U.S. NUCLEAR REGULATORY COMMISSION

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REGULATORY GUIDE

OFFICE OF STANDARDS DEVELOPMENT

REGULATORY GUIDE 8.22
BIOASSAY AT URANIUM MILLS

A. INTRODUCTION

Section 20.108, "Orders Requiring Furnishing of Bioassay Services," of 10 CFR Part 20, "Standards for Protection Against Radiation," states that, where necessary or desirable in order to aid in determining the extent of an individual's exposure to concentrations of radioactive material, the NRC may incorporate appropriate provisions in any license directing the licensee to make available to the individual appropriate bioassay services. Paragraphs 20.103(a)(1) and 20.103(a)(2) require licensees to limit intakes of materials such as uranium by individuals in restricted areas to the limits specified in Appendix B to 10 CFR Part 20. As specified in paragraph 20.103(a)(3), compliance with these limits must be determined through air sampling and bioassays, as appropriate.

Paragraph 20.103(a) permits licensees to make allowance for the use of respiratory protective equipment in determining the magnitude of an intake provided such equipment is used as stipulated in Regulatory Guide 8.15, "Acceptable Programs for Respiratory Protection." This guide states that the licensee must perform bioassays, as appropriate, to evaluate individual exposures and to assess the protection actually provided. Respiratory protection devices do not always offer sufficient protection. If one is defective, is inappropriate for the particular contaminant involved, does not fit the wearer properly, or is carelessly put in place, the wearer may unknowingly receive a significant inhalation exposure. Therefore, if the potential intake was sufficiently large, bioassay procedures are required to determine whether such devices were in fact effective.

An acceptable bioassay program for uranium mills, including exposure conditions with and without the use of respiratory protection devices, is described in this guide.

B. DISCUSSION

This guide is based on information presently available to the NRC staff. Information acquired in the future may result in revisions. In particular, if bioassay results accumulated over a sufficiently long period of time indicate that workers at uranium mills are being adequately protected from airborne uranium by means of ventilation equipment and effective air sampling programs, the guide may be revised accordingly.

C. REGULATORY POSITION

1. Working Conditions Under Which Bioassays Should Be Performed

Routine bioassays are necessary for all workers (1) routinely exposed to airborne yellowcake or directly involved in maintenance tasks in which yellowcake dust may be produced and (2) routinely exposed to airborne uranium ore dust. Baseline bioassays should be performed prior to initial assignments for such work. Bioassays should also be performed if there is any reason to suspect an inhalation exposure to yellowcake exceeding 40 x 10^{-10} μCi-h/ml in a period of 1 workweek or to ore dust exceeding 520 x 10^{-10} μCi-h/ml in a period of 1 calendar quarter.

2. Types of Bioassay

Urinalysis should be performed to enable measurements of the more soluble component of yellowcake. In vivo measurements should be made to permit control of exposure to (1) the more insoluble yellowcake component and (2) uranium ore dust.

3. Frequency

a. Urinalysis

Workers in the yellowcake concentrate areas may be exposed to transient levels of airborne yellowcake dust that may cause chemical damage to the kidney. Therefore, urinalysis should be performed with sufficient frequency to detect such exposures before the elimination of uranium from the body renders the exposure undetectable. Specimens should be collected at least every 2 weeks. The measurement sensitivity provided should be 5 μg/l or less.

b. In vivo

Annual in vivo measurements should be performed using equipment capable of measuring 9 nCi or less of uranium in the lung.

4. Action Based on Bioassay Results

Bioassay results should be carefully reviewed by qualified personnel, and appropriate action should be taken if the results exceed preselected levels. The corrective actions to be taken depend on the amount of uranium detected.

a. Urinalysis

It should be assumed that any positive urinalysis results are an indication of soluble uranium to which the kidney has been exposed. Corrective action should be taken in accordance with Table 1 of this guide.

A value of 30 μg/l in urine as shown in Table 1 is equivalent to 20 pCi/l or 62 d/m per day. Under equilibrium conditions, these are limiting values for chemical toxicity above which there is a possibility of damage to the kidneys. A value of 130 μg/l obtained within 2 weeks following a single intake of yellowcake indicates that the intake may have been sufficiently large to cause kidney damage.

b. In vivo

It should be assumed that positive in vivo results indicate the quantity of uranium in relatively insoluble form that has accumulated in the lung. Corrective action should be taken in accordance with Table 2 of this guide.

5. Time of Specimen Collection and Analysis and of Obtaining Results

a. Routine specimens should be collected at least 48 hours, but not more than 96 hours, after the most recent occupancy of the yellowcake concentrate area. (The 48-hour delay is necessary to avoid uranium that is eliminated without uptake in kidney tissues. The 96-hour limit is necessary to permit detection of an exposure before elimination renders it undetectable.)

b. Urinalysis results should be available to the person responsible for conducting the bioassay program within 20 days after specimen collection. If the urinalyses are performed by an outside laboratory, results exceeding 30 μg/l should be reported by telephone.

c. In vivo results should be available to the person conducting the bioassay program within 30 days after measurement. Results exceeding 16 nCi should be reported by telephone.

6. Prevention of Specimen Contamination

a. Collection

Specimens should normally be collected when the worker returns to the mill after being away for at least 2 (but not more than 4) days. The specimens should be collected before the worker enters a restricted area and in an area free of uranium contamination. The hands should be carefully washed prior to voiding. Disposable collection containers should be used.

Under unusual circumstances where specimens cannot be collected in this manner, the worker should shower immediately prior to voiding and should wear new plastic or rubber gloves during the voiding procedure.

b. Laboratory Analysis

All laboratory analyses should be performed in a laboratory free of uranium contamination, using containers and equipment free of such contamination. Use of the laboratory, containers, and equipment for process or environmental samples should be prohibited. (Note: The laboratory may be located within the restricted area provided these conditions are met.)

c. At least one specimen obtained from a person who is known to have no lung or systemic uranium burden other than that from natural background should be processed along with each batch of specimens collected from yellowcake workers. The purpose of this specimen is to permit the detection of uranium contamination in the laboratory or in the equipment and containers used.

d. The actions specified in Table 1 should be taken for any result that is confirmed by a second analysis, even though specimen contamination is believed to be the cause of the elevated result.

7. Quality Control

Each batch of specimens obtained from yellowcake workers should be processed with at least two additional specimens obtained from persons who are known to have no lung or systemic uranium burden other than that from natural background. Prior to processing, at least one of these specimens should be contaminated to a known concentration of 15 μg/l,

and at least one other specimen should be contaminated to a known concentration of 30 μg/l. If any of the results obtained for these quality control specimens are in error by $\pm$30% or more, repeat collection (if necessary) and analyses should be performed for the entire batch.

Aliquots from at least 25% of the specimens obtained from workers should be contaminated with a known uranium concentration (''spiked'') and processed with the routine specimens. If a result for a ''spiked'' specimen is in error by $\pm$30% or more, repeat collection (if necessary) and analyses should be performed for that specimen.

8. Use of Respiratory Protection Devices

Licensees using respiratory protective devices in accordance with paragraph 20.103(c) of 10 CFR Part 20 are required to conduct bioassay programs in accordance with Regulatory Guide 8.15 and NUREG-0041, ''Manual of Respiratory Protection Against Airborne Radioactive Materials.''*

Under certain conditions, bioassay measurements should be performed to evaluate the actual effectiveness provided by respiratory protection devices. If an individual wearing such a device is subjected to a concentration of yellowcake in air within a period of 1 week such that the exposure if he or she had not been wearing the device would have exceeded 40 x C μCi-h/ml (where C is the concentration value given in 10 CFR Part 20, Appendix B, Table 1, Column 1, for soluble natural uranium), urinalysis should be performed to test the actual effectiveness of the device. This special bioassay measurement should also be performed if for any reason the magnitude of the exposure (that would have occurred if no respiratory protection device had been worn) is unknown.

The urinalysis frequency given in Section C.3.a of this guide should not be reduced because of the use of respiratory protective devices.

* Copies may be obtained from the National Technical Information Service, Springfield, Va. 22161.

D. IMPLEMENTATION

The purpose of this section is to provide information to applicants and licensees regarding the NRC staff's plans for using this regulatory guide.

This guide reflects current NRC staff practice. Therefore, except in those cases in which the licensee or applicant proposes an acceptable alternative method for complying with specified portions of the Commission's regulations, the methods described herein will be used as a basis for the evaluation of the bioassay program of uranium mill licensees or proposed programs of applicants for such licenses.

Table 1

CORRECTIVE ACTIONS BASED ON URINARY URANIUM RESULTS

Urinary Uranium Concentration	Interpretation	Actions
Less than 15 μg/l	Uranium confinement and air sampling capabilities are adequate.	None.
15 to 30 μg/l	Uranium confinement and perhaps air sampling capabilities do not provide an adequate margin of safety.*	1. Confirm results (repeat urinalysis). 2. Determine why air samples were not representative and did not warn of excessive concentrations of airborne uranium. Make corrections. 3. Identify the cause of airborne uranium and initiate additional control measures. 4. Determine whether other workers could have been exposed and perform bioassay measurements for them. 5. Consider work assignment limitations to ensure the worker does not exceed a urinary uranium concentration of 30 μg/l.
Greater than 30 μg/l	Uranium confinement and perhaps air sampling capabilities are not acceptable.*	1. Take the actions given above for 15 to 30 μg/l. 2. Continue operations only if it is virtually certain that no other worker will exceed a urinary uranium concentration of 30 μg/l. 3. Establish work restrictions for affected employees.
Greater than 30 μg/l for four consecutive specimens or greater than 130 μg/l for any specimen	Possibility of kidney damage to worker.	1. Take the actions given above. 2. Have additional urine specimen tested for albuminuria.

*Unless the result was anticipated and caused by conditions already corrected.

Table 2
CORRECTIVE ACTIONS BASED ON IN VIVO RESULTS

Amount of Uranium Detected	Interpretation	Actions
Below 9 nCi of uranium	This result does not necessarily indicate that uranium confinement and air sampling capabilities are confirmed.	Rely on urinalysis results to determine corrective actions.
9 to 16 nCi	Confinement and air sampling capabilities unreliable.* Uranium activity in lungs undesirably high.	1. Confirm result (repeat measurement). 2. Determine why air samples were not representative and did not warn of excessive airborne uranium. Make corrections. 3. Identify the cause of airborne uranium and initiate additional control measures. 4. Determine whether other workers could have been exposed and perform bioassay measurements for them. 5. Consider work assignment limitations that will permit the lung burden to be reduced through natural elimination; ensure that the lung burden does not exceed 16 nCi.
More than 16 nCi	Confinement and air sampling not acceptable.*	1. Take the actions listed above for 9 to 16 nCi. 2. Establish work restrictions for affected workers. (Normally workers with a lung burden greater than 16 nCi are not allowed by their employer to resume work in airborne activity areas until the burden is reduced to less than 9 nCi.) 3. Perform individual case studies (bioassays) for affected workers. 4. Continue operations only when it is virtually certain no additional workers will exceed 16 nCi.

*Unless the result was anticipated and caused by conditions already corrected.

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