Dear DHSR Officers,

I am writing to submit my 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.

As a board-certified radiation protection professional in North Carolina, my comments are my own and do not necessarily represent the views of my employer. Please see the comments below.

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1. **Section .0903(a)(4)(A).** "**be** a board-certified physician…" should be "**have** a board-certified physician…", because the licensee is often not a physician, but a healthcare organization.
2. **Section .0903(a)(4)(B).** "a board-certified physicist outlined in Rule .1903(d)(1)-(3) of this Chapter", suggest to remove "board-certified" descriptor, as Rule .1903(d)(1)-(3) includes physicist qualifications without board certification.
3. **Section .0905(a).** At least some large health systems in the state employ their own qualified health physicists to conduct shielding design and/or radiation surveys of medical accelerator facilities. It is not practical for the health physicists or their employers to register as service providers to support their own facilities per Rule .0205 and health physicists generally are not Authorized Medical Physicists. I request the Commission to include qualified in-house personnel employed by a facility or corporation to be allowed to conduct the facility design and radiation surveys. Possibly an easy approach here is to reference the newly approved 15.0203 (h) for this in-house personnel exemption from registration requirement.
4. **Section .0905(c).** "…Master's Degree in physics or higher" should be "…Master's Degree in physics *or a related field*, or higher", to be more inclusive to qualified individuals with education background such as medical physics, health physics, nuclear engineering, etc.
5. **Section .0909(e).** Does this verbiage imply that accelerators which are not expected to produce appreciable airborne hazards are exempt from the annual airborne radioactivity survey requirement? E.g. medical or research accelerators that are not used to produce gaseous or volatile radioisotopes.
6. **Section .1001(a)(3)(D).** This line appears to be redundant with (F) in the same paragraph.
7. **Section .1902(30).** There are two items for (30).
8. **Section .1903(c).** I would like to recommend the Commission add one alternative pathway for authorized users:
    1. An alternative pathway to authorized user who has been named on an Agency or state accelerator license or registration, *after* the effective date of

the Rule. The existing pathway in .1903(d)(4) only applies to those who are on a license *on or before* the effective date of this Rule.

9. **Section .1903(c)(2).** Is the "and" at the end supposed to be "or" instead?
10. **Section .1903(d).** I would like to recommend the Commission add two alternative pathways for authorized medical physicists:
    1. An alternative pathway to medical physicists without board certification, qualifying through based on education, training and experience, like in 10CFR35.35.51(b) for radioactive material-based modalities. Otherwise, the "board-certified only" pathway could be problematic for North Carolina have sufficient eligible medical physicist workforce, and it would unreasonably put the AMP qualification bar for accelerators much higher than that for brachytherapy as regulated in 10CFR35.
    2. An alternative pathway to medical physicist who has been named on an Agency or state accelerator license or registration, *after* the effective date of the Rule. The existing pathway in .1903(d)(4) only applies to those who are named on a license *on or before* the effective date of this Rule.
11. **Section .1903(d).** I would also like to recommend the Commission add an alternative pathway to medical physicists without board certification, qualifying through education, training and experience, like in 10 CFR 35.51(b) for radioactive material-based modalities. Otherwise, an overly restrictive pathway option could be problematic for North Carolina have sufficient eligible medical physicist workforce, and it would unreasonably put the AMP qualification bar for accelerators higher than that for brachytherapy as regulated in 10 CFR 35. In the currently proposed framework, it is conceivable that a non-board-certified medical physicist would qualify as an AMP for brachytherapy (via the 10 CFR 35 alternative pathway) but not external beam therapy (due to the lack of an alternative pathway in NCAC).
12. **Section .1903(e).** I would like to recommend the Commission add two alternative pathways for Radiation Safety Officer qualification:
    1. An alternative pathway to Radiation Safety Officer without board certification but qualifying through education, training and experience, like in 10 CFR 35.50, for rationale similar to that listed in Item #11 above.
    2. An alternative pathway to Radiation Safety Officer who has been named on an Agency or state accelerator license or registration, *after* the effective date of the Rule. The existing pathway in .1903(d)(4) only applies to those who are on a license *on or before* the effective date of this Rule.
13. **Section .1903(j)(2).** Typo: "authorized user(s)" should be "authorized medical physicist(s)"
14. **Section .1904(a)(2)(D).** The verbiage mandates a radiation survey after "any changes in occupancy of surrounding areas". This condition should be removed as radiation exposure assessment from only a change in occupancy can be accomplished by scaling existing measurement results, instead of a survey. At least, the condition can be better qualified to something like "any increases in occupancy of surround areas beyond previous assessments", as often shielding

plans have incorporated some conservatism in the occupancy of surrounding areas.

15. **Section .1904(a)(3).** "The survey record shall include: … measured dose rate at several points in each area …" Taking this at literal value, this means that we need to document dose rates measurements for multiple points for each area on the survey report. In practice, the radiation measurements are conducted at multiple points throughout each barrier surface and often the highest reading is documented, but to require the *documentation* of the measurements at "several points in each area" in the survey record seems to be a bit too rigid.
16. **Section .1903(o)** The blanket requirement of open-ended record retention ("until disposal is authorized by the Agency") will likely create unnecessary burden on both the licensee and the Agency. Instead, it would be better for the regulation to state the specific record retention requirements clearly, to provide total clarity to both the license for operational compliance and the Agency for enforcement.
17. **Section .1904(c).** The reference to "Rule .0927" is likely a typo, possibly meant to refer to .1908, which is about instrument calibration.
18. **Section .1904(b)(4).** The word "under" should be removed.
19. **Section .1905(3).** "…to be performed that…" should be to "…to be performed if…"
20. **Section .1907 (b) (6)** The wording, "Treatment space entrances shall be provided with warning lights … which will indicate when the useful beam is "ON" and when it is "OFF"", is somewhat confusing. Is each entrance required to have two warning lights, one to indicate "ON" and the other to indicate "OFF"? The better wording would be to remove the mention of "OFF": "Treatment space entrances shall be provided with warning lights … which will indicate when the useful beam is "ON"".
21. **Section .1907 (c) (1) (A)** The proposed wording puts the responsibility of radiation safety surveys under the Authorized Medical Physicist, which is in contradiction to Rule .1904(a)(1), which also allows a "qualified expert" to perform the surveys. I recommend reducing the wording of this sub-section to "Calibrations required by Paragraph (d) of this Rule", taking out the survey responsibility.
22. **Section .1908 (a).** The topic of survey instrument calibration may be more efficiently addressed by referring to existing regulations, i.e. Rules 15.0307(d)(2) and 15.0307(k)(6), which reference 10CFR35 sections on the survey instrument calibration and documentation in medical RAM use. The survey instruments for RAM and human-use accelerators are primarily in the same instrument categories.
23. **Section .1908(a)(5).** The reference to "Paragraph (d)", which does not exist.
24. **Section .1908 (c)** Is this line supposed to be part of (b) (2) above, instead of a parallel item to 1908 (a) and (b)?
25. **Section .1909 (a)** Possible wording issue, with "Each therapeutic machine … and must consider the types of radiation ….". Adding a proper subject before "must consider…" would make the sentence better, such as "…and the licensee must consider…"
26. **Section .1911.** The scope for this section is defined for all "…US FDA cleared emerging technologies or previously unused features of a future or existing technology system". This scope looks to be overly broad and open to interpretation,

especially the second part on **previously unused features** of an existing technology system. This may cause undue confusion to the licensee community as to what new technologies/features will be subject to this section. I recommend the Commission take the issue of regulating emerging technologies within the licensing guidance, review and approval elements, in a modality/technology-specific manner, similar to how the US NRC regulates emerging technologies in medical use, for which 10 CFR 35.1000 was written in simple terms and enforce in accordance to evolving safety standards of such new technology (e.g. NRC guidance documents).

27. **Additional comment:** I recommend the Commission to consider adding an exemption, either in Section .0900 or .1900, that human-use accelerator facilities are exempt from posting radiation areas signage of the standard wording "Grave Danger: Very High Radiation Area", as required in Rule .1601 (a) (35). The wording "Grave Danger" may be detrimental to patient comfort during treatments; instead, human use facilities may benefit from posting exemption or simplified wording like "Very High Radiation Area". There is a posting exemption in Rule .1601(a)(36) which references 10 CFR 20.1903 (d), for teletherapy.

Thank you for your time and consideration.

Yours sincerely,

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