

MEETING OF THE
ADVISORY COMMITTEE ON THE
MEDICAL USES OF ISOTOPES

August 16, 2007 and September 20, 2007

MEETING SUMMARY

PURPOSE: To continue the discussion on training and experience issues related to the implementation of the medical regulations in 10 CFR Part 35, "Medical Use of Byproduct Material."

OUTCOME: The Nuclear Regulatory Commission (NRC) staff gained a better understanding of the views and opinions of the Advisory Committee on the Medical Uses of Isotopes (ACMUI), as well as other stakeholders' views and opinions. The staff will consider these views in its continuing effort to make 10 CFR Part 35 more useful, practical, and not overly burdensome on licensees, while maintaining public health and safety.

TRAINING AND EXPERIENCE

Unintended Consequence of Prescriptive Requirements on Certification Boards Resulting in NRC Setting Curriculum

Summary of Issue

Individuals who wish to be an Authorized User (AU) but have not yet passed the board certification exam must meet the requirements of the alternate pathway. Approximately 10-20 percent of those individuals who sit for the board certification exam do not pass on the first attempt; therefore, the unintended consequence is that the boards must teach to the alternate pathway. The ACMUI has no objection to the NRC indicating which topics should be covered for board certification; however, the ACMUI feels the determination for the number of hours for each topic should be under the purview of the certification boards.

Discussion

Dr. Welsh suggested that individuals who are eligible to take the board examination should not have to satisfy the alternate pathway but should be eligible as an authorized user if they have completed the requirements of board certification, even though they have not passed the exam.

Dr. Vetter raised the point that there are individuals who have passed the board certification exam; however, since the boards are only recognized for certain years, not all individuals who have passed the exam would meet the criteria to be an AU. Dr. Guiberteau of the American Board of Radiology (ABR) supported Dr. Vetter's statement and offered information on recently trained physicians who received their board certification in 2004 or 2005 but are currently not eligible through the board certification pathway to be an AU. Dr. Guiberteau explained that there are approximately 400 to 500 individuals who have written to or informed the ABR that they are ineligible under the board certification pathway and must meet the criteria of the

alternate pathway. Gerald White of the AAPM also described several classes of individuals who are impacted by the new board certification recognition. Mr. White estimated that there are potentially thousands of physicists and a large number of physicians who are unable to use their board certifications from prior to 2007.

Drs. Nag and Williamson provided personal examples and engaged NRC staff to determine whether or not they would be eligible to be an AU under various circumstances.

Conclusion

Drs. Malmud, Nag, Welsh, Williamson, Vetter, and Mr. Lieto engaged representatives from the certification boards and other stakeholders to amend motion (3) from the June 12, 2007 meeting summary to read as follows:

MOTION 1: NRC staff should revise the regulations so that board certified individuals, who were certified prior to the effective date of recognition or were certified by previously recognized boards listed in Subpart J of the previous editions of Part 35, are grandfathered.

The motion was seconded and passed unanimously.

Canadian Trained Authorized Users Not Eligible Under the Board Certification Pathway

Summary of Issue

A nuclear medicine physician certified by the American board of Nuclear Medicine but trained in Canada cannot currently be recognized as an AU by the NRC because the individual's training was not completed under the supervision of an AU. The physician must qualify for AU status under the alternate pathway even though they are board certified.

Discussion

Dr. Welsh proposed NRC staff amend the current regulations to include training under the Canadian equivalent of an AU. Dr. Henry Royal of the American Board of Nuclear Medicine (ABNM) stated that the boards regard the Canadian training program as being equivalent to the United States (U.S.). Sandra Wastler of the NRC indicated that NRC had recently received an application for recognition from the Canadian College of Physicists in Medicine (CCPM). Dr. Eggli raised the issue of a Canadian trained physician finding a preceptor to sign for their work experience. Ms. Wastler explained that currently individuals may come to the U.S., work under the supervision of an AU, and then obtain a preceptor statement from the supervising AU.

Conclusion

After a discussion with ACMUI members, other stakeholders, and NRC staff, Dr. Welsh's motion was formalized and seconded by Dr. Nag.

MOTION 2: NRC staff should revise the current regulations to include Canadian trained individuals who have passed the ABNM certification exam.

The motion carried unanimously.

Compatibility Category B vs. C for Training and Experience Requirements

Summary of Issue

The ACMUI desires Compatibility Category B for regulations so that individuals may practice anywhere in the U.S. without inconsistency in the training and experience requirements. Compatibility Category C allows states to have different training and experience requirements, allowing inconsistency among multiple jurisdictions. Some states currently have more restrictive requirements and wish to retain the flexibility of Compatibility C level regulations.

Discussion

Dr. Ron Zelac of the NRC informed the ACMUI and stakeholders that the Commission specifically directed NRC staff to assign Compatibility B for training and experience requirements for all categories of authorized users to ensure that training and experience requirements for the medical use of byproduct material are consistent between NRC and the Agreement States. NRC staff clarified the meaning of Compatibility B and C for ACMUI members.

Conclusion

MOTION 3: NRC staff should maintain Compatibility B for training and experience requirements to ensure that authorized individuals may cross state borders and practice throughout the U.S.

The motion carried unanimously.

Unavailability of Preceptor for Authorized Individuals

Summary of Issue

ACMUI and stakeholders are concerned that if a preceptor is not available or has passed on, an authorized individual may not be able to easily obtain the signature of another preceptor who is willing to attest to an individual's past training and experience that the preceptor did not personally supervise.

Discussion

Dr. Donna-Beth Howe of the NRC summarized many aspects of preceptor statements and clearly defined "preceptor" for the ACMUI and stakeholders. Dr. Eggli stated his unwillingness to sign a preceptor statement for training or experience that he did not personally supervise. This means an individual must repeat the training and experience under the supervision of the new preceptor. The ACMUI reaffirmed their dissatisfaction with the NRC's use of the word "competency" in preceptor statements. Ms. Schwarz asked that Dr. Malmud and Dr. Vetter discuss this topic directly with the Commissioners. Drs. Malmud and Vetter agreed that this is a high priority item to discuss with the Commission.

Dr. Darlene Metter of the Texas Radiation Advisory Board (TRAB) provided examples and stated issues with preceptor statements in the state of Texas. Salli Cheever with Physics Consultants, Inc. in Maine stated this issue comes up frequently. Ms. Cheever stated that authorized individuals might have obtained board certification over seven years ago and have not been listed on a radioactive materials license, and in Ms. Cheever's specific example, the individual must have the preceptor statement signed by the AU under whom they are currently working. Ms. Cheever added that this is acceptable in the state of Maine. Dr. Williamson stated that individuals previously trained at his facility have requested preceptor statements regarding their competency to function independently, and those individuals have been denied. Dr. Eggli supported Dr. Williamson's statement and confirmed the same situation occurs at his institution. Debbie Gilley of the state of Florida stated that not all Agreement States have implemented the new Part 35, and, therefore, have no current experience with this issue.

Dr. Howe confirmed that, in lieu of the NRC Form 313A, individuals can submit equivalent information to include a preceptor statement. Dr. Howe also stated that NRC has not received any requests from the NRC Regional Offices to address this issue, so NRC is unaware of any specific examples. Jackie Cook from NRC Region IV stated there was a potential issue with individuals obtaining preceptor statements; however, Roberto Torres of RIV stated he had only seen approximately one or two individuals fall into this category. In both cases the individuals gained work experience under a current AU and obtained preceptor statements within a few months.

Lynne Fairobert of the American Association of Physicist in Medicine (AAPM) and Dr. Metter of TRAB stated they both had several board certified individuals who could not practice due to the current regulations. Dr. Sue Langhorst of Washington University in St. Louis (WUSTL) stated, as the RSO, that she would not submit an application to the Radiation Safety Committee, if the individual did not currently meet the qualifications.

Dr. Eggli suggested that the ACMUI offer no further comment since motion (2) from the June 12, 2007, meeting summary fully encompassed the issue. Dr. Nag suggested the group refocus the discussion to non-board certified individuals who cannot obtain a preceptor statement due to unavailability of a preceptor.

Conclusion

After a lengthy discussion with ACMUI members and stakeholders, Dr. Nag made a motion that was seconded by Dr. Williamson.

MOTION 4: NRC staff should accept a preceptor statement from another AU for a non-board certified individual if the AU who supervised the training and work experience is not available as a preceptor.

The motion carried; however, Mr. Williamson abstained.

Seven Year Recency of Training for Individuals Seeking Authorization

Summary of Issue

10 CFR 35.59 states that training and experience must have been obtained within seven years preceding the date of the application or the individual must have had related continuing education and experience since the required training and experience was completed.

Discussion

Drs. Nag, Williamson, and Mr. Lieto provided example scenarios for individuals who would not meet the seven year training and experience requirement. Ms. Gilley of the state of Florida and Michael Ford of TRAB provided comments from the Agreement State perspective. Ms. Wastler of the NRC added that although the Agreement States do not consult with the ACMUI for license applications or amendment requests, Agreement States can use their own internal processes to determine if the individual seeking authorization has the appropriate continuing education and experience.

Conclusion

Dr. Nag stated that the ACMUI currently addresses this issue adequately and no further discussion was needed. Ms. Schwarz seconded his statement. The ACMUI did not make a formal motion or vote.

The ACMUI generally agreed that NRC staff should continue to use a case-by-case approval process for individuals who do not meet the seven-year recency of training requirement and consult the ACMUI, as needed.

Increased Complexity vs. Additional Benefit of the New 10 CFR Part 35 Training & Experience Requirements

Summary of Issue

ACMUI believes the new 10 CFR Part 35 training and experience requirements do not increase public health and safety, and the additional cost and complexity of the new regulations is not justified. Additionally, ACMUI believes the new regulations make it difficult or possibly exclude certain groups of individuals from practicing.

Discussion

Dr. Williamson summarized the issue for ACMUI members, NRC staff, and stakeholders. Dr. Langhorst of WUSTL agreed with ACMUI that there was no added health and safety benefit for Radiation Safety Officers. Dr. Nag added that the increased complexity of the regulations is less beneficial since individuals, who could otherwise be treating patients, are excluded. Dr. Thomadsen agreed with the other ACMUI members and stated his recollection of a concern about freestanding units, in which there was no hospital credentials reviewing committee. Dr. Williamson provided additional insight and stated at one time there was a concern that the board certification mechanisms did not adequately address the technical aspects of radiation safety practices; therefore, the regulations needed to be amended to be more prescriptive, and a set of criteria to accept board certification mechanisms was added to the rule language. Dr. Williamson proposed a motion which stated the current revision of the training and experience regulations has not improved public health and safety and has actually diminished safety or possibly patient access to health care. Mr. Ford of TRAB supported Dr. Williamson's statement

and added that the TRAB viewed the revisions to the training and experience requirements as a very complex solution to a non-existent problem. Dr. Nag agreed with Dr. Williamson and Mr. Ford but clarified that the new regulations have not necessarily reduced patient safety but have not increased patient safety. Dr. Metter of TRAB later added that she was unaware of any negative impact on patient care.

Conclusion

Mr. Lieto suggested this topic be discussed at the October ACMUI meeting. Dr. Fisher formally made the motion, and Mr. Lieto seconded.

MOTION 5: NRC staff should add 'increased complexity vs. additional benefit' as an agenda item for the October ACMUI meeting, so that ACMUI may continue the discussion on this topic.

The ACMUI did not vote on this motion.