Arkansas Department of Health

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Fay W. Boozman, MD, MPH, Director
Mike Huckabee, Governor

October 18, 2004

Paul H. Lohaus
USNRC
Office of State and Tribal Programs
11555 Rockville Pike
Rockville, MD 20852

Dear Mr. Lohaus:

Enclosed are comments from Radiation Control, Arkansas Department of Health, regarding the draft-final rule entitled "10 CFR Part 35, Medical Use of Byproduct Material – Recognition of Specialty Boards."

An electronic copy has been forwarded to Roger Broseus at his e-mail address.

Thank you for the opportunity to comment on the proposed changes. If you have any questions, please feel free to contact me at (501) 661-2173.

Sincerely,

Kim C. Wiebeck

Kim C. Wiebeck, Health Physicist
Radioactive Materials Program
Radiation Control

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ARKANSAS DEPARTMENT OF HEALTH
RADIATION CONTROL
COMMENTS
Medical Use of By-Product Material-
Recognition of Specialty Boards

Revised Training and Experience Requirements

Comments Regarding 35.190 and 35.290 Users

Discussion

Prior to the publication of the proposed Part 35 revision, the Agreement States had requested both verbally and formally via a recent Organization of Agreement States' Petition for Rulemaking that the training and experience requirements indicate not just the total number of training and experience hours required but also specifically indicate the number hours of classroom and laboratory training. This request was made because the Agreement States believed that in order to remain compatible with NRC and to ensure consistency across the country, it was necessary to break down the total number of hours to include minimum acceptable hours for classroom and laboratory training. The basics of radiation safety are learned in the classroom setting rather than a clinical setting. Therefore the Agreement States believes this to be a radiation safety issue rather than a practice of medicine issue. Arkansas agrees with this position.

In the Summary of Public Comments and Responses to Comments it is indicated that the NRC believes that specifying a minimum number of hours of classroom and laboratory (didactic) training, in the alternate pathway, will help to ensure that training programs are of adequate length to properly cover the topics important to the safe medical use of byproduct material. Discussion within this section of the document also indicates that the number of hours of didactic training were established by considering the relative hazards from radiation to patients, radiation workers, and the public, for each type of use. The NRC also believes that more depth of knowledge is required in radiation physics, mathematics, chemistry, biology, and protection for the higher-risk uses. Based upon these statements it can be concluded that the NRC, just as the Agreement States, believes this to be a radiation safety issue.

Using the above criteria, the NRC has concluded that higher-risk activities (use of 35.300 material) require more didactic training than lower-risk uses (use of 35.200 materials). Therefore, it has been proposed that only 80 hours of didactic training be required for 35.290 users while 35.390 users must receive 200 hours.

Comments and Questions

Comment 1
With the exception of 35.190 and 35.290 users, the proposed training requirements are the same or greater (in the case of 35.300 material) than Subpart J requirements. Has the risk from the use of 35.100 and 35.200 materials decreased significantly more than the risk from the use of other byproduct materials? For these categories of uses, has the need for an increase in clinical experience been shown as necessary?

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Comment 2

It appears in attempting to quantify the "risk" from each type of use, the NRC considered only the relative hazard from radiation. The hazard alone does not define "risk". Risk is defined by two parameters – Consequence and Probability.

While the hazards associated with 35.200 materials may be of less consequence (hazard) than 35.300 materials, the significant difference in the number 35.200 material studies performed on a daily basis as opposed to 35.300 material studies performed daily makes it much more probable that an incident will occur with 35.200 materials on a more frequent basis. Using a qualitative risk matrix, it can be concluded that risk associated with the use 35.200 materials is the same if not greater than the risk associated with the use of 35.300 materials.

If both consequence and probability are considered as defining risk, it seems that the radiation safety training (via didactic training) of 35.290 users should be the same as that of 35.390 users.

Comment 3

35.50 outlines various pathways to meet the qualification to be named as a Radiation Safety Officer. Regardless of the pathway used to qualify and individual to serve in this position, the radiation safety issues that must be addressed by the RSO will be the same. Therefore, it is reasonable to assume that the radiation safety training of all potential RSO's should be the same.

Of all the pathways listed, 35.290 users are the only category that is required to have less than 200 hours of didactic training. The alternate training pathways for RSO [35.50(b)], Authorized Medical Physicists [35.55(b)], 35.390 users [35.390(b)], 35.490 users [35.490(b)], and 35.690 users [35.690(b)] specifically indicate that the individual must have 200 hours of classroom and laboratory training. In addition, although not specified as 200 hours, the training required for Authorized Medical Physicist is more than equivalent to 200 hours of didactic training.

Why then should the classroom and laboratory training for 35.290 users be any less than all the other individuals who could be permitted to work as an RSO? The issues are the same, the responsibilities are the same, shouldn't the training be the same? After all, this is a radiation safety issue.

Conclusion

I think another Agreement State Representative summed it up nicely – If health physics basics are taught, why should all individuals not be required to take the same number of hours.

Whether these hours are established at a minimum of 200 hours or 120 hours, as suggested as an alternative, they should be the same for all categories of users because the radiation safety knowledge required to adequately function as an Authorizer User or Radiation Safety Officer is the same. In essence, why mess with something (Subpart J requirements) that has worked for years.

With the exception of limited use authorized users (35.190, 35.392, 35.394, 35.491, and 35.590), Arkansas Radiation Control recommends that the alternate pathways for all other Authorized User categories, Authorized Nuclear Pharmacists, and Radiation Safety Officer require a minimum of 200 hours of classroom and laboratory training out of a total 700 hours of training and experience.

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Preceptor Statement

During the October 5, 2004 ACMUI teleconference a question arose regarding the preceptor statement and what language would be required in the preceptor statement for Board Certified individuals. It was indicated that the Board Certified individuals preceptor statement would only have to indicate the total hours of training and experience rather than a breakdown of classroom/laboratory and clinical.

After re-reading the training and experience regulations, I noted that the proposed revision is written in such as way as to only apply the preceptor statement to the alternate pathway. For example, the preceptor statement paragraph of 35.190 and 35.290 appears as a sub-item (2) under (c), which is the alternate pathway. The same numbering is used in 35.390 where the preceptor statement appears as sub-item (b)(2). To apply the preceptor requirement to all pathways the regulation should be numbered (a) or (b) or (c) and (d) with (d) being the preceptor statement.

It was further noted that for the preceptor statement paragraphs, (c)(2), of both 35.190 and 35.290 the following is stated "... that the individual has satisfactory completed the requirements in paragraph (c)(1) of this section." The proposed (c)(1) of 35.190 and 35.290 specifically indicate the total number of hours for training and experience as well as the minimum hours of classroom/laboratory. Therefore, if these statements were simply revised to (d) using the numbering system noted above, all preceptor statements regardless of pathway would be required to indicate total hours of training and experience as well as classroom/laboratory hours.

Arkansas would recommend that all training and experience regulations be carefully reviewed to assure that they are correctly numbered, so that the intent of the regulation is incorporated into the regulation.

Radiation Safety Officer

35.50(e) states in part, "Has training in the radiation safety, regulatory issues, and emergency procedures for the types of use for which a licensee seeks approval." I foresee the potential for significant licensing issues to arise from this requirement.

Will facilities, who are permitted to appoint temporary Radiation Safety Officers (RSO), know or remember to check the individuals' qualifications to assure that they have been adequately trained in all uses approved under their license and have a preceptor statement regarding the training?

Will NRC and Agreement State license reviewers remember to check the RSO qualifications when new uses are added to the license? Will licensees' be required to provide documentation of RSO qualifications whenever a new use is added? When reviewing an amendment request or a renewal will license reviewers be able to locate original documentation submitted for a RSO who has been named on the license for several years?

We would recommend that the NRC develop licensing guidance and procedures to address these potential issues.

Didactic Training

Note: The following statements are based upon the teleconference discussion that recognized that regulation does not require training programs to comply with the "alternate pathway" T&E requirements. However, these training programs would have to structure their curriculum in such a way as to assure that individuals who did not pass their certification boards, would be able to work as authorized users via the "alternate pathway".

During the teleconference another long discussion centered on the definition of "didactic training". The NRC staff indicated that didactic was classified as classroom and laboratory training and that this was defined in the supplemental information. Several individuals indicated that training programs might have to alter their curriculum if "didactic training" did not include clinical laboratory training, such as that conducted in a facility hot lab. It was requested that the definition of didactic training be specifically spelled out in the regulations so that in years to come there would be no question as to the meaning of "didactic training".

It should be noted that proposed revisions of 35.190, 35.290, and 35.390 do not state "didactic training". The following wording is used "Has completed XX hours of training and experience, including a minimum of XX hours of classroom and laboratory training...." This is the same wording that appears in Subpart J. If the proposed hours become final, the training programs will not have to alter their curriculum, which is based on the Subpart J wording of "classroom and laboratory training", they will simply have to alter the number of hours dedicated to classroom and laboratory training.

While the revised T&E regulations do not contain the word "didactic", this wording is used in 35.509(b)(1)(i) for RSO training as well as in 35.55(b)(1)(i) for Authorized Nuclear Pharmacist training. The NRC should consider deleting the word "didactic" from Part 35 regulations and replacing it with classroom and laboratory training.

Arkansas also believes that the specialty boards should be required to meet both the total training and experience hour requirement as well as the specified hours of classroom and laboratory training. This will ensure consistency as well as specificity, and establish clearly defined criteria for certification board recognition.