Dear DHSR Officers,

I am writing to submit my comments on the proposed rules for 10A NCAC 15.0201 – .0213, in response to the NC DHHS-DHSR Memorandom, "Proposed Readoption/Amendment/Repeal of Radiation Protection Commission Rules 10A NCAC 15 .0201-.0213" Dated November 13, 2024.

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

Item 1

15.0201 (g) "*Registrants using radiation machines for non-human use at educational facilities, for forensic medicine, or by service providers for demonstration purposes are subject to the requirements of .0600 of this Chapter*."

Comment:

Is the "non-human use" a typo, and meant to be "human use" instead? Section .0600 regulates "x-rays in the healing arts", i.e. human use. Many parts of Section .0600 involve "the patient" and would not be applicable to the proposed rule as written.

Item 2

15.0201 (i) "*Registrants using ionizing radiation generating devices are subject to the requirements of Section .0800 of this Chapter.*"

Comment:

The lack of specificity for "registrants using ionizing radiation generating devices" is in conflict of the scope of the referred Section .0800. Is this line intended for non-human use only, which is the scope of Section .0800?

Item 3

15.0202 (c) "*The agency may, upon application, grant individual exemptions or exceptions from the requirements of these Rules if it will not result in a radiation dose that exceeds the limits prescribed in these Rules for the protection of public health, safety, or property.*"

Comment:

The proposed verbiage is redundant with existing statement in .0106 (a), which serves the entirety of 10A NCAC 15.

Item 4

15.0204 (b) (6) "*Shielding designs are not required to be submitted for any of the following …*"

Comment:

If shielding designs for these facilities are not required to be submitted, are formal shielding evaluations still required to be conducted by the registrant, per requirements of the rest of the section, 15.0202 (b)(1) – (5), or are they exempt?

Item 5
15.0204 (c) (1) (A) “submit a shielding design in accordance with Paragraph (A) of the Rule…”
Comment:
Is it meant to referencing Paragraph (B) instead of Paragraph (A)?

Item 6
15.0204 (c) (2)
Comment:
Both “additional requirements” in (A) and (B) are just referencing requirements listed in the same section and therefore redundant.

Item 7
15.0204 (c) (3) “*Radiation machines for clinical studies, research, and screenings shall meet the following requirements prior to use…*”
Comment:
Please define “clinical studies, research and screenings”. Are they for human use only? Is “screening” the same as “healing arts mass screening” defined in 15.0602 (a) (26), or does it have its own specific definition in this section?
Registered radiation machines at healthcare facilities and universities may frequently be used in a variety of clinical studies, research and screenings. The proposed requirement for request submission and agency review would likely cause significant burdens (time and effort) on both the registrants and the regulators, without adding meaningful safety values to the public as, at these facilities, human-use research is already subject to rigorous IRB reviews and health screenings are subject to medical practice standards.
Under the existing regulations, the line is clearly drawn with 0.0603(a)(1)(G), with minimal ambiguity and unnecessary administrative burden on clinicians, researchers and regulators. The proposed blanket requirements for “clinical studies, research and screenings” would not add new value to the radiation protection of the public in the State while creating at least a significant amount of confusion and burden on both registrants and regulators.

Item 8
15.0205 (f) “*Persons registered pursuant to Subparagraph(e)(7) of this Rule shall have all surveys, reports, or other work performed, reviewed and signed by a general health or medical physicist registered in accordance with this Rule.*”
Comment:
Please clarify: If a person is already registered as a radiation protection expert, and “all” of his/her “surveys, reports or other work” still need to be reviewed and signed by another registered general health or medical physicist? Then why would a radiation protection expert still be needed? It would be more cost-effective for the “customer” registrant to hire a consultant that qualifies as a general health or medical physicist directly.

Item 9

15.0206. (a) (2) (C)
Comment:
Remove “are requested”.

Item 10
15.0206. (a) (7) (C)
Comment:
The current verbiage should include doctorate degree or degrees in medical physics or other related fields. I recommend including these valuable training backgrounds as part of the eligible qualifications.

Item 11
15.0211 (5) (A)
Comment:
Based on the proposed verbiage, the individual responsible for the radiation protection would be responsible for “investigating and reporting to the agency” on all “known or suspected radiation exposure to an individual”. This needs to be specified to be within reason; otherwise, the RSO for a medical x-ray imaging clinic would be required to investigate and report on all justified medical exposures to the patients and normal occupational exposures to the staff.

Item 12
15.0213 Entire section.
Comment:
Please see my comments in Item 7 above, which are all applicable here. In addition:
The intent of this proposed rule appears to be redundant to existing regulations in 10A NCAC 15. For example, .0603 (a)(1)(G) clearly sets the default boundaries for human use and exemptions can be issued per .0106 (a).
Will the Agency be staffed to evaluate and approve the typical 200+ study protocols submitted annually by a major university alone in a timely fashion ("< 60 days")?
Typical university IRB turn-around time is 4 months. This will add an additional 2 months and likely more (Agency staff will understand nothing in the protocol document) for each study. This proposed requirement and process would likely not add any new, appreciable value to the radiation protection of the public in North Carolina.

Thank you for your time and consideration.

Sincerely Yours,

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