ISSUE PAPER 1

UPDATE 10 CFR PART 20 TO ALIGN WITH THE INTERNATIONAL COMMISSION ON RADIOLOGICAL PROTECTION PUBLICATION 103 METHODOLOGY AND TERMINOLOGY

I. Introduction

In Staff Requirements Memorandum (SRM) SECY-12-0064, "Recommendations for Policy and Technical Direction To Revise Radiation Protection Regulations and Guidance," dated December 17, 2012,[1] the Commission approved the U.S. Nuclear Regulatory Commission (NRC) staff's development of a draft regulatory basis for a revision to Title 10 of the *Code of Federal Regulations* (10 CFR) Part 20, "Standards for Protection against Radiation," to align it with the most recent methodology and terminology for dose assessment.

II. Objective

Develop the draft regulatory basis for updating the dose assessment methodology and terminology currently in 10 CFR Part 20 and in other portions of NRC regulations to align them with the latest recommendations of the International Commission on Radiological Protection (ICRP).

III. Background

The ICRP recommendations are supported by a series of documents that reflect scientific information on the intake, distribution, retention, and elimination of radioactive material from the body and the calculation of dose in various organs and tissues. With each revision to the ICRP recommendations, corresponding revisions have been made to tissue weighting factors, radiation weighting factors, and the dose coefficients calculated for the intake and

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[1] SRM-SECY-12-0064 is available on the NRC's public Web site at http://www.nrc.gov/reading-rm/doc-collections/commission/srm/2012/.

retention of radionuclides in the body. For example, the May 21, 1991, revision to 10 CFR Part 20 (Volume 56 of the *Federal Register*, page 23360 (56 FR 23360)), adopted the basic tenets of the ICRP system of radiation dose limitation described in ICRP Publication 26, "Recommendations of the International Commission on Radiological Protection," issued 1977. The internal dosimetry aspects of the revised 10 CFR Part 20, such as the models and parameters used to calculate internal doses and to estimate intake limits, were based on ICRP Publication 30, "Limits for Intakes of Radionuclides by Workers," Parts 1, 2, 3, and 4, issued in 1979, 1980, 1981, and 1988, respectively; this four-part series supports the recommendations in ICRP Publication 26 (1977) to the field of internal dosimetry.

ICRP Publication 45, "Developing a Unified Index of Harm," issued in 1985, recommends a reduction of the annual dose limit for members of the general public from 5 millisieverts (mSv) (500 millirem (mrem)) to 1 mSv (100 mrem). The NRC adopted this recommendation in its 1991 rulemaking. In addition, when the 10 CFR Part 20 rulemaking was near completion, the ICRP developed and published a new series of recommendations, including ICRP Publication 56 (1990), "Age-Dependent Doses to Members of the Public from Intake of Radionuclides—Part 1," issued 1990, and ICRP Publication 60, "The ICRP 1990 Recommendations of the ICRP," issued in 1991.

Following the issuance of ICRP Publication 60 (1991), the ICRP issued the following series of publications that revised internal dosimetry models:

- ICRP Publication 61, "Annual Limits on Intake of Radionuclides by Workers Based on the 1990 Recommendations," issued in 1991
- ICRP Publication 66, "Human Respiratory Tract Model for Radiological Protection," issued in 1994
- ICRP Publication 67, "Age-Dependent Doses to Members of the Public from Intake of Radionuclides—Part 2, Ingestion Dose Coefficients," issued in 1993
- ICRP Publication 68, "Dose Coefficients for Intakes of Radionuclides by Workers," issued in 1994

- ICRP Publication 69, “Age-Dependent Doses to Members of the Public from Intake of Radionuclides—Part 3, Ingestion Dose Coefficients,” issued in 1995
- ICRP Publication 71, “Age-Dependent Doses to Members of the Public from Intake of Radionuclides—Part 4 Inhalation Dose Coefficients,” issued in 1995
- ICRP Publication 72 (1995), “Age-Dependent Doses to the Members of the Public from Intake of Radionuclides—Part 5, Compilation of Ingestion and Inhalation Coefficients,” issued in 1995
- ICRP Publication 74, “Conversion Coefficients for use in Radiological Protection against External Radiation,” issued in 1996

These revised internal dosimetry models superseded many, but not all, of the models described in ICRP Publication 30 (1988) and earlier ICRP publications.

Several revisions are needed to more closely align the existing NRC regulations in 10 CFR Part 20 with the recommendations in ICRP Publication 103, “Recommendations of the International Commission on Radiological Protection,” issued 2007, regarding methodology and terminology for dose assessment. During the 30-year period from 1977–2007, the ICRP published three key radiological protection recommendations (i.e., ICRP Publication 26 (1977), ICRP Publication 60 (1991), and ICRP Publication 103 (2007)). The current NRC regulatory framework is a mixture of radiological standards, concepts, and quantities based on ICRP publications ranging from the recommendations in ICRP Publication 1, “Recommendations of the International Commission on Radiological Protection,” issued in 1959, to the modeling and numeric values in ICRP Publication 60 (1991).[2]

The current regulations at 10 CFR Part 20 are primarily based on the recommendations in ICRP Publication 26 (1977); however, one difference in terminology is worth noting. The

[2] The current regulations at 10 CFR Part 20 do not expressly incorporate the recommendations of ICRP Publication 60 (1991); however, they are based on the recommendations in ICRP Publication 26 (1977) and ICRP Publication 30. An NRC licensee must ask the agency whether it can use the internal dosimetry models in ICRP Publication 60 (1991) in place of the requirements in 10 CFR Part 20. If the NRC approves such a request, the agency will treat the licensee’s use of these ICRP models as an exemption from the requirements in 10 CFR Part 20. The NRC derives its authority to grant exemptions from the requirements in 10 CFR Part 20 from 10 CFR 20.2301, “Applications for Exemptions.” As a matter of practice in such exemption approvals, the NRC only authorizes the use of the dosimetric concepts and quantities established by the recommendations in ICRP Publication 60 (1991).

ICRP recommendations use the phrases "the sum of the dose equivalent from external exposure" and "the committed effective dose equivalent from the intake of radionuclides." The NRC's regulations use the term "total effective dose equivalent (TEDE)" to represent the summation of dose received from sources external to the body and the dose from the intake of radioactive materials (i.e., the term means the summation of internal and external exposure).

In 1991, the ICRP recommendations provided revisions to dose calculations. ICRP Publication 60 (1991) recommendations provide changes in the way tissue and radiation weighting factors were defined and used (moving from quality factors to radiation weighting factors). There was also a corresponding change in the terminology. For example, ICRP Publication 60 (1991) introduces the term "effective dose (ED)" which was defined as "the sum of the weighted equivalent doses in all the tissues and organs of the body."

Additionally, the recent ICRP Publication 103 (2007) recommendations made a number of revisions to the calculation of dose, including (1) modification of the modeling used for calculation of radiation exposures, (2) changes in values of tissue weighting factors and radiation weighting factors, and (3) substantial modifications of the metabolic models used to represent the movement of radioactive material through the human body. The human body can now be modeled as a more complex set of mathematical and "voxel"[3] phantoms as a result of advances in medical imaging technology since the 1991 10 CFR Part 20 rulemaking. These technological advances have resulted in the development of reference computational phantoms that are specific models for adult males and females; 15-year-old males and females; and various other age groups, including infants and 1-year-old, 5-year-old, and 10-year-old children. The reference phantoms for the human body are described in general terms in ICRP Publication 103 (2007) and more specifically in ICRP Publication 110, "Adult Reference

[2] Voxel is a shortened term for "volume pixel," the smallest distinguishable box-shaped part of a three-dimensional image. Voxel images are primarily used in the field of medicine and are developed from x-rays, computerized axial tomography scans, and magnetic resonance imaging, which allow medical professionals to obtain accurate three-dimensional models of the human body. (This information is available through Webopedia at www.webopedia.com.)

Computational Phantoms," issued in 2009.[4]

The availability of models for different age groups provides the opportunity to calculate the numeric values for public exposure to effluents in a more comprehensive manner as compared to the previous calculation methodology of basing assessments primarily on an adult member of the public. A general population includes individuals of both genders and various age groups that range from newborns to senior citizens. Over time, an individual matures from infancy to adulthood, which includes various stages of development. Therefore, the scientific community is evaluating the appropriate approach for a member of the public that would account for the period of time spent at different ages so that the long-term risk of exposure to radiological effluents over a number of years can be properly represented. In particular, the ICRP is considering the use of an age- and gender-weighted dose coefficient for developing a set of values for environmental intake of radionuclides. Similarly, the NRC is also considering revising the definition of the "reference person"[5] for its use in environmental dose calculations. The NRC is considering the use of the age- and gender-averaged approach to provide a more realistic representation of a member of the public that explicitly considers the presence of infants and children within the population.

The concept of a reference person may be similar to the approach documented in the U.S. Department of Energy (DOE) Technical Standard DOE-STD-1196-2011, "Derived Concentration Standard," issued April 2011 (Agencywide Documents Access and Management System Accession No. ML13323B598). The DOE-STD-1196-2011, calculates derived concentration standards using age-specific ED coefficients for reference members of the public along with age- and gender-dependent intake rates for ingestion of water and inhalation of air.

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[4] ICRP Publication 110 (2009) is available at http://www.icrp.org/publication.asp?id=ICRP Publication 110.

[5] NRC regulations use the term "reference man," which means a hypothetical aggregation of human physical and physiological characteristics arrived at by international consensus. Researchers and public health workers can use these characteristics to standardize results of experiments and to relate biological insult to a common base. (See the definition of "reference man" in 10 CFR 20.1003, "Definitions.")

The members of the public are represented by six age subgroups (newborns;[6] 1-year-old, 5-year-old, 10-year-old, and 15-year-old children; and adults). The analysis weights the ED coefficients for each subgroup by their fractional representation in the U.S. population and by their intake of the radionuclide through inhalation, ingestion, or air submersion over their lifetimes. The DOE standard is based on the weighting factors and dose coefficients in ICRP Publication 60 (1991).

As part of its development of the draft regulatory basis, the NRC staff will consider revising the regulations at 10 CFR Part 20 and making conforming changes to other agency regulations to incorporate the ICRP term ED. The NRC staff recognizes the preference from a regulatory stability standpoint for retaining TEDE; however, the agency's draft regulatory basis will analyze the advantages and disadvantages of replacing TEDE with ED in its regulations. The use of the same terminology as it is used elsewhere in the world may present qualitative benefits of consistency and ease in communication. With regard to the ICRP's dose assessment methodology recommendations, the NRC's draft regulatory basis will consider replacing the definition of weighting factor W_T[7] in 10 CFR 20.1003 with the tissue weighting factors in Table 3 of ICRP Publication 103 (2007) and replacing the quality factors in Table 1004(b).1 and Table 1004(b).2 of 10 CFR 20.1004, "Units of Radiation Dose," with the radiation weighting factors in Table 2 of ICRP Publication 103 (2007) along with other associated changes (e.g., replacing "dose equivalent" with the term "equivalent dose," replacing "effective dose equivalent (EDE)" with the term ED, and revising the definition of the term "quality factor"). If approved by the Commission, an update of 10 CFR Part 20 that reflects the tissue weighting factors and radiation weighting factors from ICRP Publication 103 (2007) would amend these sections.

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[6] The DOE standard uses the term "new born," whereas ICRP Publication 103 (2007) uses the term "infant."

[7] The weighting factor W_T for an organ or tissue is the proportion of the risk of stochastic effects resulting from irradiation of that organ or tissue to the total risk of stochastic effects when the whole body is irradiated uniformly.

The most recent ICRP tissue weighting factors are in Table 3 of ICRP Publication 103 (2007) (below). Table 3 groups organs by four weighting levels plus a set of remainder organs. The list of organs is more extensive than that considered in ICRP Publication 26 (1977).

Table 3. Recommended tissue weighting factors.

Tissue	w_T	$\sum w_T$
Bone-marrow (red), Colon, Lung, Stomach, Breast, Remainder tissues*	0.12	0.72
Gonads	0.08	0.08
Bladder, Oesophagus, Liver, Thyroid	0.04	0.16
Bone surface, Brain, Salivary glands, Skin	0.01	0.04
	Total	1.00

* Remainder tissues: Adrenals, Extrathoracic (ET) region, Gall bladder, Heart, Kidneys, Lymphatic nodes, Muscle, Oral mucosa, Pancreas, Prostate (♂), Small intestine, Spleen, Thymus, Uterus/cervix (♀).

Table 2 of ICRP Publication 103 (2007) lists the most recent ICRP radiation weighting factors, along with Figure 1 and Equation 4.3 below.

Table 2. Recommended radiation weighting factors.

Radiation type	**Radiation weighting factor, w_R**
Photons	1
Electrons[a] and muons	1
Protons and charged pions	2
Alpha particles, fission fragments, heavy ions	20
Neutrons	A continuous function of neutron energy (see Fig. 1 and Eq. 4.3)

All values relate to the radiation incident on the body or, for internal radiation sources, emitted from the incorporated radionuclide(s).

[a] Note the special issue of Auger electrons discussed in paragraph 116 and in Section B.3.3 of Annex B.

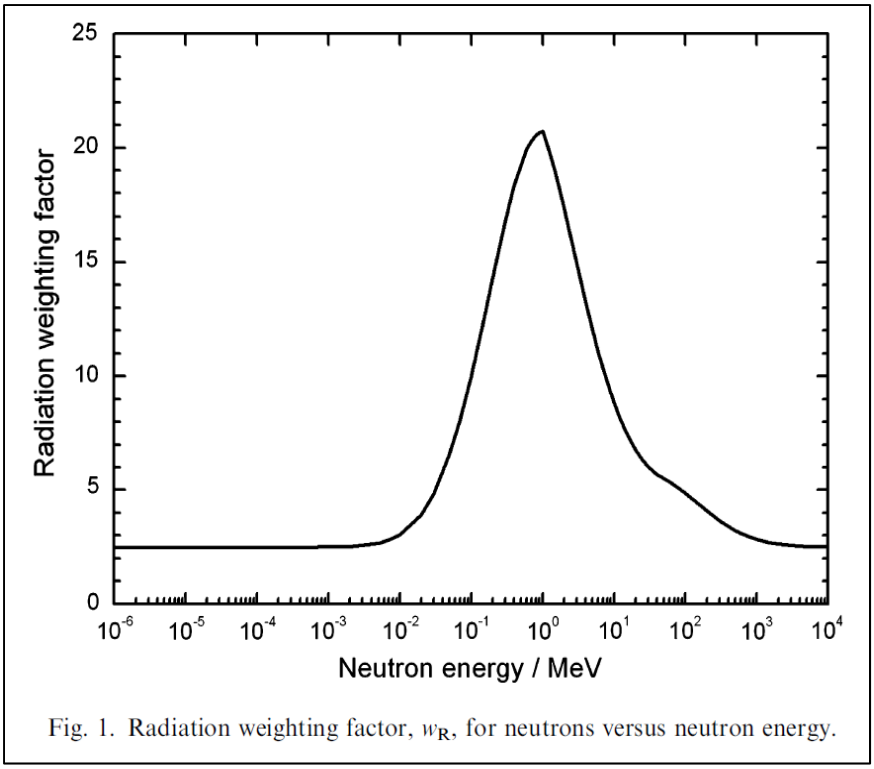

Fig. 1. Radiation weighting factor, w_R, for neutrons versus neutron energy.

$$w_R = \begin{cases} 2.5 + 18.2e^{-[\ln (E_n)]^2/6}, & E_n < 1 \text{ MeV} \\ 5.0 + 17.0e^{-[\ln (2E_n)]^2/6}, & 1 \text{ MeV} \leqslant E_n \leqslant 50 \text{ MeV} \\ 2.5 + 3.25e^{-[\ln (0.04E_n)]^2/6}, & E_n > 50 \text{ MeV} \end{cases} \quad (4.3)$$

In addition, the NRC's draft regulatory basis will consider revising the values in Table 1, "Occupational Values"; Table 2, "Effluent Concentrations"; and Table 3 "Releases to Sewers," ofAppendix B, "Annual Limits on Intake (ALIs) and Derived Air Concentrations (DACs) of Radionuclides for Occupational Exposure; Effluent Concentrations; Concentrations for Release to Sewerage," to 10 CFR Part 20 with new values for ALIs, DACs, effluent concentrations, and sewer concentrations. The NRC staff derived all the current values in Appendix B to 10 CFR Part 20 on the basis of the modeling of an adult individual and generated them using the tissue weighting factors, radiation quality factors, and radionuclide-specific information to

calculate a generic quantity of each radionuclide. The occupational values in Table 1 of Appendix B to 10 CFR Part 20 represent adults in a working environment that would result in a dose of 50 mSv (5 rem) to a reference individual. The DAC values are similarly calculated to represent the concentration of material in air, which, if breathed continuously for 2,000 hours, would result in the intake of 1 ALI. The values in Table 2 of Appendix B to 10 CFR Part 20 for effluent concentrations were also based on adult values (with additional factors added to increase the time of exposure and adjust for breathing rates) to adjust from a 50-mSv (5-rem) occupational limit to the 1-mSv (0.1-rem) public dose limit and on a factor of 2 to adjust for different ages that would be present in the public. Each of the sets of values (air and water) corresponds to a dose of 0.5 mSv (50 mrem) based on the modeling. The discussion on Appendix B to 10 CFR Part 20 explains this information in more detail.

A licensee can show compliance with the public dose limit in 10 CFR 20.1301, "Dose Limits for Individual Members of the Public," in part, by demonstrating that the annual average concentration of radioactive material released in gaseous and liquid effluents does not exceed the values specified in Table 2 of Appendix B to 10 CFR Part 20.[8] The NRC has used these values in other regulations as trigger values for certain actions, such as reporting.[9]

The ICRP has revised the modeling used for calculating radiation exposures. In addition to the updates made to the tissue weighting factors and radiation weighting factors, substantial updates have been made to the metabolic models used to represent the movement of radioactive material in the human body.

The ICRP is still in the process of preparing the updated dose coefficients that are used to calculate doses from intakes of radioactive material and to reflect the changes in ICRP Publication 103 (2007). These new dose coefficients will be compatible with the new tissue

[8] See the regulation at 10 CFR 20.1302(b)(2)(i).

[9] See the regulation at 10 CFR 50.73(a)(2)(viii).

weighting factors, radiation weighting factors, updated nuclear decay data, and metabolic model updates.

The ICRP expects to publish its first report for external exposure in 2015 and to publish the numeric values for occupational intake of radionuclides in a set of five publications over the next several years. In addition, the ICRP is developing dose conversion factors for members of the public, which it plans to publish in 2016. The revised dose conversion factors are crucial to the completion of any revision to the NRC radiation protection framework because these factors would provide the basis for revising the numeric values of weighting factors and the ALIs and DACs in various requirements in 10 CFR Part 20.

IV. Discussion

Updating the tissue and radiation weighting factors will result in some changes to the calculated values of ALIs and DACs. In some cases, the ALI values will increase, indicating that a larger quantity of material corresponds to the dose limit. In other cases, the ALI values will decrease, indicating that a smaller quantity of material corresponds to the dose limit. Providing the complete details of the changes is not possible until all the calculations have been done. The staff understands that the changes between the calculated values for the recommendations in ICRP Publication 60 (1991) and ICRP Publication 103 (2007) will not be significant. However, some more substantial differences between the recommendations in ICRP Publication 26 (1977) and ICRP Publication 103 (2007) are present.

One such change involves the ALI and DAC values for uranium and thorium, which will increase because the dose per unit intake of radionuclide is smaller than that estimated in ICRP Publication 26 (1977). Because this change was present in the values calculated for ICRP Publication 60 (1991), many of the licensees affected by this change have already requested amendments to their licenses so that they can use the newer information.

In the ICRP Publication 60 (1991), the terminology was also changed from EDE to ED or TED. The term TEDE is an NRC term and is not used by the ICRP. These changes were made to reflect the move from the quality factor approach to radiation effects weighting to the use of radiation weighting factors. If the methodologies are modified, the NRC staff will need to review related NRC regulations outside of 10 CFR Part 20 to determine the impact. The NRC would need to amend the values in Appendix B to 10 CFR Part 20 to reflect the new tissue and radiation weighting factors.

During previous stakeholder discussions, the topic of methodology was one area in which most of the stakeholders agreed that change was necessary. Many stakeholders expressed their general support for changes to reflect the more up-to-date modeling and stressed the importance of having the regulatory framework use the best available information. Furthermore, stakeholders suggested that the NRC should wait for all the information to be made available to make the changes all at once instead of undertaking a piecemeal approach, or some interim change, so that licensees would not have to make two or more sets of changes to their procedures and programs in a relatively short period of time. Stakeholders also recognized that the change in terminology as it corresponds to a change in the methods for calculations would be a logical and consistent move and would support a clear differentiation of when requirements were changed.

Stakeholders also identified some concerns with changing the terminology to that used in the recommendations in ICRP Publication 103 (2007). Stakeholders identified several issues, including the cost benefit associated with the changes. They noted that the change in terminology from TEDE to ED is not a significant change in the regulatory approach. Nevertheless, the training costs associated with the change could be significant and would be difficult to explain. Furthermore, stakeholders noted that the necessary changes to computer programs and algorithms could be substantial and therefore urged the NRC to make sure that

the changes are worth those costs.

Depending on a regulatory framework that relies on scientific information from different publication dates raises concern. In particular, the oldest methodology from the 1950s does not readily lend itself to summation exposures from intakes of radioactive material with exposure received from sources external to the body. For the methodology from the 1970s, summing internal and external exposures is possible. Changes to the modeling and weighting factors allow for a more accurate prediction of dose from an intake of radioactive material and for a consistent up-to-date assessment of exposures.

The staff recognizes the concerns of some stakeholders that an amendment of the regulation would result in both increases and decreases in ALI values for compliance with the dose limit. A consistent implementation of the new methodology and weighting factors will cause some ALI values to increase and will cause others to decrease based on the updated scientific basis. The staff believes that the changes should be made consistently, both up and down, so that the values represent a coherent set with the same scientific support.

The primary benefit for revising 10 CFR Part 20 to incorporate the recommendations and standards in ICRP Publication 103 (2007) involves the demonstration of compliance, which would be based on current scientific information. In turn, the estimates of dose used for demonstration of compliance with the dose limits would be the most accurate ones currently available. In addition, ensuring that the methodology and factors that are in use are a consistent set is important. For example, when a licensee asked the NRC whether it could use the methodology associated with the recommendations in ICRP Publication 60 (1991) to the extent that such a request deviated from the agency's requirements, one of the agency's conditions for approval was that the licensee use the same methodology for its entire radiation protection program. The NRC established this condition for approval to avoid a possible situation in which results from different systems were "cherry picked" as advantageous for one

reason or another.

The staff recognizes that the benefits of updated methodologies are not easily quantified in terms of cost versus benefit. However, having quantitative measures of costs are possible. Substantial costs will, in fact, be necessary to update procedures, computer codes, training materials, and other documents to reflect the methodology and terminology.

These costs must be balanced against the benefits of improved accuracy and consistency, the value of using a single approach to dose assessment instead of the different approaches currently required by NRC regulations, and the value of terminology that represents the updated science that is used by many other countries. As the process moves forward, the staff will need to further engage stakeholders to develop quantitative estimates of impacts and will need to examine areas in which flexibility in implementation can offset or mitigate those impacts. For example, allowing a much longer transition period for implementation of the dose assessment methodology and terminology in training and procedural documents may be possible.

In SRM-SECY-12-0064, the Commission approved the staff's development of the regulatory basis for a revision to 10 CFR Part 20 to align it with the most recent methodology and terminology for dose assessment and for the parallel alignment of Appendix I, "Numerical Guides for Design Objectives and Limiting Conditions for Operation To Meet the Criterion 'As Low as is Reasonably Achievable' for Radioactive Material in Light-Water-Cooled Nuclear Power Reactor Effluents," to 10 CFR Part 50, "Domestic Licensing of Production and Utilization Facilities."

V. Proposals

The NRC staff is developing a draft regulatory basis for a revision to 10 CFR Part 20 that will align it with the most recent methodology and terminology for dose assessment. As part of

this draft regulatory basis development, the staff is considering updating the terminology used in 10 CFR Part 20 and other NRC regulations and guidance to reflect the ICRP concept of ED. Although, from a regulatory stability standpoint, the staff recognizes the preference for retaining TEDE, it believes that changing the terms to match the corresponding change in methodology and numerical values is appropriate. Therefore, the staff would consider making any changes to terminology effective at the same time as any changes are made to numerical values for demonstrating compliance.

The staff is also considering revising the definition of the weighting factor W_T in 10 CFR 20.1003 to provide the new weighting factors in Table 3 of ICRP Publication 103 (2007). Likewise, the staff is considering revising Table 1004(b).1 and Table 1004(b).2 in 10 CFR 20.1004 by replacing the quality factors with the radiation weighting factors in Table 2 of ICRP Publication 103 (2007).

In addition, the NRC staff is considering revising Tables 1, 2, and 3 in Appendix B to 10 CFR Part 20 with new numeric values for ALIs, DACs, effluent concentrations, and sewer concentrations. ICRP is currently developing these new numeric values; therefore, they are not yet available for review and discussion. The NRC will make these new numeric values available when the ICRP completes them to discuss how they will impact 10 CFR Part 20 and other portions of the regulations. The NRC staff is currently considering the use of the age- and gender-averaged approach to provide a more realistic representation of a member of the public that explicitly includes consideration of the presence of infants and children within the population.

The various types of NRC licenses pose different challenges for the use of methodology and terminology for dose assessment. In some instances, exposures to occupational workers and members of the public at a licensed facility are only from sources external to the body. Conversely, other types of licensed facilities have the potential for significant exposures to

occupational workers and members of the public from the intake of radionuclides. These types of licenses would be more directly affected by revisions to the weighting factor W_T and the ALI and DAC values. Therefore, the staff wants to understand how the various proposals described would affect licensee activities. Likewise, the staff wants to understand the possible impacts of the proposals and, more specifically, the reasons why certain proposals would be difficult to achieve or would undermine radiation protection. Therefore, the NRC staff is seeking an understanding of the impacts of adopting the methodology and terminology for dose assessment in ICRP Publication 103 (2007) into its regulatory program.

The NRC staff believes that additional input from the public, the regulated community, and other stakeholders is necessary to understand the implications of potential options on this issue.