

Project Management Plan

for the

C-Division Bioassay Project

Analytical Services

for

ESH-4

LA-UR 99-4817

C-DIVISION BIOASSAY PROJECT
Project Management Plan

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APPROVALS

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RECORD OF REVISIONS

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1 Introduction

Personnel working in some programs at the Los Alamos National Laboratory (LANL) may handle radioactive materials that, under certain circumstances, could be taken into the body leading to a potential exposure. Los Alamos National Laboratory (LANL) has established a radiation protection program to monitor for this potential occurrence, in compliance with 10 CFR 835. In support of this program, the Chemistry (C) Division provides analytical services to the Environmental, Safety and Health (ESH) Division for the analysis of urine samples in accordance with the Bioassay Analytical Service Agreement (ASA), Contract #ESH-4-ASA-02. The ASA documents the requirements, products, and services to be provided by the C-Division to ensure analysis and data reporting for the bioassay urine samples for ESH-4. This Project Management Plan (PMP) details how the C-Division Bioassay Project will manage and operate to meet the terms and conditions of the ASA.

The C-Division Bioassay Project is a functional part of the LANL C-Division Chemistry organization. Three C-Division groups; C-Analytical Chemistry Services (ACS); and C-Isotope and Nuclear Chemistry (INC), and C-Actinide and Analytical Chemistry (AAC), provide services and/or personnel to support the C-Division Bioassay Project. Team members from C-INC and C-ACS are matrixed to the C-Division Bioassay Project to perform laboratory testing and technical support services. Computer services for the C-Division Laboratory Information Management System are provided by C-AAC.

C-Division has assigned a dedicated Bioassay Project Leader to perform the overall project planning, control, and reporting functions for the Bioassay Project. The Bioassay Project Leader has the exclusive and dedicated responsibility for the overall technical, cost, and schedule performance on this program. A strong “first team” of experienced C-Division personnel is assigned to the project. These personnel have direct access to a committed and participative C-Division management -- Group and Division Leaders -- which ensures the total and continuous visibility of program status, and is a vehicle for obtaining additional support as needed.

The Bioassay Project Leader is the focus for communications with C-Division management and ESH-4. The Project Leader has prepared this project management plan with the assistance of the C-Division managers, Quality Assurance, and Bioassay Project team members. This project plan contains a work breakdown structure (WBS), a description of the workflow and processes, and discusses the control of budgets, resources, and schedule.

2 Responsibilities

The C-Division Bioassay Project is organized within the LANL C-Division. The C-Division provides senior management support to the C-Division Bioassay Project. C-Division Bioassay Project management responsibilities flow from the C-Division Bioassay Project Leader through the C-Division 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.

Personnel for the Project are directly assigned tasks through a matrix management approach. The following positions are matrixed to the C-Division Bioassay Project Leader: the Quality Assurance (QA) officer, the POCs, and the analysts and technical support personnel.

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C-ACS provides an interface between customers and analysts through sample management services including: receiving, processing, and reporting of analytical samples; QA and quality control (QC) support; coordination of QC samples; and records management and document control.

C-INC provides Bioassay Project management and statistical expertise support. Technically, C-INC provides sample analysis support using alpha spectroscopy and thermal ionization/mass spectrometry (TIMS) for the determination of plutonium isotopes.

External contracted services include: QA officer, which includes QA oversight of analytical chemistry, operations; and preparation of QC samples.

C-AAC is responsible for design, documentation, maintenance, and improvement of the SQL*LIMS computer system that is used to enter, track, and report analytical data for the Bioassay Project. Generation and maintenance of computer interfaces between analytical instruments and the SQL*LIMS system are created and maintained cooperatively between C-Division personnel.

2.1 ESH Division Office

The ultimate responsibility for the LANL Bioassay Program rests with the ESH Division Office. Specific responsibilities for the Bioassay Program will be to negotiate and resolve any ESH-4/ C-Division Analytical Service Agreement (ASA) non-compliance. The ESH Division Office will ensure that the LANL Bioassay Program is compliant with the LANL Radiation Protection Program requirements.

2.2 C- Division Office

The C-Division Office has ultimate authority and responsibility for ensuring implementation of the requirements stipulated in the ASA within C-Division and ensuring that the appropriate C-Division programs and personnel (C-Division Bioassay Project) are compliant with the Agreement. ESH and C-Division Division will communicate as necessary to resolve any non-compliance issues within the Bioassay Program. The C-Division is responsible for providing upper management support.

2.3 ESH-4 Group Leader

The ESH-4 Group Leader will ensure the development of an ASA to be presented to C-Division for review and approval at the beginning of each fiscal year. The ESH-4 Group Leader will be responsible for ensuring the implementation and completion of all milestones contained within the ASA. Upon completion of the Bioassay Program Evaluations, the ESH-4 Group Leader will ensure that all findings are submitted to the ESH-4 and C-Division offices for review.

2.4 ESH-4 Bioassay Project Leader

The ESH-4 Bioassay Project Leader will develop the ASA and monitor the implementation and completion of all milestones contained within the ASA. The ASA will identify all quality and technical requirements for the analysis of LANL Bioassay samples. A financial section will be included to define the quantity and method of payment. The ESH-4 Bioassay Project Leader will monitor C-Division's performance relative to the ASA and communicate requirements and needs to the C-Division Bioassay Project Leader. The ESH-4 Bioassay Project Leader will monitor the allocation of funds to C-Division through the Bioassay Recharge mechanism and verify compliance with the ASA. The ESH-4 Bioassay Project Leader will be responsible for the annual Bioassay Program Evaluations as defined in the ASA. All unresolved issues of non-compliance as defined by the ASA will be communicated to the ESH-4 Group Leader and ESH Division Office.

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2.5 C-Division Bioassay Project Leader

The C-Division Bioassay Project Leader has primary responsibility for all C-Division Bioassay Project decisions and activities and is the primary Project contact.

The C-Division Bioassay Project Leader is responsible for interfacing with C-Division, ESH-4, LANL Audits & Assessments and other external organizations and for managing C-Division Bioassay Project activities such as planning, organizing, scheduling, directing, coordinating, and controlling project resources and budget. The C-Division Bioassay Project Leader will prepare and submit monthly status summaries in accordance with the ASA. The C-Division Bioassay Project Leader has authority to make C-Division commitments and will seek senior C-Division management support should a requirement arise that is out of the scope of the ASA.

The C-Division Bioassay Project Leader reports project status by preparing a monthly project progress report under C-Division procedures for tracking and reporting project status and cost accounting as described in Section 7.0, Progress Reporting. These reports include a summary of progress during the reporting period, identification of reports/correspondence issued during the period, actions planned for the next period, the schedule, and cost/expenditure status and critical items. As part of the reporting process, the C-Division Bioassay Project Leader establishes a routine for reviewing project progress with the ESH-4 Bioassay Project Leader. Progress report intervals will be established in coordination with the ESH-4 Bioassay Project Leader.

The C-Division Bioassay Project Leader shall:

- have primary responsibility for all decisions on organizational structure, technical approach, work control, priorities, and quality-related issues including work suspension for the C-Division Bioassay Project and for executing all agreements, proposals, and correspondence that obligate the Project;
- be the primary contact for the Project;
- develop, implement, and maintain the C-Division Bioassay Project Management Plan (PMP) and QAPjP and shall conduct periodic reviews to ascertain that provisions in these documents are being adhered to in Project activities;
- ensure that open lines of communication are maintained between the Project's technical and supervisory personnel of matrixed support organizations;
- be responsible for planning, organizing, scheduling, directing, coordinating, monitoring, and controlling C-Division Bioassay Project resources and budget;
- prepare and present progress reports on Project status and cost accounting; and
- coordinate long-term planning for the C-Division Bioassay Project with C-Division management.

The C-Division Bioassay Project Leader shall have the authority to:

- make C-Division commitments within the scope of the authority delegated by C-Division Director;
- monitor Bioassay Project elements and progress;
- initiate and close work suspension and corrective actions for the Project; and
- exercise final authority in administrative and operational issues for the C-Division Bioassay Project.

The C-Division Bioassay Project Leader interfaces with:

- C-Division management and Group Leaders and team leaders responsible for C-Division Bioassay Project testing laboratory services and associated technical support operations;

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- C-Division Bioassay Project customers;
- the Bioassay Project QA officer, Bioassay Project points of contact (POCs), and Project analysts and su C-Division support personnel;
- LANL Audits and Assessments personnel; and
- other internal and external organizations, as necessary.

2.6 C-Division Group Leaders

C-Division Group Leaders are responsible for activities undertaken by the group in support of the Bioassay Project.

C-Division Group Leaders shall:

- manage and lead Project personnel and ensure that agreed upon Project objectives are met;
- develop and maintain the work force to ensure that personnel are qualified for and appropriately trained to perform assigned tasks;
- assign group personnel and resources to the Bioassay Project;
- review and approve Project-related procedures and plans and ensure that procedures used in conjunction with the Bioassay Project activities are current and technically accurate;
- support and enforce work suspension requests and associated corrective actions; and
- ensure that tasks performed under their control for the Bioassay Project are in compliance with current Procedures and plans.

C-Division Group Leaders shall have the authority to:

- commit group and/or team resources to the C-Division Bioassay Project; and
- manage human resources in support of the Project.

C-Division Group Leaders interface with:

- C-Division Bioassay Project Leader;
- C-Division management;
- C-Division Group Leaders and Bioassay Project analysts and technical support personnel; and
- Group Leaders from other organizations.

2.7 Analytical Lab Team Members

The following positions are matrix-managed resources made available to the Bioassay Project Leader through the C-Division Group line management organizations.

C-Division Bioassay Project QA Officer

The C-Division Bioassay Project QA Officer is responsible for providing QA support to the Project Leader and other Project personnel in fulfilling the QA requirements of their function(s).

The C-Division Bioassay Project QA Officer shall:

- assist the Project Leader in the development implementation, maintenance, and assessment of the C-Division Bioassay Project QAPjP and associated standard operating and quality procedures;
- provide quality training for C-Division Bioassay Project personnel;

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- develop and manage the C-Division Bioassay Project quality assurance program;
- serve as the primary contact for QA and performance evaluation (PE) programs for the C-Division Bioassay Project;
- interpret Bioassay Project QAPJP requirements and determine appropriate application;
- advise the C-Division Bioassay Project Leader of quality related issues;
- assist the C-Division Bioassay Project Leader in the development, review, and tracking of nonconformance and quality improvement initiatives;
- develop performance indicators for the Project;
- coordinate the development of action plans to address trends in performance indicators;
- review procedures and other documents for quality parameters and document adequacy;
- coordinate and conduct internal quality assessments;
- coordinate or support external quality assessments including QA audits, appraisals, surveillance, inspections, and assessments;
- assist in responding to findings and observations from internal and external quality assessments and to performance issues related to bioassay PE program performance;
- assist in closure of findings and observations resulting from internal and external assessments;
- assist in closure of work suspensions;

The C-Division Bioassay Project QA Officer shall have the authority to:

- identify issues affecting quality and advise the C-Division Bioassay Project Leader;
- interface with other quality professionals in support of C-Division Bioassay Project objectives;
- independently review and assess Bioassay Project activities; and
- represent the Bioassay Project on issues concerning quality.

The C-Division Bioassay Project QA Officer interfaces with:

- C-Division and ESH Bioassay Project Leaders;
- C-Division Group and team leaders and C-Division Bioassay Project analysts and support personnel;
- QA professionals throughout the Laboratory and the DOE Complex;
- Group Leaders for other organizations; and
- bioassay PE program sponsors.

C-Division Bioassay Project Points-of-Contact

Bioassay Project points-of-contact (POCs) are responsible for providing planning and technical direction s C-Division support and for establishing and ensuring the adequacy of technical and administrative requirements and procedures for the C-Division Bioassay Project.

C-Division Bioassay Project POCs shall:

- participate in the planning for the C-Division Bioassay Project;
- provide technical direction and support to the Project;
- assist the Bioassay Project Leader in establishing and ensuring the adequacy of technical and administrative requirements and procedures for the Project;
- be the conduit to the group and team leaders and Project personnel for Project related initiative and activities;
- assist the Project Leader in the identification, development and implementation of quality improvement initiatives;
- develop, maintain, and revise procedures, as needed, and ensure that appropriate technical and quality procedures are approved and available in the work areas;

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- identify abnormal situations and advise the C-Division Bioassay Project Leader of situations that can affect Bioassay Project work quality;
- promote teamwork and good housekeeping practices, and
- conduct the analyte specific responsibilities as follow:

Alpha Spectrometry POC

- Analyzes Pu alpha spectrometry data
- Reports Pu alpha spectrometry data
- Assembles Pu alpha spectrometry data packages
- Inputs data into LIMS
- Implements QA activities in accordance with the QAPjP

Thermal Ionization Mass-Spectrometry (TIMS) POC

- Supervises analysts performing TIMS analysis
- Assembles TIMS data packages
- Reviews and approves TIMS data packages as SME
- Inputs TIMS results into LIMS
- Implements QA activities in accordance with the QAPjP

Sample Prep for Pu by alpha spectrometry POC:

- Supervises chemists performing bioassay analyses for alpha
- Provides technical guidance and support in solving problems as they arise
- Prepares the Pu-242 tracer used in analyses
- Ensures prompt response to Priority 1 requests
- Reviews and approves Pu-alpha-spec data packages as SME
- Implements QA activities in accordance with the QAPjP

Sample prep for Pu by TIMS POC

- Supervises chemists performing bioassay analyses for TIMS
- Provides technical guidance and support in solving problems as they arise
- Substitutes for analysts when required
- Ensures prompt response to Priority 1 requests
- Reviews and approves TIMS data packages
- Implements QA activities in accordance with the QAPjP

Sample Management/Records Management POC

- generate and maintain records of personnel training and qualifications;
- coordinate QC sample preparation with external supplier and management within SMO
- direct and oversee the management and archiving of C-Division Bioassay Project records; and direct and oversee C-Division Bioassay Project SMO operations.
- Direct and oversee the sample management operation
- Provide customer interface and response to issues and questions regarding SMO

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C-Division Bioassay Project POCs shall have the authority to:

- Implements QA activities in accordance with the QAPjP
- act in the role of the C-Division Bioassay Project Leader when appointed;
- coordinate and guide the assignment of work;
- provide support to the C-Division Bioassay Project Leader;
- perform ongoing surveillance and verification of work and work areas;
- develop methods for problem solving and quality improvement;
- develop and implement plans and procedures that achieve project objectives; and
- initiate work suspension and assist in corrective actions for the Project.

C-Division Bioassay Project POCs interface with:

- the C-Division Bioassay Project Leader;
- C-Division Group Leaders and Bioassay Project analysts and technical support personnel;

C-Division Bioassay Project Analysts and Technical Support Personnel

C-Division Bioassay Project analysts and technical support personnel are responsible for conducting the bioassay testing and associated technical support operations that contribute to the overall success of the Project.

C-Division Bioassay Project analysts and technical support personnel shall:

- ensure that analytical laboratory and support operations performed under their control are performed according to plans and procedures and are in compliance with the Bioassay Project QAPjP;
- ensure that appropriate certified standards are used in analytical chemistry work for the Bioassay Project;
- request adequate facilities and equipment needed to achieve quality objectives;
- know and follow current procedures for which they are qualified
- assist in the development and maintenance of appropriate quality and technical procedures within their areas of responsibility;
 - ensure that instruments and/or equipment they use or operate receive appropriate maintenance and are properly calibrated;
- identify processes that are out of control, initiate corrective action, and document the action taken;
- keep clear and complete records to support the quality of work performed and the results obtained;
- verify calculations and data, as necessary;
- ensure that the Project's analytical commitments to the customer are met in a timely fashion;
- enter results into the LIMS and report results to the appropriate individuals or organizations;
- ensure that safe and environmentally sound work processes are performed;
- participate in planning and peer reviews of analytical laboratory and other work processes;
- share lessons learned; and
- assess their own work.

C-Division Bioassay Project analysts and technical support personnel shall:

- have the authority to purchase or order supplies and materials for the Project; and
- initiate work suspension and work with Project management on corrective actions.

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C-Division Bioassay Project analysts and technical support personnel interface with:

- the C-Division Bioassay Project Leader;
- Bioassay Project POCs; and
- C-Division Group Leaders, and group and team personnel.

3 C-Division Bioassay Project Organization

3.1 Functional Organization

The C-Division Bioassay Project technical staff is assigned a functional role within the C-Division Bioassay Project. This functional organization is based on the type of bioassay analysis performed. Analytical team members are matrixed to the C-Division Bioassay Project to perform the analyses outlined in the ASA. The C-Division Bioassay Project is a functional part of the C-Division organization. As such, C-Division has the overall responsibility for the professional development, administration (e.g., performance reviews), and other factors for C-Division personnel assigned (matrixed) to the C-Division Bioassay Project. The C-Division Group Leaders and/or team leaders implement these factors for personnel assigned to the Bioassay Project.

For those C-Division personnel assigned to the C-Division Bioassay Project, specific roles and responsibilities are defined in Section 2.0. The C-Division Bioassay Project organization is shown in Figure 1.

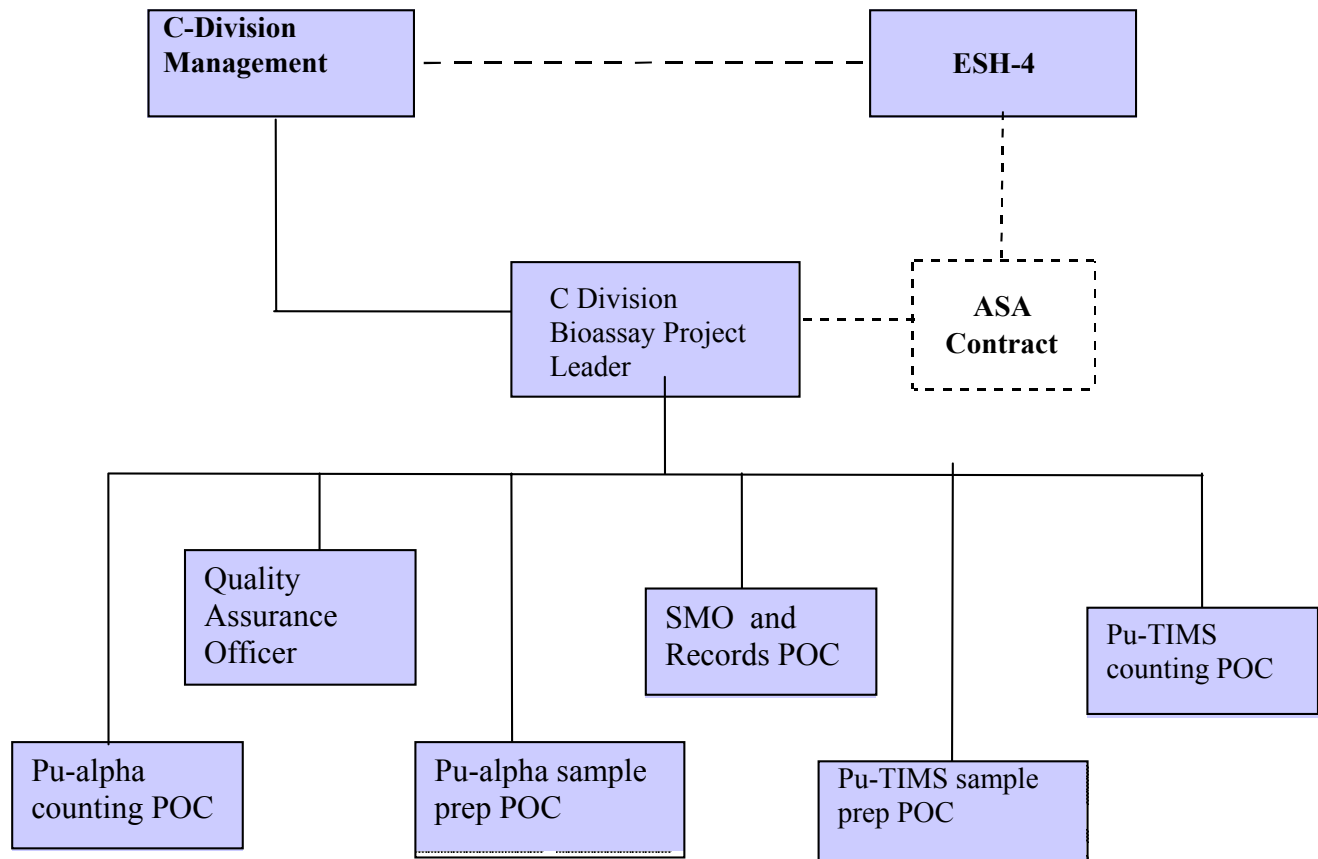
3.2 Interface with Other LANL Organizations

The C-Division Bioassay Project Leader will provide the principle point of contact between C-Division Bioassay Project personnel and the ESH-4 Bioassay Project Leader. C-Division Bioassay Project technical staff may interface with ESH-4 and other LANL personnel as necessary to accomplish work. Any non-conformances, schedule slippage, cost over-runs, conflicts (within the project or with other LANL groups) or potential changes of scope to the ASA shall be immediately brought to the attention of the C-Division Bioassay Project Leader.

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Figure 1 – C-Division Bioassay Project Organization



4 Project Work Flow

4.1 General

The work performed by the C-Division Bioassay Project can be grouped under four general areas:

1) sample management, 2) sample analysis, 3) reporting and records keeping, and 4) laboratory information management system (LIMS). The work is performed at three different locations; TA-3, TA-48 and TA-59. Sample management, including the coordination of QC samples, is accomplished at TA-59. Records management is accomplished at TA-59. The analysis for plutonium and AM in urine and fecal by alpha-spec and PU in urine by TIMS is conducted at TA-48. A detailed process flow diagram is found in Appendix 3. A list of equipment located at both TA-48 and TA-59, which is critical to the LANL Bioassay Program, is found in Appendix 4.

The LIMS utilized to report and electronically stored data generated by C-Division in the required ESH format, is operated and maintained at TA-3. LIMS services, computer software, hardware maintenance and upgrades required for support to the Bioassay Project is obtained from C-AAC through a memorandum of understanding that is revised on an annual basis between C-AAC, C-Division and ESH Divisions (see Appendix 5).

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4.2 Sample Management

Bioassay samples are received from the ESH-4 sample coordinator, who is responsible for the collection and delivery of the sample kits to TA-59. The staff of SMO accepts custody of the kits for the C-Division Bioassay Project. The SMO staff adds urine blanks generated by TIMS certified donors within the program, and QC samples prepared by Oak Ridge National Laboratory, to the batch and enters information concerning all samples into LIMS. This generates a service request and a C-Division internal chain-of-custody document. The samples, along with the appropriate documentation, are delivered to a secure holding refrigerator at TA-48. Operating procedures for these activities include BSP-904 - Sample Management; BSP-907 - Request for Analytical Services; BSP-908 - Bioassay Analysis and Reporting; BSP-909 - Chain of Custody; BSP-914 - Packaging and Transportation of Analytical Chemistry Samples (see Appendix 6).

4.3 Plutonium in Urine by Alpha Spectroscopy

Analytical process: The sample parameters (temperature, weight, and specific gravity) are determined and entered into LIMS. Separation chemistry is performed by treating the sample with calcium phosphate to precipitate the plutonium from solution. The sample is centrifuged, and the supernatant liquid decanted and discarded, leaving the precipitated plutonium solids. The solids are then dissolved in nitric acid and heated to convert all of the plutonium to the +4 valence state. The nitric acid solution is passed through an anion exchange column. The plutonium is eluted from the column with a hydrochloric/hydroiodic acid solution. The solution is evaporated to dryness. The sample is redissolved in a sodium bisulfate-sodium sulfate solution and electroplated onto a stainless steel planchette.

The electroplated sample is analyzed and quantified by alpha spectroscopy. The samples are counted for 70,000 seconds on passivated ion-implanted junction silicon detectors (or equivalent), which provide an average energy resolution of 16 keV FWHM, allowing the activities of Pu-238 and Pu-239 to be determined based on the chemical recovery of the Pu-242 tracer. The alpha spectroscopy results are entered into LIMS. A data package is prepared and reviewed by the POC and the Team leader. The final data package is forwarded to the QA officer for review. Operating procedures for this activity include BSP-365 – Sample Preparation for Plutonium in Urine by Alpha-spectrometry; BSP-356 – Counting and Calculation of Plutonium Bioassay Samples at TA-48; BQP-10 - Management of Analytical Chemistry Laboratory Records (see Appendix 6).

Detector Type and Configuration: ORTEC ULTRA-AS low-background 300 mm² ion implanted detectors or equivalent are employed. A primary and a backup spectrometer system are available. The primary system consists of three Oxford OASIS eight-channel spectrometers. Each of the 48 channels includes a vacuum chamber, detector bias supply, preamplifier, shaping amplifier, peak detector/multiplexed, 4096-channel ADC, test pulse generator and vacuum sensor. The OASIS software (current version 4.02) provides computer control of amplifier gain, detector bias, test pulse amplitude and vacuum. These controls are monitored, in addition to system temperature, dc power supply, RAM battery backup voltage and dc voltages of various test points in the processing chain, to provide real time diagnostics during counting. The software performs data backup every five minutes during counting, which provides minimal data loss in the event of power disruption. The C-INC counting facility is staffed by competent and experienced electrical and instrumentation engineers and technicians capable of troubleshooting and repairing spectroscopy systems.

In the event that the primary system becomes unavailable, a backup spectroscopy unit can be placed into routine service immediately. The backup consists of a 12-channel system of Canberra 7401 chambers. This

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system is controlled by Canberra S100 MCA software (current version 3.1) via a Canberra 1520 Mixer/Router. Vacuum is continuously maintained by a control system built in-house.

Data Reduction: The supplied software provides gross counts. Due to customer preference for background averaging, determination of activity/sample is performed on a separate Excel® spreadsheet. Calculations are performed in accordance with the ASA. Spreadsheet calculations have been validated and spreadsheet cells are protected. All data transfers are performed using validated database macros, which preclude any manual transcription of data.

The raw data are stored in a Microsoft Access® database. Macros have been developed to extract the raw data from the database and place them into an Excel® file for transfer into the calculation spreadsheet. The final results are reviewed for accuracy before running another macro, which extracts the raw data and calculated results into a text file. This file is then sent to LIMS by FTP. After LIMS assigns the data to the appropriate fields, the data are reviewed and approved the team leader and the QA Officer.

Energy Calibration: Upon new detector installation, energy calibration is performed using a three-peak standard (Pu-239, Am-241, Cm-244) provided by Amersham with NIST traceability. Each sample is monitored for tracer energy, providing effective 100% energy calibration verification. In addition, monthly efficiency verification counts provide a 3-point energy calibration check.

4.4 Thermal Ionization Mass Spectrometry (TIMS)

Analytical process: If TIMS analysis for plutonium in urine is requested, the appropriate electroplated disks from the alpha spectroscopy analysis are forwarded to the TIMS group. However, TIMS analysis will not be carried out if either a) the Pu-239 activity from RAS in sample divided by its standard deviation exceeds 5, or b) the tracer recovery was less than 15% unless the sample is a Priority 1, in which case ESH-4 (D. Lewis; G. Miller) will be consulted before the analysis is canceled.

The stainless steel planchette from the alpha spectroscopy analysis is washed with a hydrofluoric/ nitric acid solution to remove the plutonium. The plutonium solution is passed through an anion exchange column and the plutonium is eluted from the column by the addition of a hydrochloric/ hydroiodic acid solution. The sample is evaporated to dryness and redissolved in a hydrochloric acid/ peroxide solution. The sample is loaded onto a second anion exchange column and plutonium is eluted with hydrobromic acid into a quartz tube.

The solution is electroplated onto a rhenium filament, which is inserted into the ion source of the mass spectrometer. A current is passed through the filament, which causes the plutonium isotopes to ionize. The ions are accelerated through a magnetic field, resulting in a separation of the ions by mass. The amount of Pu-239 in the sample is calculated by comparing the number of those ions to those resulting from a known amount of Pu-242 spike. The data are analyzed and the results entered into LIMS. A data package is prepared and reviewed by the POC and the Team leader. The final data package is forwarded to the QA Officer for review. Operating procedures for this activity include BSP-374 – Sample Preparation for Plutonium in Urine by Thermal Ionization Mass Spectrometry; BSP-368 – Analysis of Plutonium in Urine by Thermal Ionization Mass Spectrometry; BQP-10 - Management of Analytical Chemistry Laboratory Records (see Appendix 6).

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Measures are used to evaluate the performance of the TIMS measurement system include process blanks and QC samples. The process blanks are blank samples that are put through the same chemistry as the regular samples. The blanks place a limit on possible contamination occurring during chemical processing of the samples and on the isobaric effects caused by chemical processing. Blanks provide a measure of the performance of the data acquisition-reduction system at the detection limit of the system. QC samples are known that are taken through the same process as the regular samples. QC samples provide a measure of the accuracy of the overall TIMS sample preparation, data acquisition, and data reduction process.

TIMS Data Reduction: The TIMS Data Analysis code is used to process TIMS data. The code makes no decisions based on date information. It is therefore Y2K compliant. Further, all date information manipulated by the code contains four digit year information. The current version of the code is 1.0.1. The code consists of three segments that are run sequentially. They are:

- Ratio
- Concentration
- LIMS Input

Ratio reads the comma delimited raw-data file that is generated by the mass spectrometer, and calculates the atom ratio and standard deviation of the atom ratio of unknown isotopes to the reference isotope. For bioassay plutonium analyses the reference isotope is the major spike isotope, ^{242}Pu . These data along with header information, such as sample identifier, date, notebook page number, and operator, are written to a Access database. Ratio separates the raw count data by mass and identifies the reference mass, the isotope mass(es), and the background masses. Background is typically established at half-mass. That is background for ^{239}Pu is counted at mass 238.5 and 239.5.

Ratio calculates the reference counts and backgrounds as a function of time and filament temperature. It then corrects the unknown isotope counts for background and calculates the atom ratios and standard deviations. Data rejection is based on Chauvenet's criterion. Data rejection is necessary to remove the results of phenomena, such as arcing, that occasionally occur in the mass spectrometer.

Concentration reads the ratio and spike information data from the Access database. Concentration calculates secondary atom ratios (Pu-240/239), absolute atom concentrations for individual isotopes, activities of the isotopes, and standard deviations. Concentration also calculates the average and standard deviation of each isotope (^{239}Pu and ^{240}Pu typically) of the last 30 process blanks that have been run. These averages are used to calculate a blank corrected set of results. Both uncorrected and blank corrected results are written to the Access database. (Uncorrected results are used in the average blank calculation.) The data required for input to LIMS is read from the Access database and written to a random access file.

LIMS Input reads the random access file and displays the data to be input to LIMS. Once the data has been reviewed and approved, LIMS Input writes the data to a comma delimited (CSV) file. This file is then used to write the final data to LIMS.

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4.5 QA Review and Records Management

The QA Officer reviews the data generated by each of the analyses discussed above. After the QA Officer has completed his review and approved the data package, LIMS is updated and the data are available to ESH-4 electronically. A hard copy of the results is also provided to ESH-4. The data packages are then placed in long-term storage. Operating procedures for this activity include BSP-908 – Bioassay Analysis and Reporting; BQP-10 - Management of Analytical Chemistry Laboratory Records (see Appendix 6).

5 Regulatory Requirements

5.1 DOE Laboratory Accreditation Program (DOELAP)

The DOE has issued a technical standard for the accreditation of DOE analytical laboratories (DOE-STD-1128-98). The purpose of the standard is to “encourage the development of performance standards by national consensus standards organizations, to evaluate the feasibility and technical appropriateness of the standards for application in DOE operations, and to develop and implement a routine performance testing program. The development of performance standards, blind testing programs, improvements in calibration standards, and site evaluation criteria assisted this effort. In addition, research efforts in radiobioassay calibration improvements and standards development have been supported by the DOE to enhance the quality of radiobioassay measurements.”

This technical standard is designed to implement the ANSI N13.30 American National Standard for Performance Criteria for Radiobioassay (ANSI 1996). It provides the technical specifications and assessment criteria to be met by the radiobioassay program requesting accreditation. The relevant details of the ANSI N13.30 standard are also identified where necessary. It is expected that laboratories will use this technical standard, the ANSI N13.30 standard, and other technical guidance from DOE to assure that the performance of radiobioassay measurements is adequate to meet the standards of 10 CFR 835 and related requirements and guidance. The LANL Bioassay Project is committed to meeting these various requirements.

The LANL Bioassay Program obtained DOELAP accreditation on October 12, 1999 for plutonium-239 in fecal, uranium isotopes, americium- 241, and tritium in urine. Accreditation for plutonium-238, 239 and 240 in urine was obtained in November 2000. The LANL Bioassay Program has undergone significant change in the past few years, and currently only Pu by alpha spectrometry and TIMS is performed by the C Division laboratories, all other analytes are contracted out by ESH. Every three years an on-site assessment and performance evaluation testing will be conducted to maintain DOELAP accreditation. The next scheduled assessment is for the fall of 2002.

5.2 Price-Anderson Amendments Act

The Price-Anderson Amendments Act (PAAA) directs the DOE to develop, implement and enforce safety requirements to minimize the potential of nuclear incidents and resulting liability claims. Sections 120, Quality Assurance and 835, Radiation Protection for Occupational Workers, have been passed into law.

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5.3 DOE, LANL/C-Division Requirements

This management plan was developed using the guidance contained in the following documents:

- DOE Technical Standard - Laboratory Accreditation Program for Bioassay (DOE-STD-128-98)
- ANSI N13.30, Performance Criteria for Radiobioassay
- 10 CFR 830.120, Quality Assurance
- LANL Radiation Protection Program
- DOE Order 5700.6C (430.1)
- LALP-93-47, LANL Calibration Handbook
- Analytical Chemistry Quality Management Plan

The C-Division Bioassay Project conducts its work using guidance found in the procedures and other documents listed in Appendix 6.

6 Project Control and Baseline Management

6.1 Work Breakdown Structure

The effort necessary to meet the requirements of the ASA is organized by subdividing the total project task into manageable units, according to the Work Breakdown Structure (WBS) and then matching each unit with the appropriate technical entity having the skills and equipment to perform. The WBS is shown in Figure 2.

The WBS outlines program tasks, relating them to program end items; provides framework for correlating schedules, costs and technical interfaces; ensures that derivative plans meet project objectives; identifies organizations responsible for control-level items; prevents misunderstandings or jurisdictional disputes when responsibilities overlap; establishes basis for computerized management of information systems and supplies the framework for summarizing program schedules, costs and technical status.

6.2 Cost Control

Cost control is based upon and is responsive to DOE Orders 2250.1 and 4700.1. It defines work, assigns responsibility, establishes budgets, controls costs, summarizes accomplishments, provides management visibility and supplies analytical tools. Cost/Schedule Status Reports (C/SSR), Cost Performance Reports (CPR) and Earned Value (EV) Reports are generated as part of the Reporting System. Variance analysis is performed and corrective action is taken based upon cost/schedule variance thresholds established by the Project Leader or by contractual requirements.

Cost Information imposes a corresponding discipline on the processes of Work Breakdown Structuring, Accounts Structuring, Coding, Management, Financial and Manpower Planning, Development of Estimate at Completion, and identification and reporting of actual cost. Other Direct Costs (ODC) work packages include travel, G&A, and Vendor Labor.

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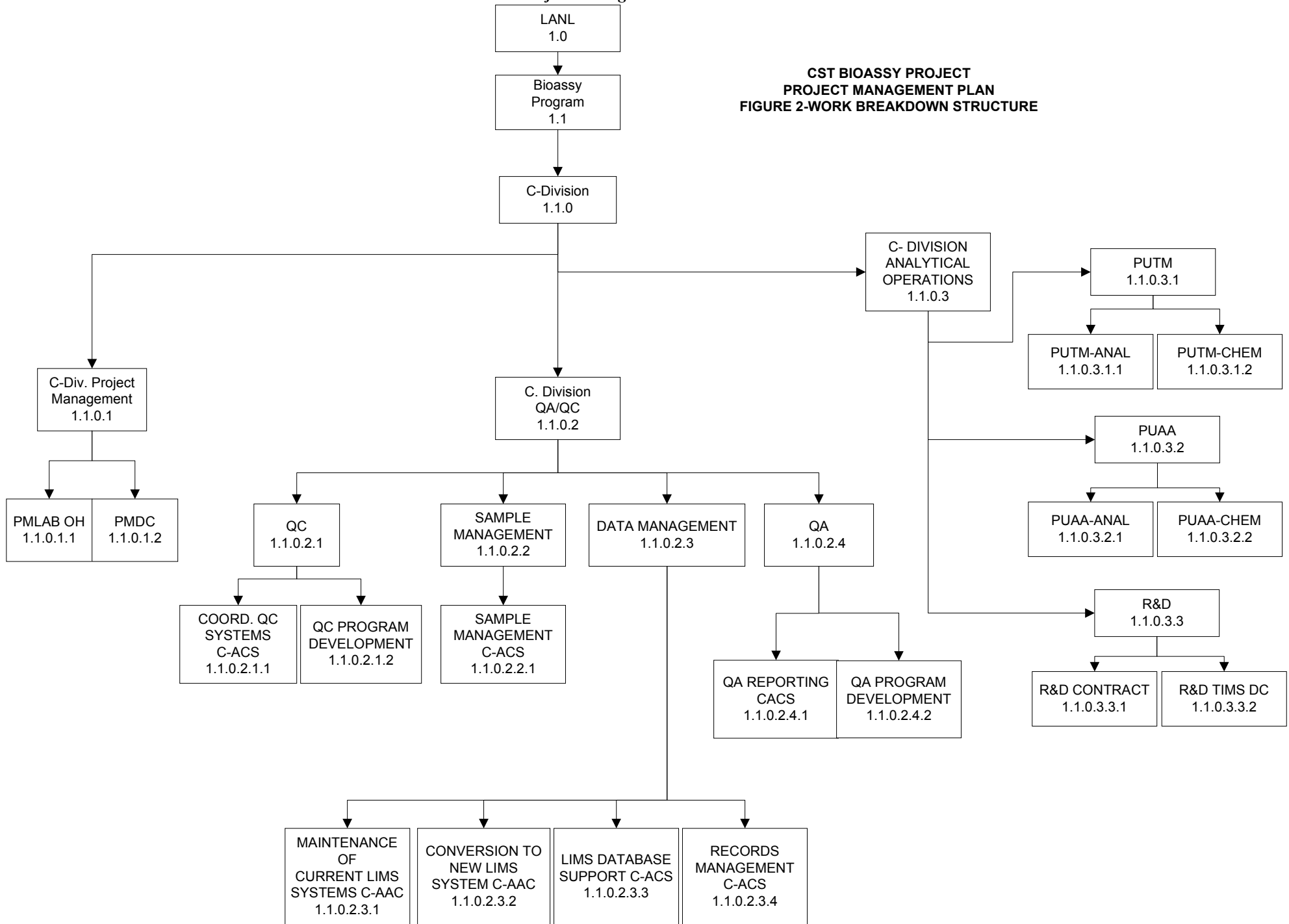
C-Division Bioassay Project costs are tracked and are reported monthly to the ESH-4 Bioassay Project Leader. The monthly reports contain:

- 1) Year to date fiscal year Bioassay Project Cost versus Budget graph containing:
 - i. BCWP: Budgeted Cost of Work Performed.
 - ii. ACWP: Actual Cost of Work Performed.
 - iii. BCWS: Budgeted Cost of Work Scheduled
 - iv. EAC: Estimate at Completion
 - v. Current Variance
 - vi. End of Year Variance
- 2) Turnaround times by analyte
- 3) Running total of completed samples and re-runs sorted by type of operation (Pu Am, RAS, TIMS) and sample priorities.
- 4) Budget breakdown by types and estimated number of analyses.
- 5) Detailed RAS budget breakdown by Pu Alpha Spec, Uranium and Americium.
- 6) Monthly ESH and C-Division costs
- 7) Monthly budgeted number of samples
- 8) Monthly sample BCWP and ACWP for the current FY
- 9) Cost and Schedule Variance
- 10) Critical Items
- 11) Forecast
- 12) Status/progress of ASA milestones

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Figure 2 - Work Breakdown Structure

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CST BIOASSY PROJECT
PROJECT MANAGEMENT PLAN
FIGURE 2-WORK BREAKDOWN STRUCTURE



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The C-Division Bioassay Project Leader reviews the cost data. The C-Division Bioassay Project cost reporting system variances include Cost Variances and Schedule Variances. A variance explanation must identify the nature of the problem, and show the impact on the immediate task as well as the impact on the total program. Cost and Schedule variances will be discussed separately. Emphasis is on specific and quantitative, not general and qualitative. Corrective actions planned/taken will be clearly stated in C-Division the Bioassay Project Monthly Reports. Specific cost, schedule and technical impacts on the project are pointed out. Individuals and organizations responsible for the corrective actions must be clearly identified. The effect of labor rate changes and technical difficulties, if any, must be clearly delineated.

6.3 Planning and Scheduling

The C-Division Bioassay Project Leader will conduct planning and scheduling of the project. The objectives of planning and scheduling are efficient use of personnel and meeting ASA milestone/schedule requirements. Factors influencing planning and scheduling include:

- LANL and C-Division Quality Assurance (QA) requirements,
- ESH-4 established delivery dates and milestones,
- Technical considerations for specific items in the ASA,
- Costs which may vary depending on technical methodologies employed and use of available resources,
- Skill mix and level of effort required,
- Interface requirements with other LANL organizations, and
- Long lead subtasks or deliverables that affect the critical path of the project.

The C-Division Bioassay Project Leader will be proactive in planning and scheduling, reporting activities and events that may effect scheduled performance. An overall schedule and tracking system will be included with monthly C-Division Bioassay Project Progress Reports. The format to be used depends on the level of detail desired and ESH-4 requirements.

6.4 C-Division/ESH-4 Management Review

Periodic reviews and reports provide C-Division and ESH-4 management with visibility on program technical, financial, and schedule status. This approach involves personnel at various levels of management in order to achieve the best possible program performance.

The C-Division Bioassay Project Leader conducts monthly internal program reviews with the C-Division Analytical Chemistry Team leaders. Emphasis is placed on technical accomplishments against the plan. Problems identified are assigned as action items to develop solutions/workarounds. Rigorous attention is given to cost/schedule evaluation. Earned value is closely reviewed and corrective action taken as needed. Meetings focus on providing necessary resources to ensure technical performance within cost and schedule.

Program Status Reviews are provided by the C-Division Bioassay Project Leader to C-Division management periodically to review the status of completed and in-process tasks, problems, planned corrective actions, changes, action items, and cost and schedule.

7 Project Reporting

C-Division Bioassay Project Leader prepares a monthly status report that addresses:

- Period of performance
- Summary of analyses performed during the reporting period
- Reports/correspondence issued during the reporting period

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- Actions planned for next reporting period
- Schedule status
- Additional reporting requirements in accordance with the ASA
- Critical items

The status report is presented to the C-Division Bioassay Team and ESH-4.

8 Change Control

This section addresses administration of change control to all technical, personnel, quality and financial aspects of the Bioassay Program.

All scope changes will be handled in accordance with this change control process. No work that is considered a change in scope will be performed until approval of the C-Division Bioassay Change Request (CBCR) described in the following section has been received.

8.1 ESH-4 Initiated Change

Per the terms of the ASA, ESH-4 may issue technical guidance. All such guidance will be reviewed immediately by the C-Division Bioassay Project Leader to determine if a change in scope to the ASA is involved. If it is believed that the instruction is a change, the C-Division Bioassay Project Leader will initiate a C-Division Bioassay Change Request (CBCR). Both C-Division and ESH-4 must agree upon a request outside the scope of the ASA. A sample CBCR is shown in Appendix 7.

8.2 C-Division Initiated

If at any time, a C-Division Bioassay Team member believes that work being proposed might be outside the ASA scope of work, the C-Division Bioassay Project Leader must be notified immediately. A complete evaluation of the situation will be performed. If a decision is made that the situation justifies it, a CBCR will be initiated.

Performance of work included in a CBCR without prior written approval from ESH-4 will not be authorized. Work will continue on those portions of the task not involved in the change until resolution or guidance is provided.

8.3 Technical Changes

ESH-4 may issue technical guidance. All such guidance will be reviewed immediately by the C-Division Bioassay Project Leader to determine if a change in scope is involved. If it is believed that the instruction is a change, the C-Division Bioassay Project Leader will initiate a CBCR.

8.4 Schedule Changes

Changes to major Project milestones will be agreed to by ESH-4 and C-Division. Anticipated delays in turn around times will be communicated in writing to ESH-4 30 days in advance of the expected delay.

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8.5 *Cost Changes*

There are variables that have a cause/effect relationship with future per-sample charges. If these situations arise, the C-Division Bioassay Project Leader will track and document those costs. The cost documentation will be brought to the attention of ESH-4 Bioassay Project Leader for future cost per-sample-charge changes.

8.6 *Maintaining Change Control*

Minor revisions to either the ASA or the C-Division Bioassay PMP are handled separately from major revisions of a more complex or technical nature. Minor revisions such as correction of clerical errors (typographic, spelling, etc.), updates of references, changes to job titles, will be made on an informal basis. The C-Division Bioassay Project Leader will review audit reports, procedure changes, and equipment changes to ensure that information impacting this plan is identified.

8.7 *C-Division Bioassay Change Request (CBCR)*

When a need to revise either the ASA or the C-Division Bioassay PMP has been identified, it is submitted to the C-Division Bioassay Project Leader on a CBCR. For minor revisions to the PMP, the C-Division Team leader notes the revision is a minor change on the CBCR and has the C-Division Bioassay PMP revised.

For other requests, the C-Division Team leaders/ POCs evaluate the accompanying documentation and indicate one of the following:

- 1) DOES NOT affect the ASA or C-Division Bioassay PMP
- 2) DOES affect ASA or C-Division Bioassay PMP

The C-Division Team leaders/ POCs forward the form to the C-Division Bioassay Project Leader.

The C-Division Bioassay Project Leader reviews and evaluates the CBCR and accompanying documents, and makes one of the following decisions:

- 1) Concurs that the information DOES NOT affect the ASA or C-Division Bioassay PMP; the CBCR and accompanying documents are filed.
- 2) Determines that the information DOES affect the ASA or C-Division Bioassay PMP.

When a CBCR indicates a change in the ASA or the PMP, the issues are negotiated with ESH-4. All ASA or C-Division Bioassay PMP sections related to the proposed revision are reviewed and a proposed change is drafted. The draft change is then reviewed and agreed upon by the C-Division Bioassay Project Leader and the ESH-4 Bioassay Project Leader.

The ASA amendments are kept on file by the C-Division Bioassay Project Leader and the ESH-4 Bioassay Project Leader. For revisions to the C-Division Bioassay PMP, the C-Division Bioassay Project Leader maintains the CBCR in the C-Division Bioassay PMP Revision Log, as shown in Appendix 8.

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8.8 Conflict Resolution

If conflicts on the understanding and/or implementation of the ASA cannot be resolved by the C-Division Bioassay Project Leader and the ESH-4 Bioassay Project Leader, then resolution of the conflict will be referred to C-Division and ESH management, who will facilitate further discussions. The Division Level Management is responsible for final conflict resolution.

9 Quality Assurance

The C-Division Bioassay Project has established a quality assurance program to ensure that analysis of samples meet ESH-12 ASA criteria and other specified project requirements to ensure that analytical operations are conducted safely, reliably, and effectively.

This program is documented in the C-Division Bioassay Quality Assurance Project Plan (QAPjP), which is found in Appendix 2. The QAPjP is based on requirements and guidance found in DOE Order 5700.6C, the LANL Quality Management Plan for 10 CFR 830.120, ANSI N13.30, and the C-Division Analytical Chemistry Quality Management Plan.

10 Personnel Training

C-Division Management is responsible for ensuring that their employees are adequately trained to perform assigned tasks and proficient at operating assigned equipment. C-Division has developed a training mechanism to fulfill the needed training requirements for C-Division owned and operated equipment. Since the C-Division Bioassay Project does not own the equipment, the C-Division Bioassay Project falls under the umbrella of the C-Division Personnel Training and Qualification Program. The quality training for the Bioassay Project is presented in detail in the QAPjP (see Appendix 2). Safety training is conducted to meet the requirements of the appropriate Hazard Control Plans for each activity, which is not a responsibility of the C-Division Bioassay Project.

11 Document Control

The C-Division Bioassay Project retains, in retrievable form, records required by ANSI N13.30 for a minimum of 3 years or for a longer period of time as specified by the federal, state, local, or contractual requirements; at LANL these records are kept for 75 years. These records include:

- Results of all quality control performance checks
- Results of quality assurance audits
- Radiobioassay equipment calibrations
- Procedures by which the measurements were made
- All data used in the determination of the sample results, including measurement spectra
- Training received
- Reported results

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Appendix 1

FY02 Analytical Service Agreement

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Appendix 2

C-Division Bioassay Project QA Plan

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Appendix 3

C-Division Bioassay Project Process Flow

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Appendix 4

List of Critical Equipment

The following is a list of critical equipment used by the C-Division Bioassay Project. It is organized by major activity and includes the name and location of the equipment.

<u>Equipment</u>	<u>Location</u>
<i>1. Detection of Plutonium and Am in Urine by Alpha Spectroscopy</i>	
Primary System:	
Oxford OASIS Alpha Spec System	TA-48 Bldg. 1 Room 206C
Chambers 1 – 8 #915636	
Chambers 9 – 16 #915637	
Chambers 17 – 24 #946588	
Chambers 25 – 32 #958582	
Chambers 33 – 40 #932473	
Chambers 41 – 48 #932472	
Backup System:	
Canberra 7401 Alpha Spec System #820580	TA-48 Bldg. 1 Room 206C
Electrodeposition Unit	TA-48, RC-45 Rm W-104B
<i>2. Detection of Plutonium in Urine by Thermal Ionization Mass Spectrometry (TIMS)</i>	
TIMS Systems 108-1, 108-2	TA-48 Bldg. 45 Room N-108

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Appendix 5

Memorandum of Understanding for LIMS Support

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Appendix 6
List of Guidance Documents

		<i>Approval Date</i>	<i>Next Review Date</i>
<i>Quality Assurance</i>			
BQP-2, R.0	Procedure Content and Format Guide	05/26/02	05/26/04
BQP-3, R.0	Developing Procedures, Plans, and Instructions for Inspection and Acceptance Testing	05/26/02	05/26/04
BQP-5, R.0	Work Suspension and Restart	05/26/02	05/26/04
BQP-6, R.0	Record of Variance	05/26/02	05/26/04
BQP-7, R.0	Inspection and Acceptance Testing of Items and Material	05/26/02	05/26/04
BQP-8, R.0	Nonconformance Reporting	05/26/02	05/26/04
BQP-9, R.0	Maintaining Laboratory Notebooks and Logbooks	05/26/02	05/26/04
BQP-10, R.0	Management of Analytical Chemistry Laboratory Records	05/26/02	05/26/04
BQP-11, R.0	Corrective Action	05/26/02	05/26/04
BQP-12, R.0	Root Cause Analysis	05/26/02	05/26/04
BQP-13, R.0	Training Program for Analytical Chemistry	05/26/02	05/26/04
BQP-15, R.0	Control and Documentation of Analytical Chemical Standards	05/26/02	05/26/04
BQP-18, R.0	Analytical Chemistry Method Validation	05/26/02	05/26/04
BQP-19, R.5	QAP: Chemistry Division Bioassay Project – QAPjP for Chemistry Division Service Laboratory Operations	05/26/02	05/26/04
<i>Quality Control</i>			
BSP-1318, R.0	Monitoring Laboratory Water Quality	05/26/02	05/26/04
BSP-1317, R.0	Cleaning Laboratory Glassware	05/26/02	05/26/04
BSP-1315, R.0	Use and Calibration Check of Automatic Pipets	05/26/02	05/26/04
BSP-1316, R.0	Analytical Balance Calibration Check	05/26/02	05/26/04
<i>Analytical – Radiochemistry</i>			
BSP-356, R.0	Counting and Calculation of Plutonium Bioassay Samples at TA-48	05/26/02	05/26/04
BSP-365, R.0	Sample Prep for Plutonium in Urine by Alpha-spectroscopy	05/26/02	05/26/04
BSP-368, R.4	TA-48 Plutonium in Urine – TIMS	05/26/02	05/26/04
BSP-374, R.0	Sample Preparation for Plutonium in Urine by Thermal Ionization MS	05/26/02	05/26/04
BSP-370, R.0	TA-48 Data Analysis and Submission – TIMS	05/26/02	
<i>Analytical – Sample Management</i>			
BSP-904, R.0	Sample Management	05/26/02	05/26/04
BSP-907, R.0	Request for Analytical Services	05/26/02	05/26/04
BSP-908, R.0	Bioassay Analysis and Reporting	05/26/02	05/26/04
BSP-909, R.0	Chain of Custody	05/26/02	05/26/04
BSP-914, R.0	Packaging and Transportation of Analytical Chemistry Sample	05/26/02	05/26/04
<i>Analytical – QC Preparation</i>			
ORNL			
07-30-11, R.2	Intercomparison Studies Program Procedure: Preparation and Verification of Radioactive Standards and Tracers	4/10/01	N/A
<i>Computing</i>			
COM-3, R.1	CMR Computer Facility -High Temperatures	01/17/01	01/17/04
COM-4, R.0	C-Division-LIMS Code Management	01/17/01	01/17/04
COM-9, R.0	SQL-LIMS Oracle Database Recovery	03/22/01	03/22/04

** procedures currently under review and revision*

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Appendix 7

C-Division Bioassay Change Request (CBCR)

C-Division Bioassay Change Request (CBCR)

Part I - TO BE COMPLETED BY THE REQUESTER

Name _____ Organization _____

Reason for Change:

.. Minor Errors

.. Analytical Method Change

.. Other _____

Description of Recommended Change:

_____ ** Continued on additional pages

Signature _____ **Date** _____

PART II – C-Division EVALUATION

C-Division EVALUATOR

.. Minor Errors

.. Change **DOES NOT** impact ASA or C-Division Bioassay PM Plan.

.. Change **DOES** impact ASA or C-Division Bioassay PM Plan.

C-Division BIOASSAY PROJECT LEADER

.. ASA or C-Division Bioassay PM Plan revision **NOT** required.

.. ASA or C-Division Bioassay PM Plan revision required.

Signature _____ **Date** _____

PART III - APPROVAL

Signature _____ **Date** _____
C-Division Bioassay Project Leader

Signature _____ **Date** _____
ESH-4 Bioassay Project Leader

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Appendix 8

C-Division Bioassay PMP Revision Log

C-Division Bioassay Project Management Plan Revision Log				
Revision	Originator	Revision Approval Date	Revision Disapproval Date	Revision Completion Date
1	Sandra Wagner	09/23/98		09/25/98
2	Sandra Wagner	12/16/98		12/18/98
3	Sandra Wagner	July 1, 1999		July 2, 1999
4	Sandra Wagner	February 8, 2000		February 9, 2000
5	Sandra Wagner	November 30, 2000		December 2, 2000
6	Sandra Wagner	February 19, 2002		