9/27/2010
75 FR 59160

(15)

PUBLIC SUBMISSION

As of: February 01, 2011
Received: January 31, 2011
Status: Pending_Post
Tracking No. 80bd6b76
Comments Due: January 31, 2011
Submission Type: Web

Docket: NRC-2009-0279
Potential Changes to Radiation Protection Regulations; Solicitation of Public Comment

Comment On: NRC-2009-0279-0019
Radiation Protection Regulations and Guidance; Public Meetings and Request for Comments

Document: NRC-2009-0279-DRAFT-0025
Comment on FR Doc # 2010-24137

Submitter Information

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General Comment

See attached file(s)

Attachments

NRC-2009-0279-DRAFT-0025.1: Comment on FR Doc # 2010-24137

SUNSI Review Complete
Template - ADM-013

E-RFDS = ADM-03
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The University of Texas M. D. Anderson Cancer Center Comments to the US NRC on Questions Regarding Rules Changes vis-à-vis ICRP 103

Issue 1: Effective Dose and Numerical Values

Question 1.1-1: 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)?

The University of Texas M. D. Anderson Cancer Center can work with either system.

Question 1.1-2: What are the anticipated impacts on reports and records?

MD Anderson feels that the effect of such a change would be relatively minor as our records are supplied by a NVLAP accredited dosimetry laboratory. These dosimeter records are provided as DDE or EDE 2 values depending on the exposure conditions.

Question 1.2-1: 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?

MD Anderson would prefer to see a single change when the data are complete instead of a steady trickle of changes over time. As a licensee of an agreement state, we typically experience a delay between changes in the federal regulations and the corresponding changes in state regulations. It would be more efficient to bundle the changes into one event. We do not foresee significant detriment to public or occupational safety in waiting for a single, complete change.

Question 1.2-2: Should the NRC use the values developed by the EPA, which will be based upon a US population, instead of the ICRP values, which are based on a more diverse world population?

MD Anderson does not anticipate any significant difference in the impact of the changes depending on the basis of the data. Although we have relatively few matters of compliance with EPA regulations, it would be easier, should we need to do so, to be using the same basis for compliance with state radiation control regulations that are derived from the NRC regulations and with EPA regulations.

Issue 2: Occupational Dose Limits

Question 2-1: Are there any significant anticipated impacts in assessing and retaining dose histories for each individual in order to comply with a multi-year average?

Although the MD Anderson workforce is relatively stable, we do see a moderate turnover in the technical staffs in radiation oncology, radiology, and nuclear medicine. We have substantial turnover in the personnel who work in many research labs as they complete the different phases of their educations and training. While the added recordkeeping required for determining multi-year averages is feasible if required, it would be an additional administrative burden and cost of providing patient care and

conducting scientific research. Because of the possibility that a job applicant had already exhausted his or her multi-year exposure limit, hiring of new personnel would be slowed down by the need to obtain dosimetry records prior to hiring. In some cases, this could compromise the privacy of an applicant who does not wish to disclose his or her job search to his or her current employer. MD Anderson would prefer not to have to comply with a system that includes multi-year averages.

Question 2-2: Are there any anticipated implementation impacts expected if the dose limit were to be decreased?

For the most part, MD Anderson's personnel doses are below the 2 rem annual limit that has been proposed. However, some are close and a few, discussed in more detail in response to question 2-4, are over. We have achieved this situation by an aggressive and effective ALARA program. If our ALARA trigger levels were to be reduced commensurate with a reduction in the annual dose limit, we would have many more events that would require administrative review and thus have a greater administrative burden with no improvement in the safety of our personnel.

Question 2-3: Is there any information about the actual dose distributions for industrial and medical licensees? What are the trends for these data? Are the data available to share with the NRC?

MD Anderson is pleased to provide our detailed experience in an accompanying document.

Question 2-4: For the medical industry, are they any potential impacts on patient care?

The cost of patient care includes the cost of radiation safety. Among the ways to comply with reduced personnel dose limits would be greater distances between sources and personnel, increased shielding between sources and personnel, and reduced time of exposure of personnel to sources. Increased distances raise the cost of building medical facilities and might not be possible to accomplish within existing facilities. Increased shielding raises the cost of building and renovating medical facilities and might not be possible in renovations if the building structure is already close to its maximum weight-bearing capacity. Reduced exposure times for personnel imply either reduced quality of care for patients or an increase in the number of personnel to allow for a dilution of the total personnel dose by more individuals. This would increase costs. Since many occupationally exposed personnel undergo arduous and prolonged education and training to be qualified to perform their jobs, such dilution might not be possible in the short run and might require as much as a decade to achieve in the case of highly specialized physicians such as interventional cardiologists and interventional radiologists. In the meantime, one effect of reduced occupational dose limits might be to deny patients necessary care if there is no one available to perform a procedure that has not already exceeded his or her occupational dose limit.

Issue 3: Doses to Special Populations

Question 3.1-1: Are there any significant impacts associated with reducing the dose limit to the embryo/fetus of a declared pregnant woman, including operational impacts?

MD Anderson has been able to keep the doses to our declared pregnant workers below the current regulatory limit by modified assignments and aggressive ALARA measures such as issuing an electronic dosimeter and having the declared pregnant worker keep a daily log of the electronic dosimeter reading and her activities that day in higher dose settings such as Nuclear Medicine. However, we could not achieve the dose limit to the embryo/fetus in ICRP 103 without severely curtailing the activities of the declared pregnant worker. This is disruptive to the work and potentially raises the cost of health care if temporary help must be hired while the declared pregnant is reassigned to limit the embryo/fetus dose during her pregnancy.

Question 3.1-2: Are there any anticipated implementation impacts on record-keeping?

MD Anderson does not anticipate an increased record-keeping burden if a lower limit were to be imposed.

Question 3.1-3: Is there a reduction in burden in assessment and record-keeping if the ICRP recommendation were to be adopted?

MD Anderson does not anticipate a reduction in assessment and record-keeping unless a large number of pregnant women were to decide not to declare their pregnancies as a consequence of the adoption of the ICRP recommendation.

Question 3.1-4: Are there technological implementation issues, such as limits of detection, which would make adoption of the ICRP recommendation difficult in certain circumstances?

No. MD Anderson currently uses OSL dosimeters with a minimum reading of 1 mrem. Thus, we anticipate being able to assess doses on the order of 10 mrem a month.

Question 3.1-5: Are there data on actual dose distributions to the embryo/fetus of a declared pregnant worker? What are the trends for these data? Are these data available to share with the NRC?

MD Anderson has supplied what data we have in an accompanying document.

Question 3.2-1: Are there any significant anticipated impacts associated with limiting the applicability of alternative public dose limits?

MD Anderson believes strongly that flexibility in alternative public dose limits is highly desirable for optimal patient care. We make extensive use of the 500 mrem limit to the most exposed person for the release of patients from radiation safety restrictions. We would ask the NRC to retain the 500 mrem limit per occasion (rather than 500 mrem a year) and to adopt the ICRP 103 stance that even this limit be flexible for specific needs such as those of the parents of a pediatric patient who is undergoing radionuclide therapy and requires intensive parental support.

Question 3.2-2: Are these impacts the same for the options of a rule change or for changes to guidance?

Yes, for MD Anderson.

Question 3.2-3: Are there data available about the actual use of the alternative dose criteria? Are these data available to share with the NRC?

MD Anderson has never formally applied for the application of an alternative dose limit. Using the guidance in NUREG 1556, Volume 9, Appendix U, we release about 230 I-131 radionuclide therapy patients each year.

Issue 4: Incorporation of Dose Constraints

Question 4-1: Are there any significant anticipated benefits and impacts associated with imposing the use of constraints in a licensee's radiation protection program?

MD Anderson agrees with the public comment at the Houston workshop that constraints become de facto limits for the conscientious licensee. We join in the public comment that we are already keeping dose as low as reasonably achievable. The negative impact of reduced limits or of constraints at levels below the limits would be to redefine the word reasonable.

Question 4-2: Are there any anticipated implementation impacts on inspection, compliance and reporting anticipated?

MD Anderson envisions an increase in the documentation and inspection effort necessary to demonstrate appropriate response to situations in which a constraint was exceeded.

Question 4-3: What relationship should a constraint have to the dose limit, if any?

MD Anderson does not favor constraints.

Question 4-4: Is a requirement to establish and use constraints an appropriate or inappropriate insertion of a regulatory requirement?

MD Anderson employs self-defined and -imposed constraints in the form of ALARA action levels. To have these codified in regulation would reduce our ability to tailor our ALARA program to specific circumstances in our Institution (such as variations in the unavoidable doses between research labs and patient care clinics).

Question 4-5: How familiar are you with the use and implementation of constraints or planning values in a radiation protection program?

MD Anderson uses ALARA action levels in our radiation protection program.

Question 4-6: Are constraints (or planning values) used in your current licensed activities and, if so, can you share insights on the use of these constraints?

MD Anderson believes that ALARA action levels are an important means by which we keep personnel doses as low as reasonably achievable. With our current ALARA levels, we typically see 25 ALARA I and 5 ALARA II events a year.