DPR 35
(76FR29171)

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Arkansas Department of Health

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Governor Mike Beebe
Paul K. Halverson, DrPH, FACHE, Director and State Health Officer

March 4, 2013

Secretary, U.S. Nuclear Regulatory Commission
Washington, DC 20555-001
ATTN: Rulemakings and Adjudications Staff

Subject: RCPD-13-001 (10 CFR Parts 30, 32, and 35)
Docket ID NRC-2008-0175

Dear U.S. Nuclear Regulatory Commission:

The Arkansas Department of Health, Radioactive Materials Program has reviewed the draft proposed rule to amend 10 CFR Parts 30, 32 and 35 and offers the following comments for review:

Revision §35.13/35.14

1. Should a revision be made to 30.32(g) if the changes to these sections go into effect?

Revision §35.50

2. Why mention in paragraph (a), (b), and (c)(1) about meeting the requirements in paragraph (d) when this isn't mentioned in (c)(2) or (c)(3) even though these two authorization routes have to comply with paragraph (d) as well due to the "and" between (c)(3) and paragraph (d)? The paragraph (d) requirement should be mentioned in each authorization route or be removed in order to prevent confusion.

3. (b)(2) could be more succinct by leaving out the phrase "is subject to the requirements in paragraph (b)(1) of this section. This is already evident by the fact that the word "and" is directly prior to sub-paragraph (2). Instead, begin (2) with "Has obtained a written attestation, signed by a preceptor..."

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4. How is the experience referenced in (c)(1), (2), and (3) to be demonstrated/documented? Currently, NRC Form 313A (RSO) (to which we have an equivalent) has the preceptor verifying this experience. With this draft, only individuals pursuing authorization via the alternate pathway would have the ability to have the preceptor verify his/her experience in radiation safety. What would be acceptable documentation/proof of this experience for the three other pathways mentioned above? Will guidance be put out concerning this?

5. Sub-paragraph (c)(3) is to enable an individual to be approved as the RSO and the AU on the same new license. Does this only apply to new licenses with just one user to be added? According to the language it seems that way. What if this AU/RSO added to a rural area's new RAM license decides to leave, so that another AU/RSO would need to be added? (c)(3) would no longer apply because the license would not be new, and possibly the second individual to be added has not been on a license before either. An amendment to the license would be required, and the license reviewer would have to authorize him as the RSO and the AU via (c)(2). New scenario: What if the applicant wants to add two users concurrently? Would you have to wait to add the second user to the license via a separate amendment in order to use (c)(3) for "the" one AU/RSO? Only having (c)(2) alone should address the rural area's dilemma – no (c)(3) is required. If you feel it is not currently clear, you could have a footnote referenced in (c)(2) saying that when simultaneously adding an individual as an AU and the RSO onto any kind of license (be it new, an amendment to the current license, or a renewal), when they are not already identified on a license, permit, etc., this can be achieved in one licensing action. This is how our State has handled this situation in the past, as one licensing action – "identifying"/adding the individual to the license as an AU (via AU T&E) then verifying the other experience and training required to be added as the RSO as well - following (c)(2) alone.

6. If (c)(3) must remain, the language appears a bit backward due to beginning the sub-paragraph with the experience portion. Consider the following: "(3) Is an individual seeking simultaneous approval both as the Radiation Safety Officer and the authorized user on the same new Commission or Agreement State license and has experience with the radiation safety aspects of the types of use of byproduct material for which the individual has Radiation Safety Officer responsibilities." Though, perhaps, "Commission or Agreement State" should be removed and "medical use," "Part 35," or say "license issued pursuant to...(and list the section number)" substituted. We are unsure if it's appropriate to list both agencies in this particular instance unless it is to point out to an out-of-state individual who has not been on a license before what the consensus of all of the States are (including NRC States). Otherwise, one would think NRC would list "Commission" only like in other instances.

7. We agree with licensees being able to list ARSO's on their license; however, the Department expresses hesitation in allowing an ARSO, who has been approved by the alternate pathway, to be a preceptor for an RSO and to provide supervision of the one year of full time radiation safety experience for a proposed RSO. For example, if an ARSO of a medical broad scope wants to be a preceptor for a proposed RSO of a small hospital, the ARSO may not have the experience of actually running a radiation safety program. Usually, an ARSO has limited responsibilities. An RSO would be able to provide more guidance in maintaining a good radiation safety program.

Revision §35.65

8. The proposed language in this section could be clearer.

   For example: It sounds as if you can have a 500 use source, and as long as it isn't aggregated with others, then you don't have to list it on the license even if it's greater than 30 mCi because you will have met the requirements in (b) as stated in 35.65(c) – due to its saying "sources in accordance with requirements in paragraphs (a) or (b).

   If (b) said "Byproduct material authorized by *paragraph (a)* shall not be..." and if paragraph (c) said "sources in accordance with the requirements in *§35.65* need not list..." the intent would be clearer. Also, consider saying in paragraph (c), "on a specific *license for medical use*" or "on a specific *license issued pursuant to...* "

Revision §35.390

9. In (b)(1)(ii)(G), the word "the" needs to be added for the sentence to read "...work experience must involve a minimum of three cases in each of *the* following categories."

Revision §35.590

10. Should the title of this section be revised to say "Training for use of sealed sources *and medical devices* for diagnosis?" This addition was made to 35.500 and seems to also apply to the training requirements for it in §35.590.

Revision §35.655

11. Why is the frequency for fully inspecting and servicing gamma stereotactic radiosurgery units changing from 5 years to 7 years? The reason for this change was not explained in the discussion of proposed amendments. Have the manufacturer's recommendations for all gamma knife units changed to a frequency of 7 years? Is there any information available supporting this change or evidence showing that radiation safety would not be compromised in any way by extending the inspection 2 more years?

Revision §35.3045

12. Should (a)(2)(iii) and (iv) say 150% instead of 50%, as discussed in the narrative?

To conclude, the Department agrees with the compatibility designations as identified in the letter dated February 28, 2013 from the Organization of Agreement States.

The Department appreciates the opportunity to comment on this rulemaking.

Sincerely,

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RulemakingComments Resource

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Subject: Comments RCPD-13-001
Attachments: PART 35 COMMENTS.pdf

Attached is the Arkansas Department of Health's comments for review. A hard copy is also being mailed.

Thank you,

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