Comments on the .600 rules

Thanks for providing an update to the .600 rules. Listed below are my requested changes/updates.

General comment for the entire section:

The .600 rules were originally made for healing arts use for both human and animals, but with this recent draft revision the .600 section includes all human use, veterinary use, and some non-human use. This is a major change and if the working group wants such a major change, then they must go line by line in every regulation and make sure that idea is consistent with all of the .600 use machines. I don't believe that line by line effort was performed and so there are a significant number of rules that are still primarily medical and contradict that newer broader purpose.

The difficulty with this newer broad purpose and scope is that the .600 rules were very specific because the rules concerned a small number of different type machines. So, the rule writers could define the specific tests necessary for each machine and the specifics of how operators needed to be trained. Now that the working group has put in many more types of machines in the .600 rules, I believe that specific method doesn't work very well without a lot of exemptions. The .800 rules were set up as guidelines, defining that individuals receive appropriate training and use the machine properly. That type of general guideline works when there are a large number of different type machines. Therefore, I believe some adoption of the .800 rule structure should occur. I have listed below only some of the problems with this specific nature of the .600 rule structure.

1. **601(b)(3)**

.....non-human use, used for forensic medicine, or used by service providers for demonstration purposes.

Comment: Clarify in multiple ways

Please define very specifically what non-human use the working group means. Seeing as the rules is written with commas in a list, which means it is regulating all non-human use, all use for forensic medicine, and all use by service providers providing demonstration purposes. That is much too broad.

In the above writing, this defines forensic medicine done on tissue and bone samples as not governed under the .800 rules but governed by .600 rules. Therefore, a lab tech performing a radiographic analysis of a sample according to rules .604 would be required

to be ARRT certified because they are performing a radiographic examination(.604i) and they are using it for forensic medicine(.601(b)(3)). This overall non-human use portion in the .600 use is much too broad. Please define exactly what the working group means by non-human use, or just delete the entire non-human use portion, and put it in the .800 use section where it belongs.

2. **601(b)(4)**

... service providers company who provide operators to end users.

Change to

service provider's company who provides operators to end users for diagnostic imaging.

Comment:

If wording is left as written, then a service provider providing an operator to operate a cabinet x-ray system would have to get a physician order to operate the cabinet x-ray.

With the new broad purpose and scope many more types of machines are under the .600 rules. The new rules have to cover all of the machines or define exactly which machines are appropriate.

3. **601(c)**

This Section provides additional requirements for the use of radiation machines by or under the supervision of a licensed practitioner authorized by and licensed, in accordance with state statutes, to practice medicine and provide professional services in chiropractic, dentistry, podiatry, ~~research,~~ and veterinary medicine.

Comment:

For simplicity sake, I would delete out research. A physician is not needed to perform a research x-ray even if it is on a human. This is defined in the federal rule section 21 CFR 56. The working group is now treading into the waters of IRB requirements and federal regulations. This gets messy regarding IRBs and other such things so I would just delete the research portion of 601(c).

4. **.602**

"Clinical training" means hands-on experience or clinical simulation to gain practical knowledge, experience, and skills.

Change to

Clinical training- involves supervised, hands-on practical learning in a real-world or simulated environment to develop x-ray imaging skills and professional behaviors for use in healthcare or other medical use settings.

Comment:

The definition of clinical training is too broad, which means .601(b)(1) is too broad. This means that anyone at any educational institution, which isn't defined, could gain hands-on experience to gain practical knowledge, experience, and skills. This would mean any x-ray use training at any educational institution would be clinical training.

5. **.602**

There needs to be definitions for clinical forensic medicine, forensic medicine, end of life imaging, educational institutions, patients, specify the " human use" of the .100 rules to exempt cadavers, and numerous others.

6. **.603(b)**

Comment:

This regulation needs to be deleted. In its present form this regulation is one of reasons a dental handheld waiver is required for every single handheld dental x-ray device. The new .603(b) is very similar to the old .0603(a)(1)(I)(iii) and that was on the standard dental handheld waiver. Therefore, since the working group basically repeated .603(a)(1)(I)(iii) regulation, this makes a dental waiver still required for every dental handheld machine in the state of NC.

In addition, this regulation makes the very standard hospital practice of imaging people at their bedside technically against regulations. We all know the bedside imaging is not done only for medical necessity, but is frequently done for convenience, lack of transporters, lack of available x-ray rooms, etc. Therefore, don't just put in an exemption for dental handheld devices to get around the waiver problem, and leave the rest of the regulation. Just delete the whole regulation.

Besides, .606e talks about portable and mobile machines being used as a primary imaging system. Further evidence that .603(b) just needs to be deleted.

7. **.603(j)**

Computed Tomography (CT) radiation machine shall meet the following additional requirements for system performance evaluations.

Change to

Computed Tomography (CT) radiation machine that are used for diagnostic imaging shall meet the following additional requirements for system performance evaluations.

Comment:

There are many nano and micro-CT machines, research CT machines, pQCT machines and others that would not meet the standards defined in .603(j). With the new broad purpose and scope many more types of machines are under the .600 rules. The new rules have to cover all of the machines.

8. **.603(k)**

Change from Computed Tomography (CT) radiation machines shall meet the following additional requirements for routine quality control (QC).

To

Computed Tomography (CT) radiation machines that are used for diagnostic imaging shall meet the following additional requirements for routine quality control (QC).

Comment:

There are many CT machines in research that will not meet medical type CT rules, because they were never designed to. With the new broad purpose and scope many more types of machines are under the .600 rules, and the new rules have to cover all of the machines. The working group decided to include various non-human imaging in its broader purpose. According to the rules as written, if someone uses a micro CT device which is very similar to a cabinet x-ray, then that machine still needs to be evaluated by a CT Qualified Expert.

9. **.604(d)**

Individuals who operate a radiation machine for research purposes or for end-of-life imaging are exempt from the requirements in Paragraphs (e),(f),(g),(h),(i), or (j) of this Rule.

Change to

…. Paragraphs (f),(g),(h),(i), (j) or (k) of this Rule.

Comment:

I appreciate the realization that research training should be different than medical, but with the present writing research users need no training. Please make their training equivalent to 10A NCAC 15 .0803(b).

10. .604(e)

The uses of Cone Beam CT, Veterinary CT, CT Simulation, and CT attenuation correction shall be exempt from the requirement in Subparagraph (i) of this Rule.

Change to

The uses of Cone Beam CT, Veterinary CT, CT Simulation, and CT attenuation correction shall be exempt from the requirement in Subparagraph (j) of this Rule.

11. .605(b)(4)

Change .605(b)(4) to

(4) Radiation exposures for non-human use, used for forensic medicine, for research, Dexa use not for diagnostic use, or by service providers for demonstration purposes are exempt from Subparagraphs (b)(1), (b)(2) and (b)(3) of this Rule.

Comment:

If the working group keeps this regulation as written in the draft rules then they have codified in NC regulations that no research using x-rays can be performed in NC because research x-rays are done for non-diagnostic imaging.

The working group greatly expanded the purpose and scope of the .600 rules. Therefore, the new rules need to fit all the new types of machines and uses that the new purpose and scope covers, not just healing arts.

12. .605(c)

As written in this rule there are the words patient and diagnostic quality.

Remember .600 rules are no longer exclusively medical. So please define patient and diagnostic quality. I don't know if patient only refers to humans in medical settings or if it also applies to research. If it applies to research that might violate the IRB because research is often done not at lowest possible dose to get images of optical quality. This is what an IRB reviews. However, the working group decided to expand the .600 rules to cover non-healing arts scans so questions like this need to be figured out, or better yet just don't include research in .600 rules.

13. .605(d)(2)

use collimation to limit the primary beam to the area of clinical interest….

Comment: Remember .600 rules are not exclusively medical anymore so change to

use collimation to limit the primary beam to the area of interest or to the image receptor, whichever is smaller;

14. .605(d)(3)

As written in this rule you have the phrase "patient sizes and clinical indication, to optimize patient dose…."

Remember .600 rules are no longer exclusively medical. So please rewrite or just define all of .605(d) to being exclusively clinical. The working group decided to expand the .600 rules to cover non healing arts scans, so questions like this need to be figured out.

15. 605(h)

Except for Dual Energy X-Ray Absorptiometry (DEXA or DXA) and intraoral dental handheld radiation machine operators, only the professional staff and individuals required for the medical procedure or those in training shall be in the room of the patient being examined during the radiographic and fluoroscopic exposures.

Change to:

Except for Dual Energy X-Ray Absorptiometry (DEXA or DXA) and intraoral dental handheld radiation machine operators, only the professional staff and individuals required for the diagnostic imaging procedure or those in training shall be in the room of the patient being examined during the radiographic and fluoroscopic exposures.

Comment:

You have diagnostic imaging defined, but you don't have medical procedure defined. If you want to keep medical procedure then put it in definitions. In addition, this change to diagnostic imaging procedure, helps you avoid all of the research based and non-human machines that were for some unknown reason put in the .600 rules. Many of those machines are used in the same room as other people.

16. 605 (k)(2)

Comment:

Don't include mandatory dosimeters for handheld machines.

a. The following paper does not recommend it and it is stating the American Dental Association recommendations.

Benavides, Erika et al. The Journal of the American Dental Association, Volume 155, Issue 4, 280 - 293.e4

b. NCRP 177 doesn't recommend required dosimeters. Quote from NCRP 177 pg 95

"Likewise, there is no need for personal radiation monitoring with handheld x-ray equipment as long as the whole-body effective dose to the operator is <1.0 mSv y–1."

If these two nationally recognized bodies(ADA, and NCRP) don't think the operator need dosimeters for intraoral dentistry is there another group that is recommending it?

17. 606(a)

Please change the rule to the following or something similar.

(a)(1) Structural barriers or controlled areas shall be implemented so that the dose limits of Rules .1601(a)(8) and .1601(a)(15) of this Chapter are not exceeded.

(a)(2) If opaque barriers are necessary between patient and operator then a window, to include a frame and lead-equivalent glass, meeting the same structural barriers as required by the adjacent barrier, or a mirror system shall be provided so the operator can see the patient from behind the protective barrier during radiation exposures.

Comment:

Structural barriers and viewing windows are not necessary or used for many medical, and or research use machine. I perform surveys on Dexa machines at 3 different hospitals/clinics and 4 research areas on campus and in all of them the dexa machines are in a room with no barrier between operator and scanner. The reason for that is that the 1 meter scattered dose from a patient is around 20-30uRem. This rule is useful for some medical x-ray devices, but the .600 rules don't cover only some x-ray devices. In addition, the .600 rules now cover a much broader scope of machines so there are multiple types of machines besides Dexa where this rule is inappropriate. I know there are exemptions in .606(i) but the fact is with the very broad purpose and scope of .601, so many machines now fall under .600 rules that you will not be able to put specific exemptions for every type of machine. So please rewrite the regulation in more of an .800 manner and provide guidelines for when barriers are appropriate and not just listing specific machines that are exempt.

18. 606(b)(1)

Please change to something similar to below.

(b) Exposure switches for mobile, portable, or stationary machines shall be installed to be behind a structural barrier, 6 feet or greater from the tube housing, or in any other manner so that rules .1601(a)(8) and .1601(a)(15) of this chapter are not exceeded.

Comment:

Structural barriers are not necessary for multiple types of machines. This is once again a very broad rule that either needs to be made very specific or people just ignore the rule. If registrants ignore the rule then it sets up every registrant for violations in case a future inspector adheres to the letter of the regulation. In addition, there are now so many types of machines in the .600 rules that compliance cannot be obtained with the present writing of the rules.

Example: According to .601 rule, analysis of tissues for forensic analysis now falls under the .600 rules. Therefore, will a lab tech be analyzing a tissue sample in a cabinet x-ray system, and then walk behind a structural barrier and look through a leaded glass viewing window to examine the cabinet which is performing an x-ray analysis. The very broad purpose and scope of .601 causes all kinds of problems with the many types of x-ray machines that are now regulated by the .600 rules.

19. 606(c)

(c) Stationary CT radiation machine operators shall maintain aural communication with the patient while the operator is required to remain behind a protective barrier at the control panel.

Change to

(c) Diagnostic stationary CT radiation machine operators shall maintain aural communication with the patient while the operator is required to remain behind a protective barrier at the control panel.

Comment:

Otherwise, nano and micro CT would need a protective barrier and they don't. With the very broad purpose and scope of .601, the rules must be specific.

20. 606(e)

Any mobile or portable radiation machine used in one location or used as a primary imaging system.....

Comment:

The working group banned mobile from being used as a primary imaging system in .603(b). however here it seems they approve it. Please clarify what you mean.