Matt Barrett Comment

I appreciate the effort that the working group has made in editing the .200 rules. Although I do have suggestions for individual rule edits, my main request is for greater clarity about the proposed rules. My confusion with the .200 rules stems from the lack of definitions, which I will explain below.

In the .200 rules, it seems the x-ray working group divided radiation machines into two broad categories. Those categories are radiation generating devices and x-ray machines. Since there are only two main groups, I expected that there would be clear definitions and separation for both groups. Unfortunately, the definitions seem to have changed or are missing entirely and therefore I do not feel the public can reasonably comment on the rules owing to this lack of clarity. In order to illustrate the lack of clarity, let me restate the definitions from the regulations.

Radiation Generating Device is defined in .0802(29).

> *Radiation generating device (RGD)- means any system, device, subsystem, or machine component that may generate, by electronic means, x-rays or particle radiation above 5 keV, but below 1 MeV, and not used for healing parts on humans or animals.* ***(I believe the rule meant healing arts not parts)***

X-ray Machine (I can't find a definition).

Since I cannot locate a definition of "X-ray machine" in the NC or federal rules that are proposed or final, the closest definition I can find is x-ray equipment/system which is defined in 10A NCAC 15 .0602(70) and (73).

> *"X-ray system" means an assemblage of components for the controlled production of x-rays. It includes minimally an x-ray high-voltage generator, an x-ray control, a tube housing assembly, a beam-limiting device and the necessary supporting structures. Additional components which function with the system are considered integral parts of the system.*

If you look at these definitions that means that a Radiation Generating Device is a type of x-ray system/x-ray equipment. Therefore, as used in the .200 rules the definition of x-ray equipment/system cannot be the one the working group meant to be for x-ray machine. The proposed rules stress x-ray machine or RGD, so therefore an RGD cannot be a type of x-ray machine.

Since I can't find a reasonable definition for an x-ray machine in the NC rules, then I am forced to assume that every radiation machine that isn't a radiation generating device is an x-ray machine.

As we saw in the definition above-RGDs are an x-ray system/radiation machine that is not used for healing arts.

> Healing arts is defined in .103(b)(4)
>
> *Healing arts- means the art or science of diagnostic examination using a source of radiation in the diagnosis or treatment of human or animal diseases.*

Therefore, assuming x-ray machine means a radiation machine used for healing arts purposes (because that is the only logical conclusion from the written approved regulations and complete definitions) then multiple proposed .200 regulations fail, because the working group is talking about x-ray machines being used for non-healing arts use.

A. Examples of this are contained in .0201(f), .0201(h) and, .0201(i), .0204(b)(1) and a significant number of other locations in the proposed .200 rules.
B. A further example of the confusion the working group incited is regulation .0204(c)(6). This regulation calls an industrial radiography radiation machine an x-ray machine. However, one doesn't register it on the x-ray machine equipment application form. It needs to be registered on the radiation generating device application form, even though it is called an x-ray machine and not a radiation generating device.

What seems to be occurring in the proposed regulations is that the working group's definition of RGDs has changed from what is printed in .0802(29). If that is correct, then the working group is asking the public to evaluate the .200 rules with the printed definition of RGDs as not correct and never providing a definition of X-ray machines. This makes it basically impossible to comment on the working group's rules because the public doesn't know what the working group is referring to when the rules refer to x-ray machines or RGDs.

A prototypical example of the resulting confusion is rule .204(b)(2) and .204(b)(3). Let me restate the rules:

a. Rule .204(b)(2)

Mobile radiation X-ray machines located out-of-state and brought into this State for use, permanently affixed within a vehicle or trailer, shall meet the following requirements:....

b. Rule .204(b)(3)

Mobile radiation generating devices located out-of-state and brought into this State for use shall meet the following requirements prior to use:.....

The basic difference between those regulations is that one is about x-ray machines and one is about RGDs. So, if there is no definition of RGD or x-ray machine, how can the public comment on rule if we don't know what machines are being referred to?

I figure I will mention one other problem with lack of clarity, and I only mention this problem because it mimicks the exact same problem regarding lack of definitions.

2. .201(h)
"**X-ray machines for non-diagnostic imaging at educational facilities**,.... are subject to the additional requirements of Section .0600 of this Chapter."

The working group hasn't defined x-ray machines and hasn't defined educational facilities. Essentially the working group is asking the public to comment on the following statement:

> *"A machine that isn't defined will be subject to specific additional requirements if it is at a location that isn't defined."*

Conclusion first part

The unfortunate fact is that without clear definitions the public is unable to understand what the working group is referring to. Therefore, during the public comment period I can't make relevant comments because I don't know what machines are being referred to. After the comment period is closed, if the definitions are then revealed, myself and others can't make comments at that time because the comment period will have passed.

So overall I think the working group should edit the .100 rules and put in x-ray machine, radiation generating devices, educational facilities and several other necessary definitions, and then re-release the .200 rules for public comment.

Besides the lack of definitions, these are my other requested changes. I limited these to ones that were not dependent on knowing the definitions of RGDs or x-ray machines.

1. .203(c)(2)(D) and the entire .211

Do not require the individual responsible for radiation protection be on site. The individuals who work at many clinics change so frequently that people would be needing to update their registration constantly. In addition, the liability for all radiation protection is on the owner of a facility which is already on the registration. If you want to put a person in charge of radiation safety that is fine, but don't require them to be on site. This is an unnecessary regulatory burden.

2. .0204(b)
   Comment: Whatever the working group decides is the definition for x-ray machine, I do not believe it is good to have exemptions for only particular listed machines. That means extra machines that are not listed in the exemption list will have to submit unnecessary shielding plans. In addition, the working group defined that even x-ray machine locations that have shielding plans need to submit new ones even if the new machine is less of a radiation risk. This again is increasing work on the agency and registrants for no safety benefit.
   According to the financial impact analysis of the .200 rules documented at the following link https://www.osbm.nc.gov/documents/files/DHHS_2024-09-13/open there was significant benefit for not having excess shielding plans submitted for three documented types of machines. These were bone density, dental handheld, and mammography. A table from the linked document is posted below illustrates that money can be saved in reg .0204 by reviewing fewer shielding plans.

Rule #	State *DHSR agency staff*		State *Law enforcement, educational, and government facilities with RGDs* Local *County law enforcement and educational facilities with RGDs* Private *Privately-owned facilities with Radiation Machines & RGDs* *Service Providers*	
	Cost	**Benefit**	**Cost**	**Benefit**
.0201 .0202 .0203	None	Minimal time savings and incremental improvements in compliance due to increased clarity.	None	Minimal time savings and incremental improvements to compliance due to increased clarity.
.0204	None	$17,024 (time savings) to DHSR staff from reviewing fewer shielding designs. *$32/hr x 2 hrs/plan 266 plans/yr* Minimal time savings from improved clarity/compliance.		$106,400 - $319,200 (cost savings) for registrants from not needing to pay for shielding design. *266 shielding designs/yr x shielding design cost range of $400 - $1,200 per design* *The percentage of the 266 shielding designs per facility type breaks down as follows:* *State: 2%* *Local: 12%* *Private: 86%* Minimal time savings and incremental improvements in compliance due to increased clarity.

Besides just those savings, the financial impact analysis had an additional interesting note.

*Subparagraph (b)(4) provides language a radiation machine shall not be replaced until a service provider confirms that the existing shielding design meets the requirements****. It also requires that documentation of this confirmation be maintained by the applicant. While already allowed under the current rules, this proposed language will emphasize that an existing shielding design might be adequate without having to pay for a new shielding design. In practice, this improved clarity could result in an unquantifiable cost savings for some registrants.***

So the original financial impact analysis document had the purpose of trying to save money and time by stopping unnecessary shielding evaluations. Is that idea still continued in the new regulations? The proposed .204(b)(4) is repeated below.

An X-ray machine shall not be replaced until the existing shielding design, acknowledged previously by the agency, is reviewed by a registered service provider in accordance with Rule .0205. The registrant shall have a service provider review the acknowledged shielding design for the proposed radiation X-Ray machine replacement to assess if the existing shielding meets the requirements of this Chapter. **The documentation provided to the registrant from the service provider shall be submitted to the agency and maintained for agency review during inspection**.

To me that seems like a substantial difference. In the first one you didn't have to submit anything to the state if the shielding was sufficient and that could result in an unquantifiable cost savings. In the second you have to submit it to the state even if the existing shielding is sufficient. In .204(c)(4) you are also requiring that a shielding plan exist for all .600 use machines, except for the three that the working group gave specific exemptions too. Overall, it seems that financial impact analysis document was trying to illustrate that the state will save money by not requiring existing shielding design to be resubmitted. The new proposed rule says even acknowledged shielding plans need to be resubmitted. Owing to this seeming contradiction, I don't think the present .204(b) follows the spirit of the financial impact analysis document and will just result in unnecessary cost for all involved. Therefore, I have edited the proposed .204(b) to the following:

(b) Shielding design requirements:

(1) Prior to installation of all x-ray machines, a review of the potential dose to public and occupational workers by the radiation machine will be conducted by a registered service provider or appropriately trained in-house personnel in accordance with rule .0205.

(A) If the proposed use of the machine in the proposed room does not exceed the dose limits of 100mRem per year or 2mRem per hour for public individuals or 500mRem per year for occupational workers, then no additional shielding is required. In addition, documentation of this evaluation will be kept onsite and be available for inspection.

(B) If the proposed use of the machine exceeds the dose limits of 100mRem per year or 2mRem per hour for public individuals or 500mRem per year for occupational workers, then additional shielding must be installed to reduce the dose to below those limits. The applicant and a registered service provider will then determine a

proposed shielding design that has floor plans, shielding specifications, and equipment arrangement.

(2) If additional shielding is necessary as determined above then the registrant shall submit the shielding design and the agency Shielding Design Review Form to the agency for review. Shielding design drawings shall include a scaled drawing. The agency form Shielding Design Review Form shall include the following information:

(A) facility and service provider name, registration number, e-mail and physical address, and phone number;

(B) equipment machine location, manufacturer, status, kVp, mA, mA min per week, facility type; and

(C) proposed date of installation.

(3) An X-ray machine that requires additional shielding shall not be installed until the applicant has received acknowledgment of the shielding design from the agency.

(4) The acknowledgment of such plans shall not preclude the requirement for additional modifications should a subsequent analysis of operating conditions indicate the possibility of a dose that exceeds the limits in section (b)(1)(A) of this rule.

(5) Shielding plans are not required to be submitted or maintained for the following radiation machines:

(A) dental handheld;

(B) dual x-ray X-ray absorptiometry (DEXA);

(C) mammography; or

(D) mobile or portable radiographic and fluoroscopic machines used in more than two locations.

3. .0212(a)

   As I commented in the simililar section of the .800 rules, there needs to be an edit at the start of the regulation which defines it saying commercially available. Otherwise, the working group is talking about research and development machines that are constantly changing so the rest of the regulation cannot be applied because the machine is changing daily. So rewrite the start of the regulation to:

   Commercially available radiation machines that do not meet the radiation X-ray machine or radiation generating device requirements....