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Washington, DC 20585

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RULES AND DIRECTIVES
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Ms. Cindy Bladey
Chief, Rules, Announcements and
Directives Branch
Office of Administration
Mail Stop 5B01M
U.S. Nuclear Regulatory Commission
Washington, DC 20555-0001

Dear Ms. Bladey:

This is in response to your September 27, 2010, Federal Register announcement requesting comments on the Nuclear Regulatory Commission (NRC) updating title 10, Code of Federal Regulations, part 20, *Standards for Protection Against Radiation*. Responses to your set of questions are enclosed.

In 2007, the Department of Energy (DOE) revised its radiation protection rule, title 10, Code of Federal Regulations, part 835, *Occupational Radiation Protection,* in a manner similar to what NRC is now considering. Some of the difficulties DOE encountered are discussed in the enclosure. If you have any further questions, please contact Dr. Patricia R. Worthington, of my staff, at (301) 903-5926.

Sincerely,

Glenn S. Podonsky
Chief Health, Safety and Security Officer
Office of Health, Safety and Security

Enclosure

SUNSI Review Complete
Template = ADM-013

E-RIDS = ADM-03
Add = M. Morgan Butler
(KRM1)

Questions and Responses to
Title 10, Code of Federal Regulations, Part 20,
Standards for Protection Against Radiation

Q1.1–1: In terms of implementing the recently changed methodology for applying TEDE, are there any potential impacts on the ability to comply with the options for dose limits (DDE vs. TED)?

Response: DOE did not encounter significant negative impacts when we went from DDE to TED.

Q1.2–1: Are there any foreseen impacts of the timing (2014) of making changes to the current numerical values and weighting factors? Should NRC consider moving forward with a more limited set of radionuclides that would be available more quickly, and make subsequent amendments to add additional values as they are published by the ICRP?

Response: DOE recommends that NRC consider moving forward with a more limited set of radionuclides that would be available more quickly, and make subsequent amendments to add additional values as they are published by the ICRP.

In 2007, DOE changed most of the dosimetric terms used in title 10, Code of Federal Regulations, part 835 (10 CFR 835) to reflect the recommendations for assessing dose and associated terminology from ICRP Publication 60, *1990 Recommendations of ICRP on Radiological Protection*, and ICRP Publication 68, *Dose Coefficients for Intakes of Radionuclides by Workers*. DOE proposed this change mainly because these recommendations were based on updated scientific models and more accurately reflect the occupational doses to workers than the models previously used by DOE.

DOE evaluated the effect of the June 2004 proposed revisions to Tissue Weighting Factors on derivation of dose conversion factors used in ICRP Publication 68. The evaluation found for radionuclides of most interest to DOE that ICRP-proposed Tissue Weighting Factors revisions would have minimal impact on ICRP Publication 68 derived secondary limits (i.e., DACs and Sealed Radioactive Source Accountability values). ICRP's June 2006 proposed revisions to Tissue Weighting Factors will also have minimal impact. Any future need by DOE to revise weighting factors should have minimal administrative impact for such activities as revising procedures and training materials. It is envisioned that over time updated recommendations to make revisions to dosimetry calculation models will periodically be made by national and international consensus groups.

DOE considered several options for amending part 835, including:

- Allowing sites to choose either converting to the newer dosimetric terminology and Tissue and Radiation Weighting Factors or retaining the existing requirements;

- Updating the Tissue and Radiation Weighting Factors to reflect the newer research without revising the dose terminology;
- Updating the Tissue and Radiation Weighting Factors to reflect the newer research and revising the dose terminology;
- Converting to the newer dosimetric terminology and Tissue and Radiation Weighting Factors and not updating the DAC values (appendices A and C to part 835) and appendix E to part 835 values; and
- Not specifying in part 835 a specific set of Tissue and Radiation Weighting Factors, but requiring sites to specify in their DOE-approved Radiation Protection Program the weighting factors to be used and the technical basis for that determination.

DOE considered its best approach was to convert all terminology and methodology, including appendices A, C, and E to part 835 values, to reflect ICRP Publications 60 and 68.

DOE received comments expressing concern that the new neutron radiation weighting factor doubles (for a specified energy range) from the previous quality factor. There was concern that this could have significant operational impacts. After careful evaluation of the neutron energy spectrums typically encountered at DOE facilities, the impact was minor. There was also a need to clarify the interface of ICRP 60 protection quantities with ICRU operational quantities. DOE published a clarification of this topic in the preamble to the 2007 amendment to 10 CFR 835, which is attached at the end of this question set, and subsequently included in the updated guidance (DOE G 441.1-1C) for implementing the amended version of 10 CFR 835.

Q1.2–2: Should the NRC use the values developed by the EPA, which will be based on a U.S. population, instead of the ICRP values, which are based on a more diverse world population? With regard to the selection of dose coefficients, NRC may want to consider several other factors in addition to the population on which the dose coefficients are based.

Response: NRC should use the factors developed by EPA for a U.S. population instead of ICRP values based on a more diverse world population. Use of EPA factors would help to ensure that NRC adequately protects the health and safety of U.S. workers and would be consistent with the current regulation of DOE facilities under 40 CFR 61, subpart H.

Particle size: ICRP recommends a default particle size of 5 microns for occupational exposure. Accordingly, NRC should use 5 microns as the default particle size when determining occupational dose from intake of radioactive materials.

Age dependence: ICRP currently provides dose coefficients for various age groups starting from newborns. For occupational exposures, the adult age group (individuals greater than 17 years of age) is appropriate. However, for environmental exposures, dose coefficients for younger individuals may be appropriate when assessing the impact of NRC operations on nonoccupational offsite individuals. Accordingly, NRC should permit the use of dose coefficients for minors, in addition to those for adults, when determining nonoccupational offsite doses from intake of radioactive materials.

Q2–1: Are there any significant anticipated impacts in assessing and retaining dose histories for each individual in order to comply with a multi-year average?

Response: DOE does not believe that assessing and retaining dose histories in order to comply with a multiyear average would involve significantly more effort than that currently spent assessing and retaining dose histories to comply with annual limits.

Q2–2: Are there any anticipated implementation impacts expected if the dose limit is decreased?

Response: DOE has very few routine doses exceeding two rems per year. Accordingly, a decrease would not have a significant impact. NRC has licensees, especially in the medical profession, where this could be a significant impact.

One possible concern with the use of a multiyear period for assessing dose is determining when an individual can return to work after an exposure greater than the dose limit. Requirements must be clear regarding an overexposed individual being permitted to return to work. Is it in the year of the overexposure, in the year following the overexposure, or at the end of the 5-year dose averaging period?

Q2–3: Is there any information about the actual dose distributions for industrial and medical licensees? What are the trends for this data? Are the data available to share with the NRC?

Response: DOE's Radiation Exposure Monitoring System has this information for DOE. The Web site is: **http://www.hss.doe.gov/CSA/Analysis/rems/**.

Q3–1: Are there any significant anticipated impacts associated with reducing the dose limit to the embryo/fetus of a declared pregnant woman, including operational impacts?

Response: DOE does not believe this would have an impact for DOE operations. NRC has licensees, especially in the medical profession, where this could be a significant impact.

Q3–2: Are there any anticipated implementation impacts on record keeping?

Response: DOE does not believe that record keeping would involve significantly more effort than is currently spent complying with the declared pregnant worker provisions.

Q3–3: Is there a reduction in burden in assessment and record keeping if the ICRP recommendation is considered for adoption?

Response: DOE believes that the simplified recommendation would be less of a burden to implement.

Q3–4: Are there technological implementation issues, such as limits of detection, which would make adoption of the ICRP recommendation difficult in certain circumstances?

Response: There will have to be adjustments in bioassay frequencies. Instead of having frequencies where DOE contractors can assure that they stay under five rem, if that is lowered to two rem, that could have significant impacts. For example, one DOE site estimated that, for Plutonium-238 instead of annual bioassay collections, they would have to have a bioassay frequency of around 14 days to be able to demonstrate compliance with the two rem limit.

Q3–5: Is there data on actual dose distributions to the embryo/fetus of a declared pregnant worker? What are the trends for this data? Is this data available to share with the NRC?

Response: DOE's rems have data on actual dose distributions to the embryo/fetus of a declared pregnant worker for at least the last 5 years.

Q3.2–1: Are there any significant anticipated impacts associated with limiting the applicability of alternative public dose limits?

Response: DOE is already implementing the 100 millirem public dose limit.

Q4–3: What relationship should a constraint have to the dose limit, if any?

Response: Per ICRP, 103 constraints are lower than dose limits.

Q4–5: How familiar are you with the use and implementation of constraints or planning values in a radiation protection program?

Response: DOE uses constraints for both occupational and environmental radiation protection.

Protection and Operational Quantities

ICRP Publication 60 dosimetric quantities adopted in title 10, Code of Federal Regulations, part 835 (10 CFR 835) have been designated by ICRP as "protection quantities" that are intended for defining and calculating the numerical limits and action levels used in radiation protection standards, such as 10 CFR 835. Protection quantities provide a way to relate the magnitude of a radiation exposure to the risk of a health effect that is applicable to an individual and that is largely independent of the type and source (internal or external) of the radiation. In addition, the protection quantities can be easily calculated for use in planning radiological work.

These goals are achieved using a combination of theoretical and practical considerations. For example, absorbed dose is assumed to be averaged over a tissue or organ. Radiation weighting factors are used to account for the biological effectiveness of various types and energies of radiation, and tissue weighting factors are used to account for the sensitivity of various tissues to radiation-induced cancer. The tissue and radiation weighting factors are based on both biological and epidemiological studies and have been updated as new research becomes available. Nevertheless, the values of these weighting factors are approximations that account for both uncertainty in the underlying data and the need to ensure that the protection quantities do not underestimate the true dose and, hence, the risk. Protection quantities used in 10 CFR 835 include: equivalent dose, effective dose, committed equivalent dose, committed effective dose, total effective dose, and cumulative total effective dose.

Because protection quantities were developed to provide an index of the risk resulting from energy imparted to tissue by radiation, they are theoretical and not measurable. Fortunately, it is possible to use the measurable properties of radiation fields and radioactive materials associated with exposure to external radiation sources or intake of radioactive materials to estimate and demonstrate compliance with the protection quantities. These measurable quantities are called operational quantities.

Although many types of operational quantities are possible, a well characterized set of operational quantities for assessing doses received from external exposure has been selected by the International Commission on Radiation Units and Measurements (ICRU) in Report 51, *Quantities and Units in Radiation Protection Dosimetry*. These operational quantities have been adopted in recommendations of ICRP and in the standards implementing ICRP recommendations written by the International Atomic Energy Agency (IAEA) and the European Union (EU). In addition, the ICRP, in Publication 74, *Conversion Coefficients for Use in Radiological Protection Against External Radiation*, compared and contrasted doses determined using the ICRP system of protection quantities with doses determined using the ICRU-based operational quantities. For almost all situations considered, doses determined with the operational quantities were greater or equal to the doses determined using protection quantities. These operational quantities and their relation to the protection quantities listed in the final version of 10 CFR 835 are listed as follows:

Relation between protection quantities and operational quantities for individual monitoring of external exposure

Protection Quantity	Operational Quantity (depth [d] in tissue [mm])
Equivalent dose to the whole body from external sources*	$H_p(10)$
Equivalent dose to the lens of the eye from external sources	$H_p(3)$
Equivalent dose to the extremity or skin from external sources	$H_p(0.07)$

Where $H_p\ (d)$ is the personal dose equivalent at depth d in tissue

See ICRU Report 51 for the definition of $H_p\ (d)$

* Same as effective dose from external sources.

For doses resulting from intakes of radioactive materials, operational quantities have been published in ICRP, IAEA, and EU documents.

Relation between protection quantities and operational quantities for individual monitoring of doses from intakes of radioactive material

Protection Quantity	Operational Quantity
Committed effective dose	$\sum_j h_{j,eff,50,inh} I_{j,inh} + \sum_j h_{j,eff,50,ing} I_{j,ing}$
Committed equivalent dose	$\sum_j h_{j,T,50,inh} I_{j,inh} + \sum_j h_{j,T,50,ing} I_{j,ing}$

Where: $h_{j,eff,50}$, is the committed effective dose per unit of radioactivity intake by inhalation (*inh*)

$h_{j,eff,50,ing}$ is the committed effective dose per unit of radioactivity intake by ingestion (*ing*)

$h_{j,T,50,inh}$ is the committed equivalent dose to a tissue (T) per unit of radioactivity intake by inhalation

$h_{j,T,50,ing}$ is the committed equivalent dose to a tissue (T) per unit of radioactivity intake by ingestion

$I_{j,inh}$ is an intake by inhalation

$I_{j,inh}$ is an intake by ingestion

j is a radionuclide

For the total effective dose, the following operational quantity is suggested.

Protection Quantity	Operational Quantity
Total effective dose	$H_p(10) + \sum_j h_{j,eff,50,inh} I_{j,inh} + \sum_j h_{j,eff,50,ing} I_{j,ing}$

In addition to the operational quantities used for individual monitoring, the following table contains operational quantities that may be measured to characterize certain aspects of radiation fields in the workplace.

Operational quantities for use in characterizing workplace radiation fields

Workplace Measurement	Suggested Operational Quantity
Control of effective dose	$H^*(10)$
Control of dose to the skin, the extremities, and the lens of the eye	$H'(0.07, \Omega)$
Control of dose to the lens of the eye	$H'(3, \Omega)$

Where: $H^*(10)$ is the ambient dose equivalent at a depth of 10 mm in tissue

$H'(0.007, \Omega)$ is the directional dose equivalent at a depth of 0.07mm in the ICRU sphere

$H'(3, \Omega)$ is the directional dose equivalent at a depth of 3 mm in the ICRU sphere

Ω defines the direction of the radiation field

See ICRU Report 51 for the definitions of ambient dose equivalent and directional dose equivalent.

To summarize the above discussion, protection quantities have been developed for use in radiation protection standards to establish dose limits and action levels that reflect the risk associated with radiation exposure and are directly applicable to all members of the population being protected. Measurable operational quantities have been selected that permit measurements which show compliance with protection quantities specified in 10 CFR 835. Additional guidance will be provided in the implementation guide for 10 CFR 835.