

June 2, 2004

MEMORANDUM TO: Michael T. Lesar, Chief  
Rules and Directives Branch  
Division of Administrative Services  
Office of Administration

FROM: Roger W. Broseus  
Rulemaking and Guidance Branch  
Division of Industrial and **/RA/**  
Medical Nuclear Safety, NMSS

SUBJECT: REGULATORY HISTORY INDEX - PROPOSED RULE:  
MEDICAL USE OF BYPRODUCT MATERIAL - RECOGNITION  
OF SPECIALTY BOARDS

Attached is the regulatory history index of those documents of central relevance to the subject rulemaking. The ADAMS Accession number is provided for each document or package. The rulemaking would amend the regulations governing the medical use of byproduct material to change requirements for recognition of specialty boards whose certification may be used to demonstrate the adequacy of the training and experience of individuals to serve as authorized users, authorized medical physicists, authorized nuclear pharmacists or radiation safety officers. The proposed rule would also revise the requirements for demonstrating the adequacy of training and experience for pathways other than the board certification pathway. The title of the proposed rule was "Medical Use of Byproduct Material-Recognition of Specialty Boards" published in the Federal Register on December 9, 2004 (68 FR 68549).

Attachment: Regulatory History Index

CONTACT: Roger W. Broseus, NMSS/IMNS  
(301) 415-7608

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Regulatory History Index

SUBJECT: PROPOSED RULE: MEDICAL USE OF BYPRODUCT MATERIAL - RECOGNITION OF SPECIALTY BOARDS  
 PROPOSED RULE (68 FR 68549)  
 RIN 3150-AH19

| Accession Number | Title/Description  | Document Date | Author | Public Availability    |
|------------------|--|---------------|--------|------------------------|
| ML040780662      | 03/02/2004 Transcript of Advisory Committee on Medical Uses of Isotopes in Rockville, MD. Pages 1-270.   | 03/02/2004    |        | Publicly Available     |
| ML031740539      | 05/20/2003 Notice of Meeting With Invited Participants of Specialty Boards to Solicit Input for Drafting Proposed Rule, 10 CFR Part 35, to Address Issues Related to Training & Experience Associated With Recognition of Specialty Boards by NRC. |               |        | Publicly Available     |
| ML033500144      | ACMUI - To ACMUI 12/03 for Review - Proposed Rule and Implementation.  |               |        | Non-Publicly Available |
| ML032390506      | ACMUI Transcript 071703.   | 07/17/2003    |        | Non-Publicly Available |
| ML032390509      | ACMUI Transcript 071703(EXEC).   | 07/17/2003    |        | Non-Publicly Available |
| ML032230049      | Agreement State Review of Draft Proposed Rule.   |               |        | Non-Publicly Available |
| ML040360210      | Implementation - ACMUI & Agreement State Review.   |               |        | Non-Publicly Available |

| <b>Accession Number</b> | <b>Title/Description</b>   | <b>Document Date</b> | <b>Author</b> | <b>Public Availability</b> |
|-------------------------|--|----------------------|---------------|----------------------------|
| ML032830046             | Implementation - Revision of Part 35 (T&E).  |                      |               | Non-Publicly Available     |
| ML033500116             | Markup - Amendments to Part 35 (T&E) - Aid to Reviewers - Markup Showing Proposed Change to Regulations.                             | 12/15/2003           |               | Publicly Available         |
| ML033500158             | Markup of ACMUI's Recommendations for Proposed Rule Text.  | 12/15/2003           |               | Non-Publicly Available     |
| ML033240506             | OMB Clearance Package for Proposed Rule: Medical Use of Byproduct Material - Recognition of Speciality Boards.                       |                      |               | Non-Publicly Available     |
| ML033140165             | Proposed Rule Revised Part 35 T&E for ADM.   |                      |               | Non-Publicly Available     |
| ML031740508             | Review and Concurrence: Proposed Rule on Recognition of Speciality Boards.   |                      |               | Non-Publicly Available     |
| ML022700166             | SECY-02-0194 - Options For Addressing Part 35 Training and Experience Issues Associated With Recognition of Specialty Boards By NRC. | 10/30/2002           | Travers W D   | Publicly Available         |
| ML032170607             | SECY-03-0145 - Proposed Rule: Medical Use of Byproduct Material - Recognition of Specialty Boards.                                   |                      |               | Publicly Available         |
| ML040340359             | SECY-04-0045 - Final Criteria for the Treatment of Individual Requirements in a Regulatory Analysis.                                 |                      |               | Publicly Available         |

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|------------------|---|---------------|-----------------|---------------------|
| ML031710268      | SRM-M030528B - Meeting with Advisory Committee on the Medical Uses of Isotopes, May 28, 2003, Rockville, MD. (Open to Public Attendance).   | 06/20/2003    | Vietti-Cook A L | Publicly Available  |
| ML030440087      | SRM-SECY-02-0194 - "Options for Addressing Part 35 Training and Experience Issues Associated With Recognition of Specialty Boards by NRC."  | 02/12/2003    | Vietti-Cook A L | Publicly Available  |
| ML032820570      | SRM-SECY-03-0145 - "Proposed Rule: Medical Use of Byproduct Material - Recognition of Specialty Boards."  | 10/09/2003    | Vietti-Cook A L | Publicly Available  |
| ML033440232      | STP-03-088, Proposed Revision to 10 CFR Part 35, "Medical Use of Byproduct Material" - Recognition of Specialty Boards.   | 12/09/2003    | Lohaus P H      | Publicly Available  |
| ML033440206      | Comment (1) submitted by Martha G. Dibblee on Proposed Rule PR-35 re Medical Use of Byproduct Material - Recognition of Specialty Board.  | 12/04/2003    | Dibblee M G     | Publicly Available  |
| ML040370497      | Comment (10) submitted by Iowa Department of Public Health, Nancy A. Farrington, on Proposed Rule PR-35 regarding Medical Use of Byproduct Material - Recognition of Specialty Board. | 12/01/2003    | Farrington N A  | Publicly Available  |
| ML040480583      | Comment (11) submitted by Texas Department of Health, Cindy Cardwell on Proposed Rule PR-35 regarding Medical Use of Byproduct Material - Recognition of Specialty Board.             | 02/13/2004    | Cardwell C      | Publicly Available  |

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|------------------|---|---------------|------------------------------|---------------------|
| ML040510238      | Comment (12) submitted by, Certification Board of Nuclear Cardiology, James E. Udelson on PR-35 re Medical Use of Byproduct Material - Recognition of Specialty Boards.                             | 02/18/2004    | Udelson J E                  | Publicly Available  |
| ML040510246      | Comment (13) submitted by, American Association of Clinical Endocrinologists, Donald Bergman, on PR -35 re Medical Use of Byproduct Material - Recognition of Specialty Boards.                     | 02/19/2004    | Bergman D                    | Publicly Available  |
| ML040550437      | Comment (14) submitted by The American College of Cardiology, Carl J. Pepine on Proposed Rule PR-35 re Medical Use of Byproduct Material - Recognition of Specialty Boards.                         | 02/23/2004    | Pepine C J                   | Publicly Available  |
| ML040550439      | Comment (15) submitted by The American Board of Nuclear Medicine, Michael M. Graham on Proposed Rule PR-35 re Medical Use of Byproduct Material - Recognition of Specialty Boards.                  | 02/23/2004    | Graham M M                   | Publicly Available  |
| ML040550440      | Comment (16) submitted by International RadioSurgery Association, Rebecca Emerick & L. Dade Lunsford on Proposed Rule PR-35 re Medical Use of Byproduct Material - Recognition of Specialty Boards. | 02/20/2004    | Emerick R L,<br>Lunsford L D | Publicly Available  |
| ML040550452      | Comment (17) submitted by American Osteopathic College of Radiology, Sheldon Kerner on Proposed Rule PR-35 re: Medical Use of Byproduct Material - Recognition of Specialty Boards.                 | 02/20/2004    | Kerner S P                   | Publicly Available  |

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| ML040560505      | Comment (18) submitted by Michael Sheetz on Proposed Rule PR-35 re Medical Use of Byproduct Material - Recognition of Specialty Boards.   | 02/23/2004    | Sheetz M  | Publicly Available  |
| ML040560508      | Comment (19) submitted by Ralph Lieto on Proposed Rule PR-35 re Medical Use of Byproduct Material - Recognition of Specialty Boards.  | 02/23/2004    | Lieto R P   | Publicly Available  |
| ML033510140      | Comment (2) submitted by Fred Mettler on Proposed Rules PR-35 re Medical Us of Byproduct Material - Recognition of Specialty Board.   | 12/12/2003    | Mettler F   | Publicly Available  |
| ML040560509      | Comment (20) submitted by American College of Radiology, et. Al. E. Stephen Amis, Joel E. Tepper, Martin S. Wienhous, Edward L. Nickoloff and Amin I. Kassis on Proposed Rule PR-35 re Medical Use of Byproduct Material - Recognition of Specialty Boards. | 02/23/2004    | Amis E S,<br>Kassis A I,<br>Nickoloff E L,<br>Tepper J E,<br>Weinhous M S | Publicly Available  |
| ML040610948      | Comment (21) submitted by the Nuclear Medicine Residency Review Committee of ACGME, Michael Graham on Proposed Rule PR-35 re Medical Use of Byproduct Material - Recognition of Specialty Boards.   | 02/23/2004    | Graham M M  | Publicly Available  |
| ML040560513      | Comment (22) submitted by The Illinois Emergency Management Agency, Joseph G. Klinger on Proposed Rule PR-35 re Medical Use of Byproduct Material - Recognition of Specialty Boards.  | 02/24/2004    | Klinger J G   | Publicly Available  |

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| ML040560612      | Comment (23) submitted by The Society of Nuclear Medicine, Henry Royal & American College of Nuclear Physicians, Warren Moore on Proposed Rule PR-35 re Medical use of Byproduct Material - Recognition of Specialty Boards. | 02/23/2004    | Moore W H,<br>Royal H D | Publicly Available  |
| ML040560614      | Comment (24) submitted by Robert E. Dansereau, NY State Department of Health on Proposed Rule PR-35 re Medical use of Byproduct Material - Recognition of Specialty Boards.  | 02/23/2004    | Dansereau R E           | Publicly Available  |
| ML040560617      | Comment (25) submitted by The American Society of Nuclear Cardiology, Robert Hendel on Proposed Rule PR-35 re Medical Use of Byproduct Material - Recognition of Specialty Boards.   | 02/23/2004    | Hendel R C              | Publicly Available  |
| ML040650464      | Comment (26) submitted by the Organization of Agreement States, Stanley Fitch on Proposed Rule PR-35 re Medical Use of Byproduct Material - Recognition of Specialty Board.  | 02/25/2004    | Fitch S                 | Publicly Available  |
| ML033530062      | Comment (3) submitted by Lynne A. Fairobent on Proposed Rule PR-35 re Medical Use of Byproduct Material - Recognition of Specialty Board.  | 12/10/2003    | Fairobent L A           | Publicly Available  |
| ML033640542      | Comment (4) submitted by the State of Alabama Dept. of Public Health, David Walter re: Proposed Rules PR-35 Medical Use of Byproduct Material - Recognition of Specialty Board.  | 12/16/2003    | Walter D                | Publicly Available  |



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|------------------|---|---------------|-------------|---------------------|
| ML040140316      | Comment (5) submitted by Arkansas Department of Health, Radiation Control and Emergency Management, Kim C. Wiebeck regarding PR 35, Medical use of Byproduct Material - Recognition of Specialty Board. | 01/12/2004    | Wiebeck K C | Publicly Available  |
| ML040140317      | Comment (6) submitted by Steven G. Marsh re PR-35, Medical Use of Byproduct Material - Recognition of Specialty Board.  | 01/12/2004    | Marsh S G   | Publicly Available  |
| ML040160580      | Comment (7) submitted by Philip Heintz supporting PR-35 re Medical use of Byproduct Material - Recognition of Specialty Board.  | 01/14/2004    | Heintz P H  | Publicly Available  |
| ML040220309      | Comment (8) submitted by Chris Alston re PR-35, Medical use of Byproduct Material - Recognition of Specialty Board.   | 01/16/2004    | Alston C    | Publicly Available  |
| ML040350547      | Comment (9) submitted by J. Charles Smith re Proposed Rule PR-35 regarding Medical use of Byproduct Material - Recognition of Specialty Boards.   | 02/03/2004    | Smith J C   | Publicly Available  |
| ML033570508      | Letter from Sandra Szendy, State of Tennessee requesting for an extension of comment period on Proposed Rule PR-35 re Medical Use of Byproduct Material-Recognition of Specialty Board.                 | 12/19/2003    | Szendy S    | Publicly Available  |
| ML040370295      | Supplement to Comment No. 4 submitted by David Walter, State of Alabama Department of Health, regarding Proposed Rule PR-35, Medical Use of Byproduct Material - Recognition of Specialty Board.        | 01/22/2004    | Walter D    | Publicly Available  |

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| ML040560516      | Supplemental to Comment No. 13 submitted by The American Association of Clinical Endocrinologists, Donald Bergman on Proposed Rule PR-35 re Medical use of Byproduct Material - Recognition of Specialty Boards. | 02/23/2004    | Bergman D A  | Publicly Available  |
| ML040780662      | 03/02/2004 Transcript of Advisory Committee on Medical Uses of Isotopes in Rockville, MD. Pages 1-270.   | 03/02/2004    |              | Publicly Available  |
| ML041540488      | Regulatory history for Proposed Rule: Medical Use of Byproduct Material - Recognition of Specialty Boards  | 06/02/2004    | Broseus, R W | Publicly Available  |