June 3, 2013

Attn: Docket ID No. EPA-HQ-OAR-2010-1064
Air and Radiation Docket and Information Center
Environmental Protection Agency
Mailcode: 6102T
1200 Pennsylvania Ave. NW,
Washington, DC 20460

Subject: (Docket ID No. EPA-HQ-OAR-2010-1064) Radiation Protection Guidance for Diagnostic and Interventional X-Ray Procedures; Comments of the American College of Radiology

On behalf of the American College of Radiology)—a professional organization representing more than 35,000 radiologists, radiation oncologists, interventional radiologists, nuclear medicine physicians, and medical physicists—we appreciate the opportunity to comment on the Environmental Protection Agency’s (EPA) Guidance Report No. 14, “Radiation Protection Guidance for Diagnostic and Interventional X-Ray Procedures,” published in the Federal Register on April 3, 2013.

The ACR is an ardent supporter of quality and safety in medical imaging and we advance these priorities through our national initiatives, such as imaging facility accreditation, practice guidelines and technical standards, Appropriateness Criteria for physicians who order imaging examinations, robust national radiology registries (including the ACR Dose Index Registry), the Image Wisely and Image Gently campaigns, and more. We encourage the EPA and federal medical facilities to leverage the programs, educational opportunities, and resources provided by the ACR for enhanced patient care, facility quality control/assessment, and patient safety.

Please see the attached general, editorial, and technical comments compiled by the Government Relations Committee of ACR’s Commission on Medical Physics. Please contact Gloria Romanelli, ACR Senior Director, Legislative and Regulatory Relations, or Michael Peters, ACR Director of Legislative and Regulatory Affairs at 202-223-1670 if you have questions or need additional information.

Sincerely,

Paul H. Ellenbogen, MD, FACR
Chair, Board of Chancellors
American College of Radiology
General Comments

The American College of Radiology (ACR) recommends that future iterations of EPA Guidance Report No. 14 include detailed information via reference or linking to evolving external sources, such as ACR’s various practice guidelines and technical standards. This would both shorten the guidance to support its intended use in busy federal medical facilities as well as keep the guidance relatively current in the future as the reference materials are updated over time.

Alternatively, EPA could include the more detailed content as an addendum and feature the recommendations and/or an executive summary as the primary guidance. This would shorten the key material for federal facilities; however, the lengthy addendum would soon become outdated.

Editorial and Technical Comments

Lines 133 and 3341, pages IV and 3341 / technical

The report suggests that federal facilities should plan for longitudinal tracking of patient radiation doses. "Longitudinal tracking" implies collection of discrete event doses for the purpose of adding them up to produce approximate lifetime doses. There is significant controversy about doing this for several reasons. For instance, experts have not yet agreed to a suitable metric relevant to an individual patient to accomplish this (for example, effective dose is not relevant to individual patients). Moreover, there is evidence that the risks may not be precisely cumulative for all cancers. Finally, this could encourage patients and ordering physicians without imaging expertise to base imaging decisions necessary for important healthcare questions on questionable dose values and thereby result in decisions detrimental to the patient's care and management. It would be preferable for the health care of patients within federal facilities to longitudinally track imaging examinations rather than dose, until the above issues are addressed by the medical physics community.

Lines 371-500, pages 1-3 / editorial

“As of 2012,” “in 2012,” and similar statements used to date the information to 2012 are frequently throughout the guidance report. To avoid redundancy, we recommend adding a sentence to the introduction indicating “all information represents the EPA’s knowledge as of 2012,” and deleting the later statements.

Lines 640-641, page 7 / technical

The statement “the facility should avoid substantial variation above a uniform monthly exposure rate of 0.5 mSv/month” implies that 0.5 mSv/m is always acceptable. We recommend that, for ALARA reasons, the sentence instead read: “the facility should avoid substantial variation above uniform monthly exposure rate as far below 0.5 mSv/month as is consistent with the worker performing her duties.” For example, if a given facility’s typical values are 0.01 mSv/month, any anomalously higher values within 0.5 mSv/month should still be investigated by that facility.

Lines 735, 749, 751, 1393, 1396, and 1429, pages 9, 24, and 25 / technical
The term “qualified physicist” should instead read “qualified medical physicist.” Only medical physicists have the qualifications and expertise to perform the qualified physicist duties discussed throughout the guidance report.

**Line 853, page 11 / editorial**
We recommend referencing the comprehensive “ACR Practice Guideline for Imaging Pregnant or Potentially Pregnant Adolescents and Women with Ionizing Radiation” ([http://www.acr.org~/media/ACR/Documents/PGTS/guidelines/Pregnant_Patients.pdf](http://www.acr.org~/media/ACR/Documents/PGTS/guidelines/Pregnant_Patients.pdf)). A new version of this practice guideline was approved in May 2013. The document will be formally published in October 2013; however, ACR could provide EPA staff with a link prior to publication if needed.

**Lines 918-920 and 961-981, page 13 and 14 / technical**
Procedures mandated by the research protocol are part of a “research study” unless there is compelling evidence otherwise. Clarification is needed because standard clinical procedures may be performed on a subject only if required by the research protocol (would not be done but for the research) or required to be performed more frequently (e.g. monthly instead of annually) than needed for clinical management in the absence of research.

**Lines 933-934, page 13 / editorial**
We recommend clarification that each organ and tissue at risk should be estimated, rather than dosimetry performed for all organs and tissues.

**Line 1064-1067, page 16 / technical**
We recommend clarification of these statements—“all exposures to radiation should involve a benefit:risk analysis” and "most appropriate radiological or non-radiological procedure is selected on the basis of its benefit:risk ratio.” "Analyses" usually tend to be complex, quantitative reports, and "ratios" are unquestionably quantitative. In practice, clinical decisions evaluating benefit versus risk are more qualitative and subjective in nature and are sometimes made quickly to save the life of the patient. The above statements should be revised to remove the quantitative terminology.

**Line 1147, page 18 / editorial**
Although it is strongly hinted by the text, EPA should include a more definitive statement that only properly credentialed radiologic technologists (i.e., licensed or certified by the appropriate organization in the applicable modality) should conduct imaging examinations when feasible. We recognize there are circumstances that require flexibility on this—for example, imaging services provided by the military in combat zones.

**Lines 1257-1258, page 20 / editorial**
“One is patient self-referral, where patients refer themselves for an imaging procedure without having a physician request (referral).” Perhaps EPA should also discuss the "self-requesting" subcategory of patient self-referral. Self-requesting patients do not have physicians, while patients self-referring do. Self-requesting patients present unique challenges, particularly if problems are found with the imaging
(see http://www.fda.gov/Radiation-EmittingProducts/MammographyQualityStandardsActandProgram/Guidance/PolicyGuidanceHelpSystem/ucm135597.htm).

**Line 1357, page 23 / editorial**
We recommend referencing the new ACR “CT Quality Control Manual” (http://www.acr.org/Education/Education-Catalog/Products/8336734).

**Line 1369, page 23 / editorial**
We recommend indicating that monitor testing should also follow the AAPM On-Line Report No. 03, "Assessment of Display Performance for Medical Imaging Systems" (commonly known as TG18) as applicable.

**Line 1359, page 23 / editorial**
“Film-screen” should be revised to read "screen-film" throughout.

**Line 1376, page 23 / editorial**
We recommend adding "it is important to note that technique factors (and resulting dose) for the same patient may vary with the manufacturer and model of the imaging equipment used in order to obtain necessary image quality."

**Line 1389, page 24 / editorial**
The term "national standards" should be changed to read "national reference levels.”

**Line 1403, pages 24-25, Table 1 / technical**
The “x” indication under “After Modification or Repair” for “Perform an Acceptance Test” should be clarified. Readers could interpret the mark to mean that acceptance testing should be done after each individual service call. Instead, acceptance testing should be limited to initial acceptance and partial acceptance testing is indicated when major repairs (e.g. new x-ray tube) are performed.

Additionally, the “task” in the sixth row of Table 1 should be revised to read "assess the typical patient dose indices for various examinations for comparison to national reference levels.”

**Line 1416, page 25 / technical**
We recommend adding "the Qualified Medical Physicist should provide a written report of the findings of acceptance testing and performance evaluation to the professional(s) in charge of obtaining or providing necessary service to the equipment and, if appropriate, to the responsible physician(s). If appropriate, the Qualified Medical Physicist should notify the facility to initiate the required service. Written reports must be provided in a timely manner consistent with the importance of any adverse findings.”

**Line 1433, page 25 / technical**
The word “rate” should be added after “entrance skin exposure.” The important quantity to measure in fluoroscopy is exposure rate.

**Lines 1466 and 3365, pages 26 and 74 / technical**

“These levels are based on exposure to a standard phantom or actual patient dose metrics for specific procedures measured at a number of representative clinical facilities.” The International Commission on Radiological Protection defines reference levels as pertaining to specific patient sizes; therefore, we recommend the following revision: “these levels are based on exposure to a standard phantom or actual patient dose metrics of standard size patients for specific procedures measured at a number of representative clinical facilities.”

**Line 1473, page 26 / technical**

The statement “U.S. reference levels are not available for most imaging studies” is no longer correct in 2013. We recommend revising this to recognize the National Council on Radiation Protection & Measurements’ report No. 172, “Reference Levels and Achievable Doses in Medical and Dental Imaging: Recommendations for the United States,” and the “ACR Practice Guideline for Diagnostic Reference Levels in Medical X-Ray Imaging” ([http://www.acr.org/~/media/ACR/Documents/P}GTS/guidelines/Reference_Levels.pdf]). A new version of this practice guideline was approved in May 2013. The document will be formally published in October 2013; however, ACR could provide EPA staff with a link prior to publication if needed.

**Line 1474, page 26 / technical**

"In order to generate national RLs for the U.S., it is essential that institutions where these procedures are performed submit radiation dose metrics to a central dose registry." Reference levels and a national dose index registry already exist, so we recommend revising the above sentence to: "In order to update national RLs for the U.S., it is essential that institutions where these procedures are performed submit radiation dose metrics to a central dose registry, such as the national ACR Dose Index Registry" ([http://www.acr.org/Quality-Safety/National-Radiology-Data-Registry/Dose-Index-Registry](http://www.acr.org/Quality-Safety/National-Radiology-Data-Registry/Dose-Index-Registry)).

**Line 1607-1608, page 30 / editorial**

We recommend deleting “primarily mAs.” The inclusion of this text is not well supported by the guidance report, and providing adequate technical details to support its inclusion would unnecessarily complicate the document.

**Line 1745, page 33 / technical**

There is sufficient controversy in the scientific community regarding what constitutes an appropriate use of gonadal shielding, and the reduction in the tissue weighting factor for gonads from 0.20 to 0.08 (ICRP 103, 2007) is indicative of the reduced significance of the hereditary effects of radiation. Further clarification is needed for federal facilities to determine when the use of gonadal shielding is appropriate and/or necessary, and when the benefit of using it exceeds the risk.

**Line 1746, page 33 / editorial**
We recommend adding the statement, "PA positioning can also be used in lieu of shielding to reduce radiation dose to the thyroid and breast" (reference http://www.acr.org/~/media/ACR/Documents/PGTS/guidelines/Scoliosis.pdf).

**Lines 1874-1877, page 38 / editorial**
The statement about the disadvantages of skin dose measurement is subjective and not entirely appropriate for a federal guidance report.

**Around line 2008, page 41 (and references) / editorial**

**Lines 2024 and 2039, page 42 / editorial**
We recommend changing “dose measurement” to “dose estimation” because dose can only be estimated.

**Lines 2032-2034, page 42 / editorial**
This pair of sentences should be rewritten or further clarified to avoid potential confusion and the appearance of contradiction. “Cumulative air kerma is readily available on fluoroscopy units purchased after mid-2006 and is an acceptable substitute for PSD. It does not correlate well with PSD in individual cases (Miller et al. 2003a; Miller et al. 2003b).”

**Line 2216, page 46 / technical**
This line should be clarified to state that not every case must be individually presented, but that a statistical summary is appropriate for institutional QA. However, known radiation injury cases should be individually included in QA.

**Line 2242, page 46 / editorial**
We recommend adding a statement about the protection of inspectors consistent with the “Dental” section: “Consideration should be given to minimizing the radiation exposure of inspectors by minimizing unnecessary fluoroscopy.”

**Line 2268, page 47 / editorial**
The use of the term “doses” is ambiguous in the context of the paragraph.

**Lines 2791-2801, page 59 / editorial**
This pair of statements should be rewritten or further clarified to avoid potential confusion and the appearance of contradiction. *"According to NCRP Report No. 145, technological advancements have eliminated the requirement for lead aprons on patients when all of the following recommendations are followed: a 60-80 kVp intraoral exposure unit is used, the source-to-image receptor distance for intraoral radiography is between 20-40 cm, a rectangular collimator is used for intraoral radiographs, and a minimum of E-speed equivalent exposure film/sensors is used. It is not unreasonable to have aprons available for patients who request their use (NCRP 2003). ... NCRP Report No. 145 states that, “thyroid shielding shall be provided for children, and should be provided for adults, when it will not interfere with the examination” (NCRP 2003)."

**Line 3224, page 70 / editorial**

"These systems should also be capable of transmitting de-identified patient radiation dose data to a central dose registry." We recommend revising the above sentence as follows: "These systems should also be capable of transmitting de-identified patient radiation dose data to a central dose registry, such as the national ACR Dose Index Registry."

**Lines 3228-3381, pages 71-74 / editorial**

We recommend that the subheadings in the “Summary and Recommendations for Facility Action” section reflect the modality headings in the main body of the guidance report. For example, radiography and computed tomography are not represented.

Moreover, we recommend moving this section to the beginning of the guidance report as an executive summary.

**Line 3357, page 73 / editorial**

EPA should consider including an appendix with a sample document discussing patients’ radiation risk written using language suitable for both the clinical and research contexts and scored at Flesch-Kincaid Grade Levels 7 or 8.

**Line 3260, page 71 / editorial**

"Facilities should use reference levels as a quality improvement tool by collecting and assessing radiation dose data. Each facility should also submit its radiation dose data to a national registry, if and when such a registry is available." This statement erroneously implies that a national registry is not already available; therefore, we recommend the following revision: "facilities should use reference levels as a quality improvement tool by collecting and assessing radiation dose data. Each facility should also submit its radiation dose data to a national registry, such as the national ACR Dose Index Registry."

**Line 3285, page 72 / technical**

We suggest deleting "or weight." Tall, thin children will require less technique (and dose) than short, heavy children of the same weight.

**Line 3287, page 72 / editorial**
"In general, facilities should ensure that neither screening nor elective x-ray examinations are performed on pregnant women." We recommend changing this sentence to: "in general, facilities should ensure that neither screening nor elective x-ray examinations where the fetus is near or in the x-ray beam are performed on pregnant women." There are elective x-ray examinations that would result in no significant dose to the fetus, and these should not necessarily be declined in every circumstance.

**Lines 3353-3356, page 73 / editorial**

With the exception of the pregnant patient, situations necessitating informed consent (i.e., "significant risks and potential complications") are quite vague and this should be further clarified. For example, the only procedure that the ACR recommends obtaining informed consent regarding radiation exposure is for interventional procedures (see [http://www.acr.org/~/media/ACR/Documents/PGBTs/guidelines/Informed_Consent_Image_Guide.pdf](http://www.acr.org/~/media/ACR/Documents/PGBTs/guidelines/Informed_Consent_Image_Guide.pdf)). The ACR does not suggest obtaining informed consent regarding radiation issues for procedures such as CT or radiography.

**Line 3371, page 74 / editorial**

"Facilities should submit radiation dose data to a national registry, if and when available." Such a national dose index registry already exists; therefore, we recommend revising this to read: "facilities should submit radiation dose data to a national registry, such as the national ACR Dose Index Registry."

**Line 3372, page 74 / technical**

"Facilities should ensure that a representative sampling and assessment of exposure indicators from each modality is performed at least annually, but preferably quarterly." A quarterly sampling and assessment is overly optimistic and unnecessary for most facilities. We recommend revising this to read: "facilities should ensure that a representative sampling and assessment of exposure indicators from each modality is performed at least annually." We also suggest revising line 1444 accordingly.

**Line 3376 and 3379, page 74 / technical**

"If the mean radiation dose at the facility exceeds the reference level, the facility should investigate as appropriate to reduce radiation dose. If the mean radiation dose is significantly lower than the reference level, the facility should evaluate image quality." This recommendation should be revised to point out that the mean dose index evaluated is for a specific phantom or standard size patient. Mean dose indices should not be compared among facilities due to variations in population patient sizes in different geographic areas or different facilities. For example, hospitals that specialize in bariatric patients should not compare mean dose indices against those with a smaller patient population. Likewise, pediatric hospitals should not compare their mean dose indices against general hospitals. We also suggest revising line 1484-5 and the statement at line 3379 accordingly.

**Line 3912, page A-1 / editorial**

The table was first published in NCRP Report 168, so the reference should be corrected to indicate the original source. The ICRP/Martin references were included in NCRP 168 to provide a historical basis—these should be deleted or revised to indicate that these refer to one column on the table rather than
the full table. Ideally, the ICRP and Martin columns should be deleted entirely, as the NCRP column should be used for the purposes of EPA Guidance Report No. 14.

**Lines 3916-3944, page A-2 / editorial**
The reading level of this sample is probably too high and likely to draw the prospective subject’s attention away from other, more substantial research risks. We recommend simplification of this statement to something that conveys radiation risk in a short and meaningful format (with a Flesch-Kincaid Grade Level of less than 8).

**Lines 3946-3990, page A-3 / editorial**
There appear to be mismatches on risk between this section and the risk table at the beginning of A-1. Both of the informed consent samples should match the NCRP column of the risk table. Moreover, the reading level is too high and should be revised to a Flesch-Kincaid Grade Level of less than 8.

**Line 3992-4420, pages REF 1-REF10 / editorial**
Most of the references to ACR practice guidelines and technical standards are out of date. Please access the following URL for the current titles and versions of those documents: [http://www.acr.org/Quality-Safety/Standards-Guidelines](http://www.acr.org/Quality-Safety/Standards-Guidelines).

We also recommend adding the ACR’s new “CT Quality Control Manual” ([http://www.acr.org/Education/Education-Catalog/Products/8336734](http://www.acr.org/Education/Education-Catalog/Products/8336734)) to the references.