ENERGYSOLUTIONS

CS-RS-PR-016

Bioassay Sampling

Revision 0

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1.0 PURPOSE AND SCOPE

Bioassay(s) are collected and analyzed to monitor project personnel for internal exposure as required in order to ensure that significant intakes have not occurred and to provide the necessary data to perform dose assessments in the event that a positive result is observed.

1.1 Purpose

It should be noted that internal monitoring via bioassay is the preferred method for measuring the intake of radionuclides; however, DAC-hr tracking may be used. This procedure provides the guidelines and specifies the sampling protocols to be followed for bioassay sample collection and packaging for transport and analysis.

1.2 Scope

This procedure is for the exclusive use of Energy*Solutions* Commercial Services Division and contractors at field project sites where Energy*Solutions* has the primary role in controlling exposures to on-site personnel. Requirements herein are applicable to no other operational entities of Energy*Solutions*.

2.0 REFERENCES

2.1 ANSI HPS N13.39, *Design of Internal Dosimetry Programs, 2001*

2.2 US NRC10CFR20, *Standards for protection against radiation*

2.3 US NRC, Regulatory Guide 8.9, *Acceptable Concepts, Models, Equations, and Assumptions for a Bioassay Program*.

2.4 US NRC, Regulatory Guide 8.34, *Monitoring Criteria and Methods to Calculate Occupational Radiation Doses*.

2.5 US DOE 10CFR835, *Occupational radiation protection*

2.6 CS-FO-PR-003, *Sample Collection and Control*

2.7 CS-RS-PG-001, *Commercial Services Radiation Protection Program*

2.8 CS-RS-PG-002, *Respiratory Protection Program for Radionuclides – Commercial Services Projects*

2.9 CS-RS-PR-010, *Personnel Monitoring for Exposure*

2.10 CS-RS-PR-018, *Internal Dose Assessments*

3.0 GENERAL

3.1 Definitions

3.1.1. *Bioassay (radiobioassay)* – the determination of kinds, quantities or concentrations, and, in some cases, the locations of radioactive material in the human body.

3.1.2. *Critical Level (L_c)* – An amount of activity or concentration above which a decision is made that a positive quantity of activity is present.

3.1.3. *In-Vitro Bioassay (in-direct)* - The estimation of radioactivity in the human body based on the measurement of radioactivity in excreta or other materials taken from the body.

3.1.4. *In-Vivo Bioassay (direct)* - The measurement of radioactivity in the body using instrumentation that detects radiation emitted from radionuclides in the body.

3.1.5. *Minimum Detectable Activity or Concentration (MDA / MDC)* - The smallest amount of activity or concentration of a radionuclide in a sample that will be detected with a 5% probability of erroneously detecting radioactivity, when in fact none was present or false positive (i.e., Type I error) and a 5% probability of not detecting radioactivity, when in fact it is present or false negative (i.e., Type II error).

3.2 Responsibilities

Note: Depending upon personnel qualifications and the size of the project, project personnel may be assigned multiple roles and/or responsibilities.

3.2.1. Commercial Services Radiation Safety Officer

The Commercial Services Radiation Safety Officer (CS RSO) maintains and oversees the implementation of the CS Radiation Protection and Respiratory Protection Programs. The CS RSO shall ensure that radiation safety, radioactive materials management, and radiological operations procedures and programs are kept up to date such that they comply with current regulations and incorporate current and relevant industry practices and regulatory guidance. The CS RSO shall assist the PHP in providing guidance on the proper personnel monitoring requirements and techniques, sampling frequencies and the specification of laboratory detection levels.

3.2.2. Corporate Dosimetry Manager

The Corporate Dosimetry Manager (CDM) is responsible for the implementation, management and data verification of the company designated Health Physics Database and the occupational radiation exposure tracking for Energy*Solutions* personnel. The CDM shall assist the Project Managers, CS RSO and Project Health Physicists with compliance of any regulatory requirements and corporate procedures as applicable regarding personnel monitoring.

3.2.3. Project Manager

The Project Manager (PM) is responsible for ensuring that the proper procedures and programs are implemented on the project site as required by customer agreements and contracts. The PM is responsible for ensuring that these programs and procedures are properly incorporated

into project specific plans and procedures. The PM is responsible for ensuring that Commercial Services and/or client programs and procedures are available for use by field personnel. The PM shall also ensure that individuals provide bioassays as required.

3.2.4. Project Health Physicist

The Project Health Physicist (PHP) is responsible for assisting the CS RSO in providing health physics support to the PM and Radiation Protection Supervisor (RPS). This includes technical support to ensure procedural and regulatory compliance and to ensure that the project specific Data Quality Objectives are met. The PHP with assistance from a Certified Health Physicist (CHP) is responsible for determining the proper personnel monitoring requirements and techniques, sampling frequencies, specifying and verifying MDAs for the analysis laboratory, specifying bioassay turn around times, reviewing laboratory analysis data, and evaluating the need for additional (special) bioassays.

3.2.5. Radiation Protection Supervisor

The Radiation Protection Supervisor (RPS) is responsible for implementing the CS Radiation Protection and Respiratory Protection Programs and the project specific radiological requirements at the field project location. The RPS manages and oversees the project personnel in regards to radiation and respiratory protection and reports directly to both the PM and the CS RSO. The RPS shall, in conjunction with the PM and the PHP, ensure that all personnel have followed the recommendations for internal monitoring including the issuance and collection of bioassay kits as necessary.

3.2.6. Project Personnel

All project personnel are responsible for providing bioassay samples as requested by the RPS and following the sampling protocols as specified.

3.3 Precautions and Limitations

Caution: Notify the RPS, PHP and/or CS RSO of any medical administration of radioisotopes for any testing that may interfere with bioassay measurements such as a stress test, gall bladder study, etc. Provide the date and time of administration and the radionuclide(s) and amounts administered during the test.

3.3.1. Understand the radionuclides of concern including the parts of the body in which the radionuclides concentrate and the primary methods of elimination to ensure proper personnel monitoring techniques.

3.3.2. All analytical laboratories shall be on the approved vendors list.

3.3.3. The shipment and transport of all bioassay materials shall be performed in accordance with all DOT regulation and analytical laboratory requirements as necessary.

3.3.4. Sample containers shall be stored away from sources of potential contamination to ensure they do not become contaminated.

3.3.5. Clean gloves shall be worn when handling bioassay containers or when direct contact with sample material is possible.

3.3.6. All personnel shall wash their hands prior to and after handling bioassay materials.

3.3.7. Food and drink shall not be kept in refrigerators, freezers and cabinets or on shelves, countertops or bench tops where bioassay samples are stored and/or handled.

3.3.8. When using dry ice, handle the dry ice with insulated gloves or tongs in a well ventilated area.

3.3.9. Do not ship dry ice by air. If dry ice is used to keep samples frozen and/or cool during shipment, the package must be shipped by ground only.

3.4 Records

3.4.1. Bioassay Sample Log

3.4.2. Chain-of-Custody

3.4.3. Sample Analysis Results

4.0 REQUIREMENTS AND GUIDANCE

4.1 Monitoring Requirements

4.1.1. The PHP (with approval from a CHP) and/or CS RSO shall determine the frequency of bioassay monitoring depending upon the potential for intake. The frequency of bioassay measurements will be based upon the detection sensitivities of the bioassay sample analyses and an estimate of the potential internal dose that could go undetected between measurements.

4.1.2. The PHP/CHP or the CS RSO shall specify the required detection limits for laboratory analysis as applicable and technically achievable. Detection limits should be as low as reasonably achievable and low enough to detect less than 100 mrem of internal exposure.

4.1.3. Confirmatory monitoring may be performed to verify exposure conditions for workers thought not likely to be exposed at levels requiring routine monitoring. This may be performed by randomly selecting personnel and submitting them to bioassay monitoring to verify the absence of any intake.

4.1.4. Routine monitoring should be performed when there is a potential for intake and involves the regular measurements of individual workers. It usually includes baseline measurements to document any pre-existing intake, periodic measurements to assess any potential intake, and a final bioassay when terminating employment or when terminating work with a specific radionuclide.

4.1.5. Special monitoring shall be performed for the confirmation of a suspected intake or for the follow-up evaluation of a confirmed intake as specified by References 2.9, CS-RS-PR-010, *Personnel Monitoring for Exposure* and 2.10, CS-RS-PR-018, *Internal Dose Assessments*. Instances that may require special monitoring include:

- High facial or nasal contamination
- Entry to airborne radioactivity areas without appropriate exposure controls
- Spills or potential airborne radioactivity excursions due to process equipment failure
- Whenever an intake ≥10 DAC hours may have occurred during the work week, based on air sampling data
- Known or suspected incidents of worker ingestion of radioactive material
- Actual or potentially contaminated wounds or skin absorptions, or
- Evidence of failure of respiratory protection equipment.

4.2 In-Vivo Monitoring

In-vivo monitoring consists of the direct measurement of radionuclides in the body. This is typically referred to as a whole body count or lung count.

4.2.1. The PHP and RPS shall make arrangements with a counting facility as necessary to provide whole body or lung counting services.

4.2.2. The PHP or RPS shall arrange the appointment for the individual and provide the date, time and driving directions to the counting facility as necessary.

4.2.3. If the individual is not able to make it to the set appointment, re-schedule the whole body or lung count as soon as possible.

4.3 In-Vitro Monitoring

In-vitro monitoring includes the sampling and analysis of bodily excretion(s) and typically consists of either 24-hour urine or fecal sampling.

Note: Sample kits are typically provided by the analytical laboratory upon request.

4.3.1. The RPS shall provide the following to personnel for in-vitro bioassay sampling as required.

4.3.1.1. Bioassay Sampling Kit

4.3.1.2. Written sampling instructions and/or protocol, see Attachment 5.2 or equivalent.

4.3.2. Provide verbal instruction to the employee.

4.3.3. Ensure the sample label is attached to the sample container.

4.3.4. Urine and fecal bioassay samples for most radionuclides should be 24-hr samples unless otherwise specified by the PHP and/or the CS RSO.

Note: Urine sampling for Tritium may be based on a single void.

4.4 Sample Collection and Control

4.4.1. Personnel shall follow the sampling instructions and protocols as provided by the RPS and/or PHP.

4.4.2. Personnel providing bioassays shall wash their hands prior to providing the bioassay.

4.4.3. Take precautions to prevent the bioassay container from becoming contaminated. Even small amounts of contamination that is not detectable by field survey instruments may cause problems for accurate quantification of the bioassay sample.

4.4.4. Begin sample collection as directed. For most bioassay samples (i.e., 24-hour) the collection will start with the first void after rising for the day and collect all voids during the day until bedtime including any voids after going to bed. Do not collect the first voiding of the next day.

4.4.5. Keep the container tightly closed and avoid getting any foreign substances in the sample.

4.4.6. Upon completion of sample, complete the sample label as appropriate and include as a minimum:

4.4.6.1. Name and last 4 digits of their SSN or their employee number

4.4.6.2. Date and time of the first and last void

4.4.7. Submit the sample to the RPS for sample control and shipment.

4.4.8. The RPS or designee shall assign the sample a unique sample ID in accordance with Reference 2.6, CS-FO-PR-003, *Sample Collection and Control* and enter the sample on the Bioassay Sampling Log, Attachment 5.1 or equivalent.

4.4.9. The RPS or designee shall enter the following information on the bioassay sampling log.

- Sample identification number
- Donor name and ID
- Date and time of first and last void
- Sample media (urine, fecal, etc.)
- Type of sample (Baseline, Routine, Special, etc.)
- Type of analysis
- COC and/or shipment tracking number

4.4.10. Store samples in accordance with Section 4.5 pending shipment for analysis.

4.4.11. If an individual does not provide a sample within a reasonable time after the due date, the person may be restricted from performing further work with radioactive materials. All failures to obtain bioassay samples, including cases when personnel are terminated without providing a sample, shall be documented.

4.5 Sample Storage

4.5.1. Bioassay samples shall be stored in a designated location away from food and drink.

4.5.2. Bioassay samples **should not** be stored for an extended period of time and should be shipped for analysis within 7 days from sample collection.

Note: Baseline samples may be stored for an extended period of time for analysis on a case by case basis in the event that personnel intake(s) are not anticipated provided they are properly refrigerated or frozen. The samples may be held for analysis if an unplanned event or exposure occurs.

4.5.3. Urine samples in storage should be refrigerated to keep the samples cool.

4.5.4. Fecal samples should be frozen.

4.6 Sample Shipment

Note: The laboratory may provide the shipping container as requested such as a cooler.

Note: DO NOT, under any circumstances, ship bioassay samples via the United States Postal Service (USPS).

4.6.1. Consult the analytical laboratory to ensure any laboratory specific requirements are met regarding the proper packaging, handling and preservation of samples.

4.6.2. Package the samples to ensure no sample loss or damage. Consideration shall be given to normal package handling hazards during transit such as heating, freezing, and breakage. As a minimum, samples will be packaged as follows.

4.6.2.1. Sample containers shall be durable enough to prevent the loss of contents during transportation.

4.6.2.2. Cushion samples as needed to ensure the integrity of the sample container during transit to prevent any breakage.

4.6.2.3. Seal the sample container lid with tape to ensure the cap will not come off during transit.

4.6.2.4. Place a custody seal on the sample signed by the individual submitting the sample.

4.6.2.5. Ensure the sample container is properly labeled as necessary in accordance with Section 4.4.

4.6.2.6. Place each individual sample inside a plastic liner or bag and seal. For liquid samples, double bag the samples and ensure adequate absorbent material such as vermiculite is placed inside the plastic bag(s) in the event that the container leaks or fails.

4.6.2.7. Place the collective samples inside a plastic lined box with additional absorbent material such as vermiculite and seal the liner and the box.

4.6.2.8. As necessary, ship the samples in a cooler containing dry ice or cooler packs in order to keep the samples cool or frozen during shipment. Dry ice may be used for ground shipments only. Any overnight shipments via air service must not use dry ice.

4.6.3. For samples containing dry ice (Ground shipment only):

4.6.3.1. Ensure the total weight of dry ice in the container does not exceed 5.5 pounds or 2.5 kilograms.

4.6.3.2. Ensure the package is properly vented such that the package does not become pressurized during transit.

4.6.3.3. Mark the outside of the package as follows to communicate that the package contains dry ice, the weight of the dry ice and what the package contains:

Dry Ice – Laboratory Samples

Contains ## Pounds of Dry Ice

4.6.4. Complete chain-of-custody (COC) in accordance with Reference 2.6, CS-FO-PR-003, *Sample Collection and Control*, and include the COC with the samples.

4.6.5. Contact an appropriate carrier for shipment and obtain a package tracking number to track the package during transit.

4.6.6. Samples should be shipped either priority or standard overnight delivery on Monday through Thursday such that samples are delivered during normal business hours during the week and to avoid samples in transit over the weekend unless special arrangements have been set up with the analytical laboratory.

4.7 Bioassay Analysis and Review

4.7.1. Bioassay and in-vivo monitoring results will be reviewed by the RPS, PHP and/or designee for any positive results including results greater than the critical level for the analysis. Analyses found to be above the MDA shall be reviewed and forwarded to the PHP and/or CS RSO for further review and dose calculations.

4.7.2. Samples in excess of the critical level, L_c, shall be re-analyzed and/or a subsequent analysis submitted. If the re-analysis or analysis of the subsequent sample is also greater than the critical level, then an internal exposure is assumed to have occurred; otherwise, no exposure is assumed.

4.7.3. An internal dose calculation shall be performed by the PHP, CS RSO or an approved CHP for all positive bioassay results in accordance with Reference 2.10, CS-RS-PR-018, *Internal Dose Assessments*. Additional follow-up bioassay samples or in-vivo measurements may also be needed to more accurately assess intakes and dose.

4.7.4. Any assigned dose as determined by the Internal Dose Assessment shall be entered into the personnel exposure monitoring history as specified in references 2.9, CS-RS-PR-010, *Personnel Monitoring for Exposure*, and 2.10, CS-RS-PR-018, *Internal Dose Assessments*.

5.0 ATTACHMENTS AND FORMS

5.1 Bioassay Sampling Log

5.2 Sample Collection Protocol

(Attachment 5.1) **Bioassay Sampling Log**

Donor Info		Sample Collection				Sample Info			
		Start		End					
Name	SSN	Date	Time	Date	Time	Media [a]	Type [b]	ID	Tracking No.

a Sample media includes urine, fecal, whole body count, etc.
b Type of sample includes, baseline, routing, confirmatory, special

Attachment (5.2) Bioassay Sample Collection Protocol

1. The following shall be provided to employees for in-vitro bioassay sampling:
   - Bioassay sample container
   - Sample collection instructions
   - Sample identification label
2. Follow the verbal sample instructions as provided.
3. Complete the identification required on the label.
4 Record the start date and time of the first void.
5. Begin sample collection with the first void after rising for the day.
6. Wash your hands prior to and after each void.
7. For a 24-hour void sample, collect all voids during the day until bedtime including any voids made after you go to bed.
8. **DO NOT** collect the first void of the next day.
9. Keep the container tightly closed and avoid getting any substances in the sample and store it in a cool place.
10. The minimum **required** volume is ____ milliliters or ____ grams (check with the lab).
11. After sample collection, write the ending date and time on the label.
12. Deliver the sample to the RPS or designated person.