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In Reply Refer To: 598/115HP/NLR

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Secretary, U.S. Nuclear Regulatory Commission
Washington, DC 20555–0001
ATTN: Rulemakings and Adjudications Staff

Subject: Docket ID NRC–2009–0279

I am responding for the Veterans Health Administration to the Request for Public Comment in the *Federal Register* on August 30, 2011, for the new International Commission on Radiological Protection recommendations on the annual dose limit to the lens of the eye.

In the field of medicine, workers most likely to receive doses to the lenses of the eyes exceeding 20 or even 50 millisievert (mSv) in a year are clinicians who perform complex fluoroscopically-guided or computed-tomography-guided interventional procedures. While fluoroscopes and CT scanners are not regulated by the Nuclear Regulatory Commission (NRC), some of these workers may also receive doses from radioactive materials regulated by NRC and so their occupational doses may be subject to NRC regulations. Furthermore, 10 CFR 20 is adopted by the agreement states and so any changes to NRC regulations would likely have a national effect on the practice of medicine.

Workers performing or assisting with these medical interventional procedures wear radiation-attenuating personal protective equipment (PPE) that shields their torsos and upper legs. The exposure of individual workers is typically monitored by a dosimeter worn at collar level outside the PPE. At some institutions, a worker also wears a second dosimeter on the body under the PPE. A worker's eyes may be protected by radiation-attenuating glasses, goggles, or a face shield. These personal protective devices are typically designed to provide protection to the eyes from radiation from the side, as well as from the front. When such eye protection is worn, monitoring the radiation intensity behind the eye protection with dosimeters to estimate the doses to the lenses of the eyes would be very cumbersome.

I recommend that the regulatory limit for the dose to the lens of the eye not be reduced below 50 mSv per year. A method by which NRC could encourage protection of workers' eyes would be to recommend, as an ALARA (i.e., as low as reasonably achievable) goal, an equivalent dose for lens of the eye of 20 mSv in a year, averaged

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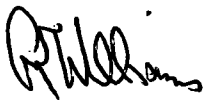
over defined periods of 5 years, with no single year exceeding 50 mSv. The wearing of radiation-protective eyewear with a protection factor sufficient to reduce the lens of the eye dose indicated on the collar dosimeter to below these values should be accepted as a method for meeting such an ALARA goal.

I am enclosing responses to the specific questions in the *Federal Register*. If you have any questions or comments, please contact me at 501-257-1572.

Sincerely,



Gary E. Williams
Director, National Health Physics Program

Enclosure

Responses to Specific Questions

1. To what extent has dose to the lens of the eye been an issue in the implementation of your radiation protection program, and would a change in the limits cause operational and administrative impacts? What other types of impacts would you foresee?

In medical radiation safety programs such as that of the VA, the dose to the lens of the eye is a significant issue, primarily in fluoroscopically-guided and sometimes in CT-guided interventional procedures. In such procedures, radiation personal protective equipment (PPE) is worn by staff whose heads and extremities receive much larger doses than their bodies. Doses to staff from such procedures are reviewed in a number of publications (NCRP Report No. 122; NCRP Report No. 168; Kim et al., Health Physics, 2008). It is common for some physicians performing more complex procedures (e.g., endovascular reconstructions and embolizations, cardiac electrophysiological studies with ablations, and transjugular intrahepatic portosystemic shunt creations) to receive annual doses on their collar dosimeters exceeding 20 mSv in a year and occasionally exceeding 50 mSv in a year. The ability of clinicians to complete procedures of long duration can be limited by their ability to bear the weight of radiation protective garments.

While these sources of radiation, fluoroscopes and CT scanners, are not regulated by the Nuclear Regulatory Commission (NRC), some of these workers may also receive doses from radioactive materials regulated by NRC and so their occupational doses may be subject to NRC regulations. Furthermore, 10 CFR 20 is adopted by the agreement states and any changes to NRC regulations would likely have a national effect on the practice of medicine.

Changes to the dose limits could have operational, administrative, economic, and quality of medical care impacts, depending upon the magnitude of changes in the dose limits and also the possible requirements for monitoring the doses to the lenses of the eyes.

2. What types of specific administrative and monitoring methods would be available in your use of radiation or radioactive materials to reduce exposures to the lens of the eye, and what would be the costs and operational impacts of implementing such methods?

Administrative and monitoring methods would not reduce the exposure to the lenses of the eyes of clinicians performing medical interventional procedures. The use of transparent ceiling-mounted radiation shields and the wearing of protective eyewear or face shielding reduce the doses to the lenses of the eyes. However, protective eyewear is heavy and can be uncomfortable during procedures of long duration.

3. What might be the anticipated impacts of a rule change on recordkeeping and reporting?

The impacts of a rule change would depend upon the extent of the changes in dose limits and what, if anything, is required to demonstrate compliance with such a rule change.

4. Are there technological implementation issues, such as limits of detection as compared to currently used radiation monitoring methods, or availability of dosimetry, that would make adoption of the ICRP recommendations difficult or impractical in certain circumstances? If possible, please provide a typical example of such a circumstance.

If actual monitoring of doses to the lenses of the eyes by dosimeters were required, this could have a significant negative effect on the practice of medicine. It would be awkward and expensive to place dosimeters behind the leaded eyewear worn by physicians performing fluoroscopically-guided or CT-guided procedures.

5. How does the recommended limit to the lens of the eye influence your views on possible changes to the limits on TEDE, given that these two quantities are expected to be essentially the same for many exposure situations?

We do not expect these two quantities to be essentially the same in medicine. In the case of fluoroscopically guided or CT guided medical interventional procedures, where worker's bodies are protected by radiation attenuating aprons, the lens of the eye dose can be several times the effective dose or the effective dose equivalent.

We recommend that the limit for the total effective dose equivalent (TEDE) not be reduced and we further recommend the dose to the lens of the eye not be reduced below 50 mSv for a year.

6. What alternatives to adoption of the new limits would you suggest in achieving the desired outcome of limiting exposure of the lens of the eye over the working lifetime of an employee?

An alternative to reducing the lens of the eye dose at all, or to reducing it below 50 mSv per year, would be to recommend an ALARA goal for the doses to the lenses of the eyes of 20 mSv per year, averaged over a period of 5 years, with the dose in a single year not to exceed 50 mSv.

7. What should be the relationship between the U.S. regulatory requirements and those adopted internationally? What impacts, either positive or negative, would result from an alignment of NRC regulatory requirements and guidance with international standards?

There is no reason that the U.S. should change its regulations to match those of other countries.

8. Should licensees be required to monitor and report LDE for foreign workers and report the values upon request? Are there other impacts (e.g., operational, administrative, costs, etc.) that should be anticipated if the U.S. regulatory structure were to be different from that being used in other countries?

We are not aware of significant adverse impacts that should be anticipated if the U.S. regulations differ from those used by some other countries.

9. Are there any other NRC regulations and regulatory guidance that might need to be reviewed and revised as a result of ICRP recommendations in reducing the allowable dose to the lens of the eye?

We recommend that NUREG-1556, Volume 9, Revision 2, "Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Medical Use Licenses," Appendix M, "Model Procedures for an Occupational Dose Program," be revised to recommend an ALARA goal for the doses to the lenses of the eyes to be 20 mSv per year, averaged over a period of 5 years, with the dose in a single year not to exceed 50 mSv.

10. How are licensees monitoring to demonstrate compliance with the existing dose limits for the lens of the eye?

In the case of fluoroscopically-guided and CT-guided medical interventional procedures, the dose to the lens of the eye is monitored by a dosimeter worn at the collar level outside the radiation PPE. This provides a reasonable estimate of doses to the lenses of the eyes when protective eyewear is not worn. When protective eyewear is worn, the collar dosimeter greatly overestimates the dose to the lenses of the eyes. If the dose limit for the dose to the lens of the eyes is reduced, NRC should permit the adjustment of the collar dosimeter reading by a factor that accounts for the shielding provided by protective eyewear.