

TELECONFERENCE MEETING OF THE
ADVISORY COMMITTEE ON THE
MEDICAL USES OF ISOTOPES

October 5, 2004
1:00-3:00 P.M.

MEETING SUMMARY

PURPOSE: To provide the Advisory Committee on the Medical Uses of Isotopes (ACMUI), the Agreement States (AS), and members of the public with an opportunity to comment on the Nuclear Regulatory Commission's (NRC) proposed recommendations to amend 10 CFR 35, "Medical Use of Byproduct Material," by adding required hours of didactic training to Sections 35.55, 35.190, 35.290, and 35.390, for the alternate pathway to Authorized Nuclear Pharmacist and Authorized User status.

OUTCOME: The NRC staff's Part 35 Steering Group will gain an understanding of the stakeholder views on the proposed amendment. NRC staff will consider these views during comment resolution and preparation of the final rule.

PART 35 STEERING GROUP PRESENTATION

Roger Broseus, NRC staff, gave an overview of the Steering Group's proposed amendment to Part 35.

ACMUI DISCUSSION

A number of ACMUI members felt that while they were not enthusiastic with the recommendation, they would be willing to accept it because of the Agreement States' needs. That being said, however, the ACMUI members felt that the proposed hours of training to be added to Sections 35.55, 35.190, 35.290, and 35.390 will unnecessarily inhibit the ability to gain status as an Authorized Nuclear Pharmacist (ANP) or as an Authorized User (AU). Dr. Eggli noted that Boards have chosen to build the alternative pathway requirements into the certification pathway, because approximately 20% of candidates fail to pass the certification exam and therefore, go through the alternate pathway. Some of the specific opinions expressed were as follows:

- The proposed allocation of hours of radiation safety training is disproportionately high. As a result, the time devoted to clinical training will be inappropriately reduced.
- NRC's proposal to add prescriptive hours of training has practice of medicine implications. Therefore, the NRC should avoid adding prescriptiveness to the rule in this manner.
- The proposed hours of training to be added to Section 35.390 are excessive.
- The term "didactic training" should be defined in Part 35.

AGREEMENT STATE DISCUSSION

AS members general consensus was that prescriptive hours of training should be added to Sections 35.55, 35.190, 35.290, and 35.390, to help ensure the competency of those seeking status as ANPs and AUs. Some of the specific opinions expressed were as follows:

- The AS focus is not on the practice of medicine. The AS's are concerned with radiation safety. Requiring standardized hours of training will enable AS regulators to more effectively evaluate candidates' ability to independently implement a radiation safety program.
- Smaller, more isolated clinical practices do not have the support and external resources that larger, major medical centers have. Therefore, it is vital that clinicians in these smaller clinical practices are thoroughly trained in all aspects of clinical practice, to include safe handling of byproduct material.
- AS agreed that 200 hours for ANP training was adequate. There was no agreement on adequate hours for AU training, but a range of 8 to 200 was suggested. Final AU training hours should be risk-based.

MEMBERS OF THE PUBLIC COMMENTS

Members of the public voiced concerns over the ability to adequately understand the proposed changes. To ensure maximum understanding of the proposed changes, it was suggested that the NRC post a redline/strikeout version of the proposed changes to the NRC web site when the final rule is distributed.

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