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Solicitation for Public Comment on Potential Changes to the Agency's Radiation Protection Regulations

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General Comment

Please see the attached comments of the American College of Radiology. Thank you for your consideration.

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Attachments

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March 29, 2010

Office of Federal and State Materials and Environmental Management Programs
U.S. Nuclear Regulatory Commission
Attn: Dr. Donald Cool and Dr. Kimyata Morgan Butler
Washington, DC 20555-0001

Subject: NRC-2009-0279; FR Doc. E9-15950; Comments of the American College of Radiology

On behalf of the American College of Radiology (ACR)—a professional organization representing more than 36,000 radiologists, radiation oncologists, interventional radiologists, nuclear medicine physicians, and medical physicists—we appreciate the opportunity to respond to the U.S. Nuclear Regulatory Commission's (NRC) request for public comments on potential changes to NRC regulations to align with the recommendations of the International Commission on Radiological Protection (ICRP) in ICRP Publication 103.

General Comments

The ACR commends the Commission and NRC staff for consulting with public stakeholders on the impact of any potential regulatory changes under consideration before deciding whether or not to pursue a rulemaking. Preliminary discussion is particularly advisable for medical stakeholders because our personnel and services are subject to additional oversight/regulation, standards, and decisions above and beyond the radiation safety aspects of patient care.

As a general comment, NRC should only revise its radiation protection regulations and/or guidance if the existing regulations do not adequately protect public health and safety or are shown to be otherwise faulty. The Commission wrote in SECY-08-0197 (April 2009) that ICRP Publication 103 "proposes measures that go beyond what is needed to provide for adequate protection." The ACR agrees with the Commissioners in this regard, and maintains that a technical basis for a rulemaking requires more evidence of a problem or scientific concern.

Occupational Dose Limit

The primary area of interest for most medical stakeholders is the ICRP's recommendation of limiting radiation worker annual doses to 20 mSv (2 rem) per year, averaged over five years (100 mSv/5 years), with the provision that effective dose should not exceed 50 mSv in any single year. This would be a significant deviation from the NRC's current adult occupational dose limit in 10 CFR Part 20.1201 of total effective dose equivalent being equal to 5 rem (50 mSv) per year. The ACR staunchly supports the health and safety of medical personnel in addition to that of our patients; however, there is a lack of scientific data showing reduced ICRP recommended levels are any safer than the current U.S. limits.

Any change to the adult occupational dose limit would likely impact interventional radiologists more than other medical stakeholders. The impact on interventional radiologists would be felt following changes to State regulations to be compatible with NRC regulations, as medical professionals who get their occupational dose entirely from fluoroscopy do not fall under NRC's traditional regulatory purview over nuclear materials.

Given that the ICRP's recommendations are extremely conservative, the method used to convert personal monitor readings into effective dose must be reasonably accurate if this type of regulatory change is

made. Most methods currently mandated by the States and NRC intentionally overestimate dose by a factor of 3 or more, and sometimes a factor of 10, as a safety measure for radiation protection purposes. More accurate dose estimation puts most interventional radiologists within the recommended 20 mSv limit. Thus, if NRC lowers the dose limit to be in accordance with ICRP Publication 103, NRC should also require use of appropriate conversion formulas for personal dosimetry. NRC should mandate use of *effective dose*, as opposed to *effective dose equivalent*, and conversion formulas designed to give accurate estimates of *E* rather than conservative overestimates (see NCRP Report No. 122).

In terms of a potential impact on other medical stakeholders, we believe that most radiation oncologists use afterloading techniques in brachytherapy and, as a result, are likely to fall under a potential 20 mSv limit; however, this may not always be the case. Likewise, we believe that most diagnostic radiologists, nuclear medicine physicians, and technologists would fall under the ICRP recommended limit. There may be an impact on the radionuclide and radiopharmaceutical industry, as well as on nuclear pharmacists, and the input of those stakeholders should be carefully reviewed.

Release of Patients After Therapy with Unsealed Radionuclides

The ACR believes the NRC's current regulations, as well as the guidance in Appendix U of NUREG 1556, Volume 9, Revision 2 combined with the supplemental guidance in Regulatory Issue Summary (RIS) 2008-11, adequately aligns with the ICRP's recommendations on release of patients after therapy with unsealed radionuclides. The decision to hospitalize or release a patient after therapy should be made on an individual basis, and patients should be advised per the explicit guidance in Appendix U of NUREG 1556, Volume 9, Revision 2 combined with RIS 2008-11. No regulatory or guidance revisions are needed to align with ICRP recommendations in this regard.

Conclusion

As always, the ACR welcomes the opportunity for continued dialogue with NRC on all topics related to medical stakeholders. Please contact Gloria R. Romanelli, Esq., Senior Director, Legislative and Regulatory Relations; or Michael Peters, ACR Assistant Director of Regulatory and Legislative Portfolio, at 202-223-1670 if the radiology community can be of assistance.

Sincerely,



James H. Thrall, MD, FACR
Chair, Board of Chancellors
American College of Radiology