Suggested modification of the 200 rules.

Rule .201

Comment:

Not seeing definitions for

Educational Facilities

Forensic medicine

Rule 203, 204, 205

Comment:

Some of the rules for service providers and facilities were combined in the same regulation with this edition of the rules. I do not think this benefits clarity. Previously there were different rules for registration of facilities and for service providers, and although at many locations throughout the state the service providers deal with both facility registration and services, at many locations the same people/company do not do both. So these combined regulations I believe will add to confusion.

For example:

Reg 203- .203(a-e) is for facilities, and .203(f-g) is for service providers.

Reg 204-.204(a-c) is for facilities, however .204(d-f) talks about persons registered. Since the word is person and not facility is used is this referring to a service provider again or should the word be facility?

Rule 203(f)(1)(C)

A Company Service application form shall be submitted prior to furnishing or offering to furnish services in Parts (A) through (C) of this Paragraph and the following additional requirements shall be met:

(1) The application shall be submitted by any person engaged in:

(A) direct sales, demonstration, leasing, or transfer of radiation machines or radiation generating devices;

(B) providing individual monitoring devices; and

(C) radiation survey equipment calibration.

Comment: I am not grasping how this is enforced. Ludlum which calibrates and manufactures many meters is not on your list and only one university, ECU, is listed on your radiation survey equipment calibration list as a service provider. However, numerous universities in the state calibrate their own meters and Ludlum is one of the biggest calibrators of radiation survey equipment. In addition, in your modified .0206(a)(6) for the educational requirements for radiation instrument calibration you say must possess a radioactive license or be registered. I understand that you want to make sure that the instruments are calibrated properly, but the wording is a little difficult.

I think this registration should be for places located in NC that are providing this as a service to other facilities/corporations and which don't have an applicable radioactive materials license.

Rule 203(g)

A Company Employee Services application form shall be submitted prior to furnishing or offering to furnish services in Parts (A) through (H) of this Paragraph and the following additional requirements shall be met:

(1) The application shall be submitted by any person engaged in providing the following services:

(A) area radiation surveys for diagnostic radiographic and fluoroscopy facilities;

(B) equipment surveys and shielding designs for radiation generating devices;

(C) general health physics consulting services to perform dose estimates, radiation output measurements, radiation safety program development, and radiation safety program training;

(D) installation or service repair of radiation machines or radiation generating devices;

(E) qualified expert consulting services for CT and mammography radiation machines;

(F) radiation protection expert;

(G) shielding designs for diagnostic radiographic and fluoroscopy facilities; and

(H) therapeutic facility and shielding design, area radiation survey, or calibration.

Comment: Every X-ray registration has an RSO listed on the registration and they are their radiation protection expert. In the wording of this regulation then , this would mean every x-ray registration would need to register their RSO, and have them fill out a company service

application form in addition to others to be registered with the state. This is the exact same problem that was stated above in the proposed .203(f) regulation. From the verbiage in the proposed regulations there is no difference between a service provider that does this for many registrations in a commercial sense vs a registrant doing it for their own facility.

Overall the state regulators have a deluge of work already, and updating constantly for every RSO at every registration would basically mean they would spend their entire workday just updating lists.

For regulations 203, 204, and 205 In the newly updated definition in regulation .103 service and service provider make no mention of commercial sense or exclusions for people at their own facility. Therefore, I believe a line similar to South Carolina's X-ray regulations would be beneficial for capable individuals dealing with their own facilities. The following regulations are copied from South Carolina x-ray regs.

RHB 2.7. Registration Requirements-Servicing and Services (~~VENDOR~~ service provider)

2.7.1.1 The owner of an x-ray system and in-house personnel employed by a facility or corporation shall be exempt from the ~~vendor~~ service provider registration requirement, provided such personnel:

2.7.1.1.1 Shall meet the education, training, and experience requirements for the appropriate vendor Class; and

2.7.1.1.2 Shall exclusively service one (1) facility or corporation.

2.7.1.2 Documentation of education, training, and experience for in-house service personnel shall be maintained by the facility or corporation and available for Departmental review.

This addition would I believe allow the RPS branch more time to inspect various x-ray facilities and less time having to maintain very long service provider lists.

This modification is obviously in direct contrast with the commission's proposed rule of .205(e-f). I believe that if a person is qualified to perform RSO functions/surveys/shielding then they can show that on inspection, and going through the process of registering with the state just adds a great deal of paperwork and lessens the amount of time the X-ray inspectors have to inspect facilities.

Reg .206, Reg .207

Comment:

If the modification to allow qualified individuals to handle their own facility then other smaller changes would be necessary in several rules. The suggested edit to regulation .0206 is below.

A person registered to provide services pursuant to Rule .0205 of this Section shall be qualified by reason of education, training, and experience to provide the services for which registration is requested.

Would change to

A person ~~registered~~ qualified to provide services pursuant to Rule .0205 of this Section shall be qualified by reason of education, training, and experience to provide the services for which registration is requested.

Similar small wordsmithing would be required for other regulations.

Reg .211

Comment:

This is the same comment as .203(g). Every RSO on every x-ray registration across the state of NC has to be registered with the state. The state will be maintaining a long list unless there is an exemption for people at their own facility.

Reg .212

(a) Commerically available ~~R~~radiation machines or radiation generating devices that are not able to meet the equipment requirements of these Rules shall not be sold, installed, or used prior to the agency completing a review of information regarding the radiation machine and determining if the use of the radiation machine is allowed. The user or manufacturer of the radiation machine shall submit the following to the agency for review:

Comment:

This needs to be clarified regarding which machines you are talking about. Is this rule concerning research and development machines, or are you future-proofing/dealing with odd machines that are not presently in the rules?

If you are future proofing/ dealing with odd machines then please add commercially available systems as edited above.

If you are talking about research and development machines that are not yet commercially available, then I don't have any edits to this rule. I would just say that enforcement of this would get complex quickly because many investigational devices are changing as they are

developing. So half of the data in any survey would change as the makers are developing it, plus a bunch of other issues of compliance. In addition, there is all of the complications regarding 21 CFR 812 and the FDA's regulations of investigational device.

Rule 213

Comment:

Thank you for making this rule. This will be very helpful, and I particularly appreciate the division of the two sections regarding with an IRB approval and without an IRB approval. However, there are a couple of edits that I would like to suggest and those are listed below.

1. There is no definition of an IRB or regulations regarding composition, function, etc. in the recently revised 100 rules or in other locations of the rules that I can find. Therefore, I think an incorporation of sections of 21 CFR 56 should be included because there is a lot of information regarding IRB boards in that section.
2. There should be a separation between the IRB approved studies and the non-IRB approved studies regarding the approval. Many IRB approved studies expire after one year or require a reapproval or extension after one year. So according to the schedule in proposed rule .213, 1/6 of any IRB approval period would be lost waiting on the state's approval. This doesn't include the gathering of information time, additional NC RPS questions, etc. and this is on studies that have already been reviewed and approved by experts who are on the IRB committee. This would also get into the possibility of a state decision overruling an FDA authorized IRB committee. I believe that is allowed regarding radiation devices but still not a great precedent to start owing to the fact that an expert committee has already reviewed the study/device.