

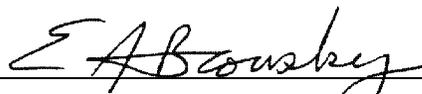


**Statement of Work
For Analytical Measurements**

**GENERAL BIOASSAY
SERVICES**

MODULE BA01-B.5

August 10, 1999

Approved: 
Analytical Services

Reviewed For Classification

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GENERAL BIOASSAY SERVICES MODULE

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GENERAL BIOASSAY SERVICES MODULE

PREFACE

This document provides a detailed summary and description of the types of bioassay samples to be expected for Radiological Health routine and special bioassay programs and the Health Effects Medical Monitoring Program at the Rocky Flats Environmental Technology Site (the Site), and the bioassay services and analytical requirements necessary to process those samples. This document defines bioassay laboratory requirements and general responsibilities of the Laboratory to include quality assurance and reporting.

This document was developed based on information in the Site Internal Dosimetry Technical Basis Manual, Version 2.0; the DOE Implementation Guide G-10CFR 835/C1 - Rev. 1, Internal Dosimetry; and the current ANSI N13.30, Performance Criteria for Radiobioassay.

GENERAL BIOASSAY SERVICES MODULE

INTRODUCTION

This module provides the technical requirements, analytical chemistry services, quality control procedures, and an analysis structure required to provide radiochemical analysis of human urine, fecal, nasal, and tissue samples in support of the Radiological Health and Health Effects Medical Monitoring Programs at the Site. The work will require various phases of radiochemical analysis including sample receipt; logging; tracking; decomposition and analysis; spectroscopy and counting; results calculations; propagation of uncertainties; archiving and reporting of data; and quality assurance.

Procedures specified herein shall be used in the preparation and analysis of urine, nasal/mouth, fecal, and tissue samples for the presence and quantitation of plutonium, americium and uranium by alpha spectrometry, and for tritium and gross alpha by liquid scintillation. In addition, requirements for performing gross alpha/beta screens for samples containing higher levels of activity are also specified. The Laboratory shall employ safe handling procedures, obtain the required licensing for handling such waste, utilize generally accepted good laboratory practices in the performance of contract requirements, and shall follow the quality assurance/quality control (QA/QC) program specified herein and as required by the General Laboratory Requirements Module, GR01.

In general, method requirements for Site General Bioassay Services are consistent with those specified in the ANSI N13.30, Performance Criteria for Radiobioassay, and 10 CFR 835, Occupational Radiation Protection. Updates to these requirements shall be used by the Laboratory following written notification by the Site. The CTR shall provide the Laboratory implementation dates for compliance to these and other applicable requirements as they are developed and promulgated.

The following modules are required for General Bioassay Support Services under this subcontract: The General Laboratory Requirement Module, GR01; the Electronic Data Deliverables Module, GR02, and the Requirements for General Bioassay Services Module, BA01. The specifications in BA01 shall supersede any GR01 specifications in the case of conflicting requirements.

EXHIBIT A

SUMMARY OF REQUIREMENTS

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GENERAL BIOASSAY SERVICES

SUMMARY OF REQUIREMENTS

1. GENERAL REQUIREMENTS AND INFORMATION

This module comprises seven Exhibits to delineate the requirements for General Bioassay Support Services. Exhibit A provides an overview of the general bioassay module and its general requirements. Exhibit B contains all reporting and deliverables requirements. Exhibit C contains Target Analyte lists and their associated Required Detection Limit (RDL). Exhibit D contains the specific analytical procedures required, defines the specific application of these procedures, and contains the method-specific QA/QC requirements. Exhibit E contains general and specific laboratory QA/QC requirements. Exhibit F contains the evidentiary requirements including, chain-of-custody and evidentiary document control requirements that the Laboratory must follow in processing samples under this subcontract, and specifies requirements for written laboratory Standard Operating Procedures (SOPs). To ensure proper understanding of language utilized in this subcontract, Exhibit G contains a glossary of terms which supplement the glossary found in GR01 Exhibit G. When a term is used in the text without definition, the glossary meaning shall be applicable.

- 1.1. **Privacy Act:** The Information submitted to the Laboratory and the data produced by the Laboratory under this SOW are covered under the privacy act of 1974 and shall be protected from unauthorized access in accordance with applicable Federal law, 10 CFR 1008 Privacy Act and (Public Law 93-579)
- 1.2. **Sample Characteristics**
 - 1.2.1. The chemical form of the radionuclide(s) in the samples may be (1) soluble, (2) a metabolized product of normal biological processes, or (3) complexed as a result of combination with a chelating agent. The Laboratory shall use methods of sample preparation that assure solubilization of the entire sample and the radionuclides of interest including the added tracer. In particular, fecal samples will require rigorous methods for sample digestion to ensure the fat is dissolved and remains with the sample.
 - 1.2.2. Samples of urine may include either (1) the total simulated or real amount of urine excreted in 24 hours, or (2) a single or "spot" excretion. The samples are collected in plastic jars with plastic lids. The lids of all jars used should have a custody seal. If a sample jar is missing the custody seal or the custody seal is broken, the Laboratory shall record the deviation and contact the CTR for further instructions
 - 1.2.3. Samples of feces consist of a single excretion. The samples are collected in a plastic container with a plastic lid. The samples will be frozen prior to shipment and should have two (2) custody seals. If the custody seals are missing or broken, the Laboratory shall record the deviation and contact the CTR for further instructions.
 - 1.2.4. Nasal/mouth swab samples consist of mucous from the mouth and nasal passages collected on cotton tipped swabs. The swabs may either be packaged in (1) empty glass liquid scintillation vials as part of the routine program, or (2) sealed in plastic bags as routine or priority sample. The routine nasal swabs shall be analyzed using liquid scintillation techniques. Priority analysis samples shall be analyzed as per the Request for Analysis and Chain of Custody.

- 1.2.5. Tissue samples are collected on a gauze pad and sealed in a plastic bag. The gauze may also contain some blood. The entire sample, including the gauze pad, shall be analyzed.
- 1.2.6. Samples submitted for Priority, Rush, or Rapid Analysis should be assumed to involve quantities of radioactive material that may pose problems for cross-contamination. These samples shall not be processed with routine (no priority) samples. Separate laboratory areas are required.
- 1.2.7. Routine samples will constitute the bulk of the total analyses. Priority, Rush, and Rapid Analysis samples may be submitted periodically and are usually associated with a potential intake or other special purposes.

IT IS ESSENTIAL THAT ALL PRIORITY, RUSH AND RAPID SAMPLES SHALL BE ANALYZED AND REPORTED WITHIN THE SPECIFIED TURNAROUND TIMES. IMMEDIATE NOTIFICATION TO THE CTR IS REQUIRED WHENEVER FAILURE TO MEET TURN AROUND TIMES IS ANTICIPATED.

- 1.2.8. At no time shall the Laboratory process different matrices or different priorities in the same batch.
- 1.2.9. Medical Monitoring samples shall be batched, processed, billed, and reported separately from Radiological Health Samples.
- 1.3. **Report Format:** The Laboratory shall report technical results in a format that is acceptable to Internal Dosimetry or Health Effects, and the Contractor Technical Representative (CTR) as given in GR01 Exhibit B and in BA01 Exhibit B.
- 1.4. **Reanalysis:** All analyte results that meet the conditions for reanalysis as described in BA01 Exhibit E, Section 11 shall not be billed by the Laboratory. In the case where the sample is consumed during the first analysis, the individual will be resampled and the analysis performed at the Laboratory's expense..
- 1.5. **Work Performed Outside Scope of SOW:** Any additional analysis costs not addressed by this SOW shall be agreed upon in writing by the CTR prior to the performance of the analysis or such costs will become the responsibility of the Laboratory.
- 1.6. **Radioactive Materials License:** The Laboratory shall meet the requirements contained in GR01 Section 1 titled, "Nuclear Regulatory Commission (NRC) License".
- 1.7. **Analysis Capabilities:** Sample analysis will vary depending on the sample. In most cases, the Site will require the determination of the quantity of certain specific radionuclides present in the sample (i.e., isotopic analysis). The Laboratory shall maintain capability of performing all analyses to the specified Required Detection Limit (RDL) as listed in the tables contained in BA01 Exhibit C.
- 1.8. **Subdivision of Priority, Rush, and Rapid Analysis Samples:** The Laboratory shall divide priority, rush, and rapid analysis samples upon receipt in order to insure that enough sample remains to provide a second analysis if required.
- 1.9. **Sample Screening:** Screening capability shall be required of the Laboratory. Screening techniques may include counting an aliquot of the sample by liquid scintillation or gamma techniques. In all cases, samples analyzed by screening techniques shall also be analyzed by isotopic methods following the screen.
 - 1.9.1. **Fecal Screening:** In addition to any requested screening for fecal samples, all fecal samples submitted for isotopic analysis shall, after the addition of tracer, undergo total

sample dissolution. Prior to analysis, the sample shall be screened to determine the appropriate aliquot for analysis.

- 1.10. **Off-Normal Business Hours:** The Laboratory shall provide a point of contact available at times outside of normal business hours to implement requests for sample screening.
- 1.11. **Holiday List:** A list of subcontractor's recognized holidays shall be submitted at subcontract award and at any time the holiday listing changes.
- 1.12. **Notification Requirements:** The Laboratory shall meet GR01 Exhibit A notification requirements for sample protection, sample integrity, and late deliverables. In addition, the following notifications shall be made:
 - 1.12.1. *Results $\geq 5 \times$ RDL:* The Laboratory shall provide immediate verbal and FAX notifications to the CTR no later than the close of the next business day for any Radiological Health sample results that exceed 5 times the RDL specified in BA01 Exhibit C. Written confirmation shall be provided to the Site no later than close of the next business day.
 - 1.12.2. *Nasal Smear Results Greater than Decision Level:* The laboratory shall provide immediate verbal and FAX notifications to the CTR no later than the close of the current business day for any nasal smear results which are greater than the decision level calculated for that sample. The CTR will issue a current directive for a call list which will include three contacts and specific directions regarding failed contacts.
 - 1.12.3. *Custody Seals:* The Laboratory shall provide immediate verbal and FAX notification to the CTR no later than close of the next business day following receipt of any samples received without custody seals or if the seals are broken.
 - 1.12.4. *Weekly Status Reports:* The Laboratory shall provide weekly status reports to the CTR with the following information:
 - The number and types of samples received
 - The number and types of samples lost, missing, or destroyed
 - The number and types of analyses in progress
 - The number of recounts in progress
 - The number and types of analyses performed with results
 - Details of delinquent samples which have been in the laboratory for greater than the specified turn around time (TAT) without valid results and the expected delivery date.
 - Sample numbers for all samples on the status report (BA01 A/1)

The weekly status report is due on Tuesday of each week.
 - 1.12.5. *Precision Statistic (S_B) Out-of-Range:* The Laboratory shall provide the CTR written notification when the S_B is out of range. Notification shall include what corrective action is being taken and when the corrective action is to be completed. The Laboratory shall also notify the CTR in writing upon completion of the corrective action prior to processing further Site samples. See BA01 Exhibit E, Section 8 for more information.
 - 1.12.6. *Average Relative Bias (B_r) Exceeding Control Limits:* The Laboratory shall provide the CTR written notification of any corrective actions taken immediately following an investigation to determine the cause for the B_r to go outside of control limits.
 - 1.12.7. *Certification Status:* The Laboratory shall provide written notification to the CTR within 14 days of Laboratory receipt of new, amended, or revoked certifications. See BA01 Exhibit E, Section 17 for certification requirements.

- 1.12.8. *Elevated Batch Matrix and/or Blind Blanks.* When three batch blanks in a calendar quarter have exceeded one-half of the contractual RDL, notification and corrective actions similar to those described in 1.12.5 above must occur. The site reserves the right to evaluate blind blanks shipped with samples when the reported results are greater than the reported decision level and request written notification of the laboratory's investigation of the problem and corrective actions.
- 1.12.9. *Priority, Rush or Rapid Missed Turn a Round Time.* The laboratory shall provide written notification to the CTR immediately when it is anticipated that turn a round times for these samples will not be met.
- 1.13. **Recount Analysis:** The Laboratory shall perform recount analysis upon request by the site. A recount analysis shall require two counts except in the case where the first recount is above the L_c where only one count is necessary. The recount deliverable is a full sample data package as described in BA01 Exhibit B, Section 2. All associated QC samples shall be recounted with the recount analysis request and be included with the sample data package. Submission of recount data packages shall follow the requirements outlined in BA01 Exhibit B, Section 6.

2. FACILITY, INSTRUMENTATION AND KEY POSITION REQUIREMENTS

- 2.1. **Facility:** The Laboratory facility shall meet all requirements of base analytical methods and the Laboratory Health and Safety Program specified in GR01.
- 2.1.1. It is expected that the Laboratory shall maintain certain facilities exclusively for low-level radioactivity analyses. The Laboratory shall ensure that facilities and instruments are constructed, maintained and operated to emphasize radiological control to preclude the possibility of cross-contamination from radiological or environmental sources.
- 2.2. **Instrumentation:** The Laboratory shall have sufficient analytical equipment and capability to meet all terms and conditions of this module and GR01, including all equipment requirements specified in base methods used to perform the analyses.
- 2.2.1. At a minimum, the Laboratory shall have the following operational instrumentation at the time of the on-site evaluation. This instrumentation shall be committed for the full duration of the contract and capable of producing data as described here in.
- Alpha Spectrometer
 - Liquid Scintillation Counter
- 2.3. **Materials:** Materials shall be of the quality and capability necessary to meet the requirements of this Statement of Work.
- 2.4. **Key Position Requirements:** The Laboratory shall assign individuals the responsibilities for the technical key positions listed below and in GR01 to perform the minimum functional requirements necessary to meet the terms and conditions of this subcontract. Minimum academic training and experience qualifications for positions specific to BA01 are identified below. All positions listed in GR01 Exhibit A, Section 1, the Sample Custodian and Document Control Officer (DCO) specified in GR01 Exhibit F, Section 4, and all of the positions listed below are considered key positions for this subcontract. A qualifying individual may fill more than one of the key positions.

2.4.1. Radiological Counting Room Specialist

Responsibility: Responsible for the proper operation, maintenance, calibration and data processing for alpha spectrometry and liquid scintillation counting.

Academic Training: A minimum of a bachelor's degree in a science discipline.

Experience: A minimum of two years of experience in the operation, maintenance, and data processing for alpha spectrometry and liquid scintillation counting. This will include formal vendor supported or accredited training or like experience in alpha spectrometry and liquid scintillation counting.

2.4.2. Technical Lead/Supervisor

Responsibility: Responsible for radiochemistry methodology as related to the scope of work outlined in this SOW. Responsibilities also include technical review for acceptability of all data produced for this SOW.

Academic Training: A bachelor's degree in chemistry with emphasis in analytical chemistry.

Experience: A minimum of five years of work experience in analytical radiochemistry to include radiochemical separation methodology, techniques, and technical supervisory responsibility. The responsible supervisor must also have a working knowledge of alpha spectrometry, liquid scintillation counting, the data produced, and all pertinent radiochemical calculations.

EXHIBIT B

REPORTING AND DELIVERABLES REQUIREMENTS

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REPORTING AND DELIVERABLES REQUIREMENTS

1. INTRODUCTION

BA01 Exhibit B contains reporting and deliverables requirements applicable to all General Bioassay Support Services line item codes defined in BA01 Exhibit C. This exhibit supplements and augments the fundamental deliverable requirements specified in GR01 Exhibit B. Requirements for Sample Data Packages, Supporting Documentation Packages (Support Package), and other deliverables specific to bioassay are detailed. The four tables in BA01 further define some of the deliverables specified in GR01 Exhibit B:

Table B1. Schedule For Sample Data Package Deliverables

Table B2. Sample Data Package Deliverable Content

Table B3. Other Deliverables

Table B4. Supporting Documentation Package Deliverables

Tables B2, B3, and B4 define major deliverable components as *Deliverable Sections* which are each assigned titles. Text accompanying the tables provides structural and content requirements. Tables and text also provide a reference lists for bioassay deliverable requirements found in this module and other modules of this SOW.

BA01 Exhibit B also contains requirements for Data Review Checklists for bioassay sample data packages and for the alpha spectrometry instrument calibration package.

Deliverable requirements and schedules specified in the General Laboratory Requirements Module, GR01, and in any of the tables of this module shall be met. However, where requirements and schedules contained in BA01 are in conflict with Module GR01, requirements in BA01 shall take precedence. All days are given in calendar days unless otherwise noted.

2. SAMPLE DATA PACKAGE REQUIREMENTS

- 2.1. **Sample Data Package Deliverable Requirements:** The sample data package deliverable requirements for General Bioassay Support Services differ from those specified in GR01. The schedule for general bioassay sample data package delivery is provided in Table B1.
 - 2.1.1. All deliverables contained in Table B1 shall be transmitted to the CTR.
 - 2.1.2. The final report shall be completed and in the Site's possession by the requested turn around time unless otherwise agreed upon in writing by the CTR.
 - 2.1.3. Facsimile transmission of the final report is acceptable for Priority, Rush, and Rapid Analysis samples provided the original hard copy is transmitted no later than 3 calendar days following submittal of facsimile.
 - 2.1.4. **Processing Designators:** Processing designators for Routine , Priority, and Rush processing are identified in GR01 Exhibit B, Section 2. Designators for rapid analysis and sample screens are "D" and "S" respectively.

TABLE B1 SCHEDULE FOR SAMPLE DATA PACKAGE DELIVERABLES

Processing	Item	Copies	Schedule	Reference
ROUTINE LINE ITEM CODES (All)	Sample data package	1	30 days after VTSR	BA01, Exhibit B/Section 2
	EDD	1	30 days after VTSR	GR02
EXCEPTION Line Item Code for Routine Nasal by Liquid Scintillation	Sample data package	1	5 days after VTSR	BA01, Exhibit B/Section 3
	EDD	1	5 days after VTSR	GR02
PRIORITY LINE ITEM CODES (All)	Sample data package	1	21 days after VTSR	BA01, Exhibit B/Section 2
	EDD	1	21 days after VTSR	GR02
EXCEPTION Line Item Code for Priority Nasal by Liquid Scintillation	Quick-turn packet	1	3 days after VTSR	BA01, Exhibit B/Section 4
	Sample data package	1	14 days after VTSR	BA01, Exhibit B/Section 3
	EDD	1	3 days after VTSR	GR02
EXCEPTION Line Item Code for Priority Nasal by Alpha Spectroscopy	Sample data package	1	14 days after VTSR	BA01, Exhibit B/Section 3
	EDD	1	14 days after VTSR	GR02
RUSH LINE ITEM CODES (All)	Sample data package	1	14 days after VTSR	BA01, Exhibit B/Section 2
	EDD	1	14 days after VTSR	GR02
EXCEPTION Line Item Code for Rush Nasal by Liquid Scintillation	Quick Turn Packet	1	1 days after VTSR	BA01, Exhibit B/Section 4
	Sample data package	1	14 days after VTSR	BA01, Exhibit B/Section 3
	EDD	1	1 day after VTSR	GR02
RAPID ANALYSIS LINE ITEM CODES	Sample data package	1	7 days after VTSR	BA01, Exhibit B/Section 2
	EDD	1	7 days after VTSR	GR02
SAMPLE SCREEN LINE ITEM CODES	Quick-turn packet	1	Relayed by fax 2 days after VTSR	BA01, Exhibit A/Section 1 BA01, Exhibit B/Section 4
	Sample data package	1	14 days after VTSR	BA01, Exhibit B/Section 2
	EDD	1	14 days after VTSR	GR02
RECOUNT LINE ITEM CODES	Sample data package	1	7 days from request	BA01, Exhibit A/Section 1 BA01, Exhibit B/Section 7
	EDD	1	7 days from request	GR02

2.2. **Sample Data Package Components:** Table B2 lists the required deliverable sections for a Sample Data Package for Bioassay Services. Each deliverable section is numbered and assigned a title. These *Deliverable Section Numbers* and *Titles* are referenced in the remainder of the accompanying text in BA01 Section 2. The *Reference* column in Table B2 contains designators which refer to modules, exhibits, and sections where more details may be found. This reference column is intended as an aid in locating requirements, but is not expected to be all-inclusive.

TABLE B2 SAMPLE DATA PACKAGE DELIVERABLE CONTENT

Deliverable Section Number	Deliverable Section Title	Reference (Module, Exhibit/Section Number)
1	Sample Data Package Cover Page	GR01, Exhibit B/Section 4
2	Table of Contents (not required for nasal smear results)	GR01, Exhibit B/Section 4
3	Sample Data Package Data Review Checklist	GR01, Exhibit B/Section 4 BA01, Appendices A
4	COC(s)	GR01, Exhibit B/Section 4
5	Narrative	GR01, Exhibit B/Section 4
6	Individual Data Reports (not required for nasal smear results)	BA01, Exhibit B/Section 2
7	Sample and QC Results Summary	GR01, Exhibit B/Section 4 BA01, Exhibit B/Section 2
8	Preparation Summary	GR01, Exhibit B/Section 4 GR01, Exhibit E/Section 5 GR01, Exhibit F/Section 4 BA01, Exhibit B/Section 2
9	Standards Summary	GR01, Exhibit B/Section 4 GR01, Exhibit E/Section 5 GR01, Exhibit E/Section 6 BA01, Exhibit B/Section 2
10	Instrument Calibration Summary	GR01, Exhibit B/Section 4 GR01, Exhibit F/Section 4 BA01, Exhibit B/Section 2
11	Counting Raw Data Summary	GR01, Exhibit B/Section 4 GR01, Exhibit F/Section 4 BA01, Exhibit B/Section 2
12	Electronic Data Deliverable (EDD) - Hard Copy	GR01, Exhibit B/Section 4 GR02

2.3. Sample Data Package General Requirements

- 2.3.1. All Sample Deliverable Sections shall meet the general and specific requirements listed in GR01 Exhibit B Section 4 as referenced in BA01 Table B2.
- 2.3.2. All Sample Deliverable Sections shall appear in the Sample Data Package in numerical order by *Deliverable Section Number*.
- 2.3.3. Deliverable Section Numbers 6 through 11 shall each be preceded by a Cover Sheet only when locations or identifiers must be mapped as described below. When a Cover Sheet is necessary it shall be titled exactly as given under the *Deliverable Section Title* column of Table B2. These Cover Sheets shall be paginated along with the rest of the Sample Data Package. Each of these Deliverable Section Cover Sheets shall comply with the following structural requirements:
 - 2.3.3.1. The Deliverable Section Title shall appear at the top
 - 2.3.3.2. If the locations of required items differ from the specified location, then these discrepancies shall be mapped in table form on the Cover Sheet of the deliverable section for the specified location. This table shall include mapping

information in columns labeled "Required Item," "Specified Location," and "Actual Location."

2.3.3.3. If identifiers for required items differ from specified identifiers, then these discrepancies shall also be mapped in table form on the Cover Sheet of the affected deliverable section. This table shall include mapping information in columns labeled "Specified Identifier" and "Identifier Used."

2.3.4. Any undocumented misplaced items shall be considered incomplete.

2.3.5. All raw data from failed analytical batches or from failed individual analyses shall be clearly labeled as "Data Not Used" and shall be included in the appropriate Deliverable Section.

2.3.6. Only required information shall be submitted. Extraneous information not required by this SOW but which may or may not be a normal output of the processing of samples will not be accepted in a sample data package without previous written approval from the CTR.

2.4. **Sample Data Package Cover Page Requirements**

(Requirements for Sample Data Package Deliverable Content Section Number 1)

Sample Data Package Cover Pages shall be included as specified in GR01.

2.5. **Table of Contents**

(Requirements for Sample Data Package Deliverable Content Section Number 2)

A Table of Contents for the Sample Data Package shall be included as specified in GR01.

2.6. **Data Review Checklist Requirements**

(Requirements for Sample Data Package Deliverable Content Section Numbers 3)

Data Review Checklists document the completeness and the quality control status of the Sample Data Package. BA01 Appendix A contains the form that must be used to complete this check for isotopic (alpha Spec) and tritium (liquid scintillation) analyses. A completed Data Review Checklist form shall be submitted with each Sample Data Package and shall be in strict conformance with the formatting and content of the form contained in BA01 appendix A. Refer to General Laboratory Requirements Module GR01 Exhibit B Section 4 for more details.

2.7. **Chain of Custody (COC)**

(Requirements for Sample Data Package Deliverable Content Section Number 4)

COC documentation shall be included in the Sample Data Package as specified in GR01.

2.8. **Sample Data Package Narrative**

(Requirements for Sample Data Package Deliverable Content Section Number 5)

Sample Data Package Narratives shall be included in the Sample Data Package as specified in GR01.

2.9. Individual Data Reports

(Requirements for Sample Data Package Deliverable Content Section Number 6)

DOE Order 1324 requires that records of bioassay data be placed in the person's Radiation Exposure Records. All bioassay data shall be reported on separate report forms for each individual. The Laboratory shall report all analytical results, including negative values and values less than the L_c , and failed results. If dissolved sample aliquots are used for analysis, the analyte results and the associated uncertainties shall be extrapolated to the total sample and reported in dpm/sample. Tritium results shall be reported in pCi/L. **An Individual Data Report is required for each analysis of a sample, including failed analyses. If a sample was analyzed three times and the first two analyses failed and the third one passed, three Individual Data Reports must be submitted with the first two clearly labeled "Invalid".**

The data on bioassay results from each form shall have the following information:

- LAST NAME, FIRST NAME, AND MIDDLE INITIAL of person providing the sample (as provided by the Site).
Note: Provide a blank field for this information if a name is not provided by the Site.
- EMPLOYEE NUMBER or SOCIAL SECURITY NUMBER of person providing the sample (as provided by the Site)
- REPORT NUMBER assigned by the Site
- SAMPLE NUMBER assigned by the Site
- LABORATORY SAMPLE NUMBER (assigned by laboratory)
- DATE OF SAMPLE RECEIPT
- SAMPLE DATE as provided by the Site
- SAMPLE TIME as provided by the Site
- BIOASSAY TYPE (Urine, feces, nasal, tissue)
- BIOASSAY RADIONUCLIDE requested
- DATE OF SAMPLE RESULTS
- MEASURED VALUE in disintegrations per minute (dpm)/sample for each analyte requested (tritium - pCi/L)
- MEASUREMENT UNCERTAINTY (1 sigma) in dpm for each analyte requested (pCi/L for tritium)
- PERCENT SAMPLE RECOVERY FOR THE ADDED TRACER
- SUBMITTED SAMPLE SIZE in volume (ml) for urine or mass (g) for fecal
- ALIQUOT SIZE ANALYZED if total sample not analyzed
- MINIMUM DETECTABLE AMOUNT (MDA)
- DECISION LEVEL (L_c) based on the blank population in dpm (pCi/L for Tritium)
- NOTATION of the sample validation by the laboratory ("V" for valid or "I" for invalid followed by date and validator's signature)
- COMMENTS regarding sample processing, sample condition, or information provided by the Site that is relevant to the bioassay result. The Sample Data Package Narrative may reference this comment.

2.10. **Sample and QC Results Summary**

(Requirements for Sample Data Package Deliverable Content Section Number 7)

In addition to the individual data sheets, the Laboratory shall supply a summary sheet for each batch including data for all QC samples.

2.10.1. *Sample and QC Sample Summary:* The sample summary shall contain the following information in a tabulated format:

- REPORT IDENTIFICATION NUMBER (RIN)
- LAST NAME, FIRST NAME, AND MIDDLE INITIAL of person providing the sample (as provided by the Site)
- EMPLOYEE NUMBER or SOCIAL SECURITY NUMBER of person providing the sample (as provided by the Site)
- LABORATORY ID
- ANALYSIS/ANALYTE (e.g. Urine/Pu239/240)
- RESULT AND ERROR AT ONE STANDARD DEVIATION
- UNITS (Isotopics - dpm/sample, Bioassay Smears - cpm/sample, Tritium in Urine - pCi/l)
- YIELD
- MDA
- DECISION LEVEL (L_c)

2.10.2. *QC Summary:* The QC summary shall contain the following information in a tabulated format:

- LCS SAMPLE NUMBER
- DATE OF ANALYSIS
- KNOWN VALUE OF LABORATORY CONTROL SAMPLE (LCS)
- OBSERVED LCS VALUE
- RELATIVE BIAS
- AVERAGE RELATIVE BIAS - List all LCS values (identified by sample number, date of analysis, and associated relative bias), used to calculate this statistic. The average relative bias shall be calculated per ANSI N13.30.
- PRECISION - Calculated from the same set of LCS values used to calculate the Average Relative Bias. The precision shall be calculated per ANSI N13.30.

2.10.3. *Blank Population Summary (If applicable):* The blank population summary shall include the following for each blank used in the blank population:

- BLANK SAMPLE NUMBER
- DATE OF ANALYSIS
- dpm of TRACER USED IN THE BLANK
- BLANK RESULT (in dpm/sample)
- TRACER RECOVERY
- DETECTOR EFFICIENCY
- STANDARD DEVIATION OF BLANK POPULATION (in dpm)
- STANDARD DEVIATION OF BLANK POPULATION (in cpm)
- MEAN BLANK VALUE OF THE BLANK POPULATION (in dpm)

2.11. Preparation Summary

(Requirements for Sample Data Package Deliverable Content Section Number 8)

- 2.11.1. Sample preparation raw data shall be documented in the form of preparation bench sheets and/or preparation logs. These documents shall follow the requirements defined the General Laboratory Requirements Module GR01 Exhibit F, Document Control Requirements.
- 2.11.2. All raw data and equations used in the determination of bioassay analysis results shall be transmitted to the Site. The raw data and equations will be used to verify randomly chosen analytical results by hand calculations.
- 2.11.3. Raw data shall include, but not be limited to the following:
 - Batch QC data
 - Preparation Logs
- 2.11.4. Preparation logs shall include the following:
 - Analytical Batch identifier (see the definition of Analytical Batch in GR01 Exhibit G)
 - Date of preparation
 - Identifier for the laboratory SOP for the preparation performed
 - Identifiers for all sample and QC solutions prepared
 - Balance identifiers with dates of use so that all measurements can be traced to the documented balance verifications performed according to GR01 Exhibit E Section 5.
 - Initial and final weights and volumes for all samples and QC samples including gross weights and tare weights where applicable
 - [Aliquot Weight](#)
 - Pipette identifiers and dates of use (if applicable)
 - Comments describing any significant sample changes or reactions which occur during preparation
 - Signatures and dates of all analysts and reviewers
- 2.11.5. A copy of the electroplating or microprecipitation preparation log for each sample and QC sample shall be included in this Deliverable Section and shall include the following information:
 - date of preparation
 - sample/QC sample ID
 - planchet or filter paper ID (if different from sample ID)
 - electroplating cell ID (if applicable)
 - analyst and reviewer's signature and date

2.12. **Standards Summary**

(Requirements for Sample Data Package Deliverable Section Number 9)

This section shall contain information for all standards used for data reported in the RIN. This shall include at least the tracer, analyte(s) in the LCS, and the Instrument Calibration Standards used for efficiency.

- Standard I. D. traced back to the primary standard I. D. (All identifiers must be traceable to standard reference material certificates received by the CTR as specified in GR01, Exhibit B, Table B2.) [Submit only the first page of the NIST certificate to establish primary standard I. D. and/or traceability.](#)
- Standard isotope, concentration, and error
- Expiration Date
- Use for this standard(tracer, LCS, efficiency, etc.)
- Date of preparation
- Sufficient dilution data to provide for calculation of the activity

2.13. **Instrument Calibration Summary (Isotopics)**

(Requirements for Sample Data Package Deliverable Section Number 10)

The Instrument Calibration Summary is a summary of the monthly energy calibration, backgrounds, and efficiency determinations for all the alpha spectrometry detectors used to analyze Site samples for the RIN and for the associated Analytical Batch QC samples. The summary shall contain the following information:

2.13.1. The monthly Instrument Calibration Package identification with the syntax of "BA01CAL_Lab ID_Date" shall be reported in the summary (e.g., "BA01CAL_XYZ_01Jan1997").

2.13.2. The following information shall be reported for the energy calibration:

- instrument and detector ID
- date of the energy calibration
- calibration isotopes

2.13.3. The following information shall be reported for the detector backgrounds:

- instrument and detector ID
- date of the background analysis
- analyte and tracer isotopes
- respective "Start" and "End" "ROI" (region of interest) in channels
- respective ROI "Background Counts" or "Background" counts/unit time
(The backgrounds for each tracer and analyte isotope used for analysis of samples in the data package shall be reported.)

2.13.4. The following information shall be reported for the detector efficiency determinations:

- instrument and detector ID
- date of the efficiency analysis, or date of original efficiency determination and the date of the monthly check source count

- "Efficiency" (If a check source is used, supply both the efficiency and the value of the efficiency determined by the check source count with its limits of acceptability.)

2.13.5. The alpha spectrometry instrument and analysis SOP(s) shall be listed.

2.14. Instrument Calibration Summary (Tritium in Urine)

(Requirements for Sample Data Package Deliverable Section Number 10)

2.14.1. Instrument Performance Assessment data for Liquid Scintillation Counters will consist of instrument background data and check source data used to document instrument stability. It is generated with unquenched, manufacturer supplied sealed standards and background vials. For tritium samples efficiency calibration (quench curves/external standardization) is required.

2.14.2. The following information will be reported for the counter background.

- instrument ID
- date of background count
- data filename, if applicable
- background count rate in tritium and carbon-14 windows
- evaluation criteria and result of assessment
- analyst and/or reviewers comments regarding resolution of abnormal background counts
- SOP used for instrument performance assessment

2.14.3. The following information shall be reported for the detector check source determinations:

- instrument ID
- date of check source analyses
- data filename, if applicable
- check source IDs
- calculated average efficiency, chi-square, and figure of merit for each check source
- evaluation criteria
- result of check source data assessment
- analyst and/or reviewers comments regarding resolution of "failed" check source data
- SOP used for instrument performance assessment

2.14.4. The following information is required for efficiency calibrations for tritium

- date of calibration
- data filename(s), if applicable
- instrument ID
- Standard ID of quench/efficiency standards
- isotope of standards
- protocol definition of counting parameters
- counting data for each standard
- calculated QIP/efficiency
- plot of quench curve

2.15. **Counting Raw Data Summary (Isotopics)**
(Requirements for Sample Data Package Deliverable Section Number 11)

2.15.1. The Counting Raw Data Summary Section includes all of the instrument raw data for each Site sample in the RIN, and the associated Analytical Batch QC samples analyzed on the Laboratory's alpha spectrometry system as follows:

- Site sample ID or respective laboratory ID
- date and time of analysis
- Data File Name
- File Name of Background(s) used
- Instrument and detector ID
- Instrument Calibration Package ID or the date(s) of analysis for the backgrounds and efficiency determinations
- " Analytical Batch ID"
- sample "Final Aliquot Size" (i.e., final net weight/volume for the analysis aliquot)
- "Count Time"
- analyte isotope
- analyte isotope "Start" and "End" "ROI" (channels or energy)
- analyte isotope ROI "Gross Counts" (or "Gross" counts/unit time)
- analyte isotope ROI "Net Counts" (or "Net" counts/unit time)
- tracer isotope
- tracer isotope "Start" and "End" "ROI" (channels or energy)
- tracer isotope ROI "Gross Counts" (or "Gross" counts/unit time)
- tracer isotope ROI "Net Counts" (or "Net" counts/unit time)
- Background Counts used for background subtraction for all relevant ROIs
- "Tracer Chemical Recovery"
- analyst and reviewer's signature and date

2.15.2. The Continuing Calibration Checks for each spectrum shall be included and consist of the following:

- observed tracer peak centroid (energy, or channels with the expected channel position)
- tracer isotope "FWHM"

2.15.3. In addition to the above, a channel by channel spectral printout that includes the ROI and an equivalent number of channels above and below the ROI for each Site sample and QC sample shall be included.

2.15.4. A copy of the instrument run log shall be included in this Deliverable Section. It shall contain the following information, at a minimum:

- date of analysis
- sample/QC sample ID
- instrument and detector ID
- analyst and reviewer's signature and date

2.16. **Counting Raw Data Summary (Tritium in Urine)**

(Requirements for Sample Data Package Deliverable Section Number 11)

2.16.1. The Instrument Raw Data Summary for Bioassay Smears and Tritium in Urine shall contain the following:

- Sample I. D.
- Employee Number
- Date of Analysis
- Data filename, if applicable
- Instrument ID
- Analytical Batch ID
- Count Time
- Counting parameters - complete counting protocol definition
- Gross Counts or Gross Count Rate
- Methodology SOP(s) with revision number or date
- Analyst and reviewer's signature and date

2.16.2. If the raw data is identified only by counting position number a table cross referencing sample ID to counting position shall be included.

2.16.3. The counting region used in calculations shall be cross referenced to Gross Counts or Gross Count Rate if more than one counting region is included on the data sheet.

2.16.4. If the vials were counted more than once, the required information shall be provided for each count. If more than one count was used to calculate the reported results, the worksheet, spreadsheet, etc. used to calculate average activity, MDA, Decision Level, propagated uncertainties, etc. shall also be included. If not all of the counts taken were used, the data which were not used shall be clearly labeled as "Data Not Used".

2.17. **Electronic Data Deliverable (EDD) - Hard Copy**

(Requirements for Sample Data Package Deliverable Section Number 12)

The EDD Hard Copy shall be included as specified in GR01, Exhibit B, Section 4.

3. SAMPLE DATA PACKAGE REQUIREMENTS - NASAL SMEARS

3.1. **Sample Data Package Deliverable Requirements:** The sample data package deliverable requirements for General Bioassay Support Services differ from those specified in GR01. The schedule for general bioassay sample data package delivery is provided in Table B1.

3.1.1. All deliverables contained in Table B1 shall be transmitted to the CTR.

3.1.2. The final report shall be completed and in the Site's possession by the requested turn around time unless otherwise agreed upon in writing by the CTR.

3.1.3. The cover sheets which are required in this module, section 2.3.3 of this Exhibit for other data packages are not required for nasal smear data packages. Deliverable sections for nasal smears shall not be preceded by a cover sheet. All sections of the data package shall be presented in the exact order given here.

3.2. **Cover Page**

Sample Data Package Cover Page shall be included as specified in GR01.

3.3. **Data Review Checklist Requirements**

Appendix D contains the DRC form to be used for Nasal Data Packages

3.4. **Chain of Custody (COC)**

COC documentation shall be included in the Sample Data Package as specified in GR01.

3.5. **Sample Data Package Narrative**

Sample Data Package Narratives shall be included in the Sample Data Package as specified in GR01.

3.6. **Sample and QC Results Summary**

The Sample and QC Results Summary shall follow the specifications in Exhibit B, Section 2.10.

- 3.6.1.1. Bioassay Smears: All bioassay smear results shall be grouped by employee number when more than one sample is taken from an individual employee (right nostril, left nostril, and mouth smears for the same employee number). Although these bioassay smears are submitted for analysis as individual samples, they shall be grouped by employee number when reported.

Samples may also arrive with all three smears from an individual in a single vial as a single sample. Refer to the Chain of Custody and sample container ID for appropriate designations.

3.7. **Preparation Summary**

The Preparation Summary shall follow the specifications in Exhibit B, Section 2.11.

3.8. **Standards Summary**

- For the batch LCS, submit the first page only of SRM certificate showing NIST traceability
- One page containing the following:
 - ✓ Standard I.D. traced back to I.D. of SRM
 - ✓ Standard isotope, concentration, and error
 - ✓ Expiration Date
 - ✓ Date of Preparation
 - ✓ Sufficient dilution data to provide for calculation of the activity

3.9. **Instrument Calibration Summary**

- Liquid Scintillation Counter print-out of data for daily Instrument Performance Assessment(1 page) to include background measurement and check source data with pass/fail designation. Data must include:
 - ✓ Instrument Identification
 - ✓ Date of background/checksource - shall correspond to the date(s) the sample data was collected

- ✓ Data file name, if applicable
- ✓ Background count rate(designate region of spectrum) with pass/fail designation
- ✓ Isotope for check source and measured activity for each check source in same units as the subsequent control chart for check source data with pass/fail designation
- Control Chart (1 page) for instrument background clearly showing acceptability limits and Control Chart for check source data clearly showing acceptability limits. Control charts must be current

3.10. **Counting Raw Data Summary**

- Instrument ID
- Date of Analysis
- Data filename, if applicable
- Complete counting protocol definition
- Sample ID (shall reference counting position to sample ID)
- Gross Count Rate(reference to counting region)
- Spreadsheet, etc. used to calculate the net activity, MDA, Decision Level, and total propagated uncertainty

If the vials were counted more than once, the required information shall be provided for each count. If not all counts taken were used, the data not used shall be clearly labeled as “Data Not Used”.

3.11. **Electronic Data Deliverable (EDD) – Hard Copy**

The EDD Hard Copy shall be included as specified in GR01, Exhibit B, Section 4.

4. **QUICK TURN PACKET REQUIREMENTS**

4.1. **Content Requirements:** Quick-turn Packets designated for Nasal Smears and for Sample Screening in BA01 Exhibit B, Table B1 shall include all items specified in the *COC* and *Narrative* sections of the Sample Data Package and shall include the following information:

- CHAIN OF CUSTODY
- RESULTS SUMMARY INCLUDING THE FOLLOWING INFORMATION
 - ✓ CLIENT ID
 - ✓ LABORATORY ID
 - ✓ ANALYSIS/ANALYTE (e.g. Urine/Pu239/240, Bioassay Nasal Smears/Gross Alpha)
 - ✓ RESULT AND ERROR AT ONE STANDARD DEVIATION
 - ✓ UNITS
 - ✓ MDA
 - ✓ DECISION LEVEL
 - ✓ TOTAL SAMPLE SIZE (in appropriate units)
 - ✓ ALIQUOT SIZE (for this analysis)
- **SPREADSHEET USED TO CALCULATE ACTIVITY, MDA AND Lc**

5. REQUIREMENTS FOR OTHER DELIVERABLES

The following table defines other required deliverables in addition to the Sample Data Package deliverables for General Bioassay Support Services. All days are in calendar days unless otherwise noted. Schedules identified as “immediate notification” imply verbal and FAX notification no later than close of the next business day.

TABLE B3. OTHER DELIVERABLES

Deliverable Title	Schedule	Recipient	Reference (Module, Exhibit/Section)
Instrument Calibration Package <ul style="list-style-type: none"> • Cover Page • Data Review Checklist - Alpha Spectrometry Instrument Calibration Package • Narrative • Instrument Calibration and Raw Data 	Monthly and/or with first use for sample analysis or within 7 days of request by CTR	CTR	GR01, Exhibit B/Section 4, Verification of Instrument Parameters BA01, Exhibit B/Section 5 BA01, Exhibit E/Section 9 BA01 Appendix C
Electronic Data Deliverable (EDD)	With each Sample Data Package	CTR	GR02 BA01, Exhibit B/Section 4
Standards/SRM Certificates	Available during audits or upon request and sent to the CTR upon first use	CTR	GR01, Exhibit E/Section 6
Point of contact for off normal hours	Upon subcontract award and immediately following a new designation	CTR	BA01, Exhibit A/Section 1
Holiday List	Upon subcontract award and immediately following a holiday list change	CTR	BA01, Exhibit A/Section 1
Qualifying test samples	Prior to subcontract award, following a period in excess of 30 consecutive days in which the laboratory is inoperative, or prior to resumption following a subcontract termination	CTR	BA01, Exhibit E/13
Notification of samples exceeding 5X the MDA	Immediate telephone notification, written confirmation and explanation within the next business day	CTR	BA01, Exhibit A/Section 1
Notification of nasal smear results exceeding calculated decision level	Immediate telephone notification.	CTR	BA01, Exhibit A/Section 1 (See directive from CTR for call list)
Notification of samples less than minimum volume/mass or with broken custody seals	Immediate notification	CTR	BA01, Exhibit A/Section 1
Notification when S_B is exceeded and when corrective actions are complete	Immediate notification when S_B is exceed Written notification of completed corrective actions prior to further sample processing	CTR	BA01, Exhibit A/Section 1 BA01, Exhibit E/Section 8

TABLE B3. OTHER DELIVERABLES (continued)

Deliverable Title	Schedule	Recipient	Reference (Module, Exhibit/Section)
Notification of corrective action taken when B_r exceeds control limits	Immediately notification following an investigation to determine the cause for the B_r to go outside of control limits	CTR	BA01, Exhibit A/Section 1 BA01, Exhibit E/Section 15
Notification of new, amended, or revoked certifications	Within 14 days of change to certification status	CTR	BA01, Exhibit A/Section 1 BA01, Exhibit E/Section 16
Notification of High Matrix Blanks	Immediate notification. Written notification of completed corrective actions	CTR	BA01, Exhibit B/Section 1
Notification of Missing Turn a Round Times for Priority, Rush or Rapid Samples	Immediate notification.	CTR	BA01, Exhibit B/Section 1 GR01, Exhibit B/Section 2
Status Report	Weekly and/or same day of request. Weekly report is due on Tuesday.	CTR	BA01, Exhibit A/Section 1
QC Report	21 days prior to subcontract award, thereafter Monthly or within 3 days of request	CTR	BA01, Exhibit E/Section 10
Resubmission Requests (days from request)	Routine: 7 calendar days Priority: 2 business days Rush: 2 business days Rapid Analysis: Same day EDD 7 calendar days	CTR	GR01, Exhibit B/Section 7 BA01 Exhibit B/Section 7
Performance Evaluation Sample Analysis Results	7 days from receipt of results	CTR	GR01, Exhibit B/Section 2 GR01, Exhibit B/Section 9 GR01, Exhibit E/Section 9

5.1. Instrument Calibration Package

- 5.1.1. The Instrument Calibration Package consists of 4 parts in the following order: (1) Cover Page, (2) Data Review Checklist- BA01 Instrument Calibration Package, (3) Narrative, and (4) Instrument Calibration and Raw Data.
- 5.1.2. *Cover Page:* The Cover Page shall be titled with the Laboratory name, Laboratory code, subcontract number and the Instrument Calibration Package identification with the syntax of "BA01CAL_Lab ID_Date" (e.g., "BA01CAL_XYZ_01Jan1997").
- 5.1.3. *Data Review Checklist:* The Data Review Checklist - Alpha Spectrometry Instrument Calibration Package, shall be completed according to instructions given in GR01 Exhibit B, Section 4, and BA01 Appendix C.
- 5.1.4. *Narrative:* A narrative describing all problems or unusual circumstances encountered during the instrument calibration process. If efficiencies are determined initially and monthly check sources are used, the Narrative must also list the Instrument Calibration Package identification in which the data for the initial efficiency determination is given and describe the monthly use of check sources in detail. If neodymium fluoride mounted sources are used, the Narrative must describe in detail the preparation of the sources and the material balance checks done to provide characterization and any statistical processes used to characterize the standards.. If efficiencies are not background subtracted, this must be documented in the *Narrative* along with the justification.

5.1.5. *Instrument Calibration and Raw Data*

- A Cover Sheet titled "Instrument Calibration and Raw Data Section" shall precede this Section.
- It is absolutely imperative that the required items in this Section are legible and clearly identified. All BA01 specified item identifications (denoted in quotation marks) shall appear exactly as given, or the identification shall be cross-referenced on the Cover Sheet (abbreviations of the delimited identifications are acceptable, where applicable).
ANY UNDISCERNIBLE ITEMS SHALL BE CONSIDERED INCOMPLETE.
- If there is an item identification discrepancy, then on the Cover Sheet, the BA01 specified item identification shall be listed under a header titled "Required Item", and the Laboratory's cross-referenced identification shall appear under an adjacent header titled "Cross-Reference"

5.2. **Instrument Calibration and Raw Data Section Content (Alpha Spectrometry):** The following information shall be included in the Instrument Calibration and Raw Data Section:

5.2.1. Energy Calibration

- instrument and detector ID
- date of the energy calibration
- "Energy Calibration Source ID" and "Expiration Date"
- energy calibration isotopes
- energy versus channels "Calibration Curve Equation", including the slope and Y-intercept
- alpha spectrometry detector "Energy Range"
- analyst and reviewer's signature and date

5.2.2. Backgrounds

- instrument and detector ID
- date of the background analysis
- "Count Time"
- respective "Start" and "End" "ROI" (in channels)
- respective ROI "Background Counts" (for each of the isotopes used for the analytical work in the package)
- [Limits of acceptability for backgrounds in each ROI used](#)
- channel-by-channel printout of the background spectrum
- analyst and reviewer's signature and date

5.2.3. Efficiencies (for efficiency determination or for monthly check source count as applicable)

- instrument and detector ID
- date of the efficiency/check source analysis
- "Efficiency Source/ Check Source ID", "Certified Value" with date of decay, and "Expiration Date"
- "Count Time"
- efficiency/check source isotope(s)

- respective "Start" and "End" "ROI" (in channels)
- respective ROI "Net Counts" or "Net" counts/unit time
- "Efficiency", "Efficiency Error" and confidence level, and measured efficiency and limits of acceptability of check source determination if used
- channel-by-channel printout of the efficiency/check source spectrum
- analyst and reviewer's signature and date

5.2.4. The detector resolution shall be reported as part of the instrument calibration based on the $^{239,240}\text{Pu}$ or ^{241}Am peak at ≥ 2000 net counts.

5.3. **Instrument Calibration and Raw Data Section Content (Liquid Scintillation)**

The following information is required for counter background, check source determinations and quench/ efficiency calibrations for tritium

- date of calibration
- data filename(s), if applicable
- instrument ID
- Standard ID of quench/efficiency standards
- isotope of standards
- protocol definition of counting parameters
- counting data for each standard
- calculated QIP/efficiency
- analysts and reviewer's signature and date
- methodology SOP for calibration

5.4. **Electronic Data Deliverable (EDD):** Requirements for the Electronic Data Deliverable (EDD) are specified in Module, GR02. An EDD is required for all analyses performed under this SOW module, unless otherwise directed in writing by the CTR.

6. **SUPPORTING DOCUMENTATION PACKAGE (SUPPORT PACKAGE) REQUIREMENTS**

6.1. **Support Package Schedules and Maintenance:** See GR01 Module B Section 5 for delivery schedules and maintenance requirements for Support Packages

6.2. **Support Package Components:** Table B4 lists required components for a General Bioassay Services support package. Each section is assigned a title. These titles are referenced in the remainder of the accompanying text in BA01 Exhibit B Section 6. The *Reference* column in Table B4 refers to the module, exhibit, and section number where more details may be found. The information in this column is intended as an aid in locating specifics, but may not be all-inclusive. Refer to Exhibits B, E, and F of the General Laboratory Requirements Module GR01 for details about these requirements.

TABLE B4. SUPPORTING DOCUMENTATION PACKAGE

Deliverable Section Title	Reference (Module, Exhibit/Section Number)
Document Inventory	GR01, Exhibit B/Section 5
Sample receipt, storage, tracking and internal COC records	GR01, Exhibit F/Section 2 BA01, Exhibit F/Section 2
Copy of Sample Data Package	GR01, Exhibit B/Sections 4, 5 BA01, Exhibit B/Sections 2, 3, 4
Original SRM and Source Certificates	GR01, Exhibit E/Section 6 BA01, Exhibit B/Section 6
Original logs and/or logbooks	GR01, Exhibit F/Section 4 BA01, Exhibit B/Section 6 BA01, Exhibit F/Section 3
Standard Operating Procedures	GR01, Exhibit F/Section 6 BA01, Exhibit F/Section 4
Quarterly QC Reports	BA01, Exhibit E/Section 10
Software Quality Assurance	GR01, Exhibit F/Section 5
Electronic Data Deliverable (EDD)	GR02 BA01, Exhibit B/Section 6

- 6.3. **Document Inventory Requirements:** See GR01 Module B Section 5 for Document Inventory requirements for Support Packages.
- 6.4. **Sample Receipt, Storage, Tracking and Internal COC Records Requirements:** The Support Package shall include sample receipt, storage, tracking, and internal COC records as required in GR01 Exhibit F Sections 2 and 3.
- 6.5. **Copy of the Sample Data Package:** The Support Package shall include a photocopy of the Sample Data Package.
- 6.6. **Original SRM and Source Certificate Requirements:** The Support Package shall include the originals of all standard certificates required for meeting GR01 Exhibit E Section 6. It is expected these originals will be included by referencing their location on the Support Package Document Inventory.
- 6.7. **Original Logs and/or Logbook Requirements:** Logs and/or logbooks include, but are not limited to, preparation logs, instrument run logs, standard dilution logs, balance calibration logs, pipette calibration logs, instrument maintenance logs, and ASTM II water logs must all be included in the Support Package. (It is expected that many of these items will be included by referencing their location on the Support Package Document Inventory.)
- 6.8. **Standard Operating Procedure Requirements:** The Support Package shall include the SOPs required for meeting BA01 Exhibit F Section 4. (It is expected these procedures will be included by referencing their location on the Support Package Document Inventory.)
- 6.9. **Quarterly QC Reports:** The Support Package shall include a copy of the Quarterly QC Report (See BA01 Exhibit E, Section 10) relevant to the RIN. (It is expected that this report will be included by referencing its location on the Support Package Document Inventory.)

- 6.10. **Software Quality Assurance:** The Support Package shall include Software Quality Assurance Documentation required by GR01, Exhibit F Section 5. (It is expected that this information will be included by referencing its location on the Support Package Document Inventory.)
- 6.11. **Support Package Electronic Data Deliverable Requirements:** The copy of the Sample Data Package contained in the Support Package may include the EDD by reference to the physical location and file identifier for a retained copy of the EDD.

7. DATA ACCEPTANCE AND RESUBMISSIONS

- 7.1. Data Acceptance: Data acceptance criteria for General Bioassay Services are given in GR01 Exhibit B, Section 7.

7.2. Resubmission Requirements

- 7.2.1. *Routine Processing:* The Laboratory shall respond to resubmission requests for samples submitted for routine processing within seven calendar days after the resubmission request is received.
- 7.2.2. *Priority and Rush Processing;* For priority and rush deliverables, the Laboratory shall respond to resubmission requests within two business days of the request.
- 7.2.3. *Rapid Analysis:* For rapid analysis the Laboratory shall respond within the same day of request or within the timeline established by the CTR.
- 7.2.4. *EDD:* For EDD resubmissions, the Laboratory shall respond to resubmission requests within seven calendar days of the request.
- 7.2.5. *Recounts:* For recount submissions, the Laboratory shall respond within seven calendar days of the request.
- 7.2.6. *Labeling and Distribution:* Resubmissions shall be labeled and distributed in the manner described in GR01 Exhibit B, Section 7.

EXHIBIT C

GENERAL BIOASSAY SERVICES TARGET ANALYTE LISTS (TAL)

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GENERAL BIOASSAY SERVICES TARGET ANALYTE LIST

1. GENERAL BIOASSAY SERVICES ANALYTE/REQUIREMENTS LISTS

The tables that follow specify analysis type, analyte, matrix, required detection limit (RDL) , and reporting units.

**TABLE C1
ROUTINE - BIOASSAY ANALYTE LIST**

Line Item Code:		BA01B001	BA01B002	BA01B003	BA01B026	BA01B004	BA01B005
Matrices:		Urine	Urine	Urine	Urine	Urine	Nasal Liquid Scintillation
Reporting Units:		dpm/sample	dpm/sample	dpm/sample	dpm/sample	pCi/l	dpm/sample
Analysis Type	Isotope	RDL	RDL	RDL	RDL	RDL	RDL
Plutonium Isotopic	^{239, 240} Pu	0.020	0.020	N/A	0.020	N/A	N/A
Americium Isotopic	²⁴¹ Am	N/A	N/A	N/A	0.020		
Uranium Isotopic	^{233, 234} U	0.10	N/A	0.10	N/A	N/A	N/A
	²³⁵ U	0.10	N/A	0.10	N/A	N/A	N/A
	²³⁸ U	0.10	N/A	0.10	N/A	N/A	N/A
Tritium	³ H	N/A	N/A	N/A	N/A	600	N/A
Gross Alpha (Liquid Scintillation)	N/A	N/A	N/A	N/A	N/A	N/A	30

**TABLE C2
PRIORITY - BIOASSAY ANALYTE LIST**

Line Item Code:		BA01B006	BA01B007	BA01B008	BA01B033	BA01B009	BA01B010	BA01B011	BA01B012	BA01B013	BA01B035	BA01B027	BA01B037
Matrices:		Urine	Urine	Urine	Urine	Urine	Urine	Urine	Fecal	Fecal	Fecal	Nasal Liquid Scintillation	Nasal Alpha Spectroscopy
Reporting Units:		pCi/L	dpm/sample	dpm/sample									
Analysis Type	Isotope	RDL	RDL	RDL	RDL	RDL	RDL	RDL	RDL	RDL	RDL	RDL	RDL
Plutonium Isotopic	^{239, 240} Pu	N/A	0.060	0.060	N/A	N/A	0.060	0.060	0.20	0.20	N/A	N/A	1
Americium Isotopic	²⁴¹ Am	N/A	0.060	N/A	0.060	N/A	0.060	N/A	0.80	N/A	0.80	N/A	1
Uranium Isotopic	^{233, 234} U	N/A	0.13	N/A	N/A	0.13	N/A	0.13	N/A	N/A	N/A	N/A	1
	²³⁵ U	N/A	0.13	N/A	N/A	0.13	N/A	0.13	N/A	N/A	N/A	N/A	1
	²³⁸ U	N/A	0.13	N/A	N/A	0.13	N/A	0.13	N/A	N/A	N/A	N/A	1
Tritium	³ H	600	N/A	N/A									
Gross Alpha (Liquid Scintillation)	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	30	N/A

Note: Samples analyzed under the Line-Item Codes listed in BA01 Exhibit C, Tables C2, C3, and C4 require one -half of the sample to be held if reanalysis is necessary. See BA01 Exhibit D, Section 4 for more information.

**TABLE C3
RUSH - BIOASSAY ANALYTE LIST**

Line Item Code:		BA01B014	BA01B015	BA01B016	BA01B034	BA01B017	BA01B018	BA01B019	BA01B020	BA01B021	BA01B036	BA01B038
Matrices:		Urine	Urine	Urine	Urine	Urine	Urine	Urine	Fecal	Fecal	Fecal	Nasal Liquid Scintillation
Reporting Units:		pCi/L	dpm/sample									
Analysis Type	Isotope	RDL	RDL	RDL	RDL	RDL	RDL	RDL	RDL	RDL	RDL	RDL
Pu Isotopic	^{239, 240} Pu	N/A	0.13	0.13	N/A	N/A	0.13	0.13	1.30	1.30	N/A	N/A
Am Isotopic	²⁴¹ Am	N/A	0.13	N/A	0.13	N/A	0.13	N/A	5.20	N/A	5.20	N/A
U Isotopic	^{233, 234} U	N/A	0.26	N/A	N/A	0.26	N/A	0.26	N/A	N/A	N/A	N/A
	²³⁵ U	N/A	0.26	N/A	N/A	0.26	N/A	0.26	N/A	N/A	N/A	N/A
	²³⁸ U	N/A	0.26	N/A	N/A	0.26	N/A	0.26	N/A	N/A	N/A	N/A
Tritium	³ H	600	N/A									
Gross Alpha (Liquid Scintillation)	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	30

Note: Samples analyzed under the Line-Item Codes listed in BA01 Exhibit C, Tables C2, C3, and C4 require one -half of the sample to be held if reanalysis is necessary. See BA01 Exhibit D, Section 4 for more information.

**TABLE C4
RAPID ANALYSIS - BIOASSAY ANALYTE LIST**

		Line Item Code:	BA01B022	BA01B023
		Matrices:	Urine	Fecal
		Reporting Units:	dpm/sample	dpm/sample
Analysis Type	Isotope		RDL	RDL
Plutonium Isotopic	^{239, 240} Pu		0.26	2.6
Americium Isotopic	²⁴¹ Am		0.26	10.4

Note: Samples analyzed under the Line-Item Codes listed in BA01 Exhibit C, Tables C2, C3, and C4 require one -half of the sample to be held if reanalysis is necessary. See BA01 Exhibit D, Section 4 for more information.

**TABLE C5
SAMPLE SCREEN - BIOASSAY ANALYTE LIST**

		Line Item Code:	BA01B024	BA01B025
		Matrices:	Urine	Fecal
		Reporting Units:	dpm/sample	dpm/sample
Analysis Type	Isotope		RDL	RDL
Screen	^{239, 240} Pu ²⁴¹ Am		100	100

**TABLE C6
RECOUNTS - BIOASSAY ANALYTE LIST**

Line Item Code:		BA01B028	BA01B029	BA01B030	BA01B031	BA01B032
Analysis Type	Isotope	RDL	RDL	RDL	RDL	RDL
Plutonium Isotopic	^{239, 240} Pu	*	N/A	N/A	N/A	N/A
Americium Isotopic	²⁴¹ Am	N/A	*	N/A	N/A	N/A
Uranium Isotopic	^{233, 234} U	N/A	N/A	*	N/A	N/A
	²³⁵ U	N/A	N/A	*	N/A	N/A
	²³⁸ U	N/A	N/A	*	N/A	N/A
Tritium	³ H	N/A	N/A	N/A	*	N/A
Gross Alpha (Liquid Scintillation)	N/A	N/A	N/A	N/A	N/A	*

* Reporting Units and RDLs shall be consistent with the originally requested analysis.

N/A indicates the analyte is not applicable to this Line Item Code.

EXHIBIT D

ANALYTICAL METHODS

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ANALYTICAL METHODS

1. INTRODUCTION

This Exhibit contains the analytical methods requirements for General Bioassay Services.

2. METHOD SELECTION AND APPLICATION

2.1. **Selection of Method:** Methods used for analysis shall meet all of the following requirements:

2.1.1. Methods shall meet the required measurement capabilities for bioassay samples as given in Tables C1 through C5 in terms of RDL. The RDLs are established based upon the RDL requirements of the ANSI N13.30, Performance Criteria for Radiobioassay, and 10 CFR 835, Occupational Radiation Protection. The Laboratory shall detect each radionuclide at the RDL or lower, with $\alpha = 0.05$ and $\beta = 0.05$ where $k(\alpha)$ represents the value for the upper percentile of the standardized normal variate corresponding to the preselected risk for concluding falsely that activity is present (α), and $k(\beta)$ represents the corresponding value for the predetermined degree of confidence for detecting the presence of activity ($1-\beta$).

2.2. **Isotopic Analysis Method:** The following shall apply to the method(s) selected for isotopic analysis for specific radionuclides:

- 2.2.1. Determinations for specific or sequential radionuclides shall be corrected for chemical recovery by use of an isotopic tracer.
- 2.2.2. Interferences shall be identified in the written procedure for each method. Procedures shall include the steps (precautions) taken to minimize the effect of interferences on performance criteria specified in the Statement of Work.
- 2.2.3. The method shall be capable of specific determinations of the radionuclide(s) of interest.
- 2.2.4. All analytical results shall be blank corrected using the mean blank value of the current blank population as defined in BA01 Exhibit E, Section 5.2. Results for batch blanks shall not be blank subtracted.
- 2.2.5. The gross counts in each target analyte and tracer region of interest (ROI) shall be corrected for the particular detector's background contribution in those same ROIs.
- 2.2.6. See BA01 Exhibit E for additional QC requirements.
- 2.2.7. In general, the following equation is the basis for calculating the target analyte:

$$DPM_A = \frac{DPM_T * CPM_A}{CPM_T}$$

where,

- DPM_A = disintegrations per minute of the target analyte
- DPM_T = disintegrations per minute of the tracer aliquot (known)
- CPM_A = counts per minute of the target analyte corrected for the respective background (measured)
- CPM_T = counts per minute of the tracer corrected for the respective background (measured)

2.3. **Smear Sample Screening:** The common method of reporting data for Bioassay smears is in counts or counts per minute because of the difficulty in preparing an adequate calibration curve from cotton tipped swabs. The following shall apply to the method(s) selected for gross alpha screening by liquid scintillation counting:

2.3.1. *Control Samples:* Smear Control Samples serve as instrument control samples. Two control samples, prepared by spiking cotton tipped swabs with Pu-239, are to be included in each batch to determine precision.

2.3.1.1. **Control Sample Known Value Determination:** The known values (in counts per minute) of controls are determined from the average of approximately 10-20 repetitive measurements. The averages obtained (and characterized by a 2s error) are used as the known values for subsequent measurements.

2.3.1.2. **Control Sample Preparation Documentation:** The procedure for nasal smears shall address how controls will be prepared and at what level they will be spiked, how known counts per minute and associated error will be established for the controls, the expiration date of controls, and the limits of acceptability for subsequent measurement of the controls.

2.3.2. *Blanks (Standard Liquid Scintillation Counter):* For a standard liquid scintillation counter, three blanks, prepared from blank cotton tipped swabs are to be included for each batch of samples. Blanks are prepared at the same time sample batches are prepared. See BA01, Exhibit D, Section 2 for calculations. The procedure for nasal smears shall address blank preparation. Blank populations are not required for nasal smears which are counted on a standard liquid scintillation counter.

2.3.3. *Blanks (Low Background Liquid Scintillation Counter):* The use of a low background liquid scintillation counter will require a blank population as described in Exhibit E, Sections 4 and 5. However the MDA and Lc as calculated from ANSI N 1330 shall be set up such that the acceptable probability of a Type I error is .1 (while for alpha spec analysis we require this probability to be set at .05). The MDA and Lc shall be calculated from the standard deviations of the blank population rather than as described above for the standard liquid scintillation counter.

2.3.4. *Calculations for Bioassay Smears (Standard Liquid Scintillation Counter)*

$$S_B = \frac{\sqrt{N_B * AVEBLK * T_B}}{N_B}$$

$$L_C = \frac{2.58 * \sqrt{(AVEBLK * T_S) + S_B^2}}{T_S}$$

$$L_D = \frac{2.71}{T_S} + 2 * L_C$$

$$Error = \sqrt{\frac{SMP}{T_S} + \frac{AVEBLK}{N_B * T_B}}$$

$ACTIVITY = SMP - AVEBLK$ (Note: Sample results are blank subtracted.
Batch blanks are not blank subtracted.)

Where:

T_S	=	SAMPLE COUNT TIME
T_B	=	BLANK COUNT TIME
N_B	=	TOTAL NUMBER OF BLANKS USED (usually 3 per batch)
AVEBLK	=	AVERAGE OF BLANKS IN CPM
SMP	=	SAMPLE CPM
L_C	=	DECISION LEVEL (cpm)
L_D	=	MDA (cpm)

For definitions of accuracy (relative bias statistic) and precision, see Exhibit E, section 8.

2.3.5. Counting of nasal smears for which three swabs are packaged in a single vial requires the use of a method to decompose the swabs prior to counting.

2.3.6. *Instrument Performance Assessment (IPA)*: IPA for liquid scintillation counters used for nasal smears

- Shall be done daily on days when samples are counted
- Shall include at a minimum a background count and at least one check source count which must be an alpha emitter.
- All daily IPA measurements must be control charted with the daily values falling within 3s of the mean of at least the last 10 measurements.

2.4. Tritium In Urine

2.4.1. *Potential Hazard Advisement*: Preparation of urine samples using conventional distillation techniques may result in violent reactions from heating these samples with permanganate. A suggested alternate method requires the samples to be distilled twice, adding permanganate and hydroxide to the fraction obtained from the first distillation.

2.4.2. *Sample Preparation*: A distillation of urine samples is required for all tritium determinations. Data substantiating equivalency of an alternate preparation method may

be submitted to the CTR for consideration, however, under no circumstances shall alternate methods be used without written authorization from the CTR.

- 2.4.3. *Blanks*: Three blanks, prepared from either synthetic or real urine shall be included for each batch of samples. Blanks are prepared at the same time sample batches are prepared. Blank populations are not required for tritium in urine. Calculations are done as described below using the three batch blanks.
- 2.4.4. *Calculations for tritium in urine*: Tritium results, decision level and MDA are reported in units of pCi/l.

$$S_B = \frac{\sqrt{N_B * AVEBLK * T_B}}{N_B}$$

$$L_C = \frac{1.645 * \sqrt{(AVEBLK * T_S) + S_B^2}}{E_S * T_S * V * 2.22}$$

$$L_D = \frac{2.71}{E_S * T_S * V * 2.22} + 2 * L_C$$

$$Error = \frac{\sqrt{\frac{SMP}{T_S} + \frac{AVEBLK}{N_B * T_B}}}{E_S * V * 2.22}$$

$$ACTIVITY = \frac{SMP - AVEBLK}{E_S * V * 2.22}$$

Where:

T _S	=	SAMPLE COUNT TIME
T _B	=	BLANK COUNT TIME
N _B	=	TOTAL NUMBER OF BLANKS USED (usually 3 per batch)
AVEBLK	=	AVERAGE OF BLANKS IN CPM
SMP	=	SAMPLE CPM
L _C	=	DECISION LEVEL (pCi/l)
L _D	=	MDA (pCi/l)
E _S	=	Sample Efficiency
V	=	Sample Volume in Liters

3. SAMPLE HOLDING TIMES AND PRESERVATION REQUIREMENTS

- 3.1. **Holding Time:** The maximum sample holding time allowable under this SOW is 90 days.
- 3.2. **Sample Preservation:** General Bioassay Samples are not preserved before shipment to the laboratory. Laboratory sample preparation methods shall address any problems which could occur because of lack of preservation.

4. SAMPLE PREPARATION REQUIREMENTS

- 4.1. **Hazardous Additions:** Sample preparation shall not introduce hazardous constituents over and beyond those which may be inherent to the sample, when alternative separation methods are available.
- 4.2. **Water Purity:** Requirements for laboratory water purity are specified in Exhibit E of the General Laboratory Requirements Module, GR01.
- 4.3. **Internal Isotopic Tracers:** The internal isotopic yield tracer shall be added to the sample prior to any treatment and/or analysis.
- 4.4. **Solubilization of Sample:** The entire sample shall be solubilized prior to the removal of an aliquot for analysis.
- 4.5. **Aliquot Size Determination:** Aliquot size will be determined by MDA considerations. To meet required MDAs for routine urine, the entire sample is most likely to be used. However, PRIORITY, RUSH, and RAPID SAMPLE processing requires a back-up fraction to be withheld.
 - 4.5.1. **Priority, Rush, and Rapid Samples:** Samples analyzed under the Line-Item Codes listed in BA01 Exhibit C, Tables C2, C3, and C4 require one-half of the sample to be held if reanalysis is necessary.
 - *Urine Samples:* For priority urine samples, the entire volume shall be measured. One-half of the total volume will be dispensed for the initial analysis and the other half will be retained for reanalysis if necessary.
 - *Fecal Samples:* For priority fecal samples, the entire sample will be, a) solubilized, b) an aliquot removed for screening and, c) an appropriate aliquot (up to one-half of the sample) removed for sample processing. The remaining portion of the solubilized sample will be retained for reanalysis if necessary.
- 4.6. **Variable Levels of Activity:** Special bioassay samples may contain high levels of activity. The precautions outlined below shall be followed to prevent cross contamination to low level urine samples:
 - 4.6.1. Routine urine samples shall be processed in a separate laboratory room used for no other purpose than analysis of actinides in routine urines.
 - 4.6.2. All glassware and equipment used for routine urine samples shall not be used for any other purpose.
 - 4.6.3. Glassware which is used for routine urine samples and which is placed in a muffle furnace shall be used "one time only".
 - 4.6.4. Alpha spectrometry detectors used for routine urine samples should not be used for any other samples. Administration of glassware cleaning, laboratory rooms, routine general

laboratory cleaning, and counting systems for the purpose of contamination control shall be addressed in applicable SOPs.

- 4.6.5. At a minimum, the glassware and applicable equipment shall be fully submersed, soaked and cleaned in a suitable decontaminating/cleaning agent, followed by a thorough acid soaking, and thorough rinsing.
- 4.6.6. Routine urine glassware and applicable equipment shall not be cleaned or soaked in the same receptacle as priority and rush samples.

EXHIBIT E

QUALITY ASSURANCE/QUALITY CONTROL REQUIREMENTS

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QUALITY ASSURANCE/QUALITY CONTROL REQUIREMENTS

1. INTRODUCTION

The purpose of this Exhibit is to describe the minimum QA/QC operations necessary to satisfy the analytical requirements associated with General Bioassay Services. These operations and those in the General Laboratory Requirements Module, GR01, are designed to ensure the generation of comparable data from all laboratories. These requirements do not release the Laboratory from maintaining its own QC checks on method and instrument performance.

2. QUALITY ASSURANCE PLAN

Requirements for the quality assurance plan are specified in GR01 Exhibit E.

3. ANALYTICAL BATCH QUALITY CONTROL REQUIREMENTS

- 3.1. **Sample Control:** All laboratory identifications used for the prepared samples through the entire analysis (identifications of beakers, planchets, filter papers, vials, etc.) shall be documented and traceable to the Site sample identifications and the respective preparation Analytical Batch Identification.
- 3.2. **QC Sample Identification:** All QC samples in the preparation Analytical Batch shall be designated with the QC type and a unique identification that is traceable to the respective preparation Analytical Batch Identification.
- 3.3. **QC Traceability To Primary SRM Certificate:** All tracer and Laboratory Control Samples (LCS) aliquot identifications shall be traceable to the respective primary SRM certificate, the standard log and the respective preparation Analytical Batch Identification.
- 3.4. **Traceability of Measuring and Testing Equipment (M&TE):** All pipet and balance identifications specified on all Analytical Batch preparation benchsheets or logs shall be traceable to the respective calibration log.
- 3.5. **Reanalysis:** All reanalyses shall be traceable to the reanalysis Analytical Batch Identification and to the reanalysis Analytical Batch QC samples.
- 3.6. **QC Sample Preparation:** All samples and QC samples in each Analytical Batch shall be spiked at the same appropriate tracer level, and shall be prepared concurrently and in the same manner.
- 3.7. **QC Sample Counting:** All QC samples shall be counted and analyzed in the same manner as the samples in the Analytical Batch; in the same time frame, for at least the same count duration, and using the same instrument calibration parameters, instrument analysis algorithms, etc. **Any re-counts of either the blank or the LCS require a re-count of the entire batch. Any re-counts of samples necessitate a re-count of the sample placed in a batch with the batch blank and LCS.**
- 3.8. **Required Internal QC:** The laboratory shall prepare and analyze matrix blanks (MB) and spiked (blind) urine and fecal laboratory control samples (LCS) for internal quality control (QC).

Synthetic samples of a matrix with characteristics similar to the actual sample may be substituted for some of the QC samples. [Acceptable synthetic matrices are given in Exhibit H.](#)

- 3.8.1. *Frequency of QC Samples:* QC samples shall be run at a frequency of one set of QC samples (MB & LCS) per 10 bioassay samples or a minimum of one set per analytical batch. Each ten Site samples shall have a matrix blank and LCS uniquely associated with them which shall pass data quality objectives for those ten sample results to be acceptable.
- 3.8.2. *Laboratory Control Sample (LCS):* Control samples shall have a matrix, volume, and other relevant characteristics similar to the actual samples being analyzed. Control sample results shall show no significant bias as determined by a test for accuracy and precision as described later in this exhibit.
- 3.8.3. *Matrix Blank (MB):* Matrix blanks shall have a matrix, volume, and other relevant characteristics similar to the actual samples being analyzed. Synthetic matrix blanks with demonstrated performance characteristics, are acceptable. Population statistics for matrix blanks may be used from a specific matching routine process.
For routine urine samples, matrix blanks shall have a volume of at least 1200 mls.

4. BLANK POPULATIONS

- 4.1. Blank populations shall be defined by laboratory procedure. [Prior to use, the blank population procedure shall be approved by the Site. All changes shall be approved by the Site prior to use.](#) At a minimum the procedure shall address the following:
 - 4.1.1. The actions required to administratively control the assignment of blanks to the population.
 - 4.1.2. The requirements for traceability and identification of blanks.
 - 4.1.3. The actions required to administratively control the removal of a blank from the blank population.
 - 4.1.4. The requirements for establishing a need for a new blank population..
 - 4.1.5. Evidence that blanks in the blank population are not identifiable and traceable may result in a **Subcontract Termination**.
 - 4.1.6. A blank should be removed only if there is a physical explanation for its rejection (e.g. fogging on the vial for Nasal and Mouth Smears). A blank should only be rejected if it can be demonstrated that the same error cannot occur during a sample count. All tests should be symmetrical with equal probabilities of detecting low and high values.
 - 4.1.7. Either a beginning or a new blank population for routine urine samples shall be selected from the best 20 of 24 consecutively analyzed blanks. For categories requiring only 5 blanks, the 5 blanks shall be 5 consecutive blanks. Random selection of blanks for beginning or new blank populations is not acceptable.
 - 4.1.8. The procedure for blank population control shall address how matrix batch blanks will be used when only an aliquot of the blank is used for analysis, i.e. how will the mean blank value for blank subtraction be determined and what will be used in the blank population to determine the standard deviation. If the entire blank is used but only aliquots of samples are used, then the procedure must also adequately address this.

- 4.1.9. The procedure for blank population control shall address blank subtraction when the mean blank value is negative.
- 4.1.10. The laboratory procedure for blank population maintenance shall not introduce any statistical bias.

5. MINIMUM DETECTABLE AMOUNT (MDA)

The laboratory shall report the value of the MDA for each sample result. The MDA shall be calculated according to the provisions of ANSI N13.30 for isotopic analysis. The choice of the method and its technical application shall be reviewed and approved in writing by the CTR prior to use for Site bioassay samples. The standard deviations used in the calculation of the MDA shall be based on the population of matrix blanks (BA01 Exhibit E, Section 4). Calculation of MDA for liquid scintillation analysis is prescribed in Exhibit D, Sections 2.3 and 2.4.

- 5.1. **MDA Limits:** The laboratory shall achieve an MDA for each sample that is equal to or lower than the RDL in BA01 Exhibit C Tables C1 through C5 for that sample category.
 - 5.1.1. The RDL for Sample Screens shall be 100 dpm/sample (see BA01 Exhibit C, Table C5). Screens may be accomplished by counting an aliquot of the sample via liquid scintillation, gamma screening, or other techniques.
- 5.2. **Use of Matrix Blanks:** The MDA shall be based on at least the 20 most recent matrix blanks for analytes listed in BA01 Exhibit C, Table C1, excluding scintillation counting. For isotopic samples listed in Tables C2 through C5, the MDA shall be based on at least the 5 most recent matrix blanks.

6. PROPAGATION OF ERROR

All measurement uncertainties shall be examined, evaluated, and carried through to the final analytical result. Each result submitted to the Site shall include an estimate of the overall error. The formula for calculating the overall error (total propagated uncertainty) of a result shall be documented in an appropriate SOP.

- 6.1. **Systematic Error:** All measurement devices used in the final determination of results shall be calibrated and the errors from such devices propagated into the uncertainty reported with final results.
 - 6.1.1. The uncertainty of known values of tracer solutions shall be propagated into the uncertainty reported with a result.
- 6.2. **Random Error:** The random counting error associated with each sample shall be propagated into the uncertainty reported with a result.

7. DECISION LEVEL (L_c)

- 7.1. The decision level for radionuclide analysis of Site samples shall be evaluated using the matrix blank and standard deviation of the population matrix blank measurement results supplied by the laboratory. The decision level shall be calculated as the *a posteriori* measurement level at which

activity is significantly above background (with 95 percent confidence except for gross alpha in nasal swabs where the confidence level is 99%) using the method defined in ANSI N13.30.

8. ACCURACY AND PRECISION

The accuracy and precision of analysis shall meet the criteria of this section and the laboratory shall document this through the use of internal audits related to a NIST standard. At least one control sample with activity in the range of 0.10 to 10.00 dpm of the analyte to be analyzed (^{239}Pu , ^{241}Am , etc.) shall be processed at the frequency specified in BA01 Exhibit E, Section 3. The laboratory shall report the relative bias and average relative bias statistic for the control sample with the bioassay sample results.

- 8.1. **Relative Bias Statistic (B_{ri}):** The relative bias statistic (B_{ri}) shall be calculated as defined in ANSI N13.30. B_{ri} for each LCS shall be between -0.25 and +0.25.
- 8.2. **Average Relative Bias (B_r):** The laboratory shall also calculate and report the average relative bias (B_r) using ANSI N13.30. See BA01 Exhibit E, Section 16 for more information.
- 8.3. **Precision Statistic (S_B):** The laboratory shall ensure and document that the precision of laboratory control sample results is in the range 0 to .20. The precision statistic shall be calculated from the same set of data as the average relative bias using the methods defined in ANSI N13.30.
 - 8.3.1. When the Relative Precision Statistic (S_B) is outside of the specified range, the laboratory shall ensure that appropriate corrective actions to improve the precision are taken and shall document the improved precision prior to processing further samples. See BA01 Exhibit A, Section 1 for notification requirements.

9. ALPHA SPECTROMETRY INSTRUMENT CALIBRATION

The purpose of the instrument calibration is to ensure that alpha spectrometry detectors used for sample analysis were initially capable of producing quality results according the specifications given in this module, and that the calibration was maintained throughout the time period in which samples were analyzed.

- 9.1. **Frequency:** All alpha spectrometry instruments shall be calibrated for the specific analytes of interest according to the specifications given in this module. Each detector used for analysis of Site samples shall be calibrated on a monthly basis (at a minimum), or more frequently, if required.
- 9.2. **Standards:** Calibrations for efficiency shall be performed with valid (not expired) standards that are traceable to NIST and shall be fully documented. Calibrations for energy and check source counts (when used) shall be performed with standards which, at a minimum, meet the requirements for a “*working reference material*” as defined in STD.ASTM C1128 and shall be fully documented. Calibrations for efficiency when done with sources mounted with neodymium fluoride shall be “*working reference materials*” as defined in STD.ASTM C1128. A material balance check shall be done which clearly demonstrates that greater than 95% of the standards used were carried on the source. The material balance check shall be done on the fraction remaining from the neodymium fluoride precipitation plus all rinses from an adequate cleaning of the microprecipitation funnel, beaker, centrifuge tube, and any other vessel used. The

estimated error in mounting the standard shall be propagated into the error of the efficiency determination.

9.3. **Deliverable Schedule:** The Instrument Calibration Package shall be completed and submitted as specified in Exhibit B of this module.

9.4. **Calibration Order:** The order of performing the Instrument Calibration shall be (1) Energy Calibration, (2) Background determinations and (3) detector Efficiency determinations.

NOTE: Energy calibration must always be done first. If the background counts are less than or equal to 1% of the total counts used for efficiency determination, then the order of background and efficiency may be interchanged.

9.5. **Energy Calibration Requirements**

9.5.1. The energy calibration for each detector shall be performed. A curve shall be fit for Energy (Y-axis) versus Channel (X-axis), and the equation with the slope and Y-intercept for the fit shall be documented.

9.5.2. The slope of the equation shall be ≤ 13 keV/channel.

9.5.3. The energy range of each detector shall include 3 to 6 MeV.

9.5.4. The energy calibration shall be performed using calibration sources which are at a minimum "*working reference materials*" as defined in STD.ASTM C1128 and at least three isotopes within the energy range of 3 to 6 Mev.

9.5.5. The final peak centroid positions of all observed isotopes shall be within ± 40 keV of the expected peak centroid.

9.6. **Background Requirements:**

9.6.1. The Background count time shall be documented and shall be at least as long as the sample count duration.

9.6.2. A control chart for detector background for the Pu-239 Region of Interest is required for all detectors used for analytical work performed for this Statement of Work.

9.6.3. The Background total counts (or counts per unit time) for all other target analyte and tracer isotope ROI shall be analyzed on each detector and documented (control charting is recommended).

9.6.4. The Background error and confidence level shall be documented.

9.7. **Efficiency Determination Requirements:**

9.7.1. The Efficiency determinations shall be performed on each detector using NIST traceable calibration sources once per month. Based on U. S. Nuclear Regulatory Commission REGULATORY GUIDE 4.15, the laboratory may do an efficiency calibration as described above with a NIST traceable source initially and thereafter a monthly calibration check with at a minimum a "*working reference material*" as described in STD.ASTM C1128.

9.7.2. If the efficiency source was plutonium and the certified value of the source was based on the total alpha, the ROI used for the efficiency determination shall cover the range of 3 to 6 MeV to include decay daughters (in-growth of ^{241}Am).

- 9.7.3. If the certified value for the Efficiency calibration source was determined for the specific isotope, the ROI used for the Efficiency determination shall also be specific for that isotope.
- 9.7.4. The Efficiency counts for the ROI shall be background corrected using the same ROI for the background unless the background counts are less than or equal to 1% of the counts used for the efficiency determination or check.
- 9.7.5. Each Efficiency shall be determined on at least 10,000 net counts in the ROI.
- 9.7.6. The Efficiency isotope shall be ≤ 100 keV FWHM.
- 9.7.7. The Efficiency error and confidence level shall be documented for either efficiency determination or check source validation.

10. LIQUID SCINTILLATION COUNTER CALIBRATION

10.1. Instrument Background

- 10.1.1. The instrument background vial shall be prepared with low-tritium or “dead” water.
- 10.1.2. The instrument background shall be determined weekly or with each sample batch.
- 10.1.3. Background count time shall be equal to the sample count time.

10.2. Calibrations

10.2.1 Continuing calibration checks (Instrument Performance Assessment) will be done daily or between sample batches.

10.2.1. Quench curves (efficiencies) shall be generated quarterly with 5 to 10 standards distributed over the expected quench range of prepared samples. Each standard will be counted long enough to accumulate at least 100,000 counts. A plot of the quench curve will be generated.

- Check sources will be counted and evaluated against established criteria which are consistent with the manufacturer's specifications.
- A sealed, unquenched background vial shall be counted for a minimum of 60 minutes.
- Check sources and background vials shall be analyzed daily or between sample sets.

NOTE: This vial is not the same instrument background referred to in section 10.1.

11. ISOTOPIC METHOD SPECIFIC QC REQUIREMENTS

The laboratory must provide data on initial compliance prior to award of contract, and on a continuing basis meet and verify QC factors concerning yields, resolution, contamination control, and quality control spikes.

11.1. Continuing Calibration Checks (Resolution and Energy)

- 11.1.1. The FWHM resolution for each sample and QC sample tracer peak shall be ≤ 100 keV. The same requirement shall be met for analyte peaks when they are present.

11.1.2. The tracer peak centroid shall be ± 40 keV of the expected. The same requirement shall be met for analyte peaks when they are present.

11.2. **Tracer and Tracer Chemical Recovery**

11.2.1. The standard material used to prepare the tracer solutions shall be valid (not expired) and traceable to NIST. The isotopic tracer aliquot shall have dpm values appropriate for the activity of the sample aliquot analyzed.

11.2.2. Tracer solutions shall be prepared so that the overall propagated uncertainty at the 2-sigma confidence level shall not be increased by more than 3% over the uncertainty of the primary SRM.

11.3. **Contamination:** The routine processing of matrix blanks will demonstrate compliance with the RDLs required by the Site. The result of the reagent blank analysis shall be at least low enough to allow meeting the contractual RDLs. The laboratory shall prepare and maintain a blank control chart. This control chart shall contain only blanks run as batch blanks with actual Site samples. The blank control chart shall be updated weekly. Any trend or sudden change towards an increase in blanks or their standard deviations that might cause the contractual RDLs to be exceeded shall be investigated and the cause eliminated. A **Subcontract Termination** may be issued pending identification and elimination of cause.

11.4. **QC Report:** A QC report shall be provided to the Site quarterly or as requested. The following shall be included:

11.4.1. Known spike levels for control samples

11.4.2. LCS results with estimated uncertainties, bias for each LCS, average relative bias for the complete data set, precision for the complete data set.

11.4.3. A complete listing of all blanks analyzed in the given time period for a matrix and analyte. The mean blank value and its standard deviation shall be summarized.

11.4.4. The Laboratory should maintain weekly QC plots of blanks, relative bias, precision and sample tracer recoveries.

11.5. **Conditions Requiring Reanalysis**

When reanalysis is warranted, the Laboratory shall identify and correct the problem which caused the failure. If additional sample remains, the Laboratory shall reanalyze the batch after the problem has been corrected. If no additional sample remains, the Laboratory shall report the invalid results and discuss in the sample data package narrative what failed and the cause for failure. These actions shall be taken when isotopic analysis or scintillation counting meet any of the applicable conditions outlined below.

11.5.1. Any one of the following conditions require either reanalysis for a particular sample and analyte, beginning with the preparation, or a discussion in the Sample Data Package Narrative describing circumstances for failure:

11.5.1.1. If any of the sample target analyte Continuing Calibration Checks are outside the limits specified in BA01 Exhibit E (resolution and energy calibration checks), reanalysis is required, beginning with the preparation and/or the instrument analysis.

11.5.1.2. If the sample aliquot is spilled or measured incorrectly, reanalysis is required.

- 11.5.1.3.If there are any unexplainable sample identification mix-ups (e.g., switched beakers, planchets, etc.), reanalysis is required.
 - 11.5.1.4.If the sample analyte activity is inappropriate for the respective tracer level, reanalysis is required.
 - 11.5.1.5.If the sample analyte spectrum contains interferences with the analyte and/or tracer ROIs, reanalysis is required.
- 11.5.2. Any one of the following conditions requires either reanalysis of the entire Analytical Batch, beginning with the preparation, or a discussion in the Sample Data Package Narrative describing circumstances for failure:
- 11.5.2.1.If the tracer chemical recovery for the Matrix Blank does not meet the required limits specified for samples in BA01 Exhibit E, Section 15, reanalysis is required.
 - 11.5.2.2.If the Relative Bias Statistic (B_{ri}) is outside the limits specified in BA01 Exhibit E, Section 8.
 - 11.5.2.3.If any of Matrix Blank target analyte Continuing Calibration Checks are outside the limits specified in BA01 Exhibit E, Section 11, reanalysis is required, beginning with the preparation and/or the instrument analysis.
 - 11.5.2.4.If there is any evidence of contaminated glassware or reagents (may or may not be demonstrated in the Matrix Blank), reanalysis is required.
 - 11.5.2.5.If any standards or standard sources are expired, reanalysis is required.
 - 11.5.2.6.If there is an unexplainable mix-up between the QC samples, either among themselves or with any samples in the Analytical Batch, reanalysis is required.

12. MEASURING AND TESTING EQUIPMENT REQUIREMENTS

Requirements for measuring and testing equipment requirements are specified in GR01.

13. DATA MANAGEMENT

Requirements for site data management are specified in GR01.

14. LABORATORY EVALUATION SAMPLES

14.1. **Qualifying Test Samples:** Any laboratory under consideration as a subcontractor for in-vitro bioassay analysis shall analyze a minimum of seven (7) test samples as a condition for subcontract award. The samples will be prepared and submitted by the Site. The results of this sample analysis, including an evaluation of matrix blanks run with the test samples, will be evaluated by the Site using laboratory testing and quality control criteria given in this SOW.

14.1.1. In addition to the test sample analysis, the prospective laboratory must provide data, when test samples are returned, demonstrating initial compliance and verification of the quality control factors identified in BA01 Exhibit E, Section 8. This shall include hand calculations of data results for one sample.

14.1.2. Qualifying test sample analysis will also be required for all laboratories, when a new laboratory operation is being set up for the first time and when a change in scope or different laboratory capability is being established. The laboratory will also perform qualifying test samples following a period when the laboratory is inoperable for more than 30 consecutive days or prior to resumption of activities following a **Subcontract Termination**.

14.2. Performance Evaluation Program Participation

14.2.1. **Required Analytes:** The Laboratory shall participate in an interlaboratory comparison study that includes each element and method used to report Site samples. Participation in interlaboratory comparison studies for methods used for sample screening is not required.

14.2.2. **Frequency:** The minimum required frequency of participation in inter-laboratory comparison studies is semi-annually.

14.2.3. **Acceptable PE Programs:** Participation in one or more of the following evaluation programs are acceptable under this statement of work. See GR01 Exhibit E, Section 9 for more requirements.

14.2.3.1. Bioassay Intercomparison Study, Oak Ridge National Laboratory

14.2.3.2. DOELAP Radiobioassay In-Vitro Pilot Study

14.3. **Site Provided PE Samples:** The Site shall have the right to submit spiked and/or blank samples on a regular basis with normal sample deliveries or on an ad hoc basis. See GR01 Exhibit E, Section 9 for more information.

15. ON-SITE LABORATORY EVALUATIONS

Requirements for on-site laboratory evaluations are specified in the General Laboratory Requirements Module, GR01.

16. PERFORMANCE EVALUATION CRITERIA

Additional performance criteria are specified in GR01 Exhibit E, Section 13.

16.1. Average Relative Bias Statistics

16.1.1. The laboratory shall meet the relative bias requirements established in BA01 Exhibit E, Section 8.

16.1.2. Average relative bias results exceeding -0.15 to +0.15 in 5 consecutive batches without evidence of corrective action may result in a **Subcontract Termination**.

16.1.3. The average relative bias for test samples shall be calculated and evaluated by the Site. The number of values used to calculate the average relative bias shall be determined by the number of spiked samples used in the test. The test samples' average relative bias shall be less than +0.15 and greater than -0.15 for activities equal to or greater than .2 dpm and less than +0.25 and greater than -0.25 for activities less than .2 dpm. New samples will not be submitted to the laboratory until the test sample analyses have passed the average relative bias test.

16.1.4. The average relative bias shall be determined initially for at least 5 values of B_{ri} , and updated thereafter using the fifteen (15) most recent values of B_{ri} on a rolling basis. At no time shall control samples be older than thirty (30) days for the samples listed in BA01 Exhibit C, Table C1 (Excluding Nasal). The laboratory shall ensure and document that the average relative bias is greater than -0.15 and less than +0.15 prior to the analysis of a batch of one or more bioassay samples. If the average relative bias is outside the stated control limits, the laboratory shall investigate, determine the cause, and report to the CTR any corrective actions. Following corrective actions, the laboratory shall reinitialize the population of control samples used for the average relative bias calculations. Average relative bias calculations exceeding the control limits in 5 consecutive batches may result in a **Subcontract Termination**.

16.2. MDA

16.2.1. The laboratory shall meet the specified MDA requirements defined in BA01 Exhibit E, Section 5. A 90% compliance level over a moving 30 day period shall be achieved. Failure to maintain this compliance level may result in a **Subcontract Termination**.

16.3. Tracer Chemical Recovery for Isotopic Analysis

16.3.1. All sample tracer recovery yields < 25% will be considered failed samples.

16.3.2. All sample tracer recovery yields > 110% will be considered failed samples.

16.3.3. Average tracer recoveries over any 30 day period must exceed 60%. Tracer recoveries over any 30 day period that average below 60% necessitate an investigation and may lead to a **Subcontract Termination** pending resolution.

16.3.4. For any 30 day period, 95% of the samples analyzed shall have tracer recoveries greater than 40%.

16.3.5. No more than 3% of samples over a calendar quarter shall have failed analysis during processing.

17. CERTIFICATIONS AND APPROVALS

Laboratories are encouraged to provide proof of certifications or approvals for any programs in which the Laboratory is participating. Proof of laboratory certifications (or approvals) delivered to the CTR according to the schedule in GR01 Exhibit B Table B2 may increase the potential sample load for Laboratories providing this proof.

17.1. Laboratories providing analytical services under Module BA01 are required to have the Clinical Laboratory Improvement Amendments (CLIA) Laboratory Certification or equivalent State Certification in conjunction with a CLIA registration number. Proof of certification is required according to the schedule in GR01 Exhibit B Table B2.

EXHIBIT F

EVIDENTIARY REQUIREMENTS

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2. SAMPLE CHAIN-OF-CUSTODY	F-2
3. DOCUMENT CONTROL PROCEDURES	F-2
4. STANDARD OPERATING PROCEDURES.....	F-2

EVIDENTIARY REQUIREMENTS

1. INTRODUCTION

- 1.1. The purpose of this Exhibit is to describe the evidentiary requirements that must be followed for the preparation and analysis of Site samples for General Bioassay Services.

2. SAMPLE CHAIN-OF-CUSTODY

- 2.1. Requirements for the following chain-of-custody procedures are specified in Exhibit F of the General Laboratory Requirements Module, GR01:
 - Sample Identification;
 - Chain-of-custody Procedures;
 - Sample Receiving Procedures; and
 - Sample Tracking Procedures.

3. DOCUMENT CONTROL PROCEDURES

- 3.1. Requirements for the following document control procedures are specified in Exhibit F of the General Laboratory Requirements Module, GR01:
 - Preprinted Laboratory Forms and Logbooks;
 - Consistency of Documentation;
 - Document Numbering and Inventory Procedures;
 - Storage of Site Files; and
 - Shipping Data Packages and SDPs.

4. STANDARD OPERATING PROCEDURES

- 4.1. Requirements for the following SOPs are specified in the General Laboratory Requirements Module, GR01:
 - SOP Specifications and Format;
 - Required Evidentiary SOPs;
 - Required Analytical SOPs;
 - Required Quality Management SOPs;
 - Handling of Confidential Information; and
 - SOP Delivery Requirements.

EXHIBIT G

GLOSSARY OF TERMS AND ACRONYMS

TABLE OF CONTENTS

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GLOSSARY OF TERMS AND ACRONYMS

Refer to General Requirements Module GR01, Exhibit G for all applicable terms and acronyms not described in this section.

1. GLOSSARY OF TERMS

DECISION LEVEL: Decision level (L_c) is the level at which the analyte is considered to be detected with a 5% probability of a type 1 error (erroneously declare the analyte to be present when it is not).

HIGHER LEVELS OF ACTIVITY: Bioassay samples that are anticipated to contain greater than 200 disintegrations per minute (dpm) of activity.

LOW LEVELS OF ACTIVITY: Bioassay samples that are expected to contain less than 0.20 dpm of activity.

MINIMUM DETECTABLE AMOUNT (MDA): The smallest amount of a radionuclide which will be detected with an b probability of non-detection of 0.05 while accepting an a probability of 0.05 for falsely detecting the activity in a matrix sample.

MODERATE LEVELS OF ACTIVITY: Bioassay samples which are anticipated to contain between 0.20 dpm and 200 dpm of activity.

POTENTIAL INTAKE: A potential inhalation, ingestion, injection or absorption of radioactive material into the human body.

RAPID ANALYSIS: A screening method of analyzing samples to determine if gross activity exists.

WORKING REFERENCE MATERIAL: A reference material usually prepared and characterized by a single laboratory for its own use as a calibration standard, as a control standard, or for the qualification of a measurement method. See ASTM C1128 for further requirements for characterizing a working reference material.

2. ACRONYMS

Refer to General Requirements Module GR01, Exhibit G for all applicable acronyms.

EXHIBIT H

REFERENCES

TABLE OF CONTENTS

<u>SECTION</u>	<u>PAGE NO.</u>
1. REFERENCES.....	H-2
2. SYNTHETIC URINE.....	H-3
3. SYNTHETIC FECAL.....	H-4

REFERENCES

1. REFERENCES

- 1.1. Site Internal Dosimetry Basis Manual, Version 2.0
- 1.2. DOE Implementation Guide G-10CFR 835/C1 - Rev. 1, Internal Dosimetry
- 1.3. ANSI N13.30, Performance Criteria for Radiobioassay
- 1.4. Bioassay Intercomparison Study, Oak Ridge National Laboratory, Oak Ridge National Laboratory, P.O. Box 2008, Oak Ridge, TN 37831-6045
- 1.5. DOELAP Radiobioassay In-Vitro Pilot Study, Idaho Field Office, 785 DOE Place, Idaho Falls, ID 803401-1562
- 1.6. 10 CFR 1008 Privacy Act and (Public Law 93-579)
- 1.7. STD.ASTM C1128 Standard Guide for Preparation of Working Reference Materials for Use in the Analysis of Nuclear Fuel Cycle Materials, Feb., 1998
- 1.8. U.S., NUCLEAR REGULATORY COMMISSION REGULATORY GUIDE 4.15 Revision 1, February, 1979.

2. SYNTHETIC URINE

Synthetic Urine Recipe

The following lists the constituents and required quantities for synthetic urine to be used for matrix blanks and matrix LCSs when real urine from unexposed individuals is not used. This formulation is the one from which samples were prepared for the second round robin bioassay intercomparison study in support of draft ANSI Standard N13.30 "Performance Criteria for Radiobioassay". For routine urine bioassay line item codes found in Exhibit C, Table C1, at least 1200 mls of this matrix is required for the batch blank and batch LCS.

<u>COMPONENT</u>	<u>g/Kg.</u>
1. Urea	16.0
2. NaCl	2.32
3. KCl	3.43
4. Creatinine	1.10
5. NaSO4(anhyd.)	4.31
6. Hippuric acid	0.63
7. NH4Cl	1.06
8. Citric acid	0.54
9. MgSO4(anhyd.)	0.46
10. NaH2PO4·H2O	2.73
11. CaCl2·2H2O	0.63
12. Oxalic acid	0.02
13. Lactic acid	0.094
14. Glucose	0.48
15. Na2SiO3·9H2O	0.71
16. Pepsin	0.029
17. Conc. Nitric acid (70%)	50.00

3. SYNTHETIC FECAL

SYNTHETIC FECAL MATRIX

The following lists the constituents and required quantities for synthetic fecal samples to be used for matrix blanks and matrix LCSs. The recipe is, in general, based on the formulation of the Department of Energy, Idaho Field Office Laboratory Quality Branch DOELAP program. In order to be able to homogenize the sample, peanut butter and water were substituted for the peanut oil. At least 65 g. of this matrix is required for each batch blank and batch LCS for line item codes for fecal samples found in Exhibit C, tables C2, C3, C4 and C5.

<u>COMPONENT</u>	<u>g/Sample</u>
1. Calcium hydroxide	0.97
2. Ferric ammonium sulfate	0.04
3. Magnesium carbonate	0.61
4. Potassium carbonate	0.83
5. Ammonium dihydrogen phosphate	2.1
6. Sodium sulfate	0.37
7. Ammonium chloride	0.04
8. Zinc sulfide	0.01
9. Leucine	7.1
10. Lysine	5.1
11. Methionine	0.8
12. Threonine	2.0
13. Palmitic acid	3.0
14. Stearic acid	2.0
15. Oleic acid	1.0
16. Cellulose	4.0
17. Gelatin	5.0
18. Peanut butter	10
19. H2O	20

A P P E N D I X A

Data Review Checklist
SAMPLE DATA PACKAGE

Data Review Checklist Sample Data Package

1. COVER PAGE	<i>Reply</i>	<i>√</i>	<i>C#</i>
a) The laboratory name, code, subcontract number, RIN, Site sample numbers, analyses, and report dates are accurately recorded.			
b) All Laboratory sample identifications associated with this RIN are cross-referenced to the COC sample identifications.			
c) The verbatim compliance and authorization statement is present with the dated signature of the Laboratory Manager or designee.			
d) Any problems with the receipt are explained.			

2. TABLE OF CONTENTS	<i>Reply</i>	<i>√</i>	<i>C#</i>
a) The Table of Contents contains all Full Data Package Deliverable Section Titles and the page numbers.			

3. DATA REVIEW CHECKLIST(DRC) and BA01 Sample Data Package (SDP)-	<i>Reply</i>	<i>√</i>	<i>C#</i>
a) The BA01 DRC is in strict conformance with the formatting and content of the form contained in the current version of the BA01, Appendix A. All discrepancies were identified and documented, accordingly.			
b) All DRC <i>Reply</i> blocks are completed with either a "Y", "N", or "N/A".			
c) All DRC <i>Reply</i> blocks completed with an "N" are explained in the Narrative.			
d) The DRC footer is completed for each page; the laboratory manager or designee signed and dated the DRC.			
e) All SDP deliverable sections appear in the SDP in order by deliverable section number.			
f) Only one SDP is submitted for each BA01 and RIN request.			
g) All components of the SDP deliverables contain original documents where possible.			
h) There is no inclusion of required items in the SDP by reference to another SDP.			
i) Site samples are exclusively used for sample matrix QC.			
j) Site and non Site samples are not reported together in any way.			
k) The complete sample data package is single sided and consecutively paginated.			

4. CHAIN-OF-CUSTODY	<i>Reply</i>	<i>√</i>	<i>C#</i>
a) The continuity of each sample's custody is evidenced by the chain of the date, time and signatures of each transaction from sample receipt to final disposition.			
b) If the continuity was corrupted, there is documentation and evidence of correspondence with the CTR.			
c) All samples are identified on the COC with the corresponding analysis.			
d) Any conflicting, incorrect, or missing information are identified and documented, and there is documentation of the resolution.			

5. NARRATIVE	<i>Reply</i>	<i>√</i>	<i>C#</i>
a) Contains a synopsis of the methodology and analysis, including all standard operating procedures used.			
b) All anomalies, caveats, deficiencies, interferences, reanalyses, and deviations from approved SOPs related to the analysis are explained.			
c) Samples requiring reanalysis are identified with the reason for reanalysis, the original and reanalysis Analytical Batch Identification Numbers, and a synopsis of the reanalysis Analytical Batch QC assessment.			
d) For any deviations that required CTR approval, the correspondence and approval are documented			

RIN: _____ **Lab Name:** _____ **Initials:** _____

Analytical Batch Identification No.(s): _____

Data Review Checklist Sample Data Package

continued	<i>Reply</i>	√	C#
e) Appropriate notification was done for samples exceeding 5X MDA per Exhibit B, Table B3?			
f) The CTR was contacted for all samples requiring reanalysis as described in BA01 Exhibit E, Section 10 .			
6. INDIVIDUAL DATA REPORTS	<i>Reply</i>	√	C#
a) All samples were analyzed and reported with the information described in BA01 Exhibit B, Section 2.			
7. SAMPLE AND QC SAMPLE RESULTS SUMMARY	<i>Reply</i>	√	C#
a) All samples including QC samples meet the tracer chemical recovery yields specified in BA01, Exhibit E, Section 15 for isotopic analysis.			
b) Samples	<i>Reply</i>	√	C#
1. All sample MDA's were equal to or below the required values specified in BA01, Exhibit C.			
c) QC Samples	<i>Reply</i>	√	C#
1) A set of QC samples were run with every Analytical Batch at the frequency specified in BA01, Exhibit E, Section 3			
2. For each QC sample (LCS and Matrix Blank), the QC Samples are clearly identifiable and contain all items specified in the Sample and QC Sample Results Summary, Exhibit B, Section 2			
3. All QC deficiencies are detailed in the Narrative			
d) Laboratory Control Sample	<i>Reply</i>	√	C#
1. The Relative Bias Statistic ;(Bri) is between -.25 and +.50			
2. The Average Relative Bias (Br) is in the range specified in BA01, Exhibit E, Section 15.			
3. The Precision defined in Exhibit E, Section 8.3 is in the range of -.20 to +.20.			
e) Blank Population Summary	<i>Reply</i>	√	C#
1. The Blank Population required data as defined in Exhibit B, Section 2.10.3 is present			
2. The Matrix Blank for this Batch is in the Blank Population and the requirements of Exhibit E, Section 5.2 have been met			
8. PREPARATION SUMMARY	<i>Reply</i>	√	C#
a) The preparation raw data (benschets and/or preparation logs) are included and document the required items as specified in the Preparation Summary Section of BA01, Exhibit B.			
b) All samples and QC samples in each Analytical Batch were prepared concurrently and in the same manner and isotopic samples were all spiked at the same appropriate tracer level.			
c) For routine urine samples, the entire sample was used. For all other samples the appropriate volume as specified in Exhibit D, Section 4.5 was used for analysis.			
9. STANDARDS SUMMARY	<i>Reply</i>	√	C#
a) For primary standards that were diluted and used for the tracers, LCS and any in-house prepared instrument calibration sources, the required items as specified in the Standards Summary Section of BA01, Exhibit B are included.			
b) If the standards used for the tracers and LCSs were NOT diluted, the required items as specified in the Standards Summary Section of BA01, Exhibit B are included.			
c) All applicable standard certificates are being maintained at the Laboratory.			
d) All standard identifications are traceable to the primary certificates, which are traceable to NIST.			
e) All standards and sources traceable to NIST were valid (not expired) at the time of use.			

RIN: _____ Lab Name: _____ Initials: _____

Analytical Batch Identification No.(s): _____

Data Review Checklist Sample Data Package

10. INSTRUMENT CALIBRATION SUMMARY			
	<i>Reply</i>	<i>√</i>	<i>C#</i>
a) Alpha Spectrometers			
1) The required items as specified in the Instrument Calibration Summary Section of BA01 Exhibit B are included for each alpha spectrometry detector and/or liquid scintillation counter used to report results for this RIN.			
2) The energy calibration was done within 30 days prior to sample count dates .			
3) The backgrounds were counted after the energy calibration and within 30 days of the sample count time.			
4) The efficiency determination and/ or check source counts for efficiency were done within 30 days prior to sample count dates.			
b) Liquid Scintillation Counter			
1) For liquid scintillation counting, the instrument background and efficiency determination were completed at the required frequency and assessed and found to be acceptable prior to analyzing samples.			
2) The required items as specified in Exhibit B, section 2.14 for Instrument Performance Assessment for Liquid Scintillation Counters are included			
c) The monthly Instrument Calibration Package, <i>Id #</i> _____ is acceptable per the BA01 requirements and has been forwarded to the CTR.			
d) The monthly Instrument Calibration Package identification is included in the Instrument Calibration Summary.			
e) All applicable source certificates used for the instrument calibration are traceable to NIST and are being maintained at the Laboratory.			
11. COUNTING RAW DATA SUMMARY			
	<i>Reply</i>	<i>√</i>	<i>C#</i>
a) The instrument counting raw data for the RIN are included and document the required items as specified in the Counting and Raw Data Section of BA01, Exhibit B. All data entries were verified as accurate by the reviewer.			
b) The spectra was reviewed, signed and dated by responsible specialist, and found to be acceptable			
c) The tracer chemical recovery, peak resolution (FWHM) and energy calibration check (peak centroid position) for alpha spectrometry data were found to be acceptable according the BA01 criteria for all samples and QC samples.			
d) Sufficient raw data are included to allow manual calculation of the final sample activity and measurement uncertainty, MDA and chemical recovery.			
e) Either the Instrument Calibration Package identification or the dates of the calibration are included with the raw data.			
f) All QC samples were counted and analyzed in the same manner as the samples in the Analytical Batch, in the same time frame, and using the same instrument calibration parameters, instrument analysis algorithms, etc.			
12. ELECTRONIC DATA DELIVERABLE (EDD)			
	<i>Reply</i>	<i>√</i>	<i>C#</i>
a) The EDD accurately reflects the data contained in the Sample Data Package.			
b) The hard copy of the EDD as specified in Exhibit B Section 2 is included with the Sample Data Package.			
c) An automated EDD verification check has been performed.			

Shaded areas are for Site use only.

RIN: _____ Lab Name: _____ Initials: _____

Analytical Batch Identification No.(s): _____

A P P E N D I X B

Data Review Checklist

**LIQUID SCINTILLATION
INSTRUMENT CALIBRATION PACKAGE**

**Data Review Checklist
 LIQUID SCINTILLATION
 INSTRUMENT CALIBRATION PACKAGE**

1. GENERAL REQUIREMENTS	Reply	√	C#
a) The Instrument Calibration Package structural requirements specified in BA01 have been met. All discrepancies were identified and documented, accordingly.			
b). The Instrument Calibration Package was assigned an identification using the syntax of BA01CAL_Lab ID_Date.			
c). The Instrument Calibration Package contains the following sections in the following order: (1) Cover Page, (2) Data Review Checklist- Liquid Scintillation Instrument Calibration Package, (3) Narrative, and (4) Instrument Calibration and Raw Data.			
d) All data were reviewed and certified as accurate. The date and signatures of all analysts and reviewers of the data are included.			

2. STANDARD AND SOURCE REQUIREMENTS	Reply	√	C#
a) All applicable certificates for SRM and purchased standard vials are maintained at the Laboratory and are available if requested by the CTR or during an audit (BA01, Exhibit B Table B3, Standards/SRM Certificates).			
b). Documentation for all laboratory prepared standards are traceable to reference materials certificates and is included in the sample data package as defined in BA01 Exhibit B, Section 2.			
c) All standard identifications are traceable to the primary certificates, which are traceable to NIST and all standards			
d) All SRM and standard vials which are traceable to NIST were valid (not expired) at the time of use.			

3. EXTERNAL STANDARDIZATION - QUENCH CURVE METHOD	Reply	√	C#
a) All required data and information specified in Exhibit B Section 4 are included in the Instrument Calibration Package.			
b) The quench curve was generated with 3 to 10 standards covering the quench range of prepared sample vials.			
c) The standards were counted long enough to accumulate 100,000 counts each.			
d) A plot of the quench curve with curve coefficients is included.			

Shaded areas are for Site use only.

*Respond to each checklist item in the "Reply" column with a Y (yes), N (no), or NA (not applicable).
 Complete footer information, including the initials of the laboratory manager or designee on each page.
 Refer to Module GR01, Exhibit B, Section 4 for instructions to complete this form.*

RIN: _____ Lab Name: _____ Initials: _____

Analytical Batch Identification No.(s): _____

A P P E N D I X C

Data Review Checklist

**ALPHA SPECTOMETRY
INSTRUMENT CALIBRATION PACKAGE**

**Data Review Checklist
 ALPHA SPECTROMETRY
 INSTRUMENT CALIBRATION PACKAGE**

1. STRUCTURAL REQUIREMENTS		<i>Reply</i>	✓	C#
a)	The Instrument Calibration Package was assigned an identification using the syntax of BA01CAL_Lab ID_Date.			
b)	The Instrument Calibration Package contains the following sections in the following order: (1) Cover Page, (2) Data Review Checklist- Alpha Spectrometry Instrument Calibration Package, (3) Narrative, and (4) Instrument Calibration and Raw Data.			
		<i>Reply</i>	✓	C#
2.	The instrument calibration (energy calibration, backgrounds and efficiency determinations) was completed and assessed to be acceptable prior to analyzing samples.			
3.	The instrument calibration was performed in the order of energy calibration first and then backgrounds, and efficiency determinations.			
4.	All sources used for the efficiency determinations were valid (not expired) and NIST traceable- copies of the certificates were sent to the CTR upon first use. Documentation for check sources/and or neodymium fluoride mounted sources which are "working reference materials" was sent to the CTR upon first use			
5.	All data were reviewed and certified as accurate- the date and signatures of all analysts and reviewers of the data are included.			
6.	The Instrument Calibration Package structural requirements specified in BA01 have been met. All discrepancies were identified and documented, accordingly			
7. ENERGY CALIBRATION		<i>Reply</i>	✓	C#
a)	The energy calibration raw data are included and document the required items as specified in the Instrument Calibration Package Section of BA01, Exhibit B.			
b)	The slope of each detector's curve equation was ≤ 13 keV/channel.			
c)	The energy range for each detector included 3 to 6 MeV.			
d)	At least three isotopes within the range of 3 to 6 MeV were used to perform the energy calibration.			
e)	All of the observed peak centroids were within ± 40 keV of the expected peak centroid as defined by BA01.			
8. BACKGROUNDS		<i>Reply</i>	✓	C#
a)	The background raw data are included and document the required items as specified in the Instrument Calibration Package Section of BA01, Exhibit B.			
9. EFFICIENCY DETERMINATIONS		<i>Reply</i>	✓	C#
a)	The efficiency and/or check source raw data are included and document the required items as specified in the Instrument Calibration Package Section of BA01, Exhibit B.			
b)	The source isotope used for the efficiency determinations was a NIST traceable calibration source.			
c)	If the efficiency source was plutonium and the certified value of the source was based on the total alpha, the ROI used for the efficiency determination covered the range of 3 to 6 MeV to include decay daughters (in-growth of ^{241}Am).			
d)	If the certified value of the source was determined for the specific isotope, the ROI used for the efficiency determination was also specific for that isotope.			
e)	The efficiency counts for the ROI were background corrected (same ROI used for the background).			

INSTRUMENT CALIBRATION PACKAGE ID: _____ **Initials:** _____

Lab Name : _____

A P P E N D I X D

Data Review Checklist

NASAL SMEARS SAMPLE DATA PACKAGE

Data Review Checklist BA01 Nasal Smears Sample Data Package

1. COVER PAGE	<i>Reply</i>	<input type="checkbox"/>	<i>C#</i>
a) The laboratory name, code, subcontract number, RIN, Site sample numbers, analyses, and report dates are accurately recorded.			
b) All Laboratory sample identifications associated with this RIN are cross-referenced to the COC sample identifications.			
c) The verbatim compliance and authorization statement is present with the dated signature of the Laboratory Manager or designee.			
d) Any problems with the receipt are explained.			

2. CHAIN-OF-CUSTODY	<i>Reply</i>	<input type="checkbox"/>	<i>C#</i>
a) The continuity of each sample's custody is evidenced by the chain of the date, time and signatures of each transaction from sample receipt to final disposition.			
b) If the continuity was corrupted, there is documentation and evidence of correspondence with the CTR.			
c) All samples are identified on the COC with the corresponding analysis.			
d) Any conflicting, incorrect, or missing information are identified and documented, and there is documentation of the resolution.			

3. NARRATIVE	<i>Reply</i>	<input type="checkbox"/>	<i>C#</i>
a) Contains a synopsis of the methodology and analysis, including all standard operating procedures used.			
b) All anomalies, caveats, deficiencies, interferences, reanalyses, and deviations from approved SOPs related to the analysis are explained.			
e) Appropriate notification was done for samples exceeding Lc per Exhibit B, Table B3?			

4. SAMPLE AND QC SAMPLE RESULTS SUMMARY	<i>Reply</i>	<input type="checkbox"/>	<i>C#</i>
a) Samples			
1. All sample MDA's were equal to or below the required values specified in BA01, Exhibit C.			
b) QC Samples	<i>Reply</i>	<input type="checkbox"/>	<i>C#</i>
1) A set of QC samples were run with every Analytical Batch at the frequency specified in BA01, Exhibit D, Section 2.3.			
2. For each QC sample (LCS and Matrix Blank), the QC Samples are clearly identifiable and contain all items specified in the Sample and QC Sample Results Summary, Exhibit B, Section 2			
3. All QC deficiencies are detailed in the Narrative			
c) Laboratory Control Sample	<i>Reply</i>	<input type="checkbox"/>	<i>C#</i>
1. The Relative Bias Statistic (Bri) is between -.25 and +.50			
3. The Precision defined in Exhibit E, Section 8.3 is in the range of -.20 to +.20.			
d) Blank Population Summary(for low background LSC only)	<i>Reply</i>	<input type="checkbox"/>	<i>C#</i>
1. The Blank Population required data as defined in Exhibit B, Section 2.10.3 is present			
2. The Matrix Blank for this Batch is in the Blank Population and the requirements of Exhibit E, Section 5.2 have been met			

RIN: _____ Lab Name: _____ Initials: _____

Analytical Batch Identification No.(s): _____

Data Review Checklist BA01 Nasal Smears Sample Data Package

8. PREPARATION SUMMARY	Reply	√	C#
a) The preparation raw data (benchsheets and/or preparation logs) are included and document the required items as specified in the Preparation Summary Section of BA01, Exhibit B.			
b) All samples and QC samples in each Analytical Batch were prepared concurrently and in the same manner.			

9. STANDARDS SUMMARY	Reply	√	C#
a) For primary standards that were diluted and used for the tracers, LCS and any in-house prepared instrument calibration sources, the required items as specified in the Standards Summary Section of BA01, Exhibit B, Section 4 are included.			
c) All applicable standard certificates are being maintained at the Laboratory.			
d) All standard identifications are traceable to the primary certificates, which are traceable to NIST.			
e) All standards and sources traceable to NIST were valid (not expired) at the time of use.			

10. INSTRUMENT CALIBRATION SUMMARY	Reply	√	C#
a) Instrument Performance Assessment(IPA)			
1) The IPA was done on the same day samples were counted.			
2) The control chart and IPA parameters are all reported.			
3) Background and check source counts fall within 3s limits of the control chart			
b) All applicable source certificates used for the instrument calibration are traceable to NIST and are being maintained at the Laboratory.			

11. COUNTING RAW DATA SUMMARY	Reply	√	C#
a) The instrument counting raw data for the RIN are included and document the required items as specified in the Counting and Raw Data Section of BA01, Exhibit B, Section 4. All data entries were verified as accurate by the reviewer.			
b) Sufficient raw data are included to allow manual calculation of the final sample activity and MDA and Lc.			
c) The batch blanks are not blank subtracted.			
d) Appropriate blank subtraction was done for the samples.			
e) All QC samples were counted and analyzed in the same manner as the samples in the Analytical Batch, in the same time frame, and using the same instrument calibration parameters, instrument analysis algorithms, etc.			

12. ELECTRONIC DATA DELIVERABLE (EDD)	Reply	√	C#
a) The EDD accurately reflects the data contained in the Sample Data Package.			
b) The hard copy of the EDD as specified in GR01 Exhibit B, Section 4 is included with the Sample Data Package. The hard copy includes data file name and means of transmittal.			
c) An automated EDD verification check has been performed.			

Shaded areas are for Site use only.

RIN: _____ Lab Name: _____ Initials: _____

Analytical Batch Identification No.(s): _____

