

1. For the rule revision, should required materials or documents be available to you upon inspection?

[Rule .03 - source tracking] Tom Lehman, BASF Catalysts LLC

[EPD Response:] Yes, all required documents and records should be available for routine inspections by the Division.

2. Who will be tracking the Sealed Source and Devices (SS&Ds)?

[Rule .03 - source tracking] Teresa Shiftlett, Georgia EPD Small Business Environmental Assistance

[EPD Response:] The NRC will be responsible for establishing and maintaining the national source tracking database. They will probably contract with Oak Ridge National Laboratory (ORNL) to update and maintain the database.

3. How do you know if the sources are being tracked?

[Rule .03 – source tracking] Rod Harrell, Honeywell Inc.

[EPD Response:] After February 6, 2007, each licensee who manufactures a nationally tracked source must assign a unique serial number to each source. A National Source Tracking Report must be generated and submitted to the NRC national source tracking database for each type of transactions involving the source.

4. Will the distributors know if the sources are being tracked?

[Rule .03-source tracking] Nazia Zakir, Georgia Institute of Technology

[EPD Response:] Information in the National Source Tracking System will be considered by the NRC as Official Use Only. This means that the information is to be protected and not disclosed to the general public. A licensee would be able to view their own data, but not the data for other licensees.

5. Is there anything the state needs in addition to what NRC needs?

[Rule .03 - source tracking] Stan Wilson, Emory University

[EPD Response:] No, the state will not need anything else in addition to the NRC requirements for the national source tracking system.

6. When will the national source tracking system be in place?

[Rule .03 – source tracking] Stan Wilson, Emory University

[EPD Response:] The National Source Tracking System is projected to be ready and in place for use by January 31, 2009.

7. Will the national source tracking requirements apply to existing sources?

[Rule .03 – source tracking] William Griffin, Med Cross Imaging

[EPD Response:] Yes, this will apply to existing sources. Some of these Category 1 & 2 sources have already been entered in to an NRC Interim database that is maintained and updated by ORNL.

8. Does the revised regulation requires that new sources received need to be reported to the national source tracking system?

[Rule .03 – source tracking] Stan Wilson, Emory University

[EPD Response:] Yes, if a licensee receives a new source that falls into Category 1 or Category 2, it needs to be reported.

9. According to the tracking system, is the end user responsible? How do you know if they are in compliance with regulation? How do you inspect that?

[Rule .03 – source tracking] Rod Harrell, Honeywell Inc.

[EPD Response:] The new rule requires that each licensee who manufactures, transfers, disassembles, or disposes of nationally track sources shall submit a Transaction Report to the Nationally Source Tracking System. This can be verified during routine inspections of the licensees' facilities.

10. Is there any periodic reporting? Does the new rule discuss system annual reporting?

[Rule .03 - source tracking] Stan Wilson, Emory University & Dennis Stevenson, Medical College of Georgia

[EPD Response:] Yes, by January 31st of each year, each licensee must submit a report confirming that the data is correct in the National Source Tracking System.

11. Is it the distributor's responsibility to report that a source is a part of the national tracking system? Rod Harrell, Honeywell Inc.

[Rule .03 – source tracking]

[EPD Response:] Yes, the distributor must submit a report to the national source tracking system, and in addition, each licensee who manufactures, transfers, receives, disassembles, or disposes of a nationally tracked source shall submit a Transaction Report.

12. Are we required to report these sources to NRC if we have them?

[Rule .03 – source tracking] Nazia Zakir, Georgia Institute of Technology

[EPD Response:] Yes, the licensee will be responsible for reporting these sources. However in 2004, the Division submitted an initial report to NRC's Interim database of Georgia licensees with sealed sources with quantities of concerns that falls under Category 1 and Category 2.

13. Will there be an effective date for initial requirements?

[Rule .03 – source tracking] Nazia Zakir, Georgia Institute of Technology

[EPD Response:] The Division plans to meet with the DNR Board in August 2008, and anticipates that the Georgia Radioactive Materials Rules, Chapter 391-3-17, will be effective in September.

14. Regarding the two pathways of training, on your presentation slides you made reference to a nationally recognized medical board. Will there be a national medical board that will certify training requirements for medical users?

[Rule .05 – training requirements] Dennis Stevenson, Medical College of Georgia

[EPD Response:] This was an error and should have been nationally recognized specialty board instead of nationally recognized medical board.

15. Will the new training requirements for authorized pharmacist eliminate the production of radiopharmaceuticals by the licensee (hospital, private clinics, etc.) on site? How will this affect the elution of Tc99m generators by nuclear medicine technologist? Will they no longer be allowed to do this on site?

[Rule .05 - training requirements] William Griffin, Med Cross Imaging

[EPD Response:] The new training requirements for authorized pharmacist will not prohibit the nuclear medicine technologist from eluting a Tc99m generator received from the pharmacy. The hospital receives the generator from the pharmacy and does not receive it directly from the manufacturer/distributor. Whenever a licensee is authorized for .05(44) to include generators, the proper license conditions are included for use and elution of generators.

16. Can the NRC eliminate term Authorized Nuclear Pharmacists?

[Rule .05 - training requirements] Dennis Stevenson, Medical College of Georgia

[EPD Response:] Since the NRC has included training requirements for Authorized Nuclear Pharmacist, it is unlikely that they will eliminate this term.

17. How will the new medical use training requirements affect the local pharmacies?

[Rule .05 - training requirements] William Griffin, Med Cross Imaging

[EPD Response:] It will not affect pharmacists who are already named on an existing license or have been approved through a notification process. But those pharmacists who are requesting authorization after the new rules go into effect will have to meet the new training requirements.

18. Under training requirements for medical physicists on page A-5 of synopsis, it refers to one year training. Is the length of training defined (i.e. fulltime, hours, topics, continuous, separate)?

[Rule .05 – training requirements] Dennis Stevenson, Medical College of Georgia

[EPD Response:] The training requirements for the medical physicist are only defined as one year of full-time training and an additional one year of full-time experience. It is not defined in terms of hours, topics, continuous, or separate. The rules do not specify as to how the training has be done. A review of the training is performed during a licensing action.

19. Will the Department rely on NRC's list of specialty boards?

[Rule .05 – training requirements] Dennis Stevenson, Medical College of Georgia

[EPD Response:] Yes, the Division will reference and use the NRC list of specialty board that will be posted on their website.

20. Under Rule .06, Transportation of Radioactive Materials, the definitions for A₁ and A₂ are different from the definition of A₁ in Rule .01, General Provisions.

[Rule .06 – definitions] Rod Harrell, Honeywell Inc.

[EPD Response:] The Division has reviewed and determined not to make changes to the definition for A₁ in Rule .01. The A₁ definition is the same as what has been proposed in Rule .06 (i.e., the maximum activity of special form radioactive material permitted in a Type A package).

21. NRC changed their definition of byproduct material, shouldn't the state do the same?

[Rule .01 – definitions] Rod Harrell, Honeywell Inc.

[EPD Response:] The NRC did expand their definition of byproduct material in Section 11e(3) and 11e(4) of the Atomic Energy Act of 1954, to include licensing authority over certain naturally occurring and accelerator produced radioactive

materials. The NRC did not change the definition of byproduct materials in 10 CFR Part 20. The Division has always regulated naturally occurring and accelerated produced radioactive materials under Chapter 391-3-17, and these terms are defined as NORM and NARM under definitions in Rule .01.

22. Need to review definition of Surface Contaminated Object in Rule .06.

[Rule .06 – definition] Rod Harrell, Honeywell Inc.

[EPD Response:] The definitions of Surface Contaminated Object were compared between Rule .06 and the corresponding NRC definition. The definition in Rule .06(1)(i) has the correct value of 1×10^{-4} microcuries (4 Becquerel). The NRC conversion of 4 Bq to microcuries left off the negative exponent, giving 10^4 microcuries. The Georgia rule definition will remain unchanged.

23. What are the double lock requirements for on portable gauges?

[Rule .02 - portable gauge security]. William Griffin, Med Cross Imaging

[EPD Response:] There is a new security requirement for portable gauges. Licensees must have a minimum of two independent physical controls that form tangible barriers to secure the gauge when it is not under the control or surveillance of the licensee.

24. Define what is meant by physical barriers for portable gauges?

[Rule .02 - portable gauge security] Paul Feist, Geo-Hydro Engineers

[EPD Response:] This may be defined as the portable gauge carrying case being bolted to the floor of a flat bed truck with two separate chains with pad locks; separate locks on the storage closet door and the entrance door to the room or area where the gauge is stored, or other mechanisms to independently secure portable gauges.

25. Rule .03(j)(9) requires inventory to the National Source Tracking System by November 2007; a date in the past. The corresponding rule in 10 CFR requires inventory by January 31, 2009. Please adjust to a future date.

[Rule .03 – source tracking] Stan Wilson, Emory University

[EPD Response:] This date has been adjusted to January 31, 2009 in the proposed rule. The NRC changed the effective date in their final regulations; Georgia's proposed rules reflect this change.

26. Rule .05(2)(gg) states "Meets the requirements in Rule .05(22)(a) or .05(22)(c)1, (26) and (27); or". This seems to exclude approval allowed by (22)(b) and that of (22)(c)2, and could be made more clear for .05(26). Suggest replacing with: ".05(2)(gg) Meets the requirements in Rule .05(22)(a), (b), or (c), or (26) and (27); or".

[Rule .05 - training requirements] Stan Wilson, Emory University

[EPD Response:] The section .05(2)(gg) [definition of Radiation Safety Officer (RSO)] states: "Meets the requirement in Rule .05(22)(a) or .05(22)(c)1. and 27". Please note Rule .05(26) has been deleted. Rules .05(22)(a) and .05(22)(c)1. reference individuals and medical physicists who are certified by a specialty board and whose certification has been recognized by the Nuclear Regulatory Commission or an Agreement. It is the Division's interpretation that if these individuals are certified by specialty boards and possess the additional training requirements, they would automatically be recognized as meeting all the

requirements for an RSO. However, for Rule .05(22)(b and .05(26) the training and experience would vary and would have to be reviewed on a case by case basis. This is a NRC Compatibility B requirement for the Agreements States, and the Division elects to keep this requirement consistent with the NRC.

- 27. Rule .05(26)(a)3. Rule allows training exceptions for RSO [Radiation Safety Officer], AMP [Authorized Medical Physicist], and ANP [Authorized Nuclear Pharmacist], but does not recognize RSO as qualified for future use. Suggest replacing the final sentence with: "A Radiation Safety Officer whose program used only accelerator-produced radioactive materials, or nuclear pharmacist, who prepared only radioactive drugs containing accelerator-produced radioactive materials, or a medical physicist, who used only accelerator-produced radioactive materials, at locations and time period identified in this paragraph, qualifies as a Radiation Safety Officer, or an authorized nuclear pharmacist, or an authorized medical physicist, respectively, for those materials and uses performed before these dates, for purposes of this chapter.**

[Rule .05 - training requirements] Stan Wilson, Emory University

[EPD Response:] The Division has considered the above comments to include recognizing the Radiation Safety Officer as qualified for future use under Rule .05(26)(a). However, this is a NRC Compatibility B requirement and the Division elects to keep this Rule consistent with the NRC.

- 28. Rule .05 (41), (43), (44), and (47). Each section references a training requirement .05(47)(c)1(ii)(VII), which requires work experience eluting generators and performing breakthrough QC. Many facilities no longer use generators, limiting the sites where this training could be achieved. Suggest allowing an exclusion of this training requirement for facilities at which no generators are used.**

[Rule .05 - training requirements] Stan Wilson, Emory University

[EPD Response:] Rule .05(47)(c)1.(ii) states: "Work experience, under the supervision of an authorized user, who meets the requirements in .05(47) or .05(47)(c)1.(VII) and Rule .05(52), or equivalent Agreement State, Licensing State or Nuclear Regulatory Commission requirements, involving:" ... The Division will take into consideration the term "involving" for all the requirements listed for .05(47)(c)1.(ii)(I) through .05(47)(c)1.(ii)(VII), and will determine on a case by case basis if the requirements for .05(47)(c)1.(ii)(VII) is applicable for the authorized use being requested.

- 29. Rule .05(41)(b) does not allow an Authorized User who is performing the study to prepare the radioactive dose, even though part of his training is in safely preparing dosages .05(43)(c)1(ii)(III). Suggest replacing with: "Prepared by an authorized nuclear pharmacist, a physician who is an authorized user and who meets the requirements specified in Rule .05(43), .05(47), or .05(52), or an individual under the supervision of either as specified in Rule .05(18); or".**

[Rule .05 - training requirements] Stan Wilson, Emory University

[EPD Response:] The Division has considered the above comment to include requirements specified in Rule .05(43). However, this is a NRC Health & Safety Compatibility requirement, and the Division elects to keep this Rule consistent with the NRC.

- 30. Rule .05(43)(b) Does not allow an Authorized User for Uptake, Dilution or Excretion studies to be accepted as an Authorized User for Uptake, Dilution or Excretion studies on another license. Suggest replacing with: "Is an authorized user under Rule .05(43), .05(47), or .05(52) or equivalent Agreement State, Licensing State, or Nuclear Regulatory Commission requirements; or".**

[Rule .05 - training requirements] Stan Wilson, Emory University

[EPD Response:] The first part of this requirement is a reference to being an authorized user under the actual Rules that are stated, and addition it references being an authorized user under an equivalent Agreement State, Licensing State or Nuclear Regulatory Commission requirements. The Division would consider an authorize user that's named on an existing license and meets the recentness of training requirements. This is a NRC Compatibility requirement and the Division elects to keep this Rule consistent with the NRC.

- 31. Rule .05(63) Does not recognize an Authorized User at a licensed facility as do other modalities. Suggest including "Is listed as an authorized user under Rule .05(63) for uses listed in .05(63) (55) or equivalent Agreement State, Licensing State, or Nuclear Regulatory Commission requirements; or".**

[Rule .05 - training requirements] Stan Wilson, Emory University

[EPD Response:] The reference to Rule .05(55) is a NRC matter of compatibility requirement, and the Division elects to keep the Rule consistent with the NRC.

- 32. Rule .05(65) Does not recognize an Authorized User at a licensed facility as do other modalities. Suggest including "Is listed as an authorized user under Rule .05(66) for uses listed in .05(65) (66) or equivalent Agreement State, Licensing State, or Nuclear Regulatory Commission requirements; or".**

[Rule .05 - training requirements] Stan Wilson, Emory University

[EPD Response:] The requirements in Rule .05(65) are a NRC matter of Compatibility requirement, and the Division elects to keep the Rule consistent with the NRC.

- 33. Rule .05(84) Does not recognize an Authorized User at a licensed facility as do other modalities. Suggest including "Is listed as an authorized user under Rule .05(84) for uses listed in .05(67) (84) or equivalent Agreement State, Licensing State, or Nuclear Regulatory Commission requirements; or".**

[Rule .05 - training requirements] Stan Wilson, Emory University

[EPD Response:] The requirements in Rule .05(84) are a NRC matter of Compatibility requirement, and the Division elects to keep the Rule consistent with the NRC.

- 34. Rule .05(23)(b): Does the "1 year of full-time training in medical physics" in addition to whatever training the physicist received during their degree coursework, or can it be concurrent?**

[Rule .05 - training requirements] Stan Wilson, Emory University

[EPD Response:] The Rules require the completion of the one year full time training in medical physics to be demonstrated, in addition to the other degreed course work. The Rule does not require whether the training is to be done sequentially or concurrently.

35. Regarding Training and Experience requirements throughout - we request clarification on the NRC-recognized Certification Boards, (<http://www.nrc.gov/materials/miau/med-use-toolkit/spec-board-cert.html>). The "before and after that date" wording is confusing. For example, do physicians who received their ABNM certifications in 2002 meet the training qualifications for (52), (53), and (54)? Their Board Certificates will not have the "United States" stamp. ABR certifications in Radiation Oncology from 2003 will not have "AU eligible", even though they were eligible at the time. Do they qualify for (63) and (84)? The requirement for presenting a preceptor attestation becomes more difficult for older, more experienced AUs. The posting on the NRC website is not dated, or versioned, nor are previous versions referenced.

[Rule .05 - training requirements] Stan Wilson, Emory University

[EPD Response:] Regarding your examples, physicians who received ABNM certifications up until October 2005 without the word "United States" appearing on the certification number will meet the requirements in for (52)(53) and (54), and the same applies up until that same date for the ABR certifications. Any special wording added to a specialty board certificates will be effective after the later date referenced this NRC website.

36. Chapter 391-3-17-.05 (Use of Radionuclides in the Healing Arts) will allow two pathways of training- certification or through documentation of training and experience. The synopsis handed out at the public meeting indicated that certification was from a "nationally recognized medical board." As discussed, the rules in Chapter 391-3-17-.05 paragraphs (22)(a), (23)(a), (24)(a) state "certified by a specialty board whose certification process has been recognized by the Nuclear Regulatory Commission or an Agreement State." Certification by a "specialty board" is applicable to the Radiation Safety Officer, Medical Physicist or Nuclear Pharmacist, for example, whereas a "medical specialty board" is applicable to specific use of radioactive materials by a physician. It should be clearly stated that "certification by a specialty board", when used, does not imply or require that the board be a "medical specialty board."

[Rule .05 - training requirements] Jim Davis, Medical College of Georgia

[EPD Response:] The reference to the specialty board can be found in the proposed rule paragraphs (22), (23), and (24). No change to the proposed rule needed. The synopsis of the proposed rule will be changed to state nationally recognized specialty board instead of nationally recognized medical board.

37. Additionally, the Nuclear Regulatory Commission publishes a list of Specialty Board(s) Certification Recognized by NRC under 10 CFR Part 35 on their web site. Training requirements include the designation of a certifying organization (e.g. American Board of Health Physics for the Radiation Safety Officer) and an applicable date (e.g. "from January 1, 2005 to present"). Radiation Safety Officers, certified by the American Board of Health Physics are initially certified by the board and are recertified every four years based on continuing education and review by the board. Current active certification by a specialty board may constitute initial certification and recertification within the time period recognized by the NRC. Certification / recertification should be clearly stated by GDNR as meeting the certification requirement to help clarify the approved specialty board criteria.

[Rule .05 - training requirements] Jim Davis, Medical College of Georgia

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[EPD Response:] The requirements in Rule .05(22) are a NRC matter of compatibility requirement, and the Division elects to keep the Rule consistent with the NRC.

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