This regulatory guide is being issued in draft form to involve the public in the early stages of the development of a regulatory position in this area. It has not received final staff review or approval and does not represent an official NRC final staff position. Public comments are being solicited on this draft guide and its associated regulatory analysis. Comments should be accompanied by appropriate supporting data. Written comments may be submitted through the federal government rulemaking Web site at http://www.regulations.gov. Alternatively, written comments may be submitted to the Rules, Announcements, and Directives Branch, Office of Administration, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001; or faxed to (301) 492-3446. Comments must be submitted by December 24, 2013.

Electronic copies of this draft regulatory guide, previous versions of this guide, and other recently issued guides are available through the NRC’s public Web site under the Regulatory Guides document collection of the NRC Library at http://www.nrc.gov/reading-rm/doc-collections/reg-guides/. The draft regulatory guide is also available through the NRC’s Agencywide Documents Access and Management System (ADAMS) at http://www.nrc.gov/reading-rm/adams.html, under Accession No. ML13168A095. The regulatory analysis may be found in ADAMS under Accession No. ML13168A096.

Related Guidance

The NRC has developed guidance related to calculating occupational doses for monitored individuals and provided criteria regarding which individuals should be monitored for radiation exposure. Such guidance includes:

(1) Regulatory Guide 8.9, Revision 1, “Interpretation of Bioassay Measurements” (Ref. 4), provides methods of determining intakes from bioassay results,

(2) Regulatory Guide 8.25, Revision 1, “Air Sampling in the Workplace” (Ref. 5), provides methods of determining intakes from air sampling measurements,

(3) Regulatory Guide 8.36, “Radiation Dose to the Embryo/Fetus” (Ref. 6), provides methods of calculating doses to the embryo/fetus, and


Purpose of Regulatory Guides

The NRC issues regulatory guides to describe to the public methods that the staff considers acceptable for use in implementing specific parts of the agency’s regulations, to explain techniques that the staff uses in evaluating specific problems or postulated accidents, and to provide guidance to applicants. Regulatory guides are not substitutes for regulations and compliance with them is not required. Methods and solutions that differ from those set forth in regulatory guides will be deemed acceptable if they provide a basis for the findings required for the issuance or continuance of a permit or license by the Commission.

Paperwork Reduction Act

This regulatory guide discusses information collection requirements covered by 10 CFR Part 20 and 10 CFR Part 50 that the Office of Management and Budget (OMB) approved under OMB control numbers 3150-0014 and 3150-0011 respectively. The NRC may neither conduct nor sponsor, and a person is not required to respond to, an information collection request or requirement unless the requesting document displays a currently valid OMB control number.
B. DISCUSSION

Reason for Revision

On December 4, 2007, the NRC revised the definition of the TEDE in 10 CFR Parts 20 and 50. Under the revised rule, the TEDE means the sum of the effective dose equivalent (for external exposures) and the committed effective dose equivalent (for internal exposures). This revision of RG 8.34 provides updated regulatory guidance on monitoring criteria and methods of calculating occupational dose based on the revised definition of TEDE.

Background

On December 4, 2007, the NRC revised the definition of the total effective dose equivalent (TEDE) in 10 CFR Part 20, “Standards for Protection against Radiation,” Section 20.1003, “Definitions” and 10 CFR 50, Section 50.2, “Definitions,” (72 FR 68043 (Ref. 8)). The revision subsequently affected the methods of monitoring and calculating occupational radiation doses and demonstrating compliance with the occupational dose limits. Previously, the definition of the TEDE was the sum of the deep dose equivalent (DDE) to account for external exposure and the committed effective dose equivalent (CEDE) to account for internal exposure. Under the revised rule, 10 CFR Part 20, Section 20.1003, “Definitions,” the TEDE was redefined by replacing the DDE with the effective dose equivalent for external exposure, hereafter referred to as the EDEX.

Old definition: \[ \text{TEDE} = \text{DDE} + \text{CEDE} \]

New definition: \[ \text{TEDE} = \text{EDEX} + \text{CEDE} \]

It should be noted that for exposures in uniform radiation fields, the EDEX is normally determined by measuring the DDE and, therefore, the revised TEDE definition has little impact during most normal operations. However, for exposures in nonuniform radiation fields, the revised TEDE definition provides greater monitoring flexibility and accuracy for licensees in monitoring worker exposures. Under nonuniform conditions, the previous TEDE definition tended to provide dose assessments that were excessively conservative.

In general, occupational dose limits are applicable during routine operations, planned special exposures, and during emergencies. Dose received during an emergency must be included in the determination of the annual occupational dose. However, the potential for exceeding a dose limit should not prevent a licensee from taking necessary actions during an emergency. As stated in 10 CFR 20.1001, “Purpose,” nothing in this part (10 CFR Part 20 regulations) shall be construed as limiting actions that may be necessary to protect health and safety.

Occupational Dose Limits for Adults, Minors, and Members of the Public

For protection of adults against stochastic effects, an annual TEDE limit of 5 rems (50 millisieverts (mSv)) is established in 10 CFR 20.1201(a)(1). For protection of adults against nonstochastic effects, an annual total organ dose equivalent (TODE) limit of 50 rems (500 mSv) is established in 10 CFR 20.1201(a)(1)(ii). For protection of the lens of the eye, an annual lens dose equivalent (LDE) limit of 15 rems (150 mSv) is established in 10 CFR 20.1201(a)(2)(i). For protection of the skin of the whole body or to the skin of any extremity, an annual shallow-dose equivalent (SDE) limit of 50 rem (500 mSv) is established in 10 CFR 20.1201(a)(2)(ii).
For minors, 10 CFR 20.1207, “Occupational Dose Limits for Minors,” establishes an annual limit at 10 percent of the adult limits. For protection of an embryo/fetus of a declared pregnant woman, 10 CFR 20.1208, “Dose Equivalent to an Embryo/Fetus,” establishes a dose equivalent limit of 0.5 rem (5 mSv).

For individual members of the public, 10 CFR 20.1301(a)(1) establishes an annual limit of 0.1 rem (1 mSv). The amount of exposure that members of the public may receive is limited by the public dose limit, regardless of where the individual is located (e.g., including temporary entries into the restricted area).

Planned Special Exposures (PSEs)

Dose received during PSE is accounted separately from the dose limits in 10 CFR 20.1201. PSEs are subject to the conditions specified in 10 CFR 20.1206, “Planned Special Exposures,” (e.g., exceptional circumstances, specific authorizations, and informing and instructing the worker). Assuming there were no doses exceeding the annual dose limits, the maximum allowable annual TEDE an individual could receive is 5 rems (50 mSv) under 10 CFR 20.1201(a)(1)(i), plus an additional 5 rems (50 mSv) as a PSE under 10 CFR 20.1206. In addition, during an individual’s lifetime, the dose from all PSEs and all doses in excess of the routine dose limits are not to exceed 25 rem (250 mSv).

A licensee cannot authorize a PSE that would cause an individual to receive a combined dose from all PSEs and all doses in excess of the dose limits greater than 5 rems (50 mSv). For example, assume an individual received an annual TEDE of 5.5 rems (55 mSv), which is 0.5 rem (5 mSv) above the routine TEDE limit. If this same individual were to be involved in a PSE, the maximum allowable PSE dose to the individual would be 4.5 rems (45 mSv).

Surveys

When a licensee assigns or permits the use of respiratory protection equipment to limit the intake of radioactive material, 10 CR 20.1703(c)(2) requires surveys and bioassays, as necessary, to evaluate actual intakes. This criterion applies when there is the potential for the intake to exceed the 10 CFR 20.1502 monitoring requirements. Indications of an intake could include facial contaminations, nasal contamination, malfunctioning respiratory protection equipment, loss of engineering controls creating an airborne radioactivity area, and work in unknown or unplanned airborne radioactivity areas.

During operations, licensees should perform airborne radioactivity surveys as required in 10 CFR 20.1502 to characterize the radiological hazards that may be present and, as appropriate, use engineering and respiratory protection equipment to reduce intakes. When it is not practical to use process or engineering controls to reduce the concentrations of airborne radioactivity to values below those that define an airborne radioactivity area, licensees are required under 10 CFR 20.1702(a), consistent with maintaining the TEDE ALARA, to increase monitoring (e.g., Derived Air Concentrations (DAC)-hour tracking, bioassay) and limit intakes by the use of access controls, limiting exposures times, or use respiratory protection equipment.

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1 Survey means an evaluation of the radiological conditions and potential hazards incident to the production, use, transfer, release, disposal, or presence of radioactive material or other sources of radiation. When appropriate, such an evaluation includes a physical survey of the location of radioactive material and measurements or calculations of levels of radiation or concentrations or quantities of radioactive material present.
Recording and Reporting of Monitoring Results

Once a licensee determines that external or internal dose monitoring under 10 CFR 20.1502 is required, the results of that monitoring must be recorded on the individual’s radiation exposure records, as required by 10 CFR 20.2106, “Records of Individual Monitoring Results.” This is required even if the actual dose received by the individual is less than the monitoring criteria in 10 CFR 20.1502.

The licensees specified in 10 CFR 20.2206, “Reports of Individual Monitoring,” are required to report the monitoring results to the NRC’s Radiation Exposure Information and Reporting System (REIRS) by an appropriate method listed in 10 CFR 20.1007, “Communications,” or via the REIRS Web site at http://www.reirs.com (see RG 8.7, “Instructions for Recording and Reporting Occupational Radiation Exposure Data” (Ref. 9)). Other licensees that are not required by 10 CFR 20.2206 to submit reports of individual monitoring may also voluntarily report their monitoring results to the NRC.

Licensees may voluntarily issue individual monitoring devices or use calculation methodologies for reasons other than required personnel monitoring under the requirements in 10 CFR 20.1502 (e.g., to provide for worker knowledge or concern). The results of monitoring when voluntarily provided, but not required by 10 CFR 20.1502, are not subject to the dose recording or reporting requirements in 10 CFR Part 20, Subpart L, “Records” or Subpart M, “Reporting.” However, licensees may voluntarily provide these reports to the exposed individual(s) and to the NRC. The results of the voluntary monitoring also may be used in a prospective assessment to determine the need for future monitoring.

Monitoring Levels

The regulations at 10 CFR 20.1502 require monitoring at levels sufficient to demonstrate compliance with the occupational dose limits, therefore monitoring methods should be appropriately accurate. If the radiation dose is highly non-uniform causing a specific part of the body to receive a substantially higher dose than the rest of the whole body, the individual monitoring device should be placed near that part of the whole body expected to receive the highest dose.

Note: Some small amount of dose may not be measured and/or accounted for as a result of (1) dosimetry system sensitivity, (2) dosimeter placement, and (3) dosimeter capability (e.g., not capable of measuring all radiation types or energies)

Harmonization with International Standards

The NRC has a goal of harmonizing its guidance with international standards, to the extent practical. The International Commission on Radiological Protection (ICRP) and the International Atomic Energy Agency (IAEA) have issued a significant number of standards, guidance and technical documents, and recommendations addressing good practices in most aspects of radiation protection. The NRC encourages licensees to consult these international documents noted throughout this guide and implement the good practices, where applicable that are consistent with NRC regulations. These documents are:

1. International Commission on Radiological Protection (ICRP) Publication 2, “Permissible Dose for Internal Radiation,” (Ref. 10),
2. ICRP Publication 26, “Recommendations of the International Commission on Radiological Protection,” (Ref. 11),
3. ICRP Publication 30, (7-volume set including supplements), “Limits for Intakes of Radionuclides by Workers,” (Ref. 12),
5. ICRP Publication 68, “Dose Coefficients for Intakes of Radionuclides for Workers,” (Ref. 14),
8. IAEA Safety Standard Series No. RS-G-1.2, “Assessment of Occupational Exposure Due To Intakes of Radionuclides,” (Ref. 17), and

It should be noted, however, that some of the recommendations issued by these international organizations do not correspond to the requirements specified in the NRC’s regulations. In such cases, the NRC’s requirements take precedence.

Documents Discussed in Staff Regulatory Guidance

Although this regulatory guide utilizes information, in part, from one or more reports developed by external organizations and other third party guidance documents, the regulatory guide does not endorse these references other than as specified in this regulatory guide. These reports and third party guidance documents may contain references to other reports or third party guidance documents (“secondary references”). If a secondary reference has itself been incorporated by reference into NRC regulations as a requirement, then licensees and applicants must comply with that requirement in the regulation. If the secondary reference has been endorsed in a regulatory guide as an acceptable approach for meeting an NRC requirement, then the reference constitutes a method acceptable to the NRC staff for meeting that regulatory requirement as described in the specific regulatory guide. If the secondary reference has neither been incorporated by reference into NRC regulations nor endorsed in a regulatory guide, then the secondary reference is neither a legally-binding requirement nor a “generic” NRC approval as an acceptable approach for meeting an NRC requirement. However, licensees and applicants may consider and use the information in the secondary reference, if appropriately justified and consistent with current regulatory practice, consistent with applicable NRC requirements such as 10 CFR Part 20.

C. STAFF REGULATORY GUIDANCE

The staff regulatory guidance is organized as follows:

1. Section C.1, provides guidance on the radiological monitoring criteria for when individual exposure monitoring is required,
2. Section C.2, provides regulatory guidance on determining whether, and what type of, occupational radiation dose monitoring is required,
3. Section C.3, provides guidance on determination of external doses,
4. Section C.4, provides guidance on determination of internal doses,
5. Section C.5, provides guidance on acceptable methods of calculating the CDE and CEDE for inhalation, submersion and absorption intake pathways
6. Section C.6, provides regulatory guidance on use of individual or material-specific information, and
7. Section C.7, provides guidance on uranium intake limitation.
1. Monitoring Criteria

The monitoring requirements have not changed and apply separately to each external and internal dose type. 10 CFR 20.1502, “Conditions Requiring Individual Monitoring of External and Internal Occupational Dose,” requires individual monitoring of external and internal occupational dose under the radiological conditions specified below. Monitoring of external radiation exposure from licensed and unlicensed sources under the control of the licensee is required by 10 CFR 20.1502(a) for any individual entering a high or very high radiation area and for any individual if the external occupational dose is likely to exceed:

a) For adults, 10 percent of the occupational dose limits in 10 CFR 20.1201(a).

Note: The EDEX is the quantity requiring monitoring for entry into a high or very high radiation area.

b) For minors in one year, a deep-dose equivalent of 0.1 rem (1 mSv), a lens dose equivalent of 0.15 rem (1.5 mSv), and a shallow-dose equivalent to the skin of the whole body or to the skin of the extremities of 0.5 rem (5 mSv).

c) For declared pregnant women during the entire pregnancy, a deep-dose equivalent of 0.1 rem (1 mSv).

Monitoring the intake of radioactive material and assessing the CEDE is required by 10 CFR 20.1502(b) if the intake is likely to exceed:

a) For adults, 10 percent of the applicable annual limit on intake (ALI)

b) For minors in one year, 0.1 rem (1 mSv).

c) For declared pregnant women during the entire pregnancy, 0.1 rem (1 mSv).

2. Determining the Need for Monitoring of Occupational Doses

Licensees are required under 10 CFR 20.1502 to monitor the occupational dose at levels sufficient to demonstrate compliance with the occupational dose limits. The definition of occupational dose, in 10 CFR 20.1003, “Definitions,” includes dose received during the course of employment in which assigned duties involve exposure to radiation or radioactive material from licensed and unlicensed sources of radiation, whether in the possession of the licensee or other person. The definition of occupational dose excludes radiation dose from background radiation, from medical administrations the individual has received, from exposure to individuals administered radioactive material and released under 10 CFR 35.75, from voluntary participation in medical research programs, or as a member of the public.

Unlicensed sources are radiation sources not licensed by the NRC or Agreement States; such as products or sources covered by exemptions from licensing requirements (e.g., 10 CFR 30.14, “Exempt Concentrations;” 10 CFR 30.15, “Certain Items Containing Byproduct Material;” 10 CFR 30.18, “Exempt Quantities;” 10 CFR 30.19, “Self-Luminous Products Containing Tritium, Krypton-85, or Promethium-147;” 10 CFR 30.20, “Gas and Aerosol Detectors Containing Byproduct Material;” 10 CFR 30.22, “Certain Industrial Devices;” 10 CFR 40.13, “Unimportant Quantities of Source Material”), naturally occurring radioactive materials that are not covered by the Atomic Energy Act, radioactive materials or nuclear facilities operated by another Federal entity such as the U.S. Department of Defense or the U.S. Department of Energy; as well as machines that produce radiation, such as x-ray radiography machines and x-ray machines used by security staff.
The definitions of occupational dose and public dose, contained in 10 CFR 20.1003, “Definitions,” were changed in 1995 (60 FR 36038 (Ref. 19)). “Public dose” means the dose received by a member of the public from exposure to radiation or radioactive material released by a licensee, or to any other source of radiation under the control of a licensee, regardless of the location of the member of the public (e.g., including when the member of the public is within a licensee restricted area).

Public dose does not include occupational dose or doses received from background radiation, from any medical administration the individual has received, from exposure to individuals administered radioactive material and released under 10 CFR 35.75, or from voluntary participation in medical research programs. Thus, regardless of where the individual is located, no licensee may cause a member of the public to receive a dose in excess of the public dose limit. In the same 1995 rulemaking, “Occupational dose” was redefined to eliminate the criteria that any dose received by an individual while in a restricted area is occupational dose. In addition, the 1995 rule change included a change to training requirements for individuals receiving occupational dose such that training is required for those individuals likely to receive an occupational dose in excess of 100 mrem (1 mSv) such as to not result in an undue burden on licensees in providing training to workers.

Licensees can comply with 10 CFR 20.1502 by performing the following activities:

a) **Designation of Individuals**

Designate, in advance, individuals as either occupationally exposed or members of the public; hence receiving “occupational dose” or “public dose.” Only those individuals designated by the licensee as occupationally exposed are subject to the occupational dose limits. Individuals not designated as receiving occupational dose must be considered as members of the public and are subject to the public dose limits (even if exposed in the restricted area).

b) **Classification of Individuals**

The licensee’s classification of individuals as occupationally exposed may be performed for each individual, or as a group or category of individuals, and can be documented in a prospective assessment. Note: Section 19.12, “Instructions to Workers,” of 10 CFR Part 19, “Notices, Instructions, and Reports to Workers: Inspection and investigations,” was revised in 1995 to require training of occupationally exposed individuals who in the course of their employment were likely to receive an annual occupational dose in excess of 100 mrem (1 mSv).

c) **Occupational Dose Monitoring at Levels Sufficient to Demonstrate Compliance**

Licensees are required to monitor exposures at levels sufficient to demonstrate compliance with the occupational dose limits in accordance with 10 CFR 20.1502. An acceptable method of determining the need for monitoring is to perform a prospective assessment that determines and documents the type of monitoring required (e.g., external dose or internal dose monitoring). The requirements in 10 CFR 20.1502 refer to each licensee individually. Doses that may have already been received or may be received in the future from employment by another licensee (or unlicensed entity) are not included in the determination of a licensee’s need to monitor occupational dose at its facility. The need for monitoring should be based on the anticipated exposure to licensed or unlicensed sources under the control of the licensee.
d) **Evaluation based on Planned Work Activities and Likely Exposure Conditions**

In performing a prospective assessment, an evaluation should be done based on planned work activities and likely exposure conditions. The licensee does not need to perform a dose evaluation for each individual; evaluations can be performed for groups or categories of employees with similar job functions or for employees located in the same work area. Radiological surveys and estimates of occupancy times may be used to estimate anticipated doses. Historical dosimetric or bioassay data at the licensee’s facility also may be considered in making this evaluation. Additionally, licensees may consider industry historical data provided in NUREG-0713, “Occupational Radiation Exposure at Commercial Nuclear Power Reactors and Other Facilities.” Prospective assessments should be revised when there are substantial changes to the radiological conditions of personnel exposure (e.g., changes in work activities, airborne concentrations, beta energy spectrums, or use of new or different types or energies of radiation producing equipment.)

e) **Engineering Controls and Respiratory Protection**

Licensees may take credit for the use of engineering controls (e.g., containment, decontamination, ventilation, and filtration) and respiratory protection when determining the need for internal dose monitoring.

3. **Determination of External Doses**

a) **Determination of the Total Effective Dose Equivalent (TEDE)**

Under 10 CFR 20.1202, if a licensee is required to monitor both external dose and internal dose, the licensee must demonstrate compliance with the dose limits by summing external and internal doses (i.e., TEDE = EDEX + CEDE). However, if the licensee is only required to monitor external doses under 10 CFR 20.1502(a), or only internal doses under 10 CFR 20.1502(b), then summation is not required to demonstrate compliance with the occupational dose limits. For example, if the internal dose is not monitored, the CEDE can be assumed equal to zero, and the TEDE is equal to the EDEX. Similarly, if the external dose is not monitored, the EDEX can be assumed equal to zero, and the TEDE is equal to the CEDE.

b) **Determination of the Effective Dose Equivalent from External Exposure (EDEX)**

The EDEX is determined using one or more combinations of the following methods in accordance with 10 CFR 20.1201(c). These methods are described in RG 8.40 as follows:

1. Measuring the DDE at the highest exposed part of the whole body with an external personal monitoring device, as required by 10 CFR 20.1201(c), when an NRC method for determining EDEX is not used.

2. Measuring external exposure with one or more external personal monitoring devices and an NRC approved method for determining EDEX such as those provided in Regulatory Guide 8.40, or as specifically approved by the NRC.
(3) Calculating the EDEX based on survey data obtained under 10 CFR 20.1501 or other radiological data, such as known source activity, dose rates, and exposure times using scientifically sound technical methods. This may be required under unique exposure situations (e.g., partial body exposed to radiation streaming of narrow beam geometries) or when the individual monitoring device was not in the region of the highest whole body exposure (per 10 CFR 20.1201(c)), or the results of the individual monitoring are not available (i.e., damaged or lost device).

Note: It is anticipated that a licensee may routinely determine EDEX for the majority of a monitoring period using method (1) above, and possibly using the methods (2) and (3) infrequently within the monitoring period for special exposure situations. The results of the different dosimetry methods must be combined to determine the EDEX for the entire monitoring period.

c) Determination of the Deep-Dose Equivalent (DDE)

The DDE is typically measured by the use of individual monitoring devices and is determined at a tissue depth of 1 centimeter (cm) (1,000 mg/cm²). When determining the EDEX with a dosimetry method, the DDE must be measured at the highest exposed part of the whole body. When using the multiple dosimetry method with compartment factors as described in RG 8.40, Section C.1, the DDE must be measured at the highest exposed portion in each of the monitored compartments. The DDE also can be calculated if the appropriate parameters (i.e., radiation source strength, exposure geometry, full or partial shielding) are known.

d) Determination of the Shallow-Dose Equivalent (SDE) and Lens Dose Equivalent (LDE)

In 2002, the NRC amended its regulations in 10 CFR Part 20 to change the definition and method of calculating shallow-dose equivalents (SDE) by specifying that the assigned SDE must be the dose averaged over the contiguous 10 cm² of skin receiving the highest exposure, rather than 1 cm² (67 FR 16298, (Ref. 20)). Licensees can also refer to Regulatory Issue Summary 2002-10, “Revision of the Skin Dose Limit in 10 CFR Part 20,” (Ref. 21) for additional information.

The SDE to the skin of the whole body or extremities is defined at a tissue depth of 0.007 cm (7 mg/cm²), and the LDE is defined at a tissue depth of 0.3 cm (300 mg/cm²). If the SDE or the LDE is being monitored with a dosimeter, then that dosimeter should be calibrated to measure the dose at a tissue depth of 7 mg/cm² or 300 mg/cm², respectively, or estimated by using the SDE as a conservative estimate of the LDE. In many exposure situations, shield glasses can be worn to prevent exposures to the lens of the eye from low energy (or low penetrating) radiations, eliminating the need for monitoring the LDE.

4. Determination of Intakes and Internal Doses

a) Determination of Intakes

An intake of radioactive material can occur through inhalation, ingestion, absorption through the skin, or through wounds. The amount of the intake may be assessed from air sampling results or based on bioassay measurements.
(1) Determining the Intake based on Air Sampling

Intakes (I) based on air sampling results can be assessed by multiplying the airborne concentration (C) by the breathing rate and the exposure time.

\[ I = C_{\text{Air sample}} \times \text{breathing rate} \times \text{exposure time} \]

where the breathing rate of "Reference Man" under light working conditions is 2E+4 ml/minute.

(2) Determining the Intake based on Bioassay Measurements

Another method of assessing the intake from inhalation, ingestion or skin absorption is based on bioassay uptake measurements. Guidance on methods of estimating intake based on bioassay results is also provided in NUREG/CR-4884, “Interpretation of Bioassay Measurements,” (Ref. 22). Method(s) for the assessment of the intakes from wounds are also generally based on bioassay measurements using a combination of whole body in vitro bioassay and hand-held instrumentation.

Note: The amount of the intake and the CDE may be assessed using updated biokinetic and dosimetric models, but the CEDE must be calculated (see below) using the organ weighting factors specified in 10 CFR 20.1003, “Definitions” (unless other weighting factors have been approved by the NRC). The use of more recent tissue or organ weighting factors, contained in ICRP Publications 60, “1990 Recommendations of the International Commission on Radiological Protection,” and ICRP Publication 103, “The 2007 Recommendations of the International Commission on Radiological Protection,” is not acceptable since 10 CFR Part 20 specifies the organ dose weighting factors that must be used.

b) Calculation of the Committed Effective Dose Equivalent (CEDE)

The dose quantity for protection against stochastic effects of internal dose is the CEDE; i.e., a 50-year committed effective dose equivalent from intakes occurring during the monitoring period. There are three fundamental methods described below for calculating the CEDE:

1. Using dose coefficients\(^3\) from the U.S. Environmental Protection Agency’s Federal Guidance Report No. 11 (FGR-11) (Ref. 23).
2. Using ALI methods.

Further details and examples on calculating the CEDE are described in Section C.5 below.

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\(^3\) Note: Federal Guidance Report No. 11 (FGR-11) uses the terminology “dose conversion factors.” However, more recent ICRP documents use the terminology “dose coefficients.” This regulatory guide is adopting the newer terminology “dose coefficients” (this change in terminology is acceptable since the terminology is not incorporated into the regulations).
Note: When performing CEDE calculations using the ALI and DAC-hour methods, the ALI and DAC values provided in Appendix B to 10 CFR Part 20 must be used, unless the licensee has obtained prior NRC approval in accordance with 10 CFR 20.1204(c)(2) to adjust the ALI or DAC values.

e) Calculation of the Committed Dose Equivalent (CDE)

The CDE is the 50-year committed dose equivalent from intake of radioactive material. Methods and examples of calculating the CDE are described in Section C.5, below.

d) Calculation of the Total Organ Dose Equivalent (TODE)

The dose limit for protection against the nonstochastic effects is expressed in terms of the TODE; i.e., the sum of the DDE and the CDE.

\[
TODE = DDE + CDE
\]

The TODE is determined by adding the DDE (measured at the highest exposed part of the whole body) to the CDE.

If only internal monitoring is being performed, the TODE is equal to the CDE to the highest exposed organ (since the DDE was not monitored and is assumed equal to zero). Further details on acceptable methods of calculating the CDE are described in Section C.5 below.

If both internal and external monitoring are being performed, the licensee must demonstrate that both the 5 rems TEDE and the 50 rems TODE limits are met. One method of demonstrating compliance with the TODE limit is by summing the DDE and the CDE to the highest exposed organ. Another acceptable method of demonstrating that the TODE limit is met is by using the mathematical fact that if the DDE is less than 5 rem, and the CEDE does not exceed 1 rem, then the TODE cannot exceed the 50 rem TODE limit. In this case, the CDE does not need to be determined since compliance was demonstrated by calculation. If the CEDE does exceed 1 rem, the CDE must be determined in order to demonstrate compliance with the dose limits.

e) Submersion Doses

Most radionuclides listed in Appendix B to 10 CFR Part 20 in the “Class” column as “Submersion,” do not have corresponding inhalation ALI values. For these radionuclides, the internal dose is negligible compared to the external dose, and may be excluded. However, the SDE for submersion gas exposure may need to be calculated based on air samples to obtain dose rate information needed (e.g., for pre-job briefings), and also to account for the SDE that may not be adequately measured by dosimeters because of low energy beta spectrums.

f) Doses from Intakes through Wounds

In accordance with 10 CFR 20.1202(d), the licensee shall evaluate and, to the extent practical, account for intakes through wounds. Any uptake of radioactive material from the site of the wound to systemic circulation may be determined by bioassay or other appropriate method. If significant, the dose contribution to the TEDE (via CEDE
component) from any systemic uptakes resulting from intakes through wounds must be assessed and accounted for in demonstrating compliance with the applicable dose limits of 10 CFR 20.1201.

In addition to the TEDE limits, 10 CFR 20.1201 also specifies two annual dose limits applicable to the skin:

1. Section 20.1201(a)(1)(ii) (the sum of the DDE and the CDE to any individual organ or tissue other than the lens of the eye being equal to 50 rem (0.5 Sv)), and
2. Section 20.1201(a)(2)(ii) (SDE of 50 rem (0.5 Sv) to the skin of the whole body or skin of any extremity).

However, because the SDE is defined only for external exposure, the limit in Section 20.1201(a)(2)(ii) is not applicable to dose from intakes. Therefore, the limit in Section 20.1201(a)(1)(ii) is the applicable limit for skin dose from intakes through wounds.

In making a skin dose calculation, the DDE component to the skin from intakes through wounds is set equal to zero (since the DDE is defined only as an external whole-body exposure). As a result, the calculated dose value is based only on the CDE. The CDE to the skin is calculated as the 50 year integrated dose averaged over the highest exposed 10 cm² of the basal layer of the skin located at a depth of 0.007 centimeters below the surface of the skin.

Although there is no regulatory limit for small volume, localized tissue doses, licensees should determine the local committed dose to underlying tissues (e.g., flesh) at the wound site to determine the potential for function impairment and whether medical intervention (e.g., surgical removal) is warranted. The guidance in NCRP Report No. 156, “Development of a Biokinetic Model for Radionuclide-Contaminated Wounds and Procedures for Their Assessment, Dosimetry, and Treatment” is acceptable for this evaluation (Ref. 24).

Note: Sections C.4.b, C.4.c, and C.4.d (above), on calculations of CEDE, CDE, and TODE, do not apply to dose assessments for wounds.

5. Acceptable Methods of Calculating the CDE and CEDE for Inhalation, Submersion and Absorption Intake Pathways

A number of methods are acceptable for calculating the CDE and CEDE from the intake of radioactive materials. Some of these methods are described below. However, calculations of the CEDE must be based on the 10 CFR Part 20 specified tissues and organ weighting factors. Because the tissues and weighting factors recommended in ICRP Publications 60 and 103 are different from those in 10 CFR Part 20, the more recent ICRP Publication 68 dose coefficients cannot be used, (unless their use has been specifically approved by the NRC).

a) Calculations of the CDE and the CEDE for Any Radionuclide, based on Bioassay Measurements using the Dose Coefficients from Federal Guidance Report No. 11

This method is based on using tabulated dose coefficients to calculate the dose. The FGR-11 provides tables of dose coefficients (DCs) (FGR-11 uses the terminology “dose
conversion factors”) for intakes by inhalation and by ingestion (see excerpt below for inhalation of Co-60). FGR-11 provides two types of DCs:

1. DCs for the CDE to an organ or tissue per unit of activity (DC\textsubscript{organ}) (e.g. the heading “Lung” below) and

2. DCs for the CEDE per unit of activity (DC\textsubscript{effective}) (as shown in the far right column of the tables under the heading “Effective”)

If site-specific information is known about the type of compound and its clearance class, the appropriate clearance class can be selected. If not, the class is normally selected based on the most conservative Class (in Example A, the DC for the lung is selected from clearance Class Y having a value of 3.45E-7). Multiplying the DCs by the intake (I) for that radionuclide calculates the CDE and CEDE for that radionuclide.

\[
\text{CDE (rem)} = \text{DC}_{\text{organ}} \left( \text{rem/µCi} \right) \times I \left( \text{µCi} \right)
\]

\[
\text{CEDE (rem)} = \text{DC}_{\text{effective}} \left( \text{rem/µCi} \right) \times I \left( \text{µCi} \right)
\]

**Example A:** Calculations of the CDE and the CEDE for Co-60, based on bioassay measurements using the DCs from FGR-11.

An intake by inhalation was estimated by a whole body count to be 360 nCi (0.36 µCi) of Co-60, Class Y aerosol. Calculate the CDE to the lung and the CEDE.

From Table 2.1 of FGR-11 (see excerpt below), the DCs for Class Y, Co-60 radionuclide are 3.45E-7 Sv/Bq for the CDE and 5.91E-8 Sv/Bq for the CEDE.

**Excerpt from Federal Guidance Report No. 11**

<table>
<thead>
<tr>
<th>Nuclide</th>
<th>Class/(f_1)</th>
<th>Gonad</th>
<th>Breast</th>
<th>Lung</th>
<th>R Marrow</th>
<th>B Surface</th>
<th>Thyroid</th>
<th>Remainder</th>
<th>Effective</th>
</tr>
</thead>
<tbody>
<tr>
<td>Co-60</td>
<td>W 5(10^{-2})</td>
<td>4.05(10^{-9})</td>
<td>4.16(10^{-9})</td>
<td>3.57(10^{-9})</td>
<td>4.25(10^{-9})</td>
<td>3.54(10^{-9})</td>
<td>3.72(10^{-9})</td>
<td>7.65(10^{-9})</td>
<td>8.94(10^{-9})</td>
</tr>
<tr>
<td></td>
<td>X 5(10^{-2})</td>
<td>4.76(10^{-9})</td>
<td>1.84(10^{-8})</td>
<td>3.45(10^{-7})</td>
<td>1.72(10^{-8})</td>
<td>1.35(10^{-7})</td>
<td>1.62(10^{-7})</td>
<td>3.60(10^{-7})</td>
<td>5.91(10^{-8})</td>
</tr>
</tbody>
</table>

The DCs in FGR-11 are tabulated in Sv/Bq and may be converted to mrem/µCi by multiplying by 3.7x10\(^9\).

\[
\text{DC}_{\text{lung}} = (3.45\times10^{-7}\text{ Sv/Bq}) \times (3.7\times10^9) = 1,277 \text{ mrem/µCi}
\]
DC_{effective} = (5.91 \times 10^{-8} \text{ Sv/Bq}) \times (3.7 \times 10^9) = 219 \text{ mrem/µCi}

The doses are calculated by multiplying these DCs by the intake of 0.36 µCi.

\[ \text{CDE}_{\text{lung}} = (1,277 \text{ mrem/µCi}) \times (0.36 \text{ µCi}) = 460 \text{ mrem} \]

\[ \text{CEDE} = (219 \text{ mrem/µCi}) \times (0.36 \text{ µCi}) = 79 \text{ mrem} \]

b) Calculation of the CEDE based on Bioassay Measurements using Stochastic ALIs

The ALI values are listed in Table 1 of Appendix B to 10 CFR Part 20. Column 1 lists the values for oral ingestion, and Column 2 lists the values for inhalation. The stochastic ALI values can be used in the calculation of the CEDE, based on the fraction of the allowable annual intake and the 5 rems (50 mSv) CEDE dose limit. When the ALI is defined by the stochastic limit, this value alone is given in the table.

\[ \text{CEDE} = \left( \frac{I}{\text{ALI}} \right) \times 5 \text{ rem} \]

Example B: Calculate the CEDE based on bioassay measurements using the stochastic ALIs.

The intake by inhalation for a worker was estimated by bioassay to be 360 nCi (0.36 µCi) of Co-60, Class Y aerosol. Calculate the CEDE.

From Appendix B above, Table 1, Column 2, the ALI for Class Y Co-60 is:

\[ \text{ALI (stochastic)} = 30 \text{ µCi} \]

\[ \text{CEDE} = \left( \frac{0.36 \text{ µCi}}{30 \text{ µCi}} \right) \times 5 \text{ rem} = 0.06 \text{ rem} = 60 \text{ mrem} \]

Note: Considering the precision of a 1 significant figure for the ALI values, this 60 mrem value compares favorably to the calculated CEDE value of 79 mrem determined in Example A above using the FGR-11 method. Either calculational method and/or result is acceptable in demonstrating compliance.

c) Calculation of the CDE based on Bioassay Measurements Using Nonstochastic ALIs

The nonstochastic ALI values can be used in the calculation of the CDE, based on the fraction of the allowable annual intake and the 50 rem (500 mSv) CDE dose limit. When the ALI is defined by the nonstochastic limit, this value is listed first in the table with its corresponding organ (see excerpt below),
and the corresponding stochastic ALIs are given in parenthesis below (e.g., 9E+1 µCi for ingestion and 2E+2 µCi for inhalation in excerpt below).

Since the nonstochastic ALI corresponds to a 50 rem (500 mSv) CDE dose limit, the CDE may be calculated based on the ratio of the intake to the nonstochastic ALI, multiplied by 50 rem (500 mSv).

\[
\text{CDE} = \left( \frac{I}{\text{ALI}} \right) \times 50 \text{ rem}
\]

**Example C:** Calculate the CDE based on bioassay measurements using the nonstochastic ALIs.

The intake by inhalation for a worker was estimated by bioassay to be 131 nCi (0.131 µCi) of I-131, Class D aerosol. Calculate the CDE to the thyroid.

From Appendix B above, Table 1, Column 2, the ALI for Class D I-131 is:

\[
\text{ALI (nonstochastic)} = 5E+1 \mu\text{Ci} = 50 \mu\text{Ci}
\]

\[
\text{CDE} = \left( \frac{0.131 \mu\text{Ci}}{50 \mu\text{Ci}} \right) \times 50 \text{ rem} = 0.131 \text{ rem} = 131 \text{ mrem}
\]

d) Calculation of the CDE based on air sampling and nonstochastic DAC-hrs

For nonstochastic radionuclides, an exposure to an airborne concentration of 1 DAC results for a 2000 hour exposure time results in 50 rem CDE; or 50,000 mrem/2,000 hours, or 25 mrem CDE per DAC-hour.

\[
\text{CDE} = [25 \text{ mrem per DAC-hr}] \times \text{number of DAC-hrs}
\]

where the number of DAC-hrs = (air concentration / DAC value) * exposure time

**Example D:** Calculation of the CDE based on air sampling and nonstochastic DAC-hrs.

Calculate the CDE to the thyroid for a 30-minute exposure based on an air sample result of 2.1E-7 µCi/ml (I-131).

The nonstochastic DAC for I-131 is listed in Appendix B (see excerpt below) as 2E-8 µCi/ml.
CDE = 25 mrem/DAC-hr * [(2.1E-7 µCi/ml) / (2E-8 µCi/ml)] number of DACs * (0.5 hrs) = 131 mrem

e) Calculations of the CEDE based on air sampling and stochastic DAC-hrs

For stochastic radionuclides (e.g., Co-60), an exposure to an airborne concentration of 1 DAC results in 5,000 mrem CEDE in 2,000 hours of exposure time; or 5,000 mrem/2,000 hours, or 2.5 mrem CEDE per stochastic DAC-hr.

CEDE = [(2.5 mrem)/DAC-hr] * No. of DAC-hrs

where the number of DAC-hrs = (air concentration / DAC value) * exposure time

Example E: Calculation of the CEDE based on air sampling and stochastic DAC-hrs.

Calculate the CEDE for a 30-minute exposure based on an air sample result of 2.1E-7 µCi/ml (Co-60).

From Appendix B below, the stochastic DAC for Co-60 clearance Class Y compound is 1E-8 µCi/ml.

CEDE = [2.5 mrem/DAC-hr] * [(2.1E-7 µCi/ml) / (1E-8 µCi/ml)] No. of DACs* (0.5 hrs) = 26 mrem

f) Calculation of the CEDE based on air sampling and calculated stochastic DAC-hrs

CEDE = [2.5 mrem/DAC-hr] * No. of DAC-hrs
No. DAC-hrs = [air concentration / calculated DAC value] number of DACs * [exposure time]

Note: Appendix B to 10 CFR Part 20 does not list the stochastic DAC values (see empty circled cell below) for radionuclides with intakes limited by the nonstochastic limits. However, the stochastic DAC values may be calculated based on the stochastic ALI values. These stochastic ALI values are listed (in parenthesis) below the limiting nonstochastic organ (see circled value of 2E+2 µCi in the table below).

Example F: Calculation of the CEDE based on air sampling and calculated stochastic DAC-hrs.

Calculate the CEDE for a 30-minute exposure based on an air sample result of 2.1E-7 µCi/ml (I-131).

The stochastic DAC value is first calculated by dividing the stochastic ALI by the breathing rate of 2.4E+9 ml/yr.

The calculated stochastic DAC (I-131) = (2E+2 µCi) / (2.4E+9 ml/yr) = 8E-8 µCi/ml or µCi/cc (since 1 ml = 1 cc)

CEDE = [2.5 mrem/hr/DAC-hr] * [(2.1E-7 µCi/ml) / (8E-8 µCi/ml)] DACs * (0.5 hrs) = 3.3 mrem

6. Use of Individual or Material-Specific Information

The regulation at 10 CFR 20.1204(c) states that “when specific information on the physical and biochemical properties of the radionuclides taken into the body or the behavior of the material in an individual is known, the licensee may...use that information to calculate the committed effective dose equivalent....” (the calculation should still make use of the organ weighting factors specified in 10 CFR Part 20). Prior NRC approval is not required, but detailed records must be kept to demonstrate the acceptability of the dose assessment.

The characteristics most amenable to such individual or site-specific consideration are the activity median aerodynamic diameter (AMAD) of the inhaled aerosol and the solubility of the material in the lungs and in the GI tract. The use of specific information on the physical and biochemical properties to calculate the CEDE requires the licensee to do considerably more work and to have greater technical expertise than the other methods, and therefore, this method may not be useful for small, infrequent intakes. Conversely, the use of specific information of the physical and biochemical properties of radionuclides taken into the body may be appropriate in the case of accidental large exposures if more accurate information would lead to a better estimate of the actual dose.
7. **Uranium Intake Limitation**

    In accordance with 10 CFR 20.1201(c), in addition to the annual dose limits, the licensee shall limit the soluble uranium intake by an individual to 10 mg in a week, in consideration of chemical toxicity.

**D. IMPLEMENTATION**

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

    Methods or solutions that differ from those described in this regulatory guide may be deemed acceptable if they provide sufficient basis and information for the NRC staff to verify that the proposed alternative complies with the appropriate NRC regulations. Current licensees may continue to use guidance the NRC found acceptable for complying with the identified regulations as long as their current licensing basis remains unchanged.
REFERENCES


4 Publicly available NRC published documents are available electronically through the NRC Library on the NRC’s public Web site at: http://www.nrc.gov/reading-rm/doc-collections/. The documents can also be viewed on-line or printed for a fee in the NRC’s Public Document Room (PDR) at 11555 Rockville Pike, Rockville, MD; the mailing address is USNRC PDR, Washington, DC 20555; telephone 301-415-4737 or (800) 397-4209; fax (301) 415-3548; and e-mail pdr.resource@nrc.gov.


6 Copies of the International Commission on Radiological Protection (ICRP) may be obtained through their Web site: http://www.icrp.org/; 280 Slater Street, Ottawa, Ontario K1P 5S9, CANADA; Tel: +1(613) 947-9750 Fax: +1(613) 944-1920.


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7 Copies of International Atomic Energy Agency (IAEA) documents may be obtained through their Web site: WWW.IAEA.Org/ or by writing the International Atomic Energy Agency P.O. Box 100 Wagramer Strasse 5, A-1400 Vienna, Austria. Telephone (+431) 2600-0, Fax (+431) 2600-7, or E-Mail at Official.Mail@IAEA.Org.

8 Copies of EPA Library Services may be obtained through their Web site: http://www.epa.gov/libraries/library_services.html.

9 Copies of The National Council on Radiation Protection and Measurements (NCRP) may be obtained through their Web site: http://www.ncrponline.org/Publications/Publications.html or by writing to the NCRP at 7910 Woodmont Avenue, Suite 400, Bethesda, Maryland 20814-3095; Ph: 301-657-2652, fax: 301-907-8768.