



HEALTH PHYSICS SOCIETY

Specialists in Radiation Safety

September 26, 2022

CRCPD
112 E. Main Street, Suite 1
Frankfort, KY 40601

John Cardarelli
President

Subject: Suggested State Regulation for Control of Radiation: Part X – Medical
Therapy

The Health Physics Society¹ (HPS) is a professional organization whose mission is to promote excellence in the science and practice of radiation safety. The HPS appreciates the opportunity to provide comments, in the attached document, as a response to the request for public comment.

If you have any questions regarding these comments, please contact the HPS Agency Liaison, Craig Little at 970-260-2810 or by email to agencyliaison@hps.org.

Sincerely,

John Cardarelli
President

cc: Craig Little, PhD, HPS Agency Liaison
Brett Burk, HPS Executive Director
Andy Miller

¹ The Health Physics Society is a non-profit scientific professional organization whose mission is to promote the practice of radiation safety. Since its formation in 1956, the Society has grown to include over 4,000 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.

Health Physics Society Comments on Proposed Suggested State Regulation for Control of Radiation: Part X – Medical Therapy

Section X.2

- Line 22 and 96: specifically listing the removal of the special dose unit rad should not be necessary.
- Line 73: Provides definition of Electronic Brachytherapy
 - A clearer definition of low energy should be included (i.e., specific energy range)
- Should add definition of Qualified Expert
 - State required qualifications in X.3. Recommend including Certified Health Physicists who have appropriate training and experience.
 - Un-delete qualified expert in X.4(b)(iii)
- Line 230: the Radiation Safety Officer's leadership of the radiation protection program is important to its overall function. As a result, we recommend including "the leadership of the Radiation Safety Officer"
- Line 233: to ensure the oversight of the radiation safety program, the Radiation Safety Officer should be included in the Radiation Oncology Safety Team. To that end, please revise the definition of Radiation Oncology Safety Team.
 - "Radiation oncology safety team" means a team that shall include, but is not limited to, the lead authorized physician, qualified medical physicist, lead radiation oncology therapist, the radiation safety officer, and other individuals as deemed necessary by the registrant (e.g. chief medical or administrative officer, department administrator/manager, nurse).

Section X.3

- Line 349 (c.): As Medical Board exams are now given after residency is completed. Requiring board certification would limit the ability of the physician to practice for 1 to 2 years after completing training. The proposed regulations would prevent an otherwise qualified physician from practicing. To address this, the alternate provisions in lines 373-434 should be retained.
- Line 436: This requires Board Certification for Medical Physicists.
 - An alternate route or exemption requirements should be discussed (i.e., for Medical Physicists in the process of getting certification).
 - Removing the alternate pathway requirements for medical physicist qualifications will exacerbate the already limited resource pool. These alternate requirements should be retained.
- Line 506: This requires the operator to demonstrate familiarity with safety procedures, rules, and emergency procedures.
 - Physical demonstration should be required for certain tasks (i.e., locations of termination switches, use of radiation survey instruments, interlocks, etc.)

- Line 554: The return to clinical service should be decided by the QMP and the responsible radiation oncologist with input from safety professionals.

Section X.4

- Line 575 - X.4(a)(ii)
 - Change first sentence to “Facility shielding and safety designs shall be performed in accordance with current published Agency regulations or recommendations or recommendations from a recognized...”
- Line 588: Specifies requirements for shielding survey
 - This section should include specific language about performing a radiation survey before performing acceptance and commissioning
- Line 607: a qualified expert is not defined. A provision should be included for a Qualified Medical Health Physicist as provided for in the American Association of Physicists in Medicine (https://w3.aapm.org/medical_physicist/fields.php) to provide radiation safety and auditing services separate from the QMP.
 - By removing "qualified expert", the CRCPD may be preventing experienced physicists such from doing shielding design and radiation protection surveys which would result in safe facilities.
 - The CRCPD should include "qualified experts" in Part X to allow non-medical physicists who have the qualifications and experience to design safe therapy facilities. Qualified experts who have sufficient education and experience in Radiation Physics related to medical therapy facilities; and are certified by the American Board of Health Physics should be allowed to do shielding design and radiation protection surveys.
- Line 635: Consistent with the recommendation above for Line 476, the definition of Medical Physicist should provide for an alternate pathway.
- Line 634 - X.4(b)(iii)
 - Please consider adding make, model, serial number, and calibration date of survey instrument(s).

Section X.5

- Line 740: With modern linacs, the treatment energy can be optimized during treatment planning and is not a crucial part of the physician’s directive. The specifications for the written directive should be left to consensus guidelines such as those from ASTRO.
- Line 790 - X.5(b)
 - For clarity, the list and definition of medical events (b)(ii)(1-4) should be presented first. Suggest that you transpose (b)(i) and b(ii).
 - The terms “administered dose” in (2) and (3) and “administered dose over the entire treatment course” as used in (4) should be defined in X.1.
- Line 803: Mentions wrong treatment technique in Medical Event Reporting
 - Should specify if this includes energy and radiation type. If this is not intended to include energy and radiation type, there should be specific language addressing energy and radiation type.

- Line 853: The requirement to “notify any other healthcare providers actively involved in the patient’s care...” is overly broad and should be further clarified. A healthcare provider may include physicians, nurse practitioners, physician’s assistants, and technologists. Using “healthcare providers directing the patient’s care”.

Section X.6

- Line 904: the first use of IEC should be spelled out as “International Electrotechnical Commission (IEC).”
 - Line 907 in paragraphs X.6(a)(i and ii), there is inconsistent use of dose units. Standard terminology calls for mGy.
- Lines 1174 & 1193: This changes the monthly safety QA checks to 36 days
 - This should be reverted to 30 days

Section X.7

- Lines 1245, 1925, 1946, & 2415: Specify requirements for survey instruments to be specific to dose rate (mrem)
 - Should also include survey meter measuring in exposure rate (mR/hr)
- Lines 1253-1254: the IEC disclaimer should only apply to points related to the specific device in this section; sections p (Line 1624) and beyond relate to facility design specifications and not the device.
- Lines 1866 & 1877: References testing termination switches twice (once in part b and again in part f)
 - Should look to consolidate
- Line 2120: References a QMP determining which persons in the treatment room require monitoring when the beam is energized
 - Should include RSO as option in this determination
- Line 2446: Requires that survey meter calibration record be maintained for the duration of the registration.
 - Should request survey meter calibrations be maintained for 3 years to match other regulations (10CFR35.2061)

Comment on items in similar sections of X.6 and X.7

- X.6(o) and X.7(p)
 - Touch sensor on powered door jam. Sensor detects when door closing is obstructed
 - Consider adding requirement that a sensor be placed on the edge of the door or door jam to detect when something (e.g., person’s body or appendage) is caught when a powered door is closing.
- X.6(p),X.7(s)
 - Second check of annual calibration by Qualified Medical Physicist
 - Consider adding requirement for peer review of QMP’s calibration, particularly when the equipment is capable of multiple modes (e.g., multiple energies, IRMR, tec.)
- X.6(q),X.7(t)

- Lack of list conditions that would require the QMP to place the machine out of service until the identified deficiency is corrected. Consider expanding this with examples

Appendix A

- Part III G & Part IV C should mimic Part II F, instead of “At least one example calculation” use “The calculations”