

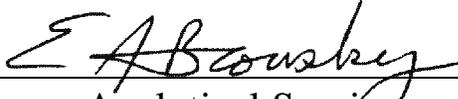
# STATEMENT OF WORK

for

## SAMPLE HANDLING AND SHIPPING SERVICES

### MODULE AS02-B.2

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Approved:   
Analytical Services

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# SAMPLE HANDLING AND SHIPPING SERVICES

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# **SAMPLE HANDLING AND SHIPPING SERVICES**

## **INTRODUCTION**

This AS02 Module or Statement of Work (SOW) provides the technical requirements, specified services or Line Item Codes (LICs), quality control requirements, and structure required for sample handling and shipping of Bioassay Samples and other General Sitewide Samples. Exhibits A through H of this AS02 Module provide the required details for Bioassay and General Sitewide Sample Handling and Shipping Services under this subcontract.

The types of bioassay samples include human urine, fecal, nasal, and tissue materials. These bioassay samples support the Radiological Bioassay Program and the Health Effects Medical Monitoring Programs at Rocky Flats Environmental Technology Site (RFETS). Bioassay samples, Shipping Blanks, Shipping Controls, and Performance Evaluation Samples are shipped or delivered by the sample receiving and handling station to laboratories to be analyzed for the presence and quantitation of plutonium, americium and uranium by alpha spectrometry, and for tritium and gross alpha by liquid scintillation.

The General Sitewide Samples include DOT Regulated and Non-Regulated sample shipments including, but not limited to, the following: surface and ground waters for environmental analyses, drinking water analyses, soils for analysis of contaminants, air-monitoring samples, industrial hygiene monitoring samples, and waste samples for characterization.

## **SCOPE**

Sample handling and shipping services include the following:

- sample receipt and login
- AST data entry
- Short-term storage in conjunction with batching and shipping of samples for laboratory submission
- maintaining a documented chain of custody until sample transfer to a laboratory
- packaging or packaging oversight activities for movement of samples of both radioactive and non-radioactive samples to a laboratory according to RFETS, DOE, and DOT packaging regulations
- sample delivery to an onsite laboratory or shipping to offsite laboratories in accordance with RFETS, DOE, and DOT shipping regulations
- Procurement of synthetic urine to be used for Bioassay Shipping Blanks
- Shipping and Receiving of Bioassay Shipping Blanks, Shipping Controls, and Performance Evaluation Samples as directed by the Bioassay Project Lead to monitor laboratory performance
- maintenance of sample shipping documentation in accordance with RFETS procedures and requirements

Procedures and requirements specified herein shall be used in the handling and shipping of all Bioassay and General Sitewide samples. The subcontractor shall employ safe handling procedures, obtain licensing and approvals, if required, for handling and shipping such samples, utilize generally accepted good laboratory practices in the performance of contract requirements, and shall follow the quality assurance/quality control (QA/QC) program requirements specified herein.

The subcontractors services and procedures for RFETS Bioassay Sample Receiving, Handling, and Shipping shall be consistent with those specified in ANSI N13.30, "Performance Criteria for Radiobioassay" and Title10 CFR 835, "Occupational Radiation Protection".

The subcontractor, following written notification from the Contract Technical Representative (CTR), shall implement updates to these requirements. The CTR shall provide the subcontractor implementation dates for compliance to these and other applicable requirements as they are developed and promulgated.



**EXHIBIT A**  
**SUMMARY OF REQUIREMENTS**

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# **SAMPLE HANDLING AND SHIPPING SERVICES**

## **SUMMARY OF REQUIREMENTS**

### **1. SUMMARY OF AS02 MODULE EXHIBITS**

This AS02 Module or Statement of Work (SOW) comprises seven Exhibits that delineate the requirements for General Bioassay and General Sitewide Sample Handling and Shipping activities. Exhibit A provides an overview of the SOW and its general requirements. Exhibit B contains all reporting and deliverable requirements. Exhibit C contains the Line Item Codes (LICs) for specified services of this SOW work scope (i.e., sample handling and shipping). Exhibit D contains the specific procedures required and defines the applications of these procedures. Exhibit E contains general and specific QA/QC requirements. Exhibit F contains the evidentiary requirements including, chain-of-custody and evidentiary document control requirements that must be followed in processing samples under this subcontract, and specifies requirements for written Standard Operating Procedures (SOPs). To ensure proper understanding of language utilized in this subcontract, Exhibit G contains a glossary of terms. When a term is used in the text without definition, the glossary meaning shall be applicable. Exhibit H contains references applicable to AS02.

### **2. GENERAL REQUIREMENTS**

#### **2.1. Privacy Act**

- 2.1.1. Sample Information submitted under this subcontract for bioassay samples is 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)
- 2.1.2. In NO case shall information be released to a third party without prior written approval of the CTR.

#### **2.2. Work Scope Guidance**

- 2.2.1. All work performed under this SOW shall be done by the subcontractor under the guidance of the CTR, or if applicable, by designated agents in accordance with contractual agreements.
- 2.2.2. **Work Performed Outside Scope of SOW:** Any additional costs not addressed by this SOW shall be agreed upon in writing by the CTR prior to the performance of the work or such costs will become the responsibility of the subcontractor.

#### **2.3. Conduct of Work**

- 2.3.1. During the conduct of work, the subcontractor shall adhere to site safety policies and procedures when performing tasks at RFETS. The subcontractor shall have established policies and procedures that address potential toxic, hazardous and radioactive contamination associated with working at RFETS whether in the office or in the field.
- 2.3.2. The subcontractor shall adhere to Site policies and procedures regarding Site Security and the handling of sensitive and classified information.

- 2.3.3. The subcontractor's personnel shall complete and stay current with all appropriate levels of RFETS, DOT, and DOE training whether the training is provided or not by the Site.
- 2.3.4. The subcontractor shall have and follow procedures for sample receiving, handling and shipping that is in accordance with RFETS, DOT, and DOE regulations and procedures. . The subcontractor shall NOT ship any DOT regulated material or Hazardous substances with out RFETS Traffic Management concurrence. For radioactive samples (Class 7) the subcontractor will NOT ship samples to off-site facilities that exceed the Limited Quantity of material as defined in the 49 CFR § 173.421 and applicable sections therein.
- 2.3.5. **Sample Transfer:** The subcontractor shall also be responsible for transfer of the samples to the laboratory designated by the Kaiser Hill Analytical Services Division (ASD). This will encompass the appropriate packaging and shipping of samples for offsite shipping as well as the transfer of samples to an onsite laboratory. At NO time shall the subcontractor ship samples to a laboratory without a RIN, Laboratory and LIC assigned by ASD. Also, the subcontractor shall only ship samples to the laboratory scheduled by the CTR or the CTR's designated representative.

2.3.6. **Expedited Multiplier**

The multiplier shall be based upon one sample shipped to an off-site lab. All samples shall be considered expedite (rush) and shall be packaged and shipped ASAP when all shipping documentation has been submitted in order to assure the TAT is not exceeded as given in Exhibit A Table A-1. Each Sample shall be received and handled according to all requirements in the other Exhibits of this AS02 SOW.

2.3.7. **DOT Regulated Multiplier (Class 7)**

The DOT Regulated Multiplier shall be based upon each event or package that requires additional time to handle the PRE and other radiological concerns to ship to an off-site lab. The multiplier is an additional charge to the appropriate base receiving and handling charge. Each sample shall be handled and shipped according to all requirements in the other Exhibits of this AS02 SOW and the additional Radioactive materials Limited Quantity requirements of 49 CFR 173.421. The subcontractor is responsible for the costs of receiving, handling, packaging and shipping costs.

2.4. **QA/QC Requirements**

- 2.4.1. The subcontractor shall strictly adhere to all QA/QC requirements prescribed in Exhibits D and E of this AS02 Module.
- 2.4.2. The Subcontractor shall adhere to all Chain-of-Custody (COC) requirements defined in Exhibit F.
- 2.4.3. The subcontractor shall be subject to assessments as described in Exhibit E of this SOW.
- 2.4.4. **Bioassay Shipping Blanks:** The subcontractor shall be responsible for procuring and shipping a Shipping Blank sample with each Radiological Health routine urine shipment. See the Glossary for a definition of a Bioassay Shipping Blank.
- 2.4.5. **Bioassay Control Samples:** The subcontractor shall be responsible for receiving and shipping Control Samples as directed by the ASD Bioassay Project Lead. Control Samples are shipped to a laboratory, usually as a Blind Sample, to measure the laboratory's bias for the results reported. Each Control Sample will be prepared from real human urine with no known isotopes of interest. Radiological Health and the ASD

Project Lead shall requisition the Control Samples from a vendor. The subcontractor shall be responsible for the following:

- shipping empty containers to the vendor for the vendor to return Control Samples to the Site
- the cost of the vendor to ship the Control Samples to the Site
- managing the receipt and handling of Control Samples
- shipping of Control Samples to laboratories as directed by the Bioassay Project Lead (PL)

2.4.6. **Bioassay Performance Evaluation Samples:** The subcontractor shall be responsible for receiving and shipping Performance Evaluation Samples as directed by the ASD Bioassay Project Lead. These samples are shipped to a laboratory, usually prior to a subcontract award, to measure the laboratory's ability to obtain acceptable levels of recovery that conform to the analytical Statement of Work. The Performance Evaluation Samples may contain various levels of activity. Radiological Health and the ASD Project Lead determine the exact amount of activity and requisition the Performance Evaluation Samples from a vendor. See the Glossary for a definition of a Bioassay Performance Evaluation Sample. The subcontractor shall be responsible for the following:

- shipping empty containers to the vendor for the vendor to return the Performance Evaluation Samples to the subcontractor
- the cost of the vendor to ship the Performance Evaluation Samples to the Site
- managing the receipt and handling of Performance Evaluation Samples
- shipping of Performance Evaluation Samples to laboratories as directed by the Bioassay Project Lead (PL)

## 2.5. **Hazards Control**

- 2.5.1. The samples to be handled by the subcontractor may contain potentially hazardous radioactive, inorganic, biological, and/or organic materials. The subcontractor personnel shall be made aware of the potential hazards associated with the handling and shipping of these samples.
- 2.5.2. The subcontractor is responsible for providing a safe working environment. The Site assumes no responsibility for the adequacy and effectiveness of the subcontractor's health and safety program or its implementation.
- 2.5.3. In the case of non-routine Bioassay Samples with potential biological hazards, the subcontractor will not ship samples without confirmation of known hazards by Rad Health or the CTR.
- 2.5.4. The subcontractor shall operate under the requirements defined in the Site Radiation Control Manual, other applicable RFETS safety documents, 10 CFR 835 and DOT49 CFR 100-172.
- 2.5.5. The subcontractor shall be responsible for the disposal of nonconforming Bioassay samples, and leaking or spilled samples delivered to a drop-off station.
- 2.5.6. The subcontractor shall have and follow procedures for Waste management as given in Exhibit F.

2.5.7. The subcontractor shall have an emergency response plan in conjunction with the RFETS plan and procedures for both on-site or off-site accidental sample spills.

2.6. **Operating Hours and Timelines**

2.6.1. **Normal Business Hours:** The subcontractor shall work the RFETS Alternate Work Schedule (AWS) and shall be available to receive samples at the sample receiving station from 6:00 A.M. to 5:00 P.M. on Monday through Thursday with the approval of the CTR. On the non-Alternate Work Schedule Fridays, the subcontractor shall be available from 6:00 A.M. to 4:00 P.M. with the approval of the CTR

2.6.2. **Off-Normal Business Hours:** The subcontractor shall provide support during off-normal business hours at the request of the CTR. A point of contact, available by phone or pager shall be provided to the CTR for requesting emergency sample handling and shipping services outside of normal business hours.

2.6.3. Timelines given in terms of Turn-Around-Times (TATs) are to be interpreted as business days throughout this SOW unless otherwise noted.

2.6.4. **Holiday List:** A list of subcontractor's recognized holidays shall be submitted at subcontract award and at any time the holiday listing changes.

2.7. **Key Identifiers:** The following *Key Identifiers* shall be used to identify and request analyses for all samples (Exhibit G gives precise definitions of these terms):

- The *Report Identification Number (RIN)*, (e.g., 99A5000)
- *Employee Identifier* (required for bioassay samples only).
- *Line Item Code (LIC)*

2.8. **Reports**

2.8.1. **Weekly Status Report:** The subcontractor shall provide a weekly status report summarizing sample handling and shipping status to the CTR. The report shall be in a format that is acceptable to the CTR and contain the contents described in Exhibit B.

2.8.2. The subcontractor shall provide a formal written report and additional information or explanations in response to sample losses and damage, and other handling and shipping problems. Those responses shall be in accordance with the deliverable schedule in Exhibit B.

2.8.3. The subcontractor shall provide Audit Response, Corrective Action, and Nonconformance Reports as directed in Exhibit E.

2.9. **Notification Requirements:** The subcontractor shall meet the following notification requirements:

2.9.1. **Minimum Urine Sample Volumes:**

- When a donor delivers a urine sample to T-891-R with less than the required minimum sample volume, the subcontractor shall direct the donor to comply with Rad Health requirements.
- When a donor delivers a urine sample to a drop-off station with less than the required minimum sample volume, the subcontractor shall notify Rad Health and they will notify the donor.

2.9.2. **Custody Seals for Bioassay Samples:** The subcontractor shall verify Donor Custody Seals were attached to samples upon receipt of samples from the donor. When a sample

is received directly from a donor without a Donor Custody Seal, the subcontractor shall direct the donor to apply a Donor Custody Seal. If there is receipt of any samples delivered by any other means than directly from the donor with no Donor Custody Seal, the subcontractor shall attach a QA/QC Custody Seal upon receipt of sample to assure custody from receipt to the laboratory as requested by Rad Health. The subcontractor shall document the custody seal condition and application of a QA/QC Custody Seal in a Bioassay Login Book and on a Bioassay Sample Receipt Form.

- 2.9.3. **Sample Protection:** The subcontractor shall ensure that all Bioassay and Sitewide samples are protected from accidental damage, theft or malicious mischief and shall immediately advise the CTR of any losses or damage as given in Exhibits B and F. The subcontractor shall complete a formal written report with a corrective action plan upon request of the CTR.
- 2.9.4. **Procedures:** The subcontractor shall maintain accurate up-to-date procedures and shall make copies available for inspection according to Exhibit B. The subcontractor shall notify the CTR in writing prior to the implementation of new or revised procedures that affect the activities performed under this SOW.
- 2.9.5. **Personnel:** The subcontractor shall notify the CTR in writing prior to any proposed personnel assignment changes in *Key Personnel*. Notification shall be given to the CTR not less than 14 calendar days prior to any proposed changes when applicable or sufficient prior notification of separation has been received. Also, a detailed resume for the new replacement of *Key Personnel* shall be provided to the CTR within 7 days of their appointment. The resume shall include position, description, title, education and experience (pertinent to the duties performed for this subcontract).

### 3. TRAINING

- 3.1. **Training Requirements:** Subcontractor sample handling personnel are required to successfully complete and pass the following Rocky Flats specific training courses before being allowed to participate in sample handling events. For those courses requiring annual refreshers, the subcontractor shall ensure that the annual training is complete prior to training expiration date.
  - IATA training (Function Specific)
  - DOT Awareness
  - DOT/DOE Transportation of HAZ Materials
  - DOT/DOE Transportation of RAD Materials
  - Function Specific Training
  - General Employee Training
  - Hazardous Communications CBT
  - Hazardous Communications W/A Indoc. Form
  - Hazardous Waste Operations 40 Hour

- Hazardous Waste Operations 3 Day Experience
- Hazardous Waste Operations 8 Hour Refresher
- Health and Safety Training (Site Specific HASP)
- Quality Assurance/Quality Control Training
- RAD Worker Level II
- RCRA Compliance
- Standard Operations Procedures Training
- Physical
- First Aid/CPR

#### 4. FACILITY AND INSTRUMENTATION

##### 4.1. Facility

- 4.1.1. The subcontractor will use the existing Site facility in T891R or other designated facilities.
- 4.1.2. The subcontractor will evaluate, upon request of the CTR, the sample handling and shipping operation and work with the CTR to determine an appropriate location on the Site to relocate the facility.
- 4.1.3. The subcontractor shall be responsible for ensuring that T891R or a new facility complies with all the pertinent RFETS requirements related to health and safety and facility management. The subcontractor shall also ensure that facilities are maintained and operated to emphasize contamination control to preclude the possibility of cross-contamination from radiological or environmental sources.
- 4.1.4. The subcontractor shall maintain a notification plan, in conjunction with the CTR and Radiological Health, to inform RFETS personnel of the location(s) for Bioassay sample Receiving and Handling.

- 4.2. **Instrumentation:** The subcontractor shall have sufficient equipment and capability to meet all terms and conditions of this module, including instrument calibration.
- 4.3. **Materials and Equipment:** The subcontractor shall supply all materials and equipment, except government-furnished-equipment (GFE), necessary to perform this Statement of Work, including collection packs for all bioassay samples, unless directed otherwise, in writing, by the CTR. Materials shall be of the quality and capability necessary to meet the requirements of this Statement of Work. All materials and equipment shall be purchased per the requirements of the subcontractor's QA Plan.

#### 5. KEY POSITION REQUIREMENTS

- 5.1. **Key Position Requirements:** The subcontractor shall assign individuals the responsibilities for the *Key Positions* listed below to perform the minimum functional requirements necessary to

meet the terms and conditions of this subcontract. Minimum academic training and experience qualifications are identified below. All positions listed below are considered *Key Positions* for this subcontract. A qualifying individual may fill more than one of the *Key Positions*.

5.1.1. *Sample Handling and Shipping Lead:*

- Responsibility: Assigned on a full-time basis to the Sample Handling and Shipping Area. Responsible for all aspects of the sample handling and shipping station as defined in this SOW.
- Academic Training: A bachelor's degree, associates degree and 4 years experience, or eight years experience in a science discipline. Certification as a "Hazmat" Employee in accordance with 49 CFR 172.
- Experience: A minimum of two years related experience which includes practice in handling biological specimens and at least one year of the experience dealing with the handling of radioactive material. Experience with radiological bioassay analysis would be desirable.
- A minimum of one year of experience in the transportation of hazardous materials.

5.1.2. *Data Management Lead:*

- Responsibility: Assigned on a full-time basis to support the Sample Handling and Shipping Area. Responsible for all aspects of the Data Management and AST data entry for the Sample Handling and Shipping Station as defined in this SOW.
- Academic Training: An associate degree or 4 years experience.
- Experience: A minimum of one year experience in computer based data management and records management. Experience in terminology associated with chemical and radiological analyses for Bioassay and Sitewide Samples would be desirable.

5.1.3. *Site Project Manager/QA Manager:*

- Responsibility: Responsible for overall aspects of this SOW and serves as the primary contact for the CTR. Responsible for assuring the subcontractor's QA Program meets all requirements of this SOW. Reports directly to upper management.
- Academic Training: A bachelor's degree, associates degree and 4 years experience, or eight years experience in a science discipline.
- Experience: A minimum of three years of project management experience with at least one year of applied experience with QA principles and practices in an analytical environment.

5.2. **Backup Personnel:** The subcontractor shall have a person meeting the qualifications for the Sample Handling and Shipping Lead and be fully trained and capable to backup the Sample Handling and Shipping Lead. This person will only perform activities under this SOW in cases where the Lead is unavailable due to vacation, sickness, etc.

**6. TURN-AROUND-TIMES**

The Table A-1 defines the sample shipping turn-around-times (TATs) that the subcontractor shall meet unless deviation is provided in writing by the CTR. For Bioassay samples, the TAT as used herein for this SOW is the time from when samples are received until the sample is shipped. For Sitewide samples, the TAT as used herein for this SOW is the time from when both sample and required shipping documentation (i.e., PRE and Rad Screen data) are received until the sample is shipped. All days are defined in business days unless otherwise directed in writing by the CTR. The subcontractor will provide weekend coverage upon request by the CTR.

**TABLE A-1 TURN-AROUND-TIMES**

SAMPLE RECEIVING STATION TURNAROUND TIME		Express in %
28 calendar day service	Routine	100%
21 calendar day rush service	Expedited	
14 calendar day rush service	Expedited	
7 calendar day rush service	Expedited	
72 hours rush service	Expedited	
48 hours rush service	Expedited	
24 hours rush service	Expedited	
DOT Regulated	DOT Regulated	

- If samples can not be delivered due to TNU being closed, the subcontractor shall contact the CTR to make arrangements for the earliest possible delivery.
- Samples received prior to 2 P.M. shall be shipped the same day and samples received after 2 P.M. shall be shipped the next day with the routine afternoon FedEx shipment.
- Samples may be delivered the next morning if approved by the CTR.
- When the subcontractor is unable to ship due to an act of nature or other uncontrolled event, time lost for such events shall not be counted against the TAT.

## 7. GENERAL INFORMATION

### 7.1. Bioassay Samples

- 7.1.1. 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.
- 7.1.2. Samples of urine are collected in plastic jars with plastic lids and must include the following:
- The minimum volume of 500 ml for simulated or real urine excreted in 24 hours
  - The minimum volume of 200 ml for a single or “spot” excretion.
- 7.1.3. The lids of all sample containers should have a Donor Custody Seal applied by the donor. If the donor delivers the sample directly to the T-891-R Sample Receiving Station with a broken or missing custody, the subcontractor shall instruct the donor on the proper application of the custody seal. The donor shall replace the custody seal prior to relinquishing the sample to the Sample Receiving and Handling Area. When a sample has a broken or missing custody seal and the donor is not available, the subcontractor shall apply a QA/QC Custody Seal in the appropriate manner per Exhibit D.
- 7.1.4. Samples of feces consist of a single excretion. The samples are collected in a plastic container with a plastic lid (supplied by Radiological Health). The samples shall be frozen upon receipt and shall be shipped on dry ice. The fecal samples should have two (2) custody seals. If the custody seals are missing or broken, the subcontractor shall follow the same instructions as described in the previous Section 6.1.3 and Exhibit D.
- 7.1.5. Nasal/mouth swab samples consist of mucous from the mouth and nasal passages collected on cotton tipped swabs. The swabs are to be packaged in glass scintillation vials, which are to have NO markings or tape on the glass portion of the vial. Identification on the vial is to be on the cap or the vial is to be inside of a plastic bag with the identification on the plastic bag.
- 7.1.6. Tissue samples are collected on a gauze pad and sealed in a plastic bag (supplied by subcontractor). The gauze may also contain some blood.
- 7.1.7. 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 stored or packaged with routine (no priority) samples.
- 7.1.8. Routine samples will constitute the bulk of the all Bioassay analyses. Priority, Rush, and Rapid Analysis for Bioassay samples may be submitted periodically, and are usually associated with a potential intake or other special purposes.
- 7.1.9. Health Effects samples shall be packaged, shipped, and billed separately from Radiological Health Samples.

### 7.2. General Sitewide Samples

- 7.2.1. General Sitewide samples may contain radionuclide(s) and/or other hazardous chemicals, which may be (1) dissolved in the sample, (2) adsorbed by the sample, (3) a residue on the sample or (3) complexed with the sample.
- 7.2.2. Samples are submitted for various processing turnaround requirements depending upon the required analysis priorities or analysis TATs.

- 7.2.3. General Sitewide Samples will primarily consist of environmental water samples for NPDES and RFCA compliance, filters for ambient air monitoring and filters for effluent stack gas monitoring, drinking water samples, industrial hygiene monitoring samples and waste characterization samples of varying matrices.
- 7.2.4. Environmental water samples will consist of surface, ground, and Sewage Treatment Plant (STP) effluents and influents, which are primarily DOT Non Radioactive samples, but also include samples with possible Rad contamination.
- 7.2.5. Industrial Hygiene samples consists of personal air monitor filters and char tubes, asbestos samples, and filter smears of equipment that may be for beryllium or other hazardous constituents analyses.
- 7.2.6. Waste Characterization Samples consist of both solids and liquids for many varied types of materials such as oils, solvents, process materials and equipment, paint chips and contaminated personal protective equipment.
- 7.2.7. The Sender/Custodian has the responsibility to obtain a Property Release Evaluation (PRE) and pertinent information to ensure that a qualified RFETS Radiological Engineer has evaluated all requirements for off-site shipments. Also, the Sender/Custodian has the responsibility to provide radiological documentation required by the PRE. The subcontractor shall not ship any samples until the Sender/Custodian has provided all required information.
- 7.2.8. The Sender/Custodian has the responsibility to provide an accurate and complete COC, for all samples from the time of collection until receipt by the receiving station to ensure that the integrity of the samples has been maintained. Also, the Sender/Custodian shall provide an On-Site Material Transfer Tag. The subcontractor shall not ship any samples until the Sender/Custodian has provided all required information.



# EXHIBIT B

## REPORTING AND DELIVERABLES REQUIREMENTS

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# SAMPLE HANDLING AND SHIPPING SERVICES

## REPORTING AND DELIVERABLES REQUIREMENTS

### 1. INTRODUCTION

This AS02 Exhibit B contains reporting and deliverable requirements applicable to all types of samples. Deliverable Requirements for all Sample Handling and Shipping Services are detailed in Table B-1 and the following Exhibit B Sections.

Deliverable requirements and schedules specified in this SOW shall be met. A week is defined as the period of time between 12:00 AM Sunday through the following Saturday.

### 2. DELIVERABLE REQUIREMENTS

- 2.1. All deliverables contained in Table B1 shall be transmitted to the designated recipient.
- 2.2. The deliverables shall be completed and in the recipient's possession by the requested schedule unless otherwise agreed upon in writing by the CTR.

The following Table B-1 defines required deliverables for all Sample Handling and Shipping Services. Schedules identified as "immediate notification" imply verbal, FAX, or e-mail notification no later than close of the next business day.

**TABLE B-1. REQUIRED DELIVERABLES**

Deliverable Title	Schedule	Recipient
Weekly Status Report	Weekly- Submitted as requested by the CTR, covering previous weeks services	CTR
Point of contact for off normal hours	Within 30 days of subcontract award and immediately following a new designation	CTR
Holiday List	Within 30 days of subcontract award and immediately following a holiday list change	CTR
Chain of Custody (COC)	Customer Generated COCs (e.g., IH) Weekly; Others Upon Request	Record Services; CTR
Rad Screens or Release Evaluations	With each shipment	As directed by CTR
Bioassay Shipping Blank and Control Sample Documentation	Upon Request	CTR
Performance Evaluation Sample Documentation (Proficiency Sample Worksheet)	When submitted as required and described in Exhibit B Section 6.3	PL
SOPs	A list of SOPs within 30 days of subcontract award and within 7 days for new or amended SOPs; Copies of SOPs upon request.	CTR
Logbooks and Documents	Available during assessments; Upon Request	CTR
Sample Loss, Damage, or Problem	Immediate verbal notification followed by e-mail notification. A formal written report with corrective action plan upon request of CTR.	CTR
Bioassay Sample Receipt Cards (BSRC)	Within 1 business day of sample receipt	Radiological Health/Internal Dosimetry

### 3. CHAIN OF CUSTODY (COC)

Original AST generated COCs shall be transmitted with associated samples at the time of sample shipment. Copies of all COCs for all samples received and transferred shall be maintained by the subcontractor and transferred to the CTR upon request. When the customer submits a sample with a transfer document that is NOT an AST generated COC, the subcontractor shall generate an AST COC, maintain a copy of the AST COC and transfer document, and return to the customer the transfer document or a copy as requested by the customer. A copy of the customer transfer document shall be forwarded to the ASD Record Services as given in Table B1.

### 4. RAD SCREENS/RELEASE EVALUATIONS

The subcontractor shall include a copy of the Rad screen analysis report from an approved ASD laboratory if available. When the Rad screen is not applicable, per the instructions of the release evaluation, then a copy of the release evaluation shall accompany the shipment of samples. Bioassay samples are exempt from this requirement.

### 5. BIOASSAY SAMPLE REQUEST CARDS (BSRC)

The BSRCs shall be filled out as directed in Exhibit D and returned to Radiological Health/Internal Dosimetry per direction from Rad Health and the CTR.

### 6. WEEKLY STATUS REPORT

6.1. **PART I – Individual Sample Information:** A Weekly Status Report shall be provided to the CTR for review and verification of Sample Handling and Shipping services. The Weekly Status Report shall have the following information for each sample handled and shipped:

- REPORT IDENTIFICATION NUMBER (RIN)
- EVENT AND SAMPLE NUMBER
- DATE SAMPLE RECEIVED
- DATE SAMPLE SHIPPED
- LABORATORY IDENTIFIER for the laboratory receiving samples
- SAMPLE PROCESSING PRIORITY (i.e., R, P, U, or D) as provided by the Project Lead
- LINE ITEM CODE (LIC) for sample handling and shipping (e.g., AS02A001)
- COMMENTS regarding sample processing, TAT, sample condition, or any problems relevant to the sample.

6.2. **Part II – Shipping Summary Report:** A weekly Shipping summary Report shall be provided to the CTR and ASD manager for reporting weekly highlights. This report summarizes the samples shipped in Part I by sample type (i.e., urine, nasals, IH), the number of samples and the laboratory to where the samples were shipped.

### 7. QC SAMPLE PREPARATION DOCUMENTATION

#### 7.1. Urine Shipping Blank Documentation

7.1.1. Upon procurement of Shipping Blanks, the subcontractor shall have adequate documentation showing vendor, date of preparation, and unique identification for each

batch. The subcontractor shall maintain documentation for each Shipping Blank batch describing the exact vendor method of preparation and each constituent present.

- 7.1.2. The subcontractor shall store urine Shipping Blanks using chain of custody protocol.
  - Each Shipping Blank shall be traceable to the unique vendor identification number for each Shipping Blank batch.
  - The Shipping Blank shall be logged as a sample in the RIN in which it is shipped with the same documentation applicable to samples.
- 7.1.3. The subcontractor shall document each Shipping Blank shipped on the COC for each urine shipment or RIN which includes the following information:
  - SHIPPING BLANK NUMBER TRACEABLE TO SHIPPING BLANK BATCH
  - ANALYSIS LIC

## 7.2. **Bioassay Control Sample Documentation**

- 7.2.1. Control samples shall be shipped to a laboratory for analysis as directed by the Analytical Services Project Lead (PL) or CTR. These samples are used to verify a laboratory's ability to comply with the requirements of the Bioassay Analytical SOW.
- 7.2.2. Control samples shall be logged in a RIN as samples but the customer sample number shall reflect that the sample is a Control Sample. The date of sample shall be the preparation date of the Control Sample.
- 7.2.3. When Control Samples are submitted to a laboratory, documentation shall include the following information:
  - REPORT IDENTIFICATION NUMBER (RIN)
  - CONTROL SAMPLE NUMBERS assigned by the Subcontractor
  - QC SAMPLE TYPE (Routine, Priority, Rush, Rapid, Screen)
  - MATRIX
  - KNOWN VALUE and UNITS OF CONTROL SAMPLE
  - ANALYSIS LIC
  - DATE PREPARED
  - DATE SHIPPED TO LABORATORY
  - PREPARATION COMMENTS AND INFORMATION

## 7.3. **Bioassay Performance Evaluation Sample Documentation:**

- 7.3.1. Performance Evaluation Samples shall be shipped to a laboratory for analysis as directed by the Analytical Services Project Lead (PL) or CTR. These samples are used to verify a laboratory's ability to comply with the requirements of the Bioassay Analytical SOW.
- 7.3.2. The PL or CTR will requisition Performance Evaluation Samples from a vendor and the subcontractor will arrange shipment of the samples from the vendor as requested by the PL.
- 7.3.3. The subcontractor shall assure that QC documentation is received with the Performance Evaluation Samples and if not received, the subcontractor shall notify the Bioassay Project Lead. The QC documentation should include the following information:

- Preparation date and time
  - SOP Identifier for the preparation performed
  - QC Sample Identifications
  - Primary Standard documentation
  - Secondary Standard documentation
  - Certification of Natural Urine used in the preparation
  - Verifications of Stock Standard Solutions (e.g., counting times, number of aliquots)
  - Weights/Volumes of Standard and Urine in Proficiency Sample
  - Balance identifiers with dates of use so that all measurements can be traced to the documented balance verifications performed
  - Pipette identifiers, dates of use and calibration (if applicable)
  - Total Propagated Uncertainties of Standard and Proficiency Sample
  - All raw data and equations used in calculations
  - Comments describing any significant sample changes or reactions which occur during preparation
  - Date and Signature of person approving the Spike Sample preparation.
- 7.3.4. The subcontractor shall submit the vendor QC documentation required in Section 6.3.3 to the PL for approval before shipping any Performance Evaluation Samples. The subcontractor shall also maintain a copy of the vendor documentation required in Section 6.3.3.
- 7.3.5. The subcontractor shall maintain the following documentation for Performance Evaluation Samples shipped to analytical labs:
- Performance Evaluation sample identification numbers
  - Analysis LIC
  - Laboratory Destination
  - RIN

## **8. LOGBOOKS AND DOCUMENTS**

Logbooks and Documents include, but are not limited to: QC logs, sample receipt logs, sample shipment logs, standards logs, and calibration logs.

## **9. STANDARD OPERATING PROCEDURES**

The SOPs required for meeting this SOW are defined in Exhibit F Sections 4 and 5. [All SOPs generated per the requirements of this SOW are the property of the contractor.](#)



# EXHIBIT C

## LINE ITEM CODES

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# SAMPLE HANDLING AND SHIPPING SERVICES

## LINE ITEM CODES

### 1. SAMPLE HANDLING AND SHIPPING LINE ITEM CODES

#### 1.1. Introduction

All services for this AS02 Module, Bioassay and General Site-wide Sample Handling and Shipping shall be performed on the basis of Fixed Unit Rate (FURs). Each service is identified by a Line Item Code (LIC). Section 1.2 lists each LIC with a description of the sample type handled and shipped or service performed. Sections 1.3 through 1.9 define the services and give the basis used for the determination of each FUR for each LIC.

- 1.2. The following Table C1 specifies the LIC to be used for each sample type handled and shipped or service performed as given in the *DESCRIPTION* column. The *DESCRIPTION* column also gives in parentheses the costing basis (e.g., per sample or set) for the LIC FUR. The *ANALYSIS* column gives possible analyses for the sample types handled for the LIC. The *REFERENCE* column contains a Section number in Exhibit C where the service is defined and more information is provided for the costing basis or FUR of each LIC.

**TABLE C1 LINE ITEM CODES**

LINE ITEM CODE	SERVICES	REFERENCE (Exhibit C Section)
AS02B001	URINE	1.3
AS02B002	FECAL	1.4
AS02B003	NASAL SMEARS	1.5
AS02B004	BERYLLIUM	1.6
AS02B005	INDUSTRIAL HYGIENE	1.7
AS02B006	AMBIENT AIR AND EFFLUENT STACKS	1.8
AS02B007	ALL OTHER SAMPLES	1.9
AS02B008	EXIT BIOASSAY KITS	1.10

#### 1.3. Basis for Urine LIC (AS02B001)

- 1.3.1. The FUR shall be based upon one sample kit or Shipping Blank, which may contain up to four bottles of sample, shipped to an off-site lab.
- 1.3.2. Routine sample kits may be packaged and shipped together in one container provided the TAT is not exceeded as given in Exhibit A Table A-1.
- 1.3.3. Non-routine (i.e. expedite or DOT Regulated) sample kits shall be packaged and shipped individually in order to assure the TAT is not exceeded as given in Exhibit A Table A-1 and to prevent potential cross contamination to routine samples.
- 1.3.4. One Shipping Blank Sample shall be packaged and shipped with each shipping package of real sample kits.

- 1.3.5. Each Sample Kit shall be received and handled according to all requirements in the other Exhibits of this AS02 SOW.
  - 1.3.6. The subcontractor is responsible for the costs of Shipping Blanks, sample bottles and all other receiving, handling, packaging and shipping costs.
  - 1.3.7. QC Samples shall be based upon one Performance Evaluation Sample, Shipping Control Sample or Shipping Blank Sample shipped to an off-site lab. A Performance Evaluation Sample or Control Sample is packaged in a Urine Kit or 4-pack and may contain up to four bottles of sample, which shall be combined by the lab for one sample analysis. A Rad Health QC Sample package or Performance Evaluation Sample Set may contain up to 5 Performance Evaluation Samples or Kits, and 1 Shipping Blank Sample. A Health Effects (Medical Monitoring) QC Sample package may contain 3 'real' (retirees) samples, and 1 Performance Evaluation Sample. No Shipping Blank Samples are sent with Health Effects samples.
  - 1.3.8. QC Samples for each RIN or program shall be packaged and shipped together in one container within the given TAT.
  - 1.3.9. Each QC Sample shall be handled and shipped according to all requirements in the other Exhibits of this AS02 SOW.
  - 1.3.10. The subcontractor is responsible for the costs of shipping empty urine kits to ORNL or other lab responsible for the preparation of Performance Evaluation Samples and Shipping Control Samples. The subcontractor is responsible for the costs of receiving, handling and performing QA/QC requirements given in AS02
  - 1.3.11. The subcontractor is responsible for the costs of Shipping Blanks, sample bottles and all other receiving, handling, packaging and shipping costs.
- 1.4. **Basis for Fecal LIC (AS02B002)**
- 1.4.1. The FUR shall be based upon one sample shipped to an off-site lab.
  - 1.4.2. All non-routine samples (i.e. expedite or DOT Regulated) shall be packaged and shipped in order to assure the TAT of each type is not exceeded as given in Exhibit A.
  - 1.4.3. Each Sample shall be received and handled according to all requirements in the other Exhibits of this AS02 SOW.
  - 1.4.4. The subcontractor is responsible for the costs of dry ice, sample bottles and all other receiving, handling, packaging and shipping costs.
  - 1.4.5. QC samples shall be based upon one Performance Evaluation Sample, or Shipping Blank sample shipped to an off-site lab. A Rad Health QC Sample package or Performance Evaluation Sample Set may contain 5 Performance Evaluation Samples, and 2 Shipping Blank Samples with each sample having a separate RIN.
  - 1.4.6. All samples for the QC Sample package or Performance Evaluation Sample Set shall be packaged and shipped together in one container within the given TAT.
  - 1.4.7. Each QC Sample shall be handled and shipped according to all requirements in the other Exhibits of this AS02 SOW.
  - 1.4.8. The subcontractor is responsible for the costs of shipping empty kits to ORNL or other lab responsible for the preparation of Performance Evaluation Samples and Shipping

Blanks. The subcontractor is responsible for the costs of receiving, handling and performing QA/QC requirements given in AS02.

- 1.4.9. The subcontractor is responsible for the costs of sample bottles and all other receiving, handling, packaging and shipping costs.

#### 1.5. **Basis for Nasal Smears LIC (AS02B003)**

- 1.5.1. The FUR shall be based upon one set of personnel samples, which may include up to three individual samples (left and right nostrils, and mouth) or one set of Performance Evaluation Samples.
- 1.5.2. Sample sets may be packaged in one container but each set shall be packaged individually within the container.
- 1.5.3. Routine sample sets may be packaged and shipped together in one container provided the TAT is not exceeded as given in Exhibit A.
- 1.5.4. Those sample set that shall be received, processed and delivered to TNU within one hour of receipt as given in Exhibit A. When samples are NOT deliverable within one hour of normal business hours, due to normal close of business, the subcontractor shall work with TNU and the CTR to make delivery of the samples to TNU at the earliest possible time. When samples must be received and delivered outside of normal business hours, the CTR shall be contacted for directions to assure that sample results are obtained within 24 hours.
- 1.5.5. Each Sample set shall be received and handled according to all requirements in the other Exhibits of this AS02 SOW.
- 1.5.6. The subcontractor is responsible for the costs of scintillation vials provided to Rad Health, and all other receiving, handling, packaging and shipping costs.

#### 1.6. **Basis for Beryllium LIC (AS02B004)**

- 1.6.1. The FUR shall be based upon a 'bundled' set of 10 samples or upon one individual sample that is shipped to an off-site lab on a daily routine basis. Samples (e.g., Be filters or Char-tubes) are considered to be 'bundled' if they are received in a manner (e.g., a sealed container) that does not allow processing and verification of each individual sample. Hence, the receiving, handling, and shipping of a bundled set of 10 samples is considered equivalent to that of an individual sample, which shall be processed and verified individually. If a RIN of a 'bundled' set of samples contains more than 10 samples, the FUR or LIC may be applied for each multiple of 10 samples in the RIN.
- 1.6.2. All Beryllium Filter samples, regardless of the sample analysis priority, received on a normal business day by 2 PM shall be shipped the same day and charged the FUR for this LIC.
- 1.6.3. All individual and 'bundled' samples may be packaged in one container but the samples for each RIN shall be packaged individually within the container.
- 1.6.4. Each sample shall be handled and shipped according to all requirements in the other Exhibits of this AS02 SOW.
- 1.6.5. The subcontractor is responsible for the costs of creating an AST COC and all other receiving, handling, packaging and shipping costs. Beryllium filter samples will usually

be sent with a hand written customer COC, which will require the subcontractor to generate an AST COC from the customer COC.

**1.7. Basis for Industrial Hygiene LIC (AS02B005)**

- 1.7.1. The FUR shall be based upon a 'bundled' set of 10 samples or upon one individual sample that is shipped to an off-site lab on a daily routine basis. Samples (e.g., Be filters or Char-tubes) are considered to be 'bundled' if they are received in a manner (e.g., a sealed container) that does not allow processing and verification of each individual sample. Hence, the receiving, handling, and shipping of a bundled set of 10 samples is considered equivalent to that of an individual sample, which shall be processed and verified individually. If a RIN of a 'bundled' set of samples contains more than 10 samples, the FUR or LIC may be applied for each multiple of 10 samples in the RIN
- 1.7.2. All Industrial Hygiene samples, regardless of the sample analysis priority, received on a normal business day by 2 PM shall be shipped the same day and charged the FUR for this LIC.
- 1.7.3. All individual and 'bundled' samples may be packaged in one container but the samples for each RIN shall be packaged individually within the container.
- 1.7.4. Each sample shall be handled and shipped according to all requirements in the other Exhibits of this AS02 SOW.
- 1.7.5. The subcontractor is responsible for the costs of creating an AST COC and all other receiving, handling, packaging and shipping costs. Industrial Hygiene samples will usually be sent with a hand written customer COC, which will require the subcontractor to generate an AST COC from the customer COC.

**1.8. Basis for Ambient Air and Effluent Stacks LIC (AS02B021)**

- 1.8.1. The FUR shall be based upon a 'bundled' set of 20 Ambient Air or Effluent Stack filters shipped to an off-site lab. Samples are 'bundled' if they are received in a manner (e.g., a sealed container) that does not allow processing and verification of each individual sample. If a RIN of a 'bundled' set of samples contains more than 20 samples, the FUR or LIC may be applied for each multiple of 20 samples in the RIN. (Excluding Blank Ambient and Effluent Stacks)
- 1.8.2. All samples are considered routine and may be packaged and shipped together in one container provided the TAT is not exceeded as given in Exhibit A.
- 1.8.3. Each sample shall be handled and shipped according to all requirements in the other Exhibits of this AS02 SOW.
- 1.8.4. The subcontractor is responsible for the costs of receiving, handling, packaging and shipping costs.

**1.9. Basis for All Other Samples LIC (AS02B007)**

- 1.9.1. The FUR shall be based upon one sample shipped to an off-site lab.
- 1.9.2. All samples are considered routine and may be packaged and shipped together in one container provided the TAT is not exceeded as given in Exhibit A.
- 1.9.3. Each sample shall be handled and shipped according to all requirements in the other Exhibits of this AS02 SOW.
- 1.9.4. The subcontractor is responsible for the costs of receiving, handling, packaging and shipping.

1.10. **Basis for Exit Bioassay Kits LIC (AS02B008)**

- 1.10.1. The FUR shall be based upon one bioassay urine kit sent to recent former RFETS employees as part of the exit process.
- 1.10.2. The subcontractor shall provide a new packing system capable of shipping 2 liters of urine in a safe manner.
- 1.10.3. The FUR shall also include, but not limited to, the following:
  - Extra absorbent material
  - Shipping empty kits
  - Shipped full kits to an off-site lab.

# EXHIBIT D

## SPECIFIC PROCEDURE REQUIREMENTS

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# SAMPLE HANDLING AND SHIPPING SERVICES

## SPECIFIC PROCEDURE REQUIREMENTS

### 1. INTRODUCTION

This AS02 Exhibit D contains the specific procedural requirements for Sample Handling and Shipping.

### 2. BIOASSAY SAMPLE RECEIVING

Immediately upon receipt of a Radiological Health Sample at T891R, the subcontractor shall document in a Sample Logbook the information for each sample type as given in the following Section 2.2 and sample custody transfer shall be documented with a Sample Receipt as directed in Section 2.3.

2.1. **Bioassay Sampling Request Card (BSRC):** The BSRC is submitted by Radiological Health to RFETS employees when Routine, Priority, Rush, Rapid and entrance/exit bioassay samples are required. The BSRC also identifies the appropriate analyses to be performed on each bioassay sample.

#### 2.2. Bioassay Sample Login

If samples of urine are NOT collected in plastic jars with plastic lids or DO NOT contain the minimum volume of sample as given in Exhibit A Section 6.1.2, do the following:

- If a minimum amount of a routine sample is submitted, direct the Donor, if present, to collect the required amount of sample and then submit the sample.
- If a routine sample is not submitted in the required containers, direct the Donor, if present, to collect the required amount of sample in the required containers and then submit the sample.
- If the sample is a routine sample with less than the required minimum volume and the Donor is NOT present, document on the Sample Request Card that the donor did not submit the minimum amount of sample, send the Sample Request Card to Rad Health, and discard the sample.
- If a routine sample is not submitted in the required containers and the Donor is NOT present, document on the Sample Request Card that the donor did not submit the sample in the required containers, send the Sample Request Card to Rad Health, and discard the sample.
- If a minimum amount of a Special sample is submitted, whether the Donor is present or NOT present, immediately contact the Bioassay Project Lead or Rad Health to determine whether the sample should be shipped.

NOTE: The Information recorded in Sample Logs is 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).

**2.2.2. Non Routine Fecal and Urine Sample Login:**

- DATE OF SAMPLE RECEIPT
- LAST NAME of person providing the sample
- EMPLOYEE NUMBER or SOCIAL SECURITY NUMBER of person providing the sample
- SAMPLE MATRIX (urine, fecal, or tissue)
- ANALYSIS PRIORITY-TAT (Routine, Priority, Rush, Rapid, Screen)
- ANALYSIS REQUESTED (e.g., Pu, U, or Am)

**2.2.3. Routine Urine Sample Login:**

- DATE OF SAMPLE RECEIPT
- LAST NAME of person providing the sample
- EMPLOYEE NUMBER or SOCIAL SECURITY NUMBER of person providing the sample
- ANALYSIS REQUESTED (e.g., Pu, U, Am, or Tritium)
- ANALYSIS PRIORITY-TAT (Routine, Priority, Rush, Rapid, Screen)
- Sufficient or Insufficient SAMPLE volume for urine
- CUSTODY SEAL CONDITION
- COMMENTS regarding sample processing, sample condition, or any problems relevant to the sample (e.g., Custody Seal OK, Container condition)

**2.3. Bioassay Receipt**

2.3.1. A Bioassay Receipt shall be completed for samples relinquished by the donor or other individual at T891R with the following information:

- DATE OF SAMPLE RECEIPT
- LAST NAME of person providing the sample
- EMPLOYEE NUMBER or SOCIAL SECURITY NUMBER of person providing the sample
- MATRIX
- ANALYSIS REQUESTED (e.g., Pu, U, Am, or Tritium)
- ANALYSIS PRIORITY-TAT (Routine, Priority, Rush, Rapid, Screen)
- SAMPLE Volume (ml) for urine/sufficient
- CUSTODY SEAL CONDITION
- COMMENTS regarding sample processing, sample condition, or any problems relevant to the sample (e.g., Custody Seal OK, Container condition)

2.3.2. The subcontractor shall obtain the signature of the person relinquishing the sample and the person receiving the sample shall sign for receipt of the sample on the Bioassay Receipt.

2.3.3. The subcontractor shall provide the completed Bioassay Receipt to the customer and retain a copy.

## 2.4. **Bioassay Sample Container Custody Seal:**

2.4.1. The subcontractor shall assure that the bioassay container lid is tight, a Donor Custody Seal is applied correctly and includes the following information:

- NAME of collector or person providing the sample
- Collector's Initials
- EMPLOYEE NUMBER or SOCIAL SECURITY NUMBER of collector or person providing the sample
- DATE OF SAMPLE

2.4.2. **Delivery Made by Sample Donor:** If a sample is delivered by the sample Donor and all of the requirements of Section 2.4.1 are not met, the subcontractor shall instruct the Donor to do one or more of the following as applicable:

- tighten the lid
- apply a new Donor Custody Seal with the required information and
- sign the appropriate documentation indicating the necessity for the new custody seal

2.4.3. **When Sample Donor is NOT Present:** If a sample is delivered by someone other than the sample donor or the sample was deposited at a drop-off station the subcontractor shall do the following as applicable:

- tighten the lid
- apply a QA/QC Custody Seal to assure sample integrity during shipment to laboratory
- document the custody seal condition and application of a QA/QC Custody Seal in a Bioassay Login Book and on a Bioassay Sample Receipt Form

2.4.4. If the donor Custody Seal does not contain the required information, the subcontractor shall instruct the donor, when present, to fill in the required information or apply another Donor Custody Seal with the required information. If the Donor is not present the subcontractor shall document the omission in the comments sections of the Bioassay Receipt and Bioassay Sample Login Book.

## 2.5. **Bioassay AST Sample Receipt Login**

2.5.1. Prior to the shipment of a sample an AST generated COC must be completed and accompany the sample shipment. The subcontractor shall assure that the following information is entered into AST, if not already entered, and contained on the COC accompanying the sample shipment:

- REPORT IDENTIFICATION NUMBER (RIN)
- COLLECTOR EMPLOYEE NUMBER or SOCIAL SECURITY NUMBER of person providing the sample
- REQUESTOR
- BOTTLE No. (RIN, EVENT and SAMPLE NUMBER)
- SAMPLE MATRIX (Urine, feces, nasal, tissue)
- SAMPLE COLLECTION DATE

- SAMPLE COLLECTION TIME as provided by the Employee
- SAMPLE LOCATION
- No./TYPE of CONTAINER
- SAMPLE ANALYSIS LIC (Pu, U, Am, Tritium, Gross  $\alpha/\beta$ , Liquid Scintillation) TAT (Routine, Priority, Rush, Rapid, Screen)
- PRESERVATION
- CHARGE NUMBER AND COST CENTER for Radiological Health or Health Effects
- COMMENTS regarding sample processing, sample condition, or any problems relevant to the sample.
- ANALYSIS LAB
- METHOD of SHIPMENT

### **3. GENERAL SITEWIDE SAMPLE RECEIVING**

3.1. The subcontractor shall have and follow a procedure for the receiving and handling of samples that is in accordance with RFETS, DOT and DOE regulations and procedures.

3.2. The subcontractor shall assure that the following required Sender/Custodian documentation is submitted with samples and documentation is complete before accepting the samples.

3.2.1. Assure that a PRE is submitted for all General Sitewide Samples and complete the following:

- Verify that there has been a PRE Number assigned to the PRE
- Verify the Expiration Date of the PRE
- Ensure there is a Sender/Custodian signature with employee number, date and phone number from the sender or custodian.
- Verify the Specific Requirements of the PRE and Comments Section.
- Verify that the Radiological Engineers have signed off on the PRE and that the name and employee number is legible.

3.2.2. Assure that a Radiological Survey Report and Rad Screen results were submitted with all samples that do not meet unrestricted release criteria and complete the following:

- Verify that Class 7 Limited Quantity Radioactive samples will meet the requirements of the RCM, RSP and CFR 49 173.421 for controlling, transferring, packaging, and shipping requirements.
- Assure that Class 7 limited Quantity samples will be controlled and secured in Radiological material refrigerators.

- 3.2.3. Assure that all samples are received with a COC and complete the following:
- Ensure that the type and number of samples agree with those received.
  - Verify Sample Preservation (if required) has been completed and documented correctly.
  - Ensure custody seals have been applied to the sample container in the proper manner and are intact.

#### **4. SAMPLE PRESERVATION AND PACKAGING REQUIREMENTS**

Samples shall be preserved and packaged according to Department of Transportation and Site Transportation requirements and the following:

##### **4.1. Urine Samples**

- 4.1.1. No preservation is required for urine samples being analyzed for Plutonium, Americium, Tritium, and Uranium.
- 4.1.2. The subcontractor shall develop standard packaging and shipping to prevent any leakage from the external packaging in case of leakage from sample bottles.

##### **4.2. Fecal Samples**

- 4.2.1. Fecal samples shall be frozen upon receipt and shipped on dry ice.

##### **4.3. Nasal Samples**

- 4.3.1. No Preservation is required for Nasal smears.
- 4.3.2. Nasal smears shall be packaged to prevent breakage of the glass vials.

##### **4.4. Tissue Samples**

- 4.4.1. Tissue samples shall be refrigerated upon receipt to maintain 4°C and packaged with “blue ice” for shipment.

##### **4.5. General Sitewide Samples**

- 4.5.1. Samples shall be preserved according to information given on the COC.
- 4.5.2. Samples shall be packaged according to subcontractor procedures in conjunction with Department of Transportation requirements and RFETS Transportation procedures.

#### **5. BIOASSAY AND GENERAL SITEWIDE SAMPLE SHIPPING REQUIREMENTS**

- 5.1. The subcontractor shall ship samples to the laboratory scheduled by the CTR or the CTR’s designated representative. The CTR or the CTR’s designated representative will determine the laboratory where the samples shall be sent based upon laboratory capacity, performance, and capability. The subcontractor shall not contact the laboratory directly unless directed in writing by the CTR.

- 5.2. The subcontractor shall only contact the laboratory directly to coordinate delivery of samples to the laboratory during off-hours. If necessary, arrangements shall be made by the CTR for any handling or processing required for the laboratory receipt of sample shipments, including picking-up samples at the nearest servicing airport, bus station, or other carrier service within the laboratory's geographical area.
- 5.3. The subcontractor shall ensure that one Urine Shipping Blank is included in every routine shipment of urine samples submitted to a laboratory and documented according to Exhibit B Section 6.1.
- 5.4. A COC shall accompany all samples. The COC should be generated by AST when practicable. When non-routine samples or other extenuating circumstances make it impossible to generate an AST COC, the subcontractor may use an original hand-written COC to deliver or ship samples. However, the COC information shall always be entered into AST at the earliest possible time.
- 5.5. Samples shipped directly to a laboratory by a commercial carrier shall be with a carrier that maintains traceability.
- 5.6. Samples shall be shipped or hand delivered according to the conditions of each LIC given in Exhibit C. In cases where an emergency situation exists, the subcontractor may be asked to hand deliver samples to a laboratory within the Denver metropolitan area.
- 5.7. At the time of sample shipment or delivery, the subcontractor shall log the Date Shipped into the ASD AST system. NOTE: Prior to shipment all other required AST information shall be completed according to Exhibit D Section 2.5.1.
- 5.8. The subcontractor shall have and follow a procedure for shipment and delivery of samples that is in accordance with DOT and DOE regulations and procedures. The subcontractor shall NOT ship any DOT regulated material or Hazardous substances without RFETS Traffic Management concurrence. For radioactive samples (Class 7) the subcontractor will NOT ship samples to off-site facilities that exceed the Limited Quantity of material as defined in the 49 CFR § 173.421 and applicable sections therein.

## **6. BIOASSAY SHIPPING BLANK PREPARATION REQUIREMENTS**

The subcontractor is responsible for the Shipping Blank preparation requirements given in Section 6.1. The subcontractor is not responsible for the preparation of Performance Evaluation and Shipping Control Samples. However, the subcontractor shall be responsible for managing the receipt of QC samples from a vendor and the shipping of the QC samples to a laboratory designated by the Bioassay Project Lead (PL). The ASD Bioassay PL shall be responsible for the requisition of Performance Evaluation Samples and Shipping Control Samples and to assure the samples meet QC requirements.

### **6.1. Shipping Blank Samples**

- 6.1.1. ASTM Type II water as defined in Exhibit E shall be used to prepare synthetic urine for Shipping Blank Samples.
- 6.1.2. All chemicals used for the preparation shall be at least ACS Reagent Grade.

- 6.1.3. Chemicals shall be weighed on a balance that meets Exhibit E Balance requirements. Measurements of chemicals with weights less than 10.0 grams must be measured on a balance with an accuracy of  $\pm 0.0005$  g and measurements for weights greater than 10 grams may be measured on a balance with an accuracy of  $\pm 0.1$  g.
- 6.1.4. Preparation shall not introduce hazardous constituents into the QC samples
- 6.1.5. The synthetic urine for Shipping Control Samples shall be prepared as follows:
- Weigh 3.5500 g of sodium silicate into a 150 mL beaker, add a teflon coated stir bar, add 100 mL of ASTM Type II water using a 100 mL graduated cylinder, and stir at moderate speed until dissolved.
  - Add 23,000 mL of ASTM Type II water using 1000 mL to 4000 mL graduated cylinders to a 60 liter polyethylene tank and set up a variable speed propeller stirrer to provide strong agitation of the water without splashing.
  - Add the following chemicals to the tank, in the order listed with stirring between additions:
 

◆ Urea	800.0 g
◆ Sodium Chloride	116.0 g
◆ Potassium Chloride	171.5 g
◆ Creatine	55.0 g
◆ Sodium sulfate, anhydrous	215.5 g
◆ Hippuric acid	31.5 g
◆ Ammonium Chloride	53.0 g
◆ Citric Acid	27.0 g
◆ Magnesium sulfate, anhydrous	23.0 g
◆ Sodium Phosphate Monobasic	136.5 g
◆ Calcium Chloride dihydrate	31.5 g
◆ Oxalic Acid	1.0000 g
◆ Lactic Acid	4.7000 g
◆ Glucose	24.0 g
◆ Pepsin	1.4500 g
  - Add the sodium silicate solution prepared above to the solution
  - Measure 1600 mL of concentrated Nitric acid using a 2000 mL graduated cylinder in a fume hood, and add to the mixture
  - Measure 25,538 mL of ASTM Type II water using 100 mL to 4000 mL graduated cylinders and add to the mixture
  - Increase the stirring speed and continue stirring for another 2 hours or until all components are dissolved
  - Transfer the mixture to 8 L jugs
  - Label as artificial urine with a hazard rating of 3, 0, 0 and unique batch identification number

# EXHIBIT E

## QUALITY ASSURANCE/QUALITY CONTROL REQUIREMENTS

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# SAMPLE HANDLING AND SHIPPING SERVICES

## QUALITY ASSURANCE/QUALITY CONTROL REQUIREMENTS

### 1. INTRODUCTION

The purpose of this AS02 Exhibit E is to describe the minimum QA/QC requirements necessary to satisfy the deliverable and data requirements associated with Sample Handling and Shipping. These requirements are designed to ensure the generation of accurate and complete sample handling and shipping documentation, traceability of samples, and the shipment of samples according to applicable regulations. These requirements do not release the subcontractor from maintaining its own QC checks on performance.

### 2. THE QUALITY ASSURANCE PROGRAM

2.1. **QA/QC Components:** The subcontractor shall establish a QA Program which shall incorporate a QA Plan, QC procedures, corrective action systems, and documentation required during sample receipt, handling, and shipment. Some of the QA Program requirements are summarized in Table E1. The *Reference* column refers the AS02 Exhibit and Section number 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 E1 QA PROGRAM REQUIREMENTS SUMMARY**

Requirement	Reference (Exhibit/Section)
Development and implementation of a QA Program and documentation of the key elements of that QA Program through a written QA Plan	Exhibit E Section 3
Preparation of and adherence to written SOPs	Exhibit F Section 5
Adherence to the specific procedures and associated QC, and documentation requirements provided in AS02	Exhibit D
Verification and documentation of reference standard materials obtained from commercial suppliers for purity and accuracy	Exhibit E Section 6
Adherence to corrective action procedures	Exhibit E Sections 8 and 9
Participation in external assessments (e.g. Analytical Services and Radiological Health personnel), completion of internal self assessments, and adherence to corrective action procedures	Exhibit E Sections 8 and 9
Compliance with Performance Criteria	Exhibit E Section 10

### 3. QUALITY ASSURANCE PLAN

- 3.1. **Schedules:** The subcontractor shall implement and maintain a written QA Plan that presents the policies, organization, objectives, and specific QA and QC activities designed to achieve the deliverable and data quality requirements of this SOW. The subcontractor shall provide the CTR with a copy of the QA Plan prior to the time the subcontractor assumes sample handling and shipping responsibilities. Changes to the QA Plan shall be submitted to the CTR prior to implementation.
- 3.2. **QA Plan Review:** The status and adequacy of the QA Plan shall be reviewed and approved once a year by the subcontractor management. This documentation shall be incorporated into each SOP. Also a system shall be developed and maintained to promote continuous quality improvement, including an internal assessment program.
- 3.3. **QA Training:** The subcontractor personnel shall receive QA training appropriate to their participation. Training shall be performed as necessary to assure that each staff member understands the QA and technical requirements applicable to their work. Documentation of training, whether function specific or general, shall be maintained by the subcontractor and be available upon CTR request and during audits.
- 3.4. **References:** The QA Plan shall be based on one or more of the following references: 10 CFR 830.10, DOE Order 414.1, ANSI/ASQC E4-1994, ASME-NQA-1-1989, ISO 9000, and/or Good Laboratory Practice Standards (40 CFR 792). Additional information relevant to the preparation of a QA Plan can be found in DOE, EPA, and ASTM publications.
- 3.5. **QA/QC Plan Key Elements:** The QA/QC Plan shall address all *Key Elements* listed below. Requirements associated with these *Key Elements* are found in this Exhibit and the references cited in the previous paragraph. Where procedures, requirements, responsibilities and documentation are indicated below, the QA/QC Plan shall include these in the QA/QC Plan or by reference to QA/QC SOPs.

#### 3.5.1. Subcontractor QA/QC Policy and Objectives

#### 3.5.2. Organization and Personnel

- Staff resumes of Key Personnel.
- Education and experience requirements
- Indoctrination and training procedures and requirements
- QA/QC management organization
- Assignment of QA and QC responsibilities
- QA/QC management reporting relationships

#### 3.5.3. Facilities, Equipment and Materials

- Guidance for measuring and test equipment calibrations
- Procedures for maintaining measurement system stability and reproducibility
- Maintenance activities and schedules
- Instrumentation and backup alternatives
- QC program for confirmation of materials (e.g., standards, reagents, sample bottles, etc.)
- QC program for control of age-sensitive materials
- QC program for reference material analysis/verification

3.5.4. **Control of Purchased Items and Services**

- Criteria for approving vendors
- Requirements for assuring procurements identify or reference quality criteria
- Procedures for acceptance of purchased items

3.5.5. **Procedures and Document Control**

- All work shall be conducted in accordance to written procedures
- Procedures for measurement process documentation
- Sample tracking/custody procedures and documentation requirements
- Logbook content, format, maintenance, and archiving
- RIN file organization, preparation, and review procedures
- Computer and Program Security Procedures
- Procedures for preparation, approval, review, revision, and control of SOP distribution

3.5.6. **Specific Handling and Shipping procedures**

- Adherence to specific SOW (AS02) procedures and requirements.
- Sample receipt, handling and storage procedures
- QC Sample preparation procedures
- Standard preparation procedures
- Calibration procedures and frequency
- Sample packaging procedures
- Sample shipping procedures
- AST Data management procedure

3.5.7. **Assessment Program**

- Participation in External Assessments
- Internal Assessment Program

3.5.8. **Nonconformance Program**

- Corrective action procedures
- Control of nonconformances

**4. BIOASSAY SHIPPING BLANK QUALITY CONTROL REQUIREMENTS**

4.1. **Sample Control:** Each Shipping Blank Sample shall have unique identification that is documented and traceable to the specific RIN.

4.2. **QC Sample Identification:** Each Shipping Blank Sample shall be designated with the QC type and a unique identification that is traceable to the Shipping Blank preparation batch.

## 5. MEASURING AND TESTING EQUIPMENT (M&TE)

The subcontractor shall comply with the following: Section 5.1, General Requirements for M&TE; Section 5.3, Thermometers and Temperature Recording Devices; and Section 5.4, Refrigerators/Freezers.

NOTE: The following Section 5.2, Balances, and Section 5.5, Automatic Pipettes and Dispensers requirements do not directly apply to subcontractor's sample handling and shipping operations but are included as requirements that may be applicable to vendors that prepare and supply QC samples and standards to the subcontractor.

### 5.1. General Requirements for M&TE

- 5.1.1. M&TE shall include balances, thermometers, pipettes and other devices used to generate QC samples and to demonstrate compliance to SOW requirements, such as preservation of samples at 4° C.
- 5.1.2. The subcontractor shall establish and document calibration methods and intervals for M&TE.
- 5.1.3. The subcontractor shall assign unique identifiers to all M&TE.
- 5.1.4. All data generated by M&TE must be labeled with the unique M&TE identifier.
- 5.1.5. The subcontractor shall maintain records (and if applicable, mark equipment) indicating calibration status. Records shall include the unique equipment identifier, calibration interval, traceable standard identifiers, chronological equipment condition history, and the personnel performing the calibration.
- 5.1.6. The subcontractor shall establish a system to identify and prevent the use of M&TE that do not meet performance standards. Failure to meet standards may be due to M&TE that are out-of-calibration, are under expired certification status, or exhibit conditions indicating compromised performance.

### 5.2. Balances

- 5.2.1. Balances shall be located in a vibration-free environment away from drafts and rapid temperature changes.
- 5.2.2. All balances shall be calibrated and labeled annually by a certified technician.
- 5.2.3. Working weights used for daily balance verifications shall be certified annually.
- 5.2.4. The type, grade, and class of weights used to calibrate balances for analytical measurements shall meet the requirements of ASTM E 617, *Laboratory Weights and Precision Mass Standards*.
- 5.2.5. Daily Balance Verification Requirements
  - The subcontractor shall check weigh the balance, at a minimum, every working day prior to use.
  - Check weighing shall be performed at two (2) points within the balance range using certified working weights
  - Results of check weight measurements shall be documented by the vendor. Documentation of check weight measurements shall be maintained by the vendor and be available for review during an on-site assessment and within seven calendar days of CTR request.

- 5.2.6. Check weight and balance certifications shall be maintained by the vendor and be available upon written CTR request.

### 5.3. **Thermometers and Temperature Recording Devices**

- 5.3.1. Liquid-in-glass thermometers shall be calibrated against a NIST traceable standard at a five year interval.
- 5.3.2. Liquid-in-glass thermometers shall be inspected annually for conditions that may degrade performance. At a minimum, this inspection must include examination for evidence of liquid column separation and evidence of other conditions that might affect the column.
- 5.3.3. Thermometer and temperature device certifications and documentation of annual inspections shall be maintained by the vendor/subcontractor and available upon written CTR request.

### 5.4. **Refrigerators and Freezers**

- 5.4.1. The temperature of refrigerators used to store Site samples shall be verified and documented each working day. Documentation shall be maintained by the subcontractor and available upon request and during on-site assessments.
- 5.4.2. The subcontractor shall develop and implement procedures for sample storage and preservation in the event of a refrigerator/freezer failure or power failure.
- 5.4.3. The subcontractor shall clearly identify refrigerators/freezers exceeding temperature requirements to prevent use until corrective actions have been completed.

### 5.5. **Automatic Pipettes and Dispensers**

- 5.5.1. The vendor/subcontractor shall calibrate all non-Class A pipettes and automatic sample dispensers used for quantitative measurement. This calibration shall be performed monthly or whenever degradation of measuring equipment performance is suspected, whichever is more frequent. Conditions that may initiate immediate recalibration include: evidence of corrosion, leakage, movement of continuously-adjustable volume settings, and improper treatment such as dropping and exposure to nonroutine temperatures.
- 5.5.2. Pipette and automatic sample dispenser calibration documentation shall be maintained by the vendor/subcontractor and be available upon request and during on-site inspections.

## 6. **STANDARDS AND REAGENTS**

This Section primarily contains acquisition, maintenance, and documentation requirements for standards, reagents, and QC samples. It is the responsibility of the ASD Project Lead to requisition Performance Evaluation and Shipping Control Samples required for the Bioassay Program. The subcontractor is responsible for receiving the QC documentation for the requisition Performance Evaluation and Shipping Control Samples, obtaining approval from the PL that the vendor met the QA/QC requirements, storing the QC samples, and shipping the QC samples to designated laboratories. Also, the subcontractor shall assure that the following requirements are met for the Shipping Blank Samples that the subcontractor prepares or obtains from a vendor.

6.1. **Purchase of Analytical Reagents, Standards and QC Samples**

- 6.1.1. The vendor/subcontractor shall have a documented program for controlling the quality of purchased reagents and standards.
- 6.1.2. The vendor/subcontractor shall have an established system for approving vendors from which to procure supplies and services. All analytical reagents, standards, and QC samples shall be obtained from these approved vendors.
- 6.1.3. Material Safety Data Sheets (MSDSs) for all reagents and standards shall be maintained by the vendor/subcontractor and submitted upon CTR request.

6.2. **Purchase of Standards:** Whenever possible, the vendor/subcontractor shall purchase NIST Standard Reference Materials (SRMs), NIST-traceable SRMs, or NIST-approved certified reference materials. If appropriate NIST reference materials are unavailable, the subcontractor can purchase standards necessary to prepare the QC samples required for this SOW from other approved suppliers. Reference standards purchased from these other suppliers must meet the following criteria:

- 6.2.1. The supplier must provide standard values with error estimates and a description of the statistical method for obtaining these estimates.
- 6.2.2. The vendor/subcontractor shall perform an independent verification of the supplier-determined standard value. This verification shall be performed by absolute or comparison methods; however, if a comparison method is used, the comparison shall be to two standard sources independent of the supplier. Vendor/subcontractor or supplier standard values shall be identical at the 5% significance level.

6.3. **Standard Certificates:** Standard certificates shall be kept on file by the vendor/subcontractor and available upon request. Copies of the standard certificates shall be made available during assessments or within 7 calendar days of request. Standard certificates shall include, at a minimum, all of the following items:

- An identifier for the standard unique to the actual material (or lot) certified
- Identification of the certifying entity
- Signature of a representative of the certifying entity, a certificate printed on official letterhead, or a certificate affixed with certification seals
- A description of the material certified [including matrix and values for parameter(s) certified]
- Error estimates for certified parameter values
- Definition of a finite certification period
- Certificates for NIST-traceable standards must contain SRM identifiers of all NIST materials used for traceability and a description of the process used for relating parameter values to NIST values shall be included.

- 6.4. **Maintaining Traceability to Primary Standards:** The certified material received by the vendor/subcontractor from NIST or other certifying entity is defined as the primary standard. The vendor/subcontractor shall be able to trace all standards used in QC sample preparation back to the certificates maintained on file. Traceability shall include control and NIST traceability for all measurement equipment used to prepare dilutions and/or reconfigurations of the primary; this measurement equipment includes, but is not limited to, pipettes, balances, and volumetric glassware.

NOTE: To maintain traceability, all standards used must be prepared, handled, and stored according to the applicable instructions. Proper storage and handling of chemical standards must be addressed in training programs, SOPs, and facility requirements in order to safeguard against decomposition and contamination and to minimize risk of human exposure. Inability to document traceability of standards to NIST or other recognized standards agencies may result in vendor/subcontract termination.

6.5. **Documentation of the Verification and Preparation of Standards and Reagents**

- 6.5.1. The vendor/subcontractor must maintain the necessary documentation to show that standards and QC samples used in the performance of this SOW conform to requirements. Supporting documentation such as standard logs, weighing logs, calculations, and detection system spectra (whether produced by the subcontractor or a vendor shall be maintained by the subcontractor and may be subject to review during on-site assessments. Standard and QC sample preparation documentation must be provided by the subcontractor if requested by the CTR for verification of SOW compliance. This documentation should be supplied by the vendor on a Proficiency Sample Worksheet supplied to the vendor by the PL.
- 6.5.2. Standard logs shall be kept for all weighing and dilutions performed for standard preparation and/or verification. All subsequent dilutions of the primary standard shall be recorded and all calculations for determining their concentrations are to be documented. Standard logs or a Proficiency Sample Worksheet shall contain the following information:
- Primary standard identification
  - Secondary standard tracking identification number
  - All compounds or components of the standard
  - Weight or volume of primary standard used
  - Final volume or dilution data
  - Final activity with units
  - Preparer's initials
  - Preparation date
  - Secondary standard expiration date

6.6. **Labeling Standards and Reagents**

- 6.6.1. The vendor/subcontractor shall label all purchased standards and reagents with the following information:
- Date received
  - Date opened
  - Expiration date

6.6.2. All secondary standard solutions shall be clearly labeled with a unique identification that is logged in a standards preparation log and traceable to its primary standard. Labels shall contain, at a minimum, the following information:

- Secondary standard tracking identification number
- Activity with units
- Preparer's initials
- Preparation date
- Secondary standard expiration date

If the container size precludes this requirement, this information shall be documented in a logbook or attached in an appropriate manner.

#### 6.7. **Expiration Dates for Reagents and Standards**

6.7.1. Expiration dates established by the manufacturer shall be used when available. The vendor/subcontractor shall not use original stock standard solutions or reagents beyond the expiration date provided by the manufacturer.

6.7.2. If an expiration date is not defined, the vendor/subcontractor shall document how the shelf life of the reagent/standards is determined.

6.7.3. The expiration date, date received, and date opened shall be clearly identified on all reagent/standard solution containers. If an expiration date is not required, it shall be indicated on the container.

#### 6.8. **Preparation of Standards for Radiochemical Parameters from Certified Stock Materials**

6.8.1. The vendor/subcontractor may prepare radioactive chemical standards from certified stock materials. The solvent used to dissolve the solute must be compatible with the method in which the standard is to be used. The solute must be soluble, stable, and non-reactive with the solvent. In the case of a multi component solution, the components must not react with each other.

6.8.2. All calculations for determining the required weight of stock material from the analyte activity of the certified material and the desired activity shall be recorded. These calculations shall be verified by a second knowledge person, and the secondary verification shall be recorded and retained with the calculations. The calculation sheet shall also record accuracy requirements for balances used in standard preparation. (Documentation of calculations in SOPs may fulfill some of these verification requirements.)

6.9. **Water Purity:** The vendor/subcontractor preparing QC samples shall have a water system that meets the following requirements:

6.9.1. The water system shall be capable of providing water meeting the American Society for Testing and Materials (ASTM) specifications for Type II water (ASTM D1193).

6.9.2. The water system shall be monitored with each use. Results of this monitoring shall be recorded at least once each day the system is in use. The conductivity shall not exceed 1.0  $\mu\text{S}/\text{cm}$  at 25° C. If this level is exceeded, the Laboratory shall take immediate corrective action before the water can be used for QC sample. Monitoring and corrective action documentation shall be maintained by the subcontractor and available upon written request by the CTR.

## 7. DATA MANAGEMENT

- 7.1. The subcontractor shall conduct all data management activities in accordance with documented QA/QC procedures that include review by a second person. Verification of AST data entry shall include all entries, updates, corrections, and deletions. Verification shall also include verification that information was saved and printed to hardcopies without errors. AS02 Exhibit F contains procedural requirements for data management and software QA.

## 8. ASSESSMENTS

- 8.1. **External Assessments:** The subcontractor shall be subject to routine and non-routine assessments or audits with follow-up assessments of either type. The subcontractor shall make all requested data and documentation related to this SOW available during assessments.
  - 8.1.1. **Routine Assessments:** A routine assessment may be a comprehensive audit or limited scope audit performed by ASD or it's designated subcontractor to verify adherence to the ASD SOW and the subcontractor's SOP requirements. The subcontractor shall be subject to routine on-site assessments not more than two times per calendar year during performance of this SOW. Written notification shall be provided to the subcontractor for routine assessments.
  - 8.1.2. **Non-routine Assessments:** A non-routine assessment may be a comprehensive audit or limited scope audit performed by DOE, the DOE primary contractor or it's designated subcontractor to verify adherence to DOE orders, the ASD SOW and the subcontractor's SOP requirements. The subcontractor shall be subject to non-routine on-site assessments whenever requested. These may be unannounced and announced assessments that may be performed at any time during the subcontract period.
  - 8.1.3. **Follow-up Assessments:** A follow-up assessment verifies that adequate corrective action has been implemented by the subcontractor in response to a previous assessment finding, that SOW requirements are met when the scope of the SOW changes or when the subcontractor relocates. Follow-up assessments will normally be performed 30 days following the implementation of a corrective action or a change in the SOW or SOP. However, on-site assessments for the purpose of identifying and resolving deficiencies or verifying corrective actions may be performed at any time during performance of the subcontract.
  - 8.1.4. **Corrective Actions and Audit Response Reports:** Following an external assessment, the assessment team will conduct a closing conference with subcontractor staff to discuss identified findings and establish a schedule for corrective action. The subcontractor shall perform Corrective Actions to resolve the findings identified during the external assessment according to the schedule set during the closing conference. The subcontractor shall also issue an Audit Response Report for the Findings and Corrective Actions that were taken or are to be taken. Failure to meet the established timeline for responding to the identified findings and/or failure to meet the established corrective action schedule may result in subcontract termination.
- 8.2. **Internal Self Assessment Program**
  - 8.2.1. The subcontractor shall implement and maintain an internal self assessment program. Each self assessment may be of limited scope, however the assessment program shall address all procedures and operations, which includes corrective action procedures.

- 8.2.2. Internal self assessments shall be conducted at a frequency of at least quarterly.
- 8.2.3. Internal self assessments shall be conducted, if possible, by personnel knowledgeable of, but independent from, the operations performed.
- 8.2.4. Internal self assessments should be conducted in accordance with written procedures and/or checklists. Self assessment reports shall identify the assessors, personnel interviewed during the assessment, a synopsis of the assessment scope, and a summary of the final results in sufficient detail to enable corrective action.
- 8.2.5. **Corrective Actions and Audit Response Reports:** Following an internal self assessment, the inspection team will conduct a closing conference with other subcontractor staff to discuss identified deficiencies and establish a schedule for corrective action. The subcontractor shall perform Corrective Actions to resolve the findings identified during the internal self assessment according to the established schedule. The subcontractor shall also issue an initial Corrective Actions for the Corrective Actions that were taken or are to be taken within 2 weeks of the audit close out conference. A copy of the internal self assessment Audit Response Report shall be provided to the CTR for evaluation and approval. The subcontractor shall complete all Corrective Actions and a final Audit Response Report by a date that is approved by the CTR.

## 9. NONCONFORMANCES

- 9.1. Nonconformances and Corrective Actions must be identified, documented, tracked, evaluated, and resolved. Conditions adverse to safety and quality shall be promptly identified and corrected.
- 9.2. Nonconforming items (e.g., expired standards) shall be identified, tagged and/or segregated until disposition.
- 9.3. The identification of adverse conditions and corrective actions shall be documented and reported to subcontractor management and the CTR.
- 9.4. The subcontractor shall implement a corrective action tracking system to ensure follow-up actions are taken to confirm and document corrective action implementation.

## 10. PERFORMANCE CRITERIA

- 10.1. **Monitoring Performance:** Subcontractor performance will be continually assessed by the CTR. The general areas of performance that are to be monitored include: safety, sample turnaround time from sample receipt to sample shipment, accuracy and timeliness of data entry, and compliance to deliverable requirements.
- 10.2. **Deliverable Expectations:** The subcontractor shall meet the delivery schedules outlined in Exhibit B Table B1 of this SOW.
- 10.3. **Sample Turn-Around-Time:** The subcontractor shall meet the requirements for sample TATs as outlined in Exhibit A Table A1 of this SOW.
- 10.4. **Data Entry and Accuracy:** The subcontractor shall meet the Analytical Services Toolkit (AST) tracking system data entry requirements as defined in Exhibit D. A 95% accuracy is required.



# **EXHIBIT F**

## **EVIDENTIARY REQUIREMENTS**

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# SAMPLE HANDLING AND SHIPPING SERVICES

## EVIDENTIARY REQUIREMENTS

### 1. INTRODUCTION

The purpose of this AS02 Exhibit F is to describe the evidentiary requirements that must be followed for the Handling and Shipping of Bioassay and General Sitewide samples.

### 2. SAMPLE CUSTODY AND CONTROL

Samples are physical evidence that must be controlled and legally defensible, whether collected as a human specimen sample or an environmental sample for the determination of exposure to radioactive materials or hazardous constituents. To accomplish this, the following sample control and Chain-of-Custody (COC) requirements shall be implemented by the subcontractor. Evidence that samples are NOT identifiable and traceable at all stages can result in data that is NOT legally defensible and may result in subcontract termination.

#### 2.1. Sample Identification

- 2.1.1. The subcontractor shall assure traceability of samples in their possession; the subcontractor shall follow a specified method for maintaining identification of samples from sample receipt at the receiving station to sample receipt at a laboratory.
- 2.1.2. Each sample shall be labeled with the Site Report Identification Number (RIN) and the Site sample number.

2.2. **Chain-of-Custody and Sample Tracking Requirements:** The subcontractor shall maintain a traceable Chain-of-Custody for samples from receipt at the Receiving Station to sample receipt at a laboratory. The subcontractor shall have procedures ensuring that Site sample custody is maintained and documented.

- 2.2.1. A sample is under custody if any of the following applies:
  - It is in your possession;
  - It is in your view after being in your possession; or
  - It was in your possession and you locked it up
- 2.2.2. The subcontractor shall maintain records documenting all phases of sample handling from receipt at the Receiving Station to sample receipt at a laboratory. This documentation shall be available upon request and during on-site assessments.
- 2.2.3. COC documents shall demonstrate the custody of the sample at all times. There shall be no gaps in the sample custody. The COC documents shall show transfer of the sample between individuals and facilities. COC records shall include the date, time, and signature of each person who relinquished the sample and each person who took receipt of the sample.
- 2.2.4. COC documentation shall be completed in accordance with RFETS procedure PRO-543-ASD-002, "Initiation, Preparation, and Implementation of Chain-Of-Custody".

### 2.3. **Sample Protection and Integrity**

- 2.3.1. The subcontractor shall ensure that security is maintained in all handling areas and shall ensure that samples are protected from accidental damage, theft, or malicious mischief. The subcontractor shall provide immediate verbal notification to the CTR followed by email notification of any losses or damage within 24 hours. The subcontractor shall also provide a formal written report with a corrective action plan when requested by the CTR. In addition, the subcontractor shall identify and document which individuals have access to secure areas. Procedures and documentation for access shall be available for review during on-site inspections and upon written request from the CTR.
- 2.3.2. Sample shipments require custody seals on the containers placed such that they cannot be opened without damaging or breaking the seal.

## 3. **DOCUMENT CONTROL REQUIREMENTS**

The goal of the subcontractor document control program is to assure that all documents will be accounted for when the project is completed and that meaningful information can be extracted from these documents when retrieved. Accountable documents used by the subcontractor shall include (but not be limited to) logbooks, COC records, SOPs, and other documents relating to the sample handling and shipping, procurement of services, and generation of deliverables. Document control procedures shall be established to assure that all records related to Site samples are properly maintained.

### 3.1. **General Requirements**

- 3.1.1. All documents and required retention copies shall be complete and legible.
- 3.1.2. All observations and results recorded by the subcontractor shall be on pre-printed forms or shall be entered into permanent laboratory logbooks.
- 3.1.3. The subcontractor name and a descriptive form name shall be included on all documents used to record information related to the receipt and handling of samples.
- 3.1.4. Unused portions of logbooks and COCs shall be Z'd out, initialed, and dated in black or blue indelible ink.
- 3.1.5. All records shall be maintained in black or blue indelible ink.
- 3.1.6. When columns are used to organize information recorded on subcontractor records such as pre-printed forms or logbook pages, the information recorded in that column shall be identified in a column heading.
- 3.1.7. To preserve confidentiality, references to the Site shall not appear in any documents accessible to non-laboratory personnel.
- 3.1.8. Information submitted under this subcontract is 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)
- 3.1.9. Any sample handling documentation that is not a part of other deliverable items shall be available during assessments and upon request.
- 3.1.10. QC sample identification on all documentation shall unequivocally denote the QC type either through the identifier or by cross-referencing the identifier with the QC type. QC identifiers shall be unique.

- 3.1.11. Sample documentation must include all Site Sample Identifiers.
  - 3.1.12. The identification scheme used must provide an unequivocal and unique link between the samples and QC samples in a RIN.
  - 3.1.13. A unique identifier assigned according to AS02 Exhibit E for Shipping Blanks must identify the unique identifier for the Shipping Blank batch or artificial urine batch.
  - 3.1.14. Applicable units shall accompany all numerical information.
- 3.2. **Error Correction:** Corrections and updates to documentation shall be performed in a manner that preserves record integrity. The following procedures must be followed when correcting errors:
- 3.2.1. A single line shall be drawn through the error and the correct information recorded in black or blue indelible ink.
  - 3.2.2. No information shall be obliterated or made unreadable.
  - 3.2.3. All corrections, additions, and crossed out information shall be initialed and dated in black or blue indelible ink.
  - 3.2.4. Use of correction fluid is prohibited.
- 3.3. **Requirements for Logbooks**
- 3.3.1. The subcontractor's name, address and a unique logbook identifier shall appear on the cover of all logbooks. The type of activity recorded within a logbook shall be on the cover of the logbook.
  - 3.3.2. Pages in both bound and unbound logbooks shall be sequentially numbered.
  - 3.3.3. Logbook entries shall be dated (month/day/year) and signed by the person responsible for performing the activity at the time an activity is performed.
  - 3.3.4. Logbook entries shall be in chronological order.
- 3.4. **Requirements for Pre-printed Forms**
- 3.4.1. Pre-printed forms shall contain the name of the subcontractor, revision date (month/day/year), and signature of the person responsible for performing the activity at the time an activity is performed.
- 3.5. **Documentation of Sample Shipment**
- 3.5.1. The subcontractor shall document shipment of samples to the laboratory on the COC and in AST. The subcontractor shall document what was sent, to whom, the date, and the method (carrier) used. A weekly report shall be submitted as defined in Exhibit B.
- 3.6. **Corrections and Updates to Submitted Deliverables:** The record of changes as corrections and updates to information originally generated, submitted, and/or resubmitted shall be documented to allow traceability of updates. Documentation shall include the following for each change:
- 3.6.1. Justification or rationale for the change.

- 3.6.2. Initials of the person making the change or changes with the date of the change or an effective date of implementation. Changes shall be reviewed and documented by a person or group independent of the source generating the deliverable.
- 3.6.3. Documentation of changes or revisions shall be retained according to the schedule of the original deliverable.
- 3.6.4. Resubmitted deliverables shall be reevaluated as a part of the subcontractor's internal assessment process prior to resubmission. The entire deliverable, not just the changes, shall be assessed.

### 3.7. **Storage of Site Files**

- 3.7.1. The subcontractor shall maintain Site documents in a location that is secured and protected from damage and deterioration.
- 3.7.2. The subcontractor shall maintain written records and documents to be used as evidence. Documents and records maintained by the subcontractor shall be legible, identifiable, and retrievable.

### 3.8. **Document Retention:** Documentation and records generated by the subcontractor shall be retained at the subcontractor facility for a period of five (5) calendar years. After this period, records may be disposed of with the following provisions:

- 3.8.1. Six months prior to the date the subcontractor intends to dispose of documentation and records related to Site samples, the subcontractor shall notify the CTR or designated representative in writing. Written approval must be obtained from the CTR prior to the disposition of documents and records.
- 3.8.2. The Site retains the right to request physical reproduction of documents and records retained by the subcontractor at any time during the retention period.

### 3.9. **Handling of Confidential Information**

- 3.9.1. The subcontractor conducting work under this SOW will receive information for Bioassay samples covered by the Privacy Act. Such information shall be handled separately from other documentation maintained for other types of samples. To accomplish this, the following procedures for the handling of confidential information have been established.
- 3.9.2. Confidential information shall be segregated from other information and stored in a locked file. Upon sample receipt, the information shall be logged into Confidential Inventory Log. The information shall only be made available to authorized personnel after they have signed that they received access. The documents shall be returned to the locked file at the conclusion of each working day. The information shall not be reproduced without approval of the CTR. A document control system shall record all information that was copied. This information shall NOT be discarded without approval of the CTR.

NOTE: This information is 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)

#### 4. SOFTWARE QA DOCUMENTATION REQUIREMENTS

The subcontractor shall maintain a program that addresses measures taken to ensure computer programs, other than AST, used to generate information are validated, verified, and documented for both vendor-supplied and in-house software packages. The AST program is except from this requirement since this requirement is fulfilled by the subcontractor managing AST. The software QA program shall incorporate the "Computer Hardware and Software" requirements from ANSI/ANQC E4-1994. This program shall include the following minimum requirements:

- 4.1. Software validation shall occur before initial use and following subsequent revisions.
- 4.2. A correlation between the validation documentation and the software shall be established.
- 4.3. A historical file of software revisions and associated validation documentation shall be maintained. The historical file shall be maintained in chronological order.
- 4.4. Computer programs and sample information on electronic media shall be handled, stored, safeguarded, and controlled to prevent damage and deterioration.

#### 5. STANDARD OPERATING PROCEDURES

A Standard Operating Procedure (SOP) is a written document that provides step-by-step directions or requirements for performance of certain tasks. These procedures are necessary to ensure that information produced and actions performed under this SOW are acceptable.

- 5.1. **The Subcontractor SOP Program:** The subcontractor shall establish and implement a system that defines when a SOP is required, and the process by which a SOP is created, reviewed, approved, controlled, updated, and retained. At a minimum, this system shall define, establish, and implement the following:
  - 5.1.1. **Document Control:** A document control process shall be established to maintain control of all SOPs. A document shall record the SOP title, unique SOP identifier, current revision, custodian, and controlled copy number of each SOP. The process shall insure that procedures are approved for release only by authorized personnel. Document control procedures shall be designed to preclude the use of outdated or inappropriate SOPs and insure that outdated or uncontrolled SOPs shall not be in the possession of subcontractor personnel.
  - 5.1.2. **Interim Change:** A document control process shall be established to formally implement changes on an interim basis until the changes can be incorporated into a revised SOP.
  - 5.1.3. **Periodic SOP Review:** SOPs shall be reviewed annually and updated as necessary when subcontract, facility, or subcontractor procedural modifications are made. The subcontractor shall maintain records documenting the annual review of SOPs.
  - 5.1.4. **Document Retention:** Current SOPs and superseded revisions of SOPs shall be retained as accountable documents by the subcontractor as described in Exhibit F Section 3.8.
  - 5.1.5. **Document Availability:** Current SOPs shall be available at the sample receiving station as appropriate. A complete set of SOPs shall be available during an external assessment.

During an external assessment, subcontractor personnel may be asked to demonstrate the application of the SOPs.

- 5.1.6. **Format and Content Requirements:** The format for SOPs may vary depending upon the kind of activity for which they are prepared. However, at a minimum, SOPs shall accurately describe the activity as performed by the subcontractor and include QC criteria and corrective action procedures. Additional content requirements follow.

## 5.2. **SOP Delivery Requirements**

- 5.2.1. The subcontractor shall provide a complete list of all current SOPs relevant to this SOW to the CTR. The list shall include procedure identifier, title, and effective date.
- 5.2.2. The CTR may request a copy of any SOP selected from this list. The subcontractor shall deliver to the CTR a copy of the requested SOP within three calendar days of the request.
- 5.2.3. During the term of performance of the subcontract, the subcontractor shall notify the CTR, in writing, of new or amended SOPs applicable to this SOW prior to implementation of the change. This notification shall identify the new or amended SOP(s) and include a revised SOP list. In the case of updated SOPs, a brief description of the change shall be included.

## 5.3. **Common SOP Requirements:** All SOPs shall:

- 5.3.1. Be functional (i.e., clear, comprehensive, up-to-date, and sufficiently detailed) to permit duplication of activities by all trained personnel.
- 5.3.2. Describe actual processes as performed by the subcontractor.
- 5.3.3. Include QC criteria and corrective action procedures
- 5.3.4. Be consistent with current DOE regulations, Federal regulations, State regulations, and AS02 Module requirements.
- 5.3.5. Provide a system to sufficiently and completely document the necessary actions and performance of each task.

## 5.4. **Requirements for Evidentiary SOPs:** The subcontractor shall develop and use a SOP or SOPs to ensure sample and information accountability. Evidentiary SOPs shall include specific procedures as the subcontractor performs them for the following processes:

- 5.4.1. **Sample Handling and Shipping:** The subcontractor shall have a written SOP for handling and shipping of each type of sample. At a minimum, a SOP shall describe the system and tasks performed to ensure compliance of receiving, handling, transportation, and shipping requirements of this AS02 module or SOW.
- 5.4.2. **Sample Identification:** The subcontractor shall have a written SOP describing steps taken to ensure compliance of Sample Identification Requirements of this AS02 module or SOW.
- 5.4.3. **Sample Security, Integrity and Custody:** The subcontractor shall have a written SOP or SOPs to ensure sample security, integrity and chain-of-custody. At a minimum, a procedure shall describe the systems and tasks that are to be performed to ensure compliance of sample security, integrity, and custody requirements of this AS02 module or SOW.

- 5.4.4. **Document and Information Control:** The subcontractor shall have a written SOP or SOPs to ensure document and information control. At a minimum, a procedure shall describe the systems and tasks that are to be performed to ensure compliance for document and information control requirements of this AS02 module or SOW.
- 5.4.5. **Waste Management**
- 5.4.5.1. The subcontractor shall have a written SOP for waste management that includes the handling and tracking of samples requiring disposition.
- 5.4.5.2. The subcontractor shall have a written SOP for management of waste generated as a result of a leaking or spilled sample.
- 5.4.5.3. The subcontractor shall have a written SOP for management of waste generated during the handling of QC samples.
- 5.4.6. **Hazard Awareness:** The subcontractor shall have written within operational SOPs hazard awareness checks which cover all aspects of sample receipt, shipment, and handling.
- 5.5. **Requirements for Quality Management SOPs:** The subcontractor shall have written SOPs for technical and managerial review of subcontractor operations, information review, and self-assessment systems. At a minimum procedures shall document the following information:
- Information flow and chain-of-command for information review
  - Procedures to assure that hardcopy deliverables are complete and compliant with the requirements in Exhibit B
  - Procedures to assure that data entry into the AST tracking system is complete, accurate, and compliant with the requirements in this SOW
  - Demonstration of internal QA assessment procedure
  - Frequency and type of internal self assessments (e.g., random, quarterly, spot checks, perceived trouble areas)
  - Demonstration of problem identification-corrective actions and the sequence resulting from internal self assessments (i.e., QA feedback)
  - Documentation of assessment reports (internal and external), subcontractor responses to assessment reports, and corrective actions taken to correct identified findings or deficiencies
  - Tracking nonconforming items for implementing corrective action procedures
  - Evaluation of nonconformances for identifying systematic errors
- 5.6. **Requirements for Document Organization SOPs:** The subcontractor shall have written SOPs for the organization and assembly of all documents relating to this SOW. The procedures shall ensure that all document assembly and organization requirements of Exhibits B, E, and F are specified. The system shall include a document numbering and inventory procedure, a description of the method used by the subcontractor to verify consistency and completeness of deliverables and procedures for the submittal of the deliverables.
- 5.7. **Requirements for Data Management SOPs:** The subcontractor shall have written SOPs for the management, handling, and reporting of information required by this SOW. At a minimum, these procedures shall include the following:
- 5.7.1. Procedure for controlling information entry errors

- 5.7.2. Procedure for reviewing changes to information and deliverables and ensuring traceability of updates
  - 5.7.3. Software QA procedures for testing, modifying and implementing changes to existing computing systems including hardware, software, and documentation or installing new systems in accordance with the "Computer Hardware and Software" requirements from ANSI/ANQC E4-1994
  - 5.7.4. Database security, backup and archival procedures including recovery from system failures
  - 5.7.5. System maintenance procedures and response time
  - 5.7.6. Individual(s) responsible for system operation, maintenance, data integrity and security
  - 5.7.7. Specifications for staff training procedures.
- 5.8. **Requirements for Subcontractor Health and Safety SOPs:** The subcontractor shall have written SOPs for health and safety compliant with all RFETS and AS02 requirements.



# EXHIBIT G

## GLOSSARY OF TERMS AND ACRONYMS

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# SAMPLE HANDLING AND SHIPPING SERVICES

## GLOSSARY OF TERMS AND ACRONYMS

### 1. GLOSSARY OF TERMS

**ANALYTICAL SERVICES DIVISION:** A division of Kaiser-Hill Environmental Systems and Stewardship that is responsible for the coordination of analytical services at RFETS.

**ANALYTICAL SERVICES TOOLKIT:** The ASD computer system for tracking analytical services, which is also known as the Analytical Services Tracking System.

**ASTM TYPE II WATER:** Deionized water with a conductivity of less than 1.0  $\mu\text{mho}/\text{cm}$  at 25° C. For additional specifications, refer to ASTM D1193-77, "Standard Specification for Reagent Water."

**BIOASSAY PERFORMANCE EVALUATION SAMPLE SET:** A Performance Evaluation Sample Set is used in the Bioassay program to evaluate the performance of a laboratory prior to the award of a contract, after a stop work order, and/or to evaluate the ongoing performance of the laboratory. A Performance Evaluation Sample Set may consist of up to 7 QC samples (e.g., 5 control samples and 2 blanks). Performance Evaluation Samples are prepared for all Bioassay matrices (i.e. urine, fecal, and nasals) and all isotopic analyses (i.e. uranium, plutonium, and americium). The Performance Evaluation Samples may contain levels of activity between 0.1 and 1.0 DPM of plutonium, americium, or uranium. Radiological Health and the ASD Project Lead determine the exact amount of activity and requisition the Performance Evaluation Samples from a vendor.

**BIOASSAY SHIPPING BLANK:** This is a unique sample, which is a synthetic urine sample provided by the subcontractor, that is shipped with each urine shipment as described in this SOW. The Shipping Blank is used to ascertain any possible levels of contamination at the laboratory that would affect sample analysis. The Shipping Blank must be totally free of any isotopes that may be requested for analysis. A Shipping Blank is currently used only for the urine matrix.

**BIOASSAY SHIPPING CONTROL SAMPLE:** This is a unique bioassay sample shipped in a RIN and used to monitor bias of results reported. The common practice at the Site is to use shipping controls for the urine matrix only. The shipping control is usually submitted for analysis by either Rad Health or Medical Monitoring as a blind sample and is identifiable by them. Each Control Sample will be prepared from real human urine with no known isotopes of interest. Radiological Health and the ASD Project Lead shall requisition the Control Samples from a vendor.

**BLIND SAMPLE:** - A surrogate sample containing known amounts of analyte(s) of interest, submitted as an audit sample.

**CALIBRATION:** The establishment of an analytical curve relating the response of an instrument to a quantifiable characteristic of the analyte in known standards.

**CALIBRATION STANDARDS:** A series of known standard solutions used by the analyst for calibration of the instrument (i.e., preparation of the analytical curve).

**CONTRACTOR TECHNICAL REPRESENTATIVE (CTR)** - Person responsible for providing technical oversight of the subcontract.

**CONTROL LIMITS:** A range within which specified measurements results must fall to be compliant. Control limits may be mandatory, requiring corrective action if exceeded, or advisory, requiring that noncompliant data be flagged.

**CURIES:** The traditional unit used to express the activity (amount) of radioactive material. The SI unit for activity is the becquerel.

1 curie (Ci)	=	$2.22 \times 10^{12}$ disintegration/minute
1 millicurie (mCi)	=	$2.22 \times 10^9$ disintegration/minute
1 microcurie ( $\mu$ ci)	=	$2.22 \times 10^6$ disintegration/minute
1 picocurie (pCi)	=	2.22 disintegration/minute
1 becquerel (Bq)	=	1 disintegration/second

**CUSTODY SEAL:** Adhesive seal applied to sample bottles to maintain Chain of Custody until sample is delivered to the laboratory.

**DAY:** Day shall mean calendar day, unless otherwise specified as for TATs in Exhibit A Table A-1. There are 365.25 days per year.

**DONOR CUSTODY SEAL:** An Adhesive seal applied by a Bioassay donor to sample bottles to maintain Chain of Custody until sample is delivered to the laboratory.

**EMPLOYEE NUMBER:** The unique identification number assigned to personnel performing work activities at the site. For employees working directly for Kaiser-Hill or one of its first level subcontractors, the employee number is a six digit number. For all other personnel, the employee number is the individual's social security number.

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

**HOLDING TIME:** The elapsed time expressed in days from the date of sampling until the date of analysis for which sample data will be considered valid.

**INDEPENDENT STANDARD:** A standard solution that is composed of analytes from a different source than those making up the standard used for the initial calibration.

**INTERNAL DOSIMETRY:** The Internal Dosimetry Department of the Rocky Flats Radiological Health Section of the Radiological Control Program.

**ISOTOPES:** Elements that contain the same number of protons, but a different number of neutrons in the nucleus.

**LABORATORY RECEIPT DATE:** The date on which a sample is received at the laboratory facility, as recorded on the shipper's delivery receipt. Also referred to as VTSR (validated time of sample receipt).

**LINE ITEM CODE:** A Line Item Code (LIC), included on the COC or other documentation received with samples, designates the requested analyses and analysis method requirements. A LIC may also designate the Sample Handling and Shipping activity and its fixed unit rate charge (e.g. AS02B001).

**LIMITED QUANTITY:** The maximum amount of a hazardous material for which there is a specific labeling or packaging exception, when specified as such in a DOT 49 CFR section applicable to the particular material.

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

**MATRIX:** The predominant material of which the sample to be analyzed is composed. For the purpose of this SOW, a sample matrix may be urine, fecal material, nasal smear, tissue, water, soil, or waste. Matrix is not synonymous with phase (liquid or solid).

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

**NIST-TRACEABLE STANDARD:** A Standard Reference Material (SRM) purchased either directly from the National Institute of Standards and Technology (NIST) or the other approved vendors who provide the traceability certificate to the NIST.

**NUCLIDE:** An atomic species characterized by the constitution of its nucleus, specifically by the number of protons and neutrons.

**PERFORMANCE EVALUATION SAMPLE:** See Bioassay Performance Evaluation Sample Set.

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

**PRIORITY SAMPLE:** A sample with a collection, handling and shipping, or analysis TAT that is shorter than a sample with a Routine processing designation. The Priority TAT varies with the type of sample. See Exhibit A Table A-1.

**QA/QC SAMPLE CUSTODY SEAL:** A custody seal applied to samples by the subcontractor when a Donor Custody Seal was not applied or was not applied correctly and the donor is not available to apply a Donor Custody Seal. The subcontractor shall document the reason for application of the QA/QC Custody Seal.

**RADIOACTIVE DECAY:** The process by which a spontaneous change in nuclear state takes place. This process is accompanied by the emission of energy and subatomic particles.

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

**REPORT IDENTIFICATION NUMBER (RIN):** A number assigned by ASD and documented in AST for a grouping of samples identified by the PL to be included in a single sample data package for a given PSA Module. A RIN may be comprised of more than one analytical batch, in which case, each analytical batch shall have a unique identifier that associates client and QC samples within the batch. Conversely, if two or more RINs are combined into one analytical batch, each RIN data package must contain all required QC results.

**ROUTINE SAMPLE:** A sample with a collection, handling and shipping, or analysis TAT that is LONGER than a sample with a Rush or Priority processing designation. The Routine TAT varies with the type of sample. See Exhibit A Table A-1.

**RUSH SAMPLE:** A sample with a collection, handling and shipping, or analysis TAT that is shorter than a sample with a Routine or Priority processing designation. The Rush TAT varies with the type of sample. See Exhibit A Table A-1.

**SAMPLE NUMBER (SITE SAMPLE NUMBER):** A unique identification number designated by the Site for each sample.

**SHIPPING BLANK:** See Bioassay Shipping Blank.

**SHIPPING CONTROL SAMPLE:** See Bioassay Shipping Control Sample.

**SITE:** The Rocky Flats Environmental Technology Site (RFETS).

**STATEMENT OF WORK (SOW):** A contractual agreement for the technical requirements between Kaiser Hill Analytical Services Division and the subcontractor. As used herein, the specific requirements Modules such as this AS02 Module for Sample Handling and Shipping.

**TURN-AROUND-TIME** As used herein, the turn-around-time (TAT) is the elapsed time from the date a sample is received at the sample receipt station to the date the laboratory receives the sample for analysis (VTSR). The TAT is a performance measure used to assess subcontractor compliance to delivery schedules.

**VALIDATED TIME OF SAMPLE RECEIPT (VTSR):** Synonymous with Laboratory Receipt Date as used herein.

## 2. ACRONYMS

<b>ANSI</b>	<b>American National Standards Institute</b>
<b>APO</b>	<b>Analytical Projects Office</b>
<b>ASD</b>	<b>Analytical Services Division</b>
<b>ASME</b>	<b>American Society of Mechanical Engineers</b>
<b>AST</b>	<b>Analytical Services Toolkit</b>
<b>ASTM</b>	<b>American Society for Testing and Materials</b>
<b>BSRC</b>	<b>Bioassay Sample Request Card</b>
<b>CFR</b>	<b>Code of Federal Regulations</b>
<b>COC</b>	<b>Chain-of-Custody</b>
<b>cpm</b>	<b>Counts Per Minute</b>
<b>CTR</b>	<b>Contractor Technical Representative</b>
<b>DOE</b>	<b>U.S. Department of Energy</b>
<b>DOT</b>	<b>U. S. Department of Transportation</b>
<b>dpm</b>	<b>Disintegration Per Minute</b>
<b>dps</b>	<b>Disintegration Per Second</b>
<b>EPA</b>	<b>U.S. Environmental Protection Agency</b>
<b>GFE</b>	<b>Government Furnished Equipment</b>
<b>ICRP</b>	<b>International Commission on Radiological Protection.</b>
<b>M&amp;TE</b>	<b>Measuring and Testing Equipment</b>
<b>MDA</b>	<b>Minimum Detectable Amount</b>
<b>NARA</b>	<b>National Archive Record Act.</b>
<b>NIST</b>	<b>U.S. National Institute of Standards and Technology.</b>
<b>NPDES</b>	<b>National Pollution Discharge Elimination System</b>

<b>NRC</b>	<b>Nuclear Regulatory Commission</b>
<b>PL</b>	<b>Project Lead</b>
<b>PRE</b>	<b>Property Release Evaluation</b>
<b>PWRE</b>	<b>Property Waste Release Evaluation</b>
<b>QA</b>	<b>Quality Assurance</b>
<b>QC</b>	<b>Quality Control</b>
<b>RAD</b>	<b>Radioactive</b>
<b>RCM</b>	<b>RFETS Rad Control Manual</b>
<b>RFCA</b>	<b>Rocky Flats Cleanup Agreement</b>
<b>RFETS</b>	<b>Rocky Flats Environmental Technology Site</b>
<b>RFP</b>	<b>Rocky Flats Plant</b>
<b>RIN</b>	<b>Report Identification Number</b>
<b>RSP</b>	<b>RFETS Radiological Safety Practices Manual</b>
<b>SOP</b>	<b>Standard Operating Procedure</b>
<b>SOW</b>	<b>Statement Of Work</b>
<b>SRM</b>	<b>Standard Reference Material</b>
<b>STP</b>	<b>Sewage Treatment Plant</b>
<b>TAT</b>	<b>Turn Around Time</b>
<b>TNU</b>	<b>Thermo NuTech</b>
<b>URC</b>	<b>Unit Rate Charge</b>
<b>VTSR</b>	<b>Validated Time of Sample Receipt</b>

# EXHIBIT H

## REFERENCES

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## REFERENCES

### 1. REFERENCES

- 1.1. ANSI N13.30, *Performance Criteria for Radiobioassay*
- 1.2. DOE Order 414.1, *Quality Assurance*, September 29, 1999, Department of Energy (Replaces DOE Order 5700.6C).
- 1.3. DOE Order 460.1A, *Packaging Transportation Safety*, October 02, 1996 (Cancels 460.1)
- 1.4. DOE Order 460.2 Chg 1, *Departmental Transportation and Packaging Management*, October 26, 1995
- 1.5. DOE G-460.2-1, *Implementation Guide for Use with DOE Order 460.2, Departmental Transportation and Packaging Management*, November 15, 1996
- 1.6. ISO-9000, *Quality Management and Quality Assurance Standards*, 1987 International Standard
- 1.7. NQA-1, 1989, *Quality Assurance Program Requirements for Nuclear Facilities*, American Society for Mechanical Engineers (ASME).
- 1.8. RFETS HSP 18.10 and APPENDIX 2 (Exempt List) Rev 1
- 1.9. RFETS Internal Dosimetry Technical Basis Manual, Version 2.0
- 1.10. RFETS MAN-T91-STSM-001, *Site Transportation Safety Manual*
- 1.11. RFETS PRO-543-ASD-002, *Initiation, Preparation, and Implementation of Chain-Of-Custody Forms*
- 1.12. RFETS PRO-T95-OSTP-002, *Off Site Transportation Procedure*
- 1.13. RFETS Radiological Control Manual
- 1.14. RFETS Radiological Safety Practices Manual
- 1.15. RFETS 1-T91-Traffic-100, *Transportation Manual*
- 1.16. RFETS 1-T92-Traffic-101, *Transportation Quality Assurance Program*
- 1.17. RFETS 1-T93-Traffic-110, *On Site Transportation Manual*
- 1.18. RFETS 1-T97-Traffic-112, *Sample Packaging and Transfers*
- 1.19. RFETS 1-T94-Traffic-115, *On Site Transfer of Non Hazardous Materials*
- 1.20. RFETS 1-T95-Traffic-120, *Off Site Transportation Manual*

- 1.21. Title 10, CFR, Part 830.120, *Nuclear Safety Management; Contractor and Subcontractor Activities*, December 1991, Department of Energy.
- 1.22. Title 10, CFR, Part 835, *Occupational Radiation Protection*.
- 1.23. Title 10, CFR, Part 835/C1, *The DOE Implementation Guide G - Rev. 1*, Internal Dosimetry
- 1.24. Title 10, CFR, Part 1008, Privacy Act and (Public Law 93-579)
- 1.25. Title 40, CFR, Parts 260-265, Protection of Environment
- 1.26. Title 40, CFR, Part 792, *Good Laboratory Practices*, Office of the Federal Register.
- 1.27. Title 49, CFR, Parts 100 through 180, DOT Shipping Regulations
- 1.28. Title 49, CFR, Part 173.421, DOT Class 7 Radioactive Material Limited Quantity Shipment