AMERICAN ASSOCIATION of PHYSICISTS IN MEDICINE

September 6, 2016

Michelle K. Austin
Rules Project Manager
Washington State Department of Health
P.O. Box 47820
Olympia, WA 98504-7820

VIA E-Mail: michelle.austin@doh.wa.gov

Re: Chapter 246-226 WAC, Radiation Protection—Computed Tomography Proposed Rules

Dear Ms. Austin:

The American Association of Physicists in Medicine (AAPM)[1] is pleased to submit comments to the Washington State Department of Health (WA DOH) regarding the proposed rules for the safe and effective use of computed tomography (CT) X-ray systems for diagnostic purposes. The AAPM commends WA DOH on its work in developing these proposed regulations, including requirements for facilities, equipment, staffing, operation and maintenance, records, and reporting requirements, intended to reduce radiation exposure to the public and to help prevent incidents of overexposure of patients and staff. However, we have the following specific comments:

1. Consistency with CRCPD SSRCR, Part F

The AAPM strongly recommends that WA DOH adopt the Conference of Radiation Control Program Directors (CRCPD) Suggested State Regulations for Control of Radiation (SSRCR), Part F[2], Medical Diagnostic and Interventional X-Ray and Imaging Systems and specifically, Sec. F.11-- Computed Tomography Equipment, as the primary basis for its CT regulations. We recognize that WA DOH began its revision to your regulations about the same time that the CRCPD began modifying SSRCR,

[1] The American Association of Physicists in Medicine (AAPM) is the premier organization in medical physics, a broadly-based scientific and professional discipline encompassing physics principles and applications in biology and medicine whose mission is to advance the science, education and professional practice of medical physics. Medical physicists contribute to the effectiveness of radiological imaging procedures by assuring radiation safety and helping to develop improved imaging techniques (e.g., mammography CT, MR, Ultrasound). They contribute to development of therapeutic techniques (e.g., prostate implants, stereotactic radiosurgery), collaborate with radiation oncologists to design treatment plans, and monitor equipment and procedures to insure that cancer patients receive the prescribed dose of radiation to the correct location. Medical physicists are responsible for ensuring that imaging and treatment facilities meet the rules and regulations of the U.S. Nuclear Regulatory Commission (NRC) and various state regulatory agencies. AAPM represents over 8,500 medical physicists.

[2] CRCPD SSRCR Part F – Computed Tomography Equipment, link: http://www.crcpd.org/SSRCRs/Fpart_2015.pdf.

Part F. When developing the SSRCRs, including Part F, CRCPD has a very rigorous development and review process prior to the Board's approval of an SSRCR. This process includes state representation of the committee to develop the SSRCR; interaction with federal regulators (e.g., the U.S. Food and Drug Administration), the medical community and equipment manufacturers; an extensive peer review; and finally, approval by the CRCPD Board of Directors. The purpose of this process is to advance greater uniformity of state regulations.

More specifically, the AAPM noted several key omissions in the draft WA DOH proposed regulations that are explicitly specified in Part F. These include:

- No requirement that all diagnostic CT x-ray systems for human use be accredited by an accrediting organization recognized by WA DOH or the Centers for Medicare & Medicaid Services.
- All definitions in Part F are not included in the WA DOH proposed rule, or are defined slightly differently than in Part F. For example, some of the Part F definitions not included in the WA DOH proposed rule are: $CTDI_{100}$, CT conditions of operation, and CT gantry.

2. Definition of QMP

As currently proposed in WAC 246-226-065 *Qualified Medical Physicist,* this provision provides three alternative pathways to be considered a "Qualified Medical Physicist". The AAPM believes that the pathways as proposed are insufficient to assure that individuals providing the designated medical physics services are qualified to do so. This is especially true given the complexity of modern CT equipment, as well as the expanded duties and expectations of the QMP (e.g., CT protocol review, policies and procedures consultation, CT event investigation duties, etc.). The AAPM recommends that WA DOH consider adopting AAPM's definition as stated in AAPM's Professional Policy Statement[3] or the definition of Qualified Medical Physicist from CRCPD SSRCR, Part F, Sec. F .11:

"Qualified medical physicist (QMP)" means an individual who meets each of the following credentials:

1. *Has earned a master's and/or doctoral degree in physics, medical physics, biophysics, radiological physics, medical health physics, or equivalent disciplines from an accredited college or university; and*

[3] AAPM Professional Policy 1, *Definition of a Qualified Medical Physicist*; link: http://www.aapm.org/org/policies/details.asp?id=316&type=PP.

2. *Has been granted certification in the specific subfield(s) of medical physics with its associated medical health physics aspects by an appropriate national certifying body and abides by the certifying body's requirements for continuing education;*

However, if WA DOH is not willing to adopt either of these definitions, then AAPM recommends the following changes to WA DOH's proposed definition:

WAC 246-226-065 Qualified medical physicist. A qualified medical physicist must meet the requirements of either subsection (1) or (2), and meet the continuing education and experience requirements of subsections (3) and (4) of this section to perform the duties of a qualified medical physicist as they apply to CT. To qualify as a qualified medical physicist, an individual must:

(1) Hold a valid certificate in:
  (a) Diagnostic medical physics, diagnostic radiological physics, diagnostic imaging physics or radiological physics from the American Board of Radiology;
  (b) Diagnostic imaging physics from the American Board of Medical Physics; or
  (c) Diagnostic radiological physics from the Canadian College of Physicists in Medicine.

(2) Complete the following education and experience:
  (a) Graduate from an accredited institution with a graduate degree in medical physics, radiological physics, biophysics or equivalent discipline from an accredited college or university; and
  (b) Independently evaluate at least ten CT X-ray systems in accordance with this chapter under the personal supervision of an individual meeting the requirements of subsection (1) of this section.

(3) **Continuing education:**
  (a) The qualified medical physicist must have earned at least fifteen continuing medical education units in the three years preceding any department review or inspection.
    (i) At least half the units must be accredited by the Commission on Accreditation of Medical Physics Education Programs (CAMPEP), Accreditation Council for Continuing Medical Education, or equivalent accreditation; and
    (ii) At least one of the units must pertain to CT.
  (b) The requirements of this subsection are waived if it has been less than three years since the qualified medical physicist met the requirements under subsection (2) of this section.

(4) **Continuing experience:** The qualified medical physicist must meet (a) or (b) of this subsection in the two years preceding any department review or inspection:
  (a) Independently evaluated at least two CT X-ray systems in accordance with this chapter; or
  (b) Evaluated at least five CT X-ray systems in accordance with this chapter under the direct supervision of a qualified medical physicist;
  (c) The requirements of this subsection are waived if it has been less than two

years since the qualified medical physicist met the requirements of subsection (2) of this section.

3. WAC 246-226-040 Operating Procedures

AAPM recommends that this section be reworked to explicitly state that "the registrant shall develop and maintain a CT Radiation Protocol Committee (RPC)" and that this follow the recommendations as defined by AAPM Medical Physics Practice Guideline (MPPG) 1.a. CT Protocol Management and Review Practice Guideline[4] or adopt the language in SSRCR Part F.

4. WAC 246-226-070 Staffing Requirement

Clarification is needed in regard to WAC 246-226-070 (4) proposed regulation that states: *the registrant shall appoint a lead interpreting CT physician and a lead CT technologist to work cooperatively to:*

(a) Develop, implement, and enforce policies, procedures, and registrant requirements that address:

(i) Radiation protection, the hazards of radiation exposure to both patients and facility personnel, and appropriate monitoring;

(ii) Identification of pregnant or potentially pregnant patients; and etc.

AAPM believes that a qualified medical physicist should also be involved in carrying out the requirements in this section, specifically WAC 246-226-070 (4) (a) (i), (ii), and (iii).

5. Require QMP for CT Dose Measurements

AAPM recommends that a QMP be required for measuring CT dose / CTDI volume. As noted above, CT technology and dosing issues have become more complex. We believe that this requirement would best ensure safety and efficacy for patients.

6. WAC 246-226-030 Design Requirements

AAPM recommends that a qualified medical physicist be involved in carrying out the requirements in this section, specifically WAC 246-226-030 (2), to be consistent with CRCPD SSRCR, Part F.

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[4] AAPM MPPG 1.a. link: http://www.aapm.org/pubs/MPPG/documents/MPPG1a.pdf.

In summary, the AAPM hopes that WA DOH will consider AAPM's recommendations when formulating the final CT rule and believes a rule based on CRCPD SSRCR Part F would provide a sound regulatory framework. Should WA DOH staff have any questions, please contact Richard J. Martin, J.D., at (571) 298-1227 or richard@aapm.org.

Sincerely,

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