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REGULATORY GUIDE 8.11

APPLICATIONS OF BIOASSAY FOR URANIUM

A. INTRODUCTION

Section 20.108, "Orders Requiring Furnishing of Bioassay Services," of 10 CFR Part 20, "Standards for Protection Against Radiation," states that the Atomic Energy Commission may incorporate in any license provisions requiring bioassay measurements as necessary or desirable to aid in determining the extent of an individual's exposure to concentrations of radioactive material. As used by the Commission, the term bioassay includes in vivo measurements as well as measurements of radioactive material in excreta. This guide provides criteria acceptable to the Regulatory staff for the development and implementation of a bioassay program for mixtures of the naturally occurring isotopes of uranium U-234, U-235, and U-238. The guide is programmatic in nature and does not deal with laboratory techniques and procedures. Uranium may enter the body through inhalation or ingestion, by absorption through normal skin, and through lesions in the skin. However, inhalation is by far the most prevalent mode of entry for occupational exposure. The bioassay program described in this guide is applicable to the inhalation of uranium and its compounds, but does not include the more highly transportable compounds UF6 and UO₂F₂.

Significant features of the bioassay program developed in this guide are listed below:

1. A bioassay program is necessary if air sampling is necessary for purposes of personnel protection. The extent of the bioassay program is determined by the magnitude of air sample results.

2. A work area qualifies for the "minimum bioassay program" so long as the quarterly average of air sample results is $\leq 10\%$ of the Derived Air Concentration (DAC) and the maximum used to obtain the average is <25% of DAC. It must be demonstrated that air sample results used for this purpose are representative of personnel exposure.

3. Under the minimum program, bioassays are performed semiannually or annually for all workers to monitor the accumulation of uranium in the lung and bone. More frequent bioassays are performed for a sample of the most highly exposed workers as a check on the air sampling program; these bioassays are performed at sufficient frequency to assure that a significant single intake of uranium will be identified before biological elimination of the uranium renders the intake undetectable.

4. If a work area does not qualify for the minimum program, bioassays in addition to the minimum program are performed at increasingly higher frequencies, depending on the magnitude of air sample results.

5. A model is used which correlates bioassay measurement results with radiation dose or with uptake of uranium in the blood (chemical toxicity).

6. Actions are specified, depending upon the dose or uptake indicated by bioassay results. These actions are corrective in nature and are intended to ensure adequate worker protection.

7. Guidance is referenced for the difficult task of determining, from individual data rather than models, the quantity of uranium in body organs, the rate of elimination, and the dose commitment.

This bioassay program encourages improvement in the confinement of uranium and in air sampling tech. niques by specifying bioassays only to the extent that confinement and air sampling can not be entirely relied upon for personnel protection.

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B. DISCUSSION

The topics treated in this guide include determining (1) whether bioassay procedures are necessary, (2) which bioassay techniques to use and how often, (3) who should participate, (4) the action to take as based on bioassay results, and (5) the particular results which should initiate such action. Taken together, these topics comprise an exposure control program. Technical bases for the criteria appearing in the guide are provided in "Applications of Bioassay for Uranium." WASH-1251, which is available from the Superintendent of Documents, U.S. Government Printing Office, Washington, D.C. 20402.

After an exposure to uranium has occurred, the difficult problems of estimating the quantity present in the body and the anticipated dose commitment arise. This subject is treated in considerable detail in WASH-1251.

C. REGULATORY POSITION

1. Special Terminology

Several of the terms used in this guide have been given special definitions and are listed in this section for the convenience of the reader.

- **Bioassay** The determination of the kind, quantity or concentration, and location of radioactive material in the human body by direct *(in vivo)* measurement or by analysis of materials excreted or removed from the body.
- **Derived Air Concentration (DAC)** Equivalent to the concentrations listed in Appendix B to 10 CFR Part 20.
- **Dome Commitment** (D_c) The total radiation doseequivalent to the body or specified part of the body that will be received from an intake of radioactive material during the 50-year period following the intake.
- **Exposure** The product of the average concentration of radioactive material in air and the period of time during which an individual was exposed to that average concentration (μ Ci-hr/cc).
- Intake The quantity of radioactive material entering the nose and/or mouth during inhalation; the product of the exposure and the breathing rate.
- In Vivo Measurements Measurement of gamma or X-radiation emitted from radioactive material located within the body, for the purpose of estimating the quantity of radioactive material present.

- Maximum Permissible Annual Dose (MPAD) The annual maximum occupational radiation dose recommended by the ICRP for the body or part of the body.
- Maximum Permissible Dose Commitment (MPD_c) A dose commitment numerically equivalent to the Maximum Permissible Annual Dose.
- Measurement Sensitivity Limit The smallest quantity or concentration of radioactive material that can be measured with a specified degree of accuracy and precision.
- Nontransportable Slowly removed from the pulmonary region of the lung by gradual dissolution in extracellular fluids, or in particulate form by translocation to the GI tract, blood, or lymphatic system; Class (W), nontransportable dust with 50-day biological half-life in the lung; Class (Y), nontransportable dust with 500-day biological half-life in the lung.
- Transportable Dissolved upon contact with extracellular fluids and translocated to the blood; Class (D), transportable dust with rapid clearance from the lung.
- Uptake The quantity of radioactive material entering the nose and/or mouth during inhalation that is not exhaled and enters extracellular fluids.
- w/o U-235 Percentage by weight of the isotope U-235 in a mixture of U-234, U-235, and U-238 (w/o U-235 in natural uranium is 0.72).

2. Programmatic Guidance

The following programmatic guides are applicable where personnel are occupationally exposed to uranium in respirable form and in sufficient quantity that measurements of uranium concentrations in air are considered to be necessary for the protection of workers in compliance with Regulatory requirements, including license conditions.

a. Basic Requirements and Minimum Capabilities

The following guides establish basic requirements and minimum capabilities which should be found in a program for protection against internal exposure from operations with uranium:

(1) Responsibilities for protection against uranium contamination should be well defined and understood by all personnel concerned and should be specified in directives from management.

(2) A comprehensive and technically sound protection program should be developed and implemented. (3) Personnel, space, equipment, and support resources should be provided as necessary to conduct the program.

(4) An effective method of periodic internal audit of the protection program should be maintained.

(5) Before assigning employees to work in an area where exposure to uranium contamination may occur, action should be taken to ensure that facility and equipment safeguards necessary for adequate radiation protection are present and operable, that the employees are properly trained, that adequate procedures are prepared and approved, that an adequate surface and air contamination survey capability exists, that a bioassay program at least equivalent to the program described in this guide will be maintained, and that survey and bioassay records will be kept.

b. Bioassay Program

In the development of a bioassay program the following guides should be implemented:

(1) Necessity

The determination of the need for bioassay measurements should be based on air contamination monitoring results in accordance with criteria contained in this guide.

(2) Preparatory Evaluation

Before assigning an employee to work in an area where substantial exposure to uranium contaminants may occur, his condition with respect to radioactive material of similar chemical behavior previously deposited and retained in his body should be determined and the necessity for work restrictions evaluated.

(3) Exposure Control

The bioassay program should include, as appropriate, capabilities for excreta analyses and *in vivo* measurements, made separately or in combination at a sufficiently high frequency to assure that engineered confinement and air and surface contamination surveys are adequate for employee protection. The program should include all potentially exposed employees.

(4) Diagnostic Evaluation

The bioassay program should include capabilities for excreta analyses and *in vivo* measurements as necessary to estimate the quantity of uranium deposited in the body and/or in affected organs and the rate of elimination from the body and/or affected organs.

3. Operational Guidance

a. Criteria for Determining the Need for a Bioassay Program

Where air sampling is required for purposes of occupational exposure control, bioassay measurements are also needed (Table 1) The bioassay frequency should be determined by air sample results as averaged over 1 quarter.

Testing should be performed to determine whether an sampling is representative of personnel exposures. Air sample results which have been verified as representative may be used to determine the quarterly average.

If the 1-quarter average does not exceed 10% of the appropriate Derived Air Concentration (DAC) from Appendix B to 10 CFR Part 20 and if the maximum result used in the calculation of the average does not exceed 25% of DAC, only a minimum bioassay program is necessary (Table 2). If the 1-quarter average exceeds 10% DAC, or if the maximum result exceeds 25% of the DAC, additional bioassays are necessary (Table 3), except as noted below. Frequency criteria for both cases are discussed in Section C.3.c. The approach is illustrated in Figure 1.

The additional bioassays are not performed for a specific individual if the licensee can demonstrate that the air sampling system used to protect the individual is adequate to detect any significant intake and that procedures exist for diagnostic bioassays following detection of an apparently large intake.

The necessity for bioassay measurements may also arise following an incident such as a fire, spill, equipment malfunction, or other departure from normal operations which caused, or could have caused, abnormally high concentrations of uranium in air. Criteria for determining this necessity are shown in Figure 2. (The term "Early Information" refers to an instrumented air sampler with an alarm device.) Reliance cannot be placed on nasal swab results from mouth breathers, bioassays should be performed.

Special bioassay measurements should be performed to evaluate the effectiveness of respiratory protection devices. If an individual wearing a respiratory protection device is subjected to a concentration of transportable uranium in air within a period of 1 week, such that his exposure with no respiratory protection device would have exceeded $40 \times DAC \ \mu Ci-hr/cc$, urinalysis should be performed to determine the resulting actual uranium uptake. If an individual wearing a

Purpose	Transportable Compounds	Non transportable Compounds		
		Choice of Measurement		
		lst	2ndª	3rd
Preparatory Evaluation ^b	u ^c	iv ^c	f¢	u
Exposure Control				
Check on Air Sampling Program	u	iv	f	u
Monitoring of Lung Burden Buildup		iv	f	u
Monitoring of Bone Burden Buildup	บ่	u	-	-
Detection of Unsuspected Intake	u	iv	f	u
Diagnostic Evaluation	. u	iv	f	u
Work Restriction Removal	u	iv	f	u

TABLE 1 SELECTION OF BIOASSAY MEASUREMENT TECHNIQUES

^aIf for any reason air sampling is not adequately effective, and the appearance of urinary uranium is long delayed by extreme nontransportability, the buildup of uranium in the lung may continue undetected until a positive *in vivo* result is obtained. Fecal analysis is an excellent and highly recommended early indicator in such cases. Fecal analysis should be considered if *in vivo* measurements are too infrequent to permit early identification of an unfavorable trend.

^bDiagnostic evaluation necessary if results are positive.

^Cu, urinalysis; f, fecal analysis; iv, in vivo.

respiratory protection device is subjected to a concentration of nontransportable uranium in air within a period of 13 weeks, such that his exposure with no respiratory protection device would have exceeded $520 \times DAC \ \mu Ci-hr/cc$, the resulting actual uranium deposition in the lung should be determined using *in vivo* measurements and/or fecal analyses. These special bioassay procedures should also be conducted if for any reason the magnitude of the exposure (with no respiratory protection device) is unknown.

b. Selection of Measurement Techniques

The appropriate selection of bioassay techniques appears in Table 1. Preparatory evaluation refers to bioassays performed for job applicants or existing employees prior to an assignment involving potential exposure to uranium. Exposure control refers to bioassays performed to assure that engineered confinement and the air sampling program are sufficiently effective in the control and evaluation of exposures. Diagnostic evaluation refers to bioassays performed following a known significant exposure. These evaluations are performed to determine the location and magnitude of uranium deposition, which would in turn aid in determining whether therapeutic procedures are indicated and whether work restrictions are necessary. The evaluations would also aid in estimating the retention function and dose commitment. Work restriction removal refers to bioassays performed for employees who, because of past depositions of radionuclides, have been restricted by management in their work involving exposure to radioactive material until the magnitude of such depositions is reduced sufficiently to permit the removal of these work restrictions.

c. Selection of Measurement Frequency

Acceptable frequencies for the minimum bioassay program are given in Table 2. Table 3 gives acceptable frequencies when additional bioassay measurements are necessary to detect unsuspected single intakes, unless the measurement capability is the limiting factor. Figures 3 through 7 present the maximum time between measurements based on measurement sensitivity considerations; the figures should be used to determine the measurement frequency unless the interval specified in Table 3 is shorter. The Class (W) curve in Figure 5 may be used for Class (Y) materials if it is known that Class (D) or Class (W) materials are present.

Table 2 specifies, for the minimum program, semiannual or annual bioassays for monitoring the accumulation of uranium in the lung and bone, plus

Dust Measurement Program Objective Frequency Classification Technique^a Check on air sampling (D) Use Figures 3 and 4 u program and on con-(W) į٧ Use Figure 6 finement procedures **(Y)** iv Semiannual Minimum^b and equipment. Adequate if Monitor lung burden (W) iv Annual QA < 1/10 DACbuildup. (Y) iv Semiannualc and M < 1/4 DAC Monitor bone burden (D) u Semiannual buildup. (W) Semiannual u (Y) Class (D) or Class (W) Not Present, Annual^d u **(Y)** Class (D) or Class (W) Present, Semiannual^d u Additional Detect unsuspected (D) u Use Table 3^e intake. **(W)** iv, f, or u Use Table 3^e Acceptable if **(Y)** iv, f, or u Use Table 3^e QA > 1/10 DACand/or M > 1/4 DAC

TABLE 2 BIOASSAY FREQUENCY FOR EXPOSURE CONTROL

^aiv, in vivo; u, urinalysis; f, fecal analysis.

^bQA, quarterly average of air sample results; M, maximum result used to determine QA.

^c These frequencies are applicable if no individuals are near work restriction limits. Quarterly or even monthly iv may become necessary as workers approach these limits.

dSpecial urinalysis should be performed each time exposure to new Class (Y) material begins to determine if more transportable component is present.

^eThese measurements are additional to those listed above for the minimum program. If it is demonstrated that air sampling provided for a specific individual is adequate to detect any significant intake and that procedures exist for diagnostic bioassays following detection of an apparently large intake, these additional measurements need not be performed.

TABLE 3

FREQUENCYª FOR ADDITIONAL BIOASSAYS BASED ON CONCENTRATION OR EXPOSURE

QA - Most recent quarterly average of concentration or most recent quarterly average of weekly exposures

M Maximum result used in the calculation of the quarterly average

u – urinalysis

iv – in vivo

Multiply numbers in first column by DAC μ Ci/cc or by 40 DAC μ Ci-hr/cc. Frequencies are given in bioassays, per year at equally spaced intervals.

Air Sample Results	Class (D)	Class (W)		Class (Y)	
	<u>u</u>	<u>u</u>	iv	<u>u</u> b	iv
0 <qa< 1="" 10<="" td=""><td></td><td></td><td></td><td></td><td></td></qa<>					
1/4 < M < 1	2 ^c	2	1	2	2
1 < M < 10	4	4	2	4	2 2 4
10 < M	12	12	4	12	4
1/10 < QA < 1/4					
0 < M < 1	26	- 2	1	4	2
I < M < 10	4	4	2	12	4
10 < M	12	12	4	26	4
1/4 < QA < 1/2					
<u><u><u></u></u><u></u><u></u><u></u><u></u><u></u><u></u><u></u><u></u><u></u><u></u><u></u><u></u><u></u><u></u><u></u><u></u><u></u></u>	2°	4	2	12	4
1 < M < 10	2 ^c 4	12	4	26	4
10 < M	12	26	12	52	12
1/2 < QA < 1					
$\overline{0 < M < 10}$	12	26	12	26	12
10 < M	26	52	12	52	12
	~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~		• 2	52	12

^a Low frequencies indicated may be precluded by measurement capability limitations; see Figures 3 through 7

^bApplicable if Class (D) or Class (W) materials are known to be present; convert 52 and 26 to 12 if they are not present. Fecal analysis may be substituted for urinalysis.

^c Frequency possible only for high w/o U-235; naturally occurring urinary uranium prohibits detection otherwise.

more frequent bioassays (based on measurement sensitivity) to check on the air sampling program. Section C.3.d indicates that all workers should participate in the bioassay program for purposes of monitoring the organ buildup, while only a sample of workers is sufficient for checking the air sampling program. If a working area does not qualify for the minimum program, additional bioassays are specified in Table 3 at somewhat higher frequencies. Any urinalysis procedure performed for one of these purposes may be used to satisfy a urinalysis requirement for another purpose, provided the frequency criteria are met. A similar statement may be made regarding *in vivo* measurements.

The purpose of the additional bioassay measurements is the timely detection of unsuspected exposures not detected by the air sampling program. Therefore, the additional bioassays are not necessary for an individual who is protected by a monitoring system that essentially assures detection of any significant intake.

Although fecal analysis is not shown in Table 3, this procedure is preferred over urinalysis for Class (W) and Class (Y) materials and may be substituted for urinalysis in the table. If *in vivo* measurements are made at the frequency shown for urinalysis, Class (W) and Class (Y), the urinalyses are unnecessary; the urinalyses prescribed in Table 2 are adequate.

The bioassay measurement frequency, as determined from Table 2 or 3 (or the associated figures), should not be decreased because of consistently low bioassay results; bioassay measurements are needed as a final check on the contamination confinement capability and on the effectiveness of the air sampling program. Consistently high bioassay results may suggest that more frequent bioassays should be performed even though there is no such indication from air samples. In this case, however, improvements in the air sampling program are required rather than more frequent bioassays. The appropriate frequency can be determined from air sample data if the air sampling program is adequately representative of inhalation exposures.

If workers are exposed to a mixture of uranium compounds, the DAC for the mixture,  $DAC_m$ , should be calculated as

$$DAC_{m} = \begin{bmatrix} n & f_{i} \\ \sum_{i=1}^{n} DAC_{i} \end{bmatrix}^{-1}$$

where  $DAC_i$  is the DAC for the *i*th compound and  $f_i$  is a fraction representing the contribution of the ith compound. The calculation of f_i depends on the exposure mode. If the material is a mixture, f_i is the activity fraction. For exposure in more than one area, f_i is the time fraction spent in the ith area. As an alternative  $DAC_m$  may be taken as the lowest  $DAC_i$ . As to the quarterly average for air samples, if the material is a mixture and exposure occurs in only one area, the quarterly average calculation, applicable to all workers in the area, should be performed as for non-mixtures, i.e., from samples characterizing conditions in the area. If exposures occur in several areas, the quarterly average for the mixture may be a time-weighted average for the individual, using carterly average air samples that characterize full-time conditions in each area, i.e.,

$$QA_m = \sum_{i=1}^n f_i QA_i$$

where  $QA_i$  is the quarterly average for the ith area and  $f_i$  is the time fraction of the quarter that the individual worked in the ith area. As an alternative,  $QA_m$  may be taken as the highest  $QA_i$ .

Figure 5 indicates that a urinalysis measurement sensitivity of about 0.7 pCi/1 is required to detect the equivalent of 1 MPD_c following a single exposure to Class (Y) materials with neither Class (D) nor Class (W) "tracer" dusts present. To obtain this sensitivity, a chemical concentration procedure is necessary. Fecal analysis is recommended as an alternative, using the frequency schedule given for urinalysis.

If work restrictions that have been imposed do not involve total exclusion from restricted areas, it is necessary to ensure that bioassay measurements made for the purpose of removing work restrictions are performed at least as frequently as would be required for purposes of exposure control. A monthly *in vivo* frequency may be reduced to quarterly if weekly fecal analyses are made, with an *in vivo* measurement at the end of the quarter. An *in vivo* measurement should be performed as soon as practicable if the excretion rate exceeds 7 pCi/day Class (Y) or 700 pCi/day Class (W). For lower results the following procedure should be followed. Results from the first 4 weekly specimens should be plotted (semilog) against time, and a best fitting curve should be extrapolated to t = 0, thus obtaining an estimate of the initial excretion rate, (dP /dt)₀, and the individual's half-life₁ T. The dose commitment, D_C, should be estimated using these values with the following equation:

$$D_{c} = 8.4 \text{ T}^{2} \left[ \frac{dP'}{dt} \right]_{o}$$

where T is in days and  $(dP'/dt)_0$  is in  $\mu$ Ci/day. The actions indicated in Table 4 should then be taken. This procedure should be repeated at the end of 8 weeks when results from 8 specimens are available. At the end of the quarter D_c should be evaluated using results from all 12 specimens. If the indicated D_c is  $\leq 3$  rems, the *in vivo* measurement may be considered unnecessary. If the D_c indicated by the fecal data exceeds 3 rems, the *in vivo* measurement should be performed.

A quarterly in vivo frequency may be reduced to semiannual if monthly fecal analyses are made, with an in vivo measurement at the end of 6 months. If any result exceeds 7 pCi/day Class (Y) or 460 pCi/day Class (W), an in vivo measurement should be performed as soon as practicable. For lower results the following procedure should be followed. Results from the first 3 specimens should be plotted (semilog) against time, and a best-fitting straight line should be extrapolated to t = 0. Values for  $(dP/dt)_0$  and T for the individual should be obtained and used in the above equation to estimate D_c. The actions indicated in Table 4 should then be taken. At the end of the fourth and fifth month, D_c should again be evaluated using results from all specimens. At the end of the 6-month period, the in vivo measurement should be performed.

Fecal specimens used for this purpose should be obtained after 2 or more days of no exposure. In the extrapolation of excretion rate data to t = 0, it is necessary to ignore data points obtained for less than 2 days after exposure.

### d. Participation

All personnel whose regular tob assignments involve work in an area where bioassay measurements are required should participate in the bioassay program. However, as long as air sample results qualify the area and group of workers for the minimum bioassay program, special consideration may be given in the case of bioassays obtained for the purpose of checking on the air sampling program, i.e., the first objective shown in Table 2. For these bioassays it is acceptable to limit participation to a representative sample of the group. The sample should be composed of the most highly exposed or potentially exposed personnel and should include at least 10% of the workers who have regular job assignments in the area if the total number of such workers is 100 or more. If the total is between 100 and 10 workers, there should be 10 participants. If the total is less than 10 workers, all should participate. Thus, where the minimum bioassay program is being conducted, all workers would participate either semiannually or annually for monitoring of uranium buildup in the lung or bone; in addition, those in the sample group would participate more frequently if required to do so by Figures 3, 4, or 6. (Note that the in vivo frequency for Class (Y) materials is semiannual in every case.) This sampling procedure will be of particular usefulness to those using Figure 4. Where bioassays in addition to the minimum program are conducted, all workers should participate (see Table 2, footnote e, for exception).

Personnel whose duties involve only observance and who spend less than 25% of the work week in areas where bioassay is required may participate on a limited basis. The interval between bioassay measurements for such personnel should be a matter of judgement based on the magnitude of the exposure.

#### e. Action Based on Results

Appropriate action as based on bioassay results is dependent first on the underlying purpose of the measurement.

#### (1) Preparatory Evaluation

Where urinalysis for uranium is used to screen personnel prior to job assignment, the presence of any urinary uranium, as detected by routine laboratory procedures, should trigger an investigation. Information regarding the location and quantity of uranium in the body should be sought, and conservative predictions as to future retention in the body should be made. This information can usually be derived from a review of the worker's previous exposure history, including previous bioassay results, and from subsequent bioassay measurements as necessary. Findings should be compared with criteria given in Section C.3.f.(8), or with other acceptable criteria, and a decision should be made to approve the job assignment if acceptable criteria are met, or to impose a delay otherwise.

#### (2) Exposure Control

When work is in progress, and bioassay measurements are being made routinely, it is essential to ensure that the measurement results are carefully reviewed by qualified personnel and that appropriate action is taken if the results are considered high. Action should be based on the organ burden, the dose commitment, or chemical damage to the kidney as indicated (however roughly) by the result. Appropriate actions are shown in Tables 4 and 5 for single intakes. In the case of chronic exposure, when bioassay results indicate that the organ burden is continuing to rise, action should be taken to assure that additional buildup will not interfere with the worker's career. When urinalysis indicates 50% or more of the maximum permissible lung burden for nontransportable uranium, in vivo measurements should be undertaken. Work restrictions should be imposed without waiting for in vivo measurements if urinalysis indicates more than 1 permissible lung burden.

### (3) Diagnostic Evaluation

Diagnostic bioassay measurements are made to estimate the quantity and distribution of radionuclides in the body after determination that a large deposition has occurred. Actions to be based on diagnostic results include (1) selection of subsequent measurement techniques and frequencies, (2) imposition or removal of work restrictions, (3) referral to a physician, and (4) the physician's decision to attempt acceleration of the nuclide elimination process.

### f. Action Points

This section presents acceptable correlations between organ burden, dose commitment, or uranium uptake and the quantities actually measured using bioassay techniques, thus providing action point criteria for purposes of exposure control. Guidance is also given for work restrictions and for referral to a physician.

These correlations are derived entirely from models. This approach is acceptable for purposes of exposure control. However, these correlations would actually predict the dose commitment or uranium uptake only if the bioassay result was without error and if every condition of the models was actually achieved.

### (1) Dose Commitment and Uptake Correlations, Single Intake, Class (D) Dust

The correlation between dose commitment to the bone and urinary uranium concentration is shown in Figure 8 for Class (D) materials. In the right hand margin of the figure the recommended actions, from Table 4, are indicated. The correlation between uptake of uranium by the blood and urinary uranium concentration is shown in Figure 9 for Class (D) materials. Recommended actions, from Table 5, are indicated.

## TABLE 4 ACTION DUE TO BIOASSAY MEASUREMENT RESULTS, RADIATION DOSE

## Result $\leq 1/5$ MPD_c^a

Contamination confinement and air sampling capabilities are confirmed. No action required.

## $1/5 < \text{Result} \le 1/2 \text{ MPD}_c$

Contamination confinement and/or air sampling capabilities are marginal. If a result in this range was expected because of past experience or a known incident, any corrective action to be taken presumably has been or is being accomplished; no action is required by the bioassay result. If the result was unexpected:

- (1) Confirm result (air sample data review, comparison with other bioassay data, additional bioassay measurements).
- (2) Identify probable cause and, if necessary, correct or initiate additional control measures.
- (3) Determine whether others could have been exposed and perform bioassay measurements for them.
- (4) If exposure (indicated by excreta analysis) could have been to Class (W) or Class (Y) dust, consider the performance of diagnostic in vivo measurements.

## $1/2 < \text{Result} \le 1 \text{ MPD}_c$

Contamination confinement and/or air sampling capabilities are unreliable unless a result in this range was expected because of a known unusual cause; in such cases, corrective action in the work area presumably has been or is being taken, and action due to the bioassay result includes action (7) only. Conditions under which a result in this range would be routinely expected are undesirable. If the result was due to such conditions or was actually unexpected, take actions (1) through (4) and:

- (5) If exposure (indicated by excreta analysis) could have been to Class (W) or Class (Y) dust, assure that diagnostic in vivo measurements are performed.
- (6) Review the air sampling program; determine why air samples were not representative and make necessary corrections.
- (7) Perform additional bioassay measurements as necessary to make a preliminary estimate of the critical organ burden; consider work limitations to ensure that the MPD_c is not exceeded.
- (8) If exposure could have been to Class (Y) dust, bring expert opinion to bear on cause of exposure, and continue operations only if it is virtually certain that the limit of 1 MPD_c will not be exceeded by any worker.

## Result > 1 MPD_c

Contamination confinement and/or air sampling capabilities are not acceptable, unless a result of this magnitude was expected because of a known unusual cause; in such cases, corrective action in the work area presumably has been or is being taken, and action due to the bioassay result includes actions (10) and (11) only. Prevalent conditions under which a result in this range would be expected are not acceptable. If the result was due to such conditions or was actually unexpected, take actions (1) through (7) and:

- (9) Take action (8), regardless of dust classification.
- (10) Establish work restrictions as necessary for affected employees.
- (11) Perform individual case studies (bioassays) for affected employees.

^aThe annual MPD_c is a 50-yr integrated dose of 15 rems to the lung or 30 rems to the bone.

### TABLE 5

## ACTION DUE TO BIOASSAY MEASUREMENT RESULTS, CHEMICAL TOXICITY

### **Result** $\leq 1/2 L^a$

Contamination confinement and air sampling capabilities are adequate. No action required.

### $1/2 L < \text{Result} \leq L$

Contamination confinement and/or air sampling capabilities do not provide an adequate margin of safety. If a result in this range was expected because of past experience or a known incident, any corrective action to be taken presumably has been or is being accomplished; no action is required by the bioassay result. If the result was unexpected:

- (1) Confirm result (air sample data review, comparison with other bioassay data, additional bioassay measurements).
- (2) Identify probable cause and, if necessary, correct or initiate additional control measures.
- (3) Determine whether others could have been exposed and perform bioassay measurements for them.
- (4) Determine why the bioassay result was not predicted by the air sampling program and make necessary corrections.
- (5) Consider work limitations to ensure that L is not exceeded.
- (6) If bioassay result was near L, bring expert opinion to bear on cause of exposure, and continue operations only if it is virtually certain that L will not be exceeded by any worker.

### Result > L

Contamination confinement and/or air sampling capabilities are not acceptable, unless a result of this magnitude was expected because of a known unusual cause; in such cases, corrective action in the work area presumably has been or is being taken, and action due to the bioassay result includes actions (7) and (8) only. Prevalent conditions under which a result in this range would be expected are not acceptable. If the result was due to such conditions or was actually unexpected, take actions (1) through (6) and:

- (7) Establish work restrictions as necessary for affected employees.
- (8) Have additional urine specimen tested for albuminuria under direction of a physician.

^aL is 2.7 mg of uranium in the blood. Assume uptake is 43% of intake.

#### (2) Class (D) Dust, Dual Action Requirements

If the urinary uranium concentration is sufficiently large, action due to both radiation dose and chemical toxicity may be necessary. Both Figures 8 and 10 should be consulted for this determination. Figure 11 presents values of specific activity acceptable for converting activity to gravimetric units.

For exposure to multiple enrichments, values from Figure 11 should be weighted to obtain an appropriate specific activity. If the weighting factors are unknown, the smallest specific activity present should be used.

## (3) Dose Commitment Correlation, Single Intake, Class (W) and Class (Y) Dust, Excreta Analysis

The correlation between dose commitment to the lung, urinary uranium concentration, and uranium fecal excretion rate is shown in Figures 12 through 14 for Class (W) and Class (Y) materials. Recommended actions, from Table 4, are indicated.

### (4) Dose Commitment Correlation, Single Intake, Class (W) and Class (Y) Dust, In Vivo

The correlation between dose commitment to the lung and the mass of U-235 measured in the thorax

by *in vivo* techniques is shown in Figure 15 for Class (W) materials and in Figure 16 for Class (Y) materials. Recommended actions, from Table 4, are indicated. These figures are applicable to uranium of 20 w/o U-235; scaling factors are provided in Figure 17 for other enrichments.

### (5) Exposure to Mixtures

If a positive urinalysis specimen is obtained following exposure to a mixture that included significant quantities of Class (Y) materials, actions (1) through (11) in Table 4 should be taken.

If the exposure was to a mixture of Class (W) dust and Class (D) dust with chemical toxicity limiting, the urinary uranium mass concentration should be determined and the curves in Figure 9 used to determine the required actions from Table 5; the activity concentration should also be determined, using Figure 12 with Table 4.

If exposure was to a mixture of Class (W) dust and Class (D) dust with bone dose limiting, it is necessary to estimate the fraction of the dust inhaled that was Class (W),  $f_w$ , and the fraction that was Class (D),  $f_d$ . It is also necessary to determine the urinary excretion factors,  $E_w$  and  $E_d$ , that would be applicable at the time the specimen was obtained; Figure 18 may be used for this purpose. If R represents the bioassay result in pCi/day,  $R_d$  the Class (D) component and  $R_w$ the Class (W) component, such that  $R = R_d + R_w$ , then

$$R_{d} = f_{d}E_{d}R/(f_{d}E_{d} + f_{w}E_{w})$$
$$R_{w} = f_{w}E_{w}R/(f_{d}E_{d} + f_{w}E_{w})$$

These results should be converted to concentration using the factor 1.4 1/day. Then the curves in Figure 8 or Figure 12 should be used to determine the required actions from Table 4.

If positive *in vivo* results are obtained following exposure to a mixture of Class (W) and Class (Y) materials, Figure 16 should be used to determine the required actions from Table 4.

#### (6) Lung Burden Correlations, Continuous Intake

In some working areas airborne uranium is routinely present and is responsible for the chronic appearance of uranium in urine. Continuous intakes of this nature may also be responsible for chronically positive *in vivo* measurement results. Under these conditions positive bioassay results are expected, and the monitoring tasks are to measure the lung burden buildup and to identify single intake peaks above this expected level. Thus it is evident that for purposes of exposure control the chronic levels due to continuous intake do not alter the approach outlined for the detection of single intakes.

The correlation between *in vivo* measurements of U-235 and lung burden is shown in Figure 19. *In vivo* measurements are considered to be much more reliable than urinalysis for Class (W) and Class (Y) materials. However, urinalysis may be used to indicate that *in vivo* measurements are promptly needed. The average value from several urinalysis results ( $\overline{R}$ ) can be used with Figure 20 to estimate the number of maximum permissible lung burdens (MPLB = 0.016  $\mu$ Ci). Arrangements for *in vivo* measurements should be undertaken when  $\phi \overline{R}$  is found to exceed 0.5. If  $\phi \overline{R} > 1$ , additional exposure should be avoided until *in vivo* results are available.

### (7) Referral to a Physician

When confirmed bioassay measurement results indicate that the Maximum Permissible Annual Dose (MPAD) to the lung or bone has been or will be exceeded by a factor of 2, the affected individual should be so informed, and referral to a physician knowledgeable in the biological effects of radiation and conversant in the nature and purpose of regulatory dose limits should be considered.

When confirmed bioassay results indicate that an exposure to uranium has resulted in an uptake by the blood of more than 2.7 mg within 7 consecutive days or less, the affected individual should be informed of his exposure and referred to a physician knowledgeable in the chemical effects of internally administered uranium.

### (8) Work Restrictions

AEC regulations establish an upper limit on exposures during a specified period of time; it follows that work restrictions may be necessary to prevent exposures from exceeding this limit. Such restrictions may also be necessary to prevent the deposition of uranium in the body in such quantity that:

- (i) the mass of uranium entering the blood will exceed 2.7 mg in 7 consecutive days;
- (ii) the activity present in the lung will produce an annual dose-equivalent to the pulmonary region exceeding 15 rems;
- (iii) the activity present in the bone will produce an annual dose-equivalent to the bone exceeding 30 rems.

For personnel who have a body burden of uranium that is producing an annual dose-equivalent greater than 15 rems to the pulmonary region of the lung or 30 rems to the bone or both, work restrictions may be imposed as necessary to assure that the additional radiation dose from sources under the control of the employer would be considered negligible by a qualified health physicist.

## 4. Diagnostic Guidance

In previous sections a monitoring program has been described which should detect every instance of serious deposition of uranium in the body. Once a deposition of this nature has been identified, the bioassay purpose changes from exposure control to diagnosis. With respect to chemical toxicity, the objective is to determine whether the uranium uptake was sufficient to cause kidney damage. The radiological objectives are to estimate (1) the quantity of uranium present in the organ of reference, (2) the rate of elimination, (3) the magnitude of the original deposition, and (4) the dose commitment. As with exposure control monitoring, use of models is necessary. However, it is usually possible in a given individual's case to use factual data rather than some of the assumptions, and every opportunity for such refinement should be taken. This subject is treated in considerable detail in WASH-1251, Section V.

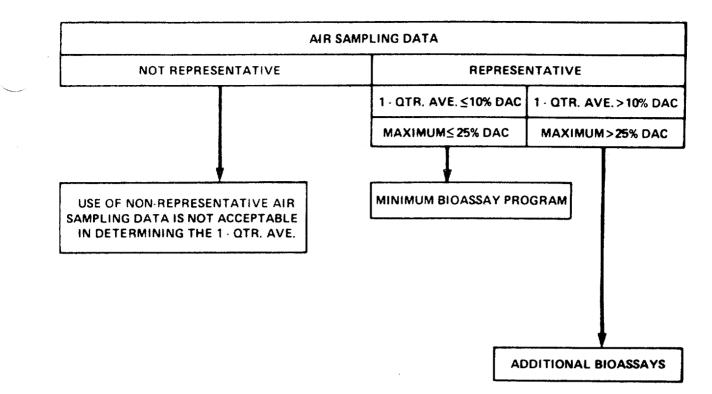


Figure 1 Criteria for Initiating Additional Bioassays, Routine Conditions

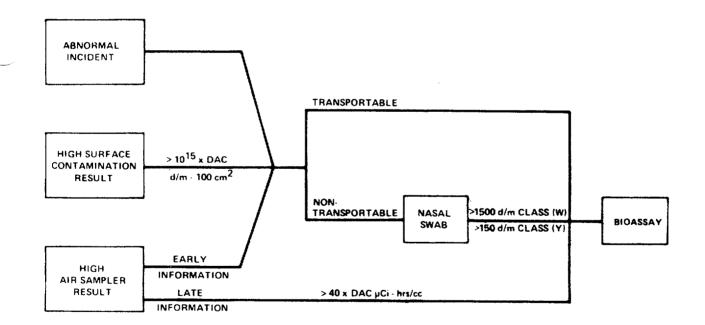


Figure 2 Criteria for Diagnostic Bioassays Durings Special Investigations

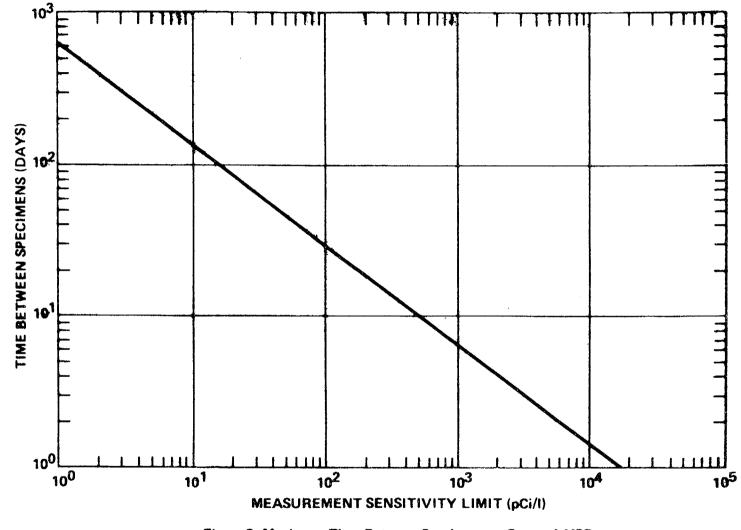


Figure 3 Maximum Time Between Specimens to Detect 1 MPD_c, Class (D) Uranium Dust, w/o U-235 >80

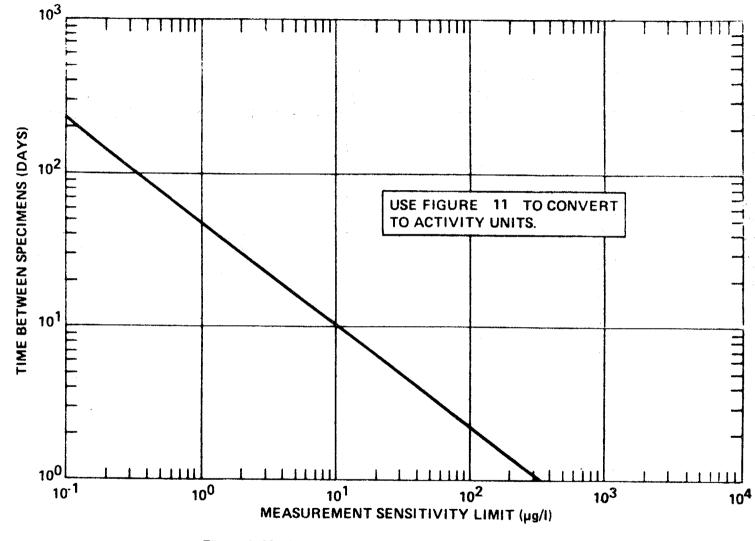


Figure 4 Maximum Time Between Specimens to Detect Uptake of 2.7 mg Class (D) Uranium, w/o U-235 ≤ 80

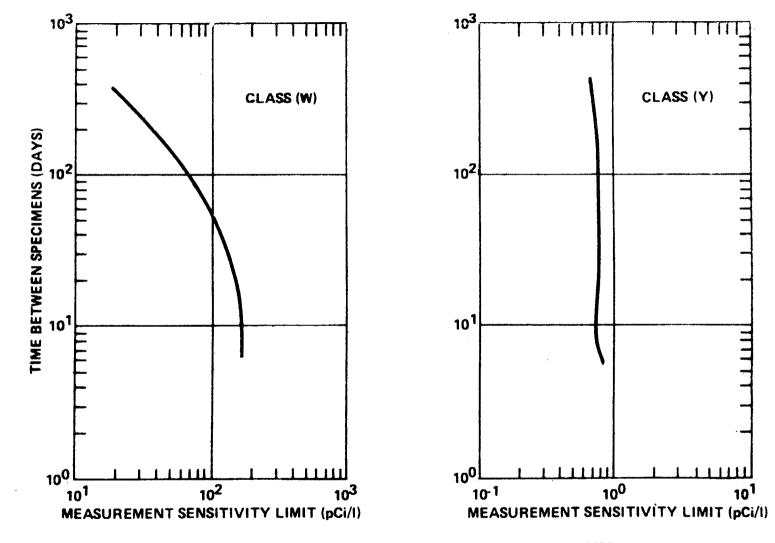
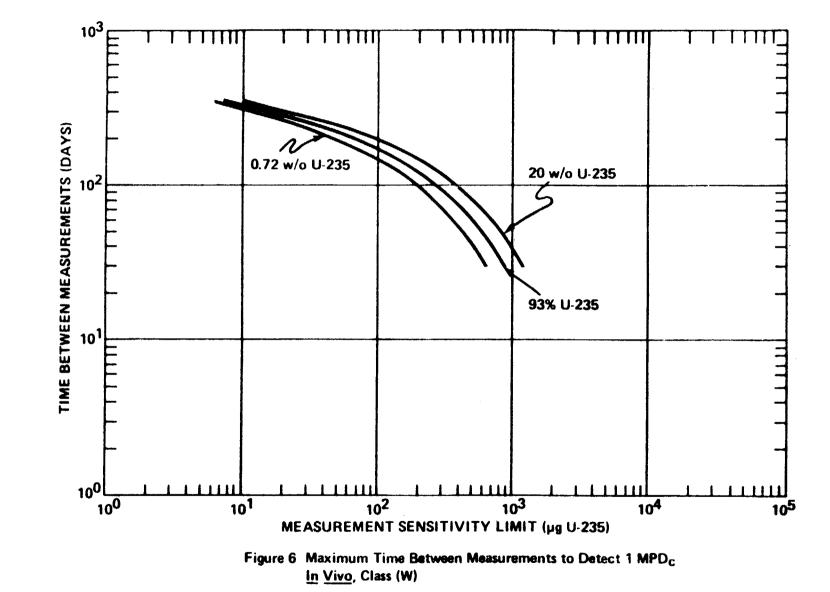
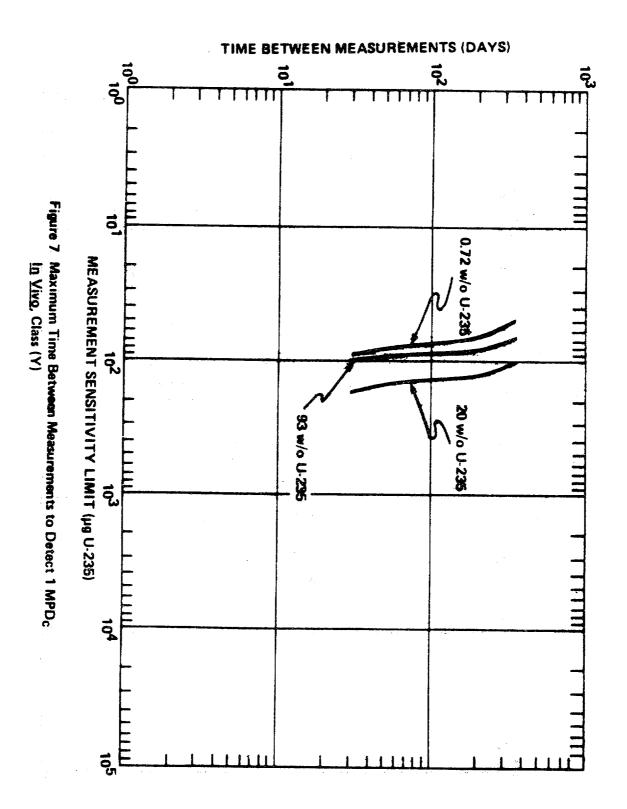
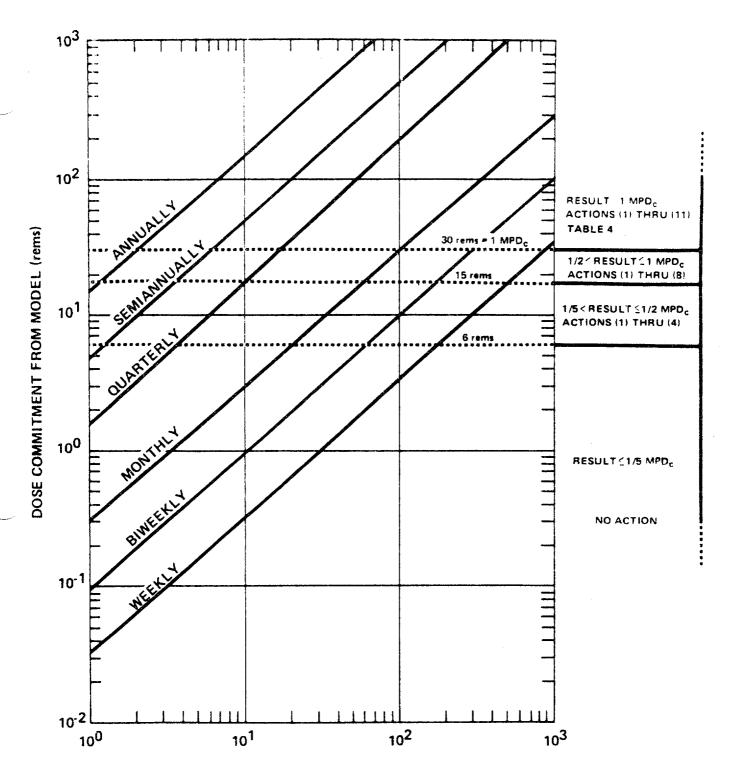


Figure 5 Maximum Time Between Specimens to Detect 1 MPD_c, Class (W) or Class (Y) Uranium



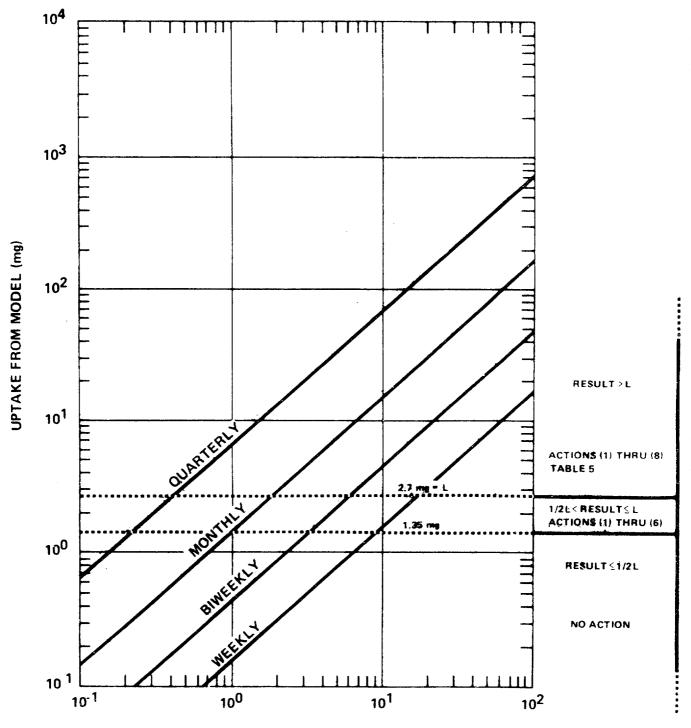


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URINARY URANIUM CONCENTRATION (pCi/l)

Figure 8 Dose Commitment Indicated by Model vs. Urinary Uranium Concentration, Class (D), Single Intake



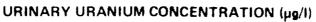
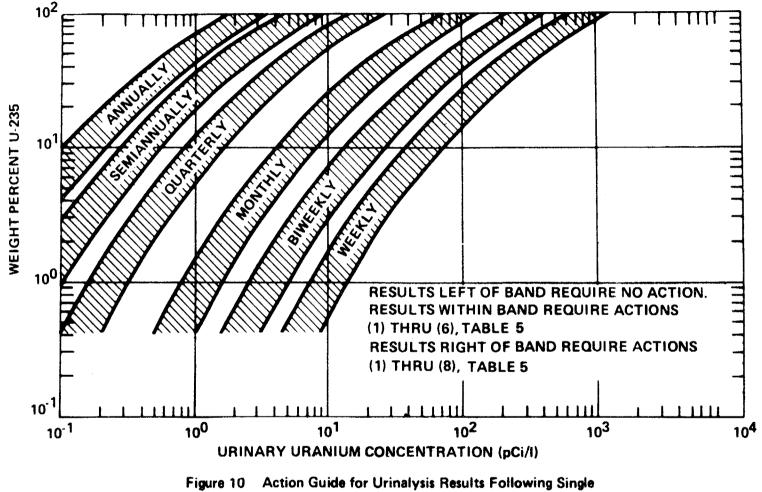


Figure 9 Uptake in Blood Indicated by Model vs. Urinary Uranium Concentration, Class (D), Single Intake



Intake of Uranium, Chemical Toxicity

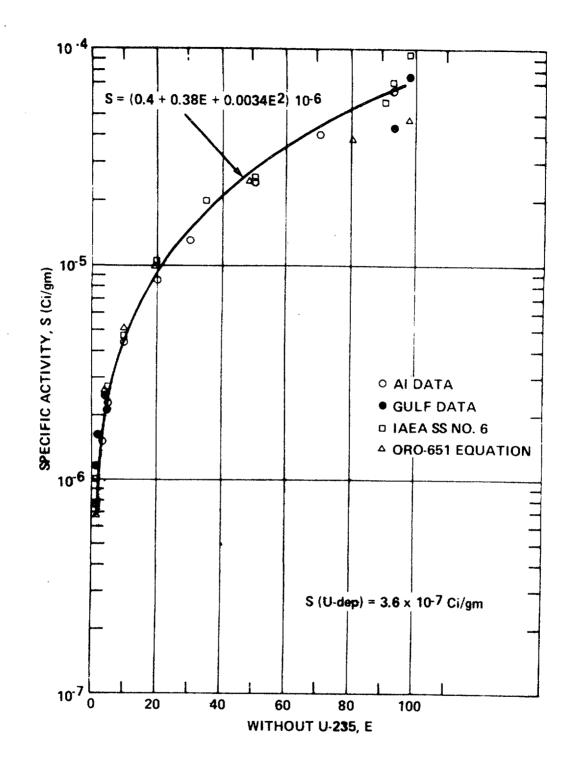


Figure 11 Specific Activity for Mixtures of U-238, U-234 and U-235

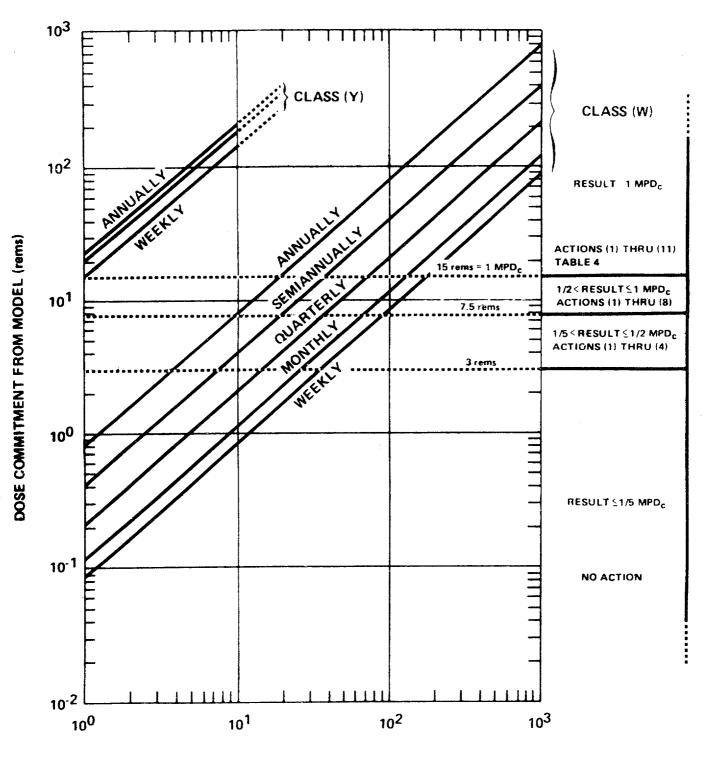




Figure 12 Dose Commitment Indicated by Model vs. Urinary Uranium Concentration, Class (W) and (Y), Single Intake

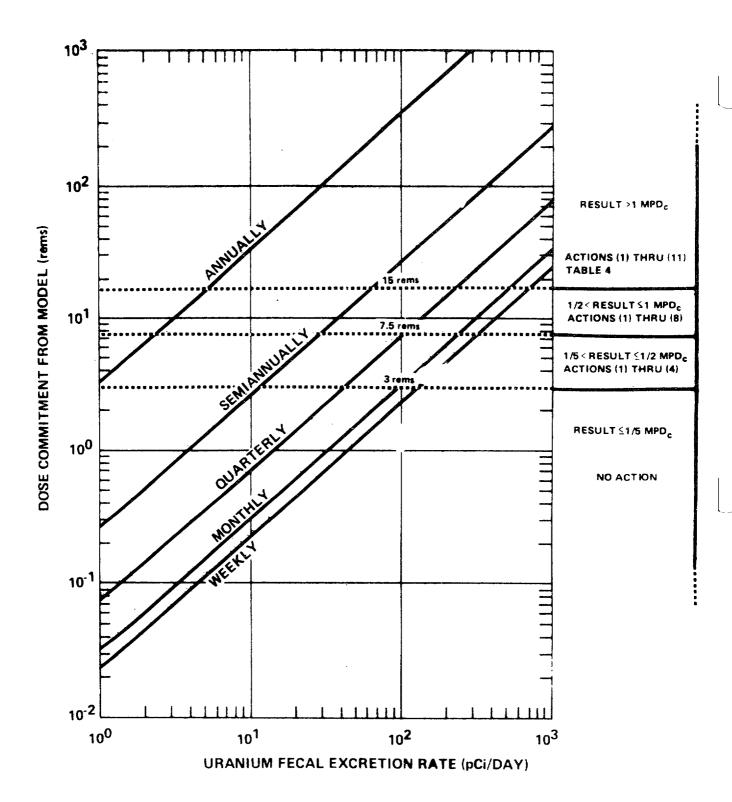
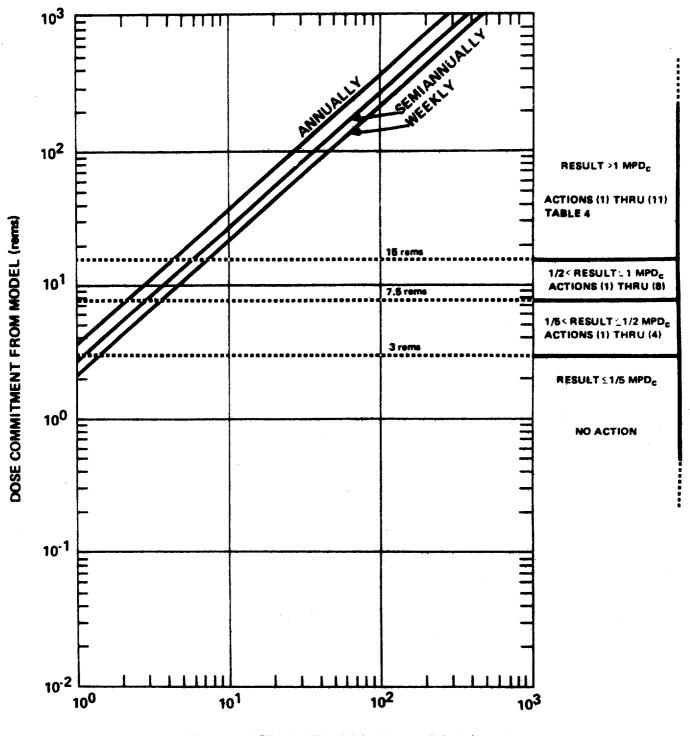
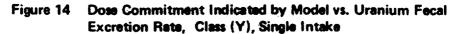


Figure 13 Dose Commitment Indicated by Model vs. Uranium Fecal Excretion Rate, Class (W), Single Intake







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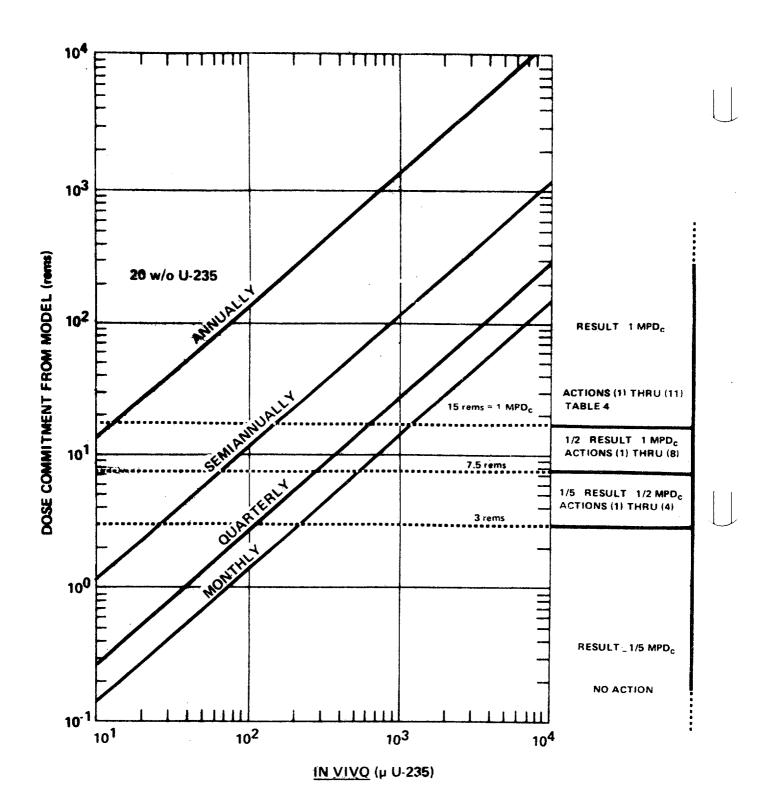
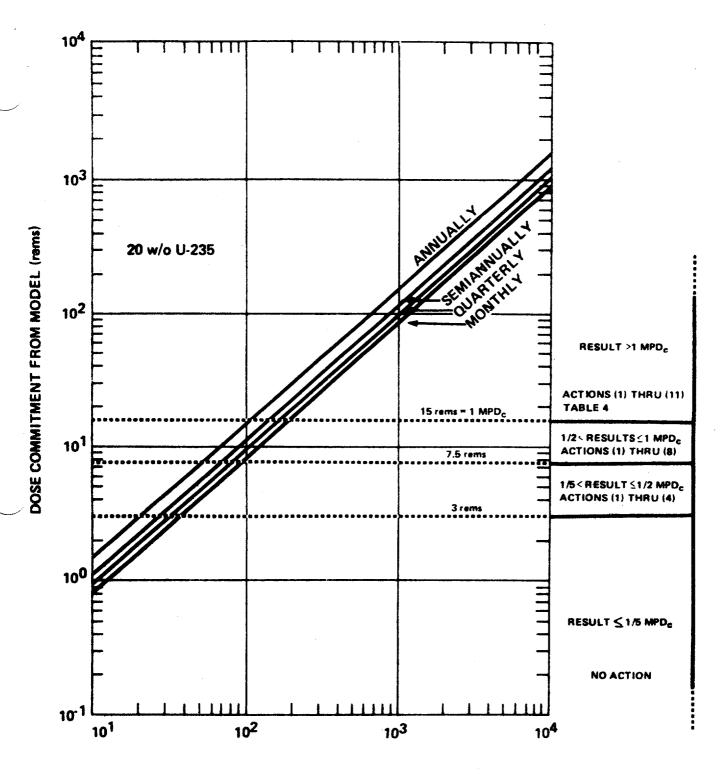


Figure 15 Dose Commitment Indicated by Model vs. In Vivo Result, Class (W), Single Intake



IN VIVO RESULT (µg U-235)

Figure 16

6 Dose Commitment Indicated by Model vs. In Vivo Result, Class (Y), Single Intake

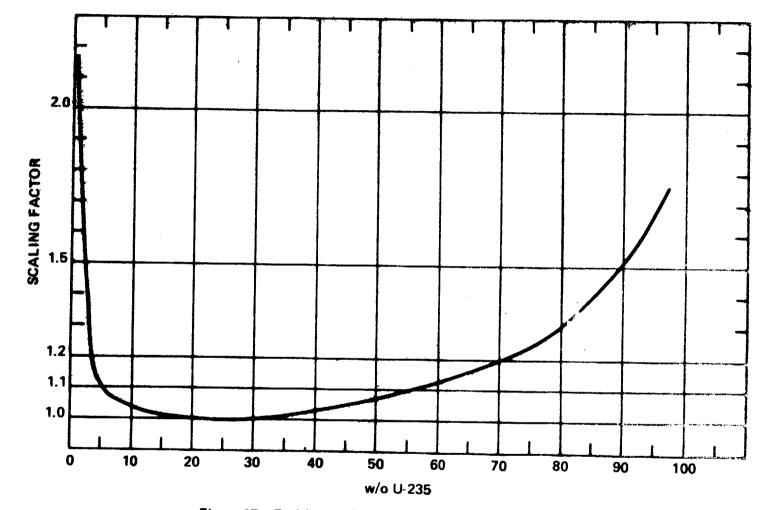


Figure 17 Enrichment Scaling Factors for Model Dose Commitment Curves, In Vivo Measurement Following Single Exposure to Class (W) or Class (Y) Uranium Dust

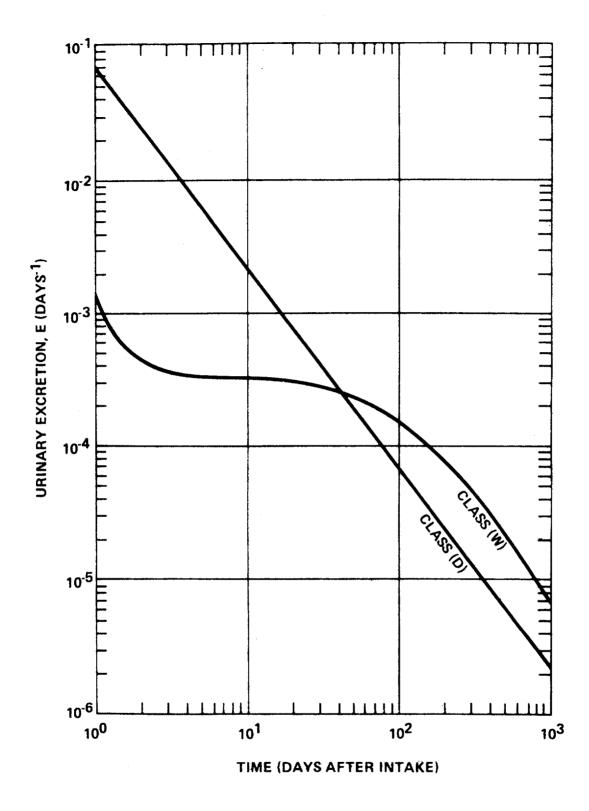


Figure 18 Urinary Uranium Excretion Factors for Determining  $R_D$  and  $R_W$ 

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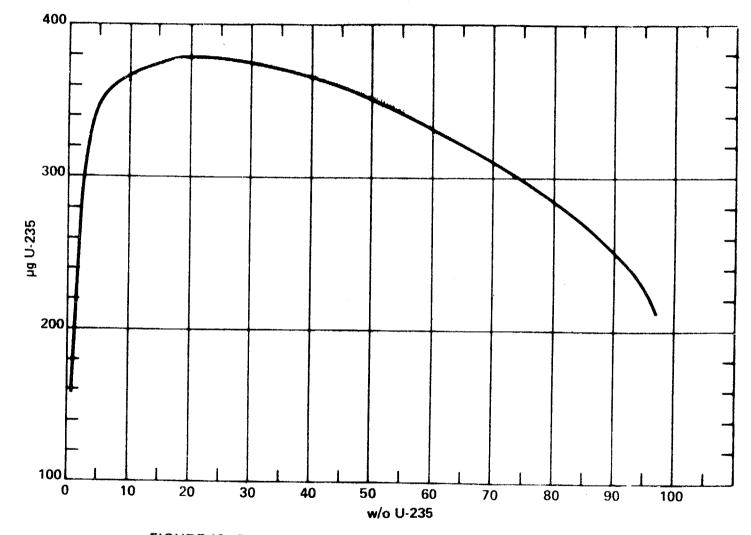


FIGURE 19 Equilibrium Mass of U-235 in the Lung Equivalent to 1 Maximum Permissible Lung Burden

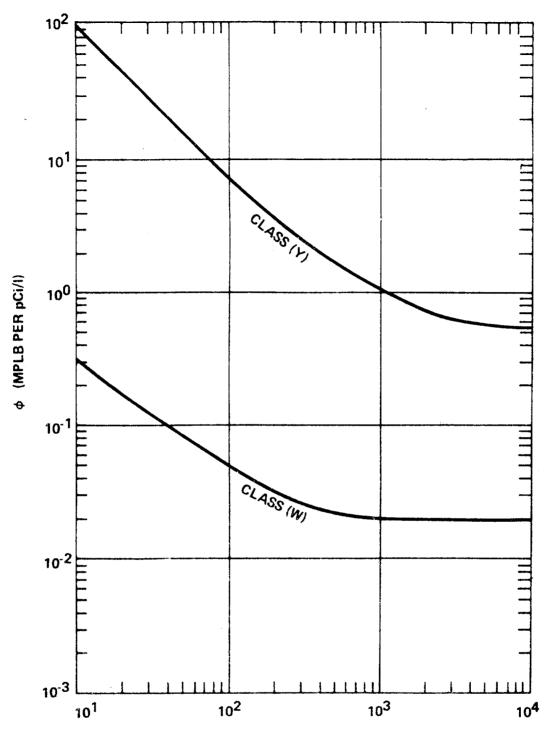




Figure 20 Model for Interpreting Urinalysis Results During Continuous Exposure to Constant Concentration of Uranium in Air