

Details of Technical Options and Issues for Revision of 10 CFR Part 20

This enclosure outlines several staff-identified technical issues that are potential areas for revision of 10 CFR Part 20 to facilitate a greater degree of alignment with the recommendations in International Commission on Radiological Protection (ICRP) Publication 103. The staff proposes to use the outlined technical issues as a starting point during stakeholder and interested party dialogue in order to understand the impacts of greater alignment. It is expected that stakeholders and interested parties will identify other issues, in addition to those initially presented by the staff, during the dialogue. Pursuing these discussions before the initiation of rulemaking will facilitate preparation of a more complete catalog of issues, options, and the technical materials needed.

A. “Total Effective Dose Equivalent” (TEDE) versus “Total Effective Dose” (TED)

Recently, the Commission amended the definitions in 10 CFR 20.1003 and 50.2 (72 FR 68058, December 4, 2007) to clarify the definition of TEDE to mean the sum of the effective dose equivalent (for external exposures) and the committed effective dose equivalent (for internal exposures). The revised definition of TEDE allows a licensee to substitute “effective dose equivalent” for “deep dose equivalent” for external exposures. A conforming change was made to 10 CFR 20.1201(c) to clarify the determination of occupational radiation dose for adults. This action was made effective on February 15, 2008 (72 FR 72233, December 20, 2007). The rule change is consistent with the current recommendations of the ICRP. Implementation of effective dose, for external exposures, may have a significant impact for some licensee communities, such as medical exposures. While licensees are becoming more aware of the change, the U.S. Nuclear Regulatory Commission (NRC) has not yet assessed the implications for licensee compliance with the dose limits.

Another issue that the staff believes that the Commission should consider is whether it is appropriate to adopt current ICRP terminology and methodology throughout 10 CFR Part 20, and other portions of the regulations, by using the term TED instead of the term TEDE. ICRP publications no longer use the term effective dose equivalent, or committed effective dose equivalent. Further, ICRP now refers to the effective dose without designating whether the value is external or internal as the terms in the calculation will indicate if the radiation source is outside the body or inside the body. The 2007 recommendations in ICRP Publication 103 use a complex phrase to indicate the sum of the calculations. However, other ICRP publications use the terminology of total effective dose, TED. 10 CFR Part 20 could simply indicate the sum as the TED.

One argument for changing the term TEDE is that it is no longer consistent with various current industry consensus standards, or international standards. A second reason may be to alert various licensee communities that the Commission has changed its requirements for calculation of external exposure.

The staff recognizes that the change in terminology could be seen as editorial, and is aware that if the Commission chooses to make the change from TEDE to TED that there is a possibility of an impact upon licensees, particularly in the areas of updating procedures and other documentation to replace TEDE with TED. In order to minimize the impact of the change, the regulations could be written to allow for a licensee to gradually change the terminology as the licensee’s procedures are updated over a reasonable period of time.

The staff notes that the U.S. Department of Energy has already moved to use of effective dose in its regulations in 10 CFR Part 835, "Occupational Radiation Protection" (72 FR 31904, July 8, 2007). If the Commission decides to update the terminology and methodology to TED, conforming changes would be made to the remaining parts in 10 CFR Chapter I where TEDE is currently used. In addition, the new term TED would be important for revisions of 10 CFR Part 50 and Part 50 Appendix I. With this change, the terminology in the NRC's regulatory framework would be made more consistent.

The staff believes that there is sufficient reason to move to use of the term TED when engaging with stakeholders and interested parties as a way to further evaluate the implications and impacts of replacing TEDE with TED.

B. Dose Limits

1. Public Exposure Dose Limits

The current NRC requirements for dose limits for members of the public align with the recommendations in ICRP Publications 60 (1990) and 103 (2007). This includes a provision for doses greater than 100 mrem (1 mSv) for certain situations. Although ICRP Publication 103 recommended that the dose for exposure to radiation for a child be limited to 100 mrem (1 mSv) in all cases, the staff believes that the regulations should continue to provide flexibility for a licensee in certain cases in which there may be a benefit to a member of the public, for example, when a family member is exposed to a patient who received radionuclide therapy. The staff has not identified changes to the public exposure dose limits as an issue, but recognizes that stakeholders and interested parties may wish to make this a point of discussion.

2. Dose Limit To An Embryo/Fetus Of A Declared Pregnant Woman

The declared pregnant woman's occupational dose and the dose to an embryo/fetus are specified in 10 CFR 20.1208. The current requirements are based on the recommendations available in ICRP Publication 26 for such exposures. The ICRP recommendations now contain a provision that the dose limit should be the same as the public dose limit, which is 100 mrem (1 mSv). Thus, there is an issue of whether NRC's requirements should be revised.

The first option is to maintain the current dose limit. Currently, 10 CFR 20.1208 specifies the dose limit to the embryo/fetus of a declared pregnant worker is 0.5 rem (5 mSv) for the gestation period with 0.05 rem (0.5 mSv) additional dose during gestation period if the dose to the embryo/fetus has already exceeded 0.5 rem (5 mSv) at the time of declaration. Arguments for maintaining the limits "as is" are that the rule as written is well established and understood, the risk difference between 0.5 rem (5 mSv) and an additional 100 mrem (1 mSv) after the declaration of pregnancy might not be considered significant by some stakeholders, and the current rule is consistent with the latest National Council on Radiation Protection recommendation (Report No. 116, 1993). The current rule requires a licensee to make a retrospective assessment of the dose to the embryo/fetus when the pregnancy is declared.

The second option is to change the requirements, and establish the value as 100 mrem (1 mSv) applicable from the declaration of pregnancy for the remainder of the gestation period. There are compelling arguments supporting consideration of the second option.

Limiting the dose to 100 mrem (1 mSv) reduces the numerical value to one consistent with the recommendations contained in ICRP Publication 103. This option also simplifies the requirement, in that a retrospective dose assessment to the embryo/fetus prior to a declaration would not be needed.

A third option is to limit the embryo/fetal dose to 50 mrem (0.5 mSv) applicable from the declaration of pregnancy for the remainder of the gestation period which reduces the numerical value to one most consistent with the requirement for the public exposure (1 mSv (100 mrem) in a year). The staff also notes that the embryo/fetus is several times more sensitive to radiation exposure than members of the general population and should be afforded additional protection.

The staff believes that there is a strong rationale for modification of the requirement, but notes that additional interactions with stakeholders and interested parties are necessary to understand the implications of this proposal on licensee activities. The staff is already aware of certain situations among medical workers, for example nuclear pharmacists, where a change could present an impact.

3. Occupational Dose Limits

The occupational dose limits of 10 rem (100 mSv) over 5 years, with a maximum of 5 rem (50 mSv) in any one year, set by ICRP in 1990, were not incorporated into the last revision of 10 CFR Part 20 because the recommendations were not available during the public comment period for the proposed rule. The staff has identified three options for consideration.

The first option would be to retain the present 5 rem (50 mSv) occupational dose limit. It could be argued that such a value is consistent with the maximum value recommended by ICRP in any 1 year, and provides the greatest operational flexibility to licensees. This approach, perhaps coupled with a strong implementation of occupational dose constraints as described below, could be seen as providing the same level of protection as a reduction in the dose limits.

The second option would be to change the dose limit to 10 rem (100 mSv) over any 5 year period, with a further limitation of 5 rem (50 mSv) in any 1 year. The option would explicitly implement the ICRP recommendations in NRC's regulatory structure and facilitate consistency with other international standards. However, such a requirement would be more complex to implement, because dose histories for each individual would be necessary in order to determine compliance with the 5 year average.

The third option would be to lower the occupational dose limit to 2 rem (20 mSv) per year. This option would align the NRC requirements with the intent of the ICRP recommendations, would be consistent with the regulations of some countries, and would be somewhat less flexible than the provisions of other countries. Such an approach would be the most straightforward change, because no dose histories would be needed to determine compliance with the 5 year average described in Option 2.

The staff has obtained information that 2 rem (20 mSv) per year is achievable for nuclear reactor licensees. The staff needs to obtain additional information about the actual dose distributions for industrial and medical licensees, in order to understand possible impacts of establishing an average occupational dose limit of 2 rem (20 mSv) per year, a

maximum of 5 rem (50 mSv) in any 1 year, and 10 rem (100 mSv) in 5 years. Initial interactions with the medical community suggest that interventional radiologists and cardiologists may be receiving doses well in excess of 2 rem (20 mSv), per year, as measured by the deep dose equivalent. These medical groups have also indicated that they believe any consideration of a change would result in a direct impact on the delivery of patient care. Initial interactions have also disclosed that compliance with the 5 rem (50 mSv) value may still be based on the deep dose equivalent, and that use of the provisions now in 10 CFR Part 20 for effective dose may make compliance somewhat less difficult. However, many of the medical licensees are in Agreement States; the regulations of the Agreement States must also be amended to clarify the definition of TEDE as explained above in Section A.

The staff believes that additional interactions with stakeholders and interested parties are necessary to understand the implications of the proposal on licensee activities, and does not have a recommended position at this time. Further, these discussions should consider the implications of the dose limits together with any proposals related to establishing constraints for occupational exposure (see discussion below on constraints).

C. Incorporation of Constraints

1. Occupational Exposure

One of the most significant modifications made by the ICRP was the use of constraints and reference levels as part of the process of optimization of protection. Licensees are currently required by 10 CFR 20.1101 to use sound radiation protection principles to achieve occupational doses and doses to members of the public that are as low as is reasonably achievable (ALARA). The term, "constraint," is already included in the definitions of 10 CFR Part 20. A constraint, as currently defined, is a value at which licensee actions are required. Many licensees are generally familiar with the concept of constraints, although the concept may be implemented through various terms, because they routinely use various planning values in their programs to ensure that the dose limits are not exceeded. Thus many established radiation protection programs already incorporate this concept. The ICRP recommendations indicate that the constraint is the starting point for optimization, serving as an upper bound on the annual dose that members of the public should receive from the planned operation of any controlled source of radiation. ICRP has stated that constraints are not considered as limits.

A radiation protection program should include dose constraints such that if an individual exceeds the designated dose the licensee should take action to control future doses and ensure that the radiation safety practices have been adjusted to minimize the possibility of future situations exceeding the constraint value. For example, the licensee should investigate the situation, and take corrective actions so that exposures for the remainder of the year will not exceed a new planning value or the dose limit. Thus, a situation in which an individual exceeds the dose constraint would not necessarily be a regulatory violation. It would, however, be a violation if the licensee were to fail to take the appropriate corrective actions.

The staff, in considering the possible impact to licensees, has also considered whether exceeding a constraint should be reportable. The staff believes that the implementation of constraints would be best served by not requiring that a situation exceeding the

constraint be reported to the NRC or the Agreement State, as appropriate. The NRC could still become aware of, and examine, the situation through the routine inspection program. For occupational exposure, the staff believes that the addition of a requirement for licensees to establish and use a dose constraint could be an appropriate change to the NRC's radiation protection framework that would assist licensees in achieving occupational doses that are ALARA. While many licensees use planning values, the use of such values is currently not required. The staff has observed applications, such as industrial radiography, where exposures are seen in excess of 2 rem (20 mSv) per year and these licensees generally do not have such optimization.

The staff believes that additional interactions with stakeholders and interested parties are necessary to understand the impact of this proposal on licensee activities. The considerations should include both whether to include the concept, and whether to impose a numerical value as the maximum that a licensee could use. An option could be to set the constraint at 2 rem (20 mSv) per year. Other values could also be considered. This option would provide alignment to ICRP recommendations, while maintaining some flexibility for licensees in the conduct of their activities. The staff believes that additional information about the actual dose distributions from stakeholders and interested parties will be of benefit to the staff in making a determination as to whether to impose a maximum numerical value, and if so, what value would be the most appropriate.

2. Public Exposure

The issue of establishing other constraints, such as for members of the public, could also be the subject of discussion. The staff does not believe that it would be necessary to specify other constraints for public exposure, because other regulations already function to keep exposures below the dose limit for members of the public. For example, doses are further restricted from residual radioactivity at a decommissioned site, including that from groundwater sources of drinking water. In addition, certain licensees are constrained by the U.S. Environmental Protection Agency's generally applicable environmental radiation standards in 40 CFR Part 190 that limit doses to members of the public. 10 CFR Part 50, Appendix I, imposes design criteria to further restrict doses from effluents. Multiple licensees at a site or facility must cooperate with one another to limit their contribution to the dose limit for a common receptor, i.e., a member of the public. The staff notes that 10 CFR 20.1101 already contains a provision for a constraint for airborne effluents from non-reactor facilities. This provision would be retained.

Nevertheless, the staff recognizes that stakeholders and interested parties may wish to engage in discussions on the use of constraints for public exposure. For example, the staff is aware that the medical community has expressed a concern with regard to the current values used in the planning for shielding of facilities.

D. Changes to Weighting Factors and Numeric Values

1. Numeric Values of Weighting Factors

The weighting factors for tissues (W_T) and types of radiation (W_R) are currently specified in 10 CFR Part 20 in the definitions section, and are based on the recommendations in ICRP Publication 26. The 2007 ICRP recommendations provide new values for both quantities. These values are therefore logical candidates for updating. One option could

be to retain the definition of the weighting factors in the definitions sections of Part 20 while the numeric values supporting the defined terms (including monoenergetic neutrons) could be updated and moved from the definitions section to an appendix to 10 CFR Part 20. Such an approach is used in other NRC regulations, for example, the terms for A_1 and A_2 are defined in 10 CFR Part 71 and cited elsewhere in 10 CFR Part 71 while the actual values for A_1 and A_2 reside in tables that are appended to 10 CFR Part 71. Such a format would clarify requirements by assuring that key numeric criteria are not “hidden” in a definition.

The staff believes that it is appropriate to amend the regulations to use the updated values, and would engage stakeholders and interested parties on possible issues and implications.

2. Numeric Values of Annual Limits on Intake (ALI) and Derived Air Concentrations (DAC) in 10 CFR Part 20, Appendix B

The staff believes that revised values for Annual Limits on Intake (ALI) and Derived Air Concentrations (DAC) should be incorporated into Appendix B when the technical basis for the numeric changes become available. At this time, the ICRP has not published new dose conversion factors incorporating the revised radiation and tissue weighting factors, and accounting for the latest biophysical models. The ICRP has indicated that these materials are being developed, although publication is generally not expected much before 2014.

The staff believes that it would be appropriate to amend the regulations to reflect revised values for ALI and DAC when these values are available, and would engage stakeholders and interested parties on possible issues and implications. In particular, the staff will explore the extent to which rulemaking could proceed before a complete set of dose conversion factors has been published by the ICRP. The staff notes that if the initiation of rulemaking is delayed until the final publication of all dose conversion factors, the implementation by licensees might not occur until 2020 or later.