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

September 21, 2011

Josephine Piccone, Director
Division of Intergovernmental Liaison
Office of Federal and State Material and Environmental Management Programs
U.S. Nuclear Regulatory Commission
Washington, D.C. 20555

Dear Dr. Piccone:

Enclosed are comments from the Department regarding the Part 35 Preliminary Draft Proposed Rule Language (May 16, 2011). The Department appreciates the efforts made to further improve Part 35.

Sincerely,

Angela Minden

Angela Minden, BS, CNMT
Health Physicist
Radioactive Materials Program
Radiation Control Section

cc: Jared Thompson, Program Manager

Enclosure: Comments regarding Part 35 draft

Template = SECY-067

DS10

Arkansas Comments
Regarding Part 35 Preliminary Draft Proposed Rule Language
(May 16, 2011)

35.13/35.14

How would the manufacturer allow the shipment of a different model number or different manufacturer of a source used for manual brachytherapy if it isn't listed on the license? We would require an amendment to the license to add the new model number and/or manufacturer. What purpose does a notification after the fact serve? Perhaps, we should just begin referencing the Sealed Source and Device Registry under the physical form column on the license, thereby allowing all manual brachytherapy manufacturers and model numbers for the indicated isotope/use. However, wouldn't this conflict with 30.32(g)?

35.50(c)

(c)(3) is to enable an individual to be approved as the RSO and the AU on the same new license – so only those requirements to become the AU have to be fulfilled? Does this only apply to new licenses with one user? What about two users? Would you have to wait to add the second user to the license via a separate amendment? It is proposed that the preceptor attestation not be required for this situation – is this still acceptable if the individual has never been on a license before as an AU or RSO? How is the experience referenced in (c)(3) to be demonstrated/documented? Is it via paragraph (e)? If so, why isn't paragraph (e) mentioned specifically? Why isn't paragraph (d) and (e) specifically referenced in the current (c)(2) like it is in (c)(1)? Also, why doesn't paragraph (b) reference (d) and (e) like with (c)(1)? The language in (c)(3) appears a bit backward due to beginning the paragraph with the experience portion; maybe there was no other understandable option. Paragraph (a) and (c)(1) individuals (certificants) may not feel it fair that they must provide a preceptor attestation, though these individuals may have the option of being approved as an RSO via their current AU status ((c)(2)) or as an AU/RSO on a new license ((c)(3)), both of which would require no preceptor attestation. What is the intent of (c)(3)? If this section wasn't included, wouldn't you just follow (c)(2) – add the individual as a user first (or AMP or ANP) then demonstrate "experience with the radiation safety aspects of the types of use..." just like (c)(3) indicates?

35.65

We feel (a)(2) should be stricken. If the sources are aggregated in a camera and used for medical use, then the authorization would fall under 500 anyway. If the sources are aggregated in a camera and not used for medical use, wouldn't this be the same scenario as storing multiple calibration sources in one location in a hot lab? These calibration sources would be authorized by 35.65 and therefore not be listed on the license.

35.396(d)(3)

Why do the parenteral administration training requirements state "A preceptor authorized user, who meets the requirements in 35.390... but 390, 392, and 394 training requirements reference 35.390(b)? Is it that with 300 uses, other than parenteral administrations, if you, as the preceptor, were authorized via the alternate pathway ((b)) you must have experience in administering dosages in the same category or categories as the individual requesting authorized user status, but, concerning parenteral administrations, no matter how you, as the preceptor, were authorized to perform them (references just 390, no (b)) you as the preceptor still must have experience in administering dosages as stated above? So, for I-131 use, for example, a preceptor authorized by board certification doesn't have to have experience in administering dosages as stated above? If this isn't the case (and maybe if it is the case), should this portion of the above training requirements be stated differently?

35.600

What is the intent/methodology behind paragraph (a) versus paragraph (b)? Is it to authorize the use of the unit/device itself like with 35.500? If so, should the title of the regulation also be revised, like with 35.500, to reflect the authorization of the use of the unit itself?

Rulemaking Comments

From: Bhalla, Neelam
Sent: Wednesday, September 21, 2011 11:59 AM
To: Rulemaking Comments
Subject: FW: Comments regarding draft proposed rule language - Part 35
Attachments: Draft proposed rule lang comments Re Part 35 cltr.pdf; Arkansas Comments Re draft proposed rule lang for Part 35.doc

Here is a comment letter from Arkansas on Part 35 prel. Rule text (NRC-2008-0175).
Neelam bhalla

From: Angela Minden [mailto:Angela.Minden@arkansas.gov]
Sent: Wednesday, September 21, 2011 11:45 AM
To: Bhalla, Neelam
Subject: FW: Comments regarding draft proposed rule language - Part 35

These are the correct two attachments. Sorry about that. ☺

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From: Angela Minden
Sent: Wednesday, September 21, 2011 10:38 AM
To: 'Bhalla, Neelam'
Subject: Comments regarding draft proposed rule language - Part 35

Please see attached letter and comments. I'm sorry for the delay. Thank you for your help!

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