April 4, 2005

Mr. Greg Wegst
DTC Video
5930 Roe Avenue
Mission KS 66205

SUBJECT: RECOGNITION OF BOARDS

Dear Mr. Wegst:

Your organization is being contacted at this time by the U.S. Nuclear Regulatory Commission (NRC) regarding possible specialty board application for NRC recognition of one or more certification processes under the board recognition requirements in the revised training and experience (T&E) requirements in Part 35, Subparts B and D through H. The revised regulations were published in the Federal Register on March 30, 2005, (70 FR 16336) and are effective April 29, 2005.

Under requirements of compatibility, the board recognition requirements of Agreement States will be equivalent to those in Part 35, Subparts B and D through H. Boards that are recognized by either the NRC or by an Agreement State will be listed on NRC's web site for Part 35 matters, at http://www.nrc.gov/materials/miau/med-use-toolkit.html. Note that after October 25, 2005 for NRC-regulated states and after October 25, 2008 for Agreement States, an individual citing board certification as part of his or her application for approved status, i.e., seeking approved status via the "board certification" pathway, will have to be a diplomate of a board whose certification process has been recognized by the NRC or by an Agreement State under the revised requirements.

Enclosed for your reference and use, if your organization should decide to establish a specialty board and to apply for NRC recognition of one or more of its certification programs, is a copy of the procedures that are being used by NRC for recognizing certification processes of specialty boards. The document also describes NRC procedures for maintenance of a board's recognized status and for withdrawing recognition (delisting) of specialty boards, if required.

Please note the following important procedural matters. Official communications to the NRC from a specialty board are to be in the form of letters signed by persons authorized to speak for the board, i.e., its chief executive officer or designee. Such communications would include those sent to the NRC for the purpose of supplying information in support of an application, change in certification procedures, or other changes that would affect recognition of the board's certification process(es) under the regulations in 10 CFR Part 35. Letters from the board should acknowledge management's commitment to and responsibility for the completeness and accuracy of the information provided to the NRC.

Your letter should clearly list the sections in Part 35 for which the board wishes to have its certification process(es) recognized. The letter should include a clear description of the board's requirements for certification and a statement that candidates for certification must complete the requirements for training and experience required by the rule section(s) applicable to the type of certification, for which the board is seeking recognition, prior to receiving board certification. The letter should provide information explaining how examinations administered by the board assess competency in radiation safety. If the specialty board posts its requirements for certification on the World Wide Web, the board should also provide the web site designation (URL). The board should indicate when the certification program being described for recognition was established, i.e., became effective. (Diplomates of the board who, prior to recognition of the board, met the requirements of the program described for recognition can be considered for approval as authorized users via the board certification pathway.) The board should also specify the length of time for which a certification is valid.

If your organization decides to establish a specialty board and to pursue recognition of one or more of its certification programs, it will be in the best interest of the future board's diplomates if your board's application is received by NRC soon, for review. Doing so will provide time for resolving any questionable matters and for NRC action to recognize certification programs of your board before its diplomates seek approved status via the "board certification" pathway.

Communications from your board associated with applying for recognition of one or more of its certification programs should be addressed to:

U.S. Nuclear Regulatory Commission
ATTN: Mr. Thomas Essig, Chief, Materials Safety
and Inspection Branch (MS T8F3)
11545 Rockville Pike
Rockville, MD 20852

For further information or for questions, please contact Dr. Ronald Zelac of my staff (301/415-7635, rez@nrc.gov).

/RA/
Thomas H. Essig, Chief
Materials Safety and Inspection Branch
Division of Industrial and
Medical Nuclear Safety
Office of Nuclear Material Safety
and Safeguards

Enclosure: Procedures for Recognizing
Certification Processes of Specialty Boards

Procedures for Recognizing Certification Processes of Specialty Boards

BACKGROUND

The Commission directed the NRC staff, in Staff Requirements Memorandum (SRM)-02-0194, dated February 12, 2003, 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 (and by Agreement States). The SRM directed the staff, as part of the rulemaking process, to discuss implementing procedures both for adding new speciality 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 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 (and to Agreement States) on how to request and evaluate applications from specialty boards to determine if their certification processes satisfy the requirements for recognition and on posting of recognized board certifications on the NRC's web site. All boards, including those whose certification processes are recognized under the current rule, will be required to apply for recognition, so that the NRC can make a clear regulatory determination that all listed board certifications 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 whose certifications are now recognized under Subparts D and J of 10 CFR Part 35, for recognition of their certifications under applicable sections of revised Subparts B and D through H. NRC staff will also provide, via telephone (with documentation), e-mail, or letter, as appropriate, information to other entities which have questions about recognition. 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 a specialty board are to be signed by a person authorized to speak for the board, i.e., its chief executive officer or designee. Such communications would include those sent to the NRC 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 process(es) under the regulations in 10 CFR Part 35. Letters from the board should acknowledge management's commitments to and responsibility for the completeness and accuracy of the information provided to the NRC. Letters of recognition to

boards should include a request that recognized boards notify the NRC, via letter, 6 months in advance, of plans for becoming inactive or disbanding as well as of changes to certification procedures that would affect the recognition of their certification processes.

Applications for Recognition of Specialty Board Certifications

1. A specialty board requesting recognition should provide, via letter, a list of sections in Part 35 for which the board wishes to have its certification process(es) recognized. The letter should include a clear description of the board's 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. The letter should provide information explaining how examinations administered by the board assess competency in radiation safety. The letter of application should be dated and signed by the chief executive officer of the board, or designee. If the specialty board posts its requirements for certification on the World Wide Web, the board should also provide the web site designation (URL). The board should indicate when the certification program being described for recognition was established, i.e., became effective. (Diplomates of the board who, prior to recognition of the board, met the requirements of the program described for recognition can be considered for approval as AMPs, ANPs, AUs, or RSOs via the board certification pathway.) The board should also specify the length of time for which a certification is valid.
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 and D 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's certification process meets an applicable set of requirements for NRC recognition, the staff will notify the board of its finding via letter and add that board certification to the list of recognized board certifications appearing on the NRC's web site for Part 35 matters. The information posted on the NRC's web site will include the dates for which the board's certification process is 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, 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 process(es) does (do) not meet the applicable criteria in Part 35, the NRC will notify the board, via letter. The NRC will also notify Agreement States of the name of the board and the date of this determination.
6. Agreement States may recognize the certification process(es) of boards that meet requirements of rules compatible, under Compatibility Category B, with those in 10 CFR Part 35. The names of these board certifications will be included in the listing of recognized board certifications on the NRC's web site, with annotations indicating which Agreement State(s) recognized the boards' certification processes, after the NRC is

notified of the recognition(s).

Maintenance of Recognized Status

1. When the NRC recognizes a board's certification process(es) and notifies the board that its certification(s) will be listed on the NRC's web site, the board will also be advised that it is to notify the NRC, via letter, 6 months in advance, of plans for changes to certification procedures that would affect recognition of its certification process(es). (See "Communications with Specialty Boards.")
2. The NRC staff will review changes to a recognized board's certification process(es), using the procedures outlined above (under "Applications for Recognition of Specialty Board Certifications") and 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 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), and notify the board regarding its finding.
3. The NRC staff will periodically request, from each board whose certification process(es) has (have) been recognized by the Commission, verification 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 the matter. The NRC staff requests to boards for verifications will be via letter, at intervals not to exceed 5 years.
4. The Agreement State which initially recognizes a board's certification process(es) will be responsible for determining that board's continued eligibility for recognition.

Procedures for Withdrawing Recognition (Delisting) of Specialty Boards

1. Delisting based on inadequate evaluation of radiation safety competency 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 competence, the staff will determine, in consultation with the ACMUI, if the trend is associated with a deficiency in the evaluation of individuals' qualifications that is traceable to inadequacies in a specialty board's certification process, including requirements for T&E related to radiation safety. If the trend is determined to be attributable to inadequate radiation safety competence that is not identified through the certification process, the NRC staff will assess whether the examinations provided by the certifying board adequately assess the knowledge/skills reflected in the requirements for T&E related to recognition of the specialty board's certification process.
    b. If the NRC staff determines that changes in evaluation of the radiation safety competence of candidates for certification by a specialty board are necessary in order for the board to maintain recognition of its certification process(es), 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 the board would propose to make, in order to maintain recognition of its certification processes by the NRC, and to identify reasons for disagreeing with NRC findings, if this is the case. 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 certification will be removed from the NRC's list of recognized board certifications.

d. The Commission and the ACMUI will be informed of any decision by the NRC staff to remove a board's certification from the list of recognized board certifications.

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 an identified deficiency in its certification process requirements, the NRC staff will determine the date when the inadequacy developed, beyond which the certification will no longer be recognized. That date will be posted on the NRC web site listing for that board's certification.

g. When a board's certification process(es) is (are) recognized by an Agreement State, that State shall be responsible for assessing inadequate evaluation of radiation safety competency of candidates for certification, for delisting that board's certification(s), and for notifying the NRC.

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(es) employed by a recognized board, determines, in consultation with the ACMUI, that the change may adversely affect the recognized status of the board's certification process(es), 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 process(es).

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(es) may adversely affect the recognition of the board's certification process(es) and the specialty board does not make changes to its certification process(es) that are considered adequate to address the NRC's concerns, then that specialty board's certification(s) will be removed from the NRC's list of recognized board certifications.

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's certification(s) is (are) to be removed from the list of recognized board certifications.

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. That date will be posted on the NRC web site listing for that board.

f. When a board's certification process(es) is (are) recognized by an Agreement State, that State shall be responsible for assessing inadequate evaluation of radiation safety competency of candidates for certification, for delisting that board's certification(s), and for notifying the NRC.

3. Delisting based on a 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 become inactive or disbanded, 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 process(es).
   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 process(es), then that specialty board's certification will be removed from the NRC's list of recognized board certifications.
   c. The Commission and the ACMUI will be informed of a staff decision to remove a board's certification from the list of recognized board certifications.
   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's certification is delisted by the NRC or an Agreement State due to the board 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. Information about the dates for which the board's certification was recognized will be posted on the NRC's web site.
   f. When a board is granted recognition by an Agreement State, that State shall be responsible for monitoring the status of the board, for taking action to de-list a board's certification(s) if the board becomes inactive or disbands, and for notifying the NRC.

<u>Evaluation of Training and Experience — "Outdated" Certifications</u>

If an individual holds certification from a board for which the NRC or an Agreement State withdraws recognition of the board's certification process, the certification will be considered valid if it was granted during the time interval that the board's certification process was recognized. The NRC will annotate the listing of board certifications 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.)