Reviewed By: CJP 1/29/2013; MDG 3/14/2013; JWC 4/1/2013; CJP 7/12/2013;	***Final Approval***: CHARLES KELSEY Digitally signed by CHARLES KELSEY DN: cn=CHARLES KELSEY, o=LOST CREEK ISR, ou=UR-ENERGYUSA, email=charles.kelsey@ur-energyusa.com, c=US Date: 2013.07.17 13:46:47 -06'00'

1.0 PURPOSE

The purpose of this Standard Operating Procedure (SOP) is to describe the bioassay program for the Lost Creek ISR (LC-ISR) project. The purpose of the bioassay program is to ensure the effectiveness of the respiratory protection program, and airborne sampling program, and to demonstrate that worker exposure to airborne uranium is not in excess of regulatory limits and ALARA. Under the scope of this SOP, bioassay will be performed by urinalysis. The program is provided as described in TR Section 5.7.5 pursuant to10 CFR 20.1204 in accordance with NRC Regulatory Guide (RG) 8.22, RG 8.9, NUREG 4884, and NUREG 0874.

2.0 RESPONSIBILITIES

The EHS Department and Radiation Safety Officer are responsible for:

- Implementing the bioassay program;
- Submitting urinalysis samples to an approved laboratory;
- Maintaining records of the bioassay program until license termination;
- Documenting compliance with corrective actions.

3.0 PREREQUISITES AND TRAINING

The RSO and HPT will be familiar with associated regulations and guidance. The RSO and HPT are also responsible for reading and understanding this SOP.

General radiation safety training shall be provided to all personnel who may be exposed to radiation resulting from uranium recovery and resulting byproduct material. Personnel being sampled for bioassay will be familiar with the reasons for a bioassay program, and will be instructed on any relevant sampling procedures.

4.0 DEFINITIONS

Accumulated Urine (Acc. Urine): This is based on the concentration of uranium in urine. In the IRF tabulated values the Accumulated Urine is the fraction of the initial intake of uranium that has been excreted up to that time.

Annual Limit on Intake (ALI)**:** Means the derived limit for the amount of radioactive material taken into the body of an adult worker by inhalation or ingestion in a year. ALI is the smaller value of intake of a given radionuclide in a year by the Reference Man that would result in a committed effective dose equivalent of 5 rems (0.05 Sv) or a committed dose equivalent of 50 rems (0.5 Sv) to any organ or tissue.

Bioassay: The determination of kinds, quantities, or concentrations, and, in some cases, the locations of radioactive material in the human body, whether by direct measurement (in-vivo counting) or by analysis and evaluation of materials excreted or removed from the human body (in-vitro analysis).

Derived Air Concentration (DAC): The concentration of a given radionuclide in air that, if breathed by Reference Man for a working year of 2,000 hours under conditions of light work (inhalation rate 1.2 cubic meters of air per hour), results in an intake of one ALI.

Derived Air Concentration-hour (DAC-hour): The product of the average concentration of radioactive material in air during a specified period of time, expressed as a fraction or multiple of the derived air concentration, and the duration of exposure to that radionuclide, in hours. The DAC-hour expresses an intake, and 2,000 DAC-hours represent an intake of one ALI, equivalent to a committed effective dose equivalent of 5 rems (0.05 Sv).

Incremental Urine (Inc. Urine): This is a method for approximating the 24hr sample. This can be accomplished by voiding the first thing in the morning, just before bed, and the next morning again.

Inhalation Class: Solubility studies have revealed notable differences in the dissolution rates of yellowcake produced under different temperature (i.e., drying and calcining) conditions due to the variation of the density, which is associated with temperature of the unit operation. For the purpose of this guide, for bioassay interpretation and dose assessment, the following distinction is made:

- Soluble yellowcake is defined as yellowcake dried under 400° C.
- Insoluble yellowcake is defined as yellowcake dried at 400° C or higher.

- Uranium ore is defined as naturally occurring earthen material that may be processed in industry to concentrate uranium minerals that it contains.
- Yellowcake areas are defined as those areas that contain uranium extracted from the ore in a liquid solution form from the ion exchange or solvent extraction stage through final packaging.

Intake**:** Activity that enters the body through the respiratory tract, gastrointestinal tract, or skin. Intake may be acute, meaning a single intake occurring over a very short time period, usually taken to be instantaneous; or chronic, occurring over a specified time period. Common units used in this guide for intake are µCi and Bq (e.g., 1 µCi = 3.7×104 Bq).

IRF (Intake Retention Function): This is a ratio of the amount of uranium in urine to the intake amount of uranium. The fraction of the intake that is retained in the body at time (t) following the intake.

Reference Man: This is a mathematical model of the average healthy male worker, and used to calculate dose.

5.0 HAZARD ASSESSMENT AND PPE

Any individual who handles a bioassay sample should be trained in blood borne pathogen safety. Blood borne pathogen information is included in the SOP_LC_ER-002: First Aid and CPR.

Disposable gloves should be used when handling samples. Wash hands after handling samples.

6.0 PROCEDURE

6.1 Sample Types

Sample collection will occur for the following types of bioassay:

- Preoperational or Baseline
- Routine
- Ad-hoc

- Post-operational or Termination

Preoperational or Baseline

Each new worker will provide a bioassay sample. Preoperational samples are used to establish a baseline value for workers. This baseline value can be compared to routine sampling or termination samples show what uranium body burden was caused by working at the site. Most preoperational samples will be non-detects, but some individuals may have been exposed to uranium from previous occupations, or from drinking water wells.

If uranium is detected in a bioassay sample before the employee begins a job assignment then the incident should be investigated. Information concerning the location and quantity in the body should be sought, and estimations of future levels in the body should be made. The causes should be investigated by looking into the work history of the individual and retrieving previous bioassay information if available. The result of the investigation should determine if the individual should be assigned to that job, and how the current uranium levels in their body will be compared to the Action Levels (Table in section 6.4).

Operational Samples

Routine sample collection will be conducted on a monthly basis. Routine bioassay samples will be collected from each worker potentially exposed to yellowcake or directly involved in maintenance tasks in which yellowcake dust may be produced. These activities most likely include yellowcake drying and packaging operations. The following list of employees will submit monthly samples because of their expected likelihood of exposure (subject to change based on activities during operation):

- Plant Operators
- Dryer Operators
- Plant Foreman
- Wellfield Operators

- Maintenance Personnel (if work is performed on the filter presses or in the dryer room)

Employees, who routinely work with the potential for exposure to uranium, will submit their monthly urine samples following 1 to 2 days off from work, or following 36 hours of working in areas not potentially exposing the individual to uranium, to allow for clearance and elimination of uranium that does not become systemic and absorbed by the kidneys. The intake exposure will be assumed to have occurred at the midpoint of the time following the previous sample collection (for intakes approaching 0.1 ALI a more conservative approach will be to assume the uptake occurred immediately following the previous sample collection).

It is standard practice to use the conservative assumption that all of the intake was immediately after the last sample was collected. This assumption can be modified based on situational information. For example, if the employer didn't work in the plant the week following the last sample, then you would assume the exposure was when he returned to the plant. If there is a likely exposure then use that date; for example, if a worker had a positive nasal swipe, or contamination on the inside of a respirator.

Ad-hoc Samples

In addition to routine monthly samples, samples may also need to be collected in response to:

- If there is any reason to suspect that an inhalation exposure to yellowcake. Exposure concentrations are determined by air sampling within the Plant (see SOP_LC_HP-008: *Air Particulate Sampling*). RG 8.22 provides an exposure action limit for suspected exposure of 1×10^{-10} µCi/mL (3.7 µBq/mL) average yellowcake concentration in air for a 40-hour workweek.

- The RSO may designate a bioassay be submitted, as part of the requirements of a Radiation Work Permit (RWP), following a non-routine task with the potential for the inhalation of airborne uranium.

- If a respirator is found to be contaminated internally, then bioassay shall be performed on the wearer (see Respiratory Protection Program SOP LC OHS-007).

- Samples will be collected from employees who may have had an uptake of airborne uranium resulting from an upset condition.

- Immediately after accidental exposure situations, if possible, a urine sample should be collected. This initial sample can be used as baseline. The first urine sample after an exposure will not likely have had time to collect uranium in the bladder. A follow-up urine sample will be collected at the next opportunity following at least 36 hours of non –exposure.

- In the case of bioassay ad-hoc sampling, the intake exposure will be assumed to have occurred at the time of the event warranting the ad-hoc sampling.

Post-operation or Termination

Upon termination of operations, after the discontinuation of uranium-related duties, each worker will be required to provide an exit bioassay within 30 days after the last possible exposure to uranium.

6.2 Sample Collection

Samples will be collected in an area free from contamination and from workers who have not been potentially exposed to uranium for at least 36 hours (RG 8.22 section 6).

The specimens should be collected before the worker enters the work area and in an area free of uranium contamination. The collection may occur at an area designated to be maintained contamination free. The hands should be carefully washed prior to voiding and disposable gloves may be used, as applicable, when voiding as an additional contamination control measure. Disposable collection containers should be used.

Acid or other preservatives may be required to keep the solution from precipitating and to prevent bacterial growth. Sufficient urine volume should be collected to complete 4 separate analyses. Samples will be submitted to an approved laboratory for analysis of uranium. The laboratory will be consulted for appropriate urine volume for the 4 separate analyses (current laboratory requires 50-100mL/4 analyses).

Under unusual circumstances where specimens cannot be collected in this manner, the worker should shower immediately prior to voiding. When a shower is not possible, disposable plastic or rubber gloves should be worn during voiding.

Spikes will be sent in with urine samples as described in section 6.6.2 of this SOP.

Sample Identification information corresponding to the sample bottle ID will be entered on the Chain of Custody Form

6.3 Laboratory Analysis

Samples will be analyzed for U-nat.

Urinalysis results should be available to the RSO within 20 days after specimen collection. The contracted laboratory must report by telephone or email results exceeding 35 µg (RG 8.22 section 6). The RSO will be responsible for documenting compliance with the corrective actions provide in Section 6.4. The corrective actions shall be included in the Annual ALARA Report. A record shall be maintained of bioassay results and associated QA/QC until license termination and in a form compliant with NRC RG 8.7.

Whenever respiratory protection has been used to maintain inhalation exposures below the action levels, the operational bioassay results will be examined by the RSO or HPT to verify the effectiveness of the respirators.

6.4 Corrective Actions

The action levels and corrective actions based on Table A-1 of Reg. Guide 8.22 (reproduced below) will be used according to the results of the analyses.

Urinary Uranium Concentration	Interpretation	Actions
< 15 µg/L	Uranium confinement and air sampling programs are indicated to be adequate.	None. Continue to review further bioassay results.
15 to 35 µg/L	Uranium confinement and air sampling may not provide an adequate margin of safety	1. Confirm results (repeat urinalysis). 2. Identify the cause of elevated urinary uranium and initiate additional control measures if the result is confirmed. 3. Examine air sampling data to determine the source and concentration of intake. If air sampling results are anomalous, investigate sampling procedures. Make corrections if necessary. 4. Determine whether other workers could have been exposed and perform bioassay measurements for them. 5. Consider work assignment limitations until the worker's urinary uranium concentration falls below 15 µg/L. 6. Improve uranium confinement controls or respiratory protection program as investigation indicates.
> 35 µg/L	Uranium confinement and perhaps air sampling programs are not acceptable	1. Take the actions given above. 2. Continue operations only if it is virtually certain than no other worker will exceed a urinary uranium concentration of 35 µg/L. 3. Establish work restrictions for affected employees or increase uranium confinement controls if ore dust or high-temperature-dried yellowcake are involved. 4. Analyze bioassay samples weekly.

Urinary Uranium Concentration	Interpretation	Actions
• Verified > 35 µg/L for two consecutive specimens, • Confirmed to be > 130 µg/L for any single specimen, or • Air sampling indication of more than a quarterly limit of intake (1/4 ALI)	Worker may have exceeded regulatory limit on intake.	1. Take the actions given above. 2. Have urine specimen tested for albuminuria. 3. Evaluate exposures. 4. Establish further uranium confinement controls or respiratory protection requirements as indicated. 5. Consider continued work restrictions on affected employees until urinary concentrations are below 15 µg/L and laboratory tests for albuminuria are negative.

6.5 Intake Determination

Using the concentration of uranium in urine samples, the intake and ultimately the dose to an individual can be calculated. The calculations are based on the metabolic models where:

- 67% of uranium entering blood is excreted via urine in first day without appreciable uptake to tissues;
- 11% of kidney uptake subsequently excreted;
- 22% is systemic uptake which is subsequently released to blood from which:
    - 67% excreted per day;
    - 11% absorbed by kidney and subsequently excreted;
    - 22% reabsorbed back to tissues at which the uptake is a bit over 4% of the original uptake.

The analysis of ad hoc bioassay samples, such as sampling after failed respirator equipment, will determine the specifics of the sampling, such as number and frequency of samples taken. The analysis of ad hoc bioassay results will follow the pertinent Regulatory Guides and NUREGs.

To approximate a 24 hour urine sample, it is assumed that the excretion rate of uranium will be constant over those 24 hours. This is reasonable, because the typically sample time for bioassay will be 30 days after the assumed exposure. The IRF table in the appendix shows a small difference between the 24-hour IRF for 30 days and 40 days

after exposure. Therefore, the 24 hour uranium excretion at the time, t (days post exposure), the sample was collected is calculated as:

$$A_{24}(t) = CEt$$

Where:

C = Uranium concentration in bioassay sample (results from lab analysis)

E = Daily excretion rate (Standard man is 1.4 L/day and Standard woman 1.0 L/day)

t = assumed to be 1 day

An Intake Retention Fraction (IRF) table is provided in the Appendix for a simplified determination of initial uptake of uranium. The IRF table for Class W U-238 is used because there isn't a U-nat table in NUREG 4884 and U-238 is the significant isotope of U-nat; also, the example problem in NUREG 4884 Appendix A Section 2 uses the IRF table for U-238.

For routine monthly bioassay results, the intake is calculated using the following formulas based on RG 8.9 sections 4.3 and 4.3.1:

$$I = \frac{A_{24}(t)}{IRF_{24}(t)}$$

I = Estimate of initial intake quantity with units the same as $A_{24}(t)$

$A_{24}(t)$ = Concentration (or mass) of uranium in bioassay sample collected at time, t, in days since exposure (routine sampling exposure assumed to be date of previous bioassay, see "Operation Sample" of section 6.1 above)

$IRF_{24}(t)$ = 24 hour urine IRF from table in the appendix for time, t, in days since estimated time of intake

6.6 Quality Assurance/Quality Control

6.6.1 Data Objectives

The uranium urinalyses sensitivity and detection shall be achieved at a minimum quantifiable concentration (MQC) of less than 15 µg/L; this is the lowest action level.

6.6.2 Measurement Quality Control

Each batch of urine specimens sent to the contracted laboratory for analysis should be accompanied by at least two control specimens. When possible, these control specimens should be taken from individuals who have not been occupationally exposed to uranium. Aliquots of each of these control urine specimens should be taken; one should be a blank, one should be spiked between 10-20 µg/L, and one should be spiked between 40-60 µg/L. (1988 RG 8.22).Uranium solution used for spiking samples will be obtained from the lab. Spike samples will be prepared as instructed by the lab. Typically 1 ml of uranium solution of known concentration will be added to a flask, and then an aliquot of a blank urine sample will be added to the flask to fill up to 100 ml. The following procedure will be followed for spiking a sample:

1.) Collect uncontaminated sample or use synthetic urine.
2.) Add 1ml of least concentrated spike solution to a 100ml Erlenmeyer flask.
3.) While occasionally swirling for mixing, fill remaining Erlenmeyer flask volume to 100ml mark with urine sample.
4.) Pour flask into sample container.
5.) Rinse flask 3 times with DI water.
6.) Rinse pipette several times with DI water.
7.) Repeat steps 2-6 for the next highest concentration of spike solution.
8.) Rinse the pipette and flask 7 times when finished.

For DOT purposes, the spike samples are exempt quantities (Table from 10 CFR 173.435). The exempt quantity limit for U-nat is 1 Bq/g (2.7×10^{-11} Ci/g) or 1×10^{3} Bq (2.7×10^{-8} Ci). The typical quantities from spike samples being shipped are 50 ug/L (.0013 Bq/g) or 7 ug (0.18 Bq).

6.6.3 Calibration

N/A

6.6.4 Data Verification and Validation

The lab reports will be reviewed by the health physics staff to ensure the data was properly analyzed and the numbers are reasonable. The sample spike measurement

should be within 30% of the amount the sample was spiked with. Data verification is also discussed in SOP_LC_AD-008: *Data Management*.

6.6.5 Audits/Corrective Actions/ALARA

Any anomalous results of control blank and spiked samples will be investigated and corrective actions proposed. Investigations will be provided in the annual Radiation Protection Program Report. Audits are also discussed in SOP_LC_AD-007: *Internal Audit and Corrective Action Program*.

Bioassay data will be reviewed when it is received to determine if actions need to be taken based on the Action Levels. The principles of ALARA will be maintained by the response to the Action Levels in section 6.4, which details when to perform exposure investigations, and when to restrict an employee's assigned tasks to prevent further exposure.

7.0 DOCUMENTS AND RECORDS

Records that shall be retained for the life of the license include:

- Analytical results;
- QA/QC results;
- ALARA investigations or corrective actions if analytical results exceed action limits;

8.0 REFERENCES

Code of Federal Regulation Title 10 Part 20: *Standards for Protection Against Radiation*

NCRP, NCRP 87: *Use of Bioassay Procedures for Assessment of Internal Radionuclide Deposition*

NRC Draft Regulatory Guide DG-8051: *Bioassay at Uranium Mills*, March 2012 (Proposed Revision 2 of Regulatory Guide 8.22, dated August 1988)

NRC License Application Technical Report, Section 5.7.5: *Bioassay Program*, April 2010

NRC NUREG-0874: *Internal Dosimetry Model for Applications to Bioassay at Uranium Mills*, July 1986

NRC NUREG-4884: *Interpretation of Bioassay Measurements*. May 1988

NRC Regulatory Guide 8.9: *Acceptable Concepts, Models, Equations, and Assumptions for a Bioassay Program*, July 1993

NRC Regulatory Guide 8.22: *Bioassay at Uranium Mills*, August 1988

SOP_LC_OHS-007: *Respiratory Protection Program*

SOP_LC_HP-008: *Air Particulate Sampling*

Surgarman, Stephen L. (2012). Rapid Internal and External Dose Magnitude Estimation. The radiation emergency assistance Center/Training Site. http://orise.orau.gov/files/reacts/rapid-internal-external-dose-magnitude-estimation.pdf

Appendix: IRF values from NUREG 4884 page B-342

CLASS W AMAD = 1 MICRON HALFLIFE= 1.16E+12 DAYS URANIUM 238

TIME AFTER SINGLE INTAKE	FRACTION OF INITIAL INTAKE IN:			
DAYS	24-HOUR URINE	ACCUMULATED URINE	24-HOUR FECES	ACCUMULATED FECES
1.00E-01		6.93E-03		8.06E-06
2.00E-01		1.37E-02		1.62E-04
3.00E-01		1.92E-02		8.17E-04
4.00E-01		2.40E-02		2.38E-03
5.00E-01		2.80E-02		5.16E-03
6.00E-01		3.15E-02		9.38E-03
7.00E-01		3.44E-02		1.51E-02
8.00E-01		3.70E-02		2.23E-02
9.00E-01		3.93E-02		3.09E-02
1.00E+00	4.13E-02	4.13E-02	4.07E-02	4.07E-02
2.00E+00	1.09E-02	5.21E-02	1.29E-01	1.70E-01
3.00E+00	4.72E-03	5.69E-02	1.08E-01	2.78E-01
4.00E+00	3.22E-03	6.01E-02	6.28E-02	3.41E-01
5.00E+00	2.69E-03	6.28E-02	3.23E-02	3.73E-01
6.00E+00	2.40E-03	6.52E-02	1.61E-02	3.89E-01
7.00E+00	2.19E-03	6.74E-02	8.29E-03	3.98E-01
8.00E+00	2.02E-03	6.94E-02	4.57E-03	4.02E-01
9.00E+00	1.88E-03	7.13E-02	2.81E-03	4.05E-01
1.00E+01	1.75E-03	7.30E-02	1.96E-03	4.07E-01
2.00E+01	1.03E-03	8.60E-02	1.03E-03	4.19E-01
3.00E+01	7.28E-04	9.44E-02	8.97E-04	4.28E-01
4.00E+01	5.75E-04	1.01E-01	7.81E-04	4.36E-01
5.00E+01	4.80E-04	1.06E-01	6.80E-04	4.44E-01
6.00E+01	4.11E-04	1.10E-01	5.92E-04	4.50E-01
7.00E+01	3.57E-04	1.14E-01	5.15E-04	4.55E-01
8.00E+01	3.12E-04	1.18E-01	4.48E-04	4.60E-01
9.00E+01	2.75E-04	1.20E-01	3.90E-04	4.64E-01
1.00E+02	2.43E-04	1.23E-01	3.40E-04	4.68E-01
2.00E+02	7.49E-05	1.37E-01	8.50E-05	4.86E-01
3.00E+02	2.33E-05	1.41E-01	2.12E-05	4.91E-01
4.00E+02	7.28E-06	1.43E-01	5.31E-06	4.92E-01
5.00E+02	2.46E-06	1.43E-01	1.33E-06	4.92E-01
6.00E+02	1.05E-06	1.43E-01	3.32E-07	4.92E-01
7.00E+02	6.35E-07	1.44E-01	8.30E-08	4.92E-01
8.00E+02	5.13E-07	1.44E-01	2.07E-08	4.92E-01
9.00E+02	4.74E-07	1.44E-01	0.00E+00	4.92E-01
1.00E+03	4.58E-07	1.44E-01	0.00E+00	4.92E-01
3.00E+03	3.28E-07	1.44E-01	0.00E+00	4.92E-01
5.00E+03	2.42E-07	1.45E-01	0.00E+00	4.92E-01
7.00E+03	1.81E-07	1.45E-01	0.00E+00	4.92E-01
9.00E+03	1.36E-07	1.46E-01	0.00E+00	4.92E-01
1.00E+04	1.18E-07	1.46E-01	0.00E+00	4.92E-01