

Steering Group Meeting – Working Group Report
Revise 10 CFR 35 - Requirements for Training and Experience
Long Notes
August 23, 2004, 1:00 P.M. – 2:30 P.M.

Attendees

Steering Group Members

Terry Frazee, State of Washington (via telecon)
Patricia Holahan (Chair), NRC, NMSS, IMNS
Michael Lesar, NRC, OCIO
Josephine Piccone (for Paul Lohaus), NRC, OSTP
Stuart Treby, NRC, OGC

Working Group Members

Roger Broseus, NRC, NMSS, IMNS
Colleen Casey, NRC, Reg III (via telecon)
Susan Chidakel, NRC, OGC
Robert Dansereau, New York State Dept. of Health (via telecon)
David Walter, State of Alabama (via telecon)
Ronald Zelac, NRC, NMSS, IMNS (via telecon)

Others

Neelam Bhalla, NRC, NMSS, IMNS, RGB
Don Cool (Steering Group Advisor), NRC, NMSS, OD
Mark Delligatti, NRC, NMSS, IMNS, RGB
Thomas Essig, NMSS, IMNS, MSIB
Scott Moore, NRC, NMSS, IMNS, RGB
Sandra Wastler, NMSS, IMNS, MSIB

Introduction

The Recommendations of the WG, Rulemaking on Revisions to 10 CFR Part 35 (T&E), includes changes and the suggestions from Susan Chidekal.

- Roger Broseus will send an electronic version after this meeting.
- The WG collectively resolved to support option 5.
- OGC advised (Susan) that if this change were made, NRC would not need to republish the rule for public comment. It would not be necessary as the public was able to comment on the previous iteration.

Recommended Option - Option 5 – Robert Dansereau

- A compromise was made: the discussion centered around “Which option can [you] live with?”
- There was one dissenting member who preferred the examination option.
- Josie Piccone asked a question, “Regarding the ‘cons,’ why would there be a ‘long time to implement’?”
 - The WG believed that at the time there would be a renote for public comment and thought that the rulemaking process would be very lengthy. If this is not renoted, then the timeline is shortened, and this “con” no longer be relevant. “A three-year rule making would be required if the issue was not addressed in guidance space.” Note that the lengthy time period referred to was not related to the 3-year allowance for AS adoption.
 - ACMUI had a concern that 3-year adoption allowance would not be allotted but the “long time to implement” addressed the rulemaking timeline.

- There was a question as to why the required hours for Part 35.390 differ from those for Part 35.290 (200 hours as opposed to 80-100 hours). David Walter? believed that the differing requirements were justified in the more complex administration of alpha, beta, and gamma therapies to kill living tissues, making the physics is more important. Increased levels of complexity for users justify the different requirements: the required mathematics may more in depth for users of Part 35.390 than Part 35.280; blocking agents may be employed; and the routes of administration may are more varied. Each situation offers a unique radiation safety issue. The possible contamination also may become a unique problem to users under Part 35.390.
- AS have been using 200 hours as basis for approval for nuclear pharmacists. All nuclear pharmacists are required by the States to have a minimum of 200 hours of classroom and laboratory training and 500 hours of supervised clinical training or experience, so the 200-hour minimum is a non-issue for nuclear pharmacists as all State pharmacy boards require more training.

Agreement State Poll – David Walter & Terry Frazee

- A copy of the summary was sent by e-mail and distributed out in paper copy. Two-thirds of the States responded to the poll. Of those responses, there were 18 “yes” responses to the first question (i.e., States could live with the option). In the second round, second question, there were 18 “yes” responses, 1 “no,” and 2 did not answer.
- Please note that States only saw what was distributed last December (2003) [the proposed rule]. That may explain why there were a few “no”s from the first set of questions. If the consensus option was sent out to be republished, then it is expected that the compromise (option 5) would elicit a more positive response.
- Ron Zelac solicited comments from the other Regions and noted no problems for users when there were no standardized minimum number of hours.
- Note that there are a few cross-trained doctors that used the current rule (old rule) to obtain authorized user status.
- David Walter indicated that the recommended hours for Option 5 were not arbitrary. While some believed that the numbers were based from (old) Subpart J, he noted that they were from a letter that he had written as a comment. When recommending the minimum hours, he had considered the relative risk for each type of use and anticipated an 8-hour class day; therefore, the hours are different for each type of user.
- While many in the nuclear community may regard clinical experience as more important as didactic training, it is more conducive to radiation safety to learn the physics (mathematics, calculation of dosages) in the classroom. Therefore, there is a preference for more didactic training for higher-risk activities.
- Roger retracted his dissenting opinion (Attachment 7) after noting that the number (and proportion) of people who would be burdened by the changes would be low. In the Reg. Analysis for the rule, the number of people who were approved through the alternative pathway (per annum), of a total of 610 authorized users, ~~only~~ 2 nuclear pharmacists, 11 users for sections 35.190 and Part 35.290, and 5 users for sections 35.390 and 35.396), or approximately 20–30 people per year in the authorized user category and nuclear pharmacists. He considered the States’ need for consistency in reaching the decision to retract.
- SG Decisions 1 and 2: Should we include training and experience, and the specified number of hours?

- Mike Lesar: Option 5 is acceptable. He noted that he was not a technical person and would recuse himself from deciding the acceptability of the number of hours.
- Stu Treby: Option 5 is acceptable. Option 5 is a reasonable compromise and addresses the concerns of the States: the need for uniformity in the alternative pathway and the autonomy of the boards (i.e., allow the boards to continue with their procedures as they currently are without being affected). He noted that the WG must look closely at the rule language and not just number of hours.
- Stu Treby (serving as proxy) for Josie Piccone (who left the meeting): Option 5 is acceptable.
- Terry Frazee: Option 5 is acceptable, and the WG-suggested hours are fine.
- Pat Holahan: Option 5, and the number of hours is reasonable.
- Don (Option 5, hours for didactic are reasonable for the risks that are involved; still uncomfortable for didactic — look for a hidden message that didactic is more important)

Renoticing the Rule

- Decision 3: Should the NRC renote rule for public comment?
- It would establish a new precedent.
- The chairman's aim is to establish stability in regulation of medical use.
- Allows time to the boards to submit for our reviews. Currently, no boards except the cardiology board are approved by NRC. Delays will be introduced if renoticed.
 - Mike Lesar: Not to renote as this is mainly a legal question, and OGC says it is legally acceptable not to renote.
 - Stu Treby: Renoticing is not legally required.
 - Stu Treby for Josie Piccone: Do not renote.
 - Terry Frazee: The State of Washington would be required to renote such a change.
 - Pat Holahan: This sets a significant precedent, and we should not renote.
 - Don Cool: Do not renote. If the topic of the rulemaking has changed then we should renote, note that Ron Zelac mentioned that the results focused on individuals and not the boards.
 - Colleen Casey: This rule needs renoticing.
 - Ron Zelac: The proposed rule focused on the changes of requirements for noticing of certification boards. This has nothing to do with rules placed on persons following the alternate pathway. The changes are not anticipated from the changes in December 2003. Comments back were not received from constituents who would be affected by the specifications of training. While not legally required, some members believed it is necessary to allow comments from stakeholders.
 - SG will not recommend renoticing. The conclusion of this rulemaking is to change the alternative pathway and to make the board-certification pathway consistent. This is not a complete package, but when the complete package is gathered, then this must be addressed (boards addressed directly). The entire intent of the package should be addressed.
- The FRN needs to address any potential issues or stakeholders who will be burdened by the rule.
- NRC also will seek input from the ACMUI when going to AS.

Next Steps

- Brief the commission TAs on this decision and “where we were planning to go.” The brief should be prepared in the next week or two and should address the schedule of didactic hours versus the whole rule; begin preparation early next week. Note that one Commissioner is not inclined to agree to the OAS petition [to add requirements for didactic hours].
- Stuart Treby (OGC) noted that Attachments 3 and 4 need to be put into context.
- Attachment 3 resulted from feedback from David Walter after the first round of questions and that Attachment 4 was revised to reflect the need for boards to note how they are ensuring safety.
- Don Cool seconded the need for context: he suggested that the WG needed to explain the underlying thought process and the totality of this package and the relationship of the items.
- We do not know how many didactic hours the physician had; however, a group at NRC monitors events and does trend analysis.
 - An authorized user’s credential can be found, even if the AU used the alternative pathway.
 - Can a performance measure be obtained to corroborate our numbers? Does this rule provide enough training for safety? Can the NRC group that reviews medical events trace incidents/events to a lack of training?
 - There is discussion in the implementation procedures that directed NRC to review and check for “adverse” medical trends. Will that data be available (i.e., can we find where did the training come from)?
- The WG expressed its appreciation to Tony Tse for his assistance, and the WG chairperson expressed his appreciation to the WG team members for their hardwork and dedication to producing a quality product.

Summary

- The SG decided to include training and experience and the specified number of hours. The SG agrees with the WG on the viability of option 5.
- The WG will develop rule language for option 5, by taking into account OGC’s concerns regarding the rule language and adjusting supplementary information.
- The WG will also include, in the FRN, discussion of the concerns for consistency for the States and for the number of didactic hours in terms of safety. The entire intent of the package should be addressed, and it should be noted that the topic of the rulemaking did not change in regards to radiation safety.
- The WG will change the guidance statement and implemental procedures sections (Attachments 3 and 4 to the report to the SG).
- The Commission’s TAs will be briefed early next week—August 30 or 31, 2004—to explain the position of the SG and WG regarding option 5; the expectations of the SG and the WG as to the viability of consensus (ACMUI, AS); and the discussion between didactic hours versus the whole rule.
- The SG does not recommend renoticing as the topic of the rulemaking has not changed. OGC has noted that renoticing is not legally required; the SG has noted that if the language were to be renoticed, then it would be precedent setting.