



U.S. Nuclear Regulatory Commission

Office of Nuclear Material Safety and Safeguards

NMSS Office Procedure

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Procedure Title: Procedures for Recognizing, Monitoring, and Terminating the Certification Process of Specialty Boards

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**NMSS Procedure MSST–70–03
Revision 2**

Summary of Changes			
Date	Description of Changes	Method Used to Announce & Distribute	Training
N/A	Initial Procedure	N/A	N/A
4/21/2014	Made into a division level P&P. Added position responsibilities. ADAMS Accession No. ML14084A395	N/A	N/A
12/14/2020	Included feedback from a self-assessment of the NRC process of recognizing, maintaining, and terminating specialty board recognition. Added Enclosures.	Office Announcement Posted to the Medical Use Licensee Toolkit public Web site	N/A

**PROCEDURES FOR RECOGNIZING, MONITORING, AND TERMINATING THE
CERTIFICATION PROCESS OF SPECIALTY BOARDS**

1. PURPOSE

The purpose of this document is to provide guidance on evaluating specialty boards to determine whether their certification processes meet U.S. Nuclear Regulatory Commission (NRC) regulations in Title 10 of the *Code of Federal Regulations* (10 CFR) Part 35, “Medical Use of Byproduct Material,” and therefore should be recognized by the NRC. It also provides guidance for the NRC on monitoring for continued satisfaction of the recognition criteria, guidance for determining whether NRC recognition should be terminated, and guidance for maintaining the NRC-recognized board certifications on the NRC public Web site.

¹ This NMSS Office Procedure provides guidance for implementing the mandatory information collections in 10 CFR Part 35 that are specific to specialty board certification entities and are subject to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 et. seq.). These information collections were approved by the Office of Management and Budget, approval number 3150–0010. Send questions regarding this information collection to the FOIA, Library, and Information Collections Branch (T6–A10M), U.S. Nuclear Regulatory Commission, Washington, DC 20555– 0001, or by e-mail to Infocollects.Resource@nrc.gov, and to the OMB reviewer at: OMB Office of Information and Regulatory Affairs (3150–0010), Attn: Desk Officer for the Nuclear Regulatory Commission, 725 17th Street, NW Washington, DC 20503; e-mail: oira_submission@omb.eop.gov.

2. **BACKGROUND**

Through Staff Requirements Memorandum (SRM)–02–0194, dated February 12, 2003, and SRM–03–0145, dated October 9, 2003, the staff was requested to: (1) implement procedures both for adding new specialty boards to the recognized listing and for removing boards from the recognized list; (2) list the boards meeting the criteria on the NRC’s Web site (Medical Uses Licensee Toolkit); and (3) implement procedures to evaluate whether a medical event may have been due to inadequate radiation safety training.

On March 30, 2005, the NRC published the final rule, “10 CFR Part 35 – Medical Use of Byproduct Material Recognition of Specialty Boards,” providing, among other things, the criteria future specialty boards must meet before they could be recognized by the NRC or the Agreement States (*Federal Register* (FR) 70 FR 16335).

After the issuance of the final rule on March 30, 2005, all specialty boards were required to apply for recognition. The specialty boards with certification processes previously recognized by the NRC reapplied to ensure that the NRC made a clear regulatory determination that all listed board certifications met the relevant criteria in the revised regulations, as required by the Commission in SRM–02–0194.

On July 16, 2018, the NRC published a final rule, “Medical Use of Byproduct Material—Medical Event Definitions, Training and Experience, and Clarifying Amendments (83 FR 33046),” in which the Commission grandfathered individuals who were certified by the boards previously recognized in 10 CFR 35, Subpart J to 10 CFR 35.57, “Training for experienced radiation safety officer, teletherapy or medical physicist, authorized user, nuclear pharmacist, and authorized nuclear pharmacist.” This section ensures that individuals who had previously been listed on an NRC or Agreement State license may continue to practice, even after the NRC updated the training and experience requirements. This section serves to grandfather certain individuals who met the criteria listed. This update also permitted those individuals certified by those boards before October 24, 2005, to be recognized as a Radiation Safety Officer, Authorized User, Authorized Medical Physicist, and Authorized Nuclear Pharmacist for those same uses performed before October 24, 2005.

3. **INSTRUCTIONS**

3.1 **Applications for Recognition of a Specialty Board Certification Process**

3.1.1. A specialty board should request NRC recognition of its certification process by applying to the NRC. The application letter should:

- a. Be on the board’s letterhead and include the date and signature of the chief executive officer of the board. If the board elects to have someone other than the chief executive officer sign, then the letter should affirm that the designated person is authorized to sign for the board.
- b. Include the section or a list of sections in 10 CFR Part 35 for which the board wishes to have its certification processes recognized.
- c. Provide a clear description of the board’s requirements regarding

training and experience (T&E) for each candidate before that individual is permitted to sit for the board's examination.

For each section for which the board is seeking recognition, the application letter should:

- i. Describe the T&E criteria mandated by the specialty board and how the board's criteria compare to the NRC requirements.
- ii. Describe the process used by the specialty board to verify that all candidates have met their T&E requirements. Describe how the board ensures that those responsible for implementing this process are selected and held accountable. Describe whether an internal review or a self-assessment is part of the process.
- iii. If the board relies on an accreditation program to establish that certain requirements are met, specify the accreditation program(s). Describe how the board ensures that all the T&E requirements of the accreditation program meet the NRC requirements, and if they do not, how the board confirms each candidate meets the NRC requirements.

Describe the frequency that the board reviews the accreditation program and provide why the frequency of the review will ensure that all NRC requirements are always met for board recognition.
- iv. Provide the website address(es) for the requirements for certification (i.e., the criteria for all candidates to meet before they can sit for the board's certification examination) if the criteria are posted on the internet.
- v. Describe the board's process for evaluating foreign candidates to verify that the foreign candidates' supervised work experience meets the NRC requirements regarding the supervisor's qualifications.
- vi. If the board evaluates the recentness of the candidate's T&E, describe the timespan that the T&E should have been received within.

Although the board is not required² to ensure that the candidates' T&E were obtained within the 7 years

² The "Recentness of Training" requirement in 10 CFR 35.59 requires the licensee to verify the timespan in which the authorized individual received their T&E. If the authorized individual did not obtain the T&E within the 7 years preceding the date of their job application, then the licensee must verify that the individual received related continuing education and experience since the required T&E was completed.

preceding the date of the candidate's application, maintaining a recentness of training metric within the specialty board review process should help to ensure that the candidates can provide quality, modern medical care.

- d. Describe how examinations administered by the diplomates of the board assess knowledge and competency in all the key topics specified by the regulations.
- i. Describe how each of the key topics specified in the regulations will be included and how those concepts will be specific to each of the specialty areas for which the board is seeking recognition.
 - ii. Describe how the specialty board will ensure the radiation safety objectives included in the examination evolve to remain relevant to the field.
 - iii. Describe how a passing grade is determined and how knowledge and competency is assessed.
 - iv. Describe who administers the examinations, how those individuals were selected, and how the board establishes that quality is maintained.
- e. Specify the NRC-recognition date (i.e., effective date) sought by the specialty board. The NRC-recognition date is the date that will appear on the "Specialty Boards Certification Recognized by the NRC under 10 CFR 35" public Web site and be used by the NRC and Agreement State staff during licensing. This date will be tied to specific certification certificates.

If the specialty board is seeking an NRC recognition date prior to the application letter or the NRC-issued recognition letter, then the board should state the proposed date and demonstrate that all past candidates met all the NRC requirements pertinent to the board's certification process. If the board seeks an NRC-recognition date that is in the present or future, then the board should describe the program changes and associated dates that will demonstrate that all current or future candidates will meet the NRC requirements.

- f. Specify the length of time for which the board's certification of a candidate is valid. If the certification is conditional on maintaining a certain level of T&E, then the board should describe the additional criteria. Describe how NRC and Agreement State licensing staff can determine whether the individual continues to be board certified.

The NRC regulations do not mandate a certification expiration. If the specialty board has chosen to set a certification expiration time, then this information should be communicated to the NRC. This information is essential to the licensing process and maintaining the public Web site.

If the board renews the certification for individuals that were certified during a period when the certification was not recognized by NRC, the board needs to describe how these certificates will be distinguished from those recognized by the NRC.

- g. Confirm that the board will contact the NRC in advance of the following changes: the name of the board, the name of its specialty area, the certification process, or certificate. The board should notify the NRC if it will become inactive or disband.
- h. State the board's commitments to and responsibility for the completeness and accuracy of all information provided to the NRC.
- i. Do not include any personal privacy or proprietary information, to the extent possible, so the documentation can be made available to the public without redaction.

In the case that the board needs to include personal privacy or proprietary information, follow the procedures in 10 CFR 2.390, "Public inspections, exemptions, requests for withholding," section (b). If the board has not followed these procedures, the NRC may return the communication to the specialty board for resubmission.

- j. Include a copy of the certificate(s) with any special terms or phrases that must appear on the certificate(s) and a "not valid" or "sample" watermark across the text of each certificate.

If it is not already included on the certificate, the board should re-submit the certificate to include the NRC-recognition date printed on the certificate as an aid in identifying the version of the certificate if there are later changes.

- 3.1.2. Once the specialty board's application letter is received by the NRC, the reviewers should enter the document (without certificates) into Agencywide Documents Access & Management System (ADAMS) as publicly available and as part of an ADAMS package. This package should also include a copy of each original certificate as a separate document that will be entered as nonpublic and a degraded copy of each certificate entered as publicly available. The reviewers should declare the document, but not the certificates, with the Document Processing Center to ensure timely release (i.e., 7 business days) in accordance with NRC policy.

The purpose of the degraded copy of each certificate is to prevent the image from being fraudulently manipulated. The degraded certificate should be included in a manner that allows the file to be easily read but prevents easy electronic copying (i.e., black and white instead of color, degraded resolution) as well as include the "Not Valid" or "Sample" watermark.

3.2 Evaluating the Certification Process

3.2.1. The reviewers should verify that the applicant submitting the application letter or notification of change is a board by reviewing the submission, reviewing the applicant's Web site(s), and/or discussion with the signatory.

- a. Determine if the applicant is a member of the American Board of Medical Specialties. NRC does not require applicants to be member boards of the American Board of Medical Specialties; however, being a member of this organization is sufficient evidence that the board is an established specialty board.
- b. Determine if the applicant is a board whose processes were already recognized by the NRC. Determine if there are any changes in organization, status, or management structure of the board that would cause the NRC to question the status or independence of the board. For example, consider whether two boards merged or whether the board is under the control of a new organization.

Organizational change that provides administrative support to the board without compromising the board's structure, independent decision making, and the criteria for determining the training and experience criteria for individuals to sit for the board examination is acceptable. Other changes may not be acceptable and could result in termination of NRC's recognition of the board.

Consider the following questions:

- i. Do the diplomates continue to run the board?
 - ii. Does the new organization have to approve the board's decisions, procedures, and other actions before the decisions can become effective?
 - iii. Can the new organization dictate certification process changes to the board?
 - iv. Does direction from the new organization conflict with the criteria for NRC to recognize the board?
- c. A common characteristic of many boards is that its development was closely associated with a professional society. While this is not a requirement of a board, it tends to confirm the professional status of the board members. Another common characteristic of boards is that they are governed by members with professional expertise in the area in which the board seeks to issue board certifications.

Consider whether the members have an elected or appointed governing body called the Board of Governors, Board of Directors, or another similar name. Consider whether the governing body approves the board certification processes that enable the board to be recognized by NRC.

Consider whether the diplomates of the board are responsible for evaluating and verifying the candidate's training and experience, including the determination of whether the candidate's training and experience adequately fulfills the NRC regulations before the candidate can sit for the board certification examination. The diplomates or individuals designated to perform this function should be free of conflict of interest.

Consider whether the board is independent of specific training courses, consultant groups, and/or manufacturers. This independence ensures that the administration of the examination to measure the knowledge and competence of the candidate is not affected by a financial or business conflict of interest. The specialty board's examination should be independently developed and administered by the board's diplomates. While a consulting company may be used to verify the quality and validity of the questions, the consulting company should be independent of any training class or instructor that provides the training and experience needed to sit for the board certification examination.

3.2.2. The reviewers should evaluate the specialty board's process in evaluating all candidates' T&E to verify that it is effective in ensuring that all candidates meet the section-specific requirements for that specialty area. The reviewers should assess the specialty board's certification process by reviewing the application or notification of change, supporting documents, the board's Web site, and/or discussion with the signatory.

- a. Consider whether the board's certification program processes, as well as the procedures and criteria supporting that process, are in accordance with the requirements established in the applicable sections of subparts B and D through H of 10 CFR Part 35 for NRC recognition of specialty board's processes.

The requirements for recognition of a board's certification for Radiation Safety Officers (RSOs) and Associate Radiation Safety Officers (ARSOs) are specified in § 35.50(a), for Authorized Medical Physicists (AMPs) 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).

- b. Determine whether the board's requirements are at least as strict as the NRC requirements. The reviewers should evaluate information, procedures, and/or program documents, including information available on the specialty board's public Web site. If the board has requirements in addition to or stricter than NRC's, the certification process is acceptable. If the application has a non-specific statement of the regulations, or a statement that reads "or equivalent," then further explanation is necessary.
- c. Consider how the board ensures that the diplomates evaluating the candidates regarding T&E requirements can verify and ensure

satisfaction of the recognition criteria.

- 3.2.3. The reviewers should consider the regulation-specific questions in the Enclosure to verify that the specialty board's certification process is robust.
- a. Enclosure 1; Analysis for Boards Seeking NRC Recognition for RSOs and ARSOs
 - b. Enclosure 2; Analysis for Boards Seeking NRC Recognition for AMPs
 - c. Enclosure 3; Analysis for Boards Seeking NRC Recognition for ANPs
 - d. Enclosure 4; Analysis for Boards Seeking NRC Recognition for Various Classes of AUs

- 3.2.4. The reviewers should verify that the specialty board's application includes specifics pertaining to the content and implementation of the examination.
- a. Verify that the specialty board's examination appropriately covers the content in NRC regulations. The examination may cover more content but should not cover less.
 - b. Verify that the examination is administered by diplomates of the board.
 - c. Consider how the specialty board ensures that the content evolves to remain current and relevant.
 - d. Evaluate how the board assesses knowledge and competency in its candidates. Consider whether the specialty board establishes criteria to differentiate between pass and fail.
 - e. If the board provides a written examination, do not enter it into ADAMS as publicly available.
 - f. Determine whether the examination is given in one part or multiple parts. Consider how this impacts the timing of the examination.

Consider whether a one-part exam, which addresses both the educational and work experience, is given at the completion of the candidate's T&E. In the instance that multiple tests are given, one may cover the training portion of the requirements and the other could cover the work experience component. The final examination needs to be administered after the completion of the candidate's T&E because the application of the basic radiation safety procedures and knowledge continue to apply, be used, and be reinforced during the daily clinical experience.

- 3.2.5. The reviewers should verify that the effective date being sought in the application letter is appropriate for the specialty board's certification process. The reviewers should consider program changes and applicable dates as well as the justification provided by the board. The board is responsible for demonstrating that all candidates met all the pertinent NRC requirements within the date ranges or by the effective date for which they applied. The reviewers should consider

whether the certificates for each of the date ranges are clear and whether the documentation provided clearly establishes that all candidates that received the certificate(s) also met the NRC requirements.

If the reviewers determine that the effective date requested in the application letter is not appropriate, then the board is provided a chance to revise and re-submit its documentation. The board may revise its certification program criteria to ensure that all future candidates will meet the NRC requirements. The board should document the program changes, the applicable date, and the newly requested effective date. The effective date should become an NRC-recognition date after the NRC recognition letter is issued.

If the board has issued certificates based on a process that NRC cannot recognize, then the board must exclude those dates from its recognition process. Another option, if the board determines that some of its past candidates met the NRC requirements, is to issue a unique certificate for those individuals meeting the NRC's requirements. The reviewers will accept date ranges when establishing NRC recognition, so long as the corresponding certificates can be distinguished.

- 3.2.6. The reviewers should verify that the application letter or the notification of change includes certificate(s) for the specialty area(s).
- a. Consider whether the certificate includes special notations and whether it's easily understood.
 - b. If the board issues more than one certification, the reviewers must verify that each certificate type corresponds to the appropriate NRC regulation and specialty area.
 - c. If the board offers another certification (for a specialty that is not regulated by NRC) then the two certifications should be easily distinguished. In this instance, the specialty board may wish to differentiate between the two processes or issue distinct certificates. The board should provide a note to accompany the certificate submission so that NRC and Agreement State license reviewers can routinely distinguish between the two.
 - d. If the application letter proposed effective date ranges, verify that the certificates and the relevant date ranges are easily distinguished.

- 3.2.7. Staff should consult with the Advisory Committee for Medical Uses of Isotopes (ACMUI) when needed.

3.3 Recognition Process

- 3.3.1. If the reviewers determine that the specialty board's certification process is sufficient, then a recognition letter, signed by the Division Director, should be sent within 60 business days from the receipt of the application or the submission of the additional requested information.

The recognition letter should clearly include:

- a. The NRC-recognition date (or date ranges) for each specialty area;
 - b. The basis for NRC's recognition. Document the reviewers' understanding of the application and why the staff concluded the specialty board's certification process was recognized;
 - c. A paragraph that requests that the board contact the NRC within 60 days of making a change to its certification process or the certificates, name change, or other change that could affect recognition of the board's certification process(es) under 10 CFR Part 35; and
 - d. Request that the board contact the NRC if the board is going to become inactive or disband.
- 3.3.2. The reviewers should add the recognition letter to the ADAMS package as publicly available.

3.4 Deficiency Process

- 3.4.1. If a board's certification process does not meet the requirements in 10 CFR Part 35, or if there is not enough information to make that determination, the NRC will notify the board.

Prior to contacting the specialty board, the reviewers should brief the Medical Radiation Safety Team (MRST) Leader to ensure that follow-up is approved. Before a deficiency letter is sent, the reviewers should try to resolve deficiencies using phone calls (with documentation), electronic mail (e-mails), and in-person meetings (with a written summary of the meeting). These methods can be used to resolve deficiencies. Direct interaction with the specialty board can be the most effective way of communicating. Documentation of these interactions should be added to the ADAMS package.

- 3.4.2. In the deficiency letter, the reviewers should specify what the specific deficiencies are and what additional information is needed to complete the NRC's review. The deficiency letter should advise the specialty board to respond within 30 days of the deficiency letter date and that, if the board does not respond within 30 days, the NRC will administratively close the board's application. The deficiency letter should be signed by the Chief of the Medical Safety and Events Assessment Branch (MSEB) and included in the ADAMS package as publicly available.

If the deficiencies are minor and easily resolved, the board should indicate whether the previous direct communication from the NRC was sufficient, and a deficiency letter would not be needed prior to the specialty board's re-submission of the application letter or submission of the requested information.

- 3.4.3. The reviewers should send a recognition letter within 60 working days from the receipt of the new information if the reviewers find the specialty board's certification process to be sufficient.

3.5 Administrative Closure Process

If the new applicant does not respond to a deficiency letter within 30 days, the request from the new applicant should be administratively closed. The administrative closure letter should be signed by the MSEB Chief, included in the ADAMS package as publicly available, and sent to the specialty board.

3.6 Denial Process

After additional information is received and the board's certification process still does not meet the applicable criteria in 10 CFR Part 35, then the reviewers should notify the board of this finding in a denial letter signed by the Division Director. The Office of General Counsel (OGC) should provide a determination of No Legal Objection (NLO). The denial letter should be added into the ADAMS package as publicly available.

3.7 Notification of Change

- 3.7.1. Specialty boards should contact the NRC, in writing, regarding a change in certification procedures, change in certificate, name change, or other change that could affect recognition of the board's certification process(es) under 10 CFR Part 35.

Specialty boards should contact the NRC if the board is going to become inactive or disband.

- 3.7.2. The NRC would like 6 months' notice ahead of a major change or as much notice as practicable.
- 3.7.3. The reviewers should add the communication to ADAMS as publicly available. The reviewers should evaluate the change(s) using only applicable sections of 3.2, "Evaluating the Certification Process," and follow up, in writing, accordingly.

3.8 NRC Public Web site

- 3.8.1. After the specialty board's certification process is recognized by the NRC, the reviewers should add the board certification to the list of NRC-recognized board certifications appearing on the NRC's public Web site. A list of the NRC-recognized specialty boards can be found at:
<http://www.nrc.gov/materials/miau/med-use-toolkit/spec-board-cert.html>.

The information posted on the Web site should include the dates for which the board's certification process is recognized by the NRC, any special terms or phrases that must appear on the certificate, and a copy of the board's certificate with a "not valid" or "sample" watermark.

- 3.8.2. The MRST Leader should make sure that this procedure, used for providing NRC recognition to specialty boards, is posted on the NRC public Web site.

3.9 Communication

- 3.9.1. Communications between the NRC staff and specialty boards should be in writing. Written communications to the NRC from a specialty board should be signed by a person authorized to speak for the board (i.e., its chief executive officer or designee) and mailed on the board's letterhead. The letter should

indicate that this individual can speak for the board. If this person or permission changes, the board should contact the NRC and provide updated contact information.

- 3.9.2. The specialty boards should address the letter to the Director of the Division of Materials Safety, Security, State, and Tribal Programs (MSST) and include “Attention: Chief, Medical Safety & Events Assessment Branch.” The NRC mailing address and addressee information is maintained on the NRC public Web site at: <http://www.nrc.gov/materials/miau/med-use-toolkit/spec-board-cert.html#specboards>.

NRC letters to the specialty boards should include the addressees’ mailing address.

- 3.9.3. E-mail is appropriate for correspondence to gain alignment and should be retained as an official record in ADAMS.
- 3.9.4. Phone calls or meetings should be summarized in writing and retained as an official record in ADAMS.
- 3.9.5. Letters to specialty boards should include the following language:

“In accordance with § 2.390, “Public inspections, exemptions, requests for withholding,” copies of all communications, including enclosures, will be made available electronically for public inspection in the NRC Public Document Room or from the NRC Agencywide Documents Access & Management System (ADAMS). The board will be informed of these requirements in advance of submitting information and encouraged to not include any personal privacy or proprietary information in communications, to the extent possible, so that they can be made available to the public without redaction. If the board includes personal privacy or proprietary information and the board has not followed the procedures specified in § 2.390(b), the NRC may return to the specialty board any communications containing personal privacy or proprietary information for resubmission.”

3.10 Agreement States

- 3.10.1. The MRST Leader should notify the Agreement States of major changes in status; including the name of the specialty board, specialty areas, and the date of the recognition, denial, or termination letter.
- 3.10.2. Agreement States may also recognize the certification process(es) of specialty boards that meet the requirements in their compatible board recognition requirements. The board recognition requirements are Compatibility Category B because of their transboundary implications.

The Agreement State should contact the MRST Leader and provide a summary of the decision as well as the supporting documents. NRC staff should update the public Web site. Specialty boards recognized by an Agreement State will be listed on the NRC’s public Web site. The entry on the Web site should be annotated to indicate which Agreement State conducted the review.

- 3.10.3. When a board's certification process is recognized by an Agreement State, that State is responsible for assessing continued satisfaction of recognition criteria and for terminating recognition of that board's certification(s) if necessary.

The Agreement State should notify the NRC of the decision to terminate the board's recognition. A summary of the decision, as well as supporting documents, should be submitted to the MRST Leader.

3.11 Monitoring Continued Satisfaction of Recognition Requirements

- 3.11.1. The reviewers should contact each of the specialty boards with a written request that the specialty board confirm that it still satisfies the board recognition criteria, if the specialty board did not submit a notification of change, revised certificate, or any other communication within the last five years.

The reviewers should request verification in writing on whether it has changed its name, the name of its specialty certifications, or its certificates. The reviewer should also request that any changes in the board's certification procedures that could affect the recognition status be communicated to the NRC for review. The board does not need to generate any new documents.

The reviewers should create a publicly available ADAMS package with the initial letter and all resulting correspondence.

- 3.11.2. The reviewers should evaluate the recognized board's publicly available Web site for changes that could affect the recognition of the board's certification process(es).
- 3.11.3. The reviewers should determine if the board's certification program continues to meet the applicable 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). The reviewers should seek the advice of the ACMUI if necessary. The reviewers should notify the board regarding any adverse findings via letter signed by the Division Director.
- 3.11.4. The reviewers should verify that the listing of NRC-recognized certifications on the NRC public Web site is up to date. The reviewers should update the listing, if needed.

3.12 Terminating NRC Recognition of Specialty Boards

- 3.12.1. A specialty board's NRC recognition may be terminated for the following reasons.
- a. A failure to satisfy NRC board recognition criteria and a failure to implement sufficient corrective actions;
 - b. The board has requested, in writing, that the NRC no longer recognize it; or
 - c. The board is inactive or has disbanded.
- 3.12.2. A reviewer should identify if an instituted or proposed change in the certification process(es) of an NRC-recognized board may adversely affect the recognized

status of the board's certification process(es). A reviewer should identify the deficiency and determine if program changes or corrective actions were sufficient.

The reviewers should brief the MRST Leader on the specialty board's failure and the applicable criteria they would need to implement or provide to be deemed acceptable.

A reviewer should issue a deficiency letter requesting justification as to why NRC recognition of the board's certification process(es) should be continued. The letter should specify what the identified deficiencies are and whether additional information is needed to complete the NRC's evaluation. The deficiency letter should advise the specialty board to respond within 30 days of the deficiency letter date and that, if the board does not respond within 30 days, the NRC will determine the date beyond which the certification will no longer be recognized. The deficiency letter should be signed by the MSEB Chief. The reviewer should inform the ACMUI of this communication.

After receiving a written response to the deficiency letter, the reviewers should determine whether the board's reply was responsive. If it was, then the reviewers should assess the content using section 3.2, "Evaluating the Certification Process" and issue a recognition letter.

If the reviewers determine that the board's certification process is still deficient and the board did not take action to sufficiently demonstrate satisfaction of recognition criteria, the reviewers and MRST Leader should brief management on their findings and propose that the NRC recognition of the specialty board's certification(s) be terminated.

If the board fails to respond within 30 days of issuance of the deficiency letter or the response is insufficient, the reviewers should determine the date beyond which the certification should no longer be recognized.

- 3.12.3. If the NRC staff becomes aware that a board has or intends to become inactive or disband, the reviewers should attempt to contact the board. The reviewers should request, via letter signed by the MSEB Chief, that the board provide information confirming whether the board has become inactive, has disbanded, or intends to become inactive or disband. The reviewers should request an explanation of why the change should not result in the termination of NRC recognition of the board's certification process(es).

If the board confirms that it is inactive or disbanding, or if the board fails to respond within 30 days, the reviewers should determine the effective date of this change in status and the date when the certification will no longer be recognized by the NRC.

- 3.12.4. The reviewers should prepare a termination letter. The termination letter should:
- a. Provide a description of the basis for termination of NRC recognition that specifies the board recognition criteria in 10 CFR Part 35 that the board fails to satisfy;

- b. Include the termination date and how that date was determined;
- c. Advise the specialty board that the Commission and the ACMUI were informed of the termination and the basis for it;
- d. Advise the board that it may apply for NRC recognition in the future if the board's program changes to meet the necessary criteria; and
- e. Be signed by the Division Director with an NLO determination by OGC.

3.12.5. The reviewers should brief management on the determination that NRC recognition of the specialty board certification process should be terminated. The Commission and ACMUI should be informed of this determination.

3.12.6. After the reviewers send the termination letter to the specialty board, the reviewers should annotate the listing of board certifications on the NRC public Web site to indicate the NRC recognition dates, including the date(s) of termination and/or date(s) through which certifications were recognized. If the program or certificate changed, the reviewers should update the date range(s) for which the specialty area certificate(s) were valid.

3.12.7. If an individual holds a certification from a board for which the NRC or an Agreement State terminates recognition of the board's certification process, the certification will be considered valid if the certificate was granted during the time interval that the board's certification process was recognized.

If the specialty board's certification is no longer recognized by the NRC during the time frame that the individual's certificate was granted, then it is no longer considered valid. The individual may seek certification through a different NRC-recognized specialty board or through the alternate pathway. The individual may seek recertification through that same specialty board if the board re-applies and the revised certification process is recognized by the NRC.

4. RESPONSIBILITIES AND AUTHORITIES

The responsibilities and authorities within and outside of the Office of Nuclear Material Safety and Safeguards (NMSS) are outlined below:

Certification Board Reviewers

- The certification board reviewers, hereafter referred to as the "reviewers," should directly interact with the specialty board and review public information including Web sites of the specialty board to gather information necessary to determine if its certification process meets the criteria to be recognized by the NRC.
- The reviewers should draft recognition, deficiency, administrative closure, denial, and/or termination letters for management concurrence and signature.
- The reviewers should enter correspondence between the specialty board and the NRC into the NRC's Agencywide Documents Access & Management System (ADAMS).

- The reviewers should review and evaluate any communication regarding notifications of change from NRC-recognized specialty boards. The reviewers should contact each of the specialty boards, once every five years, with a request that the specialty board confirm that it still satisfies the board recognition criteria.
- The reviewers should revise the “Specialty Board(s) Certification Recognized by NRC Under 10 CFR Part 35” public Web site by adding, removing, and updating the certificate(s) for a specialty board on the NRC-recognized specialty board list.

Medical Radiation Safety Team Leader

- The MRST Leader should work with the reviewers to decide whether a meeting with a specialty board is necessary.
- The MRST Leader should review any correspondence to be sent to specialty boards.
- The MRST Leader should ensure that at least once every 5 years, the reviewers determine whether each specialty board’s certificate(s) and certification process(es) have changed and whether each specialty board still satisfies the board recognition criteria.
- The MRST Leader should notify or correspond with Agreement States when a new specialty board is recognized, when a specialty board recognition is terminated, or when an Agreement State recognizes or terminates recognition of a specialty board.
- The MRST Leader should verify that this procedure, used for recognizing and terminating a specialty board, is up-to-date and posted on the NRC’s public Web site.
- The MRST Leader should ensure that this procedure allows staff to make a clear regulatory determination whether the boards meet the relevant criteria in the NRC regulations.

Chief: Medical Safety and Events Assessment Branch

- The MSEB Chief should review, concur on, and sign deficiency letters, administrative closure letters, letters requesting information regarding the specialty board’s certification processes or certificates, and general communication with the boards.
- The MSEB Chief should review and concur on all correspondence between the NRC and specialty boards that needs to be signed by the Division Director.

Director: Division of Materials Safety, Security, State, and Tribal Programs

The Division Director should review, concur on, and sign specialty board recognition, denial, and termination letters.

Office of the General Counsel

OGC staff should review denial and termination letters for a determination of NLO.

Advisory Committee for Medical Uses of Isotopes

The ACMUI should be consulted, when needed.

5. REFERENCES

10 CFR Part 35, “Medical Use of Byproduct Material.”

OMB–3150–0010, 10 CFR Part 35, Medical Use of Byproduct Material (ADAMS Accession No. ML20128J888).

SRM–02–0194, dated February 12, 2003.

SRM–03–0145, dated October 9, 2003.

70 FR 16335, “Medical Use of Byproduct Material–Recognition of Specialty Boards,” dated March 30, 2005.

71 FR 1926, “Medical Use of Byproduct Material–Recognition of Specialty Boards; Correction,” dated January 12, 2006.

83 FR 33046, “Medical Use of Byproduct Material–Medical Event Definitions, Training and Experience, and Clarifying Amendments,” dated July 16, 2018.

Specialty Board(s) Certification Recognized by NRC Under 10 CFR Part 35:
<http://www.nrc.gov/materials/miau/med-use-toolkit/spec-board-cert.html>

‘Self-assessment of Medical Specialty Board Certifications’ dated September 9, 2019 (ADAMS Accession No. ML19360A085).

6. ENCLOSURES

Enclosure 1 – Analysis for Boards Seeking NRC Recognition for Radiation Safety Officers and Associate Radiation Safety Officers

Enclosure 2 – Analysis for Boards Seeking NRC Recognition for Authorized Medical Physicists

Enclosure 3 – Analysis for Boards Seeking NRC Recognition for Authorized Nuclear Pharmacists

Enclosure 4 – Analysis for Boards Seeking NRC Recognition for Various Classes of Authorized Users

7. EFFECTIVE DATE

January 11, 2021

ADAMS ACCESSION NO.: ML19360A084

OFFICE	NMSS/MSST/MSEB	NMSS/MSST/MSEB	NMSS/MSST/MSEB
NAME	JFisher	DBHowe	MAyoade
DATE	05/18/2020	5/28/2020	6/1/2020
OFFICE	NMSS/MSST/MSEB	Info. Collection Team	OGC
NAME	LDimmick	DCullison	CEngland
DATE	6/1/2020	9/29/2020	11/10/2020
OFFICE	NMSS/MSST/MSEB	NMSS/MSST	
NAME	CEinberg	KWilliams	
DATE	11/29/2020	1/7/2021	

OFFICIAL RECORD COPY

Enclosure 1

**Analysis for Boards Seeking NRC Recognition for
Radiation Safety Officers and Associate Radiation Safety Officers**

A specialty board’s certification process should be recognized by the NRC after the specialty board demonstrates that it meets the following NRC requirements. A specialty board should state whether it is seeking recognition for both (a)(1) and (a)(2) or just one of the options.

Table 1. 10 CFR 35.50, “Training for Radiation Safety Officer and Associate Radiation Safety Officer”

NRC Requirements	Reviewer Questions
<p>(a)(1) A specialty board shall require candidates for certification to:</p> <ul style="list-style-type: none"> (i) Hold a bachelor's or graduate degree from an accredited college or university in physical science or engineering or biological science with a minimum of 20 college credits in physical science. (ii) Have 5 or more years of professional experience in health physics (graduate training may be substituted for no more than 2 years of the required experience) including at least 3 years in applied health physics; and (iii) Pass an examination administered by diplomates of the specialty board, which evaluates knowledge and competence in— <ul style="list-style-type: none"> Radiation physics and instrumentation; Radiation protection; Mathematics pertaining to the use and measurement of radioactivity; Radiation biology; and Radiation dosimetry. 	<p>How does the board verify that the minimum number of college credits in physical science are met by the candidate?</p> <p>How does the board verify that the candidate has met the professional experience requirements?</p> <p>How does the board verify that the candidate holds an appropriate degree?</p> <p>What degrees are acceptable to the board?</p> <p>What college accreditations are acceptable to the board?</p> <p>How does the board verify that the candidate graduated from an accredited college or university?</p>
Or	
<p>(a)(2) A specialty board shall require candidates for certification to:</p> <ul style="list-style-type: none"> (i) Hold a master's or doctor's degree in physics, medical physics, other physical science, 	<p>How does the board verify that the candidate has two years of full-time practical training and/or supervised experience in medical physics?</p>

<p>engineering, or applied mathematics from an accredited college or university;</p> <p>(ii) Have 2 years of full-time practical training and/or supervised experience in medical physics—</p> <p>(A) Under the supervision of a medical physicist who is certified in medical physics by a specialty board recognized by the Commission or an Agreement State; or</p> <p>(B) In clinical nuclear medicine facilities providing diagnostic or therapeutic services under the direction of physicians who meet the requirements for authorized users in §§ 35.57, 35.290, or 35.390; and</p> <p>(iii) Pass an examination, administered by diplomates of the specialty board, that assesses knowledge and competence in—</p> <p>Clinical diagnostic radiological or nuclear medicine physics; and</p> <p>Radiation safety.</p>	<p>How does the board verify that the candidate’s experiences were in a relevant area?</p> <p>How does the board verify that the candidate’s supervisor meets the criteria?</p> <p>How does the board verify that the candidate holds an appropriate degree?</p> <p>What degrees are acceptable to the board?</p> <p>What college accreditations are acceptable to the board?</p> <p>How does the board verify that the candidate graduated from an accredited college or university?</p>
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Enclosure 2

Analysis for Boards Seeking NRC Recognition for Authorized Medical Physicists

A specialty board’s certification process should be recognized by the NRC after the specialty board demonstrates that it meets the following NRC requirements.

Table 2. 10 CFR 35.51, “Training for an Authorized Medical Physicist”

NRC Requirements	Reviewer Questions
A specialty board shall require all candidates for certification to:	
(a)(1) Hold a master's or doctor's degree in physics, medical physics, other physical science, engineering, or applied mathematics from an accredited college or university.	<p>How does the board verify that the candidate holds an appropriate degree?</p> <p>What degrees are acceptable to the board?</p> <p>What college accreditations are acceptable to the board?</p>
<p>(a)(2) Have 2 years of full-time practical training and/or supervised experience in medical physics—</p> <p>(i) Under the supervision of a medical physicist who is certified in medical physics by a specialty board whose certification process has been recognized under this section by the Commission or an Agreement State; or</p> <p>(ii) In clinical radiation facilities providing high-energy, external beam therapy (photons and electrons with energies greater than or equal to 1 million electron volts) and brachytherapy services under the direction of physicians who meet the requirements in § 35.57, 35.490, or 35.690.</p>	<p>How does the board verify that the candidate’s full-time practical training and/or supervised experience in medical physics meets the two-year threshold?</p> <p>How does the board verify that the candidate’s experiences were in a relevant area?</p> <p>How does the board verify that the candidate’s medical physicist supervisor meets the criteria?</p> <p>How does the board verify the supervised experience was gained in clinical radiation facilities providing high-energy, external beam therapy (photons and electrons with energies greater than or equal to 1 million electron volts) and brachytherapy services?</p> <p>How does the board verify the clinical radiation facilities were under the supervision of</p>

	physicians meeting the appropriate criteria?
<p>(a)(3) Pass an examination, administered by diplomates of the specialty board, that assesses knowledge and competence in—</p> <ul style="list-style-type: none"> Clinical radiation therapy; Radiation safety; Calibration; Quality assurance; and Treatment planning for external beam therapy, brachytherapy, and stereotactic radiosurgery. 	<p>How does the board ensure that the examination adequately addresses each category with content specific to medical physics?</p>

Enclosure 3

**Analysis for Boards Seeking NRC Recognition
for Authorized Nuclear Pharmacists**

A specialty board’s certification process should be recognized by the NRC after the specialty board demonstrates that it meets the following NRC requirements.

Table 3. 10 CFR 35.55, “Training for an Authorized Nuclear Pharmacist”

NRC Requirements	Reviewer Questions
A specialty board shall require all candidates for certification to:	
(a)(1) Have graduated from a pharmacy program accredited by the American Council on Pharmaceutical Education (ACPE) or have passed the Foreign Pharmacy Graduate Examination Committee (FPGEC) examination.	<p>How does the board verify that the candidate has graduated from an ACPE-accredited pharmacy program?</p> <p>How does the board verify that the candidate passed the FPGEC examination, in the case that they did not graduate from an ACPE-accredited pharmacy program?</p> <p>Does the board accept any other accreditations not listed?</p>
(a)(2) Hold a current, active license to practice pharmacy.	How does the board verify that the candidate holds a current, active license to practice pharmacy?
(a)(3) Provide evidence of having acquired at least 4,000 hours of training/experience in nuclear pharmacy practice. Academic training may be substituted for no more than 2,000 hours of the required training and experience.	<p>How does the board verify that the candidate meets the required hours of training and experience in nuclear pharmacy?</p> <p>Does the board ask for a breakdown of academic and non-academic training and experience?</p> <p>How does the board verify that the hours are applicable to nuclear pharmacy practice as opposed to general pharmacy practice?</p>

<p>(a)(4) Pass an examination in nuclear pharmacy administered by diplomates of the specialty board, that assesses knowledge and competency in:</p> <ul style="list-style-type: none"> Procurement; Compounding; Quality assurance; Dispensing; Distribution; Health and safety; Radiation safety; Provision of information and consultation; Monitoring patient outcomes; and Research and development. 	<p>How does the board ensure that the examination content is specific to nuclear pharmacy for each of the categories?</p>
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Enclosure 4

Analysis for Boards Seeking NRC Recognition for Various Classes of Authorized Users

A medical specialty board’s certification process should be recognized by the NRC after the medical specialty board demonstrates that it meets the following NRC requirements.

Table 4–1. 10 CFR 35.190, “Training for uptake, dilution, and excretion studies”

NRC Requirements	NRC Staff Questions
A specialty board shall require all candidates for certification to:	
(a)(1) Complete 60 hours of training and experience in basic radionuclide handling techniques and radiation safety applicable to the medical use of unsealed byproduct material for uptake, dilution, and excretion studies including:	<p>How does the board verify that the 60-hour training and experience threshold was met for each candidate?</p> <p>How does the board verify that the training and experience hours reported were specific to basic radionuclide handling techniques and radiation safety applicable to the medical use of unsealed byproduct material for uptake, dilution, and excretion studies?</p>
(c)(1)(i) Classroom and laboratory training in the following areas— (A) Radiation physics and instrumentation; (B) Radiation protection; (C) Mathematics pertaining to the use and measurement of radioactivity; (D) Chemistry of byproduct material for medical use; and (E) Radiation biology.	How does the board verify that the candidate’s classroom and laboratory training addresses uptake, dilution, and excretion studies for each of the following categories?
(c)(1)(ii) Work experience, under the supervision of an authorized user who meets the requirements in §§ 35.57, 35.190, 35.290, 35.390, or equivalent Agreement State requirements, involving—	How does the board verify that the candidate’s supervisor meets the stated criteria?

<p>(A) Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;</p> <p>(B) Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters;</p> <p>(C) Calculating, measuring, and safely preparing patient or human research subject dosages;</p> <p>(D) Using administrative controls to prevent a medical event involving the use of unsealed byproduct material;</p> <p>(E) Using procedures to contain spilled byproduct material safely and using proper decontamination procedures; and</p> <p>(F) Administering dosages of radioactive drugs to patients or human research subjects.</p>	<p>How does the board’s review process evaluate the candidate’s work experience and verify that each category is applicable to uptake, dilution, and excretion studies?</p>
<p>(a)(2) Pass an examination, administered by diplomates of the specialty board, that assesses knowledge and competence in—</p> <p style="padding-left: 40px;">Radiation safety;</p> <p style="padding-left: 40px;">Radionuclide handling; and</p> <p style="padding-left: 40px;">Quality control.</p>	<p>How does the board ensure that the examination content is specific to uptake, dilution, and excretion studies for each category?</p>

Table 4–2. 10 CFR 35.290, “Training for Imaging and Localization Studies”

NRC Requirements	NRC Staff Questions
A specialty board shall require all candidates for certification to:	
(a)(1) Complete 700 hours of training and experience in basic radionuclide handling techniques and radiation safety applicable to the medical use of unsealed byproduct material for imaging and localization studies including:	<p>How does the board verify that the 700–hour training and experience threshold was met for each candidate?</p> <p>How does the board verify that no hours were counted twice and all training and experience hours were applicable to imaging and localization studies?</p>
(c)(1)(i) Classroom and laboratory training in the following areas— (A) Radiation physics and instrumentation; (B) Radiation protection; (C) Mathematics pertaining to the use and measurement of radioactivity; (D) Chemistry of byproduct material for medical use; and (E) Radiation biology;	How does the board verify that the candidate’s classroom and laboratory training addresses imaging and localization studies for each of the following categories?
(c)(1)(ii) Work experience, under the supervision of an authorized user who meets the requirements in § 35.57, § 35.290, or §§ 35.390 and 35.290(c)(1)(ii)(G), or equivalent Agreement State requirements. An authorized nuclear pharmacist who meets the requirements in § 35.55 or § 35.57 may provide the supervised work experience for paragraph (c)(1)(ii)(G) of this section.	How does the board verify that the candidate’s supervisor meets the stated criteria?

<p>(c)(1)(ii) Work experience must involve—</p> <ul style="list-style-type: none"> (A) Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys; (B) Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters; (C) Calculating, measuring, and safely preparing patient or human research subject dosages; (D) Using administrative controls to prevent a medical event involving the use of unsealed byproduct material; (E) Using procedures to safely contain spilled radioactive material and using proper decontamination procedures; (F) Administering dosages of radioactive drugs to patients or human research subjects; and (G) Eluting generator systems appropriate for preparation of radioactive drugs for imaging and localization studies, measuring and testing the eluate for radionuclidic purity, and processing the eluate with reagent kits to prepare labeled radioactive drugs. 	<p>How does the board’s review process evaluate the candidate’s work experience and verify that each category is applicable to imaging and localization studies?</p>
<p>(a)(2) Pass an examination, administered by diplomates of the specialty board, which assesses knowledge and competence in the following:</p> <ul style="list-style-type: none"> Radiation safety; Radionuclide handling; and Quality control 	<p>How does the board ensure that the examination content adequately addresses imaging and localization studies for each category?</p>

Table 4–3. 10 CFR 35.390, “Training for use of unsealed byproduct material for which a written directive is required.”

NRC Requirements	NRC Staff Questions
<p>A specialty board shall require all candidates for certification to:</p>	
<p>(a)(1) Successfully complete residency training in a radiation therapy or nuclear medicine training program or a program in a related medical specialty.</p> <p>Eligible training programs must be approved by:</p> <ul style="list-style-type: none"> The Residency Review Committee of the Accreditation Council for Graduate Medical Education The Royal College of Physicians and Surgeons of Canada, or The Committee on Post-Graduate Training of the American Osteopathic Association 	<p>How does the board verify that the candidates completed an approved residency program in the correct medical area?</p> <p>What medical specialty area residency programs does the board accept?</p> <p>Which accreditation programs does the board accept?</p> <p>Is the board engaged during times of process change at the accreditation board?</p>
<p>(a)(1) The residency training programs must include:</p>	
<p>(b)(1) 700 hours of training and experience, including a minimum of 200 hours of classroom and laboratory training, in basic radionuclide handling techniques applicable to the medical use of unsealed byproduct material requiring a written directive.</p> <p>The training and experience must include (i)Classroom and laboratory training in the following areas:</p> <ul style="list-style-type: none"> (A) Radiation physics and instrumentation; (B) Radiation protection; (C) Mathematics pertaining to the use and measurement of radioactivity; (D) Chemistry of byproduct material for medical use; and (E) Radiation biology. 	<p>How does the board verify that the appropriate number of training and experience hours are included in the candidates’ residency program?</p> <p>How does the board verify that no hours were counted twice, and that all training and experience hours were applicable to the medical use of unsealed byproduct material requiring a written directive?</p> <p>How does the board verify that the candidate’s classroom and laboratory training address the use of unsealed byproduct material for which a written directive is required?</p>

<p>(b)(1)(ii) Work experience, under the supervision of an authorized user who meets the requirements in §§ 35.57, 35.390, or equivalent Agreement State requirements. A supervising authorized user, who meets the requirements in § 35.390(b), must also have experience in administering dosages in the same dosage category or categories (i.e., § 35.390(b)(1)(ii)(G)) as the individual requesting authorized user status.</p> <p>The work experience must involve—</p> <ul style="list-style-type: none"> (A) Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys; (B) Performing quality control procedures on instruments used to determine the activity of dosages, and performing checks for proper operation of survey meters; (C) Calculating, measuring, and safely preparing patient or human research subject dosages; (D) Using administrative controls to prevent a medical event involving the use of unsealed byproduct material; (E) Using procedures to contain spilled byproduct material safely and using proper decontamination procedures; 	<p>How does the board verify that the candidate’s supervisor meets the stated criteria?</p> <p>How does the board’s review process evaluate the candidate’s work experience and verify that all the hours are only counted once? How does the review process ensure that all hours, including the hours in each category, are applicable to the use of unsealed byproduct material for which a written directive is required?</p>
<p>(a)(2) Pass an examination, administered by diplomates of the specialty board, which tests knowledge and competence in:</p> <ul style="list-style-type: none"> Radiation safety; Radionuclide handling; Quality assurance; and Clinical use of unsealed byproduct material for which a written directive is required 	<p>How does the board ensure that the examination content in the following categories are specific to the use of unsealed byproduct material for which a written directive is required?</p>

Table 4-4. 10 CFR 35.392, "Training for the oral administration of sodium iodide (I-131) requiring a written directive in quantities less than or equal to 1.22 gigabecquerels (33 millicuries)"

NRC Requirements	NRC Staff Questions
A specialty board shall require all candidates for certification to:	
(c)(1) Has successfully completed 80 hours of classroom and laboratory training, applicable to the medical use of sodium iodide I-131 for procedures requiring a written directive.	<p>How does the board verify that the 80-hour threshold of classroom and laboratory training was met?</p> <p>How does the board verify that all the hours of classroom and laboratory training were applicable to the medical use of sodium iodide for procedures requiring a written directive and that no hours were counted twice?</p>
<p>The training must include—</p> <ul style="list-style-type: none"> i) Radiation physics and instrumentation; ii) Radiation protection; iii) Mathematics pertaining to the use and measurement of radioactivity; iv) Chemistry of byproduct material for medical use; and v) Radiation biology. 	<p>How does the board verify that all the candidate's classroom and laboratory training was specific to the oral administration of sodium iodide requiring a written directive in quantities less than or equal to 1.22 GBq (33 µCi) for each of the following?</p>

<p>(c)(2) Has work experience, under the supervision of an authorized user who meets the requirements in §§ 35.57, 35.390, 35.392, 35.394, or equivalent Agreement State requirements. A supervising authorized user who meets the requirements in § 35.390(b) must also have experience in administering dosages as specified in §§ 35.390(b)(1)(ii)(G)(1) or 35.390(b)(1)(ii)(G)(2).</p> <p>The work experience must involve—</p> <ul style="list-style-type: none"> i) Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys; ii) Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters; iii) Calculating, measuring, and safely preparing patient or human research subject dosages; iv) Using administrative controls to prevent a medical event involving the use of byproduct material; v) Using procedures to contain spilled byproduct material safely and using proper decontamination procedures; and vi) Administering dosages to patients or human research subjects, that includes at least 3 cases involving the oral administration of less than or equal to 1.22 GBq (33 µCi) of sodium iodide I–131; 	<p>How does the board verify that the candidate’s supervisor meets the stated criteria?</p> <p>How does the board’s review process evaluate the candidate’s work experience and verify that each category is covered and applicable to the oral administration of sodium iodide requiring a written directive in quantities less than or equal to 1.22 GBq (33 µCi)?</p> <p>How does the board verify that dosages of sodium iodide requiring a written directive in quantities less than or equal to 1.22 GBq (33 µCi) were administered to at least 3 patients?</p>
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Table 4-5. 10 CFR 35.394, "Training for the oral administration of sodium iodide (I-131) requiring a written directive in quantities greater than 1.22 gigabecquerels (33 millicuries)"

NRC Requirements	NRC Staff Questions
A specialty board shall require all candidates for certification to:	
<p>(c)(1) Has successfully completed 80 hours of classroom and laboratory training, applicable to the medical use of sodium iodide I-131 for procedures requiring a written directive.</p> <p>The training must include—</p> <ul style="list-style-type: none"> (i) Radiation physics and instrumentation; (ii) Radiation protection; (iii) Mathematics pertaining to the use and measurement of radioactivity; (iv) Chemistry of byproduct material for medical use; and (v) Radiation biology; 	<p>How does the board verify that the 80-hour threshold of classroom and laboratory training was met?</p> <p>How does the board verify that all the classroom and laboratory training was applicable to the medical use of sodium iodide for procedures requiring a written directive and that no hours were counted twice?</p> <p>How does the board verify that all the training for each topic is specific to the oral administration of sodium iodide requiring a written directive in quantities greater than 1.22 GBq (33 μCi)?</p>

<p>(c)(2) Has work experience, under the supervision of an authorized user who meets the requirements in §§ 35.57, 35.390, 35.394, or equivalent Agreement State requirements.</p> <p>A supervising authorized user, who meets the requirements in § 35.390(b), must also have experience in administering dosages as specified in § 35.390(b)(1)(ii)(G)(2).</p> <p>The work experience must involve—</p> <ul style="list-style-type: none"> i) Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys; ii) Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters; iii) Calculating, measuring, and safely preparing patient or human research subject dosages; iv) Using administrative controls to prevent a medical event involving the use of byproduct material; v) Using procedures to contain spilled byproduct material safely and using proper decontamination procedures; vi) Administering dosages to patients or human research subjects, that includes at least 3 cases involving the oral administration of greater than 1.22 GBq (33 µCi) of sodium iodide I-131; 	<p>How does the board verify that the candidate’s supervisor meets the criteria?</p> <p>How does the board’s review process evaluate the candidate’s work experience and verify that each work experience category is applicable to the oral administration of sodium iodide requiring a written directive in quantities greater than 1.22 GBq (33 µCi)?</p> <p>How does the board verify that dosages of sodium iodide requiring a written directive in quantities greater than 1.22 GBq (33 µCi) were administered to at least 3 patients?</p>
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Table 4–6. 10 CFR 35.490, “Training for use of manual brachytherapy sources”

NRC Requirements	NRC Staff Questions
<p>A specialty board shall require all candidates for certification to:</p>	
<p>(a)(1) Successfully complete a minimum of 3 years of residency training in a radiation oncology program approved by:</p> <ul style="list-style-type: none"> The Residency Review Committee of the Accreditation Council for Graduate Medical Education; The Royal College of Physicians and Surgeons of Canada; or The Committee on Post-Graduate Training of the American Osteopathic Association 	<p>How does the board verify that the candidates completed an approved residency program in radiation oncology?</p> <p>Which accreditation programs does the board accept?</p> <p>Is the board engaged during times of process change at the accreditation board?</p> <p>How does the board verify that the 3-year threshold is met?</p>
<p>(a)(2) Pass an examination, administered by diplomates of the specialty board, that tests knowledge and competence in:</p> <ul style="list-style-type: none"> Radiation safety; Radionuclide handling; Quality assurance; Treatment planning; and Clinical use of manual brachytherapy 	<p>How does the board ensure that the written examination content is specific to the use of manual brachytherapy for each topic?</p>

Table 4–7. 10 CFR 35.590, “Training for use of sealed sources and medical devices for diagnosis”

NRC Requirements	NRC Staff Questions
A specialty board shall require all candidates for certification to:	
<p>(c) Has completed 8 hours of classroom and laboratory training in basic radionuclide handling techniques specifically applicable to the use of the device.</p> <p>The training must include—</p> <ul style="list-style-type: none"> (1) Radiation physics and instrumentation; (2) Radiation protection; (3) Mathematics pertaining to the use and measurement of radioactivity; and (4) Radiation biology; 	<p>How does the board verify that the 8-hour threshold of classroom and laboratory training was met?</p> <p>How does the board verify that the classroom and laboratory training were applicable to basic radionuclide handling techniques specific for the use of the device and that no hours were counted twice?</p> <p>What devices does the board include?</p> <p>How does the board verify that the training is specific to the use of sealed sources and medical devices for diagnosis for each device?</p>
(d) Has completed training in the use of the device for the uses requested.	How does the board verify that the training was specific to the use of the device for the uses requested?

Table 4–8. 10 CFR 35.690, “Training for use of remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units”

NRC Requirements	NRC Staff Questions
<p>A specialty board shall require all candidates for certification to:</p>	
<p>(a)(1) Successfully complete a minimum of 3 years of residency training in a radiation therapy program approved by:</p> <p>The Residency Review Committee of the Accreditation Council for Graduate Medical Education;</p> <p>The Royal College of Physicians and Surgeons of Canada; or</p> <p>The Committee on Post-Graduate Training of the American Osteopathic Association.</p>	<p>How does the board verify that the candidates completed an approved residency program in radiation therapy?</p> <p>Which accreditation programs does the board accept?</p> <p>Is the board engaged during times of process change at the accreditation board?</p> <p>How does the board verify that the 3-year residency training threshold is met?</p>
<p>(a)(2) Pass an examination, administered by diplomates of the specialty board, which tests knowledge and competence in:</p> <p style="padding-left: 40px;">Radiation safety;</p> <p style="padding-left: 40px;">Radionuclide handling;</p> <p style="padding-left: 40px;">Treatment planning;</p> <p style="padding-left: 40px;">Quality assurance; and</p> <p style="padding-left: 40px;">The clinical use of stereotactic radiosurgery, remote afterloaders, and external beam therapy</p>	<p>How does the board ensure that the content of the examination adequately addresses each topic specific to the use of remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units?</p>