Comments on the proposed .200 rules

Thanks to the working group for trying to revise the .200 rules. I really appreciate the effort to update the rules to be more accurate to the present-day X-ray use. Despite their substantial effort, I am struggling with understanding the proposed .200 rules and I think the rules still need to be **significantly** revised.

My confusion regarding these rules is more expansive than individual rule changes or edits. Therefore, I thought the best way to convey my confusion is to list groups of difficulties that each illustrate a broader point of things that I and others may be confused about. Within each group there are a couple of examples, but these examples are not an exhaustive list. They are only some representative examples that show my point. After the group section I also put a couple of other examples that show other noteworthy things that I believe should change or be clarified.

My largest difficulty with the .200 rules is actually what will happen with the .600 rules in the future. I disagree strongly with the belief that all human use should be in the .600 rules. There are just too many instances where other human use will not be able to follow the rules that are applicable to hospital and medical clinics. This will lead to many exemptions and waivers that are required for human use that is not occurring in a hospital or medical facility. Besides just the human use issue, there is also in the proposed .200 rules a large number of non-human use machines that will be regulated by the .600 rules. This makes very little sense to me, and will make crafting appropriate .600 rules very difficult. So overall the organization of which machines are governed by which rules needs to be clarified, and most likely substantially changed from the proposed situation.

With the above paragraphs stated, below are my individual corrections regarding the rules.

Group 1

Lack of clear definitions. I provided a sample but there are other definitions that are needed.

a) .201a- use term radiological services and this is not defined anywhere I can find. Do you mean a service provided by a service provider or is this something else.
b) .201h-Forensic Medicine-No definition anywhere in rules that I can find
c) .201h-Educational facilities- No definition is found anywhere in the rules that I can find.
d) .203(d) and a fair number of other locations-In the proposed rules it seems that you want to have radiation machines and radiation generating devices mean different

things. From my readings of G.S. 104E-5(13) and 10A NCAC 15 .0802, RGDs are a subset of radiation machines. They are not two different mutually exclusive groups. Therefore, please clarify what you are intending.

e) .205(e)- No definition of diagnostic or therapeutic for service providers. I believe clarification of this will enhance things.
f) .212(a)(7) hazard level. Not sure what this means, and don't see definition anywhere for it.

Group 2

Lack of consistency regarding organization and definitions. This makes it very hard to comment on the rules because the organizational system keeps changing. Some examples are:

a) .0807 is a human use that is not in .600 rules. Will that be moved to .600 section?
b) Definition of RGDs in .800 section says non-healing arts. That would need to be changed to non-human and non-veterinary use. If I knew the definition was saying non-human, then that would have changed some of my comments for the .800 rules.
c) .204(c)(3)(A) and in other locations the phrase human, non-human, or veterinary is used. I am not sure that its intent was to be synonymous with the word "all" but it is.
   Therefore, according to the statement of .204(c)(3)(A) everything that is for human or non-human use (which is every x-ray machine) requires a shielding design to be acknowledged by the agency. However in .805(e) it defines which machines in the .800 sections require equipment plans and they don't all require them. Therefore, as you are writing your rules you have changed fundamentally about what requires a shielding plan from the .800 use rules to the .200 rules.
d) .205(e) various classes of service providers say diagnostic and therapeutic. Since you are not defining the .600 rules as medical use, would a human use that is not diagnostic or therapeutic (aka many research uses) be a new class of service provider, would it be RGD use? I would assume yes because that is what it was, however with this change how would you define human use non-diagnostic/therapeutic service provider?

Group 3

The frequent use of defining things for .600 use that shouldn't be

a) .201(h)-using radiation machines for non-human use at educational facilities…subject to the requirements to section .0600. This would mean that if a cabinet x-ray device is used at UNC then we wouldn't use the defined cabinet x-ray rules in .800 section, we would use the .600 rules, because we are an educational institution. Is that really how you want to phrase it?
b) .201(h)-forensic medicine. Since there is no definition (problem group 1) and clinical forensic medicine would already be covered by human use. That means this must refer to pathological forensic medicine, which is mainly x-rays on cadavers and tissues. These machines would be more appropriate to .800 use rules unless we are gravely concerned with excess radiation dose to dead individuals.
c) .204(b)(3)-submit a shielding design to for every new x-ray machine. According to the proposed rule if you move a cabinet x-ray device, which according to 21 CFR1020.40(c)(1)(i) is required to have less than 0.5mR/hr emission 5 cm from surface, is relocated from one lab bench to another, then a new shielding design would be required. The problem with this rule and many others in the section is because of the phrase human, non-human, or veterinary use. Please stop using that phrase. It means "all" even if the working group didn't mean it to be that.

Group 4

The x-ray branch is ridiculously overworked. Therefore, putting a timeline on various things to get done in time I don't believe is a very good system. Also please lessen the amount of work on them overall by not including extra things for them to do, or requiring extra work on them.

a) 212(b) 90 days response. I will just say that the waiver regarding emerging technology that I submitted to the state took longer than that to get a response. Therefore, I don't believe the 90 day response is reasonable.
b) .208 radiation machines from other states. The registration for in-state machines takes much longer than the 5 day section that is illustrated in the out of state machines. So is 5 days really reasonable or should the timeline portion of that just be eliminated.
c) .204(b)(6) A couple of common medical machines were given exemptions from shielding. However, there are other machines that should be given shielding exemptions. They are not as common in hospitals, but for research they are. One example is the pQCT machine, but there are others. So please rewrite the entire shielding section to something like if a machine requires shielding then send the shielding plan to the state. If your machine doesn't require shielding then the inspectors can see that on your post-install survey that will be available for review

by the inspectors. If you don't do something like that then you are just adding work to the regulators for machines like the pQCT that shouldn't require shielding plans. Additional comment regarding this is you will never be able to predict all of the machines that don't require shielding plans, for the next ten years or until whenever these rules are rewritten. Therefore, don't just add PQCT to the list of others in the .204 exemptions. Actually, make a process to avoid doing unnecessary shielding plans for all types of machines.

Other notable problems

a. 204(c)(2)(A)- If you notice this regulation defines that it needs sections 204(c)(1)(a-c) which means it does not require a notice of registration because that is 204(c)(1)(d). However in .208(c)(1) it defines that out-of state machine require the current notice of registration from this agency. This is showing the inconsistency of the .200 rules. Out of state radiation machines are expected to have a state issued NOR in the .208 rule but not required to have an NOR in the .204 rules. I don't even know how to comment on this because I don't even know which way the commission is trying for. This type of inconsistency is throughout the .200 rules.
b. Entire .212 section of the rules. Any emerging technology will go through considerable research first. So this entire section of the rules is basically interfering with research and IRB approvals which is why you entirely removed the proposed .213 section of the earlier proposed rules.
c. The renaming of forms which are available so it makes it difficult to follow which forms are required for what items.
   Ex. .203(d) A Radiation Machine Application or Radiation Generating Devices Application form shall be submitted….

   Presently the forms that are on the website that I know of that could be these are
   1. Equipment Form - Healing Arts
   2. Equipment Form - Non-Healing Arts Industrial Radiography, Analytical or Research
   3. Equipment Form - Healing Arts Mammography
   4. Equipment Form - Healing Arts Therapy
   5. BUSINESS APPLICATION

As you can tell none of the names of the available forms match the name of the forms in the regulations. So this will just add to the confusion of people trying to register items.