING SERVICES AND SUPPLIES (NELAC 5.4.6)	9-1	01/31/2008
9.1	Overview	9-1	01/31/2008
9.2	Glassware	9-1	01/31/2008
9.3	Reagents, Standards & Supplies	9-1	01/31/2008

Section No.	Title	Page No.	Effective Date
9.4	Purchase Of Equipment/Instruments/Software	9-3	01/31/2008
9.5	Services	9-4	01/31/2008
9.6	Suppliers	9-4	01/31/2008
10.0	SERVICE TO THE CLIENT (NELAC 5.4.7)	10-1	01/31/2008
10.1	Overview	10-1	01/31/2008
10.2	Special Services	10-1	01/31/2008
10.3	Client Communication	10-1	01/31/2008
10.4	Reporting	10-1	01/31/2008
10.5	Client Surveys	10-2	01/31/2008
11.0	COMPLAINTS (NELAC 5.4.8)	11-1	01/31/2008
11.1	<u>Overview</u>	11-1	01/31/2008
11.2	External Complaints	11-1	01/31/2008
11.3	Internal Complaints	11-2	01/31/2008
11.4	Management Review	11-2	01/31/2008
12.0	CONTROL OF NON-CONFORMING WORK (NELAC 5.4.9)	12-1	01/31/2008
12.1	Overview	12-1	01/31/2008
12.2	Responsibilities And Authorities	12-1	01/31/2008
12.3	Evaluation Of Significance And Actions Taken	12-2	01/31/2008
12.4	Prevention Of Nonconforming Work	12-2	01/31/2008
12.5	Method Suspension/Restriction (Stop Work Procedures)	12-2	01/31/2008
13.0	CORRECTIVE ACTION (NELAC 5.4.10)	13-1	01/31/2008
13.1	Overview	13-1	01/31/2008
13.2	Definitions	13-1	01/31/2008
13.3	General	13-1	01/31/2008
13.4	Closed Loop Corrective Action Process	13-2	01/31/2008
13.5	Technical Corrective Actions	13-3	01/31/2008
13.6	Basic Corrections	13-4	01/31/2008
14.0	PREVENTIVE ACTION (NELAC 5.4.11)	14-1	01/31/2008
14.1	Overview	14-1	01/31/2008
14.2	Management Of Change	14-2	01/31/2008
	CONTROL OF RECORDS (NELAC 5.4.12)	15-1	01/31/2008
15.1	Overview	15-1	01/31/2008
15.2	Technical And Analytical Records	15-4	01/31/2008
15.3	Laboratory Support Activities	15-5	01/31/2008
15.4	Administrative Records	15-5	01/31/2008
15.5	Records Management, Storage And Disposal	15-6	01/31/2008
16.0	AUDITS (NELAC 5.4.13)	16-1	01/31/2008
16.1	Overview	16-1	01/31/2008
16.2	Technical And Analytical Records	16-1	01/31/2008
16.3	External Audits	16-3	01/31/2008
16.4	Audit Findings	16-5	01/31/2008
17.0	MANAGEMENT REVIEWS (NELAC 5.4.14)	17-1	01/31/2008
17.1	Quality Assurance Report	17-1	01/31/2008
17.2	Annual Management Review	17-2	01/31/2008

Section No.	Title	Page No.	Effective Date
17.3	Potential Integrity Related Managerial Reviews	17-3	01/31/2008
18.0	PERSONNEL (NELAC 5.5.2)	18-1	01/31/2008
18.1	<u>Overview</u>	18-1	01/31/2008
18.2	Education And Experience Requirements For Technical Personnel	18-1	01/31/2008
18.3	Training	18-3	01/31/2008
18.4	Data Integrity And Ethics Training Program	18-4	01/31/2008
19.0	ACCOMMODATIONS AND ENVIRONMENTAL CONDITIONS (NELAC 5.5.3)	19-1	01/31/2008
19.1	Overview	19-1	01/31/2008
19.2	Environment	19-1	01/31/2008
19.3	Work Areas	19-2	01/31/2008
19.4	Floor Plan	19-2	01/31/2008
19.5	Building Security	19-3	01/31/2008
20.0	01/31/2008 (NELAC 5.5.4)	20-1	01/31/2008
20.1	Overview	20-1	01/31/2008
20.2	STANDARD OPERATING PROCEDURES (Sops)	20-1	01/31/2008
20.3	Laboratory Methods Manual	20-1	01/31/2008
20.4	Selection Of Methods	20-2	01/31/2008
20.5	Laboratory Developed Methods And Non-Standard Methods	20-5	01/31/2008
20.6	Validation Of Methods	20-5	01/31/2008
20.7	Method Detection Limits (Mdl)/ Limits Of Detection (Lod)	20-7	01/31/2008
20.8	Instrument Detection Limits (Idl)	20-8	01/31/2008
20.9	Verification Of Detection And Reporting Limits	20-8	01/31/2008
20.10	Retention Time Windows	20-9	01/31/2008
20.11	Evaluation Of Selectivity	20-10	01/31/2008
20.12	Estimation Of Uncertainty Of Measurement	20-10	01/31/2008
20.13	Control Of Data	20-11	01/31/2008
21.0	EQUIPMENT (AND CALIBRATIONS (NELAC 5.5.5)	21-1	01/31/2008
21.1	Overview	21-1	01/31/2008
	Preventive Maintenance	21-1	01/31/2008
21.2	Support Equipment	21-3	01/31/2008
21.4	Instrument Calibrations	21-5	01/31/2008
21.5	Policy On Tentatively Identified Compounds (Tics) – Gc/Ms Analysis	21-13	01/31/2008
21.6	Policy On Gc/Ms Tuning	21-14	01/31/2008
22.0	MEASUREMENT TRACEABILITY (NELAC 5.5.6)	22-1	01/31/2008
22.1	Overview	22-1	01/31/2008
22.2	Nist-Traceable Weights And Thermometers	22-2	01/31/2008
22.3	Reference Standards / Materials	22-2	01/31/2008
22.4	Documentation And Labeling Of Standards, Reagents, And Reference Materials	22-2	01/31/2008
23.0	SAMPLING (NELAC 5.5.7)	23-1	01/31/2008
23.1	Overview	23-1	01/31/2008
20.1		<u></u>	51/51/2000

Section No.	Title	Page No.	Effective Date
23.2	Sampling Containers	23-1	01/31/2008
23.3	Field Quality Control (Qc)	23-2	01/31/2008
23.4	Definition Of Holding Time	23-2	01/31/2008
23.5	Sampling Containers, Preservation Requirements, Holding Times	23-3	01/31/2008
23.6	Sample Aliquots / Subsampling	23-3	01/31/2008
24.0	HANDLING OF SAMPLES (NELAC 5.5.8)	24-1	01/31/2008
24.1	Chain Of Custody (Coc)	24-1	01/31/2008
24.2	Sample Receipt	24-2	01/31/2008
24.3	Sample Acceptance Policy	24-4	01/31/2008
24.4	Sample Storage	24-5	01/31/2008
24.5	Hazardous Samples And Foreign Soils	24-5	01/31/2008
24.6	Sample Shipping	24-6	01/31/2008
24.7	Sample Disposal	24-6	01/31/2008
25.0	ASSURING THE QUALITY OF TEST RESULTS (NELAC 5.5.9)	25-1	01/31/2008
25.1	Överview	25-1	01/31/2008
25.2	Controls	25-1	01/31/2008
25.3	Negative Controls	25-1	01/31/2008
25.4	Positive Controls	25-2	01/31/2008
25.5	Sample Matrix Controls	25-4	01/31/2008
25.6	Acceptance Criteria (Control Limits)	25-6	01/31/2008
25.7	METHOD DETECTION LIMITS (Mdls)	25-8	01/31/2008
25.8	Additional Procedures To Assure Quality Control	25-8	01/31/2008
26.0	REPORTING RESULTS (NELAC 5.5.10)	26-1	01/31/2008
26.1	Overview	26-1	01/31/2008
26.2	Test Reports	26-1	01/31/2008
26.3	Reporting Level Or Report Type	26-3	01/31/2008
26.4	Electronic Reporting And Signature Policy	26-4	01/31/2008
26.5	Supplemental Information For Test	26-5	01/31/2008
26.6	Environmental Testing Obtained From Subcontractors	26-7	01/31/2008
26.7	Client Confidentiality	26-7	01/31/2008
26.8	Format Of Reports	26-7	01/31/2008
26.9	Amendments To Test Reports	26-8	01/31/2008
26.10	Policies On Client Requests For Amendments	26-8	01/31/2008