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IMPLEMENTATION GUIDE

For Use With

Title 10, Code of Federal Regulations, Part 835
OCCUPATIONAL RADIATION PROTECTION

INTERNAL DOSIMETRY PROGRAM

ASSISTANT SECRETARY for ENVIRONMENT, SAFETY and HEALTH

DRAFT GUIDE - FOR REVIEW WITH PROPOSED 10 CFR 835 AMENDMENT ONLY

U.S. Department of Energy
IMPLEMENTATION GUIDE

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U.S. Department of Energy
IMPLEMENTATION GUIDE

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INTERNAL DOSIMETRY PROGRAM

I. PURPOSE AND APPLICABILITY

This Implementation Guide (IG) provides an acceptable methodology for establishing and operating an internal dosimetry program that will comply with U.S. Department of Energy (DOE) requirements specified in Title 10 of the Code of Federal Regulations (CFR), Part 835, Occupational Radiation Protection *(DOE, 1996a)*; hereinafter referred to as 10 CFR 835. For completeness, this IG also identifies applicable recommendations contained in the DOE Radiological Control Standard *(DOE, 1997a*), hereinafter referred to as the RCS; and secondary documents (American National Standards Institute (ANSI) Standards, etc.) invoked by these and other primary documents.

This IG amplifies the regulatory requirements of 10 CFR 835 and provides guidance for the structure, function, and operations of an internal dosimetry program. The criteria for internal dosimetry programs to serve epidemiology, risk assessment, and litigation are not within the scope of this IG. The requirements of 10 CFR 835 are enforceable under the provisions of Sections 223(c) and 234A of the Atomic Energy Act of 1954, as amended *(AEC, 1954).*

Except for requirements mandated by a regulation, a contract, or by administrative means, the provisions in this IG are DOE's views on acceptable methods of program implementation and are not mandatory. Conformance with this guide will, however, create an inference of compliance with the related regulatory requirements. Alternate methods that are demonstrated to provide an equivalent or better level of protection are acceptable. Contractors are encouraged to go beyond the minimum requirements and to pursue excellence in their programs.

The word "shall" is used in this IG to designate requirements from 10 CFR 835. The requirements of 10 CFR 835 are mandatory except to the extent an exemption has been granted pursuant to 10 CFR 820, *Procedural Rules for DOE Nuclear Activities (DOE, 1993).* The words "should" and "may" are used to represent optional program recommendations and allowable alternatives, respectively.

This IG is applicable to all DOE activities involving occupational exposure to ionizing radiation of DOE employees and/or DOE-contractor/subcontractor employees.

II. DEFINITIONS

activity median aerodynamic diameter (AMAD): The diameter of a sphere having a density of 1 g cm^{-3} and the same terminal settling velocity in air as that of the aerosol particle whose activity is the median for the entire aerosol.

administrative control level: A numerical dose constraint established at a level below the regulatory limits to administratively control and help reduce individual and collective radiation exposure.

air monitoring: Actions to detect and quantify airborne radiological conditions by the collection of an air sample and the subsequent analysis either in real-time or off- line laboratory analysis of the amount and type of radioactive material present in the workplace atmosphere.

alpha (α): The probability (not to be confused with an alpha particle) of a *Type I error* or *false positive*. Also called the false positive probability.

analyte: The material to be detected in a quantitative analysis.

annual limit on exposure (ALE): The limit for *potential alpha energy exposure* to the progeny of ^{222}Rn or ^{220}Rn, expressed in WLM. An implicit ALE for other radionuclides is 2000 *DAC*-hours.

annual limit on intake (*ALI*) (for radon and thoron progeny): The *ALI* for ^{222}Rn and ^{220}Rn progeny is expressed in megaelectronvolts (MeV) or joules (J) of *potential alpha energy*.

baseline bioassay: An appropriate bioassay measurement obtained from a bioassay program participant prior to beginning or resuming work with radioactive material.

beta (β): The probability (not to be confused with a beta particle) of a *Type II error* or *false negative*. Also called the non-detection probability.

biokinetic model: A series of often empirically determined mathematical relationships formulated to describe the intake, deposition in respiratory tract (if applicable), uptakes by the transfer compartment from intake compartment(s), uptakes by tissues or organs from the transfer compartment, translocation, retention, and elimination of a radionuclide from the body.

censored data: Data that have been recorded as "less than" values rather than the observed numerical values (whether positive, zero, or negative).

committed dose equivalent ($H_{T,50}$) to lung for radon and thoron progeny: For exposures to the short-lived radioactive progeny of radon-222 and radon-220, see the definition of committed effective dose equivalent.

committed effective dose equivalent ($H_{E,50}$) for radon and thoron progeny: For exposures to the short-lived radioactive progeny of radon-222, committed effective dose equivalent is calculated directly from workplace

measurements of potential alpha energy exposure using a dose conversion factor of 1.25 rem (0.0125 Sv) per Working Level Month. For exposures to the short-lived radioactive progeny of radon-220, committed effective dose equivalent is calculated directly from workplace measurements of potential alpha energy exposure using a dose conversion factor of 5/12 rem (5/1200 Sv) per Working Level Month. Since the lung is the only tissue significantly irradiated by radon and thoron, the committed dose equivalent to lung due to exposures to radon and thoron is calculated by dividing committed effective dose equivalent from radon and thoron by the tissue weighting factor for lung (w_T = 0.12).

compartment: The smallest element in a biokinetic model for which a mathematical representation of a retained quantity is given. Compartments may be organs (e.g., lung, liver), tissues (e.g., bone marrow), or systemic (e.g., the *transfer compartment*).

confirmed intake: An intake confirmed by follow-up bioassay, by association with a known incident, or by investigation.

continuous air monitor (CAM): An instrument that continuously samples and measures the levels of airborne radioactive materials on a "real-time" basis and has alarm capabilities at preset levels.

decision level (*DL*): The value of a net observation (result) at or above which a decision is made that a positive quantity of the *analyte* is present. The *DL* depends on the acceptable probability (α) of incorrectly concluding that there is analyte present (a Type I Error); α is usually taken as 0.05.

decorporation: Accelerated removal of radionuclides from the body, usually by medical or dietary intervention such as chelation, blocking, excision, lavage, diuresis, increased fluid intake, etc.

derived investigation level (*DIL*): A value of a bioassay or air monitoring measurement that triggers an investigation.

direct (in vivo) bioassay: The assessment of radionuclides in the body by detection of radiations emitted using external detector and analyzer systems.

elimination: The biological removal of a radionuclide from the body by excretion, perspiration, exhalation, secretion (e.g., breast milk), exfoliation (sloughing of dead tissue), or excision.

embryo/fetus: A developing human organism from conception until birth. Same as unborn child.

equilibrium factor (*F*): The equilibrium factor *F* with respect to potential alpha energy is the ratio of the *EEC* to the actual activity concentration of radon or thoron in air.

equilibrium equivalent concentration (*EEC*): The *EEC* of a non-equilibrium mixture of short-lived radon or thoron progeny is that activity concentration of radon or thoron in radioactive equilibrium with its short-lived progeny that has the same potential alpha energy concentration as the non-equilibrium mixture to which the *EEC* refers.

evaluation: The process of arriving at a value for intake or dose that uses, among other inputs, measurement results.

excretion: The biological removal of a radionuclide from the body via one or more excretion pathways: urine and feces.

exposure: The general condition of being subjected to ionizing radiation, such as by exposure to ionizing radiation from external sources or to ionizing radiation sources inside the body. In this document, exposure does not refer to the radiological physics concept of charge liberated per unit mass of air.

false negative: A *Type II (β) error,* that is, concluding that *analyte* is not present when in fact it is.

false positive: A *Type I (α) error*, that is, concluding that there is *analyte* present when it is not.

gastrointestinal (GI) tract model: A mathematical representation of the behavior of radionuclides in the contents of the human gastrointestinal tract.

group of radionuclides: Two or more radionuclides that are contained in a matrix such that an individual could not have an intake of one without simultaneously having an intake of all of the radionuclides in that matrix.

indirect (in vitro) bioassay: The measurement or analysis of radionuclides in excreta or other biological samples removed from the body.

intake: The amount of radionuclide taken into the body by inhalation, absorption through intact skin, injection, ingestion, or through wounds. Depending on the radionuclide involved, intakes may be reported in mass (e.g., µg, mg), activity (e.g., µCi, Bq), or potential alpha energy (e.g., MeV, J) units.

intake compartment: One of four compartments from which *systemic uptake* can occur: the respiratory tract; the GI tract; a wound; or intact skin.

intake retention fraction: The fraction of an intake present in the systemic body or excreta at some time after intake.

intake route: A pathway by which radioactive material enters the body. The main intake routes are inhalation, ingestion, absorption through the skin, and entry through injection or a cut or wound in the skin.

investigation level (*IL*): The value of the committed effective dose equivalent from an intake(s) of a radioactive material by a worker at or above which, for regulatory purposes, is regarded as sufficiently important to justify further investigation.

lifetime control level: An administrative value used to limit a worker's lifetime occupational radiation dose. The lifetime control level is equal to N times 1 rem (N times 0.01 sievert), where N is the age of the worker in years.

minimum detectable amount/activity (*MDA*): The smallest amount/activity of a radionuclide in a sample that will yield a result above the decision level with a β probability of non-detection (*Type II error*) while accepting an α probability of erroneously detecting that radionuclide in an appropriate blank sample (*Type I error*). The *MDA* is computed using the same value of α as used for the *DL*. The *MDA* depends on both α and β. Measurement results are compared to the *DL*, not the *MDA*; the *MDA* is used to determine whether a program has adequate detection capability. The *MDA* will be greater than or equal to the *DL*.

minimum detectable (effective) dose: The minimum detectable committed (effective) dose equivalent associated with a bioassay program. Formerly called "missed dose."

potential alpha energy concentration (*PAEC*): The kinetic energy potentially released in a unit volume of air by alpha particles emitted by the short-lived radioactive progeny of radon-222 (i.e., polonium-218 and polonium-214) or radon-220 (i.e., polonium-216, bismuth-212, and polonium-212). *PAEC* is expressed in working levels (WL).

potential alpha energy exposure (*PAEE*): The average potential alpha energy concentration (*PAEC*) to which a worker is exposed multiplied by the time of exposure in working months of 170 hours -- that is, *PAEE* = *PAEC* × *time*. *PAEE* is expressed in working level months (WLM).

radon: Unless otherwise specified, the isotope ^{222}Rn.

Reference Man: A reference human model with the anatomical and physiological characteristics defined in the International Commission on Radiological Protection (ICRP) Publication 23, Report of the Task Group on Reference Man, ICRP 23 *(ICRP, 1975)*. The ICRP Reference Man includes parameters for males and females of various ages.

respiratory tract model: A mathematical representation of the behavior of particles and gases in the human respiratory tract.

retained quantity: The amount of material which, after being taken into the body by inhalation, ingestion, entry through an open wound, or absorption through the skin, exists in the whole body, a compartment, an organ, or a tissue at a specified time.

routine bioassay monitoring: Any bioassay measurement made on a predetermined, periodic schedule, to establish whether a worker has had any intake of radioactive material since previous bioassay measurements.

special bioassay monitoring: Any bioassay measurement that is not required for routine bioassay, but that is required for confirmation of a suspected intake of radionuclides, or is required for follow-up evaluation of confirmed intakes.

special control level: An individualized exposure control level invoked for individuals with a lifetime occupational dose exceeding the lifetime control level, and for workers with special concerns.

state-of-the-art: The most advanced technology that is commercially available and successfully field tested.

termination bioassay: A bioassay measurement performed for the purpose of documenting the retention of radioactive materials in the body due to occupational exposure either upon termination of employment or upon the cessation of potential exposure to a specific nuclide.

thoron: The isotope ^{220}Rn, also symbolized by Tn. Thoron is a "trivial name" like tritium.

translocation: Movement within the body of a radioactive material, such as from bone to kidney.

Type I error: Incorrectly concluding from a result that there is analyte present; the probability (α) of a Type I error is usually taken as 0.05. The *decision level* is determined on the basis of an acceptable level of Type I errors.

Type II error: Incorrectly concluding from a result that there is no analyte present; its probability (β) is usually taken as 0.05.

working level (WL): The unit of *potential alpha energy concentration (PAEC)*, defined as any combination of the short-lived radioactive progeny, in one liter of air without regard to the degree of equilibrium, that will result in the ultimate emission of 1.3×10^5 MeV of alpha energy (1 WL = 2.083 E-05 J/m^3).

working level month (WLM): The unit of *potential alpha energy exposure (PAEE)*, defined as exposure for 1 working month (of 170 hours) to an airborne concentration of 1 WL. (1 WLM = 1 WL × 170 hours = 0.00354 J·h/m^3).

wound compartment: The compartment in a biokinetic model whose retained quantity is the amount of radioactive material in a wound that has not moved to the transfer compartment.

III. DISCUSSION

Internal dosimetry is the analysis and measurement of radionuclides in humans or bioassay samples and the evaluation of intakes and doses from those measurements. It involves evaluation of bioassay data, evaluation of the intake, distribution, retention, and elimination of radionuclides, and evaluation of various absorbed doses and dose equivalent quantities. Internal dosimetry is inherently indirect in nature. It is not possible to determine the exact organ absorbed dose, dose equivalent, or effective dose equivalent in a living human being resulting from an intake of radioactive materials. Internal dose is usually a derived or inferred quantity, obtained by evaluation of indirect measurements and computational models. This is particularly true for alpha- and beta-emitting radionuclides in the body which have low photon emission abundances. Direct measurements of internalized photon-emitting radionuclides in organs also may be difficult because of attenuation and scattering by overlying tissues.

Radiation protection programs for limiting intakes are based on the DOE policy of controlling radioactive material at the source. It is nonetheless recognized that low-level, chronic occupational exposures to some materials are difficult to avoid due to the types of material handled or processed, their chemical or physical forms, and the nature of operations, and that incidents may cause unplanned releases of radioactive material. Either or both of these conditions necessitate an internal dosimetry program at most DOE and DOE contractor facilities.

Internal dose evaluations, along with associated individual monitoring measurements on which such evaluations are based, are the primary methods for demonstrating compliance with dose limits for protecting workers. 10 CFR 835 states that the estimation of internal dose shall be based on bioassay data rather than air concentration values unless bioassay data are unavailable, inadequate, or internal dose estimates based on representative air concentration values are demonstrated to be as or more accurate (10 CFR 835.209(b)). In cases where there is no practical bioassay, representative air monitoring must be used as the basis for dose evaluations. More detail is given below.

IV. IMPLEMENTATION GUIDANCE

This section provides basic guidance for conducting internal dosimetry programs for workers who have the potential for intakes of radioactive materials. It includes guidance for design and implementation of the bioassay program, and guidance for evaluating, recording, reporting, and managing internal doses. Additional technical guidance is provided in DOE-STD-XXXX, Standard: Internal Dosimetry (DOE 1996).

The essential elements of an acceptable internal dosimetry program are as follow:

-- Adequate staff with appropriate technical training;

-- internal dosimetry technical basis documentation giving scientific information and other rationale explaining each element of the internal dosimetry programs to support dose evaluation methods;

-- written policies and procedures covering each step in the activities used to determine worker internal dose;

-- defined criteria for identifying workers who need to participate in the bioassay program;

-- appropriate bioassay measurement methods and frequencies;

-- adequate detection capability and quality of bioassay measurements;

-- defined criteria and actions for identifying individuals with suspected intakes, based on workplace measurements and bioassay measurements;

-- appropriate workplace monitoring programs, including air monitoring;

-- appropriate action level guidelines;

-- methods for control, accountability, and safe handling of samples;

-- timely analysis of bioassay samples and measurements, transmission of results, dose evaluation, and recommendations to operations management;

-- appropriate dosimetric models and default parameters for evaluating internal dose;

-- quality assurance program covering all steps in the activities that determine worker internal dose;

-- defined program to report internal doses to workers, management, and DOE;

-- historical records of bioassay measurement results and dose evaluations; and

-- historical records of the program, and changes in the program over time.

A. Organization, Staffing, Training, and Facilities

1. Organization

The internal dosimetry program should be a function of the radiation protection organization at each DOE and DOE contractor facility. The manager of the radiation protection organization should have overall responsibility for the internal dosimetry program. Each internal dosimetry program should have a designated leader with demonstrated expertise in internal dose evaluation.

When elements of the internal dosimetry program are performed by one or more subcontractors, the radiation protection organization should ensure that subcontractors meet all requirements pertaining to internal dosimetry in 10 CFR 835, and that subcontractors follow this IG and the internal dosimetry technical basis documentation. A copy of all relevant subcontractor procedures should be incorporated in the historical record files of the DOE contractor.

Where one DOE contractor on a multiple-contractor site conducts the internal dosimetry program, or parts thereof, letters of agreement should detail the responsibilities, authority, and communication requirements of the respective parties. A copy of this agreement should be in the internal dosimetry technical basis documentation and the historical file.

2. Staffing

The radiation protection organization management should ensure that the internal dosimetry program is adequately staffed to carry out its functions.

The analysis of workplace and bioassay measurement data and the evaluation of internal dose involve complex evaluation and professional judgment. Personnel with responsibility for internal dose evaluation should have the necessary expertise and skill, based on appropriate education and training in conjunction with practical experience, to perform their assigned duties. It is important that internal dosimetry specialists be capable of recognizing conditions warranting follow-up bioassay and dose evaluation. Personnel should be familiar with the relevant internal dosimetry literature and the recommendations of national and international scientific organizations with regard to internal dose evaluation.

3. Training, Experience, and Continuing Education

Management of the radiation protection organization should establish minimum qualifications for those staff who evaluate internal doses. The qualifications should include both experience and education requirements.

Educational background and formal training needed for internal dosimetry programs are listed below. Members of the dose evaluation staff should meet these requirements, or the staff should have access to persons with the required background (perhaps through interdepartmental agreements or contracted services). It is not necessary for all personnel on the staff to have expertise in all of the listed subject areas. The internal dosimetry organization should have or have access to personnel who have education and formal training in the following areas:

-- Advanced mathematical methods, such as calculus, differential equations, and statistical analyses;

-- radiochemistry and radiometric methods and concepts;

-- computer technology and software used for dose evaluation;

-- anatomy and physiology of the human body and effects of ionizing radiation on biological systems;

-- nuclear radiation physics;

-- radiochemical behavior of relevant radionuclides;

-- principles of radiation dosimetry including national and international guidance;

-- operational health physics; and

-- technical writing.

New internal dose evaluators should undergo a period of apprenticeship commensurate with their experience and education. In addition, other radiation protection staff should be cross-trained in internal dose evaluation to ensure adequate staffing during vacations, absences, and vacancies.

The program should be supported by trained dosimetry technicians, counting system operators, and radiochemistry staff, all of whom should receive training commensurate with job requirements. Management should establish continuing education requirements for all staff performing internal dose evaluations. Retraining and/or continuing education are essential for maintaining an adequate level of expertise and familiarity with current concepts and requirements for internal dose evaluation. The same subjects as listed above under the minimum educational qualifications should be considered in establishing continuing education requirements. Retraining and continuing education should include changes in procedures, changes in systems or equipment, changes in federal guidance and regulations, and significant operating events that occurred in the facility or at other DOE or commercial facilities that are relevant to internal dosimetry.

4. Facilities and Resources

Computational facilities and software tools used by internal dosimetry personnel should be adequate for performing calculations required for the evaluation of dose from radionuclides in the body.

A library of handbooks, reference materials, scientific publications, and other resources pertaining to internal dosimetry should be readily available.

B. Internal Dosimetry Technical Basis Documentation

Internal dosimetry technical basis documentation (or other organized collection of documents) should be developed and should give the scientific and technical foundation for the internal dosimetry program. The internal dosimetry technical basis documentation should provide the approach to evaluating internal doses from bioassay data, and where appropriate, from workplace monitoring data. It should describe: (1) physical and chemical characteristics of radioactive materials encountered in the workplace; (2) methods for calculating internal doses; (3) methods for documenting calculations; (4) dose evaluation quality assurance; (5) methods for evaluating dose equivalents from specific radionuclides, mixtures of radionuclides, and materials of differing chemical characteristics; (6) recording and reporting practices for internal dosimetry; (7) selection of workers for monitoring; and (8) establishment of the type and frequency of measurements to be used.

The technical basis for evaluating dose from both routine and special bioassay, and for evaluating data from personal air samplers and other monitoring equipment should be included in the internal dosimetry technical basis documentation. Biokinetic models, model parameters, assumptions, and default parameters used in dosimetric modeling and evaluation should be clearly identified. Statistical methods for evaluating bioassay data, identifying bioassay results above environmental background values, using appropriate blanks, and analyzing trends should be described.

To preclude the "double counting" of intakes and resultant doses, the methodology to account for the portion of a bioassay result that may be due to one or more prior confirmed intakes should be described in the internal dosimetry technical basis documentation. The derivation of decision levels should also be documented in the internal dosimetry technical basis documentation. Default trigger levels and preliminary actions to be taken for exposures to the different radionuclides present at the facility following suspected or confirmed intakes at various levels should be described in the internal dosimetry technical basis documentation. Additional topics to be addressed in the internal dosimetry technical basis documentation are found throughout this IG.

The internal dosimetry technical basis documentation should be reviewed at least once every two years to assure that the scientific bases are current and updated, as necessary. The internal dosimetry technical basis documentation should be a controlled document and retained as a radiological protection program record with copies of all previous revisions and changes retained for future program review. The requirements for maintenance of the internal dosimetry technical basis documentation should be specified, including responsibilities for authorship, review, approval, and distribution.

C. Procedures

All elements of the internal dosimetry program should be specified in written procedures. These procedures should be consistent with 10 CFR 835, the RCS, the relevant DOE Orders, this IG, and the internal dosimetry technical basis documentation. In summary, the methods and requirements for measurement (bioassay and air monitoring used for internal dosimetry) and evaluating and recording internal dose should be specified. The procedures should specify methods for consistent collection of workplace and personnel monitoring data, its evaluation, documentation of results, and records maintenance. The components of the internal dosimetry program and the organizational structure to which it reports should be documented in procedures. Responsibilities of line management and members of the dose evaluation group should be described. Elements of the workplace and individual monitoring programs that are germane to internal dosimetry should also be included. Guidelines for

prompt follow-up of radioactive material intakes should be carefully defined, and appropriate follow-up response to intakes, including the medical management of individuals with excessive intakes, should be described.

The procedures should be reviewed at least once every two years and updated as necessary. The requirements for maintenance of procedures should be specified, including responsibilities for authorship, review, approval, and distribution.

D. Design of Individual Monitoring Programs for Internal Dosimetry

DOE has always emphasized bioassay measurements as the best foundation for evaluations of dose from intakes of radioactive material. However, there are situations in which there is no practical bioassay, such as exposure to the short-lived decay products (progeny) of radon or thoron, or other short-lived radionuclides. In such situations, representative air monitoring (e.g., breathing zone (BZ) air monitoring) is the only measurement method on which to base dose evaluations. Furthermore, there may be technology shortfall (see below) for routine bioassay programs, so that BZ air monitoring may be needed when bioassay data are unavailable, inadequate, or when air monitoring data can be shown to be as accurate or more accurate for dose evaluation. The term "individual monitoring" refers to both bioassay monitoring and the BZ air monitoring (if applicable). Details of program design are given in the Internal Dosimetry Standard *(DOE 1996c*).

The individual monitoring program should: (1) Provide for investigation of suspected intakes; (2) provide data for evaluating internal dose; and (3) provide results that are adequate to demonstrate compliance with the radiation dose limits given in 10 CFR 835. The primary methods of routine and special worker bioassay are *in vivo* counting (direct bioassay) and *in vitro* excreta analyses (indirect bioassay). Breathing zone air monitoring may be done using personal (lapel) air samplers or properly located fixed or portable air samplers.

1. General Guidance

Bioassay and BZ air sample measurements should be of the appropriate type, frequency, timeliness, and of sufficient accuracy, to demonstrate that dose limits have not been exceeded, and that doses are maintained ALARA.

2. Investigation Level

In this IG, DOE adopts an investigation level *(IL)* of 0.1 rem (0.001 Sv) committed effective dose equivalent from intakes occurring in a year for general employees. Each facility should evaluate the need for special *IL*s for declared pregnant workers, minors, and members of the public because their dose limits are lower than the limit for general employees (see 10 CFR 835.402(c)(2) and (3) for dose levels requiring personnel monitoring). Throughout this document, *IL* refers to the *IL* for the appropriate group unless otherwise specified.

To ensure that all dose limitation and dose control requirements of 10 CFR 835 are met, the internal dose evaluation program should be capable of evaluating intakes of radioactive materials that occur in a year and that deliver a committed effective dose equivalent to the *IL*.

3. Derived Investigation Levels

Derived investigation levels (*DIL*s) are values of routine bioassay results, such as organ or body contents, or excreta concentrations or excretion rates, or activity detected by BZ air monitoring, that indicate an intake resulting in a dose exceeding an *IL*. Internal dosimetry programs should establish *DIL*s for each individual monitoring method applied for the analysis of all radionuclides to which workers are likely to be exposed and document the derivation of such *DIL*s in the internal dosimetry technical basis documentation. The physical and chemical characteristics of the radioactive material which may be taken into the body should be taken into account in establishing *DIL*s. If an internal dosimetry program chooses to use Reference Man (ICRP Publications 23 and 30) default parameters in conjunction with modeling and assumptions recommended in ICRP Publications 30 and 54 in deriving a *DIL*, these choices should be justified in the internal dosimetry technical basis documentation.

4. Factors Affecting the DIL

Factors such as significant clearance of a radionuclide in less than a year (e.g., tritium), the frequency of bioassay monitoring, and the likelihood of multiple exposures during a year (or under chronic intake conditions) should be considered in establishing a *DIL*. The *DIL* should be established so that a committed effective dose equivalent of one *IL* from all intakes in a year is likely to be detected by the monitoring program, i.e., the minimum detectable dose should be less than one *IL*. If a non-routine or an unexpected intake of a radionuclide or group of radionuclides occurs, the minimum detectable dose may be calculated assuming a single intake that occurred on either the date of the intake, if known; or the date that would result in the largest committed effective dose equivalent. If intermittent or chronic intakes are expected, the minimum detectable dose may be calculated assuming a chronic intake during the sample period.

For nonroutine or unexpected intakes, the *DIL* for each independent radionuclide or group of radionuclides should be based on the objective that a committed effective dose equivalent of not more than one *IL* would be missed in the year from intakes of that radionuclide or group.

If it is known or is likely that an individual has or could have intakes during the year from different sources that could result in doses above the *IL*, appropriately smaller *DIL*s should be determined and the basis for those *DIL*s included in the internal dosimetry technical basis documentation.

5. Methods of Measurement

The internal dosimetry program staff should determine the minimum detectable amount/activity (*MDA*) for each bioassay and BZ air monitoring method for each radionuclide present in a facility to which workers are likely to be exposed. In determining *MDA*s, the value of beta (non-detection probability) should be chosen to be 5% or less. The value of alpha (false positive probability) should be chosen considering the effect on bioassay measurement time, the disruption and inconvenience of false positive results, the costs of improved analytical technology, and handling, analysis, and record-keeping costs associated with the program. The *MDA*s should be documented in procedures and their statistical bases given in the internal dosimetry technical basis documentation. For the *MDA* to be valid, the false positive probability used for setting the decision level for the bioassay method should be the same as the one used in the calculation of the *MDA*.

Procedures should contain descriptions of the method(s) of individual monitoring measurements (e.g., urinalysis, fecal analysis, *in vivo* counting, BZ air monitoring), analytical methodology (e.g., chemical separation followed by

alpha counting), and measurement parameters (e.g., counting time or instrument efficiency) to be used in each component of the individual monitoring program.

Several other factors affect the method of bioassay used and its associated *MDA*. They include:

-- The possible need for improved detection capability to assess worker dose during the special bioassay following an intake requiring internal dose evaluation, due to diminishing amounts of material in bioassay compartments as time goes on;

-- the need for improved precision and accuracy if residual retention and excretion from prior intakes interferes with the detection of additional intakes in subsequent years;

-- timeliness of results needed to manage workers and keep subsequent intakes low enough to avoid exceeding dose limits;

-- convenience to the workers;

-- costs, including lost production time while workers are participating in the bioassay program; and

-- the impact of the method of bioassay on the frequency of bioassay measurements.

The method of individual monitoring, analytical methodology, and measurement parameters should result in an *MDA* less than the corresponding *DIL* for all radionuclides to which a worker might be exposed.

The methods of bioassay and air monitoring measurements, their *MDA*s, and accuracies should be specified in the internal dosimetry technical basis documentation, along with a rationale or justification for the methods chosen.

6. Frequency of Measurement

Representative air monitoring should be done so that an exposure to all radionuclides combined of 40 or more DAC-hours is detected and quantified.

The routine bioassay measurement frequency depends on the bioassay measurement method and associated *MDA*. The frequency should be chosen so that it is unlikely that intakes by a worker in a year will result in doses exceeding one *IL* without detection. Other factors affect the choice of routine bioassay measurement frequency. They include:

-- Expected frequency, duration, and magnitude of elevated airborne radioactive material concentrations;

-- cost of bioassay measurements and the cost of lost production time while workers are participating in the bioassay program;

-- magnitude of a worker's assessed internal dose resulting from prior intakes;

-- convenience to the workers;

-- need to confirm an unexpected bioassay result at or above the *DL* including time for sampling and analyses;

-- need to assess dose from chronic intakes; and

-- need to confirm the effectiveness of workplace air monitoring and personal controls such as respiratory protection or limitation of exposure time.

Recommendations for selecting the appropriate bioassay frequencies for given work areas are available in Section 4 of National Council on Radiation Protection and Measurements Report No. 87, Use of Bioassay Procedures for Assessment of Internal Radionuclide Deposition *(NCRP, 1987)*, ICRP Publication 54, and DOE's Internal Dosimetry Standard. The frequency of the routine bioassay program should be specified in procedures. Justification for the bioassay monitoring frequencies should be specified in the internal dosimetry technical basis documentation, along with an evaluation of the largest internal dose (i.e., minimum detectable dose) from an intake (acute or chronic) that could go undetected with the chosen frequency.

7. Supplementing Routine Bioassay Programs (Where the DIL < the MDA)

It is recognized that *DIL*s for reasonable and practical routine bioassay programs may be significantly less than the achievable *MDA* for certain radionuclides such as plutonium.

By definition, a technology shortfall for routine bioassay exists when the routine bioassay program's derived investigation level is less than the minimum detectable amount/activity of the routine monitoring method (*DIL* less than *MDA*). A technology shortfall occurs when a performance objective (expressed as a *DIL*) cannot be achieved with current or state-of-the-art methods and equipment.

In the case of a technology shortfall for routine bioassay, the facility should:

-- Enhance workplace monitoring and the use of indicators (e.g., unexpected glove or surface contamination, increase in airborne radioactive material contamination) to trigger early special bioassay monitoring;

-- enhance personal contamination monitoring (e.g., clothing, skin, nasal smears) to trigger special bioassay monitoring;

-- use the best practical state-of-the-art bioassay monitoring methods;

-- implement enhanced design, operation, controls, and personnel protection equipment and procedures to minimize intakes;

-- consider supplementary air monitoring; and

-- document and justify the planned supplementary approach in the facility's internal dosimetry technical basis documentation in accordance with Section IV.B of this IG.

When air monitoring data are used, each worker's stay times (in hours) and the average concentration (in DACs) to which the worker is exposed should be multiplied to yield exposures to airborne radioactive materials in units of DAC-hours. Forty (40) DAC-hours corresponds to 0.1 rem (0.001 Sv) committed effective dose equivalent when the stochastic DAC is used.

A technology shortfall for routine bioassay is not sufficient cause for failing to place workers on a minimum or best-available bioassay program.

Alternative approaches and assumptions used in dose calculations and the level of intake or committed effective dose equivalent detection achieved should be described and documented in the facility's internal dosimetry technical basis documentation. If DAC-hour calculations are used to assess exposures to airborne radioactive materials, any permitted adjustment to such calculations to account for the use of respiratory protection should be documented in the internal dosimetry technical basis documentation.

8. Representative Air Monitoring When There Is No Practical Bioassay Method

Representative (BZ) air monitoring is the only approach available for demonstrating compliance with 10 CFR 835 when there is no practical bioassay. This is the case for materials with short half-lives, including the short-lived decay products of ^{222}Rn ("radon;" decay products ^{218}Po, ^{214}Pb, ^{214}Bi, and ^{214}Po) and ^{220}Rn ("thoron;" primary decay products ^{212}Pb and ^{212}Bi). For detailed information on non-background exposures to radon and thoron, see the DOE Internal Dosimetry Standard (DOE 1996).

E. Participation in the Individual Monitoring Program

Workers may be selected to participate in either routine or special bioassay programs and/or BZ air monitoring programs. The routine bioassay program is generally used to monitor workers to detect the occurrence of an intake of radioactive materials, and special bioassay sampling is generally used to obtain follow-up data from suspected or confirmed intakes. The BZ air monitoring program is used to supplement a routine program in case of technology shortfall and when there is no practical bioassay. Technical details of participation in individual monitoring program are given in the DOE Internal Dosimetry Standard (DOE 1996).

1. Routine Individual Monitoring Programs

If a practical bioassay is available, the routine bioassay program should include baseline bioassay measurements for workers (if appropriate based on work history) before initiating a period of work assignment at a facility and a final termination bioassay measurement upon termination of work at a facility. Such measurements should be made before and after any potential for exposure, respectively.

Workers should continue to participate in the bioassay program even when the *DIL* is less than the *MDA*. While it may not be possible, in these circumstances, to detect intakes resulting in one *IL*, it is important to detect and evaluate larger intakes.

If no practical bioassay is available, workers should participate in a routine BZ air monitoring program if they are likely to have exposures of 40 DAC-hours or 0.08 WLM in a year.

2. Special Bioassay Program

If a practical bioassay method exists, workers should participate in a special bioassay program to confirm or rule out radionuclide intakes when routine bioassay program results are unexpectedly above the appropriate *DIL*, or when workplace monitoring program results, knowledge of facility operating conditions, or other information indicate that it is likely that a worker may have had an intake resulting in a dose in excess of an *IL*.

Special bioassay analyses should be performed when any of the following occur: (a) facial or nasal contamination is detected that indicates a potential for internal contamination; (b) airborne monitoring indicates the potential for intakes leading to a committed effective dose equivalent exceeding 0.1 rem (0.001 Sv); or (c) upon direction of the radiation protection organization when an intake is suspected. Special bioassay analyses should also be performed when burns, wounds, or punctures occur which may or may not result in intake of radioactive material by tissue, or positive results from wound monitoring are obtained indicating the presence of residual radioactive contamination in the damaged tissue.

Reasons for suspecting an intake may include:

-- Detection of contamination on the head or neck, hands or forearms, or inside of respirator;

-- detection of extensive or extended personal skin or personal clothing contamination;

-- loss of containment;

-- failure of ventilation system or respiratory protection equipment; or

-- elevated air sampling or contamination results in occupied areas.

Special bioassay sampling should be performed for workers following exposure to radionuclides in air when the potential intake leads to a dose that exceeds one *IL* during an incident or over a short period of time, and for workers with confirmed intakes.

3. Exception to Routine Individual Monitoring Requirement

A minimal internal dosimetry program should suffice if the probability of a measurable intake of radioactive material at a facility is low or negligible. The minimal program should consist of workplace monitoring and periodic review of operations involving radioactive materials to ensure that intake probability remains low. However, if an intake in a year for any worker at a facility would result in a committed effective dose equivalent greater than one *IL* projected from air monitoring results, special bioassay (if practical) and dose evaluation should be performed.

Facilities with the potential for intakes by workers but with no routine bioassay program of their own should have written contingency plans detailing air monitoring result action level guidelines, bioassay sample collection procedures, and arrangements with other qualified organizations for *in vivo* counting, excreta measurements, and internal dose assessment, as appropriate.

4. Timely Receipt of Bioassay and Air Monitoring Results

Results of bioassay and air monitoring measurements should be provided to dose evaluators in a short enough time to provide an adequate degree of worker protection. Consideration of timeliness should include the following:

-- The need to support decisions on implementing and/or continuing medical intervention;

-- the need to support rapid reporting to the worker, management, and DOE and subsequent follow-up for significant intakes;

-- the need to confirm a suspected intake based on a high routine measurement before the detection capability is lost due to rapid clearance from the bioassay compartment;

-- the need to support the ALARA program with timely information; and

-- 10 CFR 835.801(b) requires that reports of exposures shall be provided within 90 days of the termination of an employee, if so requested by that employee.

The internal dosimetry program should establish with laboratories analyzing bioassay samples and air samples an agreement of needed turnaround times, *MDA*s for special and routine samples, and priorities for classification of samples (e.g., routine, special, emergency). These arrangements should be documented in procedures and the internal dosimetry technical basis documentation.

Following suspected intakes, consideration should be given to performing additional sampling while awaiting initial results to ensure an adequate amount of data at early times after intake for dose evaluation purposes. Additional sampling may include the evaluation of air sample media, source terms, contamination surveys, respirator filters, nasal or mouth swabs, irrigation fluids from personal decontamination, and wound debris.

F. Detection and Confirmation of Intakes

The decision level (*DL*) for bioassay and air sample measurements should be set by considering the acceptable rate of false positives, the cost and consequences of false positives, and the dosimetric consequences of false negatives.

Bioassay results above the *DL* may be expected in the absence of a new intake due to normal statistical fluctuations, non-occupational or environmental sources, or prior confirmed intakes. The analytical laboratory decision level should be based on a reagent blank. The occupational intake decision level should be based on both the analytical laboratory *DL* and considerations of expected levels of activity in unexposed workers due to environmental exposures.

If a bioassay result above the *DL* is unexpectedly observed, or if air monitoring indicates an intake that could be confirmed by special bioassay, follow-up bioassay measurements should be promptly made to either confirm the result as a true intake or identify it as a false positive result. An intake signaled by bioassay measurements should be considered confirmed when:

-- A bioassay result exceeding the *DL* is associated with a known incident; or

-- a bioassay result exceeding the *DL* is shown not to be a false positive by investigation or by appropriate statistical analysis of follow-up measurements.

An intake signaled by air monitoring results should be considered confirmed if investigation cannot rule out a probable intake or if special bioassay results can confirm it.

Investigations for the purpose of confirming an intake should consider many factors, including evaluation of radionuclides detected versus those expected (e.g., to rule out an unreported medical administration of radioactive materials); evaluation of area survey results versus radionuclide types and quantities detected; evaluation of skin or clothing contamination contribution to bioassay indications; evaluation of co-workers' bioassay and air monitoring results; and verification of results through measurements of radionuclide transport within and out of the body.

In the absence of other confirming data, one acceptable decision rule for confirming an intake based on bioassay measurements is the observation that 2 out of the first 3 measurements in a bioassay series are above the *DL*. Follow-up bioassay samples should be scheduled and obtained in response to an initial positive bioassay result exceeding the *DL*.

If appropriate confirmatory follow-up measurements to an unexpected bioassay measurement or air monitoring measurement above the *DL* are not obtained, two options should be considered depending on the magnitude of the bioassay measurements. The first option is to simply presume an intake has occurred if the committed effective dose equivalent (CEDE) from the intake is projected to be less than one *IL*. This option minimizes costly and disruptive investigations that would not be performed for comparable external doses.

The second option is to perform an investigation if the CEDE from the intake is projected to equal one *IL* or more. If an investigation is performed, and fails to provide sufficient evidence to establish that an intake did not occur, then an intake should be presumed to have occurred. The basis for projecting a CEDE of one *IL* from bioassay results should be documented in the internal dosimetry technical basis documentation.

Both the need for promptness of the follow-up or confirmatory bioassay measurement and the determination of the *MDA* used for the analysis depend on a variety of factors. These include the clearance time of the particular radionuclide, its chemical and physical form, the mode of intake, the CEDE corresponding to the suspected intake, the usefulness of the confirming measurement in assessing the internal dose, the possibility of elevated bioassay results from non-occupational sources (e.g., medical applications, diet, or radon progeny), and the likelihood of the worker receiving additional intakes between the first and second bioassay measurement. These factors should be considered by the internal dosimetry staff in determining the follow-up or confirmatory actions to be taken in response to positive bioassay results.

These actions should be addressed in formal procedures. The internal dosimetry technical basis documentation should contain the rationale for the formal action procedures. The procedures should also address who will establish confirmatory bioassay requirements in cases not covered by the procedures.

Guidance given in Section IV.F of this IG should not be applied to historical bioassay data prior to January 1, 1989, where follow-up bioassay samples were not required on positive bioassay samples or where documentation is lacking (counter efficiency, chemical recovery, minimum detectable amount/activity, etc.). In these instances, the internal dosimetry technical basis documentation should describe the site policy for confirming intakes.

G. Internal Dose Evaluation

Technical details and extensive references for internal dose evaluation are given in the Internal Dosimetry Standard *(DOE 1996c)*.

1. Guidance

Internal doses should be evaluated for all confirmed intakes, as defined in Section IV.F of this guide. For intakes confirmed with bioassay results below the *DIL*, no further investigation or follow-up bioassay are indicated. For intakes confirmed with bioassay results above the *DIL* or exposures greater than 40 DAC-hours, follow-up bioassay (if practical) and investigation should be performed.

The extent of the investigation and the number and frequency of special bioassay measurements following a suspected or confirmed intake should be determined and documented on an individual, case-specific basis, taking into account the potential magnitude of the intake, the effective clearance half-time, the health of the worker, and the number of measurements needed to evaluate the internal dose.

The schedule and frequency of long-term special bioassay measurements to evaluate the CEDE to an individual who has had an intake resulting in a dose in excess of one *IL* should depend on the expected magnitude of the CEDE and the likelihood of the individual receiving additional intakes.

While the investigation should be tailored to the specific individual and exposure circumstances, the trigger levels and preliminary actions to be taken for exposures to the different radionuclides encountered at the facility should be documented in the internal dosimetry technical basis documentation and procedures.

Methods of evaluating the committed dose equivalent from internal sources of radiation should be appropriate to the workplace conditions. The methods should be consistent to the extent possible with EPA, NCRP, and ICRP recommendations and DOE good practices.

2. Interpretation of Bioassay Data

Biokinetic models should be used to interpret bioassay data and assess initial radionuclide intake. The particular biokinetic models used for internal dose evaluation should relate well to the available bioassay data and should account specifically (when possible and if known) for the chemical and physical characteristics of the material taken into the body. When the available data are lacking or are contradictory, professional judgment will be needed to make a dose evaluation.

Since the evaluations of internal dose depend on knowing the intake profile with respect to time, the dose evaluation staff should base the time course of intake on known incidents, air monitoring data, records of perturbations in facility operations, and/or discussions with the worker(s) by radiation protection staff. If the time course of intake cannot be plausibly established, then the procedure for evaluating doses based on the internal dosimetry technical basis documentation should be used.

Evaluations of CEDE from a specific intake should account for expected values of bioassay measurements from prior confirmed intakes.

3. Evaluation of Internal Dose from Bioassay and Air Monitoring Data

Internal dosimetry program staff should evaluate the CEDE from the intake. The data necessary to calculate committed doses to tissues or organs of concern should be maintained for possible future reevaluation.

Methods for evaluating the various doses from intakes should be specified in the internal dosimetry technical basis documentation. The methods should be based on recommendations given in ICRP Publications 30, 48, and 54, and other reports of the ICRP and NCRP which embody improvements and updates of the science of internal dosimetry. Other methods may be used provided they are documented and justified in the procedures and/or internal dosimetry technical basis documentation.

In the calculation of internal doses less than one *IL*, default parameters may be used. These parameters (e.g., intake date, deposition probabilities, retention functions, organ masses, absorption fractions) should be based on the recommendations of the ICRP, NCRP, Federal Guidance Report 11, or facility-specific factors as documented in the internal dosimetry technical basis documentation.

If the initial evaluation of an intake indicates a worker dose in excess of 10 times an *IL*, individual-specific and facility-specific factors should be used when more appropriate parameters are expected to change the dose calculations by a factor of 1.5 or more (ICRP, 1988, paragraph 74). The basis for determining which individual-specific and facility-specific factors are expected to change the dose calculations by a factor of 1.5 or more should be documented in the internal dosimetry technical basis documentation. Determination of individual retention patterns for a worker requires participation in the special bioassay program and may require temporary work restriction or reassignment to prevent subsequent intakes from confounding the dose evaluation.

4. Periodic Reevaluation of Internal Dose

In the case of certain well-retained radionuclides (e.g., plutonium), long-term follow-up and reevaluation of doses may be required. The internal contribution to lifetime occupational dose should continue to be reevaluated as further bioassay results and improved methods for evaluating internal dose become available.

Evaluations for active workers with prior confirmed intakes should be revised when information demonstrates a change in the currently evaluated CEDE of 0.5 rem (0.005 Sv) or a factor of 1.5 of the previously assigned dose for that intake, whichever is higher. In cases where intakes are detected or confirmed in a year subsequent to the year of the intake, the CEDE should be attributed to the known or assumed year of the intake, and all records and reports for that year should be amended as appropriate.

H. Internal Dose Management

DOE requires internal dose evaluation programs for evaluating internal doses to radionuclides and for maintaining adequate worker exposure records.

Each site should have a plan that documents the dose management practices. The plan should include procedures for managing workers with retained radionuclides so that: (1) Monitoring is appropriate; (2) additional exposures may be averted; (3) workers may receive adequate medical care (including decorporation therapy), if necessary; (4) internal doses can be appropriately evaluated and recorded; (5) total dose (external and internal) may be

assessed against appropriate annual administrative control levels, dose limits, and lifetime control levels; (6) workers are informed of the states of follow-up investigations and dose evaluation; and (7) consideration is given to temporary work restrictions to avoid exposures to radionuclides similar to those being evaluated in the ongoing investigation.

1. Baseline Bioassay for New Employees or Workers Initiating or Resuming Work with Radioactive Materials

Each new general employee should be evaluated for internally retained radionuclides before the worker begins any work with radioactive materials or resumes such work if he or she is likely to receive intakes resulting in a committed effective dose equivalent greater than 0.1 rem (0.001 Sv). Similarly, students, minors, members of the public, and declared pregnant workers should receive a baseline bioassay before they begin any work with radioactive materials or resume such work if they are likely to receive intakes resulting in a committed effective dose equivalent greater than one *IL*.

Baseline bioassay measurements should be requested if the worker has had previous intake. If a worker is going to work with radioactive material for which the presence of naturally occurring radioactive materials is detectable in bioassay measurements (e.g., uranium in urine), baseline bioassay monitoring should be considered regardless of prior occupational exposure.

If a worker has retained radioactive material from prior intakes, the effect of those levels on the ability of the program to detect new exposures must be assessed. Special monitoring procedures may be required for such cases.

2. Dose Limitation

Committed dose equivalents and CEDEs should be calculated for intakes of radioactive materials that take place during a year, and should not include any contributions from intakes occurring in prior years. These doses should be recorded and reported to the worker and management as being assigned in the year of intake.

3. Lifetime Dose Control

To administratively control a worker's lifetime occupational radiation dose, a lifetime control level of N rems (N times 0.01 Sv) should be established where N is the age of the individual in years. Special Control Levels should be established for individuals who have doses exceeding N rems (N times 0.01 Sv).

For compliance purposes, the lifetime occupational dose should be compared to the Lifetime Control Level.

4. Accidental Dose Control

Action levels for administrative response to intakes of radionuclides by workers should be detailed in the internal dosimetry technical basis documentation and in internal dosimetry program procedures.

I. Recording Internal Doses and Related Information

1. Requirements

Requirements and guidance for recording internal doses and related information are provided in Implementation Guide G-10 CFR 835/H1, Occupational Radiation Protection Record-keeping and Reporting.

2. Individual Information

Requirements and guidance for recording individual information relted to internal doses are provided in Implementation Guide G-10 CFR 835/H1, Occupational Radiation Protection Record-keeping and Reporting.

3. Intake Records

For each confirmed intake, the following information should be recorded:

-- Magnitude of intake in terms of activity or mass for each radionuclide or potential alpha energy for radon and thoron progeny;

-- time course of intake including date(s) and time(s) and whether known or assumed;

-- intake route (inhalation, ingestion, skin puncture, etc.) and whether known or assumed;

-- radionuclides involved and their physical and chemical forms whether known or assumed, including, as appropriate, particle size, equilibrium factor, unattached fraction, etc.;

-- bioassay information pertinent to evaluation of the intake; and

-- methods and assumptions used for dose evaluation.

4. Dose Evaluation Records

All information that is necessary to review or recalculate each evaluated dose should be recorded including uncensored bioassay data, models, assumptions, parameters, and additional bioassay data as appropriate. The names of the evaluator and reviewer and the outcome of the review should be recorded.

Recording a bioassay result as "less than *DL*" rather than recording a numerical value is called censoring data. No censoring of data should be done, that is, actual numerical results should be recorded whether negative, zero, positive below the *DL*, or positive at or above the *DL*. The information contained in reports to individuals is discussed in Section IV.J. of this IG.

Reevaluations of internal doses performed in accordance with this IG (Section IV.G.4) should be documented such that a complete historical record of preliminary and final CEDE estimates is retained.

Future refinements in radiation risk assessment and dosimetric modeling may require reconsideration of the actual time course and organ distribution of doses. The internal dosimetry records should therefore include as much information as is available to reconstruct the organ or tissue absorbed dose.

J. Reporting Requirements

Amended reports of CEDE by radionuclide or group of radionuclides for intakes in prior years, if reevaluations are performed, should be reported to the individual and entered in the individual's records as well as reflected in the TEDE, cumulative TEDE, and lifetime occupational dose reported under provisions of other Orders.

K. Medical Response

Facilities with potential for intakes approaching dose limits should be prepared to follow an action plan for medical response to any potential or accidental intake of radioactive material. The plan should be developed as a cooperative effort between medical and radiation protection organizations and should include activation of key response functions (internal dosimetry, analytical laboratory, *in vivo* counting, medical assistance, etc.), training, and action levels for response. The elements of this plan should include:

-- Action levels for medical response;

-- responsibilities of the affected worker, radiation protection staff, internal dose evaluation staff, health physicist, medical staff, and management;

-- guides for immediate medical care, decontamination, monitoring, and long-term evaluation; and

-- provisions for periodically reviewing, updating, and rehearsing the action plan.

Since there is no consensus on the decision levels for medical treatment of workers, action levels should be established in the internal dosimetry technical basis documentation based on decisions reached among medical, management, and radiation protection staff (RCM 523.6). Planning for such emergency actions should include the provision of facilities and materials that will be required.

L. Quality Assurance

1. General Requirements

The internal dose evaluation program shall be adequate to demonstrate compliance with 10 CFR 835 subpart C, and shall be either accredited in accordance with the DOE Laboratory Accreditation Program (DOELAP) for Radiobioassay or be excepted from DOELAP Radiobioassay accreditation (10 CFR 835.402(d)). Internal audits of the radiation protection program, including examination of program content and implementation, shall be conducted through a process that ensures that all functional elements are reviewed no less than every 36 months (10 CFR 835.102).

From the initial step (such as urine sample collection or reporting for an *in vivo* count) through sample analysis and dose evaluation to recording of the results, every step in an internal dosimetry program is important in protecting workers and demonstrating compliance with 10 CFR 835 and DOE Orders. All steps in the activities that control or evaluate worker internal doses should be covered by written procedures that provide appropriate quality control and quality assurance. Quality assurance practices, such as having supervisors ensure that bioassay

samples are submitted on an appropriate frequency, will enable corrective action when necessary. Quality control will provide the needed documents and records for demonstrating compliance.

Computer software is normally used to perform internal dose evaluations. Procedures for software quality assurance should be developed and implemented to address:

-- Software documentation per ANSI/ANS 10.3, Guidelines for the Documentation of Digital Computer Programs *(ANSI, 1986)*;

-- validation and verification of models, data, assumptions, and algorithms per ANSI/ANS 10.4, Verification and Validation of Scientific and Engineering Computer Programs for the Nuclear Industry *(ANSI, 1987)*;

-- software security;

-- configuration management;

-- periodic testing to assure proper function; and

-- actions to be taken in the event that software errors are detected.

Hand calculations should be independently verified by a second qualified internal dose evaluator. This review should be documented.

2. Independent Review

The internal dosimetry program should receive periodic assessment by the site radiation protection organization to review technical basis documentation, dose assessment procedures, instrumentation and analytical methods, qualifications of personnel, quality assurance program elements, and other elements of the program, as necessary to ensure that the program maintains the capability to stay abreast of scientific developments in internal dosimetry and provides a quality radiation protection service to workers. External peer-review by qualified individuals on a periodic basis is also recommended.

Internal dosimetry program accreditation (as distinct from DOELAP for Radiobioassay), when it becomes available, should provide formal external review and testing of program capabilities. Each site should work toward and plan for eventual accreditation. Internal dosimetry program personnel should participate in the conduct of intercomparison studies and should use the "DOE Phantom Library." Radiochemical laboratories, in-vivo counting facilities, and laboratories where air samples are analyzed, whose measurements are used by internal dosimetry programs are expected to have quality assurance programs, documented regular equipment calibration programs, National Institute of Standards and Technology traceable standards (when available), and written procedures that can be referenced by internal dosimetry programs.

M. Guidance for Monitoring in the Workplace

The objectives of the workplace monitoring program are to verify the integrity of radioactive material containment, detect the release of radioactive materials from some routine operations, detect inadvertent releases of those

materials in the workplace, evaluate and provide the basis for modification to containment systems, and provide a basis for design of bioassay programs.

1. Performance Requirements

For the purpose of workplace monitoring, air samplers positioned in the breathing zone of workers may be used to complement fixed-station and portable air samplers, as necessary to ensure that representative air samples are obtained. Bioassay measurements may be used to help verify the adequacy of the workplace air monitoring program, but should not provide the primary basis for monitoring for loss of radionuclide control in the workplace.

2. Allowance for Physical and Chemical Form

The specific physical and chemical characteristics of the materials potentially involved should be determined and taken into account in the design of the monitoring program. These include radionuclide composition, mode of intake, activity median aerodynamic diameter and particle-size distribution, solubility and transportability from the lung to other organs, and gastrointestinal absorption into the systemic circulation. Accounting for physical and chemical characteristics may necessitate a different set of secondary protection limits (ALIs and DACs as specified in 10 CFR 835 Appendix A) applied to specific work locations. The basis for revised secondary limits should be documented in the internal dosimetry technical basis documentation.

3. Recourse for Technology Shortfall

The technology needed to perform workplace measurements for some radioactive materials at levels indicative of a committed effective dose equivalent of 0.1 rem (0.001 Sv) may not be available. If the performance requirement cannot be achieved for this reason, the facility should: (1) Continue to use the best practicable (state-of-the-art) monitoring methods; (2) document the level of intake detection achieved; and (3) implement enhanced design, operation, controls, and personnel protection equipment and procedures to minimize intakes.

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UNITED STATES
DEPARTMENT OF ENERGY
Office of Worker Protection Programs and Hazards Management (EH-52/270CC)
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REQUEST FOR CHANGES TO IMPLEMENTATION GUIDE ON POSTING and LABELING for RADIOLOGICAL CONTROL
(Use Multiple Pages as Necessary)

Page No. _____	_____ Facility Requesting Change
Column No. _____	_____ Contact Person
Line No. _____	_____ Telephone Number - Fax Number

Description of Change Request:

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Suggested Specific Word Changes:

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EH-52 Guidance Program Contact: Steven G. Zobel, (301) 903-2305