



# REGULATORY GUIDE

OFFICE OF NUCLEAR REGULATORY RESEARCH

## REGULATORY GUIDE 8.22

(Task OP 013-4)

## 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, as appropriate, through bioassays.

Paragraph 20.103(b)(2) permits licensees to make allowance for the use of respiratory protection equipment in determining the magnitude of intake provided such equipment is used as stipulated in paragraphs 20.103(c) through (g). These paragraphs require the licensee to perform bioassays, as appropriate, to evaluate individual exposure and to assess the protection actually provided. Respiratory protection devices do not always offer efficient protection. If a device 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 should be performed to determine whether such devices were in fact effective.

This guide describes a bioassay program acceptable to the NRC staff for uranium mills (and applicable portions of uranium conversion facilities where the possibility of exposure to yellowcake dust exists), including exposure conditions with and without the use of respiratory protection devices.

Any information collection activities mentioned in this regulatory guide are contained as requirements in 10 CFR Part 20, which provides the regulatory basis for this guide. The information collection requirements in 10 CFR Part 20 have been cleared under OMB Clearance No. 3150-0014.

## B. DISCUSSION

This guide is based on information from the references, public comments received on the versions published in July 1978 and January 1987, data submitted by the milling industry, and an analysis by the staff of the Office of Nuclear Regulatory Research (NUREG-0874, "Internal Dosimetry Model for Applications to Bioassay at Uranium Mills," Ref. 1). Information acquired in the future may result in revisions to this guide; 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. DEFINITIONS

Recent solubility studies have revealed notable differences in the dissolution rates of yellowcake produced under different thermal conditions. For the purpose of this guide, the following distinction is made:

- a. Low-fired yellowcake is defined as yellowcake dried at temperatures less than 400° C.
- b. High-fired (calcined) yellowcake is defined as yellowcake dried at temperatures of 400° C or more.

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Two important areas in a uranium mill where workers are exposed to uranium are defined as follows:<sup>1</sup>

- a. Ore-dust areas, under normal conditions, are defined as those areas beginning with the transfer of ore from the ore pad to the crusher through the final thickening stage of the leaching operation.
- b. Yellowcake areas are defined as those areas that contain uranium extracted from the ore in a solution form from the ion exchange or solvent extraction stage through final packaging.

## 2. WORKING CONDITIONS UNDER WHICH BIOASSAYS SHOULD BE PERFORMED

Routine bioassays are considered by the NRC staff to be necessary for workers (1) routinely exposed to airborne yellowcake or directly involved in maintenance tasks in which yellowcake dust may be produced or (2) routinely exposed to airborne uranium ore dust. Baseline urinalysis bioassays should be performed for each worker prior to initial assignments for such work. Bioassays should be performed if there is any reason to suspect an inhalation exposure exceeding that resulting from exposure to an average yellowcake concentration<sup>2</sup> of  $10^{-10}$   $\mu\text{Ci/mL}$  ( $3.7 \times 10^{-6}$  Bq/mL) for a 40-hour workweek or to an average ore-dust concentration of  $10^{-10}$   $\mu\text{Ci/mL}$  ( $3.7 \times 10^{-6}$  Bq/mL) (based on the concentration of gross alpha activity in air) for a period of 1 calendar quarter; if respiratory protection is used to maintain inhalation exposures below these quantities, bioassay should be performed to verify the effectiveness of the respirators.

## 3. TYPES OF BIOASSAY

Urinalysis should be performed to monitor exposures to uranium in ore dust as well as in yellowcake as they clear from the kidney before elimination renders them undetectable. In vivo thorax measurements should be made to detect the presence of (1) the more insoluble yellowcake component and (2) uranium in ore dust in the lung when air-sampling results indicate an exposure exceeding that resulting from exposure to such materials at an average concentration of  $10^{-10}$   $\mu\text{Ci/mL}$

<sup>1</sup>If these definitions do not apply to a specific milling operation, the applicant may submit different definitions for consideration.

<sup>2</sup>The  $1 \times 10^{-10}$   $\mu\text{Ci/mL}$  ( $3.7 \times 10^{-6}$  Bq/mL) value is not exactly consistent with the  $0.2 \text{ mg/m}^3$  concentration limit for soluble uranium in Footnote 4 of Appendix B to 10 CFR Part 20 because of the rounding off of values in Appendix B. Since the  $1 \times 10^{-10}$   $\mu\text{Ci/mL}$  limit is more restrictive, this value has been used in the calculation of all the action levels (weekly and quarterly) in this guide. For compliance purposes, Footnote 4 to Appendix B sets the weekly limit for soluble uranium compounds, which can be converted to radiological units using the specific activity of natural uranium ( $6.77 \times 10^{-7}$  Ci/g or  $2.5 \times 10^4$  Bq/g). As now defined in 10 CFR Part 20, the curie of natural uranium differs from the original definition in ICRP-2 (Ref. 2). The present definition of the curie of natural uranium in 10 CFR Part 20 refers to the total activity of all uranium isotopes in the natural uranium mixture. When natural uranium is defined to be 0.711% by weight  $^{235}\text{U}$  and the  $^{234}\text{U}$  is assumed to be in secular equilibrium with  $^{238}\text{U}$ , 1 Ci of natural uranium is composed of 0.489 Ci  $^{234}\text{U}$ , 0.0225 Ci  $^{235}\text{U}$ , and 0.489 Ci  $^{238}\text{U}$ . Actual percentages of  $^{235}\text{U}$  may be  $0.711 \pm 0.1\%$ .

( $3.7 \times 10^{-6}$  Bq/mL) (based on the concentration of gross alpha activity in air) in a period of 1 calendar quarter.

## 4. FREQUENCY

### 4.1 General Considerations

The prescribed frequency of urinalysis and in vivo lung measurements is a function of the dissolution rates of the inhaled ore dust or yellowcake in the lungs. Workers in the yellowcake concentrate areas may be exposed to transient levels of airborne uranium that may cause chemical damage to the kidney. Therefore, urinalysis should be performed with sufficient frequency to detect such exposures before elimination from the body renders them undetectable. Guidance on selecting appropriate frequencies is available in NUREG-0874 (Ref. 1). The applicant may use the simplified system of frequencies and action levels presented in this guide.

### 4.2 Urinalysis for Workers from Yellowcake Areas

Specimens from workers, regardless of whether or not respiratory protection devices were used, should be collected and evaluated at least once per month, and additional special specimens should be collected and evaluated if for any reason an inhalation exposure exceeding that resulting from an exposure to an average yellowcake concentration of  $10^{-10}$   $\mu\text{Ci/mL}$  ( $3.7 \times 10^{-6}$  Bq/mL) for a 40-hour workweek is suspected or air sampling data are not available.

### 4.3 Urinalysis for Workers from Ore-Dust Areas Exclusively

Specimens from workers, regardless of whether or not respiratory protection devices were used, should be collected and evaluated at least once per month, and additional special specimens should be collected and evaluated if for any reason an inhalation exposure exceeding that resulting from an exposure to an average ore-dust concentration of  $10^{-10}$   $\mu\text{Ci/mL}$  ( $3.7 \times 10^{-6}$  Bq/mL) (based on the concentration of gross alpha activity in air) for a period of 1 calendar quarter is suspected.

### 4.4 In Vivo Lung (Thorax) Measurements

The lung counting procedure should be capable of detecting (at the lower limit of detection (LLD)) 9 nCi (330 Bq) or less of uranium in the lungs.

When urinalysis results call for in vivo measurements (see Section 5), they should be performed as quickly as possible to determine if corrective measures are required.

When air monitoring or exposure calculations call for in vivo measurements (see Section 3), they should be performed as quickly as practicable but no later than 3 months after such indication.

### 4.5 Measurement Detection Limits

The measurement sensitivity for urine analyses should be such that the LLD (for a probability of 0.05 for a Type I or a Type II statistical error) is 5  $\mu\text{g}$  of uranium per liter of urine or

less (see Appendix A for an example of the determination of LLD). The LLD for uranium counting in vivo should be 9 nCi (330 Bq) or less of uranium in the lungs.

## 5. ACTION BASED ON BIOASSAY RESULTS

Bioassay results should be promptly and 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. Action levels and actions in Tables 1 and 2 are acceptable as a basis for a uranium mill bioassay program. Proposals for other action levels and actions from an applicant will be considered on a specific-case basis if accompanied by a description of how the information in NUREG-0874 (Ref. 1) was used to derive those different criteria.

It should be assumed that any confirmed positive urinalysis results are an indication of soluble uranium to which the kidney has been exposed.

### 5.1 Urinalysis for Workers from High-Fired-Yellowcake Areas

The corrective actions to be taken depend on the amount of uranium detected and are given in Table 1. Figure 1 and other information in NUREG-0874 (Ref. 1) may be used to determine acceptable action levels for a single intake as a function of time for workers from high-fired-yellowcake areas.

### 5.2 Urinalysis for Workers from Low-Fired-Yellowcake Areas

The corrective actions to be taken depend on the amount of uranium detected and are given in Table 1. Figure 2 and other information in NUREG-0874 (Ref. 1) may be used to obtain acceptable action levels for a single intake as a function of time for workers from low-fired-yellowcake areas.

### 5.3 Urinalysis for Workers from Ore-Dust Areas Exclusively

The corrective actions to be taken depend on the amount of uranium detected and are given in Table 1. Figure 3 and information in NUREG-0874 (Ref. 1) may be used to obtain acceptable action levels for a single intake as a function of time for workers from ore-dust areas.

### 5.4 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.

## 6. TIME OF SPECIMEN COLLECTION AND AVAILABILITY OF RESULTS

Routine and special urine specimens for analysis of uranium compounds pertinent to mill operations should usually be collected at least 36 hours after the most recent

occupancy in the mill. The 36-hour delay is necessary to avoid uranium that is eliminated without uptake in kidney tissues. (However, if compounds are encountered that mainly produce a very short-lived component, Morrow (Ref. 3, p. 6) recommends the use of two action levels: a 1 µg/L Monday morning urinary excretion rate and an exposure-associated urinary output of 100 µg/L during the first 24 hours after the exposure. Tables 1 and 2 would not necessarily be applicable to these results.) Sufficient volume should be collected for four analyses, each of which should be capable of achieving an LLD of 5 µg/L (see Appendix A).

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 35 µg/L should be reported by telephone.

In vivo results should be available to the person conducting the bioassay program within 20 days after measurement. Results exceeding 16 nCi (590 Bq) should be reported by telephone.

## 7. PREVENTION OF SPECIMEN CONTAMINATION<sup>3</sup>

### 7.1 Collection

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 outside the mill specifically designated to be maintained contamination free. 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. When a shower is not possible, disposable plastic or rubber gloves should be worn during voiding.

### 7.2 Laboratory Analysis

All laboratory analyses should be performed in a laboratory essentially free of uranium contamination using containers and equipment essentially free of such contamination. Both on-site and off-site laboratories should maintain the quality control procedures specified in Section 8 of this guide. Use of the laboratory, containers, and equipment for process or environmental samples should be restricted to low-level samples. (Note: The laboratory may be located within the restricted area provided these conditions are met.)

### 7.3 In Vivo Counting Precautions

For in vivo measurements, employee and clothing contamination are major sources of measurement bias. Care must be taken to minimize these factors. Only new clothing or clothing washed in a facility separate from those used for

<sup>3</sup>The appropriate 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.

potentially contaminated clothing should be worn during the in vivo measurement. If the in vivo measurement results indicate contamination, the subject should reshower, use clean clothing, and be recounted.

## 8. QUALITY CONTROL

A quality control program for bioassay measurements should be incorporated in each uranium mill bioassay program. A quality control program consistent with that recommended in the draft standard ANSI/HPS-N13.30 (Ref. 4) will be acceptable. Alternatively, the following specific quality control program for bioassay at uranium mills will be acceptable.

### 8.1 Urinalysis

Each batch of specimens sent to the laboratory for analysis should be accompanied by at least two control urine specimens. When possible, these control specimens should be taken from individuals who are not and have not been occupationally exposed to uranium; otherwise simulated controls known to contain a uranium concentration less than 1  $\mu\text{g/L}$  may be used. Aliquots of each of these control urine specimens should be taken; one should be a "blank," one should be spiked with uranium to obtain a concentration of 10 to 20  $\mu\text{g/L}$ , and one should be spiked to 40 to 60  $\mu\text{g/L}$ , the actual spiked concentrations being recorded confidentially and not available to the analytical laboratory. When results are received, the licensee should ensure that each reading is corrected for the reading of the corresponding blank, that the net reading of each spiked sample is recorded, and that an average of the percent deviation of the spiked sample net reported values from the "true" amount of spiked uranium sample is calculated. The percent deviation for the spiked samples accompanying each batch of urine specimens should be within 30% of the spiked values. Otherwise, the most recent batch of affected samples should be rerun, and steps should be taken to correct the procedures for spiking or the procedures for laboratory analyses, or both.

In order to provide adequate quality control within the analytical laboratory as well as to provide a check on the quality control program of the mill, the analytical laboratory should duplicate the analysis of 10% to 20% of the samples received, including the blanks and spikes received from the mill. In addition, the laboratory should measure its own reagent and urine blanks and spiked standards as appropriate to check its own procedures, provide its own calibration factors, check its LLDs, and evaluate its results for each batch. The laboratory should report the results of

its own blank and standard samples along with the other results reported to the mill.

### 8.2 In Vivo

For in vivo measurements, a quality control program using persons known to have no lung or systemic uranium burdens and phantoms spiked with known amounts of uranium should be used to test the counting system before measurements on each group of employees.

## 9. USE OF RESPIRATORY PROTECTION DEVICES

Licensees using respiratory protection devices in accordance with paragraph 20.103(c) of 10 CFR Part 20 are to conduct bioassay programs in accordance with paragraph 20.103(c)(2) and NUREG-0041, "Manual of Respiratory Protection Against Airborne Radioactive Materials" (Ref. 5).

Under certain conditions, bioassay measurements should be performed to ensure the proper evaluation of personnel exposure and to evaluate the actual effectiveness provided by respiratory protection devices. If a worker wearing such a device is subjected for a period of 1 week to an average concentration greater than  $10^{-10}$   $\mu\text{Ci/mL}$  ( $3.7 \times 10^{-6}$  Bq/mL), as given in Table 1, Column 1, of Appendix B to 10 CFR Part 20 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 time that the sample for this special measurement was collected should be recorded; it should be consistent with the need to relate bioassay results to kidney exposure (see Section 6).

The appropriate urinalysis or in vivo measurement given in Section 3 of this guide should not be reduced because of the use of respiratory protection devices.

### 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.

Except in those cases in which an applicant or licensee proposes an acceptable alternative method for complying with specified portions of the Commission's regulations, the method described in this guide will be used in the evaluation of existing bioassay programs of uranium mill licensees or proposed programs of applicants for such licenses.

Table 1

CORRECTIVE ACTIONS BASED ON MONTHLY URINARY URANIUM RESULTS<sup>a</sup>

Urinary Uranium Concentration	Interpretation	Actions
Less than 15 $\mu\text{g/L}$	Uranium confinement and air sampling programs are indicated to be adequate. <sup>b</sup>	None. Continue to review further bioassay results.
15 to 35 $\mu\text{g/L}$	Uranium confinement and air sampling may not provide an adequate margin of safety. <sup>b</sup>	<ol style="list-style-type: none"> <li>1. Confirm results (repeat urinalysis).</li> <li>2. Identify the cause of elevated urinary uranium and initiate additional control measures if the result is confirmed.</li> <li>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.</li> <li>4. Determine whether other workers could have been exposed and perform bioassay measurements for them.</li> <li>5. Consider work assignment limitations until the worker's urinary uranium concentration falls below 15 <math>\mu\text{g/L}</math>.</li> <li>6. Improve uranium confinement controls or respiratory protection program as investigation indicates.</li> </ol>
Greater than 35 $\mu\text{g/L}$	Uranium confinement and perhaps air sampling programs are not acceptable. <sup>c</sup>	<ol style="list-style-type: none"> <li>1. Take the actions given above.</li> <li>2. Continue operations only if it is virtually certain than no other worker will exceed a urinary uranium concentration of 35 <math>\mu\text{g/L}</math>.</li> <li>3. Establish work restrictions for affected employees or increase uranium confinement controls if ore dust or high-temperature-dried yellowcake are involved.</li> <li>4. Analyze bioassay samples weekly.</li> </ol>
Confirmed to be greater than 35 $\mu\text{g/L}$ for two consecutive specimens, confirmed to be greater than 130 $\mu\text{g/L}$ for any single specimen, or air sampling indication of more than a quarterly limit of intake	Worker may have exceeded regulatory limit on intake.	<ol style="list-style-type: none"> <li>1. Take the actions given above.</li> <li>2. Have urine specimen tested for albuminuria.</li> <li>3. Obtain an in vivo count if worker may have been exposed to Class Y material or ore dust.</li> <li>4. Evaluate exposures.</li> <li>5. Establish further uranium confinement controls or respiratory protection requirements as indicated.</li> <li>6. Consider continued work restrictions on affected employees until urinary concentrations are below 15 <math>\mu\text{g/L}</math> and laboratory tests for albuminuria are negative.</li> </ol>

<sup>a</sup>Use Figures 1-3 to adjust action levels for other frequencies of bioassay sampling. The model used in NUREG-0874 (Ref. 1) employs fractional composition values ( $F_1$ ,  $F_2$ ,  $F_3$ ) for Class D, Class W, and Class Y components of yellowcake compounds. The assigned values in NUREG-0874 are based on data from available literature. The use of alternative values of  $F_1$ ,  $F_2$ , and  $F_3$  specific for a particular operation are acceptable provided (1) details regarding their determination are described and mentioned in employee exposure records (see paragraph 20.401(c)(1) of 10 CFR Part 20) and (2) the model as published in NUREG-0874 is then used in the determination of alternative urinalysis frequencies and action levels.

<sup>b</sup>However, if a person is exposed to uranium ore dust or other material of Class W or Y alone, refer to Section 6 of NUREG-0874 about the possibility of the need for conducting in vivo lung counts on selected personnel or about using alternative urine sampling times and associated action levels computed using NUREG-0874.

<sup>c</sup>Unless the result was anticipated and caused by conditions already corrected.

Table 2

CORRECTIVE ACTIONS BASED ON IN VIVO RESULTS<sup>a</sup>

Amount of Uranium Detected	Interpretation	Actions
Below 9 nCi (330 Bq)	May be below detection limit. This result does not necessarily indicate that uranium confinement and air sampling programs are validated.	Rely on urinalysis results to determine corrective actions (unless air sampling indicates quarterly intake limits are exceeded for ore dust).
9 to 16 nCi (330 to 590 Bq)	Confinement and air sampling programs should be examined. <sup>b</sup> Uranium activity in lungs could be too high.	<ol style="list-style-type: none"> <li>1. Confirm result (repeat measurement within 6 months). Ensure that results are not caused by body surface activity.</li> <li>2. Examine air sampling data to determine source and concentrations of intake. If air sampling results are anomalous, investigate air sampling procedures. Make corrections, if necessary.</li> <li>3. Identify the cause of elevated activity and initiate additional uranium confinement control measures.</li> <li>4. Determine whether other workers could have been exposed and perform special bioassay measurements for them.</li> <li>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 (590 Bq).</li> </ol>
More than 16 nCi (590 Bq)	Uranium confinement and air sampling probably are not acceptable. <sup>b</sup> Uranium activity in the lungs should be reduced by increased protection measures for the workers involved.	<ol style="list-style-type: none"> <li>1. Within 90 days, take the actions listed above for 9 to 16 nCi (330 to 590 Bq).</li> <li>2. Establish work restrictions for affected workers or increased uranium confinement control measures. (Normally workers with a lung burden greater than 16 nCi (590 Bq) are not allowed by their employer to resume work in airborne activity areas until the burden is reduced to less than 9 nCi or 330 Bq.)</li> <li>3. Perform individual case studies (bioassays) for affected workers.</li> <li>4. Continue operations only when it is virtually certain no additional workers will exceed 16 nCi (590 Bq).</li> </ol>

<sup>a</sup>The model used in NUREG-0874 (Ref. 1) employs fractional composition values ( $F_1$ ,  $F_2$ ,  $F_3$ ) for Class D, Class W, and Class Y components of yellowcake compounds. The assigned values in NUREG-0874 are based on data from available literature. The use of alternative values of  $F_1$ ,  $F_2$ , and  $F_3$  specific for a particular operation are acceptable provided (1) details regarding their determination are described and mentioned in employee exposure records (see paragraph 20.401(c)(1) of 10 CFR Part 20) and (2) the model as published in NUREG-0874 is then used in the determination of alternative urinalysis frequencies and action levels.

<sup>b</sup>Unless the result was anticipated and caused by conditions already corrected.

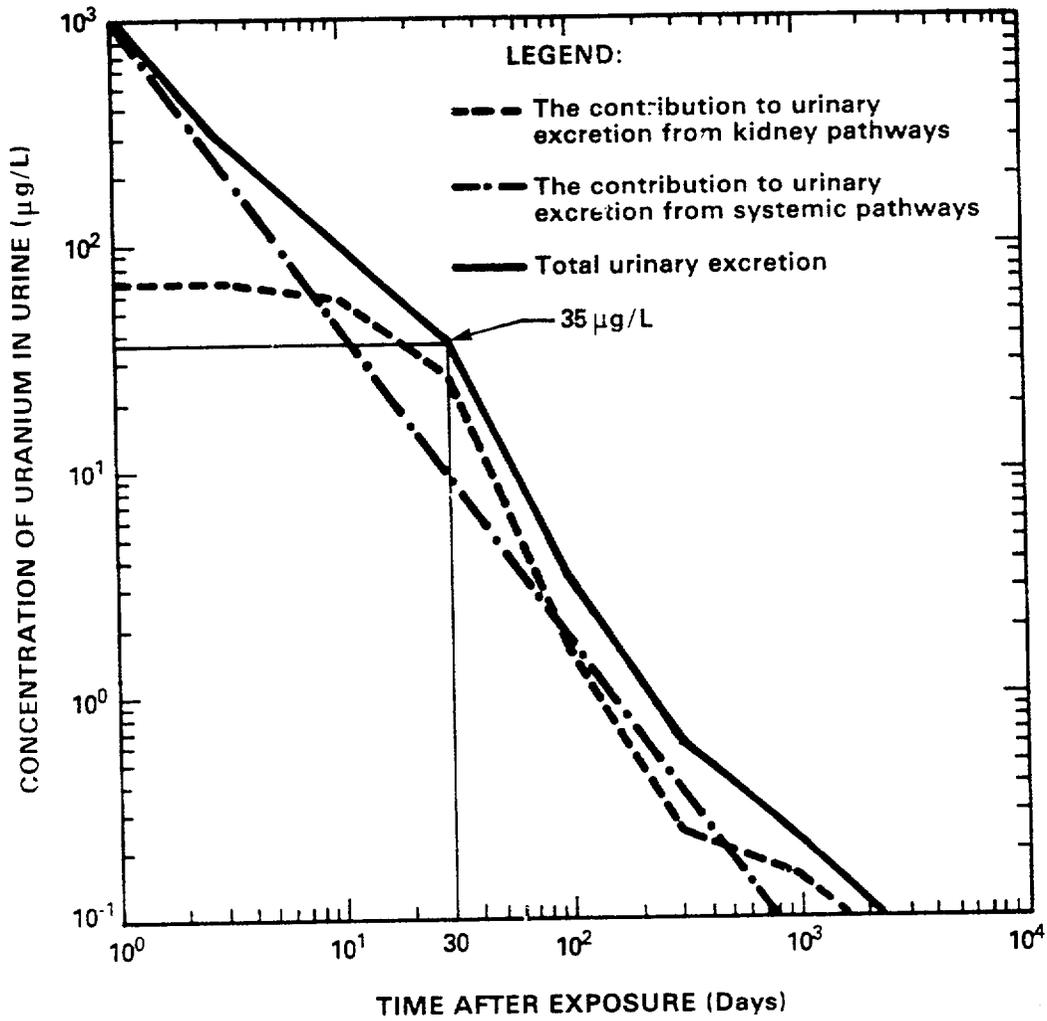


Figure 1 Uranium Concentration in Urine Following Single Exposure to High-Fired Yellowcake (Intake = 160,000 µg U = 1 ALI) (from NUREG-0874, Ref. 1)

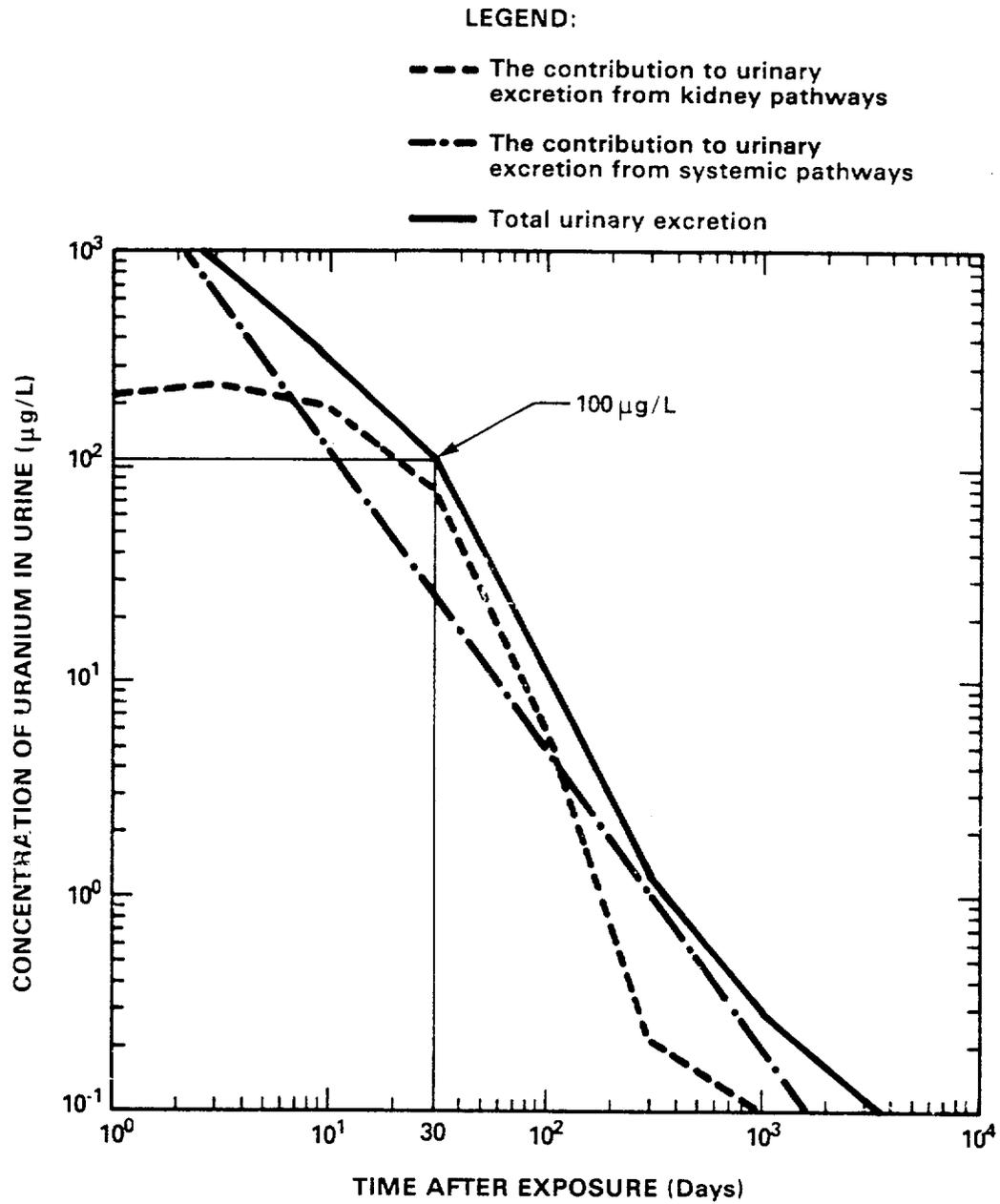


Figure 2 Uranium Concentration in Urine Following Single Exposure to Low-Fired Yellowcake (Intake = 260,000  $\mu\text{g U} = 1$  ALI) (from NUREG-0874, Ref. 1)

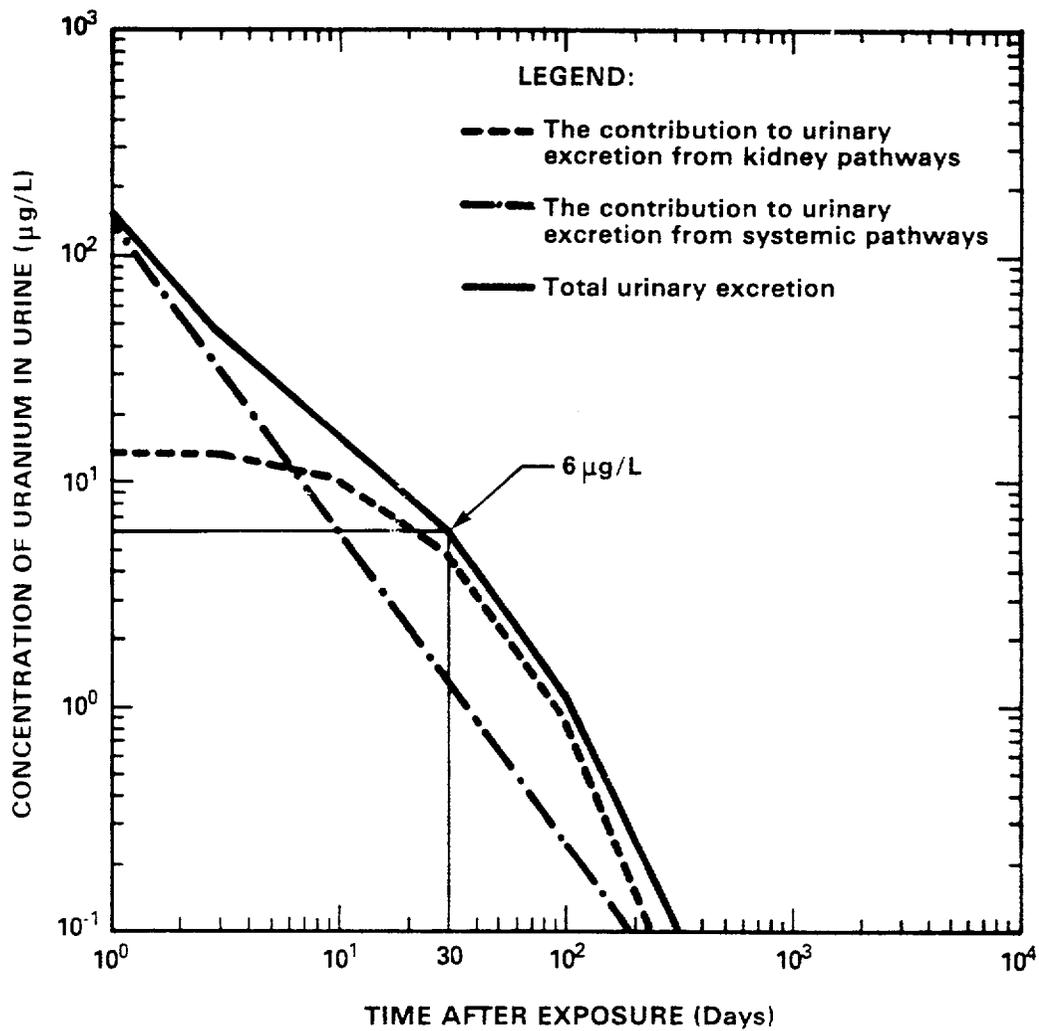


Figure 3 Uranium: Concentration in Urine Following Exposure to Ore Dust (from NUREG-0874, Ref. 1)

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\*\*ICRP publications are available from Pergamon Press, Fairview Park, Elmsford, NY 10523.

\*\*\*Available from the Health Physics Society, 1340 Old Chain Bridge Road, Suite 300, McLean, VA 22101.

## APPENDIX A

### LOWER LIMIT OF DETECTION OF URANIUM

For the purposes of this guide, the lower limit of detection (LLD) is defined as the smallest concentration of radioactive material in urine that has a 95% probability (chance) of being detected when measurement procedures are set so that the concentration level at which detection is considered significant produces only a 5% chance of calling a background reading a positive sample.\* Radioactive material is then called "detected" when the value obtained from an instrument reading is above the LLD and is thus high enough to permit a conclusion that activity above the system background is determined to be present. Thus, for a fluorometric measurement that may include a radiochemical separation in which the "blank" urines fluctuate with a standard deviation  $S_b$ , the LLD corresponds to an activity that is defined as:

$$LLD = \frac{4.65S_b}{K \epsilon Y e^{-\lambda t}}$$

Where

LLD = the lower limit of detection ( $\mu\text{g/L}$  or  $\mu\text{Ci/L}$ ),

$S_b$  = the standard deviation of fluctuations in fluorometer blank measurements or count rate (counts per second) for a specific time of measurement and specific aliquot volume,

K = conversion or calibration factor to convert units of  $S_b$  from instrument scale reading units to mass or activity units; units of K may be  $\mu\text{g}$  or  $\text{d}/\text{sec} \cdot \mu\text{Ci}$  if activity is counted to obtain the final result (this term is omitted if  $S_b$  is given in microcuries directly by use of a calibration standard),

$\epsilon$  = the counting efficiency (counts per disintegration); it is 1 when a fluorometric standard is measured in the same geometry as the sample,

v = volume (in liters) of aliquot taken from the urine sample and added to the flux in the fusion dish. Note: As long as the concentration of uranium in the aliquot is the same as the concentration in the original urine sample, the volume of the original urine sample does not affect this calculation.

Y = the fractional radiochemical yield or recovery (if applicable),

$\lambda$  = the decay constant for the particular radionuclide, and

t = the elapsed time between sample collection and counting for correcting for radioactive decay when decay during time t is significant, but decay is negligible during the fluorometric measurement.

#### EXAMPLE: LLD FOR URANIUM WHEN FLUOROMETRIC ANALYSIS IS USED

This example is worked in terms of micrograms of natural uranium per liter of urine. The LLD could just as well be calculated in terms of microcuries or becquerels of uranium per liter. A conversion factor of  $6.77 \times 10^{-7} \mu\text{Ci}/\mu\text{g}$  ( $0.025 \text{ Bq}/\mu\text{g}$ ) for natural uranium can be used if the uranium quantity is known in micrograms. The quantity of uranium added to the fusion dish will be determined, and then it will be divided by the volume of urine in the aliquot taken from the total collected sample.

First, determine the standard deviation of the background measurement (blank urine) (which will approximate an estimate of the standard error of the average of a triplicate measurement if calculated as shown below). In this example, urine samples were taken from 12 individuals who worked in areas of the plant where no uranium exposure could have occurred. For each of these "blank" urines, three (triplicate) measurements were made; each measurement consisted of taking 0.2 mL from an individual urine sample and pipetting it into a platinum dish containing a NaF pellet, which was then fused and placed into a fluorometer for measurement. The readings (in microamperes in this case) of the three 0.2 mL aliquots of each individual "blank" urine were then averaged.

The 12 triplicate averages for the blank urines were:

Sample Number, i	Average Fluorometer Readings ( $X_i$ ) (microamperes)
1	0
2	0.07
3	0.07
4	0.07
5	0
6	0
7	0.13
8	0.13
9	0.17
10	0.10
11	0.13
12	0

The standard deviation  $S_b$  (same as an estimate of the standard error of the triplicate average) may be calculated by the following equation (or a computer or calculator programmed for this equation):

\*This definition of LLD was chosen to be consistent with the NRC position previously stated in Tables 1 and 3 of Regulatory Guide 4.8, "Environmental Technical Specifications for Nuclear Power Plants." The definition is also used in other regulatory guides, among them 4.14, "Radiological Effluent and Environmental Monitoring at Uranium Mills"; 8.14, "Personnel Neutron Dosimeters"; and 8.30, "Health Physics Surveys in Uranium Mills."

$$S_b = \left( \frac{1}{n-1} \sum_i^n (X_i - \bar{X})^2 \right)^{1/2}$$

$n$  = the number of samples

$X_i$  = the average reading for triplicate  $i$  from sample  $i$

$\bar{X}$  = the average of all triplicate averages

For the data above, the standard deviation is:

$$S_b = \pm 0.0612 \mu\text{A} \text{ and } \bar{X} = 0.0725 \mu\text{A}$$

Convert  $S_b$  to micrograms of uranium. On this fluorometer, samples of pure  $\text{U}_3\text{O}_8$  averaging  $0.012 \mu\text{g}$  added to the fusion dish gave readings in the fluorometer averaging  $3.44 \mu\text{A}$ . The fluorometer will thus have a calibration factor of  $287 \mu\text{A}/\mu\text{g} \text{ U}_3\text{O}_8$ . The  $\text{U}_3\text{O}_8$  compound is 85% uranium by weight ( $238 \times 3 = 714$ ,  $16 \times 8 = 128$ ,  $714/842 = 0.85$ ). Therefore, the fluorometer will read  $338 \mu\text{A}/\mu\text{g}$  of elemental uranium ( $287/0.85 = 338$ ).

Now, the standard deviation in micrograms of uranium is calculated:

$$S_b = \frac{0.0612 \mu\text{A}}{338 \mu\text{A}/\mu\text{g}} = 0.000181 \mu\text{g of uranium.}$$

If this is converted to microcuries using the conversion factor given before, then

$$\begin{aligned} S_b &= 0.000181 \mu\text{g} \times 6.77 \times 10^{-7} \mu\text{Ci}/\mu\text{g} \\ &= 1.23 \times 10^{-10} \mu\text{Ci} \quad (4.55 \times 10^{-6} \text{ Bq}) \end{aligned}$$

In the equation for LLD, the counting efficiency will be 1. (The term  $E$  is not applicable to a fluorometric analysis.) The aliquot volume of  $0.2 \text{ mL}$  is used in the LLD equation since the numerical value for each fluorescence reading is related to this volume of urine. Also, for a fluorometric reading compared against a calibration factor, the radiochemical yield is not applicable, and  $Y$  should be set equal to 1. The exponential term for radioactive decay,  $\exp(-\lambda t)$ , will also be equal to 1 since the half-life of uranium is so long that the amount of decay between collection and analysis will be negligible. Therefore, the LLDs in mass and activity concentration units become:

$$\text{LLD}_m = \frac{4.65 \times 0.000181}{0.0002} = 4.21 \mu\text{g/L}$$

$$\begin{aligned} \text{LLD}_a &= \frac{4.65 \times 1.23 \times 10^{-10}}{0.0002} \\ &= 2.86 \times 10^{-6} \mu\text{Ci/L} \quad (0.106 \text{ Bq}) \end{aligned}$$

## VALUE/IMPACT STATEMENT

A draft value/impact statement was published with Proposed Revision 1 to Regulatory Guide 8.22 (Task OP 013-4) when the draft revised guide was published for public comment in January 1987. No significant changes were necessary, so a separate value/impact statement for

the final guide has not been prepared. A copy of the draft value/impact statement is available for inspection and copying for a fee at the Commission's Public Document Room at 1717 H Street NW., Washington, DC, under Task OP 013-4.

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