LOS ALAMOS NATIONAL LABORATORY
CHEMISTRY DIVISION
ISOTOPE NUCLEAR CHEMISTRY GROUP
(C-INC)

Procedure Number: BQP-19, R.7

Approval Date: 9/20/02

Next Review Date: 9/20/03

QUALITY ASSURANCE PLAN:

CHEMISTRY DIVISION BIOASSAY PROJECT – QUALITY ASSURANCE PROJECT PLAN FOR CHEMISTRY DIVISION SERVICE LABORATORY OPERATIONS

Type of Procedure:	Status:
☒ Quality Procedure (BQP)	☐ New
☐ Standard Operating Procedure (BSP)	☐ Major Revision
☐ Radiological ☐ Instrument Operation	☒ Minor Revision
☐ Inorganic ☐ Instrument Calibration	☐ Review Only, No Change
☐ Organic ☐ Miscellaneous	
☐ Sample Management	

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REVISION HISTORY
(as of 9/2002)

Revision 5.0 (2/2002):

1. **Major reorganization of document**
2. **Addition of Configuration Management requirements to Section 4.2 - Criterion 6**
3. **Separated QC requirements into a separate section (Section 6)**
4. **Removed NRIP PE Sample Program reference**
5. **Addition of Attachment 2**

Revision 6.0 (7/2002):

1. **Changed all procedure references to current BQP and BSP citations**
2. **Updated this version to comply with new Bioassay Project procedure numbering system and new title page**

Revision 7.0 (9/2002):

1. **Added text to Quality Control for management of matrix blanks that show elevated analyte levels**

CHEMISTRY DIVISION BIOASSAY PROJECT – QUALITY ASSURANCE PROJECT PLAN FOR CHEMISTRY DIVISION SERVICE LABORATORY OPERATIONS

Chemistry Division

1 PROJECT QUALITY POLICY STATEMENT

The Los Alamos National Laboratory (LANL), Chemistry Division (C-Division) Bioassay Project is committed to achieving the highest quality possible in the bioassay testing laboratory services and associated technical support operations it performs.

2 INTRODUCTION

The Radiobioassay Project's (Bioassay Project) mission is to provide quality in-vitro bioassay laboratory testing and technical support services for the measurement of radionuclides, specifically plutonium, in urine. As an effective and efficient means towards assuring quality bioassay laboratory testing and technical support services, C-Division has developed and is committed to implementing and maintaining a Quality Management System that is outlined within this Quality Assurance Project Plan (QAPjP) for the Bioassay Project.

This QAPjP complies with Department of Energy (DOE) Orders, the LANL Laboratory Performance Requirement on Quality, the LANL Nuclear Weapons Directorate Quality Assurance Requirements Document, and the Project Management Plan for the Bioassay Project (PMP). The QAPjP provides the Quality Management System blueprint for the services provided. The QAPjP confirms our commitment to customer satisfaction through continuous quality improvement and enables each employee to continuously improve their work quality with the goal of *Doing it right the first time, every time* (ISO 9001 4.1.1/ANSI-ASK Q2 5.1.2).

The QAPjP is therefore binding on all C-Division personnel performing bioassay testing and technical support as part of the Bioassay Project. C-Division is also committed to performing all Bioassay Project activities in compliance with Occupational Safety and Health Administration (OSHA), state, and federal regulations, as well as with Laboratory Administrative Requirements, DOE Orders, the PMP, and associated contracts and service agreements.

In this QAPjP, each criterion and associated requirement found in DOE Order 414.1 (supercedes DOE Order 5700.6C), "Quality Assurance," 10 CFR §830.120, and the LANL Laboratory Performance Requirement, LPR 308-00-00, "Quality," are specifically addressed. Within each criterion section are the detailed Project requirements that both satisfy the general requirements of the Order and provide the framework and philosophy for this QAPjP. The criteria fall into three main areas: management, performance, and assessment.

In addition, the requirements of the DOE-STD-1112-98, "DOE Technical Standard: The Department of Energy Laboratory Accreditation Program for Radiobioassay" are included by reference and addressed individually, where appropriate.

3 MANAGEMENT CRITERIA

3.1 Criterion 1 —Program

Requirement: "*A written QAP shall be developed, implemented, and maintained. The QAP shall describe the organizational structure, functional responsibilities, levels of authority, and interfaces for those managing, performing, and assessing the work. The QAP shall describe management processes, including planning, scheduling, and resource considerations.*"

3.1.1 Quality Assurance Program

The Bioassay Project Quality Assurance (QA) Program consists of two tiers of documents. The upper tier document, the QAPjP, delineates the project-specific Quality Management System requirements. The lower tier documents consist of the operational procedures that provide basic step-by-step instructions on how activities are performed. Routine analytical and quality procedures are part of the lower tier documentation.

The QAPjP describes how C-Division will implement the LANL Laboratory Performance Requirement on Quality, the LANL Nuclear Weapons Directorate Quality Assurance Requirements Document, the PMP, the DOE Orders, and the Code of Federal Regulations (CFR) in work performed. The QAPjP is part of the PMP and is incorporated into the PMP as Appendix 2.

This QAPjP meets the basic requirements of the following:

- "Quality Assurance," 10 CFR §830.120 (May 1994).
- "Quality Assurance," U.S. Department of Energy Order 1 (November 1998) (supercedes DOE Order 5700.6C).
- "Quality," LANL Performance Requirement LPR 308-00-00.0 (February 19, 1999).
- "The Department of Energy Laboratory Accreditation Program for Radiobioassay," U.S. Department of Energy Technical Standard DOE-STD-1112-98 (1998).
- "Performance Criteria for Radiobioassay," American National Standards Institute Standard N13.30 (1996).
- "Quality Systems – Model for Quality Assurance in Design, Development, Production, Installation, and Servicing," American National Standards Institute/American Society for Quality Control Standard ANSI/ASQC Q9001 (1994).

Other documents whose requirements and good practices have been addressed in this QAPjP are found in Attachment 1.

Mandatory program requirements are specified throughout this document by the use of the terms "shall" or "must." Guidance is designated by the term "should." The terms "can" and "may" refer to ability and permission, respectively.

3.1.2 Quality Assurance Project Plan

The QAPjP provides a framework for consistency throughout C-Division's bioassay laboratory testing and technical support services to ensure, through formalized documentation, that operations are well defined and effectively administered. It ensures that bioassay-testing data reported by the C-Division analytical chemistry laboratory operations are of the highest quality, that evolving customer needs and requirements are satisfied, and that costs are minimized because of better management controls.

This QAPjP applies to all activities and work processes that contribute to the achievement of the Bioassay Project quality objectives. Bioassay Project management uses the graded approach in the planning process to institute the appropriate level of rigor and formality needed to ensure success in a safe, high quality, and cost-effective manner for Bioassay Project activities.

3.1.3 General Program Requirements

This QAPjP shall be used to guide C-Division personnel in performing bioassay laboratory testing and technical support services for the Bioassay Project. The QAPjP specifies QA requirements and quality-related activities that shall be complied with to ensure the validity of data and results of analytical service work and technical support operations. QA requirements and quality-related activities shall only apply to items and actions that can directly affect the quality of analytical results to be reported.

Compliance with the QAPjP ensures that Bioassay Project analysts and technical support personnel can identify activities that affect quality before analytical or technical support work begins and perform them correctly the first time. This approach ensures that the activity will be completed on time, at the agreed upon cost, and be of known quality. This QAPjP specifies requirements for the development and maintenance of technical and quality procedures that might be prepared to meet Program requirements. Implementation plans and formal procedures shall be developed using a graded approach.

3.1.4 Organizational Structure

The Bioassay Project is a functional part of the LANL C-Division organization. The Bioassay Project organizational structure and associated organizational chart are delineated in Section 3 "Bioassay Project Organization" of the PMP.

3.1.5 Functional Responsibilities

The Bioassay Project is organized within the LANL C-Division. The C-Division Office provides senior management support to the Bioassay Project. Bioassay Project management responsibilities flow from the Bioassay Project Leader through the Bioassay Project Points-of-Contact (POCs) to the participating organizations that can be internal and external to the Laboratory including contractors, subcontractors, and equipment and service suppliers. The Bioassay Project functional responsibilities are delineated in Section 2 "Responsibilities" of the PMP.

3.1.6 Management Processes

The Bioassay Project Leader plans, organizes, directs, and controls analytical effort and obtains, disburses, and controls funding for the Bioassay Project. The Bioassay Project management processes are delineated in the PMP.

3.1.7 Work Suspension

Bioassay Project personnel shall be responsible for identifying conditions that adversely impact the quality of work or that are in violation of requirements or regulations, and for reporting existing or developing adverse conditions to the responsible POC or group leader for evaluation and remedial action.

For conditions involving an issue of quality, project analysts and technical support personnel are empowered to suspend work if they determine the work to be of unacceptable quality. This will be known as a **work suspension** and must be documented according to BQP-5: *Work Suspension and Restart*. In such situations, an appropriate resolution including corrective actions must be pursued and implemented by the analyst or technical support person and the appropriate POC.

Work suspension is related to conditions adverse to quality only. This is in contrast to *work stoppage*, which is related to conditions adverse to safety. Work stoppage is not within the scope of the QAPjP and should be distinguished from work suspension.

3.1.8 Review and Revision of Program Documentation

The QAPjP shall be reviewed annually after the initial issuance and revised as necessary or whenever significant changes are required. Per the PMP, Bioassay Project personnel and customers affected by such changes shall be notified by the Project Leader.

3.2 Criterion 2—Personnel Training and Qualification

Requirement: "*Personnel shall be trained and qualified to ensure they are capable of performing their assigned work. Personnel shall be provided continuing training to ensure that job proficiency is maintained*."

3.2.1 Personnel Training and Qualification

Bioassay Project training requirements fall into one or more of the following categories:

Institutional: defined by LANL and C-Division management to ensure that employees have the needed general knowledge about the organization's mission and requirements.

Facility-specific: defined by management of the facility in which the Bioassay Project operations will take place.

Project-specific: defined by the management of the Bioassay Project to ensure Project personnel have the needed general knowledge about the Project's mission and QA objectives and requirements and quality control (QC) operations.

Because Project personnel are assigned Project tasks through the matrix management approach, institutional training and facility-specific training are the responsibility of C-Division management. Project-specific training, including quality training, is the responsibility of the Project Leader and the appropriate Bioassay POC. This criterion is implemented for the Bioassay Project by procedure BQP-13: *Training Program for Bioassay Project*.

3.2.2 Personnel Training and Job Responsibilities

3.2.2.1 Project personnel shall have the skills, knowledge, abilities, experience, and training to successfully perform their assigned Project activities.

3.2.2.2 LANL position descriptions and position postings may be used to document education requirements, identify required qualifications, and define responsibilities, including documentation of Subject Matter Expert (SME) qualification.

3.2.2.3 Training shall be conducted in accordance with Laboratory policy and the C-Division training procedure, BQP-13: *Training Program for Bioassay Project*.

3.2.2.4 C-Division Group Leaders shall ensure that personnel are aware of, trained in, and follow applicable LANL institutional and facility-specific training requirements.

3.2.2.5 C-Division Group Leaders and the Bioassay Project Leader shall cooperate to ensure that employees are fully and adequately trained to perform assigned tasks.

3.2.2.6 The Bioassay Project Leader, in cooperation with the appropriate C-Division Group Leaders, shall develop and approve training plans to fulfill the training needs and requirements for the tasks assigned to the Bioassay Project personnel. Training plans should consider both the needs of the Bioassay Project and the professional development of the employee.

3.2.2.7 The Bioassay Project Leader shall ensure that personnel are aware of, are trained in, and follow Bioassay Project-specific training requirements. The Bioassay Project Leader may delegate this responsibility to the appropriate Bioassay Project POC. The POCs shall coordinate with the Bioassay Project Leader and appropriate Group Leaders on project-specific training requirements.

3.2.2.8 The Bioassay Project Leader shall ensure that personnel are instructed in and maintain current knowledge of provisions of this QAPjP and applicable bioassay standard operating procedures (BSP) and quality procedures (BQP). The Bioassay Project Leader may delegate this responsibility to the appropriate POC. The Bioassay Project Leader and/or POCs shall coordinate personnel training on applicable standard operating and quality procedures with the designated SME.

3.2.2.9 SMEs shall have the appropriate procedural skills, knowledge, abilities, and experience. SME qualification shall be documented and maintained in the records management system.

3.2.3 Formal Analyst Qualification/Certification

3.2.3.1 The Bioassay Project Leader shall determine when analysts must be formally qualified on technical procedures in accordance with applicable standards and/or Laboratory requirements.

3.2.3.2 The Bioassay Project Leader shall identify QC and performance evaluation criteria required to maintain analysts' qualifications and to ensure quality data. The Bioassay Project Leader may delegate this responsibility to the appropriate Bioassay Project POC.

3.2.3.3 Analysts that require qualification on technical procedures shall be scheduled for re-qualification on procedural performance to ensure that Bioassay Project requirements are met, in accordance with DOE-STD-1112-98. The Bioassay Project Leader shall define the procedural performance metric(s).

3.2.3.4 In addition to annual qualification reviews, POCs shall verify demonstration of analyst proficiency periodically. The procedure use validation shall be conducted by the appropriate POC via unannounced, documented surveillance of analysts while they perform critical, procedure-based activities. Procedure use validation shall be documented on the qualification form used for initial analyst qualification, or the on-the-job training (OJT) form from BQP-13: *Training Program for Bioassay Project*.

3.2.3.5 Failure of an analyst to successfully meet the procedural performance metric(s) shall result in a non-conformance report and procedure use validation for the analyst for that procedural activity. Failure of an analyst to successfully meet a procedural performance metric three times during a one-year period shall result in a work suspension. The Bioassay Project Leader shall elevate the issue to the appropriate Group Leader for personnel action and/or resolution.

3.2.4 Training Records Management

3.2.4.1 Laboratory-sponsored training shall be recorded. Laboratory training records shall be maintained and tracked in the Laboratory's Employee Development System (EDS).

3.2.4.2 Project required training, including OJT, shall be recorded. Project-specific training records, especially OJT forms and qualification review records, shall be maintained by the appropriate Group Training Coordinator and in the Project records management system by the Document Control Coordinator (DCC), as well as in the EDS, whenever possible. Project-specific training records may be maintained as either paper or electronic copy.

3.3 Criterion 3— Quality Improvement

Requirement: "*Processes to detect and prevent quality problems shall be established and implemented. Items, services, and processes that do not meet established requirements shall be identified, controlled, and corrected according to the importance of the problem and the work affected. Correction shall include identifying the causes of problems and working to prevent recurrence. Item characteristics, process implementation, and other quality-related information shall be reviewed and the data analyzed to identify items, services, and processes needing improvement*."

3.3.1 Quality Improvement Processes

The Bioassay Project is committed to customer satisfaction through continuous quality improvement and empowerment of each employee to continuously improve the quality of their work with the goal of *Doing it right the first time, every time.* The Bioassay Project Quality Management System includes, in addition to standard quality control measures, quality improvement processes designed to facilitate continuous improvement and customer satisfaction in all Project deliverables.

The quality of laboratory testing and technical support services is monitored using traceable quality control samples (blanks and blind samples) and matrix spike analysis (tracer analysis), with the results identifying areas for improvement. In addition to monitoring, the Quality Management System includes documenting and tracking problems, determining appropriate corrective actions, performing root cause analyses to determine causal factors, and tracking the performance and completing remedial efforts. Management review of the Quality Management System is implemented through quarterly review meetings.

This criterion is implemented for the Bioassay Project by procedures BQP-8: *Nonconformance Reporting*, BQP-11: *Corrective Action*, BQP-5: *Work Suspension and Restart*, and BQP-12: *Root Cause Analysis*.

3.3.2 Non-Conformance Reporting

3.3.2.1 Non-conformances (i.e., failure to fulfill a quality requirement) can occur in bioassay laboratory testing, reporting of analysis data, and in technical support operations. Project personnel shall monitor for non-conformances at all times.

3.3.2.2 All non-conformances shall be reported to the appropriate POC and QA Officer immediately upon discovery. An assessment of the severity and potential impact of the non-conformance shall be determined by the POC and/or appropriate SME, and the QA Officer.

3.3.2.3 Non-conformances are categorized as follows:

(1) **Minor** – Those for which data have not yet been reported, and for which a simple, immediate correction will remove the condition.

(2) **Major** – Those that currently affect or have affected the quality of reported data, or a condition that is recurrent (regardless of whether it is major or minor in nature). Major non-conformances shall require a corrective action. Corrective action subsequently requires a root cause analysis to be performed.

3.3.2.4 Both the non-conformance and any actions implemented to correct it shall be documented and reported using a non-conformance report (NCR), as described in BQP-8: *Non-Conformance Reporting*.

3.3.2.5 Non-conformances identified as a result of internal and external review, assessment, or audit; customer concern or complaint; evaluation of analytical performance; QC tests; and/or faulty equipment shall be directed to the appropriate POC for corrective action by the Bioassay Project Leader. The POC shall advise the appropriate Group Leader, the Bioassay Project Leader, and QA Officer of the area of concern. The Bioassay Project Leader and/or POC shall determine the appropriate level of corrective action(s) and report plans to the QA officer.

3.3.2.6 All non-conformances shall be reviewed by the QA Officer and a quarterly management review meeting shall be conducted involving the Bioassay Project Leader and the POCs.

3.3.3 Corrective Actions

3.3.3.1 Corrective action is required whenever a major non-conformance has been identified, when a non-conformance has become recurrent, or at the discretion of the POC, Bioassay Project Leader, or QA Officer. Note that all corrective actions require the completion of a root cause analysis, described in Section 3.4.4, below.

3.3.3.2 Corrective actions shall be scheduled and documented through the Corrective Action Request (CAR) report, as described in BQP-11: *Corrective Action*.

3.3.3.3 Corrective actions shall be given a scheduled completion date by the responsible POC. The Bioassay Project Leader shall have approval authority over corrective action schedules and milestones.

3.3.3.4 The Bioassay Project Leader shall ensure the timely implementation of corrective action(s).

3.3.3.5 The QA Officer shall verify implementation and completion of the corrective action, track the status of CARs, and advise the Bioassay Project Leader and the appropriate Group Leader and POC of CAR status.

3.3.3.6 All corrective actions shall be reviewed by the QA Officer and a quarterly management review meeting shall be conducted involving the Bioassay Project Leader and the POCs.

3.3.4 Root Cause Analysis

3.3.4.1 All CARs require the execution of a root cause analysis, in accordance with BQP-12: *Root Cause Analysis*.

3.3.4.2 Root cause analysis shall be performed by the POC and/or SME who is responsible for the corresponding CAR.

3.3.4.3 The root cause analysis shall be documented by memo, e-mail, or other written traceable means to the Bioassay Project Leader and the QA Officer, according to BQP-12: *Root Cause Analysis*.

3.3.5 Work Suspension Requests

3.3.5.1 Any Bioassay Project personnel may initiate a work suspension request (WSR) when the quality of a process or activity is deemed to be out of control or does not meet the QAPjP requirements. Frequently, a WSR will be the result of a non-conformance.

3.3.5.2 All WSRs shall be documented by memo, e-mail, or other written traceable means to the Bioassay Project Leader and the QA Officer, according to BQP-5: *Work Suspension Requests*. Written notification shall include, at a minimum, the condition/reason for the WSR, the date of the WSR, the area(s) affected by the WSR, and the condition(s) that will allow for the resumption of work. Reference to a corresponding NCR and CAR are recommended.

3.3.5.3 The Bioassay Project Leader shall verify the condition and work with the appropriate POC and the QA Officer to resolve the issue.

3.3.6 Quarterly Management Review

3.3.6.1 Project management, including the Bioassay Project Leader, POCs, and QA Officer shall hold regular quarterly meetings to review the status of NCRs, CARs, WSRs, and QC performance data and to discuss outstanding quality issues.

3.4 Criterion 4— Documents and Records

Requirement: "*Documents shall be prepared, reviewed, approved, issued, used, and revised to prescribe processes, specify requirements, or establish design. Records shall be specified, prepared, reviewed, approved, and maintained*."

The Bioassay Project requires that documents in support of Project bioassay laboratory testing and technical support services be developed, reviewed, approved, implemented, and maintained. Documents such as BSPs and BQPs that are used in the Bioassay Project are available to Project personnel through an electronic distribution system. Records resulting from these operations are managed (i.e., archived and retrievable) according to LANL and DOE requirements. This criterion is implemented for the Bioassay Project by procedure BQP-10: *Management of Bioassay Project Analytical Records*.

Development of procedures and supporting documents is discussed in Section 3.5, Criterion 5 – Work Processes.

3.4.1 Document Control

3.4.1.1 Bioassay Project BQPs, and BSPs, shall be maintained and controlled in an electronic document system. Bioassay project personnel shall have access to the procedures in the electronic document system for the tasks they perform.

3.4.1.2 The electronic version of the document *is the only controlled version*.

3.4.1.3 Project personnel are responsible for reading, understanding, using, and working to the latest version of a document or procedure. Procedures shall be readily available in the area, e.g. room, laboratory, or office, where the task is being performed, either by electronic means or by availability of a current hardcopy.

3.4.1.4 Procedures used in the facility may be either in electronic format or hardcopy. Hardcopy versions of procedures are defined as working copies and are not controlled. If hardcopy procedures are used in an area, the procedures shall be maintained in a notebook or file and only the current version of the procedure shall be maintained. Out-dated, retired, or superceded hardcopy procedures shall be removed from the area and disposed of, preferably by shredding and recycling.

3.4.1.5 The Bioassay Project Leader shall ensure that instructions, procedures, specifications, and/or drawings for the tasks to be performed for the Bioassay Project are prepared, reviewed, approved, issued, used, and revised, when necessary. Work instructions, procedures, specifications, and/or drawings shall become effective on the approval date unless the group leader or Bioassay Project Leader explicitly directs another effective date for implementation.

3.4.1.6 The Bioassay Project Leader, through the appropriate POC, shall verify new or revised procedure implementation within 30 days following the approval date or effective date.

3.4.1.7 The Bioassay Project Leader, through the appropriate POC, shall ensure that Bioassay Project personnel have and are using appropriate instructions, procedures, specifications, and/or drawings for the tasks being performed.

3.4.1.8 Revisions to instructions, procedures, specifications, and drawings shall be prepared, reviewed, approved, and distributed in the same manner as the original document.

3.4.1.9 Bioassay Project documents including this QAPjP, BSPs, BQPs, specification documents, and work instructions shall be controlled. The original approved copies of these documents shall be maintained in the Project Records Management System.

3.4.2 Records Management

3.4.2.1 The Bioassay Project leader shall establish and enforce compliance with the Project Records Management System that is outlined in BQP-10: *Management of Bioassay Project Analytical Records*.

3.4.2.2 The Bioassay Project Leader shall verify that required records are prepared as work is performed to provide documentary evidence of the quality of items and activities. The Bioassay Project shall maintain records from sample submittal through laboratory analysis, data verification/validation, reporting, and sample disposal.

3.4.2.3 The Bioassay Project Leader shall ensure that required records are approved and transmitted to the QA Officer.

3.4.2.4 The Bioassay Project QA Officer shall ensure that received records are retained, protected, and retrievable. Bioassay Project records shall be retained, in retrievable form, for 75 years. Records disposition other than archival storage must be reviewed and approved by a Laboratory Records Information Specialist.

3.4.2.5 Bioassay Project records, including analytical laboratory testing data and reports, audit reports, calibration and maintenance records, technical document changes, logbooks and notebooks, and validation reports shall also be controlled.

3.4.2.6 Secured areas shall be used for the storage of controlled records. Access to these areas shall be restricted. Records storage will also comply with applicable

LANL Laboratory Implementation Requirements (LIR) requirements for protection and access.

4 PERFORMANCE CRITERIA

4.1 Criterion 5— Work Processes

Requirement: "*Work shall be performed to established technical standards and administrative controls using approved instructions, procedures, or other appropriate means. Items shall be identified and controlled to ensure their proper use. Items shall be maintained to prevent their damage, loss, or deterioration. Equipment used for process monitoring or data collection shall be calibrated and maintained*."

The Bioassay Project Quality Management System requires that any work process that is critical to data quality, involves equipment maintenance, or requires training to ensure compliance, be documented in a written, controlled procedure and associated work instructions. All work processes for the Bioassay Project are documented in the PMP as a work process flow sheet. Each process and the implementing procedure(s) are included on the PMP flowchart.

To ensure that critical items, equipment, and software are available and operational at all times, a critical system configuration management system is used to maintain control. Critical items (i.e., standard reference materials), equipment, and software are tracked and documented in the PMP (see also Section 4.3, Design Criterion). Additionally, all measurement equipment are regularly calibrated and/or checked for accuracy using traceable reference standards.

Implementing procedures are developed by recognized SMEs, and undergo a peer review process prior to approval and issuance. New technical procedures are also first validated to ensure that they are correct, complete, and effective.

Applicable procedures implementing this criterion are listed in the PMP. Note that equipment maintenance/replacement procedures (i.e., procedures for bringing equipment into service after replacement and/or repair) are included in their respective BSPs.

4.1.1 Procedures

4.1.1.1 The Bioassay Project Leader shall examine Bioassay Project work activities so that the appropriate level of control and documentation is applied. The Bioassay Project Leader may delegate this responsibility to the appropriate Bioassay Project POC.

4.1.1.2 Procedures for methods of analysis, data calculations and evaluation, and data package assembly and storage shall be prepared and reviewed by the POC, SME, and approved by the Bioassay Project Leader, QA Officer, appropriate group leader, and authorized derivative classifier.

4.1.1.3 Bioassay Project personnel shall follow approved and controlled procedures.

4.1.1.4 Project personnel conducting the work shall be trained to implement these procedures through classroom, OJT, and/or self-paced training, as appropriate.

4.1.1.5 All technical procedures (i.e., BSPs) shall require initial OJT and annual performance-based re-qualification, which is documented according to BQP-13: *Training Program for Bioassay Project*.

4.1.1.6 Procedures shall be updated as necessary and reviewed on a two-year cycle basis on the last approval date.

4.1.1.7 Project personnel shall follow written procedures for identifying and controlling materials and equipment. The QAPjP describes methods for controlling limited shelf life or operating life items to preclude use of items whose shelf or operating life has expired.

4.1.1.8 Project personnel performing work shall comply with implementing procedures. However, when work cannot be accomplished as described in the implementing procedure or accomplishment of such work would result in an undesirable situation, a condition adverse to quality, or an unacceptable safety risk, the work shall be suspended (quality) or stopped (safety) until the appropriate procedure changes are implemented.

4.1.1.9 Temporary procedure changes shall be implemented and documented using an approved Record of Variance (ROV), according to the procedure BQP-6: *Record of Variance*. Prior to implementing any procedural modifications, the ROV must be approved by the Bioassay Project Leader and QA Officer.

4.1.1.10 Project personnel shall be responsible for working to current copies of standard operating procedures and quality procedures for which they have been qualified and are performing. These procedures shall be readily available in the area, e.g., room, laboratory, or office, where the task is performed.

4.1.2 Reporting

4.1.2.1 Analysts shall certify the accuracy of reported results by signing or initialing and dating the report prior to release. Bioassay Project analytical reports and data packages shall be routed through a review process that should include the analyst, a secondary reviewer, the POC, and the QA officer.

4.1.2.2 The Bioassay Project shall meet the DOE Laboratory Accreditation Program (DOELAP) data requirements for accuracy, precision, and completeness through the use of proven methodologies.

4.1.3 Sample Management and Control

4.1.3.1 Bioassay Project samples shall be controlled according to the following procedures:

- BSP-904, *Sample Management*, and

- BSP-909, *Chain of Custody* procedures.

4.1.4 Instrument Calibration

4.1.4.1 Calibration standards shall be certified National Institute of Standards and Technology (NIST) traceable sources, derived NIST-traceable sources, or standards maintained by an equivalent internationally recognized standards organizations when available. A record of all reference materials used for calibration or verification of instruments and procedures shall be maintained. The Bioassay Project Leader shall maintain Certificates and/or other evidentiary information regarding traceability.

4.1.5 Control of Standards and Reagents

4.1.5.1 Chemical standards and reagents shall be identified and maintained to ensure conformance with certified specifications. Chemical standards and reagents for use by the Bioassay Project shall be dated and initialed by the analyst upon receipt.

4.1.6 Equipment Maintenance and Calibration

4.1.6.1 Maintenance logbooks shall be maintained for instruments and equipment used for the Bioassay Project that could impact quality. Maintenance logs shall be used to record instrument or equipment modifications, routine maintenance, vendor service, associated dates, and an explanation of the nature of the maintenance or service.

4.1.6.2 Instrument run logbooks shall be maintained for instruments used for the Bioassay Project. Run logs shall be used to record sample numbers or submission identification (ID) numbers for sample batches run on a specific instrument, associated dates, and instrument run parameters.

4.1.6.3 Calibration logbooks shall be maintained for balances and mechanical/automatic pipettors. Balance and pipettor calibration checks shall be performed on a daily basis prior to use.

4.2 Criterion 6—Design

Requirement: "*Items and processes shall be designed using sound engineering/scientific principles and appropriate standards. Design work, including changes, shall incorporate applicable requirements and design bases. Design interfaces shall be identified and controlled. The adequacy of design products shall be verified or validated by individuals or groups other than those who performed the work. Verification and validation work shall be completed before approval and implementation of the design*."

4.2.1 All items, processes, and procedures shall be designed using sound scientific principles and applicable standards. The adequacy of the designed item, process, or procedure shall be independently verified and validated prior to implementation using an applicable method. Validation shall be independently verified as discussed in Section 4.3.2, below. Revisions to the design of all items, processes, and procedures shall also meet these same requirements.

4.2.2 Analytical processes and procedures shall follow published standard methods or shall be verified and validated prior to implementation using appropriate standards. Results of verification and validation shall be documented and records thereof maintained as quality records.

4.2.3 If non-routine analyses, tests, or data-gathering activities are requested of the Bioassay Project, performance of these tasks might require unique procedures, facilities, hardware, and/or software that could affect the validity of results. In these situations, the necessary detailed procedures, technical specifications, engineering design plans, configuration plans, and/or verification plans shall be prepared under the direction of the person responsible. A peer group designated by the responsible POC and the Bioassay Project Leader will then review these documents. In addition, the Project QA officer will review them for compliance with this QAPjP.

4.2.4 All systems, equipment, and software necessary for the processing of samples and/or calculation of results shall be reviewed to determine criticality to operations. If any system, equipment or software is identified as critical, it shall be documented as such.

4.2.5 Identified critical system, equipment, and software shall be managed using a documented configuration management system.

4.2.6 All revisions to critical systems, equipment, or software shall be implemented only after being reviewed and approved by a system-knowledgeable engineer/scientist, the responsible POC, and the Project Leader.

4.2.7 All revisions to non-critical systems, equipment, or software shall be implemented after being reviewed and approved by a system-knowledgeable engineer/scientist and the responsible POC.

4.3 Criterion 7—Procurement

Requirement: "*Procured items and services shall meet established requirements and perform as specified. Prospective suppliers shall be evaluated and selected on the basis of specified criteria. Processes to ensure that approved suppliers continue to provide acceptable items and services shall be established and implemented*."

4.3.1 The Laboratory procurement process is used to ensure that items and services meet established requirements and perform as specified. This process defines the responsibilities of personnel and the interface with the Laboratory procurement group in Business Operations (BUS) Division.

4.3.1.1 The stringency of procurement requirements should be commensurate with the importance of the purchased item or service.

4.3.1.2 The extent of procurement control shall ensure that purchased items and services comply with requirements appropriately reflect the relative importance and risks associated with the items or services being procured.

4.3.1.3 QA controls shall be implemented when the requester believes that failure of the item or service being procured could result in:

- nuclear or chemical hazards,
- environmental contamination,
- significant hazards to people, or
- failure to meet critical work requirements.

In addition, QA controls shall be implemented as required when purchasing specific items designated by BUS or when required by codes or Laboratory standards.

4.3.1.4 The Bioassay Project Leader shall be responsible for ensuring that procurement requests incorporate the appropriate level of QA and all necessary specification, codes, testing requirements and reports, or other product qualifying criteria. The specifications of the procured item or service must be based on established technical and administrative criteria, taking into consideration the intended application of the item or service. Procedures to identify acceptance criteria made within the QA program should be included in the procurement documents.

4.3.1.5 Only qualified suppliers shall be selected and used. Suppliers shall establish and maintain documented procedures to ensure purchased products conform to specified requirements. The Laboratory procurement process provides guidance on the roles of C-Division and BUS to evaluate prospective suppliers and to ensure that approved suppliers continue to provide acceptable items and services. Selection shall be coordinated between the requester and the vendor from BUS.

4.3.1.6 The procurement process must provide methods for accepting purchased items and services. Methods for accepting items and services shall be identified and incorporated into the contractual agreements in coordination with BUS.

4.3.1.7 Nonconforming items or materials identified as unacceptable at any point in the acceptance process shall be evaluated and segregated to preclude use until the required technical requirements are satisfied.

4.4 Criterion 8 - Inspection and Acceptance Testing

Requirement: "*Inspection and testing of specified items, services, and processes shall be conducted using established acceptance and performance criteria. Equipment used for inspections and tests shall be calibrated and maintained*."

4.4.1 Inspection, acceptance testing, and calibration are designed to verify that systems, materials, items, and components are acceptable to the organization performing the work and to ensure that the resulting work or product can be shown to be acceptable for the intended function.

4.4.2 Group Leaders shall be responsible for inspection, acceptance testing, and calibration activities within C-Division and for ensuring that detailed test plans and procedures are developed and implemented based on customer requirements or on the requirements derived from implementing the design process described in Section 4.3 of this document. Group Leaders may delegate this responsibility to the Bioassay Project Leader, who may then delegate this responsibility to the appropriate POC.

4.4.3 Qualified personnel shall conduct inspection, acceptance testing, and calibration of instruments or equipment. Inspection and calibration may be conducted by a qualified internal or external service organization.

4.4.4 Items and equipment should be maintained and serviced based upon the manufacturer's - recommendations and quality requirements established for the product.

4.4.5 Only traceable, tested, and accepted quality items shall be used or installed.

4.4.6 Physical identification or physical separation shall be used to prevent the use of incorrect or defective items.

4.4.7 The correct identification of items shall be verified and documented before release for processing, use, storage, or shipping. Identification necessary to provide traceability for an item (when specified) must be contained on the item or on documents traceable to the items from initial receipt through its useful lifetime.

4.4.8 Inspection activities shall be conducted under controlled conditions.

4.4.9 The Bioassay Project Leader shall be responsible for ensuring the inspection, acceptance testing, and calibration of equipment. The Bioassay Project Leader may delegate this responsibility to the appropriate POC.

4.4.10 Instruments and equipment used for the Bioassay Project shall be maintained and calibrated in accordance with the applicable procedure and/or manufacturer's

recommendations and the quality requirements of the item. A graded approach for the calibration of equipment shall be used depending on the critical nature of the equipment as it applies to the desired end product. Calibration may also be conducted in accordance with the manufacturer's recommendations regarding maintenance and service schedules.

4.4.11 Calibration tags or marks shall be placed on each piece of calibrated equipment to identify the status of the equipment or instrument and to allow tracking of measuring and testing equipment. Alternatively, the calibration status of equipment may be maintained in a calibration/maintenance logbook.

4.4.12 Reference materials or solutions shall be obtained from vendors who provide certification of the accuracy of the standard. Calibration standards shall be certified NIST traceable sources, derived NIST-traceable sources, or standards maintained by an equivalent internationally recognized standards organizations when available.

4.4.13 The status of inspection, acceptance testing, and calibration activities shall be clearly defined on the items or in documents associated with the items or processes to prevent inadvertent bypassing of required inspections and/or tests.

4.4.14 The records of inspections, acceptance tests, or calibrations should identify the following:

- item tested,
- date of test,
- test interval,
- tester or data recorder,
- traceability,
- observations,
- results and acceptability, and
- actions taken concerning deviations in test.

5 ASSESSMENT CRITERIA

5.1 Criterion 9 - Management Assessment

Requirement: "*Managers shall assess their management processes. Problems that hinder the organization from achieving its objectives shall be identified and corrected.*"

5.1.1 Management assessment is designed to establish a process for verifying that the system used to achieve and ensure quality is effective. This includes, but is not limited to, an assessment of the effectiveness of the management controls and the adequacy of the resources and personnel assigned to achieve and ensure quality.

5.1.2 The Bioassay Project Leader shall annually evaluate Bioassay Project performance. Processes assessed shall include project strategic planning, organizational interfaces, communication, performance schedules, cost control, use of performance indicators, staff training and qualifications, and supervisory oversight and support.

5.1.3 Management assessment results shall be used as input to the project's continuous improvement process. Observations in areas where quality management has improved work performance, management actions, and effective business practices should also be documented.

5.2 Criterion 10 — Independent Assessment

Requirement: "*Independent assessments shall be planned and conducted to measure item and service quality, to measure the adequacy of work performance, and to promote improvement. The group performing independent assessments shall have sufficient authority and freedom from the line to carry out its responsibilities. Persons conducting independent assessments shall be technically qualified and knowledgeable in the areas assessed*."

5.2.1 Independent assessment is designed to obtain impartial evaluations of Bioassay Project management systems and work processes to determine their effectiveness and to promote quality improvement. Participation in interagency performance evaluation (PE) programs provides continuing independent assessment of analytical performance for the Bioassay Project.

5.2.2 An annual independent assessment of the Bioassay Project shall be conducted. The Bioassay Project Leader shall be responsible for scheduling the independent assessment. Independent assessments shall be conducted by technically qualified personnel who are independent of the activity being assessed. Independent assessments may be conducted by LANL Internal Assessments and/or by organizations external to C-Division and LANL.

5.2.3 Independent assessments shall be scheduled through the Bioassay Project Leader in accordance with "Assessments and Audits" (Director's Policy #111).

5.2.4 Each assessment observation and/or finding shall be treated s a non-conformance according to Section 3.4.2 of this QAPjP. The Bioassay Project Leader shall initiate a root cause analysis to determine the cause(s) of deficiencies and to avoid recurrences. The Bioassay Project Leader may delegate this responsibility to the appropriate POC.

5.2.5 The Bioassay Project QA Officer shall monitor compliance deficiencies and associated corrective actions resulting from assessment and PE program activities.

6 QUALITY CONTROL PROGRAM

6.1 Quality Control Program

6.1.1 The Quality Control Program (QCP) is designed to adequately measure and verify conformance with requirements.

6.1.2 QC provisions shall be designated for operations from sample receipt through issue of the analysis report.

6.1.3 POCs and SMEs shall include appropriate QC provisions in procedures under their control.

6.1.4 The Bioassay Project shall maintain an effective, ongoing interlaboratory QCP to measure and verify laboratory performance for the analytes routinely determined and provide corrective action as needed. The Bioassay Project shall participate in one or more of the following interlaboratory bioassay PE programs:

- Oak Ridge National Laboratory (ORNL) In-vitro Bioassay Intercomparison Study (for urine)
- DOELAP for Bioassay Performance
- NIST Low Level Intercomparison of ICP-MS, Thermal Ionization Mass Spectroscopy (TIMS), and Fission Track Methods for Pu-239 (for synthetic urine) when offered.

The Bioassay Project QA officer shall develop annually in the first quarter of the fiscal year a schedule for interlaboratory QCP participation for the Bioassay Project Service Laboratory Operations. The Bioassay Project leader shall approve the annual interlaboratory QCP participation schedule.

6.1.5 The Bioassay Project shall maintain an effective, ongoing intralaboratory QCP to measure and verify laboratory performance for the analytes routinely determined. The intralaboratory QCP shall conform to the requirements in American National Standards Institute (ANSI) N13.30 and the HSR-4 Analytical Services Agreement (ASA).

6.1.6 QC samples including preparation or reagent blank samples, laboratory control samples, blind QC samples, and replicate or duplicate samples shall be analyzed at a frequency of at least 5% of the total samples analyzed (e.g., one per analysis batch of 20 or fewer samples). The analysis of replicate or duplicate samples shall be determined based on the availability of adequate sample for the analyte to be determined.

6.1.7 Radiochemistry tracer spikes shall be incorporated into the analysis procedure as appropriate.

6.1.8 Minimum Detectable Activities (MDAs) shall be specified in analysis procedures.

6.1.9 The following QC standards of performance shall be applied to Bioassay Project data:

6.1.9.1 Urine blank results shall be acceptable if the result is within + or – of the MDA for the analyte being determined. Samples associated with a preparation or reagent blank result outside the acceptance criteria shall be reanalyzed when adequate sample is available; if not, the Bioassay Project leader shall be notified, who shall notify the customer.

6.1.9.2 For blind QC samples at 10 times the MDA, results shall be acceptable when:

1) The relative bias of the result is within –0.25 to +0.25 of the "true" value of the analyte being determined, and

2) The "true" analyte concentration of the blind QC sample is equal to or greater than the customer's minimum testing level (MTL). For blind QC results where the "true" value of the analyte being determined is below the

customer's MTL, the performance criteria for relative bias shall not be expected to be met. The customer's MTL, if specified, must be at least 10 times the customer's contractually specified MDA. When the customer does not specify MTLs, the MTLs given in ANSI N13.30, Section 6, Table 2 shall be used. The unacceptable performance on the blind QC sample shall be noted in the case narrative.

NOTE: In all cases, the ASA should be referred to for specific acceptability criteria.

6.1.9.3 Radiochemical tracer spike recoveries for plutonium determinations using alpha spectrometry procedures shall be acceptable if the percent recovery is greater than or equal to 40% and less than or equal to 110%; if not, the Bioassay Project leader shall be notified, who shall notify the customer.

6.1.9.4 Radiochemical tracer spike recoveries for plutonium determination using the thermal ionization mass spectrometry procedure shall be acceptable if the percent recovery is greater than or equal to 15% and is less than or equal to 110%; if not, the Bioassay Project leader shall be notified, who shall notify the customer.

ATTACHMENT 1. REQUIREMENT/GUIDANCE DOCUMENTS

- *Bioassay Project Management Plan*, (most recent revision).
- *Bioassay Project Analytical Service Agreement*, (most recent revision).
- *Bioassay Project Process Flow Diagram*, (most recent revision).
- ISO Guide 25, *General Requirements for the Competence of Calibration and Testing Laboratories*, International Standards Organization, December 1990.
- ANSI N42.2, *Measurement Quality Assurance for Radioassay Laboratories*, American National Standards Institute, February 9, 1994.
- ANSI N13.30, *Performance Criteria for Bioassay*, American National Standards Institute, January 1993, draft.
- ANSI/ASQC Q2-1991, *Quality Management and Quality System Elements for Laboratories-Guidelines*, American National Standards Institute/American Society for Quality Control, 1991.

ATTACHMENT 2. ANNUAL RECERTIFICATION FORM

Los Alamos NATIONAL LABORATORY
memorandum
CHEMISTRY

To/MS:
Thru/MS:
From/MS:
Phone/Fax:
Symbol:
Date:

C-Division Bioassay Project – Annual Re-certification of Analyst Qualifications

Subject: <Analyst Name>

The purpose of this memo is to document the annual re-certification of **<Analyst Name>** to the following technical procedure(s):

<Procedure 1>

<Procedure 2>

<Procedure 3>

This re-certification is effective as of **<DATE>**.

Proficiency and re-certification has been established based upon:

<___> Successful execution of procedure steps without assistance/prompting

<___> Successful completion of sample preparation and/or analysis with acceptable results

<___> Other: <_____>

Acknowledgements

POC: <POC> Signed: _____ Date: _____

QA Officer: <QAO> Signed: _____ Date: _____

Project Leader: <BPL> Signed: _____ Date: _____