REGULATORY GUIDE 8.9
(Draft was issued as DG-8009)

ACCEPTABLE CONCEPTS, MODELS, EQUATIONS, AND ASSUMPTIONS FOR A BIOASSAY PROGRAM

A. INTRODUCTION

Section 20.1204 of 10 CFR Part 20, "Standards for Protection Against Radiation," requires that each licensee, when required by 10 CFR 20.1502, take suitable and timely measurements of quantities of radionuclides in the body, quantities of radionuclides excreted from the body, concentrations of radioactive materials in the air in the work area, or any combination of such measurements as may be necessary for detection and assessment of individual intakes of radioactive material. Furthermore, 10 CFR 20.1204 (c) (1) allows for the use of specific information on the physical and biochemical properties of the radioactive material deposited in the body in determining an individual's internal dose. Also, as stated in 10 CFR 20.1703(a) (3) (ii), if respiratory protection equipment is used to limit intakes of airborne radioactive material, the licensee's respiratory protection program is to include bioassay measurements, as appropriate, to evaluate actual intakes of airborne activity.

Because of differences in physical properties and metabolic processes, each individual's dose resulting from an exposure is unique. In other words, the same exposure to multiple individuals will cause different doses to each individual. However, for the purpose of demonstrating compliance with dose limits, standard approaches for determining intake and calculating a dose have been developed. For certain unusual circumstances, such as exposures at or near the limits, special consideration may need to be given to the specifics of an individual's retention and excretion in determining the intake. It is not the intent of this regulatory guide to constrain licensees from performing more detailed analyses when the licensee determines that the magnitude of the exposure warrants further investigation.

This guide describes practical and consistent methods acceptable to the NRC staff for estimating intake of radionuclides using bioassay measurements. Alternative methods acceptable to the NRC staff are in ICRP Report No. 54, "Individual Monitoring for Intake of Radionuclides by Workers: Design and Interpretation" (Ref. l), and NCRP Report No. 87, "Use of Bioassay Procedures for Assessment of Internal Radionuclide Deposition" (Ref. 2).

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 approved by the Office of Management and Budget, Approval No. 3150-0014.

B. DISCUSSION

Bioassay measurements include the analysis of radioactive material in body organs or in the whole body (in vivo measurements) and in biological material excreted, eliminated, or otherwise removed from the body (in vitro measurements). The in vivo measurements are made using a whole body counter, thyroid counter, lung counter, or other similar device. The in vitro measurements involve collection of urine, feces, *or* tissue samples that are measured directly, or after radiochemical separation, by gamma spectrometry, or by alpha or beta counting of the separated radionuclide as appropriate.

ICRP Publication 30, "Limits for Intakes of Radionuclides by Workers" (with accompanying addenda) (Ref. 3), has been used by the NRC as the basis for its annual limits on intake (ALI) and derived air concentrations (DAC) listed in Appendix B to §§ 20.1001 through 20.2401. Likewise, the modeling in ICRP-30 serves as the basis for interpreting the bioassay measurements in NUREG/CR-4884, "Interpretation of Bioassay Measurements" (Ref. 4). Since the issuance of ICRP-30 (Ref. 3), improvements in the metabolic modeling for a few radionuclides have resulted in dosimetric modeling equally acceptable to the NRC staff. For example, a model developed by Jones (Ref. 5) provides acceptable estimates of urinary fractional excretions of plutonium. Also, a tritium metabolic model developed by Johnson and Dunford (Ref. 6) provides acceptable (and often improved) estimates of time-dependent tritium excretion. As additional research is conducted, it is expected that refinements in the metabolic modeling will further improve the methods available for correlating bioassay measurements to actual intake and the resultant dose to an individual.

Metabolic modeling, such as that presented in ICRP-30 (Ref. 3) and ICRP-54 (Ref. l), has been used for evaluating bioassay measurements through the development of time-dependent values for the bodily retention or excretion (or both) of the ingested or inhaled radioactive material. NUREG/CR-4884 (Ref. 4) presents a comprehensive set of data on intake retention and excretion fractions developed from these models. These data, and the accompanying description of the modeling and methods, provide useful information for using bioassay measurements to estimate intake. In addition, ICRP-54 (Ref. 1) presents metabolic models accompanied by data and figures of bodily retention and excretion for many of the radionuclides of importance to NRC licensees.

ICRP-30 (Ref. 3) and ICRP-54 (Ref. 1) are based on general considerations (i.e., standard chemical forms and standard man or woman metabolic modeling). Each individual's physiological characteristics and biochemical processes may be different. In addition, the particulars of the exposure situation, such as particle size distribution, will affect the lung compartment deposition fractions and the resultant biological clearances. For example, particles larger than 20 μm AMAD[1] will deposit mainly in the naso-pharyngeal (N-P) region and tend to show biological retention and excretion characteristics more typical of an ingestion intake than of an inhalation intake of the default 1 μm AMAD. These characteristics are due to the fact that a large fraction of particles deposited in the N-P region is cleared by the ciliated epithelial cells to the throat and subsequently swallowed, thereby appearing to be an ingestion intake. Fitting an individual's bioassay measurement data for a particular exposure situation to the standard modeling will, however, provide reasonably accurate estimates for most situations.

This guide contains methods for evaluating bioassay data that will result in calculated intakes that are acceptable to the NRC staff for evaluating compliance with the occupational dose limits of 10 CFR 20.1202. Examples of specific exposure situations and the physical and biochemical processes considered in the assessment of the exposures are in Appendix A to this guide. Additional information on bioassay measurements, interpretation of bioassay data, and bioassay program components can be found in ICRP-30 (Ref. 3), ICRP-54 (Ref. 1), NCRP-87 (Ref. 2), and NUREG/CR-4884 (Ref. 4).

The following terms, which have not been defined in 10 CFR 20.1003, have been used in this guide.

Evaluation Level-The level at which an intake should be evaluated beyond the initial bioassay measurement. The evaluation level is 0.02 times the annual limit on intake (ALI), which is equivalent to 40 derived air concentration (DAC) hours.

Excretion Fraction-The fraction of the intake that has been excreted by the body at time (t) following the intake.

Intake Retention Fraction-The fraction of the intake that is retained in the body at time (t) following the intake.

Investigation Level-The level at which an intake should be investigated. The investigation level is any intake greater than or equal to 0.1 times the annual limit on intake (ALI).

C. REGULATORY POSITION

NOTE: The regulatory positions in this regulatory guide supersede the information contained in NRC IE Information Notice No. 82-18, "Assessment of Intakes of Radioactive Material by Workers."

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[1] Activity Median Aerodynamic Diameter (AMAD): The diameter of a unit density sphere with the same terminal settling velocity in air as that of an aerosol particle whose activity is the median for the entire aerosol.

1. AVAILABILITY OF BIOASSAY SERVICES

The purposes of bioassay measurements are to confirm the adequacy of radiological controls and to determine compliance with the occupational dose limits. Bioassay services should be available if the types and quantities of radioactive material licensed for use at the facility could, under normal operational occurrences, result in airborne levels in normally occupied areas exceeding DACs. Provisions should be made for the collection of appropriate samples, analysis of bioassay samples, and evaluation of the results of these analyses to determine intakes.

2. FREQUENCY OF REQUIRED BIOASSAY MEASUREMENTS

Determining the appropriate frequency of routine bioassay measurements depends upon the exposure potential and the physical and chemical characteristics of the radioactive material and the route of entry to the body. Elements that should be considered include (1) the potential exposure of the individual, (2) the retention and excretion characteristics of the radionuclide, (3) the sensitivity of the measurement technique, and (4) the acceptable uncertainty in the estimate of intake and committed dose equivalent. Bioassay measurements used for demonstrating compliance with the occupational dose limits should be conducted often enough to identify and quantify potential exposures and resultant intakes that, during any year, are likely to collectively exceed 0.1 times the ALI.[2]

Two separate categories of bioassay measurements further determine the frequency and scope of measurements: routine measurements and special measurements.

2.1 Routine Measurements

Routine measurements include baseline measurements, periodic measurements, and termination measurements. These measurements should be conducted to confirm that appropriate controls exist and to assess dose.

2.1.1 Baseline Measurements

An individual's baseline measurement of radioactive material within the body should be conducted prior to initial work activities that involve exposure to radiation or radioactive materials, for which monitoring is required.

2.1.2 Periodic Measurements

In addition to the baseline measurements, periodic bioassay measurements should be performed. The frequency of periodic measurements should be determined on an a priori basis, considering the likely exposure of the individual. In determining the worker's likely exposure, consider such information as the worker's access, work practices, measured levels of airborne radioactive material, and exposure time. Periodic measurements should be made when the cumulative exposure to airborne radioactivity, since the most recent bioassay measurement, is ≥ 0.02 ALI (40 DAC hours). Noble gases and airborne particulates with a radioactive half-life less than 2 hours should be excluded from the evaluation since external exposure is generally controlling for these radionuclides.

As a minimum, periodic measurements should be conducted annually. Periodic measurements provide additional information on any long-term accumulation and retention of radioactive material in the body, especially for exposures to concentrations of airborne radioactive material below monitoring thresholds.

2.1.3 Termination Measurements

When an individual is no longer subject to the bioassay program, because of termination of employment or change in employment status, termination bioassay measurement should be made, when practicable, to ensure that any unknown intakes are quantified (see Example 2 in Appendix A to this guide).

2.2 Special Monitoring

Because of uncertainty in the time of intakes and the absence of other data related to the exposure (e.g., physical and chemical forms, exposure duration), correlating positive results to actual intakes for routine measurements can sometimes be difficult. Abnormal and inadvertent intakes from situations such as a failed respiratory protective device, inadequate engineering controls, inadvertent ingestion, contamination of a wound, or skin absorption[3] should be evaluated on a case-by-case basis. Circumstances that should be considered when determining whether potential intakes should be evaluated include:

- The presence of unusually high levels of facial and/or nasal contamination,

- Entry into airborne radioactivity areas without appropriate exposure controls,

- Operational events with a reasonable likelihood that a worker was exposed to unknown quantities of airborne radioactive material (e.g., loss of system or container integrity),

- Known or suspected incidents of a worker ingesting radioactive material,

- Incidents that result in contamination of wounds or other skin absorptions,

- Evidence of damage to or failure of a respiratory protective device.

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[2]The 10% ALI criterion is consistent with 10 CFR 20.1502(b), which requires licensees to monitor intakes and assess occupational doses for exposed individuals who are likely to exceed 10% of the applicable limit (i.e., intakes likely to exceed 0.1 ALI for adults).

[3]The skin absorption of airborne tritium has been included in the determination of its ALI and DAC values for occupational inhalation exposures in Appendix B to §§20.1001-20.2401.

2.3 Estimating Intakes-Evaluation and Investigation Levels

Licensees should estimate the intake for any bioassay measurement that indicates internally deposited radioactive material resulting from licensed activities. The scope of the evaluation should be commensurate with the potential magnitude of the intake. For individual exposures with an estimate of intake less than 0.02 ALI, minimum bioassay measurements are adequate to provide a reasonable approximation of intake. Repeated follow-up measurements or additional exposure data reviews are not necessary, provided a reasonable estimate of the actual intake can be made based on available data.[4]

2.3.1 Evaluation Level

For very small intakes, a single bioassay measurement is generally adequate to estimate intake.[5] For intakes that represent a significant contribution to dose, other available data should be evaluated. If initial bioassay measurements indicate that an intake is greater than an evaluation level of 0.02 ALI, additional available data, such as airborne measurements or additional bioassay measurements, should be used to obtain the best estimate of actual intake.

2.3.2 Investigation Level

For single intakes that are greater than 10% of the ALI, a thorough investigation of the exposure should be made. Therefore, if a potential intake exceeds an investigation level of 0.1 ALI, multiple bioassay measurements and an evaluation of available workplace monitoring data should be conducted. If practical, daily measurements should be made until a pattern of bodily retention and excretion can be established. Such a determination is feasible after as few as three measurements; however, physiologically related variations and uncertainties require that measurements be continued over a longer period of time in some cases. For potential intakes near or exceeding the ALIs, the bioassay data evaluations should consider any additional data on the physical and chemical characteristics and the exposed individual's physical and biokinetic processes.

3. TYPE OF MEASUREMENTS

Characteristics such as mode of intake, uptake, and excretion and mode of radioactive decay should be considered in selecting the most effective and reliable types of measurements. For example, in vivo lung or total body measurements shortly following ex-

posure generally provide reliable estimates of intakes for most gamma emitting radionuclides. In vitro measurements should be used for radionuclides that emit little or no gamma radiation. However, in vitro urine or fecal measurements for the first voiding following exposure, while providing important information for assessing potential significance, do not generally represent equilibrium conditions and thereby should not be relied upon in evaluating actual intakes. ICRP Publication 54 (Ref. 1) and NCRP Report No. 87 (Ref. 2) provide guidance acceptable to the NRC staff for determining the types of bioassay measurements that should be made considering the physical and biological characteristics of the radioactive material.

4. INTERPRETATION OF BIOASSAY MEASUREMENTS

The specific scope and depth of the evaluation of bioassay measurements, as discussed in Regulatory Position 2.3, depends on the potential significance of the intake. The methods presented below are acceptable to the NRC staff for correlating bioassay measurements to estimates of intakes for the purpose of demonstrating compliance with the occupational dose limits of 10 CFR 20.1201.

4.1 Time of Exposure

Accurate estimation of intake from bioassay measurements is dependent upon knowledge of time of intake. Generally, the time of intake is known considering work activities and other monitoring data, such as air sample data. Therefore, the time of intake will be known for all but unusual situations. When the time of intake cannot be determined from monitoring data, it can often be determined from information provided by the individual. When information is insufficient to determine the time of intake, it is acceptable to assume that the intake occurred at the midpoint of the time period since the last bioassay measurement. This initial assumption should be refined by using any available information such as the individual's work schedule, facility operations data, historical air monitoring data, and the effective half-life of the radionuclides detected (see Example 2 of Appendix A).

4.2 Acceptable Biokinetic Models

Determining a worker's intake from bioassay measurements involves comparing the measured bodily retention or excretion to a tabulated value. The models and methods used for evaluating bioassay measurements should provide a reasonable assessment of the worker's exposure. For intakes that are a small fraction of the limit, greater inaccuracy in the estimate of intake can be accepted without significant impact on the overall assessment of a worker's dose. However, for annual exposures for which monitoring is required by 10 CFR 20.1502(b), these methods

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[4] The purpose of this guidance is to describe the scope of the bioassay measurements that should be considered for assessing intakes. It is not intended to limit the types of reviews that may be warranted for assessing the overall significance of an intake.

[5] For radionuclides that are difficult to detect, such as alpha emitters, a single measurement may not be adequate to determine intakes.

should not lead to significant underestimation or overestimation of the actual intake.

Variations from predicted retention and excretion for specific individuals can be expected. Excretion of radionuclides may be influenced by the worker's diet, health condition, age, level of physical and metabolic activity, or physiological characteristics. The lung deposition and clearance of the inhaled radionuclide, the particle size distribution; and the time of the excretion also influence the excretion rate of radionuclides.

Important considerations for evaluating bioassay measurements include:

- Appropriate measurement technique (in vivo or in vitro) based on radionuclide decay characteristics (i.e., types of radiation emitted) and biokinetic characteristics (i.e., systemic uptake and retention and urine and fecal excretion fractions),

- The effects of diuretics or chelation to reduce systemic uptake and to increase excretion or excretion rates,

- Representativeness of measurements such as 24-hour or accumulated urine or fecal measurements,

- The appropriate lung clearance class (D, W, or Y), if known (see definition of class in 10 CFR 20.1003). If no information on the biological behavior or chemical form is available, the most restrictive clearance class relevant for the particular element should be assumed (i.e., that class that gives the lowest value of ALI),

- Particle size distribution,

- Chemical toxicity as in the case of uranium (see 10 CFR 20.1201(e)).

The metabolic models in ICRP-30 and accompanying addenda (Ref. 3) and ICRP-54 (Ref. 1) present acceptable bases for estimating intake from bioassay measurements. Other acceptable models are the tritium model developed by Johnson and Dunford (Ref. 6) and the plutonium urinary excretion model developed by Jones (Ref. 5).

The use of computer codes that apply these models is also acceptable for evaluating bioassay measurements provided it can be demonstrated through documented testing that the models and methods employed provide results that are consistent with the acceptable models. There are several commercially available computer codes for interpreting bioassay measurements; these codes may be used as long as the software application is based on acceptable models and provides results that correctly implement the models. No specific computer codes are endorsed by the NRC staff. Licensees are responsible for ensuring that computer codes are appropriate for use in their particular circumstances.

4.3 Intake Retention and Excretion Fractions for Calculating Intakes

ICRP-54 (Ref. 1) presents urinary excretion and fecal excretion equations as a function of time following intake for a number of radionuclides. By differentiating these equations, intake retention functions can be derived. The solution of these equations over a range of times allows the development of tabulated intake retention and excretion fractions. The intake retention fractions[6] (IRFs) contained in NUREG/CR-4884 (Ref. 4) were developed in this manner and represent an acceptable basis for correlating bioassay measurements to estimates of intake. To apply the use of IRFs for calculating an individual's radionuclide intake from a single bioassay measurement, divide the total activity in 24-hour urine, 24-hour feces, accumulated urine, or accumulated feces,[7] or the radionuclide content in the total body, systemic organs, lungs, nasal passages, or GI tract, by the appropriate IRF value in NUREG/CR-4884.

Equation 1 demonstrates this method:

$$I = \frac{A(t)}{IRF(t)} \qquad \text{Equation 1}$$

where:

I   =   Estimate of intake with units the same as A(t),

A(t)   =   Numerical value of the bioassay measurement obtained at time t (decay corrected to time of sampling for in vitro measurements) with appropriate units (µCi, Bq, or µg).

IRF(t) = Intake retention fraction corresponding to type of measurement for time t after estimated time of intake,

4.3.1 Evaluating Spot Samples

If the total urine or feces is not collected for the 24-hour period, the following equations may be used to estimate the total activity excreted or eliminated over the 24-hour period based on less frequent sampling (spot samples).

$$\triangle A_i = C_i E(t_i - t_{i-1}) \qquad \text{Equation 2}$$

$$A_i = \triangle A_1 + \triangle A_2 + ... \triangle A_i \qquad \text{Equation 3}$$

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[6]For purposes of this guide and the application of the data from NUREG/CR-4884, the parameter IRF denotes both intake retention fractions and intake excretion fractions.

[7]The term "24-hour urine" means the total urine output collected over a 24-hour period, and the term "24-hour feces" means the total feces output collected over a 24-hour period. "Accumulated urine" and "accumulated feces" mean the total output since time of exposure.

where:

$\triangle A_i =$ Activity or amount of radioactive material in sample i

$i =$ The sequence number of the sample

$C_i =$ The radionuclide concentration in urine (activity/liter) or feces (activity/gram) of sample i, decay corrected to the time of sampling

$E =$ Daily excretion rate (use measured rates when available, or assume values of 1.4 liters/day for urine and 135 grams/day for feces for standard man or 1.0 liter/day for urine and 110 grams/day for feces for standard woman)

$t_i =$ The time (days) after intake that sample i is collected

$A_i =$ Total activity excreted or eliminated Up to time t_i

This method is applicable only if spot samples are collected with a frequency that is consistent with the significance of changes in the excretion rates. In general, spot samples should be collected frequently enough that there is no more than a 30% increase in the IRFs between bioassay measurements. For example, if the IRF for accumulated urine increases at a rate of 30% per day, spot samples should be collected daily. If the rate is 10% per day, collecting spot samples once every 3 days would be adequate. Also, the rapid clearance and excretion of inhaled particles from the N-P region of the lung makes it important that at least one spot sample be collected within the first 24 hours after exposure. Otherwise, the reliability of using accumulated samples and excretion fractions for calculating intakes should be examined; calculations based on spot samples correlated to 24-hour samples may provide better estimates.

For spot samples used to estimate an equivalent 24-hour sample, correcting for abnormal conditions of high or low fluid intake or excessive loss of fluids by perspiration may be warranted. NCRP-87 (Ref. 2) presents the following method, based on a relationship between the specific gravity (sp. gr.) of the sample to the average specific gravity of urine (1.024 g/ml).

$$\text{corr. conc. } = \text{ meas. conc. } \frac{1.024 - 1 \ (g/ml)}{\text{meas. sp. gr. } - \ 1 \ (g/ml)}$$

Equation 4

An alternative to this method is a correction based on the expected creatine excretion rate of 1.7 grams/day for men and 1.0 grams/day for women. Refer to NCRP-87 (Ref. 2) for additional information.

Logarithmic interpolation should be used for interpolating retention and excretion fractions (see Example 2 in Appendix A). For example, using the NUREG/CR-4884 (Ref. 4) data, an IRF value for 2.8 days post-intake should be calculated by a logarithmic interpolation between the 2-day and the 3-day IRF values.

Examples of the application of intake retention and excretion fractions based on the NUREG/CR-4884 data set are provided in Appendix A.

4.3.2 Evaluating Multiple Bioassay Measurements

When multiple bioassay measurements are made, a statistical evaluation of the data should be performed. Numerous statistical methods are available for evaluating multiple measurements, but the results will be no better than the reliability of the data set. Measurements that are suspect or known to be inaccurate should be excluded from the analysis. Additional measurements should be used for obtaining an appropriate data set. For the evaluation of multiple measurements, NUREG/CR-4884 (Ref. 4) recommends the use of unweighted, minimized chi-squared statistics, assuming all variances are the same (i.e., a least squares fit). This method is acceptable to the NRC staff; it is simple and straightforward for evaluating multiple bioassay measurements. The equation is as follows:

$$I = \frac{\Sigma_i IRF_i(t) \ x \ A_i(t)}{\Sigma_i IRF_i(t)^2}$$

Equation 5

Other statistical analyses of the data may provide a better fit of the data, considering the particulars of the measurements. For example, a minimized chi-squared fit weighted by the inverse of the variance may be used. Several methods are available for estimating the variance of measurements. One approach, applicable to radioactivity measurements, is to assume that the variance is proportional to the value of the measurement itself. Another is the assumption that the variance is proportional to the expected value (Ref. 7).

In selecting the statistical method to be used for evaluating multiple measurements, consideration should be given to available information, particularly observed variability of the data and reliability of individual measurements. Other statistical methods are acceptable to the NRC staff provided it can be demonstrated that the results provide reasonable estimates of intake.

4.4 Adjusting Intake Estimates for Multiple and Continuous Intakes

In practice, a worker may receive repeated exposures to the same radionuclide over a period of time. These intakes should be treated as separate acute intakes if measurements collected through the period

allow for the individual quantification of each exposure. As a general rule, if intakes are separated in time so that the retained or eliminated fraction from an earlier intake is less than 10% of the retention or excretion fraction for the next intake, each intake may be evaluated separately without regard to any previous intakes.

Continual intakes that are distributed equally in size and time may be approximated using a relationship based on time integration of the IRF. The total intake is estimated by dividing the measured activity by the appropriate time-integrated retention or excretion fraction. An example using the IRF values from NUREG/CR-4884 (Ref. 4) would be to perform a numerical integration over the individual IRF values covering the time period of interest. Any one of a number of standard integration techniques, including numerical and analytical solutions, can be used. For example, using the trapezoidal rule (see Example 7 in Appendix A) yields the following method:

For bioassay measurements taken during an exposure time interval, the equation is:

$$I = \frac{A(t) \times T}{\int_0^t IRF(u)\ du} \quad \text{for } t < T \qquad \text{Equation 6}$$

Using the trapezoidal rule to solve Equation 6 yields the following approximation:

Equation 7

$$I \cong \frac{A(t) \times T \times n}{t \times \left[\frac{IRF(t) + IRF(t = 0.1\ days)}{2} + IRF(u_1) + ... + IRF(u_n - 1) \right]}$$

For bioassay measurements taken after an exposure interval, the equation is:

$$I = \frac{A(t) \times T}{\int_{t-T}^t IRF(u)\ du} \quad \text{for } t \geq T \qquad \text{Equation 8}$$

Likewise, Equation 8 may be approximated using the trapezoidal rule, which yields Equation 9:

Equation 9

$$I \cong \frac{A(t) \times n}{\left[\frac{IRF(t - T) + IRF(t)}{2} + IRF(u_1) + ... + IRF(u_n - 1) \right]}$$

where:

I = Total intake during period T

$A(t)$ = Amount of activity in compartment or whole body at time t following onset of intake

T = Duration of intake (exposure time period)

t = Time from onset of intake to time of measurement

$IRF(u)$ = Intake retention fraction at time u in compartment or whole body for a single intake of a radionuclide

u = Variable time between integration limits

n = number of increments

The number of increments to be used for a numerical integration should be selected to minimize unnecessary errors associated with the particulars of the IRF values over which the integration is being performed. In general, errors associated with the integration technique used should be limited to less than 10%.

4.5 Correcting Intake Estimates for Particle Size Differences

The models used for deriving intake retention and excretion fractions, such as those in NUREG/CR-4884, are typically based on 1-micrometer activity median aerodynamic diameter (AMAD) particles. It is acceptable to correct intake estimates for particles of different sizes. These corrections often help explain retention or excretion rates different from those expected, such as would occur for larger particles preferentially deposited in the upper region of the respiratory tract (N-P region) with more rapid clearance times. Guidance for determining AMADs is provided in Regulatory Guide 8.25, "Air Sampling in the Workplace" (Ref. 8).

Equation 10, taken from Appendix B to NUREG/CR-4884 (Ref. 4), should be used for revising the total body IRFs in NUREG/CR-4884 to particle size distributions between 0.1 to 20 μm AMAD.

Equation 10

$$IRF_{AMAD} = IRF_{1\ \mu m} \sum_T \left[f_{N-P,T} \frac{H_{50T} W_T}{\sum_T H_{50T} W_T} \frac{D_{N-P}(AMAD)}{D_{N-P}(1\ \mu m)} \right.$$

$$+ f_{T-B,T} \frac{H_{50T} W_T}{\sum_T H_{50T} W_T} \frac{D_{T-B}(AMAD)}{D_{T-B}(1\ \mu m)}$$

$$\left. + f_{P,T} \frac{H_{50T} W_T}{\sum_T H_{50T} W_T} \frac{D_P(AMAD)}{D_P(1\ \mu m)} \right]$$

where:

IRF_{AMAD} = IRF for the activity median aerodynamic diameter (AMAD) of interest

$\text{IRF}_{1 \mu m}$ = Total body IRF for inhalation of 1 μm AMAD aerosols (these IRFs are given in Appendix B to NUREG/CR-4884 (Ref. 4))

Σ_T = Summation over all tissues (and organs) T

N-P, T-B, P = The compartments or regions of deposition of the respiratory tract: the nasopharyngeal passage region (N-P), the tracheobronchial region (T-B), and the pulmonary region (P)

$f_{\text{N-P,T}}$, $f_{\text{T-B,T}}$, $f_{\text{P,T}}$ = The fraction of committed dose equivalent in the tissue T resulting from deposition in the N-P, T-B, and P regions, respectively. (Values for individual radionuclides are contained in the Supplements to Part 1 of ICRP-30 (Ref. 3).)

H_{50T} = Committed dose equivalent for tissue (or organ) T per unit intake

W_T = Tissue (or organ) weighting factor, from 10 CFR 20.1003

$D_{\text{N-P}}$, $D_{\text{T-B}}$, D_P = Regional deposition fractions for an aerosol entering the respiratory system. (Values presented in Table 1 below.)

Equation 10 may not provide valid corrections for time periods shortly following intakes. The time after intake for which Equation 10 begins to yield satisfactory results is less than 1 day for Class D compounds. For Class W compounds, this time is about 7 days following intake, and for Class Y compounds, about 9 days following intake.

Table I
Aerosol AMAD

	0.2 μm	0.5 μm	0.7 μm	1.0 μm
$D_{\text{N-P}}$	0.05	0.16	0.23	0.30
$D_{\text{T-B}}$	0.08	0.08	0.08	0.08
D_P	0.50	0.35	0.30	0.25
Total Deposition	0.63	0.59	0.61	0.63

	2.0 μm	5.0 μm	7.0 μm	10.0 μm
$D_{\text{N-P}}$	0.50	0.74	0.81	0.87
$D_{\text{T-B}}$	0.08	0.08	0.08	0.08
D_P	0.17	0.09	0.07	0.05
Total Deposition	0.75	0.91	0.96	1.00

Equation 10, for revising the IRF for different particle sizes, is applicable for the total body IRF. ICRP-54 (Ref. 1) provides graphs of IRF values for 0.1 μm, 1 μm, and 10 μm AMAD particles for other tissues and excreta. Intake retention and excretion functions are derived for other AMAD particles based on the acceptable biokinetic modeling as discussed in Regulatory Positions 4.2 and 4.3.

It is acceptable to take into account particle size distribution and its effect on lung deposition and transfer in evaluating an individual's dose. ICRP-30 (Ref. 3) (with supplements) provides data and methods for use in evaluating the lung deposition and resultant doses for particle sizes between 0.1 and 20 μm AMAD. For particles with AMADs greater than 20 μm, complete deposition in the N-P region can be assumed.

It is acceptable to compare the estimate of intake for different particle sizes with the ALIs in Appendix B to §§20.1001-20.2401 for demonstrating compliance with intake limits. The ALIs are based on a particle size of 1 micrometer. However, modifying the ALI values for different particle size distributions requires prior NRC approval (10 CFR 20.1204(c) (2)).

4.6 Use of Individual Specific Biokinetic Modeling

Individual specific retention and excretion rates may be used in developing biokinetic models that differ from the reference man modeling (10 CFR 20.1204(c)). The quality and quantity of data used for this type of individual specific modeling should be sufficient to justify the revised model. Licensees should not attempt to develop individual specific retention and excretion fractions in the absence of ac-

tual biochemical and particle size information. Individual specific modeling is not required but may be developed; the modeling as presented above in Regulatory Position 4.2 is acceptable for evaluating regulatory compliance.

5. CALCULATING DOSE FROM ESTIMATES OF INTAKE

Regulatory Guide 8.34, "Monitoring Criteria and Methods To Calculate Occupational Radiation Doses" (Ref. 9), contains additional guidance on determining doses based on calculated intakes once the intake is determined.

6. RECORDKEEPING

Records of measurement data, calculations of intakes, and methods for calculating dose must be maintained as required by 10 CFR 20.1204(c), 20.2103(b), and 20.2106(a). For additional information on recordkeeping and reporting occupational exposure data, including intakes, refer to Revision 1 of Regulatory Guide 8.7, "Instructions for Recording and Reporting Occupational Radiation Exposure Data" (Ref. 10).

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 proposes an acceptable alternative method for complying with specified portions of the Commission's regulations, the methods described in this guide will used by the NRC staff for evaluating compliance with 10 CFR 20.1001-20.2401.

REFERENCES

1. International Commission on Radiological Protection, "Individual Monitoring for Intake of Radionuclides by Workers: Design and Interpretation," ICRP Publication 54, Pergamon Press, New York, 1988.

2. National Council on Radiation Protection and Measurements, "Use of Bioassay Procedures for Assessment of Internal Radionuclide Deposition," NCRP Report No. 87, February 1987.

3. International Commission on Radiological Protection, "Limits for Intakes of Radionuclides by Workers," ICRP Publication 30, Part 1, and ICRP Publication 30, Supplement to Part 1, Appendix A, Pergamon Press, New York, 1978.

4. E. T. Lessard et al., "Interpretation of Bioassay Measurements," U.S. Nuclear Regulatory Commission, NUREG/CR-4884,* July 1987.

5. S. R. Jones, "Derivation and Validation of a Urinary Excretion Function for Plutonium Applicable Over Ten Years Post Intake," *Radiation Protection Dosimetry,* Volume 11, No. 1, 1985.

6. J. R. Johnson and D. W. Dunford, *GENMOD - A Program for Internal Dosimetry Calculations,* AECL-9434, Chalk River Nuclear Laboratories, Chalk River, Ontario, 1987.

7. K. W. Skrable et al., "Intake Retention Functions and Their Applications to Bioassay and the Estimation of Internal Radiation Doses," *Health Physics Journal,* Volume 55, No. 6, 1988.

8. U.S. Nuclear Regulatory Commission, "Air Sampling in the Workplace," Regulatory Guide 8.25,' Revision 1, June 1992.

9. U.S. Nuclear Regulatory Commission, "Monitoring Criteria and Methods To Calculate Occupational Radiation Doses," Regulatory Guide 8.34,' July 1992.

10. U.S. Nuclear Regulatory Commission, "Instructions for Recording and Reporting Occupational Radiation Exposure Data," Regulatory Guide 8.7, Revision 1,* June 1992.

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*Copies may be purchased at current rates from the U.S. Government Printing Office, Post Office Box 37082, Washington, DC 20013-7082 (telephone (202) 512-2249 or (202) 512-2171; or from the National Technical Information Service by writing NTIS at 5285 Port Royal Road, Springfield, VA 22161.

APPENDIX A

EXAMPLES OF THE USE OF INTAKE RETENTION FRACTIONS

The following examples illustrate the use of retention and excretion functions for calculating intakes based on bioassay measurements. The data used for these examples are taken from NUREG/CR-4884, "Interpretation of Bioassay Measurements."* These examples do not illustrate the use of all possible bioassay or health physics measurements that may be available (e.g., excreta and air sampling measurements) during a specific exposure incident. The purpose of these examples is not to define the total scope of a bioassay program, rather, these examples demonstrate the use of the calculational techniques presented in Regulatory Position 4 of the guide for correlating measurements to intake. The examples demonstrate the use of retention and excretion fractions to:

- Estimate intake from one or several bioassay measurements,

- Adjust intake estimates for multiple or continuous intakes, and

- Correct intake estimates for particle size differences.

The examples in this appendix are:

Example 1: Calculating Intake Following an Inadvertent Exposure Based on a Single Bioassay Measurement

Example 2: Calculating Intake with Unknown Time of Intake

Example 3: Using Multiple Measurements To Calculate Intake

Example 4: Uranium Intake

Example 5: Comparison of Air Sampling and Bioassay Measurement Results

Example 6: Correcting Intake Estimates for Particle Size Difference

Example 7: Adjusting Intake Estimates for Multiple and Continual Intakes

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*E. T. Lessard et al., "Interpretation of Bioassay Measurements," U.S. Nuclear Regulatory Commission, NUREG/CR-4884, July 1987.

EXAMPLE 1

Calculating Intake Following an Inadvertent Exposure Based on a Single Bioassay Measurement

Determination that Intake Occurred

In'10 CFR Part 35, "Medical Use of Byproduct Material," 10 CFR 35.315(a)(8) requires licensees to perform thyroid burden measurements for all occupationally exposed individuals who were involved in the preparation or administration of therapeutic dosages of ^{131}I. These measurements are to be performed within 3 days following the preparation or administration.

In this example, the required bioassay measurements are conducted for all involved individuals following a therapy patient iodination. It is identified that the technologist who prepared the dose has a measured thyroid content of 0.080 μCi of ^{131}I. It is determined that the technologist most likely received an inhalation intake when a difficulty was encountered during the preparation of the dosage. The time of the measurement is determined to be 24 hours after the estimated time of intake.

Evaluation Procedure

The lung clearance class for all chemical compounds of iodine is Class D. Since no information is available on particle size distribution, a 1 μm AMAD particle size must be assumed. Using Equation 1 from Regulatory Position 4.3 for estimating intake from a single bioassay measurement, the intake can be estimated as follows:

$$I = \frac{A(t)}{IRF(t)}$$

where:

I = Estimate of intake in the same units as for $A(t)$

$A(t)$ = Thyroid content at time (t) of measurement

$IRF(t)$ = Intake retention fraction for measured ^{131}I at time interval (t) after estimated time of intake.

The table of thyroid IRF values for ^{131}I is found on page B-103 of NUREG/CR-4884. The IRF value at time after intake of 24 hours (t=24 hours) is 0.133.

Substituting the measured thyroid content and the corresponding thyroid IRF value into the above equation and solving yields the following:

$$I = \frac{0.080 \ \mu Ci}{0.133} = 0.60 \ \mu Ci \quad (2.2 \ E + 4 \ Bq)$$

As discussed in Regulatory Position 2.3, if a bioassay measurement indicates that the potential intake is greater than the evaluation level of 0.02 ALI, additional exposure data or additional bioassay measurements should be examined for determining the best estimate of intake. The ALI for Class D ^{131}I is $5E+1$ μCi* (from Appendix B to §§20.1001-20.2401); therefore, the evaluation level is 1 μCi (0.02 times the ALI value of 5E+1 μCi). Since the estimated intake is less than this level, no further evaluation is warranted.

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*Since the tables in NUREG/CR-4884 are given in special units (rad, rem, and curie), this guide presents special units followed by SI units in parentheses.

EXAMPLE 2

Calculating Intake with Unknown Time of Intake

Determination that Intake Occurred

While conducting a routine termination bioassay measurement of a maintenance worker at a nuclear power plant, a whole body content of 0.40 μCi of ^{60}Co was measured. Since the worker had entered a contaminated area earlier in the day, she was instructed to shower and don disposable coveralls to ensure that no external contamination of her skin or clothing was present. A second bioassay measurement was conducted and a whole body content of 0.40 μCi of ^{60}Co was confirmed. Routine surveys show that ^{60}Co at this facility is generally Class W.

Evaluation Procedure

The health physics supervisor was notified. In an attempt to determine the cause and time of exposure, an examination was conducted of plant survey data, including airborne activity measurements for areas of the plant where she had recently worked. This examination failed to identify a source of exposure; all areas to which the maintenance worker had access over the past several days were found to be minimally contaminated and no elevated levels of airborne radioactive material had been experienced. This information, in addition to the determination that the worker was not externally contaminated, indicated that the intake did not occur during the past several days. In the absence of any other information, the licensee assumed that the intake occurred at the midpoint in the time since the worker's last bioassay measurement. This assumption allows for an initial assessment of the potential significance of the intake. In this case, the most recent bioassay measurement was conducted 6 months (180 days) before, which represented her initial baseline measurement at the time of hire. Using these assumptions, the calculation of intake is as follows:

$$I = \frac{A(t)}{IRF(t)}$$

where:

I = Estimate of intake in units the same as A(t)

A (t) = Whole body content at time (t) of measurement

IRF(t) = Intake Retention Fraction for measured ^{60}Co at time interval t after estimated time of intake (half of 6 months or 90 days)

Substituting the measured body content and the corresponding IRF value into the above equation and solving yields the following:

$$I = \frac{0.40 \ \mu Ci}{6.39E\text{-}2} = 6.26 \ \mu Ci$$

The ALI for Class W ^{60}Co is 2E+2 μCi; therefore, the evaluation level is 2E+2 μCi times 0.02 or 4 μCi. Since the calculated intake is greater than the 4 μCi evaluation level, additional information should be sought.

As part of the additional review, the health physics supervisor conducted a further review of the individual worker's activities in an attempt to determine the actual time of exposure. A review of air sample data and worker access failed to indicate any abnormal exposure conditions. For unknown situations, the exposed individual is most often the best source of information when attempting to define the exposure conditions. The individual may remember unusual circumstances that at the time may have seemed acceptable, but upon further examination could have resulted in the unexpected exposure. In this case, the maintenance worker remembered breaching a contaminated system to remove a leaking valve. The system was supposed to have been depressurized and drained. However, she remembered that when the system was breached, a slight pressure relief was experienced and a small amount of water was drained. Following a review of the Radiation Work Permit (RWP) log and the containment entry log, it was determined that this incident occurred 28 days prior to the measured body content. Prior to and since that time, her other work activities have been in areas only moderately contaminated; an additional intake would have been unlikely. Based on these data, the most likely time of intake was determined to have occurred during the contaminated system breach 28 days before.

The appropriate IRF 'values for this exposure should be for a time of 28 days post-intake. Also, the "total body" IRF values should be used, since the body content has been determined by an in vivo total body measurement. A 28-day IRF value is calculated by performing a logarithmic interpolation between the 20-day value and the 30-day value.

$$IRF \ (day \ X) = exp\left[\left(\frac{\ln \ (IRF(day \ Z)) \ - \ \ln \ (IRF(day \ Y))}{(day \ Z) \ - \ (day \ Y)}\right) \times \ (day \ X \ - \ day \ Y) + \ln \ (IRF \ (day \ Y))\right]$$

where:

IRF (day X) = Interpolated IRF value, calculated at day X, which lies between two IRF values occurring at days Y and Z; in this case, X = 28 days, Y = 20 days, and Z = 30 days

IRF (day Y) = IRF value occurring at day Y, in this example, 20 days

IRF (day Z) = IRF value occurring at day Z, in this example, 30 days

Solving this interpolation yields:

$$IRF\ (28\ days) = \exp\left[\left(\frac{\ln\ (IRF(30\ days))\ -\ \ln\ (IRF(20\ days))}{30\ days\ -\ 20\ days}\right)\right.$$

$$\left. x\ (28\ days\ -\ 20\ days) + \ln\ (IRF\ (20\ days))\right]$$

$$= \exp\left[\left(\frac{\ln\ (0.123)\ -\ \ln\ (0.140)}{10\ days}\right)\ x\ 8\ days\ +\ \ln(0.140)\right]$$

$$= 0.126$$

Substituting this interpolated IRF value into the equation for calculating intake and solving yields:

$$I = \frac{0.40\ \mu Ci}{0.126}$$

$$= 3.17L\ \mu Ci\ (11.7\ E+4\ Bq)$$

Since this calculated intake was less than the evaluation level (i.e., less than 0.02 times the ALI value of 2E+2 μCi for 1 μm AMAD, Class W, ^{60}Co), and the data reviews did not indicate any other source of exposure, no further evaluation is warranted. However, had this calculated intake exceeded the evaluation level of 4 μCi, additional bioassay measurements over the next several days should be considered. If the licensee had previously determined that monitoring for internal exposure was required pursuant to 10 CFR 20.1502(b), this intake would have been recorded in the worker's exposure records and provided to the worker as a part of her termination exposure report, for which NRC Form 5 may be used.

EXAMPLE 3

Using Multiple Measurements To Calculate Intake

Determination that Intake Occurred

A laboratory worker accidentally breaks a flask containing a volatile compound of ^{32}P. The worker exits the work area. Contaminated nasal smears indicate that the worker may have received an acute inhalation intake. The results of work area air sampling measurements are reviewed, indicating increased airborne levels. Bioassay measurements are initiated to assess the actual intake.

Evaluation Procedure

From a review of the biokinetics for inhalation intakes of ^{32}P, it is determined that urine sample collection followed by liquid scintillation detection would provide the best bioassay data for calculating intake. For the particular ^{32}P compound involved, the appropriate lung clearance class is Class D. Also, lacking other data, a particle size distribution of 1 μm AMAD must be assumed.

The first voiding is analyzed and the results verify the occurrence of an intake. However, because of the particular characteristics of the sample (e.g., collection time relative to time of exposure), the results are not considered reliable for calculating an intake. Follow-up 24-hour urine samples are collected. The results of a second-day 24-hour sample indicate a total activity of 1.50 μCi, decay corrected from the time the sample is counted to the end of the 24-hour sample collection period. Using Equation 1 from Regulatory Position 4.3, an initial estimate of the intake is calculated as follows:

$$1 = \frac{A(t)}{IRF(t)}$$

$$= \frac{1.50 \ \mu Ci}{4.17E\text{-}02}$$

$$= 36 \ \mu Ci \ (1.3E + 6 \ Bq)$$

where:

I = Estimate of the ^{32}P intake

IRF(t) = Excretion fraction for 24-hour urine collected 2 days post-intake, which equals 4.17E-02 (see NUREG/CR-4884, page B-25)

A(t) = 1.5 μCi, value of the second-day 24-hour urine sample

The' ALI value for inhalation intakes of Class D compound of ^{32}P is 9E+2 μCi. The initial estimate of intake of 36 μCi exceeds the evaluation level of 0.02 ALI, which is the recommended level above which multiple bioassay measurements should be considered for assessing actual intake. Follow-up measurements are made. By examining the tabulated IRF values for 24-hour urine for ^{32}P, the RSO determines that 24-hour urine samples should be collected for the 10th and 20th day.

Note: Daily measurements should be considered if the initial assessment indicates an intake greater than the investigation level of 0.1 ALI. The time periods above were selected for purposes of demonstrating the calculational method. In actuality, one would typically examine the third-day results before deciding on the need and frequency of additional measurements.

The following table summarizes the results of the 24-hour urine sample measurements, the corresponding IRF value from NUREG/CR-4884, and the calculated intake based on the individual measurements using the above method.

Table 3A. Calculated Intake

(t$_i$) Time After Intake (Days)	(A$_i$) Decay-Corrected Activity in 24-Hour Urine Sample (μCi)	IRF	(I$_i$) Estimated Intake Based on Single Samples (μCi)
2	1.5E+0	4.17 E-2	36
10	1.3E-1	4.34 E-3	30
20	6.0E-2	1.55 E-3	39

EXAMPLE 4

Uranium Intake

Determination that Intake Occurred

An accident at a facility that produces UF_6 (uranium hexafluoride) results in a worker being exposed to an unknown concentration of UF_6 with a natural uranium isotopic distribution. Based on information in Appendix B to §§20.1001-20.2401, the UF_6 is identified as an inhalation lung Class D compound.

Evaluation Procedure

The health physics supervisor examines the significance of the exposure. Based on potential airborne radioactive material levels, it is determined that bioassay measurements should be conducted. Examining the biokinetics and decay characteristics for uranium isotopes, the health physics supervisor determines that urine sample collection and analysis should be performed.

Spot urine samples are collected over the following few days with the results presented in the following table.

Time of Sample (Days Post-Intake)	Concentration of Uranium in Urine ($\mu g/l$)
1.8	460
2.4	210
3.0	140

Using the results of the spot samples, accumulated urine activities can be calculated using Equations 2 and 3 from Regulatory Position 4.3. The concentration of uranium in the urine samples is presented in units of micrograms per liter. Because of the long half-lives of uranium isotopes, decay correction to time of sampling is not required.

Using Equation 2, the amount of uranium in the first sample is calculated as follows:

$$\triangle A_1 = C_1 \times E \times (t_1 - t_{1-1})$$

$$= 460 \times 1.4 \times (1.8 - 0)$$

$$= 1160 \; \mu g$$

where:

$\triangle A_1$ = Activity or amount of uranium in the first sample

C_1 = Concentration of uranium in the first sample

E = Daily excretion rate of 1.4 liter/day for urine for reference man (reference woman rate is 1.0 liter/day)

t_1 = Time (in days) after intake to when the first sample was taken

t_{1-1} = Time (in days) after intake to when the previous sample was taken (0 days in this case)

The accumulation for the second sample is calculated in a similar manner:

$$\triangle A_2 = C_2 \times E \times (t_2 - t_{2-1})$$

$$= 210 \times 1.4 \times (2.4 - 1.8)$$

$$= 176 \; \mu g$$

Accumulation for the final sample is similarly calculated.

$$\triangle A_3 = C_3 \times E \times (t_3 - t_{3-1})$$

$$= 140 \times 1.4 \times (3.0 - 2.4)$$

$$= 118 \; \mu g$$

The accumulated urine through the third spot sample collected on day 3 is calculated by summing all the accumulations.

$$A_3 = \triangle A_1 + \triangle A_2 + \triangle A_3$$

$$= 1,160 + 176 + 118$$

$$= 1,450 \; \mu g$$

where:

A_3 = Accumulated activity up to time, t, of the third sample collected on the third day post-intake

Using the calculation for accumulated urine activity, the intake may be calculated by applying the method of Equation 1 from Regulatory Position 4.3. The IRF for this calculation would be that for the accumulated urine for uranium, Class D, from Appendix B to NUREG/CR-4884 (page B-163). Because of the long radiological half-lives, the IRFs for all the uranium isotopes are essentially the same; the values for ^{238}U have been used for this example.

$$I = \frac{A(t)}{IRF(t)}$$

$$= \frac{1,450}{0.291}$$

$$= 4,980 \ \mu g$$

where:

I   = Estimate of intake with units the same as A(t)

IRF(t) = Intake retention fraction for uranium, Class D inhalation for the accumulated urine in the third day following time of intake

A(t)   = Value of the calculated accumulated urine based on the three spot samples (μg)

A conversion from a mass (μg) to activity (μCi) for the different percentages of the uranium isotopes can be performed based on isotopic specific activity. Natural uranium is composed of three isotopes: [234]U at 0.0056% atom abundance, [235]W at 0.72%, and [238]U at 99.274%. Based on these abundances and the radioactive decay constants for these isotopes, the corresponding weight to activity conversion factors are 3.5E-01 μCi/g for [234]U, 1.5E-2 μCi/g for [235]U, and 3.3E-01 μCi/g for [238]U. Using these conversions, the following activity intakes are calculated:

Activity = U$_{(weight)}$ x μCi/g conversion

= 4,980 μg x 0.35 μCi/g x 1E-06 g/μg
  = 1.7E-03 μCi (64 Bq)   U-234

= 4,980 μg x 0.015 μCi/g x 1E-06 g/μg
  = 7.5E-05 μCi (2.8 Bq)   U-235

= 4,980 μg x 0.33 μCi/g x 1E-06 g/μg
  = 1.6E-03 μCi (61 Bq)   U-238

These calculated activity intakes for the uranium isotopes are much less than the evaluation level of 0.02 ALI, at which additional evaluations (e.g., measurements) should be considered. Therefore, considering the significance of the radiation exposure, the bioassay measurements conducted provide an adequate basis for calculation of the intake.

A separate limit of 10 milligrams in a week for soluble uranium is contained in 10 CFR 20.1201(e) and Appendix B to §§20.1001-20.2401. This limit is based on the chemical toxicity, which should be evaluated in addition to the radiation exposure. The above evaluation determines that the total intake was 4,980 μg (4.98 mg). Therefore, the 10 mg/wk limit of 10 CFR 20.1201(e) wcs not exceeded.

EXAMPLE 5

Comparison of Air Sampling and Bioassay Measurement Results

Determination that Intake Occurred

During fabrication of a ^{137}Cs source, the airborne radioactive material levels to which the worker is exposed are sampled, using a continuous low-volume air sampler. At the end of the 8-hour shift, the technologist counts the filter and calculates that the average airborne activity during the sample period was 5.4E-7 µCi/ml (20,000 Bq/m^3) of ^{137}Cs. The elevated levels are unexpected and the health physicist compares the measured levels with the ^{137}Cs Class D DAC value from Appendix B to §§20.1001-20.2401. The 8-hour average concentration is 9 times the DAC value for ^{137}Cs of 6E-8 µCi/ml. The worker was not wearing a respiratory protective device during the fabrication process as elevated airborne radioactive material levels were not anticipated.

The health physicist evaluates the significance of the exposure by calculating the intake (based on the air sample data) and comparing the result with the ALI value for ^{137}Cs from Appendix B to §§20.1001-20.2401 (^{137}Cs, inhalation ALI = 200 µCi).

As a first approximation, the health physicist assumes that the worker was exposed to the average airborne ^{137}Cs concentration represented by the activity on the air sampler filter for the entire 8 hours of the work shift. A worker breathing rate of 1.2 m^3/hour (light work activity) is also assumed. The following intake is calculated:

$$\text{Intake} = 8 \text{ hours} \times 1.2 \frac{m^3}{hours} \times 5.4E\text{-}7 \frac{\mu Ci}{ml} \times 1E6 \frac{ml}{m^3}$$

$$= 5.2 \ \mu Ci \ (1.9E5 \ Bq)$$

This calculated intake is greater than the evaluation level of 0.02 ALI. The health physicist orders an in vivo bioassay measurement to be performed on the worker.

Evaluation Procedure

The in vivo measurement is performed the following morning, approximately 20 hours after the estimated time of intake. Since the exposure time spans an 8-hour work period and time-dependent airborne activities are unknown, the worker's exposure is assumed to have occurred at the midpoint in the 8-hour shift. The results indicate a total body activity of 0.21 µCi of ^{137}Cs. The corresponding intake may be estimated by using Equation 1 from Regulatory Position 4.3. Inhalation Class D is assigned for all chemical compounds of cesium (refer to Appendix B to §§20.1001-20.2401). The table of inhalation IRFs for ^{137}Cs may be found on page B-111 of NUREG/CR-4884. The IRF value for the total body, 0.8 day after intake, is 6.26E-01. Substituting these values into Equation 1, the calculation of the intake is:

$$I = \frac{A(t)}{IRF(t)}$$

$$= \frac{0.21 \mu Ci}{6.26E\text{-}01} = 0.34 \ \mu Ci \ (12,400 \ Bq)$$

The two calculated estimates of ^{137}Cs intake are significantly different. The health physicist discusses the work activities leading to the exposure with the individual and determines that the differences could be attributable to several factors:

- A difference in the breathing rate assumed for reference man and that of the worker,

- A difference in the concentrations of airborne radioactive material as sampled by the low-volume sampler and the levels as breathed by the worker. These differences could be due to the location of the sampler and the worker relative to the source of airborne material and the direction of air flow, and

- A difference in exposure time assumed for the worker (i.e., the actual exposure was less than the full d-hour shift).

The available data cannot resolve the difference between the air sampling results and the in vivo bioassay analysis: additional bioassay measurements and a review of the worker's exposure relative to the workplace ambient air sampling should be conducted to resolve the difference.

The estimate to be used as the dose of record should be the value considered to better represent the actual exposure situation. In general, bioassay measurements will provide better estimates of actual worker intakes, provided the data are of sufficient quality. Air sampling results typically represent only an approximation of the level of radioactive material in the air breathed by the worker. Appropriately collected and analyzed, bioassay results can provide a better indication of actual intakes.

This example does not address the health physics issues concerning the elevated airborne levels and potential worker exposure to levels greater than DACs.

EXAMPLE 6

Correcting Intake Estimates for Particle Size Difference

Annual limits on intake and the intake retention fractions (in NUREG/CR-4884) are based on a 1-μm AMAD particle size distribution. Rarely (if ever) will the actual distribution of airborne particulates be completely characteristic of 1-μm AMAD particles. Evaluating different particle size distributions can assist in explaining retention and excretion rates that are different than would be expected, based on the standard modeling (see 10 CFR 20.1204(c)(l)).

In this example, it is assumed that the actual particle size distribution has been determined to be characterized as a 2-μm AMAD of Class W compound of ^{60}Co. It is assumed that the intake occurred 20 days before the bioassay measurements were made.

Evaluation Procedure

The IRF may be adjusted for a 2.0-μm AMAD particle size using Equation 10 of Regulatory Position 4.5. The approximation relationship of this equation is applicable to the total body IRFs for particle sizes between 0.1 μm and 20 μm AMAD.

Values for D_{N-P}, D_{T-B}, and D_P derived from the data in Part 1 of ICRP Publication 30 (pages 24 and 25) are presented in the following table. (Note: the deposition fractions presented in Table B.8.1 of NUREG/CR-4884 (page B-801) contains errors and should not be used.)

Table 6A. Regional Deposition Fractions for Aerosol with AMADs Between 0.2 and 10 μm

	0.2 μm	0.5 μm	0.7 μm	1.0 μm
D_{N-P}	0.05	0.16	0.23	0.30
D_{T-B}	0.08	0.08	0.08	0.08
D_P	0.50	0.35	0.30	0.25
Total Deposition	0.63	0.59	0.61	0.63
	2.0 μm	5.0 μm	7.0 μm	10.0 μm
D_{N-P}	0.50	0.74	0.81	0.87
D_{T-B}	0.08	0.08	0.08	0.08
D_P	0.17	0.09	0.07	0.05
Total Deposition	0.75	0.91	0.96	1.00

The values of $f_{N-P,T}$, $f_{T-B,T}$, and $f_{P,T}$ for Class W ^{60}Co needed for Equation 10 are listed in the Supplement to Part 1 of ICRP Publication 30 on page 40. These values in ICRP Publication 30 are given as percentages and must be converted to decimal fractions before use. The decimal fractions for each tissue, along with its weighting factor and committed dose equivalent factor, are presented in the following table.

Table 6B. Input Values

Tissue	$f_{N-P,T}$	$f_{T-B,T}$	$f_{P,T}$	W_T^*	H_{50T} (per unit intake) [1] [1] (Sv/Bq)
Gonads	0.35	0.21	0.44	0.25	4.0E-09
Breast	0.19	0.17	0.64	0.15	4.2E-09
Red Marrow	0.20	0.17	0.63	0.12	4.2E-09
Lungs	0.02	0.02	0.96	0.12	3.6E-08
Thyroid				0.03	
Bone Surface				0.03	
LLI Wall	0.45	0.15	0.40	0.06	8.2E-09
Liver	0.21	0.19	0.60	0.06	9.2E-09
Remainder	0.10	0.09	0.81	0.06	8.0E-09

*Tissue weighting factors from 10 CFR 20.1003.
**Committed dose equivalent per unit intake.

The following equation is used to estimate the IRF for 2-μm particles.

$$IRF_{(AMAD)} = IRF(1\mu m) \sum_T \left[f_{N-P,T} \frac{H_{50T}W_T}{\sum_T H_{50T}W_T} \frac{D_{N-P}(AMAD)}{D_{N-P}(1\mu m)} \right.$$

$$+ f_{T-B,T} \frac{H_{50T}W_T}{\sum_T H_{50T}W_T} \frac{D_{T-B}(AMAD)}{D_{T-B}(1\mu m)}$$

$$\left. + f_{P,T} \frac{H_{50T}W_T}{\sum_T H_{50T}W_T} \frac{D_P(AMAD)}{D_P(1\mu m)} \right]$$

Substituting input values from the table into the above equation results in the following:

Total Body IRF(2 μm)
at 20 days after intake = 8.5 E-02

This IRF could be used to estimate intakes as illustrated in previous examples.

The above method for revising the IRF for different particle sizes is applicable for the total body IRF. ICRP-54 provides graphs of IRF values for 0.1 μm, 1 μm, and 10 μm AMAD particles for other tissues and excreta.

EXAMPLE 7

Adjusting Intake Estimates for Multiple and Continual Intakes

The following is a simplified example showing the application of the numerical integration of IRFs over a continual exposure period. It is recognized that most exposure situations do not involve chronic exposures to airborne radioactive material; most intakes can be reasonably characterized as acute exposures. However, when exposures extend over a longer period of time (i.e., more than a few days) it may be necessary to adjust the IRFs, which are based on single acute intakes, to account for the extended exposure period.

Urinalysis performed on a Friday indicated an uptake of ^{3}H for a worker. It was determined that the worker was continually exposed to ^{3}H as HTO (water vapor) for the 5 work days of the prior week (i.e., Monday through Friday of the previous week). Results of the 24-hour urine sample reveal 10 μCi (3.7E+05 Bq) of ^{3}H.

Evaluation Procedure

Since the exposure occurred over an extended period of time and the measurement was taken after the exposure interval, the methods of Equation 9 from Regulatory Position 4.4 should be used.

$$I \cong \frac{A(t)}{\left[\dfrac{IRF(t - T) + IRF(t)}{2} + IRF(u_1) + \ldots + IRF(u_{n-1})\right]}$$

where:

A(t) = Amount of activity in compartment or whole body at time t following onset of intake

I = Total intake during period T

T = Duration of intake (exposure time period)

t = Time from onset of intake to time of measurement

u = Variable time between integration limits

IRF(u) = Intake retention fraction at time u in compartment or whole body for a single intake of a radionuclide

n = Number of increments

For this example, the time interval values are:

T = 5 days (period of intake)

t = 11 days (number of days following onset of intake)

The integration period is for the time (t-T) to t; therefore the interval consists of a total of 6 days. For the numerical integration, the 6-day time interval has been divided into 6 equal 1-day increments.

The IRF values for the calculation, taken from NUREG/CR-4884 (page B-711), are listed in the following table. If IRF values are not presented for the day of interest, a logarithmic interpolation should be performed to calculate the value.

Time Intervals from (t-T) to t (in 1-day Increments)	IRF (24-hr Urine)
6	2.85E-02
7	2.66E-02
8	2.48E-02
9	2.31E-02
10	2.16E-02
11	2.02E-02

Substituting the IRFs and the interval length into the above equation yields:

$$I \cong \frac{10 \text{ μCi} \times 6}{\left[\dfrac{2.85E\text{-}02 + 2.02E\text{-}02}{2} + 2.66E\text{-}02 + 2.48E\text{-}02 + 2.31E\text{-}02 + 2.16E\text{-}02\right]}$$

$$\cong 5.0E\text{+}02 \text{ μCi} \quad (1.8E\text{+}07 \text{ Bq})$$

This calculated intake is less than 0.02 ALI for ^{3}H (i.e., 500 μCi < 0.02 times the ALI value of 8E4 μCi). Additional bioassay measurements would not be necessary to determine the intake. However, additional radiation safety measures may be needed to evaluate the incident and prevent future occurrences.

REGULATORY ANALYSIS

A separate regulatory analysis was not prepared for this regulatory guide. The regulatory analysis prepared for 10 CFR Part 20, "Standards for Protection Against Radiation" (56 FR 23360), provides the regulatory basis for this guide and examines the costs and benefits of the rule as implemented by the guide. A copy of the "Regulatory Analysis for the Revision of 10 CFR Part 20" (PNL-6712, November 1988), is available for inspection and copying for a fee at the NRC Public Document Room, 2120 L Street NW., Washington, DC, as an enclosure to Part 20.