

October 22, 2003

MEMORANDUM TO: Charles L. Miller, Director
Division of Industrial and
Medical Nuclear Safety, NMSS

FROM: Thomas Essig, Chief
Materials Safety and Inspection Branch
Division of Industrial and ~~IRA~~ by
Medical Nuclear Safety, NMSS

SUBJECT: DRAFT PROCEDURES FOR RECOGNITION OF PROFESSIONAL
SPECIALTY BOARD CERTIFICATIONS

This memorandum serves to establish draft procedures to be used by the NRC staff for recognizing the certifications of professional specialty boards. This is to implement revised requirements in 10 CFR 35, "Medical Use of Byproduct Materials" to demonstrate adequacy of training and experience of individuals to be approved as a radiation safety officer (RSO) or an authorized medical physicist (AMP), authorized nuclear pharmacist (ANP) or authorized user (AU) as specified in 10 CFR Part 35, §§ 35.50(a), 35.51(a), 35.55(a), 35.190(a), 35.290(a), 35.390(a), 35.392(a), 35.394(a), 35.490(a), 35.590(a), and 35.690(a). The procedures for establishing and maintaining a listing of recognized board certifications, as directed by the Commission in SRM-02-0194 (February 12, 2002), and SRM-03-0145 (October 9, 2003) appear in the attachments to this memorandum. The instructions include procedures for monitoring the status of recognized boards and for delisting of boards.

IMNS staff plans to transmit draft implementation procedures to OSTP for posting on their web site for a 30 day comment period. OSTP will issue an All-Agreement States letter to request comment from Agreement States. The draft procedures will also be distributed to the Advisory Committee on the Medical Use of Isotopes for comment. If changes to the procedures are necessitated by comments received during the public comment period for the proposed rule to amend 10 CFR 35, revised draft procedures will be made available for Agreement State comment. The final procedures will be posted on the NRC's web site when the final rule is published.

Attachments:

1. Draft Procedures for Recognizing Certifications of Specialty Boards
2. SRM-02-0194
3. SRM-03-0145

cc: Dirs, NMSS, OSTP, STreby

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Attachment 1

Draft Procedures for Recognizing Certifications of Specialty Boards

Procedures for Recognizing Certifications of Specialty Boards

BACKGROUND

The Commission directed the NRC staff, in SRM-02-0194, dated February 12, 2002, to prepare a proposed rule to modify the training and experience (T&E) requirements in 10 CFR Part 35 relating to the recognition of specialty board certifications by the NRC. The SRM directed the staff, as part of the rulemaking process, to discuss implementing procedures both for adding new specialty boards to the recognized listing and for removing boards from the recognized list. All boards that meet criteria for recognition are to be listed on the NRC's web site rather than in the rule itself. In SRM-03-0145, dated October 8, 2003, the Commission instructed the NRC staff to discuss its plans, in the specific situation when a medical event may have been due to inadequate radiation safety training, to assess whether the examinations adequately assess the such knowledge/skills. The procedures provided below implement the Commission's direction as specified in the SRMs.

PROCEDURES

The following procedures provide guidance to the NRC staff on how to evaluate applications from specialty boards to determine if their certification processes satisfy the requirements for recognition and posting of recognized board certifications on the NRC's web site. All boards, including those recognized under the current rule, will be required to apply for recognition so that a clear regulatory determination that all boards meet the relevant criteria in the revised regulations, as required by the Commission in SRM-02-0194. The NRC staff will request applications, via letter, from specialty boards now recognized under Subpart J of 10 CFR Part 35, for recognition of their certifications under applicable sections of Subparts B through H. The procedures also provide methods for monitoring the status of recognized board certifications and for delisting of boards, should the need arise.

Communications with Specialty Boards

Communications between the NRC staff and specialty boards should be in writing, via letter. Communications to the NRC from specialty boards for the purpose of supplying information in support of an application, change in certification procedures, or other change that would affect recognition of the board's certification under the regulations in 10 CFR Part 35, are to be signed by a person authorized to speak for the board, i.e., its chief executive officer or delegate; the letter from the board should acknowledge management's commitments to and responsibility for the completeness and accuracy of the information provided to the NRC.

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Applications for Recognition of Specialty Board Certifications

1. Specialty boards requesting recognition should provide, via letter, a list of sections in Part 35 for which the board wishes to have its certification(s) recognized. The letter should include a clear description of their requirements for certification and a statement that candidates for certification must complete the requirements for training and experience required by the section(s) applicable to the type of certification, for which the board is seeking recognition, prior to receiving board certification and indicate that the letter of application should be dated and signed by the chief executive officer or delegate of the board. The board should also provide the location on the world wide web (URL), if the board posts its requirements for certification on the web. Include in letters to boards a request that boards notify the NRC, via letter, 6 months in advance, of plans for becoming inactive or disbanding as well as material changes to certification procedures that would affect their recognition status under the section of 10 CFR Part 35 that is applicable to their certification.
2. The NRC staff will review the procedures and requirements of specialty boards for conferring certifications to determine if they are in accord with the criteria established in the applicable sections of subparts B through H of 10 CFR Part 35 for NRC recognition of specialty board certifications. The requirements for recognition of a board's certification for Radiation Safety Officers (RSOs) appear in § 35.50(a), for Authorized Medical Physicists in § 35.51(a), for Authorized Nuclear Pharmacists (ANPs) in § 35.55(a), and for various classes of Authorized Users (AUs) in §§ 35.190(a), 35.290(a), 35.390(a), 35.392(a), 35.394(a), 35.490(a), 35.590(a) and 35.690(a). The NRC's Advisory Committee for Medical Uses of Isotopes (ACMUI) will be consulted when the staff determines that such consultation is necessary.
3. When the NRC staff finds that a board meets an applicable set of requirements for NRC recognition, the staff will notify the board via letter of its finding and add the board's name to the list of recognized boards appearing on the NRC's web site for Part 35 matters. This information will be posted on the NRC's web site to indicate the dates for which the board's certification are recognized.
4. If the NRC staff is unable to make a determination about the adequacy of a board's certification process, or if a determination is made that the board's process does not meet the appropriate set of requirements in Part 35, the board will be notified of the NRC staff's finding and requested to provide additional information or clarifications, in writing. The NRC staff will review the additional information provided by the board and make a determination as noted in 2, above.
5. If the NRC determines that a board's certification processes do not meet the applicable criteria in Part 35, the NRC will notify the board, via letter, and Agreement States of the name of the board and the date of this determination.
6. Agreement States may recognize the certifications of boards that meet requirements of rules compatible with those in 10 CFR Part 35. These boards will be included in the listing of recognized boards on the NRC's web site, with an annotation indicating which Agreement States recognized the boards.

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Maintenance of Recognized Status

1. When the NRC recognizes a board's certification process(es) and notifies it that its name will be listed on the NRC's web site, the board will also be advised that the board is to notify the NRC, via letter, 6 months in advance, of plans for material changes to certification procedures that would affect its recognition status under the section of 10 CFR Part 35 that is applicable to its certification(s). (See item 1 under "Applications for Recognition of Specialty Board Certifications.")
2. The NRC staff will review the changes to certification process(es), using the procedures outlined above (under "Applications for Recognition of Specialty Board Certifications") and will seek the advice of the ACMUI if the staff determines that such consultation is necessary. The NRC staff will determine if the board's certification procedures continue to meet the criteria for recognition of board certifications, as established in §§ 35.50(a), 35.51(a), 35.55(a), 35.190(a), 35.290(a), 35.390(a), 35.392(a), 35.394(a), 35.490(a), 35.590(a), and 35.690(a), and notify the board regarding its finding.
3. The NRC staff will periodically, at intervals not to exceed 5 years, ask, via letter, each board whose certification process(es) has (have) been recognized by the Commission, to verify in writing that all changes in its certification procedures, that would affect the recognition of its certification(s), have been communicated to the NRC for review. If a board does not respond, the NRC staff will investigate why and delist the board.
4. The Agreement State which initially recognizes a board will be responsible for determining that board's continued eligibility for recognition.

Procedures for Delisting Specialty Boards

1. Delisting based on inadequate radiation safety training of candidates for certification.
 - a. The NRC staff will monitor trends in medical events. If a trend in medical events for a particular speciality is attributable to inadequate radiation safety training, the staff will determine, in consultation with the ACMUI, if the trend is associated with a deficiency in the training of individuals traceable to inadequacies in a specialty board's certification process. If the trend is determined to be attributable to inadequate training related to the certification process, the NRC staff will assess whether the examinations provided by the certifying boards adequately assess the knowledge/skills reflected in the requirements for T&E related to recognition of specialty board certifications.
 - b. If the NRC staff determines that changes in training required of candidates for certification by a recognized specialty board are necessary in order for the board to maintain its recognized status, the board will be contacted and advised of this determination. The NRC staff will send a request to the board to provide a description of any changes it proposes to make to maintain its recognition by the NRC and to identify reasons for findings the board disagrees with. The NRC staff will use the procedures discussed under "Applications for Recognition of Specialty Board Certifications," item 1, as a guide in this process.
 - c. In the event that the board fails to respond or if, after reviewing the board's response, the NRC still believes that changes to certification requirements are necessary and the specialty board does not make changes to its requirements for certification that are considered adequate to address the NRC's concerns, then that specialty board's name will be removed from the NRC's list of recognized boards.

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- d. The Commission and the ACMUI will be informed of any decision by the NRC staff to remove a board's name from the list of recognized boards.
 - e. The NRC will notify the board that this action has been taken, and advise the board that it may supply new information for review by the NRC staff to determine if the board's procedures are adequate to resolve the NRC's concerns.
 - f. If a board is delisted by the NRC or an Agreement State due to inadequacy of its certification process requirements, the NRC staff will determine the date when the inadequacy developed, beyond which the certification will no longer be recognized.
 - g. When a board is granted recognition by an Agreement State, that State shall be responsible for delisting that board.
2. Delisting based on change in the certification process.
- a. If the NRC staff, in reviewing an instituted or proposed change in the certification process employed by a recognized board, determines, in consultation with the ACMUI, that the change may adversely affect the recognized status of the board, the board will be contacted and advised of this determination. The board will be requested to provide information to support continuation of NRC recognition of the board's certification.
 - b. In the event that the board fails to respond or if, after reviewing the board's response, the NRC staff still believes that the change in the board's certification process may adversely affect the recognized status of the board and the specialty board does not make adjustments to its certification process that are considered adequate to address the NRC's concerns, then that specialty board's name will be removed from the NRC's list of recognized boards.
 - c. The NRC will notify the board that this action has been taken, and advise the board that it may supply new information for review by the NRC staff to determine if the board's procedures are adequate to resolve the NRC's concerns.
 - d. The Commission and the ACMUI will be informed of an NRC staff determination that a board is to be removed from the list of recognized boards.
 - e. If a board is delisted by the NRC or an Agreement State due to inadequacy of its certification process requirements, the NRC staff will determine the date when the inadequacy developed, beyond which the certification will no longer be recognized.
 - f. When a board is granted recognition by an Agreement State, that State shall be responsible for delisting that board.
3. Delisting based on a recognized board becoming inactive or disbanding.
- a. If the NRC staff becomes aware that a board has or intends to become inactive or disband, the staff will attempt to contact the board. The NRC staff will request that the board provide information confirming whether the board has, or intends to, become inactive or disband, and if so, why the change should not result in withdrawal of NRC recognition of the board's certification.
 - b. In the event that the board fails to respond or if, after reviewing the board's response, the NRC still believes, after consulting with the ACMUI, that the board has changed its status and that this change should result in withdrawal of the NRC's recognition of the board's certification, then that specialty board's name will be removed from the NRC's

- list of recognized board certifications. Information about the dates for which the board's certification was recognized will be posted on the NRC's web site.
- c. The Commission and the ACMUI will be informed of any staff decision to remove a board's name from the list of recognized boards.
 - d. The NRC will notify the board that this action has been taken, and advise the board that it may supply new information for review by the NRC staff to determine if the board's procedures are adequate to resolve the NRC's concerns.
 - e. If a board is delisted by the NRC or an Agreement State due to becoming inactive or disbanding, the NRC staff will determine the effective date of this change in status and the date when the certification is no longer to be recognized.
 - f. When a board is granted recognition by an Agreement State, that State shall be responsible for monitoring the status of the boards and taking action to de-list a board's certification if it becomes inactive or disbands.

Evaluation of Training and Experience — "Outdated" Certifications

If an individual holds certification from a board for which the NRC or an Agreement State withdraws recognition, the certification will be considered valid if it was granted before the board's certification process is determined to be inadequate for recognition of the board's certifications by the NRC. The NRC will annotate the listing of boards on its web site to indicate the effective dates of recognition of board certifications, including the date(s) of delisting and date(s) through which certifications were recognized. The listing will also indicate the length(s) of time for which the board certifications are valid. (Note: the recentness of training requirements contained in 10 CFR 35.59 must also be satisfied.)

Attachment 2

SRM-02-0194

Attachment 3

SRM-03-0145