HEALTH PHYSICS SOCIETY

"Specialists in Radiation Safety"

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Air and Radiation Docket and Information Center
Environmental Protection Agency
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Subject: **Docket ID No. EPA-HQ-OAR-2010-1064** (Proposed Federal Guidance Report No. 14: Radiation Protection Guidance for Diagnostic and Interventional X-Ray Procedures)

The attached comments are submitted on behalf of the Health Physics Society (HPS)[1], a professional organization whose mission is to promote excellence in the science and practice of radiation safety. The HPS appreciates the opportunity to respond to the solicitation of public comments on Proposed Federal Guidance Report No. 14: Radiation Protection Guidance for Diagnostic and Interventional X-Ray Procedures.

The attached comments were collected from the Medical Health Physics Section of HPS and reviewed by the HPS Board of Directors. We would be pleased to answer any questions they generate.

Sincerely,

Richard J. Vetter

[1] The Health Physics Society is a nonprofit scientific professional organization whose mission is to promote the practice of radiation safety. Since its formation in 1956, the Society has grown to approximately 5,000 scientists, physicians, engineers, lawyers, and other professionals representing academia, industry, government, national laboratories, the department of defense, and other organizations. Society activities include encouraging research in radiation science, developing standards, and disseminating radiation safety information. Society members are involved in understanding, evaluating, and controlling the potential risks from radiation relative to the benefits. Official position statements are prepared and adopted in accordance with standard policies and procedures of the Society.

Proposed Federal Guidance Report No. 14: Radiation Protection Guidance for Diagnostic and Interventional X-Ray Procedures

(Docket ID No. EPA-HQ-OAR-2010-1064)

Comments from the Health Physics Society
May 31, 2012

General Comments

HPS supports the exclusive use of the International System of Units (SI Units), and encourages federal agencies to move to their exclusive use.[1] This includes the use of terminology consistent with international terms, such as the use of "effective dose" rather than "effective dose equivalent," the latter term no longer being used by the International Commission on Radiological Protection.[2]

The document uses, introduces or defines a number of terms related to radiology personnel, including "Referring Medical Practitioner," "Radiological Medical Practitioner," "Licensed independent practitioner," "radiologist," and "medical radiologic technologist." The use of the terms is not always consistent throughout the document and may not capture the gamut of licensed practitioners that may order radiological exams, such as dentists, chiropractors, podiatrists and veterinarians; or, as is the case with the term "medical radiologic technologist," the term may be too close to a term (or terms) defined differently by other entities, such as the term "medical radiation technologist," defined by the International Atomic Energy Agency,[3] potentially resulting in confusion. Perhaps a return to fewer and simpler generic terms, with an explanation in the introductory material of how those terms are used in the document would increase the readability and clarity of the document.

In the discussions of worker training that appear throughout the document, there does not appear to be a specific reference to existing materials on this topic, such as ICRP Publication 113, "Education and Training in Radiological Protection for Diagnostic and Interventional Procedures."[4] It may be helpful to provide some discussion of the available resources for establishing and maintaining a radiation safety education and training program. In addition, in all sections on training and education, it may be important to emphasize the fact that training

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[1] HPS Position Statement 025, "Exclusive Use of SI Units to Express Radiological Quantities," (Feb 2012).
[2] Nuclear Energy Agency, Organisation for Economic Cooperation and Development, "Evolution of ICRP Recommendations, 1977, 1990 and 2007." OECD 2011. NEA No. 6920.
[3] International Atomic Energy Agency, "Radiation Protection and Safety of Radiation Sources: International Basic Safety Standards – Interim Edition, IAEA Safety Standard Series No. GSR Part 3 (Interim), IAEA, Vienna (2011).
[4] ICRP Publication 113, "Education and Training in Radiological Protection for Diagnostic and Interventional Procedures, JAICRP 39(5).

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should include training on the specific equipment (manufacturer and model) workers will be using.

Specific Comments

Lines 71 – 83 characterizes the risk from medical imaging as an "important public health issue," and cites a potential for 1 in 270 women (0.37%) and 1 in 600 men (0.17%), undergoing Computed Tomography Coronary Angiography (CTCA) at age 40, to develop a radiation-related cancer in their lifetime. Given that the baseline lifetime risk of cancer for women age 40 is 38% and for men age 40 is 42% with uncertainties that can range up to 0.5%, it is difficult to comprehend in what way the increased risk from a single CTCA (or other CT) procedure constitutes an "important public health issue." [5] As discussed in the HPS position, "Radiation Risk in Perspective," [6] below doses of 50 millisievert (in one year) or 100 millisievert (in a lifetime) "expressions of risk should only be qualitative…emphasizing the inability to detect any increased health detriment (that is, zero health effects is a probable outcome)."

Lines 148-150 recommend the development of national reference levels for use as quality assurance and quality improvement tools. There are reference levels currently available in NCRP Report No. 172, "Reference Levels and Achievable Doses in Medical and Dental Imaging: Recommendations for the United States" (2012),[7] and the American College of Radiology "Practice Guideline for Diagnostic Reference Levels in Medical X-ray Imaging"[8] (currently undergoing revision[9]). Adding these references as examples, would provide valuable guidance for identifying authoritative reference levels.

Lines 851 – 871 discuss precautions for pregnant patients, and conclude with a statement that if a previously unrecognized pregnancy is identified after the procedure, the patient should be counseled as appropriate. Consideration should be given to adding a remark about a fetal dose assessment by a qualified physicist, consistent with the guidance given in lines 886 – 888.

Lines 897 – 899 recommend that for children, alternative imaging modalities that do not use ionizing radiation should be considered. There does not appear to be any reason that this advice should not apply to adult patients as well.

Lines 908 – 925 discuss radiological procedures used in research, and refer to the research subjects as "patients," but not all research subjects are patients. Many studies involve the use of normal, healthy subjects. It may be helpful to clarify this difference in the text. In addition, this section describes "medically indicated" (standard of care) procedures as not requiring the review required for research related (non-standard of care) procedures. Further clarification may be needed to identify the difference between those routine clinical procedures that are

[5] http://seer.cancer.gov/csr/1975_2009_pops09//results_merged/topic_lifetime_risk.pdf,
[6] HPS Position Statement 010-2, "Radiation Risk in Perspective," (Rev. July 2010).
[7] http://www.ncrponline.org/Publications/Press_Releases/172press.html
[8] http://www.acr.org/~/media/ACR/Documents/PGTS/guidelines/Reference_Levels.pdf, (2008).
[9] http://www.aapm.org/announcements/ReferenceLevelsFieldReviewDraft.pdf.

medically indicated and those that are solely research related; e.g., if routine clinical follow-up of a medical condition requires an imaging procedure every 8 weeks, but a research study requires the same procedure every 6 weeks, the additional procedures would not be “medically indicated,” even though someone not enrolled in the research study would have the same type (but not the same number) of procedures.

Lines 944 – 959 discuss the estimate of effective dose to quantify risks for research subjects. It may be worth noting that there are a number of reliable online resources available to estimate effective dose for many common procedures.

Lines 1403 – 1404, Table 1, provides that there should be a periodic review of all CT protocols. It is not clear why a periodic review of protocols for other imaging modalities is not necessary.

Lines 1412 – 1418 discuss actions when equipment fails to meet performance specifications, and recommends the equipment be promptly adjusted, repaired, or removed from service. International guidance suggests that with an appropriate risk assessment, and clear restrictions on the equipment’s use, the equipment may be used for limited purposes.[10]

Lines 1438 – 1439 describe the reasons for imaging procedures as answering a clinical question or assisting in making a diagnosis.” A third reason is to facilitate an interventional procedure after a diagnosis has been made, using fluoroscopy-guided and CT-guided interventional procedures.

Lines 1453 – 1535 further discuss “reference levels.” Please refer to our remarks regarding lines 148 – 150, and the publication of NCRP Report No. 172, and specifically take note that the statement at line 1473, “as of 2012, U.S. reference levels are not available for most imaging studies,” may no longer be accurate.

Lines 1687 – 1691 discuss the fact that pediatric imaging carries unique concerns. It may be appropriate to include a reference to the recent recommendations relating to pediatric imaging, in see ICRP Publ. 121, “Radiological Protection in Paediatric Diagnostic and Interventional Radiology.”[11]

Lines 2563-2633 describe the use of patients in precision testing and cross-calibrations for dual energy x-ray absorptiometry (DXA) equipment, and specify that this activity is not considered research. We suggest this section be reconsidered in light of state laws and other guidance documents, which generally prohibit, or recommend against, exposing a person to radiation when it is not medically indicated or not done pursuant to an approved research protocol.

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[10] European Commission, Radiation Protection No. 162 “Criteria for Acceptability of Medical Radiological Equipment used in Diagnostic Radiology, Nuclear Medicine, and Radiotherapy,” Directorate-General for Energy, Directorate D – Nuclear Safety and Fuel Cycle, Unit D – Radiation Protection (2012) (http://ec.europa.eu/energy/nuclear/radiation_protection/doc/publication/162.pdf).

[11] ICRP Publ. 121, “Radiological Protection in Paediatric Diagnostic and Interventional Radiology JAICRP 42(2).

Lines 3376 – 3378 recommend that if a facility's mean dose for a procedure exceeds a reference level, steps should be taken to reduce the dose, and conversely, if the mean dose is significantly lower than a reference dose, that image quality should be reviewed. We suggest consideration of these two factors, patient dose and image quality, be taken together in either case (doses lower or higher than a reference level), and that the two factors be optimized in tandem.

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