Jennifer O'Daniel, PhD Dept of Radiation Oncology Duke University School of Medicine

Shanah Black Divison of Health Service Regulation 809 Ruggles Drive, 2701 Mail Service Center Raleigh, NC 27699-2701

May 27, 2025

Dear DHSR Officers,

I am writing to submit comments on the proposed rules for 10A NCAC 15, in response to the NC DHHS-DHSR Memorandum, "Proposed Readoption/Amendment/Repeal of Radiation Protection Commission Rules 10A NCAC 15 .0501, .0608-.0609, .0802-.0803, .0901-.0910, .1001, .1601, .1901-.1911, .2001-.2011.", dated April 1, 2025.

Thank you for your work in updating these regulations. We were particularly pleased to see the new section .1900 created to specifically address therapeutic linear accelerators. I am an ABR-certified medical physicist, serving an an authorized medical physicist and radiation safety officer on two North Carolina state licenses. I have reviewed the proposed regulations and discussed them with my colleagues in the Duke Department of Radiation Oncology. The comments represent the opinion of our group and do not necessarily represent the views of Duke as a whole. Please see our comments below.

- Rule .0905(a): In addition to the stated registered qualified experts and authorized medical physicists on a site's license, we recommend allowing in-house personnel who meet the requirements of Rule .0214(a)(7)(A) or (B) to be able to be conduct the facility design and to perform radiation surveys. Large health care enterprises such as Duke will often have dedicated radiation safety personnel (health physicists) that are not Authorized Medical Physicists.
- 2. **Rule .0905(c):** Recommend changing "Master's Degree in physics..." to "Master's Degree in physics or a related field..." to be inclusive of individuals with backgrounds in nuclear engineering, etc.
- 3. **Rule .0909(e):** We would like to add clarification that linear accelerators producing photon radiation up to 18MV are not considered to produce significant airborne hazards and therefore would not require these annual surveys.

- Reference: Tana L, Ciolini R, Ciuffardi E, Romei C, d'Errico F. Evaluation of air photoactivation at linear accelerators for radiotherapy. J Radiol Prot. 2015 Jun;35(2):239-48. doi: 10.1088/0952-4746/35/2/239. Epub 2015 Mar 11. PMID: 25760952.
- 4. Rule .1902(a)(17): We recommend updating the definition of isocenter to include collimator and couch motion. "...the center of the sphere through which the useful beam axis passes while the gantry, <u>collimator, and couch</u> move through <u>their</u> full <u>ranges</u> of motion."
- 5. Rule .1902(a)(30): Defines a "qualified expert" by referring to Rule .0206(a)(7)(A) or (B). When we look up Rule .0206, it refers to reports of installation and does not give any information regarding qualified expert requirements. Is this meant to refer to Rule .0214(a)(7)(A) or (B) instead?
- 6. **Rule .1903(c)(2):** Should this section end with "or" instead of "and"? We recommend allowing the 6 year grace period stated in this section without requiring the physician to already be an AU as currently stated in section .1903(c)(3).
- 7. **Rule .1903(d):** We recommend allowing a pathway to AMP for medical physicists who have completed an approved residency program and are in the process of attaining board certification (similar to the pathway allowed for AU in .1903(c)(2)). The ABR certification allows a physicist to take the Part 2 exam the August following 2 years of residency, and Part 3 one year later. This means that physicists will be working in the clinic for at least 1 year before being able to complete the ABR certification process. An alternative pathway for AMP is currently allowed in 10 CFR 35.51(b).
- 8. **Rule .1903(e)(4):** We recommend adding "certified by the American Board of Radiology in Therapeutic Medical Physics" as appropriate training for RSO
- 9. **Rule .1903(I):** Per the American Society for Radiation Oncology and the American Association for Physicists in Medicine, it is best clinical practice to have a radiation oncologist (not a physician of any specialty) on site during all patient treatments. We strongly recommend having an authorized user on site and accessible.
 - a. Reference: <u>https://www.astro.org/practice-support/quality-and-safety/safety-is-no-accident</u>
- Rule .1904(a)(2)(D): A radiation survey should not be needed due to a change in occupancy. The shielding should be reassessed but that could be calculated with prior survey data. We recommend removing occupancy from this list of items which require a new survey.
- 11. Rule .1904(c) refers to Rule .0927, which we cannot find. Is this meant to refer to .1908?
- 12. **Rule .1907(e)(2):** We recommend clarifying the wording "calibration measurements" to be "therapeutic radiation machine output calibration measurements".
- 13. Rule .1907(f)(2): We recommend adding the Imaging and Radiation Oncology Core: Houston Quality Assurance Center (IROC-Houston) as an alternative for independent verification. While operating similar to an ADCL, they are tasked with verifying radiation

machine performance for any institution participating in NCI clinical trials: <u>https://irochouston.mdanderson.org/</u>. IROC-Houston currently independently measures the output of all photon energies and at least 3 electron energies on an annual basis for all therapeutic linear accelerators that treat patients enrolled in clinical trials in the United States. It would cause a significant burden with no additional benefit if we had to have an independent output verification from both IROC-Houston and an ADCL.

14. **Rule .1907(g)(3):** We believe the wording "cause for a parameter exceeding tolerance...shall be corrected before the system is used for patient...irradiation" is overly strict. Per the AAPM's report on linear accelerator performance tests, "tolerance levels represent the intrinsic performance of a system and can be set based on vendor guidance....while action limits are clinically relevant thresholds that if exceeded may significantly impact patient care." Machines should be allowed to operate within the warning range between tolerance/action criteria while a qualified medical physicist is investigating the underlying cause and working to arrange the repair. While tolerance levels are useful to ensure optimal machine performance, action levels should be determined by the qualified medical physicist to maintain high standards of patient care. Requiring the linear accelerator to cease patient treatments for any tolerance level violation, regardless of the input from the QMP, would create massive delays to patient care with no additional safety benefits.

Thank you for your efforts.

Sincerely,

Jennifer Maniel

Jennifer O'Daniel, Ph.D., DABR, FAAPM Associate Professor, Radiation Physics, Duke School of Medicine Radiation Safety Officer, Duke Regional Hospital