From: Angela Hill
To: RulemakingComments Resource
Subject: State of Arkansas Comments on NRC-2008-0175 and NRC-2014-0030 Due Today
Date: Tuesday, November 18, 2014 4:30:57 PM
Attachments: BYPRODUCT MATERIAL REGS., PARTS 30, 32, AND 35.pdf

Good afternoon,

Please see the attached letter dated today and signed by Bernard Bevill, Section Chief, regarding Proposed Amendments to Medical Use of Byproduct Material Regulations, 10 CFR Parts 30, 32 and 35
(Docket ID NRC–2008–0175) and Draft Guidance (Docket ID NRC–2014–0030).

If you need anything, please let us know.

Thank you.

Sincerely,

Angie D. Hill

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From: Sandra Page
Sent: Tuesday, November 18, 2014 3:15 PM
To: Angela Hill
Subject: NRC Letter

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Governor Mike Beebe
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November 18, 2014

Neelam Bhalla, Division of Material Safety, State, Tribal,
and Rulemaking Programs
U.S. Nuclear Regulatory Commission
Washington, D.C. 20555-0001

Cindy Bladey, Rules, Announcements, and Directives Branch
Office of Administration
Mail Stop: 3WFN-06-A44MP
U.S. Nuclear Regulatory Commission
Washington, D.C. 20555-0001

RE: Proposed Amendments to Medical Use of Byproduct Material Regulations, 10 CFR Parts 30, 32 and 35 (Docket ID NRC–2008–0175) and Draft Guidance (Docket ID NRC–2014–0030).

Dear Ms. Bhalla and Ms. Bladey:

Thank you for the opportunity to respond to the Proposed Amendments to Medical Use of Byproduct Material Regulations, 10 CFR Parts 30, 32 and 35 and the associated Draft Guidance. The Arkansas Department of Health supports the comments made by the Organization of Agreement States in the letter dated November 18, 2014 and by the Conference of Radiation Control Program Directors in the letter dated November 17, 2014. The Department offers the following additional comments:

1. Section IV.D.(4) of 79 FR 42410:

   The Department strongly recommends that medical event reporting requirements in §35.3045 remain a Compatibility C designation. This designation allows the States the flexibility to be more restrictive.

2. Section IV.D.(2) of 79 FR 42410:

   The Departments supports the 180 day turnaround time of the final rule to become effective.

3. Revision §35.50:

Why mention in paragraph (a), (b), (c)(1), and (c)(2) about meeting the requirements in paragraph (d) when this isn't mentioned in (c)(3) even though all authorization routes have to comply with paragraph (d) 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. If the intent is to not make (c)(3) individuals subject to the training required in (d), then this section will need to be restructured so that it does not read like they are subject to (d). On page 25 in the proposed guidance, (d) is not mentioned in reference to the (c)(3) pathway. On page 31, it says (d) is required for (c)(3). On proposed NRC Form 313A, (d) is not mentioned/required for (c)(3) individuals.

Should the "experience in radiation safety" mentioned in (c)(1), (2), and (3) not use the same language in order to avoid confusion? (c)(1) says "...experience in radiation safety for similar types of use..." (c)(2) says "...experience with the radiation safety aspects of similar types of use..." (c)(3) says "...experience with the radiation safety aspects of the types of use..." With (c)(1) and (c)(2) saying the experience just has to be similar/somewhat the same, then that implies that (c)(3)'s experience has to be with the exact same types of use for which he/she is seeking approval.

How is the experience with pertinent radiation safety (aspects) referenced in (c)(1), (2), and (3) to be demonstrated/documented? Currently, NRC Form 313A (RSO) has the preceptor verifying this experience for (c)(2) individuals only. There is not a designated area on the proposed 313A to document this experience that the regulations require; this could cause confusion. In reading the proposed guidance, it seems that on page 25 the (c)(1) individuals must only provide his/her certificate and proof of (d), but on page 30 it appears that (c)(1) individuals must submit a copy of their certification as well as a description of the experience specified in (c)(1) and the training and experience detailed in (d). Page 25 somewhat implies that the submitting of a (c)(2) certification is separate from demonstrating experience in the radiation safety aspects... On page 31, (c)(2) individuals must submit a copy of the license/permit he/she is listed on that indicates the individual is an AU, AMP, or ANP and has experience with the pertinent radiation safety aspects (i.e., being on the license alone is evidence that the aforementioned experience has been achieved – no description of the experience is required). For (c)(3) individuals, the Department sees no mention in guidance of a requirement for this particular kind of experience (whether to document it somehow or not)...though the proposed regulations state it to be a requirement. Acceptable documentation/proof of this experience for these three pathways should be clear. If the experience does not have to be documented, then it should not be required in regulation.

In the proposed NRC Form 313A (RSO), the Department is unsure how to document training and experience for (c)(1) individuals (medical physicists) since #1 Board Certification is now specified for certification processes recognized under 10 CFR 35.50. (c)(1) talks of specialty boards recognized under 35.51(a). Clarification would be helpful.

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 due to the use of "the" authorized user instead of

"an" authorized user. If the intent is to use "the" in a singular fashion, so as to limit the use of this authorization pathway to rural settings/one authorized user on the license, then the Department is unsure that this pathway wouldn't actually be used by license reviewers to add the first AU/RSO as part of a new license application and then in a separate licensing action add multiple other AU's they are requesting to add. As discussed above, if (d) training and experience is not meant to be demonstrated by (c)(3) applicants (though the use of "and" between (c)(3) and (d) in the proposed regulations indicates they should), then having the (c)(3) pathway in regulation could lead to a large institution applying for a new license having an RSO that did not have to demonstrate compliance with paragraph d. Only having the (c)(2) pathway alone should address the rural area's dilemma – no (c)(3) is required – unless the intent is for (c)(3) individuals to not be subject to (d). Our State has handled the AU/RSO 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 by paragraph (d) in order for the individual to be added as the RSO as well - following (c)(2) alone.

The language appears a bit backward in (c)(3) due to beginning the sub-paragraph with the experience portion. Consider the following: "(3) Is an individual who is seeking simultaneous approval both as the Radiation Safety Officer and the authorized user on the same new Commission or Agreement State license and who has experience with the radiation safety aspects of the types of use of byproduct material for which the individual has Radiation Safety Officer responsibilities."

Perhaps a chart in guidance would be helpful that delineates exactly what should be submitted by each authorization route…where each route would be listed on a row ((a), (b), (c)(1), (c)(2), and (c)(3)) and across the top would be what is required to be submitted (copy of board certificate, training documentation pursuant to paragraph (b), radiation safety aspects training, paragraph (d) training and experience, and preceptor attestation). An "X" would be placed in each cell where that type of documentation was required for that particular authorization route.

4. Revision §35.190, 290, 390, 392, 394, 396, 490, 690:

The Department believes the "Committee on Post-Graduate Training" of the American Osteopathic Association mentioned in these sections is now called the Council on Postdoctoral Training. The name in quotes is also used in the draft NRC Form 313A (AUD).

We appreciate the opportunity to comment on the proposed rules and draft guidance. If you have any questions, please contact us at 501-661-2301.

Sincerely,

Bernard Bevill, Section Chief
Radiation Control Section

BB: AH: AM