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Public Meeting of the Advisory Committee on the Medical Uses of Isotopes

May 20-21, 2003

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ACMUI Meeting
May 20, 2003
U.S. Nuclear Regulatory Commission
Two White Flint North, T2B3

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	NAME		NAME
1	~~Mate M~~	19	Paul Lohaus
2	Marissa Bailey	20	Scott Flanders
3	Bob Mooy	21	Patricia Hoban
4	Bill DAM	22	[signature]
5	Rob Forrest	23	James Hevesi
6	PAUL PUNTO	24	Angela Lee
7	Lynne Fairobent	25	[signature]
8	Bill UFFELMAN	26	Tony Tse
9	DONNA-Beth Howe	27	Robert Lewis
10	Joe Way	28	Kent T. Gates
11	TRACIE M. CLEMONS	29	P. NRIPUNANEMI
12	ALAN MAUER	30	J.E. MORRIS
13	Jeffry Siegel	31	C. Taylor (Cynthia)
14	Laura Thurnot	32	
15	David Hussey	33	
16	Nancy K Dudley	34	
17	James A. Baciall Jr.	35	
18	Bill VanDecke	36	

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ACMUI Meeting
May 21, 2003
U.S. Nuclear Regulatory Commission
Two White Flint North, T2B3

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NAME	NAME
1 Karl Tyrko	19
2 Jim Hewerl	20
3 David Hassey	21
4 Jerry White	22
5 Lynne Fairobent	23
6 Bill Uffelman	24
7 P. TRIPURANENI	25
8 Rob Forrest	26
9 Jeff Siegel	27
10 Laura Thurnot	28
11 Angela Lee	29
12 Nancy K Dale	30
13 Sandra Wastler	31
14 James A. Ballall Jr.	32
15	33
16	34
17	35
18	36

ACMUI SPEAKERS and PARTICIPATING STAFF
May 20-21, 2003

Manuel D. Cerqueira, M.D., ACMUI Chairman

Robert L. Ayres, PhD., NRC/NMSS

Roger W. Broseus, PhD., NRC/NMSS

Thomas H. Essig, NRC/NMSS, Designated Federal Official

Ryan T. Coles, U.S. Government Accounting Office

Charles Cox, NRC/NMSS

William R. Hendee, PhD., President, American Board of Radiology

Donna-Beth Howe, PhD., NRC/NMSS

Leon S. Malmud, M.D., ACMUI, Healthcare Administrator

Michael Markley, NRC/NMSS

Linda M. Psyk, NRC/NMSS

Jeffry Siegel, M.D., Society of Nuclear Medicine

Roberto Torres, NRC/NMSS

Angela R. Williamson, NRC/NMSS

Ronald E. Zelac, PhD., NRC/NMSS

ADVISORY COMMITTEE ON THE MEDICAL USES OF ISOTOPES

May 20-21, 2003
U.S. Nuclear Regulatory Commission
Two White Flint North Building, Room T2B3
Rockville, Maryland 20852-2738

AGENDA

MAY 20 MEETING

CLOSED SESSION

8:00 - 8:05 Addition of Vice Chair Position to ACMUI – Thomas Essig, NRC/NMSS

8:05 - 8:30 Discussion: ACMUI Role – Thomas Essig, NRC/NMSS

8:30 - 9:00 Briefing on NRC activities to address security and control in the Materials area - Frederick Sturz and Charles Cox NRC/NMSS

9:00 - 9:30 Briefing on NRC Staff Organization in Support of the Medical Program – Thomas Essig, NRC/NMSS

9:30 - 10:00 Discussion of Critera to Use in Selecting ACMUI Members – Angela Williamson, NRC/NMSS

10:00 – 10:15 **BREAK**

10:15 – 10:45 ACMUI Self-Evaluation – Angela Williamson, NRC/NMSS

10:45 – 11:30 Discussion among ACMUI about the Commission Briefing – ACMUI

11:30 – 12:00 Prebrief to IMNS Division Director re: Commission Briefing – ACMUI

12:00 - 1:00 **LUNCH**

OPEN SESSION

1:00 - 1:05 Opening Remarks – Thomas Essig, NRC/NMSS

1:05 - 1:10 Society of Nuclear Medicine Licensing Guide – Thomas Essig, NRC/NMSS

1:10 - 1:20 Update: GAO's Review of Domestic Regulation of Nuclear Material – Ryan T. Coles, U.S. Government Accounting Office

1:20 - 2:00 Training, Education, Board Certification and the New Part 35 – Dr. William Hendee, President, American Board of Radiology

2:00 - 2:15 Discussion: NRC Licensing Timelines, Proposal for Monthly /Bi-Monthly ACMUI Teleconferences – Thomas Essig, NRC/NMSS

2:15 - 2:30 T&E Rulemaking, Status and Discussion – Roger Broseus, PhD, NRC/NMSS

2:30 - 2:45 Sealed Source Model Numbers as License Conditions – Donna Beth Howe, PhD, NRC/NMSS

2:45 - 3:00 **BREAK**

3:00 - 3:30 National Materials Program Pilot Project on Operating Experience Evaluation – Michael Markley, NRC/NMSS

3:30 - 4:00 Content and Status of the Direct Final Rule to Clarify Definitions, Notification Requirements, and Recordkeeping Requirements; and to Eliminate a Certain Restriction – Anthony Tse, PhD, NRC/NMSS

4:00 - 4:15 HHS Database of Regulatory Actions: Status And Discussion – Linda Psyk, NRC/NMSS

4:15 - 4:30 Discussion: Written Directives for Brachytherapy not Associated with Permanent Implants – Ronald Zelac, Ph.D., NRC/NMSS

4:30 - 4:35 Downloading Part 35 from the NRC Webpage – Thomas Essig, NRC/NMSS

4:35 - 5:00 Society of Nuclear Medicine's Suggested Guidance for Therapy Applications – Dr. Jeffry Siegel, Society of Nuclear Medicine

5:00 **ADJOURN**

MAY 21 MEETING

8:00 - 9:00 Review of "Complicated" Licensing Issues Since 10/24/02 - Donna-Beth Howe, PhD, NRC/NMSS

9:00 – 10:00 Physical Presence Requirements during Stereotactic Radiosurgery Treatments – R. Ayres, PhD, NRC, NMSS

10:00 - 10:15 **BREAK**

10:15 - 10:45 Discussion: The Listing of Certain Practitioners in 35.1000 – L. Malmud, M.D., ACMUI

10:45 - 11:15 Interpretation of 10 CFR 35.61(b) – Ronald Zelac, PhD, NRC/NMSS

11:15 - 12:00 Review of Medical Area Operating Experience and Enforcement Actions: One Year and Since 10/24/02 – Roberto Torres, NRC/NMSS

12:00 - 1:00 **LUNCH**

1:50 - 2:00 Update: Recommendations from Fall 2002 Meeting – Angela Williamson, NRC/NMSS

2:00 - 2:30 Part 35 Question and Answer Process – Ronald Zelac, PhD, NRC/NMSS

2:30 - 3:00 Pt. 35.1000 Licensing Guidance – Donna-Beth Howe, PhD, and Robert Ayres, PhD, NRC/NMSS

3:00 - 3:15 **BREAK**

3:15 - 4:00 10 CFR 35.1000 Subcommittee Working Meeting (presentations by stakeholders, etc.) – TBA

4:00 - 4:45 Discussion: 10 CFR Part 35.1000 Subcommittee – ACMUI

4:45 - 5:00 Administrative Conclusion:
Next Meeting Date
Agenda Topics
Meeting Summary

5:00 **ADJOURN**

NOTICE OF CLOSED SESSION AGENDA TOPICS

The following agenda topics are closed session topics and must not be distributed to, nor discussed with members of the public:

- ADDITION OF VICE CHAIR POSITION TO ACMUI
- DISCUSSION: ACMUI ROLE
- BRIEFING ON NRC ACTIVITIES TO ADDRESS SECURITY AND CONTROL IN THE MATERIALS AREA
- BRIEFING ON NRC STAFF ORGANIZATION IN SUPPORT OF THE MEDICAL PROGRAM
- DISCUSSION OF CRITERA TO USE IN SELECTING ACMUI MEMBERS
- ACMUI SELF-EVALUATION
- DISCUSSION AMONG ACMUI ABOUT THE COMMISSION BRIEFING
- PREBRIEF TO IMNS DIVISION DIRECTOR RE: COMMISSION BRIEFING

SNM LICENSING GUIDE

NO HANDOUT PROVIDED

UPDATE: GAO REVIEW OF DOMESTIC REGULATION OF NUCLEAR MATERIAL

HANDOUT PROVIDED AT MEETING

TRAINING, EDUCATION, BOARD CERTIFICATION AND THE NEW PT. 35

HANDOUT PROVIDED AT MEETING

DISCUSSION: NRC LICENSING TIMELINES, PROPOSAL FOR MONTHLY/BI-MONTHLY ACMUI TELECONFERENCES

NO HANDOUT PROVIDED

Proposed Rule to Amend 10 CFR Part 35: Requirements for Training and Experience

Roger W. Broseus, CHP, Ph.D.
Office of Nuclear Material Safety and Safeguards,
Division of Industrial and Medical Nuclear Safety

Defining the Problem

- Revised 10 CFR Part 35 scheduled for publication Spring, 2002
- ACMUI briefed Commission, Feb 2002
- Boards did not meet criteria in rule to have certifications recognized by the NRC
- Concerned that shortage of authorized users (physicians), RSOs, AMPs, ANPs would develop

NRC's Solution

- Subpart J was retained in rule for 2 years from effective date of rule – until Oct 24, 2004
- Staff work with ACMUI to develop solution
- ACMUI subcommittee developed proposal
- 3 options to Commission, Oct 2002
- Commission approved Option 3, as communicated in SRM-02-0194

Commission Direction

SRM-02-0914 directed staff to:

- Modify T&E requirements based on ACMUI's recommendations (SECY-02-0194, Attachment 2)
- List recognized specialty boards on NRC's web site
- Keep preceptor statement "as written" in current rule
- Clarify preceptor statement:
  - Attestation of clinical competency not required
  - Require attestation to be sufficient to demonstrate that a candidate has knowledge to fulfill the duties of position for which certification is sought

Key Points in SRM

- Require a clear regulatory determination that all boards meet criteria
- Provide implementing procedures for the addition to / removal from list of recognized boards
- When de-listing boards, consider:
  - No inspections of boards
  - Monitor trends in medical events

Drafting the Proposed Rule

- Using ACMUI's recommendations in Att. 2 to SECY-02-0194 as basis for proposed rule
- Staff's evaluation:
  - Need for some wording changes
  - Review recommendations that also introduced changes in 'alternate pathway' for satisfying NRC's T&E requirements

ACMUI Recommendation to Add A Residency Approving Entity

- Added the "Royal College of Physicians and Surgeons of Canada" to the list of approving entities for recognition of residency training programs in:
  - 35.390, 490, 690 board cert. pathway, and
  - 'alternate pathway' in 490(b)(2), 690(b)(2)
  - Basis?

Additions to ACMUI Recommended Rule Text

- Preceptor statement from 'alternate pathway' adopted to board-certification pathway, while retaining original rule language
- Retain option for board to satisfy 'alternate pathway' – adds an "or" to board cert. path

Staff Changes to ACMUI's Wording

- Added "radiation dosimetry" to list of subject areas for training in 35.50(a)(1)(iii)
- Retained "Radiation dosimetry" in 35.50(b)(1)(i)(E)
- "permit issued by a Commission master material licensee" retained in 35.50(b)(1)(ii)

Wording (cont.)

- 35.51 Terminology: medical physics vs. radiation oncology physics
  - Is use of more general, medical physics, term more appropriate?
  - Some boards use more general term; others the more specific term
- 35.390: staff recommends: "quantities for which a written directive is required" rather than "therapeutic quantities"

Wording (cont.)

- ACMUI recommended changing "calibrate" to "performing quality control procedures" in several sections on requirements for experience, e.g., 35.190(c)(1)(ii)(B)
  - ACMUI Draft - no change in 35.392(c)(2)(ii) and 35.394(c)(2)(ii)
  - For parallelism, staff changed to "performing quality . . ." in 392 & 394

Wording (cont.)

- Retained "running" in "running inventories" - 35.490(b)(1)(ii)(D)
- Retained "handling" in "basic radionuclide handling techniques" - 35.490(b)(2):

Implementation

- Listing of a board
  - Board submits to NRC an application describing certification process – application form w/ check list
  - Staff compares to requirements in rule
  - Consult with ACMUI if needed
- Maintenance of recognition
  - Boards notify NRC of changes in their requirements for certification

Implementation (cont.)

- De-listing (possible reasons):
  - Medical events increase / trace to fault in cert process
  - Board changes requirements, no longer meets regulatory requirement
- Agreement States List / De-list

Process for "De-listing" of a Board

- NRC identifies a potential problem
- Board contacted – opportunity to respond
- NRC evaluates response
- Consult with ACMUI
- Notify Commission of findings
- Notify board of determination

Path Forward

- Distribute draft proposed rule to Agreement States for 30-day comment period: June 2003
- Proposed Rule to Commission: July 2003
- Commission Decision
- Publish in FR, Sep. – 75 day comment period
- Final Rule
- Obtain input from boards & ACMUI on staff approach by May 30th

AGENDA TOPIC: T&E Rulemaking

RULEMAKING ISSUE
NOTATION VOTE

October 30, 2002 SECY-02-0194

FOR: The Commissioners

FROM: William D. Travers
Executive Director for Operations

SUBJECT: OPTIONS FOR ADDRESSING PART 35 TRAINING AND EXPERIENCE ISSUES ASSOCIATED WITH RECOGNITION OF SPECIALTY BOARDS BY NRC

PURPOSE:

To present options for Commission consideration in resolving issues associated with the training and experience (T&E) requirements in the recently published final rule amending 10 CFR Part 35, as they apply to the recognition of specialty boards by NRC.

SUMMARY:

On April 12, 2002, the Commission issued a Staff Requirements Memorandum (SRM), in response to COMSECY-02-0014, that approved a final rule regarding "Medical Use of Byproduct Material." The final rule was published in the Federal Register on April 24, 2002 (67 FR 20250) and will become effective on October 24, 2002. In a supplemental SRM issued on April 16, 2002, the Commission directed the staff to "develop a SECY paper that discusses various options for addressing the T&E issue before the revised final rule becomes effective." This Commission paper presents three options for Commission consideration. Option 1 is to retain the existing requirements in the final rule. Option 2 is to prepare a proposed rule to modify T&E requirements based on the recommendations submitted by the Advisory Committee on the Medical Uses of Isotopes (ACMUI). Option 3 is the same as Option 2 with a

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(301) 415-6233

minor modification (i.e., listing all specialty boards recognized by NRC on the website rather than, as recommended by ACMUI, listing some boards in the regulation and others on the website). The staff recommends that the Commission adopt Option 3.

BACKGROUND:

The issue in question concerns the new requirements in the final rule governing the recognition of specialty boards (boards) by NRC. These requirements are in the final rule at 10 CFR 35.50, 35.51, 35.55, 35.190, 35.290, 35.390, 35.392, 35.394, 35.490, 35.590, and 35.690. The boards represent one of two alternative pathways for certifying authorized individuals (e.g., radiation safety officers (RSOs), authorized medical physicists (AMPs), authorized nuclear pharmacists (ANPs), and authorized users (AUs)). The other alternative is through evaluation of individual training and experience (T&E process).

During development of the Part 35 proposed and final rules, there was a general belief that the boards currently recognized by NRC would meet, or could make adjustments to meet, the new requirements and that they would continue to be recognized by NRC. However, when applications for recognition were received, the staff determined that, except for one board, the boards did not meet all the requirements specified in the final rule. Specifically, the boards' certification programs failed to meet the requirements in the final rule regarding preceptor certification and work experience. The only board that currently meets the revised requirements is the Certification Board of Nuclear Cardiology, because it developed its certification program based on the final rule. On various occasions, the staff discussed with the boards as to whether the boards would modify their certifying programs to meet all the requirements specified in the rule. No board indicated that they plan to change their process.

On February 19, 2002, ACMUI briefed the Commission and expressed a concern that if the draft final rule became effective 6 months after the publication date, there could be potential shortages of authorized individuals. Without changes in the draft final rule, the ACMUI was concerned that the boards would no longer be qualified for recognition by NRC. Thus, a board's future diplomats could no longer be granted authorized individual status by NRC or an Agreement State based on their board certification. The ACMUI argued that this might result in a shortage of authorized individuals.

Furthermore, the ACMUI expressed the concern that the boards may become "marginalized." Under the final rule, the pathway to gain authorized status through the board process would include all the requirements in the T&E process, which would require a specified length of training and a written certification signed by a preceptor. Because there are extra requirements for the board certification process, such as board written/oral examinations, potential candidates seeking authorized status may bypass the board certification pathway and select the simpler T&E process.

Based on these concerns, ACMUI urged the Commission to implement temporary measures to address the T&E issue in the draft final rule and to find a permanent solution after publication of the final rule. Subsequently, the staff changed the final rule by reinserting Subpart J (as contained in the proposed rule) for a 2-year transition period.

DISCUSSION:

There are three main reasons why the boards listed in Subpart J would no longer be qualified for recognition under the final rule.

1. T&E Requirements

Under the current Part 35, boards are not required to meet specific didactic/laboratory training and experience requirements to attain NRC recognition. Before a board was listed in Subpart J, ACMUI reviewed its certification program and determined the adequacy of the program. The T&E provisions of the final rule, however, specifically mandate that an individual must be certified by a medical specialty board whose certification process requires an individual to meet all the applicable requirements listed in Part 35 for the alternative pathway of the T&E process. This resulted in situations where the requirements of the board do not match the specific criteria of the final rule. A comparison between NRC's didactic/laboratory and experience requirements in the final rule and boards' requirements is presented in Attachment 1.

2. Preceptor Certification

Under the current rule, preceptor certification is not required for board certification. The final rule requires preceptor certification including a signature by an authorized individual. This requirement applies to both board certification and the T&E process. Attachment 1 provides a comparison between NRC's preceptor certification in the final rule and boards' certification or reference requirements. Some boards require certification by a qualified individual, such as the program director. However, this qualified individual need not necessarily be an authorized individual, as required of a preceptor by the final rule.

During the board certification process, the board makes its judgment that a candidate has satisfactorily completed the board's program and that the individual will be able to carry out the duties of this certification. The questions that could be raised are: (1) whether another qualified individual (e.g., a program director, a department head, or a professor) could also sign the certification; and (2) in the case of the board certification process, whether the members of the board could collectively act as a "preceptor."

3. New Modalities

The T&E requirements in the final rule were expanded to address two new modalities that were not considered in the current rule (i.e., remote after loader units and gamma stereotactic radiosurgery units, as described in 10 CFR 35.690). These requirements were geared to address unique health and safety issues raised by these modalities. However, the boards' programs do not specifically include T&E for the new modalities. This raises a concern as to how existing qualified individuals will obtain and demonstrate competence in radiation safety in a new modality.

The problem associated with the T&E requirements for new modalities can be illustrated as follows. If a medical institution has only a teletherapy unit and its AMP is authorized for teletherapy only, and the institution plans to add a High Dose Rate Remote After loader unit

(HDR), the questions that could be raised are: (1) what are the T&E requirements for the AMP to gain authorized status for HDR; (2) does the AMP need to go to another medical institution for additional training; (3) what is the length of training; (4) how many cases should the AMP perform independently; and (5) could the AMP receive the training for HDR in a manufacturer's facility or in a university setting, instead of another medical institution.

ACMUI AND OTHER STAKEHOLDERS' INPUT:

ACMUI formed a Subcommittee to develop recommendations on the T&E issue. A public Subcommittee meeting was held on June 21, 2002, at NRC. Representatives from more than 13 boards, associations, or societies participated in the meeting. In addition, more than 8 boards or societies provided written comments to ACMUI Subcommittee on its recommendations. After considering the comments from the meeting and letters, the Subcommittee developed a final recommendation and submitted it to the full committee for consideration. The staff noted that these interactions were substantive and that ACMUI appeared to be responsive to stakeholder concerns while still maintaining a clear focus on the desired radiation safety outcomes associated with adequate board certification criteria.

The ACMUI full Committee discussed the Subcommittee's recommendation via a public teleconference meeting on July 8, 2002. Members of the public and representatives from the Society of Nuclear Medicine participated in the conference call meeting. The ACMUI's report was submitted to NRC on August 1, 2002 (Attachment 2). The Subcommittee's recommendations and the ACMUI report were posted on the NRC website. Discussions at the public meetings primarily focused on the draft regulatory language contained in the Subcommittee recommendations.

ACMUI RECOMMENDATIONS:

The ACMUI indicates that the reasons why the boards recognized in Subpart J would no longer be qualified for recognition under the final rule are that the T&E provisions of the final rule: (1) require that a board's certification process include all of the T&E requirements in the alternative pathway; (2) require that the preceptor be an authorized individual who meets the requirements of the final rule, and (3) include new modalities not considered in the current rule.

The ACMUI states that, for completeness, its recommendations are written to resemble rule language. However, the ACMUI states that it is not the intention of the Committee to specify rule language.

As detailed in the ACMUI correspondence (Attachment 2), these recommendations are based on the following assumptions:

(1) Currently accepted boards should be listed explicitly in the regulations,

(2) To facilitate addition of future certification mechanisms to the T&E qualification process without rulemaking initiatives, criteria should be included in the rule to provide a basis for recognizing new boards,

(3) It is expected that the currently accepted boards will meet the criteria in (2),

(4) The preceptor concept should be modified to become documentation for completion of a training program rather than a testament to clinical competence, and

(5) Specific training should be required for certain new devices or modalities. This training is considered to be a separate requirement that is decoupled from the core training and supervised experience.

OPTIONS:

Option 1 No change in the final rule. Continue to require a board to meet the T&E requirements specified in the final rule, including didactic/laboratory training, work experience, and preceptor certification.

Option 2 Adoption of ACMUI recommendations. Prepare a proposed rule to modify the T&E requirements based on ACMUI recommendations and using the ACMUI suggested rule language as a starting point for the proposed rule and supporting regulatory analysis.

Option 3 Same as option 2 (i.e., adoption of ACMUI recommendations) except that all current or new boards that meet the criteria for recognition by NRC will be listed on the NRC website, not in the regulations.

COMPARISON OF OPTIONS:

Option 1, which affirms the requirements of the final rule, would require the boards to modify their certification programs as necessary to comply with the specified requirements. If the boards chose not to change, they could not continue to certify authorized individuals after the transition period ends. Candidates who desired to become authorized individuals would have to be certified through the T&E process. The burden for allowing authorized individuals to work would be increased because licensees would have to submit amendments and receive NRC approval before individuals certified through the T&E process could serve as authorized individuals. However, if boards chose not to modify their programs, the concerns for a potential shortage of authorized individuals would remain.

Under Option 2, the NRC would initiate rulemaking to propose modifying the regulations to specify separate T&E criteria for recognition of boards. The regulations would continue to specify T&E requirements for individuals seeking authorized status, specify separate T&E requirements for new modalities, and modify the preceptor certification to be signed by a qualified individual. Under this option, the concerns regarding the radiation safety for new modalities and the preceptor certification would be resolved. Option 2 is expected to increase stakeholder confidence because of the avoidance of concerns over potential disruption of medical services due to a shortage of authorized individuals. A disadvantage of this option is that, if some boards are listed in the rule and others on the NRC website, a licensee would not have a single location to verify qualified boards. In addition, if a board were to be deleted from the rule listing, the staff would have to amend the listing through rulemaking.

Option 3 is the same as Option 2 with the exception that all current and new boards that meet the criteria will be listed on the NRC website, not in regulations. Placing the currently approved boards and newly approved boards on the website would eliminate an unnecessary division between the two groups of boards. Individuals would not be required to review two locations for a listing of approved boards. Additional advantages include eliminating added burden on licensees and increasing the efficiency and effectiveness of NRC resources.

Adoption of the ACMUI recommendations would eliminate the problems for recognizing the boards without compromising radiation safety. In addition, listing all boards on the NRC website rather than listing some boards in the regulation and others on the website is more effective and efficient. The staff therefore recommends Option 3.

AGREEMENT STATES INPUT:

A draft of this Options Paper was forwarded to Agreement States for comment. Four comment letters were received: one each from States of Alabama, Illinois, Iowa, and Washington (Attachment 3).

Alabama recommended that the NRC adopt Option 1, with certain caveats. Iowa and Washington stated that the NRC appears to be proposing a lesser T&E standard for board-certified authorized users as compared to non-certified authorized users. They suggested that the certifying boards should be held to the same standards as the non-certified alternative (e.g., the certifying boards should be held to the same number of hours of T&E as specified in the final rule, such as 700 hours for imaging and localization studies). Although the requirements are not identical, the T&E standard for recognizing certifying boards would not be lesser than the standard for the non-certified alternative. The board certification process requires a candidate to have an academic degree, complete practical experience or a residency program, and pass an examination. The examination tests the knowledge and skills required to perform the activities responsible by the authorized users, including activities to ensure radiation safety. The staff considers that the combination of degree, practical experience, and examination in the criteria for recognizing certifying boards would be equivalent to the number of hours of didactic and experience specified for the non-certified alternative.

Washington stated that the preceptor requirement should be modified as recommended by ACMUI. However, Illinois suggested that NRC retain the preceptor certification in the final rule (i.e., including certification of competency) for individuals seeking to achieve authorized status through the alternative (i.e., non-board certification) pathway. For board certified individuals, Illinois expects that the board certification process contains prerequisites, inherent milestones, and internal certifications that are predictive of effective performance, and that therefore board certified individuals typically will be competent in the duties required by a medical use licensee. Alabama agreed that the NRC should allow the boards to accept another individual to sign on behalf of the actual preceptor, as long as the individual is the preceptor's supervisor, such as a department head or program director, and submits a list of the preceptors as reference. The staff will solicit ACMUI's input on whether the preceptor certification should be retained in the T&E requirements for the alternative pathway in preparing a proposed rule.

In addition, Illinois suggested adding a training requirement as paragraph (d)(1)(iv) in Section 35.12, "Application for license, amendment, or renewal," for emerging technologies (35.1000). The staff believes it is not necessary to add such a training requirement. This issue was considered during the development of the final rule. As explained in the Supplementary Information to the final rule, Section 35.1000 does not include any T&E requirements because there is no way of knowing what training requirements will be necessary for the safe use of byproduct material in new technologies. Applicants are required by 35.12(b) to provide information as to the T&E for the AU, ANP, or AMP as appropriate to the NRC, which will be evaluated on a case-by-case basis. See 67 FR 203321 (April 24, 2002).

Illinois further stated that the ACMUI should assume an active role in establishing specific training and experience criteria when future technologies are identified. After the criteria are established, the NRC should promptly post these criteria on the website. This would make them quickly available to the regulated community and the Agreement States. The staff is generally supportive of the recommendation, and it is consistent with our implementation plans for the new rule.

Both Illinois and Washington stated that they support ACMUI recommendations (except as stated above) and NRC's plan to list boards on the website, not in regulations.

AGREEMENT STATE COMPATIBILITY:

For Agreement States, adopting the new T&E requirements by October 24, 2005, would result in shortening the time frame to develop compatible T&E requirements. During the Organization of Agreement States (OAS) meeting in October 2002, the Agreement States voiced their concern regarding the adoption of compatible T&E requirements by October 24, 2005. The staff indicated at the meeting that it would provide States additional time after the OAS meeting, to submit any additional concerns regarding the timeline for adoption of the new rule. However, to date the staff has not received any additional comments. Therefore, the staff intends to proceed with a proposed rule and will specifically solicit comments from all stakeholders on the issue of the timing of the adoption of compatible T&E requirements by Agreement States.

COORDINATION:

The Office of the General Counsel has no legal objection to the use of any of the options presented in this paper. The Office of the Chief Financial Officer has reviewed this Commission Paper for resource implications and has no objections.

RESOURCES:

If the Commission adopts Option 3 associated with rulemaking, an initial estimate would be 0.5 FTE for the proposed rule and 0.4 FTE for the final rule. These resources are currently identified within the NMSS budget for rulemaking activities. No contractual support is anticipated.

SCHEDULE:

If the Commission accepts the staff recommendation, the staff endorses proceeding directly to develop a proposed rule without generating an additional rulemaking plan. Immediately developing a proposed rule will allow staff to meet the Commission's directive in the SRM dated

April 16, 2002. The staff would work closely with the ACMUI and Agreement States for developing the proposed rule. In accordance with the Commission's Policy Statement on Adequacy and Compatibility of Agreement State Programs, the Agreement States have three years from the effective date of the Part 35 final rule to develop compatible requirements (i.e., no later than October 24, 2005).

It is expected that the proposed rule would be submitted to the Commission for approval approximately 6 months after Commission decision and direction through an SRM on a rulemaking, allowing time for Agreement State interaction. The final rule is expected to be submitted to the Commission for approval approximately 6 months after the closing of the public comment period for the proposed rule. This schedule will allow the revision to be effective before the end of the 2-year transaction period for Subpart J on October 24, 2004.

RECOMMENDATION:

That the Commission adopt Option 3 and direct the staff to proceed with a proposed rulemaking.

/RA/

William D. Travers
Executive Director
for Operations

Attachments:
1. Comparison Between NRC Requirements and Boards Certification Programs
2. ACMUI Recommendations
3. Agreement State Comment Letters

AGENDA TOPIC: T&E Rulemaking

ATTACHMENT 1

COMPARISON BETWEEN NRC REQUIREMENTS AND BOARDS CERTIFICATION PROGRAMS

This Attachment contains tables showing comparisons between NRC's T&E requirements, as specified in the final rule, and the boards' certification programs.

The comparisons include the following authorized individuals:

Table 1	Radiation safety officer (§ 35.50)
Table 2	Authorized medical physicist (§ 35.51)
Table 3	Authorized nuclear pharmacist (§ 35.55)
Table 4	Authorized user in uptake, dilution, and excretion studies (§ 35.190)
Table 5	Authorized user in imaging and localization (§ 35.290)
Table 6	Authorized user in unsealed byproduct material requiring written directive (§ 35.390)
Table 7	Authorized user in manual brachytherapy sources (§ 35.490)
Table 8	Authorized user in remote after loader units, teletherapy units, and gamma stereotactic radiosurgery units (§ 35.690)

AGENDA TOPIC: T&E Rulemaking

Table 1 - Certification Requirements for Radiation Safety Officer (RSO) (35.50)

Final rule	Certification Through T&E Process			Certification Through Board Process
	(A) Didactic training	(B) Experience	(C) Certification	
	35.50(b)(1)(i) 200 hours in: 1. Rad phy/instrument 2. Rad protection 3. Math for use/meas of radioactivity 4. Rad biology 5. Rad dosimetry	35.50(b)(1)(ii) One year supervised radiation safety experience in similar uses in: 1. Shipping/receiving & rad surveys 2. Performing checks on instruments 3.Securing/controlling byproduct material 4. Using controls to avoid mistakes in administration of byproduct material 5. Using procedures to prevent contamina & proper decontam 6. Using emergency procedures to control byproduct material 7.Disposing byproduct material	35.50(b)(2) Signed by a preceptor RSO that the individual satisfies (A) + (B) + can function independently	35.50 (a) (A) + (B) + (C) + Additional Board Requirements (e.g. examination)

Example of Boards Listed in Subpart J	Training/Education	Experience	Certification/ References	Additional Board Requirements
Am B of Health Physics In Comprehensive Health Physics	BS deg in physical science, engineering, or biological science with minor in physical science or eng.	6 yrs prof exp - at least 3 yrs in applied heath physics (MS, subst 1 yr exp; PhD subst 2 yrs)	**Certification:** Board Chairperson certifies met prof standards of the board **References:** The individual's supervisor; 2 other professionally qualified to evaluate candidates ability in HP(at least 1 certified)	Written Exam: Part I- fundamental HP; Part II- applied HP; covering 5 domains: measurements, regulation/standards, facilities/equipment, operation/procedure, education/training

Table 2 - Certification Requirements for Authorized Medical Physicist (AMP) (35.51)

Final rule	Certification Through T&E Process		Certification Through Board Process
	(A) Training & Experience	(B) Certification	
	35.51(b)(1) 1. Master/doctoral deg in physics, biophysics, radiological physics, or medical physics 2. One year training in therapeutic radiological physics 3. Additional year work experience under an AMP at medical institution, including the following specific tasks, as applicable: a. 35.67 Reqs for sealed sources & brachytherapy sources b. 35.433 Decay of Sr-90 sources c. 35.632 Full calibration measurements on teletherapy units d. 35.633 Full calibration meas on remote after loader units e. 35.635 Full calibration meas on gamma radiosurgery units f. 35.642 Periodic spot-check for teletherapy units g. 35.643 Periodic spot-check for remote after loader units h. 35.645 Periodic spot-check for gamma radiosurgery units i. 35.652 Radiation surveys	35.51(b)(2) Signed by a preceptor AMP who meets 35.51 that the individual satisfies (A) + can function independently for each type of therapeutic medical unit	35.51(a) (A) + (B) + Additional Board Requirements (e.g. examination)

Examples of Boards Listed in Subpart J:	Training/ Education	Experience	Certification/ References	Additional Board Requirements
A. Am B of Radiology in: 1.Therapeutic radiology physics 2. Roentgen ray and gamma ray physics 3. X-ray and Radium physics 4. Radiology physics	1.Bachelor deg in phy, eng, etc. and 2.Master/doc deg in med phy, phy, eng, etc. and 3.Formal course work in biological sciences	3 yrs exp with clinical department (MS subst 6 month, PhD subst 12 month) under supervision of cert physicist or radiologic physician	One certif physician & one certif physicist in the same specialty Physicist must directed the special training References must have personal knowledge of the applicant	**1. Written exam:** Part 1 includes measurements, radiation protection, clinical aspects of radiological physics Part 2 includes 3 subparts: Therapeutic phy; diagnostic phy, and medical nuclear phy (radioactive sources, calibration, rad protection). **2. Oral exam:** 5 parts, including radiation safety & patient safety, patient related measurement, equipment, etc.
B. Am B of Medical Physics in radiation oncology physics	Graduate deg in physics, med phy, or other related field	1. Clinical residency training from an accredited program or 2. MS-6 yrs, MS (med phy)-4 y MS(med phy, accredited)-3 y PhD-4 y PhD (med phy)-3 y PhD (m.p. accr)-2 y	2 Ltrs of endorsement to verify work experience and professional qualifications-must be from a certified medical physicist and a certified physician who practice in the medical specialty and who has personal Knowledge	**1. Written exam:** Part I: Fundamental medical physics, including radiation protection, radiation measurements Part II: For specialty areas in: medical health physics, radiation oncology phy, etc. **2. Oral exam:** include rad safety/hazards

Table 3 - Certification Requirements for Authorized Nuclear Pharmacist (ANP) (35.55)

Final rule	Certification Through T&E Process			Certification Through Board Process
	(A) 700 hrs structured educational program		(B) Certification	
	35.55(b)(1)(i) Didactic training in: 1. Rad phy/instrument 2. Rad protection 3. Math for use/meas of radioactivity 4. Chemistry of byproduct material for med use 5. Rad biology	35.55(b)(1)(ii) Supervised practical experience in a nuclear pharmacy in: 1. Shipping/receiving & rad surveys 2. Performing checks on instruments 3. Calc, assay, & safely preparing dosages 4. Using controls to avoid mistakes in administration of byproduct material 5. Using procedures to prevent contamina & proper decontam	35.55(b)(2) Signed by a preceptor ANP that the individual satisf (A) + can function independently	35.55 (a) (A) + (B) + Additional Board Requirements (e.g. examination)

Example of Boards Listed in Subpart J	Training/ Education	Experience	Certification/ References	Additional Board Requirements
Board of Pharmaceutical Specialties as a nuclear pharmacist	1. Graduation from a pharmacy program accredited by Am Council on pharmaceutical Education 2. Must have current license to practice pharmacy	4000 hours experience (MS or PhD in nuclear pharmacy subst 2000hrs.)	None	Written exam in 9 domains, including health and safety domain

Table 4 - Certification Requirements for Authorized User in Uptake, Dilution, and Excretion Studies (35.190)

Final rule	Certification Through T&E Process			Certification Through Board Process
	(A) 60 hrs of Training and Experience		(B) Certification	
	35.190(c)(1)(i) Classroom and laboratory training in: 1. Radiation phy/instrument 2. Rad protection 3. Math for use/meas of radioactivity 4. Chemistry of byproduct material for med use 5. Rad biology	35.190(c)(1)(ii) Work experience under AU (who meets 35.190, 290, or 390) in: 1. Ordering/receiving, unpacking, rad surveys 2. Calibrate dose instrument & performing checks on survey meter 3. Calc, measuring, & safely preparing dosages 4. Using controls to prevent medical events involving unsealed byproduct material 5. Using procedures to contain spills & proper decontam 6. Administering dosages	35.190(c)(2) Signed by a preceptor AU (who meets 35.190, 290, or 390) that the candidate satisfies (A) + can function independently	35.190(a) (A) + (B) + Additional Board Requirements (e.g. examination)

Example of Boards Listed in Subpart J	Training/ Education	Experience	Certification	Additional Board Requirements
Am B of Nuclear Medicine in nuclear medicine	1.Graduation from a medical school approved by the Liaison Committee on Medical Education 2. Valid license to practice of medicine	1. One or more yrs of preparatory post-doc training and 2. Two-yr formal residency training	Requires residency program directors to certify the applicant is competent in clinical nuclear medicine.	Written exam

Table 5 - Certification Requirements
Authorized User in Imaging and Localization Studies (35.290)

Final rule	Certification Through T&E Process			Certification Through Board Process
	(A) 700 hrs of Training and Experience		(B) Certification	
	35.290(c)(1)(i) Classroom and laboratory training in: 1. Radiation phy/instrument 2. Rad protection 3. Math for use/meas of radioactivity 4. Chemistry of byproduct material for med use 5. Rad biology	35.290(c)(1)(ii) Supervised work under AU (who meets 35.290 or 35.390) in: 1. Ordering/receiving, unpacking, rad surveys 2. Calibrating dose instrument & performing checks on survey meter 3. Calc, measuring, & safely preparing dosages 4. Using controls to prevent medical events involving unsealed byproduct material 5. Using procedures to contain spills & proper decontam 6. Administering dosages 7. Eluting generator systems & preparing radioactive drugs	35.290(c)(2) Signed by a preceptor AU who meets 35.290 or 35.390 that the candidate satisfies (A) + can function independently	35.290(a) (A) + (B) + Additional Board Requirements (e.g. examination)

Example of Boards Listed in Subpart J	Training/ Education	Experience	Certification	Additional Board Requirements
Am B of Nuclear Medicine in nuclear medicine	1.Graduation from a medical school approved by the Liaison Committee on Medical Education 2. Valid license to practice of medicine	1. One or more yrs of preparatory post-doc training and 2. Two-yr formal residency training	Requires residency program directors to certify the applicant is competent in clinical nuclear medicine.	Written exam

Table 6 - Certification Requirements
Authorized User in Unsealed Byproduct Material Req Written Directive (35.390)

Final rule	Certification Through T&E Process			Certification Through Board Process
	(A) 700 hrs of Training and Experience		(B) Certification	
	35.390(b)(1)(i) Classroom and laboratory training in: 1. Radiation phy/instrument 2. Rad protection 3. Math for use/meas of radioactivity 4. Chemistry of byproduct material for med use 5. Rad biology	35.390(b)(1)(ii) Supervised work under AU (who meets 35.290 or 35.390) in: 1. Ordering/receiving, unpacking, rad surveys 2. Calibrating dose instrument & performing checks on survey meter 3. Calc, measuring, & safely preparing dosages 4. Using controls to prevent medical events involving unsealed byproduct material 5. Using procedures to contain spills & proper decontam 6. Eluting generator systems & preparing radioactive drugs 7. Administering dosages (at least 3 cases in each of 4 categories)	35.390(b)(2) Signed by a preceptor AU who meets 35.390(a) or (b) and who has experience in same dose categories that the individual satisfies (A) + can function independently	35.390(a) (A) + (B) + Additional Board Requirements (e.g. examination)

Example of Boards Listed in Subpart J	Training/ Education	Experience	Certification	Additional Board Requirements
Am B of Nuclear Medicine	1.Graduation from a medical school approved by the Liaison Committee on Medical Education 2. Valid license to practice of medicine	1. One or more yrs of preparatory post-doc training and 2. Two-yr formal residency training	Requires residency program directors to certify the applicant is competent in clinical nuclear medicine.	Written exam

Table 7 - Certification Requirements for Authorized User in Manual Brachytherapy Sources (35.490)

Final rule	Certification Through T&E Process				Certification Through Board Process
	(A) Didactic	(B) Work Experience	(C) Clinical Experience	(D) Certification	
	35.490(b)(1)(i) 200 hours Classroom and laboratory training in: 1. Radiation phy/instrument 2. Rad protection 3. Math for use/meas of radioactivity 4. Rad biology	35.490(b)(1)(ii) 500 hours work experience under AU (who meets 35.490) in: 1. Ordering/receiving, unpacking, rad surveys 2. Checking survey meters 3. Preparing, implanting, removing sources 4. Maintaining running inventories 5. Using controls to prevent medical events involving byproduct material 6 Using emergency procedures to control byproduct material	35.490(b)(2) 3 years supervised clinical experience under AU (who meets 35.490)	35.490(b)(3) Signed by a preceptor AU (who meets 35.490) that the individual satisfies (A) + (B) + (C) + can function independently	35.490(a) (A) + (B) + (C)+ (D) + Additional Board Requirements (e.g. examination)

Example of Boards Listed in Subpart J	Training/ Education	Experience	Certification	Additional Board Requirements
Am B of Radiology	1. Graduation from a medical school 2. Is a specialist in Radiation Oncology 3. Have high moral & ethical standards in his/her profession	five yrs - 4 yr must be in Radiation Oncology	A written statement from current program director of special training attesting that the applicant will have satisfactorily completed the required special training & will have achieved adequate professional qualifications for the exam in radiation oncology	1. Written exam 2. Oral exam

Table 8 - Certification Requirements for Authorized User in Remote Aterloader Units, etc. (35.690)

Final rule	Certification Through T&E Process				Certification Through Board Process
	(A) Didactic	(B) Work Experience	(C) Clinical Experience	(D) Certification	
	35.690(b)(1)(i) 200 hours Classroom and laboratory training in: 1. Radiation phy/instrument 2. Rad protection 3. Math for use/meas of radioactivity 4. Rad biology	35.690(b)(1)(ii) 500 hours work experience under AU (who meets 35.690) in: 1. Reviewing full calibration & spot check 2. Preparing treatment plans & calc treatment dose/time 3. Using adm controls to prevent med events 4. Implementing emergency procedures for abnormal operation 5. Checking/using survey instruments 6 Selecting proper dose & how it is to be administered	35.690(b)(2) 3 years supervised clinical experience under AU (who meets 35.690)	35.690(b)(3) Signed by a preceptor AU (who meets 35.690 for each type relevant therapeutic unit) that the individual satisfies (A) + (B) + (C) + can function independently	35.490(a) (A) + (B) + (C)+ (D) + Additional Board Requirements (e.g. examination)

Example of Boards Listed in Subpart J	Training/ Education	Experience	Certification	Additional Board Requirements
Am B of Radiology	1. Graduation from a medical school 2. Is a specialist in Radiation Oncology 3. Have high moral & ethical standards in his/her profession	five yrs - 4 yr must be in Radiation Oncology	A written statement from current program director of special training attesting that the applicant will have satisfactorily completed the required special training & will have achieved adequate professional qualifications for the exam in radiation oncology.	1. Written exam 2. Oral exam

AGENDA TOPIC: T&E Rulemaking

ATTACHMENT 2

ACMUI RECOMMENDATIONS

August 1, 2002

RECOMMENDATIONS OF THE NRC ACMUI SUBCOMMITTEE ON TRAINING AND EXPERIENCE REQUIREMENTS

INTRODUCTION

A revision of 10 CFR Part 35, Medical Use of Byproduct Material, was published on April 24, 2002 (Federal Register Vol. 67(79) 20371-20397). The revision contains new training and experience requirements for individuals to become authorized as a radiation safety officer (RSO), authorized medical physicist (AMP), authorized nuclear pharmacist (ANP), and authorized user (AU). These new requirements provide several options for individuals to become authorized. One option is for individuals to be certified by a specialty board whose certification process includes all the requirements in an alternate pathway. The alternate pathway includes specified numbers of hours of training and written certification signed by a preceptor that the individual has satisfactorily completed the training requirements and has achieved a level of competency sufficient to function independently as an RSO, AMP, ANP, or AU. Currently, most specialty boards do not require candidates to meet these specific requirements.

The Advisory Committee on Medical Uses of Isotopes (ACMUI) appointed a subcommittee on training and experience requirements to develop recommendations that would restore board certification as the default pathway for individuals to become authorized as RSO, AMP, or AU. The subcommittee held a meeting on June 21 in Rockville, Maryland and a meeting on July 8 by conference call to discuss draft recommendations and to receive public input. The following recommendations include consideration of discussion from these meetings.

For completeness these recommendations are written to resemble rule language. However, it is not the intention of the subcommittee to specify rule language.

RATIONALE

These recommendations are based on the following assumptions:

(1) Currently accepted boards should be listed explicitly in the regulations;
(2) To facilitate addition of future certification mechanisms to the T&E qualification process without rulemaking initiatives, criteria should be included in the rule to provide a basis for recognizing new boards;
(3) It is expected that the currently accepted boards will meet the criteria in (2);
(4) The preceptor concept should be modified to become documentation for completion of a training program rather than a testament to clinical competence; and;
(5) Specific training should be required for certain new devices or modalities. This training is considered to be a separate requirement that is decoupled from the core training and supervised experience.

The intent of these recommendations is to provide minimum training and experience requirements for an individual to become an AMP, ANP, AU, or RSO. The objective of these requirements is to assure the safe use of byproduct material used in medical practice.

Several pathways are provided to demonstrate adequate knowledge of the safe use of byproduct material. For AMP, ANP, RSO, and most categories of use for AU, adequate knowledge may be demonstrated by obtaining certification by a specialty board. The subcommittee's examination of various specialty board criteria for admission of candidates revealed that few specialty boards meet the specific requirements of revised Part 35 published April 24, 2002. However, the subcommittee concluded that individuals who had completed the certification process by appropriate specialty boards had demonstrated adequate knowledge in the safe use of byproduct material for their specialty. Thus the subcommittee recommends that these boards be specifically listed as approved boards.

Additional specialty boards may be identified in the future. Therefore, the subcommittee developed specific criteria for recognition of specialty boards. To the best of our knowledge, those specialty boards that are listed in these recommendations meet these specific criteria.

As an alternative to board certification, an individual may demonstrate completion of specified training and experience requirements as provided in revised Part 35.

In addition to meeting the minimum training and experience requirements, authorized individuals would be expected to demonstrate training or experience in the use of byproduct material or specific modalities, as appropriate, which are identified on the licensee's license. This would require a licensee to assure that newly hired authorized individuals have appropriate training and experience and that current authorized individuals receive appropriate training when a new modality is added to the licensee's program.

§ 35.50 Training for Radiation Safety Officer

Except as provided in § 35.57, the licensee shall require the an individual fulfilling the responsibilities of the Radiation Safety Officer as provided in § 35.24 to be an individual who –

(a) Is certified by:
  (1) American Board of Health Physics in Comprehensive Health Physics;
  (2) American Board of Medical Physics in Medical Health Physics; or
  (3) American Board of Science in Nuclear Medicine in Radiation Protection; or

(b) Is certified by a specialty board whose certification has been recognized by the Commission and requires all diplomats:
  (1) To hold a bachelors 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;
  (2) To have five or more years of professional experience in health physics (graduate training may be substituted for no more than two years of the required experience) including at least three years in applied health physics;
  (3) To provide a written statement from the supervising physicist or Radiation Safety Officer attesting that the individual has completed the training and experience described in paragraph (b)(2) of this section; and
  (4) To pass an examination administered by diplomats of the specialty board, which evaluate knowledge and competence in radiation physics and

instrumentation, radiation protection, mathematics pertaining to the use and measurement of radioactivity, and radiation biology; or

(c) (1) Has completed a structured educational program consisting of 200 hours of didactic training in the following areas--
  (i) Radiation physics and instrumentation;
  (ii) Radiation protection;
  (iii) Mathematics pertaining to the use and measurement of radioactivity;
  (iv) Radiation biology; and

(2) Has one year of full-time radiation safety experience under the supervision of an individual identified as the Radiation Safety Officer on a Commission or Agreement State license that authorizes similar types(s) of use(s) of byproduct material involving the following--
  (i) Shipping, receiving, and performing related radiation surveys;
  (ii) Using and performing checks for proper operation of instruments used to determine the activity of dosages, survey meters, and instruments used to measure radionuclides;
  (iii) Securing and controlling byproduct material;
  (iv) Using administrative controls to avoid mistakes in the administration of byproduct materials;
  (v) Using procedures to prevent or minimize radioactive contamination and using proper decontamination procedures;
  (vi) Using emergency procedures to control byproduct material; and
  (vii) Disposing of byproduct material; and

(3) Has provided a written statement from the supervising physicist(s) or Radiation Safety Officer(s) attesting that the individual has completed the training and experience described in paragraph (c)(1) and (c)(2) of this section; or

(d) Is an authorized user, authorized medical physicist, or authorized nuclear pharmacist identified on the licensee's license and has experience with the radiation safety aspects of similar types of use of byproduct material for which the individual has Radiation Safety Officer responsibilities.

(e) In addition to meeting the requirements of (a), (b), (c), or (d) of this section, the licensee shall require a Radiation Safety Officer to have training in the radiation safety, regulatory issues, emergency procedures, and proposed clinical procedures of any modality for which the licensee seeks authorization. This training requirement may be satisfied by completing training that is supervised by an Authorized Medical Physicist, Authorized User, or Radiation Safety Officer as appropriate, who is authorized for the modality for which the licensee is seeking authorization.

§ 35.51 Training for an Authorized Medical Physicist.

Except as provided in § 35.57, the licensee shall require the authorized medical physicist to be an individual who –

(a) Is certified by the one of the following specialty boards in radiation oncology physics ("radiation oncology physics" understood to be that branch of medical or radiological physics that is applied to clinical practice of radiation oncology)
  (1) American Board of Radiology in therapeutic radiological physics;
  (2) American Board of Radiology in roentgen ray and gamma ray physics;

(3) American Board of Radiology in x-ray and radium physics;
(4) American Board of Radiology in radiological physics; or
(5) American Board of Medical Physics in radiation oncology physics; or

(b) Is certified by a specialty board in radiation oncology physics whose certification has been recognized by the Commission and requires all diplomats;
(1) To hold a master's or doctor's degree in physics, medical physics, other physical science, engineering, or applied mathematics from an institution accredited by a regional accrediting body;
(2) To have two years of full-time practical training and/or supervised experience in radiation oncology physics
(i) Under the supervision of a medical physicist who is certified in radiation oncology physics by the board in question, a board specified in paragraph (a) of this section; or a specialty board recognized by the Commission according to this paragraph (b) of this section
(ii) In a clinical radiation oncology facility providing megavoltage external beam therapy and brachytherapy services under the direction of physicians who meet the requirements for authorized users in 35.400 or 35.600;
(3) To obtain a written statement from a medical physicist, certified by a specialty board listed in paragraph (a) of this section or recognized by the Commission according to paragraph (b) of this section and who has personal knowledge of the candidate's training and experience, attesting that the individual has satisfactorily completed the training and experience described in paragraph (b)(2) of this section; and
(4) To pass an examination administered by diplomats of the specialty board, which assesses knowledge and competence in clinical radiation oncology, radiation safety, calibration, quality assurance, and treatment planning for external beam therapy, brachytherapy and stereotactic radiosurgery; or

(c) (1) Holds a master's or doctor's degree in physics, medical physics, other physical science, engineering, or applied mathematics from an institution accredited by a regional accrediting body;
(2) Has completed 1 year of full-time training in radiation oncology physics and an additional year of full-time work experience under the supervision of an individual who meets the requirements for an authorized medical physicist for the modality in which the individual is seeking authorization in a clinical radiation oncology facility that provides megavoltage external beam therapy and brachytherapy services that include
(i) performing sealed source leak tests and inventories;
(ii) performing decay corrections;
(iii) performing full calibration and periodic spot checks of external beam treatment units, stereotactic radiosurgery units, and remote afterloading units as applicable; and
(iv) conducting radiation surveys around external beam, remote afterloading and stereotactic radiosurgery units as applicable; and
(3) Has obtained a written statement from the supervising medical physicist attesting that the individual has satisfactorily completed the training and experience described in paragraph (c)(2) of this section and identifies the byproduct material modalities included.

(d) In addition to meeting the requirements of (a), (b), or (c) of this section, an authorized medical physicist must have training in the modality for which authorization is sought that includes "hands on" device operation, safety procedures, clinical use, and operation of treatment planning system. This training requirement may be satisfied by satisfactorily completing a training program provided by the vendor or by training supervised by an AMP authorized for the modality in which the individual is seeking authorization.

§ 35.55 Training for an authorized nuclear pharmacist.

Except as provided in § 35.57, the licensee shall require the authorized nuclear pharmacist to be a pharmacist who –

(a) Is certified as a nuclear pharmacist by Board of Pharmaceutical Specialties in Nuclear Pharmacy; or

(b) Is certified as a Nuclear Pharmacist by a Nuclear Pharmacy specialty board whose certification process has been recognized by the Commission and requires that all diplomats:

(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;

(2) Hold a current, active license to practice pharmacy;

(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.

(4) Pass an examination in nuclear pharmacy administered by diplomats of the specialty board, which assesses knowledge and competency in procurement, compounding, quality assurance, dispensing, distribution, health and safety, provision of information and consultation, monitoring patient outcomes, research and development; or

(c) (1) Has completed 700 hours in a structured educational program applicable to consisting of

(i) Didactic 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; and

(ii) Supervised practical experience in a nuclear pharmacy involving –

(A) Shipping, receiving, and performing related radiation surveys;

(B) Using and performing checks for proper operation of instruments used to determine the activity of dosages, survey meters, and, if appropriate, instruments used to measure alpha or beta-emitting radionuclides;

(C) Calculating, assaying, and safely preparing dosages for patients or human research subjects;

(D) Using administrative controls to avoid medical events in the administration of byproduct material; and

(E) Using procedures to prevent or minimize radioactive contamination and using proper decontamination procedures; and

(2) Has obtained a written statement signed by a preceptor authorized nuclear pharmacist (ANP) attesting that the individual has completed the required training listed in (c)(1)(ii) of this section.

Sec. 35.190 Training for uptake, dilution, and excretion studies.

Except as provided in Sec. 35.57, the licensee shall require an authorized user of unsealed byproduct material for the uses authorized under Sec. 35.100 to be a physician who–

(a) Is certified in–

(1) Nuclear medicine by the American Board of Nuclear Medicine;

(2) Diagnostic radiology by the American Board of Radiology;

(3) Diagnostic radiology by the American Osteopathic Board of Radiology;

(4) Nuclear medicine by the Royal College of Physicians and Surgeons of Canada;

(5) Nuclear medicine by the American Osteopathic Board of Nuclear Medicine; or

(b) Is certified by a medical specialty board whose certification has been recognized by the Commission and:

(1) Includes all of the requirements in paragraph (d) of this section; and

(2) Requires diplomats to pass an examination administered by diplomats of the specialty board, which assesses knowledge and competence in radiation safety, radionuclide handling, and quality control; or

(c) Is an authorized user under Secs. 35.290 or 35.390 or equivalent Agreement State requirements; or

(d) (1) Has completed 60 hours of training and experience in basic radionuclide handling techniques applicable to the medical use of unsealed byproduct material for uptake, dilution, and excretion studies. The training and experience must include–

(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; and

(ii) Work experience, under the supervision of an authorized user who meets the requirements in Sec. 35.190, Sec. 35.290, or Sec. 35.390 or equivalent Agreement State requirements, involving–

(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; and

(F) Administering dosages of radioactive drugs to patients or human research subjects; and

(2) Has obtained a written statement, signed by a preceptor authorized user who meets the requirements in Secs. 35.190, 35.290, or 35.390 or equivalent Agreement State requirements, or, if the training was received in conjunction with a residency or fellowship program, a written statement signed by the training program director, attesting that the individual has satisfactorily completed the requirements in paragraph (d)(1) of this section.

Sec. 35.290 Training for imaging and localization studies.

Except as provided in Sec. 35.57, the licensee shall require an authorized user of unsealed byproduct material for the uses authorized under Sec. 35.200 to be a physician who–

(a) Is certified in–

(1) Nuclear medicine by the American Board of Nuclear Medicine;

(2) Diagnostic radiology by the American Board of Radiology;

(3) Diagnostic radiology by the American Osteopathic Board of Radiology;

(4) Nuclear medicine by the Royal College of Physicians and Surgeons of Canada;

(5) Nuclear medicine by the American Osteopathic Board of Nuclear Medicine;

(6) Nuclear cardiology by the Certification Board of Nuclear Cardiology; or

(b) Is certified by a medical specialty board whose certification process has been recognized by the Commission and:

(1) Includes all of the requirements in paragraph (d) of this section; and

(2) Requires diplomats to pass an examination administered by diplomats of the specialty board, which assesses knowledge and competence in radiation safety, radionuclide handling, and quality control; or

(c) Is an authorized user under Sec. 35.390 or equivalent Agreement State requirements; or

(d) (1) Has completed 700 hours of training and experience in basic radionuclide handling techniques applicable to the medical use of unsealed byproduct material for imaging and localization studies. The training and experience must include, at a minimum,–

(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;

(E) Radiation biology; and

(ii) Work experience, under the supervision of an authorized user, who meets the requirements in Secs. 35.290 or 35.390 or equivalent Agreement State requirements, involving–

(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; and

(2) Has obtained a written statement, signed by a preceptor authorized user who meets the requirements in Secs. 35.290 or 35.390 or equivalent Agreement State requirements, or, if the training was received in conjunction with a residency or fellowship program, a written statement signed by the training program director, attesting that the individual has satisfactorily completed the requirements in paragraph (d)(1) of this section.

Sec. 35.390 Training for use of unsealed byproduct material for which a written directive is required.

Except as provided in Sec. 35.57, the licensee shall require an authorized user of unsealed byproduct material for the uses authorized under Sec. 35.300 to be a physician who

(a) is certified by
(1) The American Board of Nuclear Medicine;
(2) The American Board of Radiology in radiation oncology;
(3) The Royal College of Physicians and Surgeons of Canada in nuclear medicine or radiation oncology;
(4) The British Royal College of Radiology in radiation oncology; or
(5) The American Osteopathic Board of Radiology in radiation oncology; or

(b) Is certified by a medical specialty board whose certification has been recognized by the Commission and requires all diplomats
(1) To successfully complete a minimum of three years of residency training in a radiation oncology or nuclear medicine training program or a program in a related medical specialty that includes 700 hours of training and experience as described in paragraphs (c)(1) of this section. Eligible training programs must be approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education or Royal College of Physicians and Surgeons of Canada or the Committee on Post-Graduate Training of the American Osteopathic Association;
(2) To provide a written statement from the residency program director attesting to successful completion of the training requirement in paragraph (b)(1) of this section and;
(3) To pass an examination administered by diplomats of the specialty board, which tests knowledge and competence in radiation safety, radionuclide handling, quality assurance, and clinical use of unsealed byproduct material; or

(c) (1) Has completed 700 hours of training and experience in basic radionuclide handling techniques applicable to the medical use of unsealed byproduct material requiring a written directive. This training and experience must include--

(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; and

(ii) Work experience, under the supervision of an authorized user who meets the requirements in Sec. 35.390(a), Sec. 35.390(b), or equivalent Agreement State requirements. A supervising authorized user, who meets the requirements in Sec. 35.390(b), must have experience in administering dosages in the same dosage category or categories (i.e., Sec. 35.390(b)(1)(G)(1), (2), (3), or (4)) as the individual requesting authorized user status. This work experience must involve--

(A) Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;

(B) Performing quality control procedures on instruments used to determined 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;

(F) Eluting generator systems, measuring and testing the eluate for radionuclidic purity, and processing the eluate with reagent kits to prepare labeled radioactive drugs; and

(2) Has obtained written statement attesting that the individual has satisfactorily completed the requirements in paragraph (b)(1) of this section. The written statement must be signed by a preceptor authorized user who meets the requirements in Sec. 35.390(a), Sec. 35.390(b), or equivalent Agreement State requirements, or, if the training was received in conjunction with a residency or fellowship program, the written statement must be signed by the training program director. The preceptor authorized user, who meets the requirements in Sec. 35.390(b), must have experience in administering dosages in the same dosage category or categories (i.e., Sec. 35.390(d)(1), (2), (3), or (4)) as the individual requesting authorized user status.

(d) In addition to meeting the requirements of (a), (b), or (c) of this section, an authorized user of byproduct material authorized under 35.300 must have experience, under the supervision of an authorized user, administering dosages of radioactive drugs to patients or human research subjects involving a minimum of three cases in each of the following categories for which the individual is requesting authorized user status—

(1) Oral administration of less than or equal to 1.22 Gigabecquerels (33 millicuries) or sodium iodide I-131;
(2) Oral administration of greater than 1.22 Gigabecquerels (33 millicuries) or sodium iodide I-131. Experience with at least three cases in Category (d)(2) also satisfies the requirement in Category (d)(1);
(3) Parenteral administration of therapeutic quantities of any beta emitter or a photon-emitting radionuclide with a photon energy less than 150 keV;
(4) Parenteral administration of any other radionuclide in therapeutic quantities.

Sec. 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).

(c) (3) Has obtained written statement attesting that the individual has satisfactorily completed the requirements in paragraphs (c)(1) and (c)(2) of this section. **[competency statement removed].** The written certification must be signed by **[....remainder of paragraph unchanged]**

Sec. 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).

(c) (3) Has obtained written statement attesting that the individual has satisfactorily completed the requirements in paragraphs (c)(1) and (c)(2) of this section. **[competency statement removed].** The written certification must be signed by **[....remainder of paragraph unchanged]**

Sec. 35.490 Training for use of manual brachytherapy sources.

Except as provided in Sec. 35.57, the licensee shall require an authorized user of a manual brachytherapy for the uses authorized under Sec. 35.400 to be a physician who—

(a) Is certified by
  (1) The American Board of Radiology in radiation oncology;
  (2) The Royal College of Physicians and Surgeons of Canada in radiation oncology;
  (3) The British Royal College of Radiology in radiation oncology; or
  (4) The American Osteopathic Board of Radiology in radiation oncology; or
(b) Is certified by a medical specialty board whose certification has been recognized by the Commission and requires all diplomats
  (1) To successfully complete a minimum of three years of residency training in a radiation oncology program approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education or Royal College of Physicians and Surgeons of Canada or the Committee on Post-Graduate Training of the American Osteopathic Association;
  (2) To obtain a written statement from the residency program director attesting to successful completion of the training requirement in paragraph (b)(1) of this section and;
  (3) To pass an examination administered by diplomats of the specialty board, which tests knowledge and competence in radiation safety, radionuclide handling, treatment planning, quality assurance, and clinical use of high and low dose-rate brachytherapy; or

(c) (1) Has completed a structured educational program in basic radionuclide techniques applicable to the use of manual brachytherapy sources that includes--

(i) 200 hours of 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; and

(D) Radiation biology; and

(ii) 500 hours of work experience, under the supervision of an authorized user who meets the requirements in Sec. 35.490 or equivalent Agreement State requirements at a medical institution, involving--

(A) Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys:

(B) Checking survey meters for proper operation;

(C) Preparing, implanting, and removing brachytherapy sources;

(D) Maintaining inventories of material on hand;

(E) Using administrative controls to prevent a medical event involving the use of byproduct material;

(F) Using emergency procedures to control byproduct material; and

(2) Has completed 3 years of supervised clinical experience in radiation oncology, under an authorized user who meets the requirements in Sec. 35.490 or equivalent Agreement State requirements, as part of a formal training program approved by the Residency Review Committee for Radiation Oncology of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Committee on Postdoctoral Training of the American Osteopathic Association. This experience may be obtained concurrently with the supervised work experience required by paragraph (c)(1) of this section; and

(3) Has obtained a written statement attesting that the individual has satisfactorily completed the requirements in paragraphs (c)(1) and (c)(2) of this section. The written certification must be signed by the supervising authorized user or if the training was obtained in a residency training program, by the program director.

Sec. 35.491 Training for ophthalmic use of strontium-90.

(b) (3) Has obtained a written statement signed by a preceptor authorized user who meets the requirements in Sec. 35.490, Sec. 35.491, or equivalent Agreement State requirements, attesting that the individual has satisfactorily completed the requirements in paragraphs (a) and (b) of this section. **[competency statement removed].**

Sec. 35.590 Training for use of sealed sources for diagnosis.

Except as provided in Sec. 35.57, the licensee shall require the authorized user of a diagnostic sealed source for use in a device authorized under Sec. 35.500 to be a physician, dentist, or podiatrist who–

(a) Is certified in–
  (1) Diagnostic radiology, or radiation oncology by the American Board of Radiology;
  (2) Nuclear medicine by the American Board of Nuclear Medicine;
  (3) Diagnostic radiology by the American Osteopathic Board of Radiology; or
  (4) Nuclear medicine by the Royal College of Physicians and Surgeons of Canada; or

(b) Is certified by a specialty board whose certification has been recognized by the Commission and includes all of the requirements in paragraph (c) of this section; or

(c) Has completed 8 hours of classroom and laboratory training in basic radionuclide handling techniques specifically applicable to the use of the device. The training must include–
  (1) Radiation physics and instrumentation;
  (2) Radiation protection;
  (3) Mathematics pertaining to the use and measurement of radioactivity; and
  (4) Radiation biology.

(d) In addition to meeting the requirements of paragraph (a), (b), or (c) of this section, an authorized user under this section must have training in the use of the device for the uses requested.

Sec. 35.690 Training for use of remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units.

Except as provided in Sec. 35.57, the licensee shall require an authorized user of a sealed source for a use authorized under Sec. 35.600 to be a physician who—

(a) Is certified by
  (1) The American Board of Radiology in radiation oncology;
  (2) The Royal College of Physicians and Surgeons of Canada in radiation oncology;
  (3) The British Royal College of Radiology in radiation oncology; or
  (4) The American Osteopathic Board of Radiology in radiation oncology; or

(b) Is certified by a specialty board whose certification has been recognized by the Commission and requires all diplomats
  (1) To successfully complete a minimum of three years of residency training in a radiation oncology program approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education or Royal College of Physicians and Surgeons of Canada or the Committee on Post-Graduate Training of the American Osteopathic Association;
  (2) To obtain a written statement from the residency program director attesting to successful completion of the training requirement in paragraph (b)(1) of this section and;
  (3) To pass an examination administered by diplomats of the specialty board, which tests knowledge and competence in radiation safety, radionuclide handling, treatment planning, quality assurance, and clinical use of stereotactic radiosurgery, high and low dose-rate brachytherapy, and external beam therapy; or

(c) (1) Has completed a structured educational program in basic radionuclide techniques applicable to the use of a sealed source in a therapeutic medical unit that includes--

(i) 200 hours of 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; and

(D) Radiation biology; and

(ii) 500 hours of work experience, under the supervision of an authorized user who meets the requirements in Sec. 35.690 or equivalent Agreement State requirements at a medical institution, involving--

(A) Reviewing full calibration measurements and periodic spot-checks;

(B) Preparing treatment plans and calculating treatment doses and times;

(C) Using administrative controls to prevent a medical event involving the use of byproduct material;

(D) Implementing emergency procedures to be followed in the event of the abnormal operation of the medical unit or console;

(E) Checking and using survey meters; and

(F) Selecting the proper dose and how it is to be administered; and

(2) Has completed 3 years of supervised clinical experience in radiation oncology, under an authorized user who meets the requirements in Sec. 35.690 or equivalent Agreement State requirements, as part of a formal training program approved by the Residency Review Committee for Radiation Oncology of the Accreditation Council for Graduate Medical Education or Royal College of Physicians and Surgeons of Canada or the Committee on Postdoctoral Training of the American Osteopathic Association. This experience may be obtained concurrently with the supervised work experience required by paragraph (c)(1) of this section; and

(3) Has obtained a written statement attesting that the individual has satisfactorily completed the requirements in paragraphs (c)(1) and (c)(2) of this. The written statement must be signed by the supervising authorized user or if the training was obtained in a residency training program, by the program director.

(d) In addition to meeting the requirements of paragraphs (a), (b), or (c) of this section, an authorized user of a sealed source authorized under 35.600 must have training in the modality for which authorization is sought. This includes training in device operation, safety procedures, and clinical use. This training requirement may be satisfied by satisfactorily completing the training program provided by the vendor for new users or by receiving training supervised by an authorized user or authorized medical physicist, as appropriate, who is authorized for the modality in which the individual is seeking authorization.

AGENDA TOPIC: T&E Rulemaking

ATTACHMENT 3

AGREEMENT STATES COMMENT LETTERS

From: "Johns, George" <GJOHNS@health.state.ia.us>
To: "'lmp1@nrc.gov'" <lmp1@nrc.gov>
Date: 8/8/02 12:29PM
Subject: Iowa's response to Draft Options Paper on Part 35 Training and Experience

The Chief of Iowa's Bureau of Radiological Health has reviewed the following and requested that it be forwarded to you.

The current rule requires 200 hours of classroom training, 500 hours of supervised clinical experience and 500 hours of supervised work experience for use of radiopharmaceuticals in imaging and localization studies. The new rule states that a physician must only have 750 hours and is non-specific. Based on the Draft Options Paper, it would appear that the board certifications do not even meet the reduced standards, which take effect October 24, 2002. In other words, despite a 500-hour reduction in the training and experience requirements, only the Certification Board of Nuclear Cardiology meets the new NRC standards.

If the board certification process includes testing, which effectively evaluates a physician's didactic and clinical knowledge, IDPH would normally have little problem accepting that certification. However, because the regulatory community is tasked with promulgating rules to protect the health and safety of the patient, the staff, and the physician, the question that arises is: How much training can be avoided without compromising health and safety?

It seems odd that a certifying body would not be interested in establishing consistent training and experience standards. IDPH does not agree that the standards should be altered to accommodate the boards.

The certification process, if properly designed, can be used to determine competency. However, when considering training for non-board certified physicians, the difficulty that arises is determining how much training and experience should be required in lieu of a board certification. I believe that the primary objection expressed by many other Agreement States is that the NRC appears to be proposing a lesser training and experience standard for physicians with a board certification. Again, the standard has already been diminished. At what point does the NRC wish to say that the level of training is too little? It would appear that the NRC believes that the certification boards are capable of making that decision. It is Iowa's opinion that the NRC should not abdicate its responsibility.

In summary, the NRC has determined that regulations pertaining to training

and experience are a Compatibility B. The final rule has already reduced the training and experience requirements to a level that many believe to be compromising health and safety. The standard should not be further compromised. Therefore, the certifying boards, which have inconsistent standards among themselves, should be held to the new standards. Board certified and non-certified physicians should meet those same standards. Finally, if Agreement States are required to be consistent with the NRC, IDPH believes that the training and experience for physicians should be also consistent.

AGENDA TOPIC: T&E Rulemaking

From: "Frazee, Terry" <Terry.Frazee@DOH.WA.GOV>
To: "'LMP1@nrc.gov'" <LMP1@nrc.gov>
Date: 8/27/02 1:28PM
Subject: STP-02-061 -- Comments on Part 35 T&E

I have reviewed the Draft Options Paper presented on the Technical Conference Forum and have the following comments:

The ACMUI request is proof of what the Agreement States have known for a long time -- "Authorized Users" are clinicians (or "authorized prescribers", if you will) and, for the most part, NOT "users" or "handlers" of radioactive material; and obviously the Board process reflects that. The new T&E regulations (Option 1) are written as minimum requirements for the "use" or handling of radioactive material, i.e., with radiation safety in mind, and should be maintained "as is". An eleventh hour realization that the "clinical practice" Boards are "just that" does not negate the value of the T&E requirements geared to radiation safety!

Bottom line: The training and experience requirements represent the MINIMUM radiation safety requirements applicable to ALL "users" (even Board certified individuals) and should be kept for ALL. We don't "buy" the shortage argument. The Boards have two years to show how they meet (or will meet) or exceed the minimum requirements. Even if the ACMUI (rather than NRC staff) is used to "approve" Boards, the standard should be the same. Professional judgment can be used, BUT the STANDARD remains the same. The concern that "candidates seeking authorized user status may bypass the board certification pathway and select the simpler T&E process" is more reflective of Board concern for losing its candidates than for diminution of radiation safety. Our concern as regulators should be that the individuals we approve as "authorized users" are adequately trained with sufficient experience to handle the radioactive materials safely. Our first responsibility is to "do it right", not just pick the "easy way".

Therefore:

1. Leave the basic T&E alone. A lot of time and effort has been expended getting the "minimum" radiation safety standard to this point. "Last minute" changes are suspect.

2. Modify the certification (preceptor) requirement as recommended by ACMUI. This makes sense for Board certifications and further makes it clear that radiation safety rather than clinical skills are the focus of the regulatory requirement.

3. Set specific training requirements for new devices or modalities that can build upon the basic requirements for existing modalities. Existing authorized users should already have the basic radiation safety training and

experience and need only specific training for the new device or modality.

4. Publish "Approved Boards" on the web site (and not in regulation) for ease and convenience of all concerned.

If there are any lessons to be learned here, one is: "license the techs" and leave the physicians to their Boards (with ACMUI setting the bar for "authorized prescribers"); and the other is: last minute jockeying to change the "standard" means the rule may not be "perfect" and therefore "casting it in concrete" (compatibility B) may be premature!

Note to Agreement States: comments are due by August 30!

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"The Department of Health works to protect and improve the health of people in Washington State"
****

This message from Terry C. Frazee
e-mail terry.frazee@doh.wa.gov

Quick ways to reach me:
Voice = 360-236-3221
FAX = 360-236-2255

Also, visit our Home Page at
http://www.doh.wa.gov/ehp/rp

CC: "NRC-Lloyd (E-mail)" <lab@nrc.gov>, "AL-KirkseyWhatley (E-mail)" <kwhatley@adph.state.al.us>, "AR-JaredThompson (E-mail)" <jwthompson@healthyarkansas.com>, "AZ-AubreyGodwin (E-mail)" <agodwin@arra.state.az.us>, "CA-EdBailey (E-mail)" <EBailey@dhs.ca.gov>, "CA-KentPrendergast (E-mail)" <KPrender@dhs.ca.gov>, "CO-JakeJacobi (E-mail)" <jake.jacobi@state.co.us>, "FL-BillPassetti (E-mail)" <bill_passetti@doh.state.fl.us>, "GA-TomHill (E-mail)" <thill@dnr-gwia2.dnr.state.ga.us>, "IA-Flater (E-mail)" <dflater@idph.state.ia.us>, "IL-Collins (E-mail)" <collins@idns.state.il.us>, "KS-TomConley (E-mail)" <tconley@kdhe.state.ks.us>, "LA-MikeHenry (E-mail)" <m_henry@ldeq.org>, "MD-RolandFletcher (E-mail)" <rfletcher@mde.state.md.us>, "MA-Hallisey (E-mail)" <bob.hallisey@state.ma.us>, "MS-RobertGoff (E-mail)" <rgoff@msdh.state.ms.us>, "NC-BevHall (E-mail)" <beverly.hall@ncmail.net>, "ND-KenWangler (E-mail)" <kwangler@state.nd.us>, "ND-TerryOclair (E-mail)" <toclair@state.nd.us>, "NE-JuliaSchmitt (E-mail)" <julia.schmitt@hhss.state.ne.us>, "NH-WayneJohnston (E-mail)" <wjohnsto@dhhs.state.nh.us>, "NM-BillFloyd (E-mail)" <william_floyd@nmenv.state.nm.us>, "NV-StanMarshall (E-mail)" <smarshall@bhps.state.nv.us>, "NYCH-GeneMiskin (E-mail)" <gmiskin@health.nyc.gov>, "NYDEC-Merges (E-mail 2)" <pjmerges@gw.dec.state.ny.us>, "NYDOL-Brandt (E-mail)" <usccjb@labor.state.ny.us>, "NYSH-Salame-Aflie (E-mail)" <asa01@health.state.ny.us>, "OH-Suppes (E-mail)" <rsuppes@gw.odh.state.oh.us>,

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AGENDA TOPIC: T&E Rulemaking

STATE OF ILLINOIS

DEPARTMENT OF NUCLEAR SAFETY

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George H. Ryan
Governor

Thomas W. Ortciger
Director

September 11, 2002

U.S. Nuclear Regulatory Commission
ATTN: Linda M. Psyk, NMSS
Mail Stop TWFN 8-F-5
Washington, D.C. 20555

Re: Draft Options Paper, Part 35 - Training and Experience Requirements (STP-02-061)

Dear Ms. Psyk:

The Illinois Department of Nuclear Safety hereby submits the following comments on the above-identified draft options paper. The paper describes a recommendation by the NRC's Advisory Committee for Medical Use of Isotopes (ACMUI). The recommendation suggests a basis for the NRC to recognize training approved by professional specialty boards and provides an alternative training and experience pathway for individuals without board certification. It also proposes training and experience requirements for those working with remote afterloaders and gamma stereotactic radiosurgery units. The options paper concludes that the NRC should accept the advisory committee's recommendation.

Except for misgivings about the ACMUI's idea for the preceptor concept, the Department of Nuclear Safety does not object to either the advisory committee's recommendation or the NRC's plan to list recognized specialty boards on its website instead of in Part 35. We believe that with one additional change, the ACMUI's recommendation would provide effective training and experience requirements. We also have suggestions that would clarify the NRC's expectations for training of individuals working with future technologies.

The Preceptor Concept. We strongly oppose the idea of reducing the amount of assurance required of a preceptor when vouching for an individual seeking authorized status on a medical use license. The revision of Part 35 that will go into effect on October 24, 2002, requires a preceptor to verify that the individual is competent to

perform independently the duties required by a medical use license. The Department of Nuclear Safety believes that this principle must be preserved if the revision is to be effective over time.

The ACMUI recommends two traming and experience pathways leading to authorized status on a license. The more common track is certification by a professional specialty board. The Department of Nuclear Safety supports the ACMUI's vision of how this should be done. We believe that the board certification process contains prerequisites, inherent milestones, and internal certifications that are predictive of effective performance by board-certified individuals. We expect these individuals typically to be competent in the duties required by a medical use license.

The alternative training and experience pathway provides a method other than board certification for an individual to achieve authorized status on a medical use license. It allows the individual to acquire training and experience and then furnish a preceptor statement asserting that he or she is prepared to effectively perform the duties required by a license. Although this is a valid process overall, we strongly oppose the ACMUI's idea of reducing the assurance that would be required of a preceptor. Instead of an attestation of competency, the ACMUI wants the NRC to require only verification that training was completed. Thus, the NRC is asked to accept less assurance of competency from the alternative pathway than through board certification.

The NRC removed many prescriptive requirements from the revision of Part 35, in part because of assurances that the regulated community would assume increased responsibility for the performance of its members. Indeed, when the revision was being drafted, the ACMUI was not opposed to preceptors appraising the competence of individuals seeking authorized status on medical use licenses. We believe that the ACMUI recognized the need for increased self-regulation if Part 35 were to become more performance-based.

In the interim, however, it appears that a misunderstanding has arisen between the ACMUI and the NRC. We believe that the wording of the revision of Part 35 has led the ACMUI to conclude that the NRC is seeking a guarantee of clinical competency. Instead of such a broad guarantee, we believe that the NRC actually requires only an *opinion* about the ability of an individual to independently perform the *duties required by a license.* This opinion would not require the preceptor to vouch for the individual's overall clinical competency.

We believe that the positions of both the NRC and the regulated community would be served if this nuance were clarified. Here is a suggestion to modify the several requirements for preceptor statements in Part 35:

> Has obtained a written statement attesting that the individual has satisfactorily completed the requirements in paragraph_____ of this section. The written statement shall be signed by a preceptor_____ who meets the requirements in _____ or equivalent Agreement State requirements, and shall include verification that, to the preceptor's best knowledge, the individual is competent to function independently as an_____ for-the medical uses authorized under_____ .

Future Technologies. The ACMUI's recommendation includes a training requirement for remote afterloaders and gamma stereotactic radiosurgery units. The recommendation would require modality-specific training in device operation, safety procedures, and clinical use. The Department of Nuclear Safety supports this recommendation.

Besides the training requirements for the above modalities, however, we suggest that the NRC also identify its training expectations for future technologies. Here is a clarification to subsection 35.12(d) of Part 35 that we believe would accomplish this:

> 35.12(d)(1)(iv) Specialized training beyond that described in paragraph (b)(l) of this section. A radiation safety officer, authorized user, authorized medical physicist, or authorized nuclear pharmacist for a use authorized under section 35.1000 shall have training in the use for which authorization is sought. This includes training in device operation, safety procedures, and clinical use. This training requirement may be satisfied by satisfactorily completing the training program provided by the vendor for the appropriate position. It may also be satisfied by receiving training supervised by a radiation safety officer, authorized user, authorized medical physicist, or authorized nuclear pharmacist, as appropriate, who is authorized for the use for which authorization is sought.

A Role for the ACMUI. The Department of Nuclear Safety believes that the ACMUI should assume an active role in establishing specific training and experience criteria for future technologies. We suggest that the NRC ask the advisory committee to recommend training specifics for each new use under section 35.1000. This recommendation should describe the training and experience qualifications necessary under paragraph (b)(l) of section 35.12. It should also specify the number of hours or cases required to satisfy the specialized training requirement suggested above [new paragraph (d)(1)(iv)]. This practice would capitalize on the advisory committee's familiarity and expertise in new technologies.

After evaluating the ACMUI's recommendation, the NRC should promptly post new training and experience requirements on its website. This would make them quickly available to the regulated community and the Agreement States, thereby standardizing requirements for new technologies as they emerge.

Thank you for the opportunity to comment on this draft options paper. My telephone number is 217-785-9930 if you have questions or comments.

Sincerely,

Joseph G. Klinger, Chief
Division of Radioactive Materials

JGK:kjg

cc: Jim Lynch
NRC Region III

AGENDA TOPIC: T&E Rulemaking

Linda M. Psyk, NMSS
U.S. Nuclear Regulatory Commission
Mail Stop TWFN 8-F-5
Washington, DC 20555

Re: STP-02-061 - Part 35 - Training and Experience Requirements

Dear Ms Psyk:

This letter serves as my comment on the above referenced document. I have submitted comments to you earlier, via e-mail, regarding the ACMUI Subcommittee recommendation dated July 17, 2002.

In reading the above document, I find some inaccurate statements. The following is my response to each of these items.

1) If the draft final rule became effective 6 months after the publication date, there could be potential shortages of authorized individuals.

Response: This appears to be a key item of concern to the ACMUI. However, I fail to see the problem. During the last few years, nuclear cardiologists have not had a board certification available to them, yet there has been no shortage of nuclear cardiologists applying for, and receiving, authorized user status.

2) The ACMUI expressed concern that the boards may become "marginalized", because potential candidates seeking authorized user status may bypass the board certification pathway and select the simpler T&E process.

Response: When the NRC revised Part 35 in the 1980's, the various boards were queried as to their radiation safety requirements for board eligibility. These requirements became the basis for the optional training and experience requirements. Therefore, an individual who was not board certified, was required to be board eligible (in regards to radiation safety) in order to be approved as an authorized user. If any changes were made to the radiation safety training and experience required to sit for a board listed in Part 35, the NRC should have been made aware so they could review the possible impacts on radiation safety.

During the rule revision process, the Part 35 Working Group (of which I was a member) spent many hours with the ACMUI as well as their subcommittees for diagnostic and therapeutic uses. Many changes were made in the training and experience requirements

based on the discussions and recommendations of the members. It was made very clear that only those boards that showed they required that a board candidate meet the optional training and experience requirements would be "recognized" by the NRC, and placed on the on the NRC website list. Over and over again, between 1998 and 2000, the ACMUI membership expressed understanding and approval of the Working Group's revisions to the training and experience requirements.

Board certification should represent the best the respective field has to offer! Certification isn't for everyone. Certification should indicate that an individual has "gone the extra mile", not only to be the best they can be in their field, but to continue to strive to maintain that high level of overall competence in their chosen profession. Surely being board certified is worth more than just the ability to easily become an authorized user on a radioactive material license!

I perceive the currently listed boards did not pay attention to the revised training and experience requirements, so they are not prepared for the implementation of the new rule. I do not see this as a reason for changing the rule. I commend the Certification Board of Nuclear Cardiology for being attentive to the revised rule, and preparing for its implementation.

The following are my responses to the discussion topics.

1) Under the current Part 35, boards are not required to meet specific didactic/laboratory training and experience requirements to attain NRC recognition.

Response: As I stated above, when the training and experience requirements were revised during the 1980's, the intent was that the boards would meet the specified didactic/laboratory training and experience requirements to attain NRC recognition. However, this intent seems to have been forgotten over the years. The revised rule only reaffirms the old intent, leaving no doubt to a perspective board as to what radiation safety training and experience requirements they must have to attain NRC recognition.

2) Under the current rule, preceptor certification is not required for board certification. During the board certification process, the board makes its judgement that a candidate has satisfactorily completed the board's program and that the individual will be able to carry out the duties of this certification. Could another qualified

individual (e.g. a program director, a department head, or a professor) also sign the certification? In the case of the board certification process, can the members of the board collectively act as a "preceptor"?

Response: I again state that the intent of the current rule was that the boards require preceptor certification. I do not have a 1980's NRC definition for "preceptor", so I cannot say that the definition has not changed. In the revised rule, Preceptor is defined as "...an individual who provides or directs the training and experience required for an individual to become an authorized user, an authorized medical physicist, an authorized nuclear pharmacist, or a Radiation Safety Officer". Using this definition would not allow the boards to accept certification from a "qualified individual".

I believe that another individual can be allowed to sign on behalf of the actual preceptors. However, such an individual should be the preceptor's supervisor, such as a department head or program director, and a list of the preceptors should be included as reference.

I do not believe that members of the board, who have no personal knowledge of the "qualified individual", should be able to collectively act as a preceptor. I believe the "qualified individual" should be able to submit signatures of preceptors, or the preceptor's supervisor as specified in the previous paragraph, as part of their qualifications. The members of the board could decide to allow an individual to participate in any examination process without the individual submitting the necessary preceptor signatures. However, final certification should be withheld until the required preceptor signatures are submitted.

3) Board programs do not specifically include training and experience requirements for new modalities.

Response: It was the intent of the working group, in conjunction with recommendations from the ACMUI, that the training and experience requirements for other medical uses of byproduct material (emerging technologies) be handled on a case-by-case basis. No one can currently state what isotopes, chemical forms, physical forms, or routes of administration will fall into this area in the years to come. That is the reason the rule seems so vague. The intent is to make clear to the licensee what will be required of them to request licensed use of a new medical use not covered by the current rules. The example of a medical physicist with no experience in the use of

an HDR does not fall under this rule. Rather, it falls under 35.51. To try and tie down 35.1000 to something we are currently aware of has been pointed out as improper in public meetings. Specifically, the working group was using intravascular brachytherapy as an example of an emerging technology covered under this rule. Cardiologists and physicists pointed out that they do not consider intravascular brachytherapy an emerging technology. They consider it a current technology.

Existing qualified individuals wishing to use emerging technologies will have to submit information regarding the radiation safety hazards of the use to the NRC, and the NRC will then determine the necessary radiation safety training and experience requirements to become an authorized user, authorized medical physicist, etc.

Regarding the two options, my recommendation is as follows:

I believe the NRC should adopt Option 1, with two caveats. The ability of the Certification Board of Nuclear Cardiology to meet the revised requirements has proven that it can be done. However, the NRC could consider extending the old Subpart J training and experience requirements, as they are currently, until October 24, 2004. This gives the current boards another two years to meet the new requirements.

I also believe the NRC should allow the boards to accept another individual to sign on behalf of the actual preceptor, as long as the individual is the preceptor's supervisor, such as a department head or program director, and they submit a list of the preceptors as a reference.

Thank you for the opportunity to comment on this options paper. Should you have any questions, please feel free to contact me at 334-206-5391, or by e-mail at dwalter@adph.state.al.us.

Sincerely,

David Walter, Director
Radioactive Materials Licensing
Alabama Office of Radiation Control

AGENDA TOPIC: T&E Rulemaking

February 12, 2003

COMMISSION VOTING RECORD

DECISION ITEM: SECY-02-0194

TITLE: OPTIONS FOR ADDRESSING PART 35 TRAINING AND EXPERIENCE ISSUES ASSOCIATED WITH RECOGNITION OF SPECIALTY BOARDS BY NRC

The Commission (with Chairman Meserve and Commissioners McGaffigan and Merrifield agreeing) approved the subject paper as recorded in the Staff Requirements Memorandum (SRM) of February 12, 2003. Commissioners Dicus and Diaz disapproved the subject paper.

This Record contains a summary of voting on this matter together with the individual vote sheets, views and comments of the Commission.

Annette L. Vietti-Cook
Secretary of the Commission

Attachments:
1. Voting Summary
2. Commissioner Vote Sheets

cc: Chairman Meserve
Commissioner Dicus
Commissioner Diaz
Commissioner McGaffigan
Commissioner Merrifield
OGC
EDO
PDR

AGENDA TOPIC: T&E Rulemaking

VOTING SUMMARY - SECY-02-0194

RECORDED VOTES

	APRVD	DISAPRVD	ABSTAIN	NOT PARTICIP	COMMENTS	DATE
CHRM. MESERVE	X				X	1/16/03
COMR. DICUS		X			X	1/14/03
COMR. DIAZ		X			X	1/22/03
COMR. McGAFFIGAN	X				X	2/3/03
COMR. MERRIFIELD	X				X	1/16/03

COMMENT RESOLUTION

In their vote sheets, Chairman Meserve and Commissioners McGaffigan and Merrifield agreeing) approved the subject paper. Commissioners Dicus and Diaz disapproved the subject paper. Subsequently, the comments of the majority of the Commission were incorporated into the guidance to staff as reflected in the SRM issued on February 12, 2003.

AGENDA TOPIC: T&E Rulemaking

Commissioner Comments on SECY-02-0194

Chairman Meserve

I agree with Option 3, subject to the following comments. Under Option 3, the staff will develop a proposed rule governing the training and experience (T&E) requirements of Part 35 along the lines of a recommendation submitted by the Advisory Committee on the Medical Uses of Isotopes (ACMUI), but with all specialty boards recognized by the NRC to be listed on a website, rather than listing certain existing boards.

The final rule for Part 35 requires written certification by a preceptor that the individual seeking certification has completed the relevant requirements and "has achieved a level of radiation safety knowledge sufficient to function independently as a _____." See 10 C.F.R. 35.50(b)(2) (radiation safety officer); 35.51(b)(2) (medical physicist); 35.55(b)(2) (nuclear pharmacist); 35.190(c)(2), 35.290(c)(2), 35.390(b)(2), 35.392(c)(3), 35.394(c)(3), 35.490(b)(3), 35.690(b)(3) (authorized user). This evidently has been interpreted by the ACMUI as requiring a testament of general clinical competence. ACMUI Recomendations, at 1 (SECY-02-0194, Att. 2); see Letter from J.G. Klinger, Illinois Department of Nuclear Safety, to L.M.Psyk, NRC (Sept. 11, 2002)(SECY-02-0194, Att. 3). As a result, the ACMUI has recommended that the preceptor attest only to the completion of the training and experience requirements. I believe this weakens the intended certification too significantly. In my view, the whole point of the certification is to obtain a bottom-line assessment that the candidate has the knowledge and ability to fulfill the duties required by the license. The existing language of Part 35 may encompass this concept adequately, but staff might clarify that this language does not require an attestation of general clinical competency. This form of attestation should be preserved for both pathways of certification (i.e., through board certification or through training and experience).

One consequence of the acceptance of Options 2 or 3 is that the requirements that now exist in the revised Part 35 concerning didactic training and experience in specific subject areas will no longer be applicable to those who obtain board certification. These requirements are presumably intended as an indirect measure of competence and, so long as there is an adequate attestation of actual competence from an approved specialty board, I conclude it is appropriate to relieve these prescriptive requirements.

As noted above, the chief difference between Option 2 and Option 3 is that Option 2 would list certain existing boards in the rule, whereas under Option 3 all boards that are recognized would be listed only on the NRC website. Staff recommends Option 3 on the basis that there is efficiency in having only one source of information -- the website -- for the list of acceptable certification boards. This seems a weak justification because staff would not be prohibited in Option 2 from listing all boards on the website. There is another major difference in the two approaches, however. The ACMUI approach would effectively grandfather certain existing boards, while Option 3 would require the staff to determine that both existing and new boards meet the criteria for recognition. In this connection, the ACMUI notes that "[t]o the best of our knowledge, those specialty boards that are listed in these recommendations meet [the] specific criteria [for listing as approved boards]." ACMUI Recommendations, at 5 (emphasis added). Because of the important role of Board certification, a clear regulatory determination that all Boards, both new and existing, meet the relevant criteria should be required. I thus favor Option 3, but for different reasons than those expressed by staff.

In order to speed the modification of the rule, I endorse the staff's proposal that the staff proceed directly to the development of a proposed rule without the generation of an additional rulemaking plan. The ACMUI, the Board, and the Agreement States that assisted in the development of the proposal should be commended for their assistance.

Commissioner Dicus

I disapprove the staff's recommendation to prepare a proposed rule to modify the training and experience based on the recommendations submitted by the ACMUI and do not agree with the staff's or the ACMUI's proposal to modify 10 CFR Part 35 to accommodate the certification boards.

When the revisions to Part 35 were drafted and debated over the past several years, one of the Commission's main initiatives was to increase the level of awareness and documentation of experience regarding basic radiation safety training and knowledge for those individuals involved with the use or handling of radioactive materials in medical applications. During this very open, public rulemaking process, all parties, including the Certification Boards, were able to provide comments on the viability of this change to the training and experience requirements of Part 35. At the time the Commission approved Part 35, many of the Boards participating in our rulemaking workshops agreed that their exams should include more radiation safety-related questions for certification. Since being established, these requirements represent the minimum radiation safety requirement applicable to all users, including Board certified individuals, and in my view, should be required for all.

The Certification process, if properly designed, could be used to assess the competency of an individual licensed to use radioactive material for medical use. The primary concern that I have, along with those of several Agreement States, is that the proposal before the Commission appears to be proposing a lesser training and experience requirement for physicians with a Board certification. Based on SECY-02-0194, it would appear that the proposed ACMUI proposal for Board certifications would not even meet the reduced requirements, despite a 500-hour reduction for training and experience. I would like to point out that the only Board that currently meets the revised requirements is the Certification Board of Nuclear Cardiology, because it took the initiative, time, and effort to develop its certification program based on the final rule. They are to be commended for their efforts.

I recommend that the training and experience requirements stay as they are currently as written, but that changes to the certification (preceptor) requirement be clarified as proposed by the ACMUI. This will clarify that radiation safety, which is clearly within the NRC's purview, rather than clinical skills, are the focus of these regulatory requirements. In addition, I would recommend that the ACMUI set specific training requirements for new devices or modalities that can build upon the basic requirements for other existing modalities. Lastly, I would support the staff's proposed use of the website for publication of NRC-approved Boards.

Commissioner Diaz

I continue to support the existing training and experience requirements in Part 35, which focus on radiation safety. Therefore, I disapprove staff's recommended Option 3. Board certification, in most cases, is the preferred path to meet the requirements in this part; however, before a board is

recognized by NRC, the board should be able to certify that individuals who are board-certified by their respective board meet the training and experience requirements in Part 35. In addition, the ACMUI-proposed requirements for NRC recognition of new boards include areas involving the practice of medicine, which is contrary to the 2000 Medical Policy Statement that specifically states that "NRC will minimize intrusion into . . . areas traditionally considered to be a part of the practice of medicine." We should uphold the principles in the Medical Policy Statement in all areas of our medical regulations, including recognition of new boards.

The staff should work with stakeholders to seek resolution of specific problems with the training and experience requirements, such as: (1) the requirement for a preceptor statement for radiation safety officers; and (2) the requirements for authorized medical physicists.

Commissioner McGaffigan

I agree with the staff's recommendation and approve the staff to move forward with Option 3 which incorporates the recommendations of the Advisory Committee on the Medical Uses of Isotopes (ACMUI) except that all boards that meet the criteria for recognition by the NRC will be listed on the NRC website rather than in the rule itself. I also agree with Chairman Meserve that the preceptor statement should remain as written in the final Part 35 rule.

In 1997, the Commission directed the staff to revise Part 35 to be more risk-informed and, where appropriate, more performance based while maintaining radiation safety. I believe that the staff accomplished this task admirably and developed a more risk informed regulation with a great deal of coordination with external stakeholders. The ACMUI, however, has recently stated that the medical boards would like Part 35 to be less prescriptive in the area of Training and Experience (T&E) requirements. The ACMUI has offered modifications to the rule which would allow the boards to have more latitude in making the determination that an individual is sufficiently trained and capable of performing his or her duties in radiation safety. I believe that the ACMUI proposed revisions would make the final rule more performance based but this must be balanced with NRC's statutory obligations regarding the radiation safety of workers and the public, including patients. I believe Chairman Meserve's vote is a good compromise between these two issues.

The Chairman's vote stated that the rule should allow certain approved board certifications to be one path an individual could take to demonstrate sufficient knowledge and training in radiation safety. It also stated that the rule should maintain the current preceptor statement as written in the final Part 35. I agree. If the boards are willing to take on the responsibility for determining that an individual is fully trained in radiation safety and is capable of performing his/her duties, then the boards should be required to sign a preceptor statement to that effect. The preceptor statement, in addition to the NRC's review of a board's program prior to approving that board to be listed on the web site, will give NRC the assurance that a board certified individual has sufficient radiation safety training to handle radioactive material safely.

I also agree with the staff and the Chairman that all specialty boards should be listed on NRC's web site rather than in Part 35. Changes to the regulations can be burdensome and time consuming. I think it is most beneficial for the NRC, the boards, and the medical professionals that are seeking board certification for the NRC's list of approved boards be current and that changes be completed quickly and efficiently.

Commissioner Merrifield

I approve the staff's recommended option 3 and the proposal to direct the staff to proceed with rulemaking without generating a separate rulemaking plan as stated in SECY-02-0194.

I recognize that training associated with 10 CFR Part 35 is a controversial area. In the last revision to Part 35, some Agreement State representatives were particularly concerned when we significantly reduced the number of training hours and focused the training on radiation safety. The old Part 35 recognized training provided by speciality boards listed in the regulations. However, these previously approved speciality boards (with one exception) do not meet the detailed training requirements in the new Part 35. The ACMUI reviewed the existing speciality boards and concluded, with concurrence by the NRC staff, that the existing speciality boards meet the intent of the required training even if they do not meet the exact wording in the regulations. The ACMUI and staff have recommended an alternative rule which would resolve the dilemma by approving existing boards reviewed by the ACMUI and providing criteria for qualifying new speciality boards in the future. The new training criteria also requires authorized users, besides being certified by a speciality board or receiving other general training, to also receive training for the equipment or function for which the licensee is seeking authorization. Given the fact that a significant majority of past medical events (formally known as misadministrations) were attributed to technicians, equipment, or procedures and not inadequate training by the speciality boards of authorized users, I will accept the staff recommendations.

I also approve the staff recommendation that approved speciality boards be listed on our web site as opposed to being listed in the regulations. It is a more timely and efficient process to add or remove items from our web site than it is to change our regulations for issues which can be adequately addressed in this manner.

The draft rule contains criteria for new speciality boards to achieve recognition by the NRC. As part of the rulemaking process, I would expect the staff to discuss implementing procedures both for adding new speciality boards to the approved listing and for removing boards from the approved list. While I do not expect NRC staff to conduct inspections of the approved speciality boards, I do expect staff to monitor trends in medical events. If a particular speciality for some reason has a series of medical events that can be attributed to inadequate training, the staff will need to determine if the training should have been site specific or should have been provided by the speciality boards. If the staff determines that changes in training by an approved speciality board are necessary and the speciality either cannot or will not make adequate changes to its training program to address our needs, then that speciality board should be removed from our approved list. However, appropriate due process would require that the procedures are established in advance for removing a speciality board from the approved list. In addition, the Commission should be informed of any staff decision to remove a board from the approved list.

LISTING SEALED SOURCES ON MEDICAL USE APPLICATIONS AND LICENSES

May 2003 ACMUI Meeting

Donna-Beth Howe, Ph.D.

LISTING SEALED SOURCES

ACMUI Recommendation

The ACMUI recommends that NRC initiate a rulemaking process to modify 10 CFR Part 35 to override 10 CFR Part 30.32(g)(1), to allow more generic listing of interstitial seeds and sources on NRC licenses.

LISTING SEALED SOURCES

Staff Decision: Protect Public Health and Safety

- Rulemaking may ultimately reduce radioactive source accountability.
- 30.32 (g)(1), ensures licensees maintain full accountability (accurate inventory and prevent loss) of their sources/devices
- Identification requirements for all sources-devices are reasonable to ensure accountability
- Not prudent to reduce accountability of radioactive material in today's environment of heightened public awareness and sensitivity.

LISTING SEALED SOURCES

§30.32 Application for specific licenses.

- (g) An application for a specific license to use byproduct material in the form of a sealed source or in a device that contains the sealed source must either –
- (1) Identify the source or device by manufacturer and model number as registered with the Commission under §32.210 of this chapter or with an Agreement State; or
- (2) Contain the information identified in §32.210(c).

LISTING SEALED SOURCES

§32.210 Registration of product information.

(c) The request for review of a sealed source or a device must include sufficient information about the design, manufacture, prototype testing, quality control program, labeling, proposed uses and leak testing and, for a device, the request must also include sufficient information about installation, service and maintenance, operating and safety instructions, and its potential hazards, to provide reasonable assurance that the radiation safety properties of the source or device are adequate to protect health and minimize danger to life and property.

NATIONAL MATERIALS PROGRAM: PILOT ON OPERATING EXPERIENCE EVALUATION

May 21, 2003

Michael T. Markley, NRC/IMNS
mtm@nrc.gov

PURPOSE OF THIS BRIEFING

- Seek early ACMUI input on the pilot
- Identify concerns and issues to pursue during implementation
- Highlight plans to report back on pilot status, successes and challenges, and results and recommendations

PILOT OBJECTIVES

- Optimize the common use of operating experience information from licensed facilities and trending in integrated decision-making
- Test a structured process for evaluating cumulative data and performance and develop strategies to make the process more transparent
- Produce consistent results when implemented by NRC or Agreement States

WHAT DO WE MEAN BY OPERATING EXPERIENCE?

- Domestic and foreign event data
- Inspections, special studies, and generic reviews
- Industry-wide analyses
- Risk insights and metrics
- Performance indicators and associated thresholds for regulatory action

SCOPE OF ACTIVITIES

- Examine process for evaluating events for generic implications and possible regulatory action
- Consider process for providing information on significant nuclear materials issues and adverse licensee performance to the Commission
- Address applicable recommendations in incident and working group reports (e.g., St. Joseph)

EVALUATION OF CURRENT PROGRAMS

- Identify gaps in NRC and Agreement State processes and opportunities for improvement
- Develop tools and metrics to test the use of cumulative data, a standard format, and decision criteria
- Examine lessons learned from past operating experience and associated root causes, risk insights, and corrective actions

PROPOSED REGULATORY FRAMEWORK

- Propose enhancements to procedures, organizational review and evaluation methods, sources of information, and methods to better communicate operating experience information
- Provide recommendations to enhance the efficiency and effectiveness of materials oversight programs, including matters related to duplication of effort and burden reduction

CURRENT PILOT STATUS AND FUTURE ACTIVITIES

- Pilot charter approved, participants identified
- Partnering with States to develop work product plan
- Meetings with CRCPD, OAS, and ACMUI
- Public meetings with stakeholders

RELATED ACTIVITIES

- NRR/RES Operating Experience Task Force and Steering Committee
- RES evaluation of options for developing a more robust materials-focused program
- NMSS Operating Experience Committee

FOCUS QUESTIONS

- How can operating experience information be better communicated between NRC and Agreement States?
- How can operating experience information and trending optimize NRC and Agreement State resource utilization?
- How can risk insights be better integrated into regulatory decision making?

AGENDA TOPIC: NATIONAL MATERIALS PROGRAM PILOT PROJECT

National Materials Program Pilot Project 3
Operating Experience Evaluation

Charter

Objectives

The objective of the Operating Experience Evaluation Pilot is to optimize the common use of operating experience information from licensed facilities and trending in integrated NRC and Agreement State review, assessment, and decision-making processes. The pilot should develop and test a structured process for evaluating cumulative licensee data and performance, identify gaps in NRC and Agreement State processes, and develop strategies and tools to make the programs more scrutable, predictable, and transparent. The revised process should produce consistent analyses and results when implemented by the NRC or Agreement States.

Scope of Activities

The pilot will examine NRC and Agreement State processes for collecting, reviewing, analyzing, and disseminating concerns and lessons learned from operating experience. Operating experience information may include: domestic and foreign event data, major team inspections and special studies leading to generic reviews and/or generic communications, industry-wide analyses of performance and trends, insights and metrics amenable to risk-informed decision making, and performance indicators and associated thresholds for increased regulatory attention.

This pilot should: (1) examine the process for evaluating a collective set of Agreement State and NRC licensee events for generic implications and possible additional regulatory action, (2) consider the proposed process, in SECY-02-0216, for providing information on significant nuclear materials issues and adverse licensee performance, and (3) address applicable recommendations identified in incident or working group reports (e.g., Schlumberger Augmented Inspection Team, Davis-Besse Lessons Learned Task Force report, etc.).

The pilot is expected to identify gaps in NRC and Agreement State regulatory processes and opportunities for improvement in program effectiveness. The pilot should develop a set of evaluation tools and metrics to be tested using cumulative data, a standard format, and decision criteria. The pilot should examine and implement lessons learned from past operating experience and associated root cause analyses, risk insights, and corrective actions. Of particular importance are precursor events that provide leading indication of change/problems and/or highlight weakness in regulatory oversight programs. The pilot should also examine methods to advance materials-related contributions to the annual report to the Commission on performance trends in the materials area.

The pilot should develop a proposed regulatory framework and associated program recommendations for consideration by the NRC and Agreement States. The framework should propose enhancements to procedures, organizational review and evaluation methods, sources of information, and methods to better communicate operating experience information. This pilot should provide recommendations for enhanced efficiency and effectiveness of materials oversight programs, including matters related to duplication of effort and/or burden reduction, particularly with regard to the allocation and use of inspection resources.

The pilot should seek broad stakeholder input including the views of the Organization of Agreement States (OAS), Committee of Radiation Control Program Directors (CRCPD), Advisory Committee on the Medical Use of Isotopes (ACMUI), and from open-public meetings with licensees and concerned citizens, as appropriate.

Work Products

The pilot should prepare: (1) an overall work product plan for developing and testing methods to systematically evaluate operating experience information, and (2) a final work product and associated recommendations for improving the efficiency, effectiveness, and consistency of operating experience evaluation.

Organization

The Working Group should comprise one member from IMNS (Mike Markley, Chair), at least one representative from each of two participating States, and one NRC representative from an NRC Regional Office materials program. NRC membership shall not exceed Agreement State participation, excluding representation by the Working Group Chair.

Schedule

3/19/03	First monthly conference call (3rd Wednesday each month)
3/28/03	Submit Work Product Plan (due to STP, OAS, and CRCPD)
4/15/03	Work Product Plan Concurrences
5/4-5/03	Brief CRCPD on pilot
5/20/03	Brief ACMUI on pilot and solicit early feedback
5/30/03	Identify candidate activity, guidelines, and criteria for pilot testing
6/13/03	Begin pilot test
9/12/03	Complete pilot testing, identify gaps, and proposed enhancements
10/03	Brief ACMUI and OAS on progress and solicit feedback
10/14-17/03	Brief OAS on pilot
11/14/03	Develop draft framework proposal
1/9/04	Complete draft pilot report
2/2/04	Submit final report (to STP, OAS, and CRCPD Chairs)
3/04	Public meeting to solicit stakeholder/public input (tentative)
4/15/03	Draft report concurrences due
5/04	Brief CRCPD

6/15/04	Complete draft report to Commission
7/30/04	End of comment period on draft report
8/31/04	Finalize report to Commission
9/30/04	Obtain concurrences
10/29/04	Final concurrences/comments reconciled
11/30/04	Report to Commission

Level of Effort

Approximately two person-days per month will be required of participants. The Working Group Chair will require, on average, eight person-days per month for this effort. Actual Working Group travel should not exceed three meetings per year. Teleconferencing and video technology will be used to limit costs.

Part 35 Direct Final Rule

Clarifying and Minor Amendments

Anthony Tse, NRC

Status

- DFR published on April 21, 2003
- Companion PR for 30-day comment – comment period ends May 21
- FR effective on July 7, 2003 – unless significant adverse comments received

Why DFR Needed?

- After publication of Part 35, the staff identified
  - Unnecessary restrictions
  - Inconsistencies

What Are the Changes? For Consistency

- 35.2 Definition Add those certified in Subpart J

  AU means an individual who meets 35.190(a) ..., **or, before October 24, 2004, 35.910(a), 35.920(a) ...**

- Similar changes to:
  35.51, 35.100, 35.190, 35.200, 35.290, 35.300 35.390, 35.392, 35.394, 35.490, 35.491, 35.690

Provide Flexibility

- Section 35.310 Safety instruction

  Replace "the AU" by "An AU"

  Example: 35.310(a)(5): Notification of the RSO ... and **an AU** if the patient or the human subject has a medical emergency or dies.

- Similar change to 35.315, Safety precautions

For Clarification

- 35.432 Calibration of brachytherapy sources

  Add an introductory phrase to (b)

  35.432(b): **Instead of a licensee making its own measurements as required in (a),** the licensees may use ...

Provide Flexibility

- 35.491 Training for ophthalmic use of Sr-90

  Add "clinic or private practice"

  35.491(b) ... under the supervision of an AU at a medical institution, **clinic, or private practice** that includes ...

04/24/03 7

Correct the Title of NIST

- 35.630 Dosimetry equipment

  Replace "Science" by "Standards"

  35.630(a)(1): ... traceable to the National Institute of **Standards** and Technology ...

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For Consistency

- 35.2432 Records of calibration of brachytherapy sources

  Make it consistent with 35.432

  35.2432(b)(5): **The name of the individual, the source manufacturer, or the calibration laboratory that performed the calibration**

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Proposed Rules

Federal Register
Vol. 68, No. 76
Monday, April 21, 2003

This section of the FEDERAL REGISTER contains notices to the public of the proposed issuance of rules and regulations. The purpose of these notices is to give interested persons an opportunity to participate in the rule making prior to the adoption of the final rules.

DEPARTMENT OF AGRICULTURE

Agricultural Marketing Service

7 CFR Parts 916 and 917

[Docket No. FV03–916–3]

Nectarines and Peaches Grown in California; Announcement of Public Meeting To Review Orders

AGENCY: Agricultural Marketing Service, USDA.

ACTION: Notice of public meeting and request for comments.

SUMMARY: Notice is hereby given that a public meeting will be held to provide information to the U. S. Department of Agriculture (USDA) on whether the Federal marketing order programs for California nectarines and peaches should be continued, modified or terminated. Growers, handlers, and other interested persons are invited to submit written comments to USDA and/or present oral comments at the meeting with respect to the continued operations of the marketing order programs.

DATES: The public meeting will begin at 8:30 a.m. P.D.T. on May 20, 2003, and continue until 5 p.m. The meeting will continue on May 21, 2003, from 8:30 a.m. to 12 p.m., if necessary. The meeting will be held at the Dinuba Memorial Building, 249 South Alta Avenue, Dinuba, California; telephone: 559–591–2223. Written comments will be received through June 20, 2003.

ADDRESSES: Written comments should be sent to California Marketing Field Office, Marketing Order Administration Branch, Fruit and Vegetable Programs, AMS, 2202 Monterey Street, Suite 102B, Fresno, California 93721, Attention: Kurt Kimmel; telephone: (559) 487–5901, Fax: (559) 487–5906 or E-mail: *moab.docketclerk@usda.gov.* All written comments should reference the docket number and the date and page number of this issue of the Federal Register and will be made available for public inspection in the California Marketing Field Office during regular business hours or can be viewed at: *http://www.ams.usda.gov/fv/moab.html.* Written comments received before the meeting will also be available for public inspection at the meeting.

FOR FURTHER INFORMATION CONTACT: Kathleen M. Finn, Marketing Order Administration Branch, Fruit and Vegetable Programs, AMS, USDA, 1400 Independence Avenue, SW., STOP 0237, Washington, DC 20250–0237; telephone: (202) 720–2491, or Fax: (202) 720–8938.

SUPPLEMENTARY INFORMATION: Continuance referenda were held from January 6 through January 31, 2003, to determine whether the marketing order programs for nectarines, pears and peaches grown in California should be continued. Results of the pear continuance referendum demonstrated support for the pear program to be continued. However, in the nectarine and peach referenda, fewer than two-thirds of those voting supported continuation of the programs. This notice announces a meeting to provide additional information for USDA on the marketing order programs for nectarines (M.O. 916) and peaches (M.O. 917) to evaluate the future of these programs.

On March 27, 2003, USDA announced it would hold listening sessions in the production area. The meeting will provide an opportunity for those in the industry to present detailed information on the present performance of the two marketing order programs. Information regarding present performance may include an analysis of the programs' cost effectiveness with regard to administration, research and advertising. USDA also seeks comments on whether amendment of some of the regulatory aspects of the two programs would make the programs more effective and create more support among growers and handlers. Finally, USDA seeks views on whether the orders for nectarines and peaches should be terminated. Interested persons are encouraged to send written comments to USDA and/or present oral comments at the meeting. Because we do not intend to transcribe the oral comments at the meeting, oral commenters are encouraged to submit their comments also in writing for best consideration.

Written comments, views, opinions, and other information regarding the nectarine, pear, and peach marketing orders' impact on small businesses are invited.

Dated: April 15, 2003.

A.J. Yates,

Administrator, Agricultural Marketing Service.

[FR Doc. 03–9672 Filed 4–18–03; 8:45 am]

BILLING CODE 3410–02–P

NUCLEAR REGULATORY COMMISSION

10 CFR Part 35

RIN 3150–AH08

Medical Use of Byproduct Material: Clarifying and Minor Amendments

AGENCY: Nuclear Regulatory Commission.

ACTION: Proposed rule.

SUMMARY: The Nuclear Regulatory Commission (NRC) is amending its regulations regarding the medical use of byproduct material. This action would clarify the definitions of authorized users, authorized medical physicists, authorized nuclear pharmacists, and radiation safety officers; clarify the notification requirements if the patient is in a medical emergency or dies; clarify the recordkeeping requirements for calibration of brachytherapy sources; correct the title for the National Institute of Standards and Technology; clarify that prior to October 24, 2004, individuals who meet the training and experience requirements in Subpart J may undertake responsibilities specified in certain sections in Subparts B and D–H; and eliminate a restriction that training for ophthalmic use of strontium-90 can only be conducted in medical institutions. These amendments are necessary to clarify certain inconsistencies within the regulations and to allow training in ophthalmic treatment to be conducted in eye clinics or private practices, in addition to medical institutions.

DATES: Comments on the proposed rule must be received on or before May 21, 2003.

ADDRESSES: You may submit comments by any one of the following methods. Please include the following number (RIN 3150-AH08) in the subject line of your comments. Comments on rulemakings submitted in writing or in electronic form will be made available

to the public in their entirety on the NRC rulemaking Web site. Personal information will not be removed from your comments.

Mail comments to: Secretary, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, ATTN: Rulemakings and Adjudications Staff.

E-mail comments to: *SECY@nrc.gov*. If you do not receive a reply e-mail confirming that we have received your comments, contact us directly at (301) 415–1966. You may also submit comments via the NRC's rulemaking Web site at *http://ruleforum.llnl.gov*. Address questions about our rulemaking Web site to Carol Gallagher (301) 415–5905; email *cag@nrc.gov*.

Hand deliver comments to: 11555 Rockville Pike, Rockville, Maryland 20852, between 7:30 a.m. and 4:15 p.m. Federal workdays. (Telephone (301) 415–1966).

Fax comments to: Secretary, U.S. Nuclear Regulatory Commission at (301) 415–1101.

Publicly available documents related to this rulemaking may be examined and copied for a fee at the NRC's Public Document Room (PDR), Public File Area O1 F21, One White Flint North, 11555 Rockville Pike, Rockville, Maryland. Selected documents, including comments, can be viewed and downloaded electronically via the NRC rulemaking Web site at *http://ruleforum.llnl.gov*.

Publicly available documents created or received at the NRC after November 1, 1999, are available electronically at the NRC's Electronic Reading Room at *http://www.nrc.gov/NRC/ADAMS/index.html*. From this site, the public can gain entry into the NRC's Agencywide Document Access and Management System (ADAMS), which provides text and image files of NRC's public documents. If you do not have access to ADAMS or if there are problems in accessing the documents located in ADAMS, contact the NRC Public Document Room (PDR) Reference staff at 1–800–397–4209, (301) 415–4737 or by email to *pdr@nrc.gov*.

FOR FURTHER INFORMATION CONTACT: Dr. Anthony N. Tse, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, telephone (301) 415–6233, email: *ant@nrc.gov*.

SUPPLEMENTARY INFORMATION: For additional information see the direct final rule published in the Rules and Regulations section of this Federal Register.

Because the NRC considers this action noncontroversial and routine, we are publishing this proposed rule concurrently as a direct final rule. The direct final rule will become effective on July 7, 2003. However, if the NRC receives significant adverse comments on the direct final rule, by May 21, 2003, the NRC will publish a document that withdraws the direct final rule. If the direct final rule is withdrawn, the NRC will address the comments received in response to the proposed revisions in a subsequent final rule. Absent significant modifications to the proposed revisions requiring republication, the NRC will not initiate a second comment period for this action if the direct final rule is withdrawn.

A significant adverse comment is a comment where the commenter explains why the rule would be inappropriate, including challenges to the rule's underlying premise or approach, or would be ineffective or unacceptable without a change. A comment is adverse and significant if:

(1) The comment opposes the rule and provides a reason sufficient to require a substantive response in a notice-and-comment process. For example, a substantive response is required when—

(A) The comment causes the staff to reevaluate (or reconsider) its position or conduct additional analysis;

(B) The comment raises an issue serious enough to warrant a substantive response to clarify or complete the record; or

(C) The comment raises a relevant issue that was not previously addressed or considered by the staff.

(2) The comment proposes a change or an addition to the rule and it is apparent that the rule would be ineffective or unacceptable without incorporation of the change or addition.

(3) The comment causes the staff to make a change (other than editorial) to the rule.

List of Subjects in 10 CFR Part 35

Byproduct material, Criminal penalties, Drugs, Health facilities, Health professions, Medical devices, Nuclear materials, Occupational safety and health, Radiation protection, Reporting and recordkeeping requirements.

For reasons set out in the preamble and under the authority of the Atomic Energy Act of 1954, as amended; the Energy Reorganization Act of 1974, as amended; and 5 U.S.C. 553; the NRC is proposing to adopt the following amendments to 10 CFR part 35.

PART 35—MEDICAL USE OF BYPRODUCT MATERIAL

1. The authority citation for part 35 continues to read as follows:

Authority: Secs. 81, 161, 182, 183, 68 Stat. 935, 948, 953, 954, as amended (42 U.S.C. 2111, 2201, 2232, 2233); sec. 201, 88 Stat. 1242, as amended (42 U.S.C. 5841).

2. In § 35.2, the definitions for *authorized medical physicist*, *authorized nuclear pharmacist*, *authorized user*, and *radiation safety officer*, are amended by revising paragraph (1) of each definition to read as follows:

§ 35.2 Definitions.

* * * * *

Authorized medical physicist means an individual who—

(1) Meets the requirements in §§ 35.51(a) and 35.59; or, before October 24, 2004, meets the requirements in §§ 35.961(a), or (b), and 35.59; or

* * * * *

Authorized nuclear pharmacist means a pharmacist who—

(1) Meets the requirements in §§ 35.55(a) and 35.59; or, before October 24, 2004, meets the requirements in §§ 35.980(a) and 35.59; or

* * * * *

Authorized user means a physician, dentist, or podiatrist who—

(1) Meets the requirements in §§ 35.59 and 35.190(a), 35.290(a), 35.390(a), 35.392(a), 35.394(a), 35.490(a), 35.590(a), or 35.690(a); or, before October 24, 2004, meets the requirements in §§ 35.910(a), 35.920(a), 35.930(a), 35.940(a), 35.950(a), or 35.960(a) and 35.59; or

* * * * *

Radiation Safety Officer means an individual who—

(1) Meets the requirements in §§ 35.50(a) and 35.59; or, before October 24, 2004, meets the requirements in §§ 35.900(a) and 35.59; or

* * * * *

3. In § 35.51, the second sentence of paragraph (b)(2) is revised to read as follows:

§ 35.51 Training for an authorized medical physicist.

* * * * *

(b) * * *

(2) * * * The written certification must be signed by a preceptor authorized medical physicist who meets the requirements in § 35.51, or, before October 24, 2004, § 35.961, or equivalent Agreement State requirements for an authorized medical physicist for each type of therapeutic medical unit for which the individual is requesting authorized medical physicist status.

4. In § 35.100, paragraph (b) is revised to read as follows:

§ 35.100 Use of unsealed byproduct material for uptake, dilution, and excretion studies for which a written directive is not required.

* * * * *

(b) Prepared by:

(1) An authorized nuclear pharmacist;

(2) A physician who is an authorized user and who meets the requirements specified in §§ 35.290, 35.390, or, before October 24, 2004, § 35.920; or

(3) An individual under the supervision, as specified in § 35.27, of the authorized nuclear pharmacist in paragraph (b)(1) of this section or the physician who is an authorized user in paragraph (b)(2) of this section; or

* * * * *

5. In § 35.190, paragraph (b), the introductory text of paragraph (c)(1)(ii), and paragraph (c)(2) are revised to read as follows:

§ 35.190 Training for uptake, dilution, and excretion studies.

* * * * *

(b) Is an authorized user under §§ 35.290, 35.390, or, before October 24, 2004, §§ 35.910, 35.920, or 35.930, or equivalent Agreement State requirements; or

* * * * *

(c) * * *

(1) * * *

(ii) Work experience, under the supervision of an authorized user who meets the requirements in §§ 35.190, 35.290, 35.390, or, before October 24, 2004, §§ 35.910, 35.920, or 35.930, or equivalent Agreement State requirements, involving—

* * * * *

(2) Has obtained written certification, signed by a preceptor authorized user who meets the requirements in §§ 35.190, 35.290, 35.390, or, before October 24, 2004, §§ 35.910, 35.920, or 35.930, or equivalent Agreement State requirements, that the individual has satisfactorily completed the requirements in paragraph (c)(1) of this section and has achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized under § 35.100.

6. In § 35.200, paragraph (b) is revised to read as follows:

§ 35.200 Use of unsealed byproduct material for imaging and localization studies for which a written directive is not required.

* * * * *

(b) Prepared by:

(1) An authorized nuclear pharmacist;

(2) A physician who is an authorized user and who meets the requirements specified in §§ 35.290, 35.390, or, before October 24, 2004, § 35.920; or

(3) An individual under the supervision, as specified in § 35.27, of the authorized nuclear pharmacist in paragraph (b)(1) of this section or the physician who is an authorized user in paragraph (b)(2) of this section;

* * * * *

7. In § 35.290, paragraph (b), the introductory text of paragraph (c)(1)(ii), and paragraph (c)(2) are revised to read as follows:

§ 35.290 Training for imaging and localization studies.

* * * * *

(b) Is an authorized user under § 35.390, or, before October 24, 2004, § 35.920, or equivalent Agreement State requirements; or

(c) * * *

(1) * * *

(ii) Work experience, under the supervision of an authorized user, who meets the requirements in §§ 35.290, 35.390, or, before October 24, 2004, § 35.920, or equivalent Agreement State requirements, involving —

* * * * *

(2) Has obtained written certification, signed by a preceptor authorized user who meets the requirements in §§ 35.290, 35.390, or, before October 24, 2004, § 35.920, or equivalent Agreement State requirements, that the individual has satisfactorily completed the requirements in paragraph (c)(1) of this section and has achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized under §§ 35.100 and 35.200.

8. In § 35.300, paragraph (b) is revised to read as follows:

§ 35.300 Use of unsealed byproduct material for which a written directive is required.

* * * * *

(b) Prepared by:

(1) An authorized nuclear pharmacist;

(2) A physician who is an authorized user and who meets the requirements specified in §§ 35.290, 35.390, or, before October 24, 2004, § 35.920; or

(3) An individual under the supervision, as specified in § 35.27, of the authorized nuclear pharmacist in paragraph (b)(1) of this section or the physician who is an authorized user in paragraph (b)(2) of this section; or

* * * * *

9. In § 35.310, paragraph (a)(5) is revised to read as follows:

§ 35.310 Safety instruction.

(a) * * *

(5) Notification of the Radiation Safety Officer, or his or her designee, and an authorized user if the patient or the human research subject has a medical emergency or dies.

* * * * *

10. In § 35.315, paragraph (b) is revised to read as follows:

§ 35.315 Safety precautions.

* * * * *

(b) A licensee shall notify the Radiation Safety Officer, or his or her designee, and an authorized user as soon as possible if the patient or human research subject has a medical emergency or dies.

11. In § 35.390, the introductory text of paragraph (b)(1)(ii) and paragraph (b)(2) are revised to read as follows:

§ 35.390 Training for use of unsealed byproduct material for which a written directive is required

(b) * * *

(1) * * *

(ii) Work experience, under the supervision of an authorized user who meets the requirements in §§ 35.390(a), 35.390(b), or, before October 24, 2004, § 35.930, or equivalent Agreement State requirements. A supervising authorized user, who meets the requirements in § 35.390(b) or, before October 24, 2004, § 35.930(b), must also have experience in administering dosages in the same dosage category or categories (*i.e.*, § 35.390(b)(1)(ii)(G)(*1*), (*2*), (*3*), or (*4*)) as the individual requesting authorized user status. The work experience must involve—

* * * * *

(2) Has obtained written certification that the individual has satisfactorily completed the requirements in paragraph (b)(1) of this section and has achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized under § 35.300. The written certification must be signed by a preceptor authorized user who meets the requirements in §§ 35.390(a), 35.390(b), or, before October 24, 2004, § 35.930, or equivalent Agreement State requirements. The preceptor authorized user, who meets the requirements in § 35.390(b) or, before October 24, 2004, § 35.930(b), must also have experience in administering dosages in the same dosage category or categories (*i.e.*, § 35.390(b)(1)(ii)(G)(*1*), (*2*), (*3*), or (*4*)) as the individual requesting authorized user status.

12. In § 35.392, paragraph (b), the introductory text of paragraph (c)(2), and paragraph (c)(3) are revised to read as follows:

§ 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).

* * * * *

(b) Is an authorized user under §§ 35.390(a), 35.390(b) for uses listed in § 35.390(b)(1)(ii)(G)(*1*) or (*2*), § 35.394, or, before October 24, 2004, §§ 35.930, 35.932, or 35.934, or equivalent Agreement State requirements; or

(c) * * *

(2) Has work experience, under the supervision of an authorized user who meets the requirements in §§ 35.390(a), 35.390(b), 35.392, 35.394, or, before October 24, 2004, §§ 35.930, 35.932, or 35.934, 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 (*2*). The work experience must involve—

* * * * *

(3) Has obtained written certification that the individual has satisfactorily completed the requirements in paragraphs (c)(1) and (c)(2) of this section and has achieved a level of competency sufficient to function independently as an authorized user for medical uses authorized under § 35.300. The written certification must be signed by a preceptor authorized user who meets the requirements in §§ 35.390(a), 35.390(b), 35.392, 35.394, or, before October 24, 2004, §§ 35.930, 35.932, or 35.934, or equivalent Agreement State requirements. A preceptor authorized user, who meets the requirement in § 35.390(b), must also have experience in administering dosages as specified in § 35.390(b)(1)(ii)(G)(*1*) or (*2*).

13. In § 35.394, paragraph (b), the introductory text of paragraph (c)(2), and paragraph (c)(3) are revised to read as follows:

§ 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).

* * * * *

(b) Is an authorized user under §§ 35.390(a), 35.390(b) for uses listed in § 35.390(b)(1)(ii)(G)(*2*), or, before October 24, 2004, §§ 35.930 or 35.934, or equivalent Agreement State requirements; or

(c) * * *

(2) Has work experience, under the supervision of an authorized user who meets the requirements in §§ 35.390(a), 35.390(b), 35.394, or, before October 24, 2004, §§ 35.930 or 35.934, 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)(*2*). The work experience must involve—

* * * * *

(3) Has obtained written certification that the individual has satisfactorily completed the requirements in paragraphs (c)(1) and (c)(2) of this section and has achieved a level of competency sufficient to function independently as an authorized user for medical uses authorized under § 35.300. The written certification must be signed by a preceptor authorized user who meets the requirements in §§ 35.390(a), 35.390(b), 35.394, or, before October 24, 2004, §§ 35.930 or 35.934, or equivalent Agreement State requirements. A preceptor 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*).

14. In § 35.432, paragraph (b) is revised to read as follows:

§ 35.432 Calibration measurements of brachytherapy sources.

* * * * *

(b) Instead of a licensee making its own measurements as required in paragraph (a) of this section, the licensee may use measurements provided by the source manufacturer or by a calibration laboratory accredited by the American Association of Physicists in Medicine that are made in accordance with paragraph (a) of this section.

* * * * *

15. In § 35.490, the introductory text of paragraph (b)(1)(ii), paragraphs (b)(2), and (b)(3) are revised to read as follows:

§ 35.490 Training for use of manual brachytherapy sources.

* * * * *

(b) * * *

(1) * * *

(ii) 500 hours of work experience, under the supervision of an authorized user who meets the requirements in § 35.490, or, before October 24, 2004, § 35.940, or equivalent Agreement State requirements at a medical institution, involving—

* * * * *

(2) Has obtained 3 years of supervised clinical experience in radiation oncology, under an authorized user who meets the requirements in § 35.490, or, before October 24, 2004, § 35.940, or equivalent Agreement State requirements, as part of a formal training program approved by the Residency Review Committee for Radiation Oncology of the Accreditation Council for Graduate Medical Education or the Committee on Postdoctoral Training of the American Osteopathic Association. This experience may be obtained concurrently with the supervised work experience required by paragraph (b)(1)(ii) of this section; and

(3) Has obtained written certification, signed by a preceptor authorized user who meets the requirements in § 35.490, or, before October 24, 2004, § 35.940, or equivalent Agreement State requirements, that the individual has satisfactorily completed the requirements in paragraphs (b)(1) and (b)(2) of this section and has achieved a level of competency sufficient to function independently as an authorized user of manual brachytherapy sources for the medical uses authorized under § 35.400.

16. In § 35.491, paragraph (a), the introductory text of paragraph (b)(2), and paragraph (b)(3) are revised to read as follows:

§ 35.491 Training for ophthalmic use of strontium-90.

* * * * *

(a) Is an authorized user under § 35.490, or, before October 24, 2004, §§ 35.940 or 35.941, or equivalent Agreement State requirements; or

(b) * * *

(2) Supervised clinical training in ophthalmic radiotherapy under the supervision of an authorized user at a medical institution, clinic, or private practice that includes the use of strontium-90 for the ophthalmic treatment of five individuals. This supervised clinical training must involve—

* * * * *

(3) Has obtained written certification, signed by a preceptor authorized user who meets the requirements in §§ 35.490, 35.491, or, before October 24, 2004, §§ 35.940 or 35.941, or equivalent Agreement State requirements, that the individual has satisfactorily completed the requirements in paragraphs (a) and (b) of this section and has achieved a level of competency sufficient to function independently as an authorized user of strontium-90 for ophthalmic use.

17. In § 35.630, paragraph (a)(1) is revised to read as follows:

§ 35.630 Dosimetry equipment.

(a) * * *

(1) The system must have been calibrated using a system or source traceable to the National Institute of Standards and Technology (NIST) and published protocols accepted by nationally recognized bodies; or by a

calibration laboratory accredited by the American Association of Physicists in Medicine (AAPM). The calibration must have been performed within the previous 2 years and after any servicing that may have affected system calibration; or

* * * * *

18. In § 35.690, the introductory text of paragraph (b)(1)(ii), and paragraphs (b)(2) and (b)(3) are revised to read as follows:

§ 35.690 Training for use of remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units.

* * * * *

(b) * * *

(1) * * *

(ii) 500 hours of work experience, under the supervision of an authorized user who meets the requirements in § 35.690, or, before October 24, 2004, § 35.960, or equivalent Agreement State requirements at a medical institution, involving—

* * * * *

(2) Has completed 3 years of supervised clinical experience in radiation oncology, under an authorized user who meets the requirements in § 35.690, or, before October 24, 2004, § 35.960, or equivalent Agreement State requirements, as part of a formal training program approved by the Residency Review Committee for Radiation Oncology of the Accreditation Council for Graduate Medical Education or the Committee on Postdoctoral Training of the American Osteopathic Association. This experience may be obtained concurrently with the supervised work experience required by paragraph (b)(1)(ii) of this section; and

(3) Has obtained written certification that the individual has satisfactorily completed the requirements in paragraphs (b)(1) and (b)(2) of this section and has achieved a level of competency sufficient to function independently as an authorized user of each type of therapeutic medical unit for which the individual is requesting authorized user status. The written certification must be signed by a preceptor authorized user who meets the requirements in § 35.690, or, before October 24, 2004, § 35.960, or equivalent Agreement State requirements for an authorized user for each type of therapeutic medical unit for which the individual is requesting authorized user status.

19. In § 35.2432, paragraph (b)(5) is revised to read as follows:

§ 35.2432 Records of calibration measurements of brachytherapy sources.

* * * * *

(b) * * *

(5) The name of the individual, the source manufacturer, or the calibration laboratory that performed the calibration.

Dated at Rockville, Maryland, this 31st day of March, 2003.

For the Nuclear Regulatory Commission.

William D. Travers,

Executive Director for Operations.

[FR Doc. 03-9602 Filed 4-18-03; 8:45 am]

BILLING CODE 7590-01-P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA-2003-14693; Airspace Docket No. 03-AGL-03]

Proposed Modification of Class E Airspace; South Bend, IN

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking.

SUMMARY: This document proposes to modify Class E airspace at South Bend, IN. Standard Instrument Approach Procedures (SIAPS) have been developed for South Bend Regional Airport, South Bend, IN. Controlled airspace extending upward from 700 feet or more above the surface of the earth is needed to contain aircraft executing these approaches. This action would increase the area of the existing controlled airspace for South Bend Regional Airport.

DATES: Comments must be received on or before June 16, 2003.

ADDRESSES: Send comments on the proposal to the Docket Management System, U.S. Department of Transportation, Room Plaza 401, 400 Seventh Street, SW., Washington, DC 20590-0001. You must identify the docket Number FAA-2003-14693/ Airspace Docket No. 03-AGL-03, at the beginning of your comments. You may also submit comments on the Internet at *http://dms.dot.gov*. You may review the public docket containing the proposal, any comments received, and any final disposition in person in the Dockets Office between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The Docket Office (telephone 1-800-647-5527) is on the plaza level of the Department of Transportation NASSIF Building at the above address.

An informal docket may also be examined during normal business hours at the office of the Regional Air Traffic Division, Federal Aviation Administration, 2300 East Devon Avenue, Des Plaines, Illinois 60018.

FOR FURTHER INFORMATION CONTACT: Denis C. Burke, Air Traffic Division, Airspace Branch, AGL-520, Federal Aviation Administration, 2300 East Devon Avenue, Des Plaines, Illinois 60018, telephone (847) 294-7568.

SUPPLEMENTARY INFORMATION:

Comments Invited

Interested parties are invited to participate in this proposed rulemaking by submitting such written data, views, or arguments as they may desire. Comments that provide the factual basis supporting the views and suggestions presented are particularly helpful in developing reasoned regulatory decisions on the proposal. Comments are specifically invited on the overall regulatory, aeronautical, economic, environmental, and energy-related aspects of the proposal. Communications should identify both docket numbers and be submitted in triplicate to the address listed above. Commenters wishing the FAA to acknowledge receipt of their comments on this document must submit with those comments a self-addressed, stamped postcard on which the following statement is made: "Comments to Docket No. FAA-2003-14693/Airspace Docket No. 03-AGL-03." The postcard will be date/time stamped and returned to the commenter. All communications received on or before the specified closing date for comments will be considered before taking action on the proposed rule. The proposal contained in this action may be changed in light of comments received. All comments submitted will be available for examination in the Rules Docket, FAA, Great Lakes Region, Office of the Regional Counsel, 2300 East Devon Avenue, Des Plaines, Illinois, both before and after the closing date for comments. A report summarizing each substantive public contact with FAA personnel concerned with this rulemaking will be filed in the docket.

Availability of NPRM's

An electronic copy of this document may be downloaded through the Internet at *http://dms.dot.gov*. Recently published rulemaking documents can also be accessed through the FAA's Web page at *http://www.faa.gov* or the Superintendent of Document's Web page at *http://www.access.gpo.gov/nara*.

Additionally, any person may obtain a copy of this notice by submitting a request to the Federal Aviation Administration, Office of Air Traffic

Healthcare Integrity and Protection Data Bank Status and Discussion

Linda M. Psyk
Division of Industrial and Medical Nuclear Safety

ACMUI Meeting
May 20, 2003

Healthcare Integrity and Protection DB

Discussion Outline

- What is the HIPDB
- What the NRC Reports
- How the NRC Reports
- Status of Management Directive 8.6
- Examples of Past Actions Requiring Reporting
- Agreement State Reporting

What Is the HIPDB?

- *Health Insurance Portability and Accountability Act of 1996*
  - Health care fraud
    - Burdens US with enormous financial costs and threatens health care quality and patient safety
  - Required DHHS to create a national health care fraud and abuse control program
  - Established a national data bank to receive and disclose certain final adverse actions against health care practitioners, providers, and suppliers

What Is the HIPDB? Cont.

- Contents of HIPDB are confidential
  - No access to general public
- Entities reported to HIPDB are notified
- HIPDB information available to
  - State and Federal Agencies
  - Health plans
  - Health care practitioners, providers, and suppliers requesting information concerning themselves

What is the HIPDB? Cont.

- Codified in 45 CFR Part 61
- Requires reporting from:
  - State and Federal Government Agencies responsible for the licensing or certification of health care practitioners, providers, and suppliers
  - Health plans (insurance, programs that provide health benefits)

What the NRC Reports

- 3 Criteria for Reportable Action:
  - Final negative actions or findings
  - Actions that are publicly available
  - Related to medical practice or healthcare
- Examples
  - Revocation or suspension of a license
  - Actions that limit the scope of practice

What the NRC Reports cont.

- NRC reports NRC licensees and employees working under an NRC license:
  - Physicians
  - Medical physicists
  - Health physicists
  - Technologists
  - Hospitals
  - Clinics
  - Radiopharmacies
  - Medical source replacement contractors

How the NRC Will Report

- Management Directive 8.6
- Regional staff to collect information
- Office of Enforcement to input data into HIPDB
- Reporting actions taken since August 21, 1996

Status of Management Directive 8.6

- Memorandum to ACMUI 1/29/03
- NRC Offices and Regions Review for Final Comment Due 5/30/03
- Comments Incorporated - Then Final Concurrence
- Projected Completion Date 8/4/03

Examples of Past Actions Requiring Reporting

- IA 02-017Perry M. Beale 9/23/02
  - Order prohibiting involvement in NRC-licensed activities.
- EA-97-137 Jose L. Fernandez, M.D. 6/11/97
  - Oder modifying license due to over 100 misadministrations from incorrectly calibrated Sr-90 device, failure to have QMP, unauthorized users.

Examples of Past Actions Requiring Reporting

- EA-01-313 Advanced Medical Imaging and Nuclear Services 12/14/01
  - A immediately effective Order Suspending License was issued. The order was based on the licensee's possession and use of radioactive materials (including the diagnostic administration to patients) without a required authorized user or Radiation Safety Officer.
- EA-96-505 Fairbanks Memorial Hospital 4/1/97
  - NOV with a civil penalty due to deliberate failure to obtain the signature of the physician authorized user on a written directive before administering a dosage of I-131 of greater than 30 microcuries to a patient.

Agreement State Reporting

- AS required to report adverse actions to HIPDB
- NRC to provide a letter to AS when Management Directive is complete -reminder

Summary

- NRC to report adverse actions taken against licensees which pertain to health care
- Information submitted to HIPDB in accordance with Management Directive 8.6
- Agreement States also required to report to HIPDB

Written Directives for Brachytherapy Not Associated With Permanent Implants

Ronald E. Zelac, Ph.D., CHP, CMP
Senior Health Physicist
NMSS/IMNS/MSIB
ACMUI Meeting
May 20, 2003

Question

- Are the Part 35 written directive requirements for brachytherapy (other than HDR*) appropriate for procedures not associated with permanent implants?

*high dose remote afterloading

Rule Section

- 10 CFR 35.40(b)(6)
  (for all brachytherapy except HDR)

Specific Requirements

- Before implantation: treatment site, radionuclide, dose
- After implantation, but before completion of procedure: treatment site, radionuclide, number of sources, total source strength and exposure time (or total dose)

Changes from Previous Requirements

- Number of sources now entered after implantation, rather than before
- Individual source strengths no longer required
- Treatment site and dose now required prior to implantation, besides after implantation

Basis for Changes

- Discussion with the ACMUI of comments received on the proposed rule
- Consistency with requirements for other sealed source therapies

Answer to Question

- Yes. The Part 35 written directive requirements for brachytherapy (other HDR) are appropriate for procedures not associated with permanent implants.

Questions?

DOWNLOADING PT. 35 FROM THE NRC WEBPAGE

NO HANDOUT PROVIDED

AGENDA TOPIC: SNM SUGGESTED GUIDANCE FOR THERAPY APPLICATIONS

SOCIETY OF NUCLEAR MEDICINE

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MEMORANDUM

To: SNM Board of Directors
ACNP Board of Regents
Members of the ACNP/SNM GRC

From: Jeffry Siegel, PhD, Chair, ACNP/SNM GRC
Becky Haines, Director of Publications, SNM
Bill Uffelman, General Counsel and Director of Public Affairs

Re: Review of *Nuclear Regulatory Commission Regulation of Nuclear Medicine: Compliance Guide for Therapeutic Nuclear Medicine*

The enclosed manuscript is the companion guidance document for therapeutic nuclear medicine that follows the successful completion and distribution of the *Nuclear Regulatory Commission Regulation of Nuclear Medicine: Compliance Guide for Diagnostic Nuclear Medicine* (see attached).

We are submitting a copy of this near final draft document to you and now ask that you review it to help us determine whether it can be improved or if we have missed anything. As this is not the final version of the document, we ask that you not share it with anyone and that you return it to us with your comments so that we can compile them.

Your comments should be recorded on the enclosed reviewer sheet. To facilitate the coordination of the review process among more than 40 reviewers, it is imperative that you note your changes and comments following the format noted on the reviewer sheet.
Your comments should be returned to the SNM Office using the Business Reply Envelopes provided no later than May 10, 2003

Please remember that you are engaging in a confidential peer-review process and that your comments should not be shared outside of the review group noted in the address line above.

Thank you.

NUCLEAR REGULATORY COMMISSION REGULATION OF NUCLEAR MEDICINE: GUIDE FOR THERAPEUTIC NUCLEAR MEDICINE

Jeffry A. Siegel, Ph.D.
Chair, ACNP/SNM Joint Government Relations Committee

TABLE OF CONTENTS

1. Introduction

This book was developed to provide guidance to therapeutic nuclear medicine applicants and/or licensees in the implementation of the U.S. Nuclear Regulatory Commission's (NRC's) newly revised 10 CFR Part 35, *Medical Use of Byproduct Material*. This guidance is aimed at all therapeutic nuclear medicine licensees using unsealed byproduct material for which a written directive (i.e., a written order for the administration of byproduct material to a specific patient or human research subject) is required.

Recently, the Society of Nuclear Medicine and the American College of Nuclear Physicians published a guidance document, *Guide for Diagnostic Nuclear Medicine*, as an alternative to NRC licensing guidance, for implementation of the revised Part 35 regulations applicable to the practice of diagnostic nuclear medicine. The SNM/ACNP worked collaboratively with the NRC to develop this guide and it has been licensed by the NRC for distribution to the medical community via the NRC web site. The NRC has stated that the SNM/ACNP *Guide for Diagnostic Nuclear Medicine* "provides information that may be useful to nuclear medicine professionals in understanding the applicability of NRC requirements to the medical use of byproduct material in diagnostic settings, and provides measures that practitioners may use to facilitate implementation of the revised rule."

Additional guidance is necessary for the therapeutic use of unsealed byproduct material in nuclear medicine. The radiation protection policies and implementing procedures suggested in this book are an alternative to those given in NRC licensing guidance (NUREG-1556, Volume 9, *Consolidated Guidance About Material Licenses: Program-Specific Guidance About Medical Use Licenses*). These policies and procedures were developed based on NRC regulations. They may not apply to therapeutic nuclear medicine facilities in Agreement States. This book was designed to meet that need and serves as a companion guide to the *Guide for Diagnostic Nuclear Medicine*. Diagnostic and therapeutic nuclear medicine licensees will need to combine this book and the *Guide for Diagnostic Nuclear Medicine* for a comprehensive guide for the use of unsealed byproduct materials in nuclear medicine.

2. The Practice of Therapeutic Nuclear Medicine

The use of unsealed byproduct material in therapeutic nuclear medicine involves administering a radionuclide therapy agent to treat (including to palliate) a particular disease. The most common use of unsealed byproduct material for therapy is the treatment of hyperthyroidism with ^{131}I sodium iodide. Other therapeutic procedures include ablation of thyroid cancer and its metastases, treatment of bone metastases in cancer patients, radioimmunotherapy of non-Hodgkin's lymphoma, treatment of malignant effusions, treatment of polycythemia vera and leukemia, and radiation synovectomy for rheumatoid arthritis patients. Other radioimmunotherapy agents are likely to be used for cancer treatment in the near future.

The following radionuclides are most commonly used in therapeutic radiopharmaceuticals: ^{131}I, ^{153}Sm, ^{89}Sr, ^{90}Y, and ^{32}P. The most common therapeutic nuclear medicine procedures using these radiopharmaceuticals and their typical administered activities are shown in Table 2.1.

Table 2.1
Most Common Therapeutic Nuclear Medicine Procedures

Radionuclide	Agent	Indication	Administered Activities (mCi)
^{32}P	Phosphate	Polycythemia Vera	4
	Chromic Phosphate	Neoplastic Effusions and Radiation Synovectomy	3-5
^{89}Sr	Chloride	Bone pain	4
^{90}Y	Ibritumomab Tiuxetan	Non-Hodgkin's Lymphoma	32 (maximum)
^{131}I	Sodium iodide	Hyperthyroidism	10-30
	Sodium iodide	Thyroid Cancer	100-400
^{153}Sm	EDTMP	Bone pain	70

3. Revised Part 35 Requirements Applicable to Therapeutic Nuclear Medicine

The revised 10 CFR Part 35 does not use or define the term "therapeutic nuclear medicine". Medical uses are categorized according to the written directive (i.e., a written order for the administration of byproduct material to a specific patient or human research subject) requirement (§ 35.40 and § 35.41) and physical form of byproduct material (unsealed material or sealed sources). Written directives are required for the administration of (1) ^{131}I sodium iodide in amounts greater than 30 μCi (1.11 MBq); and (2) a therapeutic dosage of any other radiopharmaceutical.

Therapeutic nuclear medicine procedures are understood to be described or referenced in Subpart E, *Unsealed Byproduct Material – Written Directive Required*, specifically in section 10 CFR 35.300, *Use of unsealed byproduct material for which a written directive is required.*

This book is applicable for all therapeutic nuclear medicine licensees using § 35.300 materials. Compared to diagnostic nuclear medicine licensees as detailed in the SNM/ACNP *Guide for Diagnostic Nuclear Medicine*, licensees performing radionuclide therapy are required to have additional training and experience, use written directives, perform additional radiation surveys, and may be required to institute a bioassay program.

The revised Part 35 rule is organized into Subparts A though N. The requirements for diagnostic and therapeutic medicine are intermingled. As a first step in making these requirements more "user-friendly", they were reviewed and only those requirements applicable to diagnostic nuclear medicine were presented in the SNM/ACNP *Guide for Diagnostic Nuclear Medicine*. The additional requirements for the therapeutic use of § 35.300 materials in nuclear medicine are shown in the following list. Essentially all of these requirements will be covered in Chapters 4 and 5.

Subpart A - General Information
35.15 Exemptions regarding Type A specific licenses of broad scope.
Subpart B - General Administrative Requirements
35.40 Written directives.
35.41 Procedures for administrations requiring a written directive.
Subpart C - General Technical Requirements
35.70 Surveys of ambient radiation exposure rate.
35.75 Release of individuals containing unsealed byproduct material or implants containing byproduct material.
Subpart E - Unsealed Byproduct Material - Written Directive Required
35.300 Use of unsealed byproduct material for which a written directive is required.

35.310 Safety instruction.
35.315 Safety precautions.
35.390 Training for use of unsealed byproduct material for which a written directive is required.
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).
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).

Subpart J - Training and Experience Requirements (retained for 2-year period)

35.930 Training for therapeutic use of unsealed byproduct material.
35.932 Training for treatment of hyperthyroidism.
35.934 Training for treatment of thyroid carcinoma.

Subpart L - Records

35.2040 Records of written directives.
35.2041 Records for procedures for administrations requiring a written directive.
35.2070 Records of surveys for ambient radiation exposure rate.
35.2075 Records of the release of individuals containing unsealed byproduct material or implants containing byproduct material.
35.2310 Records of safety instruction.

Subpart M - Reports

35.3045 Report and notification of a medical event.
35.3047 Report and notification of a dose to an embryo/fetus or a nursing child.

4. Training and Experience Requirements for Therapeutic Nuclear Medicine

It is important to the radiation safety of workers and the public, including patients, to designate certain individuals who have adequate training and experience in radiation safety principles as applied to therapeutic nuclear medicine to reduce unnecessary radiation exposure. Training and experience requirements to demonstrate sufficient knowledge and skills in radiation protection practices and procedures are essential for identifying individuals who may be recognized as:

Authorized User Physician (AU)
Radiation Safety Officer (RSO)
Authorized Nuclear Pharmacist (ANP)
Authorized Medical Physicist (AMP)

The high level of protection afforded to patients, workers, and the public by the practice of therapeutic nuclear medicine is in part due to the training and experience of these authorized individuals. Usually, these authorized individuals supervise other workers who are involved in medical use and they must direct these supervised individuals to ensure that unsealed byproduct material is handled safely. Many of these supervised individuals are nuclear medicine technologists, but there are no NRC requirements for their training and experience. Nationally approved training programs for these technologists have been in existence for many years. In some states, students must pass an examination to be identified as a certified nuclear medicine technologist in order to be licensed to practice in that state.

NRC requires than an applicant/licensee be qualified by training and experience to use licensed materials for the purposes requested in such a manner as to protect health and minimize danger to life or property (§ 30.33). Therapeutic nuclear medicine purposes are the use of unsealed byproduct material for which a written directive is required and these uses are covered by 10 CFR 35.300, as previously discussed. Essentially all therapeutic nuclear medicine licensees perform the studies in 10 CFR 35.300 and may use *any* unsealed byproduct material requiring a written directive prepared for medical use that is:

1. Obtained from a manufacturer or preparer that is appropriately licensed by NRC or equivalent Agreement State requirements;
2. Prepared by an authorized nuclear pharmacist, a physician who is an authorized user and who meets the requirements in § 35.390, or an individual under the supervision of either as specified in § 35.27;

3. Obtained from and prepared by an NRC or Agreement State licensee for use in research in accordance with an Investigational New Drug (IND) protocol accepted by FDA; or
4. Prepared by a licensee for use in research in accordance with an IND protocol accepted by FDA.

There are also NRC training and experience requirements for AUs whose practices are limited to the oral administration of ^{131}I sodium iodide requiring a written directive in quantities less than or equal to 1.22 GBq (33 mCi) pursuant to § 35.392 or in quantities greater than 1.22 GBq (33 mCi) pursuant to § 35.394. Since the practice of therapeutic nuclear medicine is not limited to only these studies, the interested reader is referred to these latter pertinent regulations in 10 CFR Part 35.

The NRC training and experience (T&E) requirements for AUs involved with § 35.300 materials and procedures will be detailed below. NRC training and experience for RSOs was detailed in the SNM/ACNP *Guide for Diagnostic Nuclear Medicine* and will not be reproduced here. Since most diagnostic and therapeutic nuclear medicine facilities do not employ ANPs or AMPs, their T&E requirements are not included. The interested reader is referred to the pertinent regulations (ANP: § 35.55, § 35.57, § 35.59, § 35.980, § 35.981; AMP: § 35.51, § 35.57, § 35.59, § 35.961).

The T&E requirements in the revised Part 35 rule basically require that AUs meet either of the following 2 criteria:

1. Certified by a medical specialty board whose certification process includes stated requirements and whose certification has been recognized by NRC or an Agreement State;

OR

2. Completed specified hours of didactic training and work experience under an AU;

AND

Obtained written certification signed by a preceptor AU.

Previously AUs were required to either be certified by certain specialty boards that were recognized or obtain the requisite training and experience without written certification by a preceptor. As of April 2003, with the exception of the Certification Board of Nuclear Cardiology, no certifying boards are recognized by

the NRC. The revised rule therefore includes a two-year transition period for T&E requirements. During this time the current or revised requirements can be used. According to 10 CFR Part 35.10, prior to October 25, 2004, a licensee can satisfy the requirements for AU status by complying with either:

1. The appropriate training requirements in subpart J (§ 35.930); or
2. The appropriate training requirements in § 35.390 (and/or § 35.57, § 35.59).

Subpart J of Part 35 has been retained for a 2-year period.
Note: As a result of NRC's Advisory Committee on the Medical Uses of Isotopes (ACMUI) concerns, as of February 12, 2003, the Commission has directed the staff to prepare a proposed rule to modify the T&E requirements.

Authorized User (AU) Physician

10 CFR 35.390 Training for use of unsealed byproduct material for which a written directive is required.

To become an AU of unsealed byproduct material for the uses authorized under § 35.300 a physician must meet one of the following criteria (except as provided in § 35.57):

1. Certified by a medical specialty board whose certification process includes all of the requirements in item 2 and whose certification has been recognized by the Commission or an Agreement State.
2. Completed 700 hours of training and experience including all of the following:
    a. Classroom and laboratory training in:
        i. Radiation physics and instrumentation;
        ii. Radiation protection;
        iii. Mathematics pertaining to use and measurement of radioactivity;
        iv. Chemistry of byproduct material for medical use; and
        v. Radiation biology.
    b. Work experience under supervision of AU who meets requirements in § 35.390 (Note: a supervising AU who is not board certified must have experience in administering dosages in the same dosage category or categories as the individual requesting AU status) or equivalent Agreement State requirements, involving:
        i. Ordering, receiving, and unpacking radioactive materials safely and performing related radiation surveys;

ii. Calibrating 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 medical events involving use of unsealed byproduct material;
v. Using procedures to safely contain spilled byproduct material and using proper decontamination procedures;
vi. Eluting generator systems, measuring and testing the eluate for radionuclidic purity, and processing eluate with reagent kits to prepare labeled radioactive drugs; and
vii. Administering dosages of radioactive drugs to patients or human research subjects involving a minimum of three cases in each of the following categories for which the individual is requesting AU status:
(1). Oral administration of less than or equal to 1.22 GBq (33 mCi) of ^{131}I sodium iodide;
(2). Oral administration of greater than 1.22 GBq (33 mCi) of ^{131}I sodium iodide (experience with 3 cases in this category also satisfies the requirement in category 1);
(3). Parenteral administration of any beta emitter or a photon-emitting radionuclide with a photon energy less than 150 keV; and/or
(4). Parenteral administration of any other radionuclide.

c. Obtained written certification, signed by a preceptor AU who meets requirements in § 35.390 or equivalent Agreement State requirements, that the individual has satisfactorily completed the requirements in 2a and 2b and has achieved a level of competency sufficient to function independently as an AU for the medical uses authorized under § 35.300.
(Note: A preceptor AU who is not board certified must have experience in administering dosages in the same dosage category or categories, i.e., 2b(vii)(1-4), as the individual requesting AU status.)

10 CFR 35.930 Training for therapeutic use of unsealed byproduct material. (Subpart J; retained for 2 years)

To become an AU of radiopharmaceuticals in § 35.300, a physician must meet one of the following criteria (except as provided in § 35.57):

1. Certified by any of the following:

a. The American Board of Nuclear Medicine;
b. The American Board of Radiology in radiology, therapeutic radiology, or radiation oncology;
c. The Royal College of Physicians and Surgeons of Canada in nuclear medicine; or
d. The American Osteopathic Board of Radiology after 1984.

2. Completed training and experience including all of the following:
   a. 80 hours of classroom and laboratory training in:
      i. Radiation physics and instrumentation;
      ii. Radiation protection;
      iii. Mathematics pertaining to use and measurement of radioactivity; and
      iv. Radiation biology.
   b. Supervised clinical experience under supervision of AU at a medical institution that includes:
      i. Use of ^{131}I for diagnosis of thyroid function and the treatment of hyperthyroidism or cardiac dysfunction in 10 individuals; and
      ii. Use of ^{131}I for treatment of thyroid carcinoma in 3 individuals.

10 CFR 35.57 Training for experienced Radiation Safety Officer, teletherapy or medical physicist, authorized user, and nuclear pharmacist.

Physicians identified as AUs for the medical use of byproduct material on a license issued by the Commission or Agreement State, a permit issued by a Commission master material licensee, a permit issued by a Commission or Agreement State broad scope licensee, or a permit issued by a Commission master material license broad scope permittee before October 24, 2002 who perform only those medical uses for which they were authorized on that date need not comply with the training requirements of § 35.390.

10 CFR 35.59 Recentness of training.

The training and experience specified in § 35.390 and § 35.930 must have been obtained within the 7 years preceding the date of application or the individual must have had related continuing education and experience since the required training and experience was completed.

5. Radiation Protection Program

A radiation protection program has been detailed in the SNM/ACNP *Guide for Diagnostic Nuclear Medicine*, and most of these recommendations still apply to nuclear medicine practitioners involved in therapeutic medical uses of unsealed byproduct materials. The areas covered in Chapter 9 of the *Guide* were:

1. Radiation Protection Program (General)
2. Occupational Dose Limits
3. Dose Limits for Members of the Public
4. Minimization of Contamination/Spill Procedures
5. Material Receipt and Accountability/Ordering, Receiving, and Opening Packages
6. Radiation Surveys and Calibration of Survey Instruments
7. Caution Signs and Posting Requirements
8. Labeling Containers, Vials, and Syringes
9. Determining Patient Dosages
10. Sealed Source Inventory and Leak Testing
11. Waste Disposal and Decay-In-Storage
12. Records
13. Reports
14. Safety Instruction for Workers
15. Audit Program
16. Mobile Diagnostic Nuclear Medicine Services

Additional guidance is necessary for therapeutic nuclear medicine practitioners. Some of the above areas are expanded and additional areas (written directives, release of individuals containing unsealed byproduct material, and safety procedures for treatment when patients are hospitalized) are given in order to provide:

(1) All pertinent NRC requirements for the medical use of byproduct material in the practice of therapeutic nuclear medicine. These have been summarized in the interest of space; licensees should read the actual regulations. It should be noted that these are NRC regulations and, as such, may not apply in Agreement States. Nuclear medicine practitioners in Agreement States must contact their respective rulemaking bodies.
(2) A discussion of the requirements; and
(3) Suggested procedures for compliance.

Note: Diagnostic and therapeutic nuclear medicine licensees will need to combine this Chapter and Chapter 9 in the *Guide for Diagnostic Nuclear Medicine* for a comprehensive radiation protection program.

5.1 Occupational Dose Limits

5.1.1 Pertinent Regulations

1. 10 CFR 20.1202 Compliance with requirements for summation of external and internal doses.

If a licensee is required to monitor workers for both external and internal radiation dose under § 20.1502, the licensee must demonstrate compliance with the annual occupational dose limits by summing both contributions.

2. 10 CFR 20.1204 Determination of internal exposure.

If a licensee is required to measure internal dose under § 20.1502 to demonstrate compliance with occupational dose limits, the licensee must take suitable and timely measurements of:

1. Concentrations of radioactive materials in air in work areas; or
2. Quantities of radionuclides in the body; or
3. Quantities of radionuclides excreted from the body; or
4. Combinations of these measurements

3. 10 CFR 20.1502(b) Conditions requiring individual monitoring of internal occupational dose.

Licensees must monitor the occupational intake of radioactive material and assess the committed effective dose equivalent (CEDE) to all of the following individuals:

a. Adults likely to receive an annual intake in excess of 10% of the applicable annual limit on intake (ALI);
b. Minors likely to receive an annual CEDE in excess of 0.1 rem (1 mSv); and
c. Declared pregnant women likely to receive a CEDE in excess of 0.1 rem (1 mSv) during entire pregnancy.

5.1.2 Discussion of the Requirements

Radiation workers can potentially receive radiation doses by two distinct sources: external exposure and internal intake. The total effective dose equivalent (TEDE) concept makes it possible to combine these dose components in assessing

the overall risk to the health of an individual; the TEDE is equal to the sum of the deep-dose equivalent (DDE), due to external exposures, and the committed effective dose equivalent (CEDE), due to internal exposures. These two sources of radiation dose must also be considered for demonstrating compliance with the annual dose limit for any individual organ or tissue, known as the total organ dose equivalent (TODE); the TODE is equal to the sum of the committed dose equivalent (CDE), due to intakes, and the DDE from external radiation sources.

Licensees often decide to monitor all workers who are likely to be exposed to radioactive materials, regardless of the magnitude of the exposure. However, personnel monitoring devices for measurement of external dose are only required for those workers who are likely to receive exposures in excess of the specified threshold of 500 mrem from external radiation sources. Likewise, licensees are also required only to monitor the occupational intakes of those workers who are likely to exceed 10% of the specific annual limit on intake (ALI) or CEDE limit. An intake of activity can occur by ingestion, inhalation, or skin absorption. The likelihood of internal intake by ingestion or inhalation depends on the radionuclide and its chemical and physical form.

If it can be demonstrated by air sampling or calculations that adult radiation workers are not likely to receive an annual intake in excess of 10% of an ALI (i.e., a CEDE per year dose of 500 mrem since the intake of one ALI results in a CEDE of 5 rem), and that minors and declared pregnant women are not likely to receive a CEDE in excess of 100 mrem (i.e., 2% of an ALI), monitoring occupational intakes in these individuals would not be required. Appendix B to Part 20 specifies ALIs (in units of μCi) of radionuclides for occupational exposure. The ALIs in this Appendix are the annual intakes of a given radionuclide which would result in either: (1) a CEDE of 5 rem (stochastic ALI); or (2) a CEDE of 50 rem to an organ or tissue (non-stochastic ALI). However, these ALIs are based on generalized metabolic and biochemical properties and are not recommended for use by therapeutic nuclear medicine licensees. When specific information on the physical and biochemical properties of the radionuclides taken into the body or the behavior of the material in an individual is known, the licensee may use that information to calculate the CEDE (§ 20.1204 (c)).

According to NUREG-1556, Vol. 9, Appendix U, *Release of Patients Administered Radioactive Materials*, an estimate of the maximum likely internal dose (i.e., CEDE) to an individual exposed to a radioactivity source (in rem) from internal exposure can be calculated as:

$$CEDE = Q\,(10^{-6})(DCF)$$

where Q = activity handled (mCi)

10^{-6} = assumed fractional intake
DCF = dose conversion factor (rem/mCi).

A common rule of thumb, or heuristic, is to assume that no more than 1 millionth of the activity being handled will become an intake to an individual working with radioactive material. This rule was developed for cases of worker intakes during normal workplace operations, worker intakes from accidental exposures, and public intakes from accidental airborne releases from a facility. (Note: NRC recommended a value of 10^{-5} without justification except to add a degree of conservatism to the calculation; see further discussion in Chapter 5.4.2.2.) The DCF converts intakes in mCi to an internal CEDE and values are available for both the ingestion and inhalation pathway in EPA Federal Guidance Report No. 11, *Limiting Values of Radionuclide Intake and Air Concentration and Dose Conversion Factors for Inhalation, Submersion, and Ingestion.* These values and the resulting CEDEs are shown in Table 5.1 for the most commonly used radionuclides in therapeutic nuclear medicine:

Table 5.1
Dose Conversion Factors and Resulting CEDEs for Commonly Used Radionuclides in Therapeutic Nuclear Medicine

Radionuclide (Activity [mCi])	Ingestion DCF (rem/mCi) (CEDE [mrem])	Inhalation DCF (rem/mCi) (CEDE [mrem])
^{32}P (4)	0.88 (0.0035)	0.61 (0.0024)
^{89}Sr (4)	0.93 (0.0037)	0.65 (0.0026)
^{90}Y (30)	1.08 (0.032)	0.79 (0.024)
^{131}I (100)	53.28 (5.3)	32.89 (3.3)
^{153}Sm (70)	0.30 (0.021)	0.20 (0.014)

It is important to note that the DCFs used to generate Table 5.1 are accurate for the radionuclide and not necessarily for the radiopharmaceutical for which the intake may occur due to differences in biodistribution. In addition, the fact that all

commercially available preparations of ^{131}I sodium iodide (capsules and liquid) are now stabilized against volatility was not taken into account. Thus, the inhalation CEDE values are overly conservative. Nevertheless, all values of the CEDE, with the exception of those associated with the use of unstabilized ^{131}I, are extremely low and demonstrate that the dose component due to internal intake is not likely to pose any danger for individuals as a result of therapeutic nuclear medicine procedures. For example, the highest estimated CEDE (0.032 mrem) is due to ingestion associated with the use of 30 mCi of ^{90}Y (e.g., use of FDA-approved Zevalin for treatment of patients with non-Hodgkin's lymphoma). In order for an adult worker to exceed the 10%-of-the-ALI threshold (i.e., 500 mrem CEDE) requiring occupational intake monitoring, that individual would have to perform more than 62 of these procedures per day (a minor or declared pregnant woman would have to perform more than 12 procedures per day to exceed the 100 mrem CEDE threshold); certainly an unlikely possibility. It is essential to point out that intakes of ^{131}I in nuclear medicine personnel have been monitored for years without any significant occurrences. This is, no doubt, due to stabilization of the preparations against volatility.

Thus, therapeutic nuclear medicine licensees are not required to monitor the internal component of the occupational radiation dose and can demonstrate compliance with the annual dose limits by monitoring only external exposure. The only possible exception would be in the event that a licensee uses unstabilized ^{131}I in large amounts (e.g., for radiolabeling of antibodies). In this case, an internal dose assessment may be necessary.

5.1.3 Suggested Procedures for Compliance

The model procedures given in the SNM/ACNP *Guide for Diagnostic Nuclear Medicine* should be followed. The types and quantities of radioactive material manipulated for therapeutic medical uses do not provide a reasonable possibility for internal intake by workers, with the possible exception of unstabilized ^{131}I used for radiolabeling antibodies and other agents. Workers using these radiopharmaceuticals should of course perform labeling procedures in a fume hood; in addition, their thyroids should be monitored for radioactivity intake.

For those applicants/licensees using ^{131}I in amounts much greater than 100 mCi (3.7 GBq) or with a frequency of 3 or more treatments of 100 mCi (3.7 GBq) each per week, it may be prudent to measure the quantity of ^{131}I in the body of individuals after working with this radionuclide. This can be accomplished using standard counting techniques over the thyroid gland with a thyroid uptake probe. The bioassay procedure should provide for baseline, routine, emergency, and follow-up measures.

5.2 Radiation Surveys

5.2.1 Pertinent Regulations

1. 10 CFR 35.70 Surveys of ambient radiation exposure rate.

Licensees must survey with a radiation detection survey instrument at the end of each day of use all areas where unsealed byproduct material requiring a written directive was prepared for use or administered.

Licensees do not need to perform these surveys in areas where patients or human research subjects are confined when they cannot be released under § 35.75.

A record of each survey must be retained in accordance with § 35.2070.

5.2.2 Discussion of the Requirements

Licensees are required to perform daily surveys in all areas used for the preparation and administration of radiopharmaceuticals for which a written directive is required. When the licensee administers radiopharmaceuticals requiring a written directive in a patient's room, the licensee is not required to perform a daily survey. Daily radiation surveys are also not required in areas where patients or human research subjects are confined when they cannot be released under § 35.75.

5.2.3 Suggested Procedures for Compliance

The model procedures given in the SNM/ACNP *Guide for Diagnostic Nuclear Medicine* should be followed. In addition, daily surveys must be performed, and their records retained, in all areas used during preparation and administration of radiopharmaceuticals for which a written directive is required. If radionuclide administration occurs in a patient's room, daily surveys are not required. Further, any areas where patients or human research subjects are confined when they cannot be released under § 35.75 are not required to be surveyed. However, area surveys are required before releasing for unrestricted use the room of a patient who had been confined in accordance with § 35.75 (see Chapter 5.5). Patients treated as inpatients for medical reasons, not radiation safety reasons (i.e., those patients that are releasable under § 35.75), generate no special requirements for radiation surveys. Also, rooms occupied by these patients need not be posted with caution signs pursuant to 10 CFR 20.1903(b). These patients are not considered as sources of external exposures.

5.3 Written Directives

5.3.1 Pertinent Regulations

1. 10 CFR 35.27 Supervision.

Licensees must instruct all supervised individuals in the licensee's written directive procedures and require that the supervised individuals follow these procedures.

2. 10 CFR 35.40 Written directives.

A written directive must be dated and signed by an AU before the administration of ^{131}I sodium iodide in amounts greater than 30 μCi (1.11 MBq) or any other therapeutic dosage of unsealed byproduct material.

If, because of the emergent nature of the patient's condition, a delay in order to provide a written directive would jeopardize the patient's health, an oral directive is acceptable. The information contained in the oral directive must be documented as soon as possible in writing in the patient's record. A written directive must be prepared within 48 hours of the oral directive.

The written directive must contain the patient's or human research subject's name and the following information:

(1) For any administration of quantities greater than 30 μCi (1.11 MBq) of ^{131}I sodium iodide: the dosage; or

(2) For any administration of a therapeutic dosage of unsealed byproduct material other than ^{131}I sodium iodide: the radioactive drug, dosage, and route of administration.

A written revision to an existing written directive may be made if the revision is dated and signed by an AU before the administration of the dosage. If, because of the patient's condition, a delay in order to provide a written revision to an existing written directive would jeopardize the patient's health, an oral revision is acceptable. The oral revision must be documented as soon as possible in the patient's record. A revised written directive must be signed by the AU within 48 hours of the oral revision. The licensee must retain a copy of the written directive in accordance with § 35.2040.

3. 10 CFR 35.41 Procedures for administrations requiring a written directive.

For any administration requiring a written directive, the licensee must develop, implement, and maintain written procedures to provide high confidence that:

(1) The patient's or human research subject's identity is verified before each administration; and

(2) Each administration is in accordance with the written directive.

At a minimum, the required written procedures must verify (1) the identity of the individual; and (2) that the administration is in accordance with the written directive. The licensee must retain a copy of the required procedures in accordance with § 35.2041.

5.3.2 Discussion of the Requirements

Licensees must develop, maintain, and implement procedures for dosage administrations that require written directives. Licensees must instruct all supervised individuals in the licensee's written directive procedures and require that the supervised individuals follow these procedures. Written directives must be prepared for any administration of ^{131}I sodium iodide in amounts greater than 30 μCi (1.11 MBq) and for a therapeutic dosage of any other radiopharmaceutical. The written directive must contain the information described in 10 CFR 35.40 and be retained in accordance with 10 CFR 35.2040. The AU physician may indicate a dosage range instead of a single dosage, or a dosage that could deviate by plus or minus a specified percentage. Note that NRC defines prescribed dosage in § 35.2, *Definitions*, as the specified activity or range of activity of unsealed byproduct material.

5.3.3 Suggested Procedures for Compliance

The following procedures can be followed:

1. Written directives must contain the patient's or human research subject's name and (1) for any administration of quantities greater than 30 μCi (1.11 MBq) of ^{131}I sodium iodide: the dosage; or (2) for an administration of a therapeutic dosage other than ^{131}I sodium iodide: the radioactive drug, dosage, and route of administration. It is recommended that the AU physician write the written directive in such a manner as to indicate a range of dosage or a dosage that is allowed to vary by plus or minus a specified percentage. A simple form should be developed with blanks for all the required information to simplify the written directive process.
2. An AU must sign and date a written directive prior to the administration of any therapeutic dosage. A copy of the written directive must be retained. Written directives may also be maintained in patients' charts.
3. Prior to administering a dosage, the patient's or human research subject's identity will be positively verified as the individual named in the written directive. This may be accomplished by examination of the patient's ID

bracelet, hospital ID card, driver's license, social security card, or asking the patient to state their name. It is best to avoid procedures where the patient can answer "yes" or "no".

4. The specific details of the administration will be verified, including the dosage, in accordance with the written directive. All components of the written directive (e.g., radionuclide, total dosage) will be confirmed to be in agreement with the written directive prior to dosage administration. This confirmation should include determination of the dosage and checking the labeled vial or syringe containing the therapeutic dosage.
5. When deviations from the written directive or the established procedures are found, the cause of each deviation and the action required to prevent recurrence should be identified.
6. All supervised individuals will be instructed in and required to follow the written directive procedures.
7. The AU may wish to be present when there is a therapeutic administration. This is also helpful in that if there is a deviation in the written directive, the AU can easily acknowledge and approve the change. This greatly reduces the possibility of medical events because the dose is administered in accordance with the AU's directive regardless of what the written directive says. The AU can later modify the written directive to reflect the change.
8. Conduct periodic reviews to ensure that the written directive procedures are effective.

5.4 Release of Individuals Containing Unsealed Byproduct Material

5.4.1 Pertinent Regulations

1. 10 CFR 35.75 Release of individuals containing unsealed byproduct material or implants containing byproduct material.

Licensees may authorize the release from its control of any individual who has been administered unsealed byproduct material if the TEDE to any other individual from exposure to the released individual is not likely to exceed 0.5 rem (5 mSv).

Licensees must provide the released individual, or the individual's parent or guardian, with instructions, including written instructions, on actions recommended to maintain doses to others as low as is reasonably achievable (ALARA) if the TEDE to any other individual is likely to exceed 0.1 rem (1 mSv).

If the TEDE to a nursing infant or child could exceed 0.1 rem (1 mSv) assuming there were no interruption of breast-feeding, the instructions must also

include (1) guidance on the interruption or discontinuation of breast-feeding; and (2) information on the potential consequences, if any, of failure to follow the guidance.

Licensees must maintain a record of the basis for authorizing patient release in accordance with § 35.2075(a) and a record of instruction provided to a breast-feeding female in accordance with § 35.2075(b).

5.4.2 Discussion of the Requirements

NRC regulations (10 CFR 35.75) for the release of patients administered radioactive material authorize patient release according to a dose-based limit, i.e., the dose to other individuals exposed to the patient. The dose-based limit, which replaces the previous activity- or dose-rate based release limit (<30 mCi or <5 mrem/h at one meter), better expresses the NRC's primary concern for the public's health and safety. A licensee may now release patients if the total effective dose equivalent (TEDE) to another individual from exposure to a released patient is not likely to exceed 0.5 rem (5 mSv). Compliance with this dose limit has been demonstrated by licensees by either using a default table for activity or dose rate provided in NUREG-1556, Volume 9, which supercedes Regulatory Guide 8.39, or performing a patient-specific dose calculation. A regulatory analysis on the new dose-based limit concludes that it is safe according to standard radiation protection principles, results in less hospitalization, thus significantly reducing national health care costs, and also has personal and psychological benefits for the patients and their families (Schneider S, McGuire SA. Regulatory analysis on criteria for the release of patients administered radioactive material. NUREG-1492 (Final Report). Washington, DC: U. S. Nuclear Regulatory Commission; 1996).

In addition to demonstrating compliance with the 0.5 rem (5 mSv) TEDE limit, the licensee must:

1. Provide written instructions to the released patient, or the patient's parent or guardian, on actions recommended to maintain doses to other individuals as low as reasonably achievable (ALARA) if the TEDE to any other individual is likely to exceed 0.1 rem (1 mSv). These instructions must also include guidance on interruption or discontinuation of breast-feeding and information on the potential consequences, if any, of failure to follow this guidance if the dose to a breast-feeding infant or child could exceed 0.1 rem (1 mSv).

2. Maintain records according to § 35.2075(a), for 3 years after date of patient release, documenting the basis for patient release, if the TEDE is calculated by:

a. Using retained activity rather than the activity administered;
b. Using an occupancy factor less than 0.25 at 1 meter;
c. Using the biological or effective half-life; or
d. Considering the shielding by tissue (i.e., using measured dose rate).

3. Maintain records according to § 35.2075(b), for 3 years after date of patient release, documenting that instruction was provided to breast-feeding women if radiation dose to infant or child from continued breast-feeding could result in a TEDE exceeding 0.5 rem (5 mSv).

5.4.2.1 External Dose Component

The following equation can be used to estimate the dose an individual is likely to receive from exposure to a released patient:

$$D(\infty) = (34.6\ \Gamma\ Q_0\ T_p\ E) / r^2 \qquad (1)$$

where,

$D(\infty)$ = total dose in mrem from exposure to gamma radiation,
Γ = exposure rate constant (mR cm^2/mCi h),
Q_0 = administered activity in mCi,
T_p = physical half-life of radionuclide in days,
E = occupancy factor at 1 m = 0.25, and
r = distance from patient = 1 m = 100 cm.

This "patient-release" equation, which is based on the physical half-life of the radionuclide (i.e., no biological elimination is assumed), is essentially the same as introduced in 1970 by NCRP Report No. 37 (National Council on Radiation Protection and Measurements. NCRP Report No. 37, *Precautions in the Management of Patients Who Have Received Therapeutic Amounts of Radionuclides*, NCRP Report No. 37. Bethesda, Maryland: National Council on Radiation Protection and Measurements; 1970) with the exception of the occupancy factor. The selection of an occupancy factor of 0.25 at 1 meter is based on the professional judgment of time-distance combinations that are believed likely to occur when appropriate instructions are given to minimize time spent close to the patient.

Using the various half-lives and exposure rate constants for the radionuclides commonly employed in radionuclide therapy, Equation 1 can be used to determine the maximum allowable administered activities and/or dose rates at 1 m

for authorizing patient release based on the 0.5 rem (5 mSv) TEDE limit pursuant to § 35.75(a).

Release Based on Administered Activity

$$Q_0 \text{ (mCi)} < D(\infty)\, r^2 / (34.6\, \Gamma\, T_p\, E) < 578034.7 / (\Gamma\, T_p) \qquad (2)$$

Release Based on Measured Dose Rate at 1 m

Since dose rate at 1 m (DR) = $(\Gamma\, Q_0) / r^2$,

$$DR \text{ (mrem/h)} < D(\infty) / (34.6\, T_p\, E) < 57.8 / T_p \qquad (3)$$

The appropriate parameters and release activities and dose rates for the most commonly used radionuclides in therapeutic nuclear medicine are given in Table 5.2.

Table 5.2
Maximum Activities and Dose Rates for Authorizing Patient Release

Radionuclide	Half-Life (days)	Γ (mR cm^2/mCi h)	Activity (mCi)	Dose Rate (mrem/h)
^{32}P	14.29	4.05*	9988	4.0
^{89}Sr	50.5	3.14*	3645	1.1
^{90}Y	2.67	5.64*	38,385	21.6
^{131}I	8.04	2200	33	7.2
^{153}Sm	1.946	425	699	29.7

* NRC in NUREG-1556, Vol. 9 does not determine activity and dose rate limits for beta emitters "because of the minimal exposures to members of the public resulting from activities normally administered for diagnostic or therapeutic

purposes." The exposure rate constants given in Table 5.2 for the pure beta-emitting radionuclides ^{32}P, ^{89}Sr, and ^{90}Y are specific bremsstrahlung constants (Zanzonico PB, Binkert BL, Goldsmith SJ. Bremsstrahlung radiation exposure from pure β-ray emitters. J Nucl Med 1999; 40:1024-1028).

In compliance with the dose limit in 10 CFR 35.75(a), licensees may release patients from their control if the activity administered or measured dose rate at 1 m is no greater than the values given in Table 5.2. If release is based on administered activity, no record is required. If release is based on measured dose rate, a record is required because the release is based on considering shielding by tissue. Patient instructions are only required if the TEDE to individuals is likely to exceed 0.1 rem (1 mSv). This would correspond to 1/5 of the values in Table 5.2, since these values were determined based on a TEDE of 0.5 rem (5 mSv). For example, it is easily determined that the activity values to ensure that individuals exposed to the patient are not likely to receive a dose exceeding 0.1 rem (1 mSv) from ^{32}P, ^{89}Sr, ^{90}Y, ^{131}I, and ^{153}Sm are 1998 mCi, 729 mCi, 7677 mCi, 7 mCi, and 140 mCi, respectively. Since patients will be administered activities less than these values, with the exception of patients receiving ^{131}I, all patients receiving pure beta-emitting radionuclides or ^{153}Sm for radionuclide therapy are releasable; no records or instructions are required.

The release approach taken thus far has utilized the physical half-life, but not the effective half-life, of the radionuclide. This is reasonable for the beta-emitting radionuclides and ^{153}Sm, but is inappropriate for ^{131}I sodium iodide. Therapy patients receiving ^{131}I do not retain radioactivity for the physical half-life of the radionuclide; rather, the administered activity is rapidly excreted.

As a result, patient-specific dose calculations should be performed for ^{131}I therapy patients to provide a more complete and appropriate estimation of dose to individuals likely to be exposed to the patient. These calculations may involve the use of any of the following four patient-specific factors:

1. Retained Activity
2. Occupancy or Exposure Factor (E) less than 0.25 at 1 meter
3. T_{eff} or T_b (i.e., measured biological elimination)
4. Attenuation/Shielding by Tissue (i.e., measured dose rate).

It should be noted that NRC has stated that in those instances for which a case-specific calculation applies to more than one patient release, the calculation need not be performed again. The record for a particular patient's release could reference the calculation done for the class of patients.

Release of Patients Administered ^{131}I Sodium Iodide for Treatment of Thyroid Cancer and Hyperthyroidism

Equation 1 was modified in NUREG-1556, Vol.9, Appendix U, Model Procedure for Release of Patients or Human Research Subjects Administered Radioactive Materials, in Supplement B, to account for the uptake and retention of the radionuclide by the patient in both the thyroid and the remainder of the body (i.e., thyroidal and extrathyroidal terms). The modification also included a term to account for the fact that during the initial hours following administration of the radiolabeled material, the patient may not void and the activity is therefore not removed from the body. The following equation was used:

$$D(\infty) = [34.6\,\Gamma\,Q_0]/(100\text{ cm})^2\,\{\,E_1T_p(0.8)(1 - e^{-0.693(T_{NV})/T_p}) + e^{-0.693(T_{NV})/T_p}\,E_2F_1T_{1eff} + e^{-0.693(T_{NV})/T_p}\,E_2F_2T_{2eff}\,\} \qquad (4)$$

where:

E_1 = occupancy factor for nonvoid period = 0.75;
T_{NV} = nonvoid period in days = 0.33 (8 hours);
E_2 = occupancy factor from 8 hours to total decay = 0.25;
F_1 = extrathyroidal uptake fraction = 0.20 in hyperthyroid patients; = 0.95 in thyroid cancer patients;
T_{1eff} = effective half-life of extrathyroidal component = 0.32 days in hyperthyroid patients; = 0.32 days in thyroid cancer patients;
F_2 = thyroidal uptake fraction = 0.80 in hyperthyroid patients; = 0.05 in thyroid cancer patients; and
T_{2eff} = effective half-life of thyroidal component = 5.2 days in hyperthyroid patients; = 7.3 days in thyroid cancer patients.

Equation 4 can be solved for the maximum allowable administered activities and dose rates at 1 m for authorizing patient release based on the 0.5 rem (5 mSv) TEDE limit. These values are given in Table 5.3 for occupancy factors (E_2) of 0.25 and 0.125.

Table 5.3
Maximum activities and dose rates at 1 m for authorizing patient release for thyroid cancer and hyperthyroid patients (based on NUREG-1556, Vol. 9)

Releasable Activity (mCi)			Releasable Dose Rate (mrem/h)		
E_2 =	0.25	0.125	E_2 =	0. 25	0.125
Thyroid cancer	221	303	Thyroid cancer	48.5	66.7
Hyperthyroidism	57	101	Hyperthyroidism	12.4	22.3

E_2 = Occupancy factor from 8 h to total decay; an occupancy factor of 0.125 must be justified (e.g., patient lives alone and expects no visitors).

Licensees can use the values in Table 5.3 as their basis for patient release. These values for activity and dose rate at 1 m can be applied to all patients. As previously stated, individual patient-specific dose calculations need not be performed for thyroid cancer and hyperthyroid patients.

This approach is highly conservative and unnecessarily restrictive. It must be noted that several assumptions were made in assigning values to the parameters used in Equation 4 in determining patient release activities and dose rates. These include:

(1) Use of the exposure rate constant, which is a point source in air value;
(2) Use of an 8-hour nonvoid period;
(3) Use of an occupancy factor of 0.75 during nonvoid period; and
(4) Use of representative values for uptake fractions and effective half-lives for thyroidal and extrathyroidal components.

Licensees may therefore choose to perform more realistic calculations and not use Table 5.3. Dose rates should be measured and allowable release limits should not be based on the use of an exposure rate constant which does not account for radionuclide distribution and patient attenuation. To account for distribution and attenuation of ^{131}I in the patient, for example, a value of 1700 mR cm^2/mCi h should be used in place of the value of 2200 given in Table 5.2 (Carey JE, Kumpuris TM, Wrobel MC. Release of patients containing therapeutic dosages of iodine-131 from hospitals. J Nucl Med Technol 1995; 23:144-149). Smaller values for the nonvoid period (0 to 1 hour for well hydrated patients) are justified and could be used; similarly, an occupancy factor (E_1) of 0.25 could be used for the nonvoid period, if any. Lastly, licensees may wish to measure the biokinetics in an individual patient to get better values for the uptake fractions and effective half-times. Use of any of these more patient-specific approaches will permit less conservative release limits, if so desired.

For example, using Equation 4, but now with an exposure rate constant corrected for attenuation equal to 1700 mR cm^2/mCi h, a nonvoid period of 1 hour and an occupancy factor of 0.25 during this period, the maximum allowable activities and dose rates for authorizing patient release are given in Table 5.4.

Table 5.4
Maximum activities and dose rates at 1 m for authorizing patient release for thyroid cancer and hyperthyroid patients (based on SNM/ACNP)

Releasable Activity (mCi)			Releasable Dose Rate (mrem/h)		
E_2 =	0.25	0.125	E_2 =	0. 25	0.125
Thyroid cancer	493	954	Thyroid cancer	83.8	162.2
Hyperthyroidism	80	160	Hyperthyroidism	13.7	27.2

Licensees can use the values in Table 5.4 as their basis for patient release. The maximum activity and dose rate values are higher in Table 5.4 than in Table 5.3 due to the use of less conservative and more realistic parameter values in Equation 4.

The usual instructions given to patients released under the old regulations should be given to these higher activity releasable patients; however, these instructions should be in place for a longer period of time. In 1987, the Society of Nuclear Medicine, in collaboration with NRC, published a pamphlet, *Guidelines for Patients Receiving Radioiodine Treatment*, that provided information for patients receiving treatment with radioiodine. The NRC still considers the instructions in this pamphlet to be acceptable provided the times given for the instructions are appropriate for the activity and medical condition.

However, today radioactive articles in the household trash of nuclear medicine patients are appearing at solid waste landfills that have installed radiation monitors to prevent the entry of any detectable radioactivity, and alarms are going off around the country. These monitors are set to alarm at extremely low activity levels (Siegel JA, Sparks RB. Radioactivity appearing at landfills in household trash of nuclear medicine patients: Much ado about nothing? Health Phys. 2002; 82:367-372). Even though the NRC has stated that the low activity levels potentially contained in any radioactive household waste of patients released in accordance with § 35.75 pose an insignificant hazard to the public health and safety or to the environment, nuclear medicine professionals can take steps in order to avoid issues with landfill owners and operators and even individual States. It is probably wise to instruct patients to avoid or minimize use of items that cannot be disposed of via plumbing (e.g., toilet, sink, dishwasher, washing machine), such as plastic utensils and paper plates.

There are many references available to help guide the nuclear medicine practitioner in the performance of a patient-specific dose calculation for patients receiving ^{131}I sodium iodide, as well as ^{131}I labeled monoclonal antibodies, and in the issuance of release instructions to such radionuclide therapy patients. These include:

(1) Siegel JA. Outpatient radionuclide therapy. In, *Radiation Protection in Medicine: Contemporary Issues*. Proceedings of the Thirty-Fifth Annual Meeting of the National Council on Radiation Protection and Measurements, Proceedings No. 21. National Council on Radiation Protection and Measurements; 1999, pp 187-199.
(2) Zanzonico PB, Siegel JA, St. Germain J. A generalized algorithm for determining the time of release and the duration of post-release radiation precautions following radionuclide therapy. Health Phys. 2000; 78:648-659.
(3) Siegel JA, Kroll S, Regan D, Kaminski MS, Wahl RL. A practical methodology for patient release after tositumomab and ^{131}I-tositumomab therapy. J Nucl Med. 2002; 43:354-363.
(4) Siegel JA, Marcus CS, Sparks RB. Calculating the absorbed dose to others from the radioactive patient: Line source model versus point source model. J Nucl Med. 2002; 43:1241-1244.
(5) Marcus CS. Considerations in determining whether or not patients may be given significant quantities of radiopharmaceuticals as outpatients. Accessed through California Chapter of ACNP web site at http://www.acnp-cal.org/radiopharmaceuticals.html.

5.4.2.2 Internal Dose Component

So far the TEDE has been assumed to be due exclusively to the external radiation dose. The internal radiation dose component, referred to as the committed effective dose equivalent (CEDE), has not been considered. It must be pointed out NRC regulations do not require determination of the internal dose contribution if it is likely to be less than 10 percent of the external dose.

A common rule of thumb is to assume that no more than 1 millionth of the activity being handled will become an intake to an individual working with the material. This rule of thumb, or heuristic, was developed for cases of worker intakes during normal workplace operations, worker intakes from accidental exposures, and public intakes from accidental airborne releases from a facility (Brodsky A. Resuspension factors and probabilities of intake of material in process (or "Is 10^{-6} a magic number in health physics?"). Health Phys 1980; 39:992-1000), but it does not specifically apply for cases of intake by an individual exposed to a patient. There are limited data for thyroid uptakes in

family members exposed to $Na^{131}I$ patients. Two studies (Buchan RCT, Brindle JM. Radioiodine therapy to out-patients - the contamination hazard. Br J Radiol 1970: 43:479-482 and Jacobson AP, Plato PA, Toeroek D. Contamination of the home environment by patients treated with iodine-131: initial results. Am J Public Health 1978; 68:230-235) regarding the intakes of individuals exposed to patients administered ^{131}I indicated that intakes were generally on the order of 1 millionth of the activity administered to the patient and that internal doses were far below external doses; the *maximum* observed fractional internal intake for these two studies was 0.2×10^{-5} and 0.4×10^{-5}, respectively.

According to NUREG-1556, Vol. 9, Appendix U, an estimate of the maximum likely CEDE from internal exposure can be calculated according to:

$$CEDE = Q\,(10^{-6})(DCF) \qquad (5)$$

where CEDE = Maximum likely internal committed effective dose equivalent to the individual exposed to the patient in rem
Q = Activity administered to the patient in mCi
10^{-6} = Assumed fractional intake
DCF = Dose conversion factor to convert an intake in mCi to an internal committed effective dose equivalent, equal to 53 rem/mCi for $Na^{131}I$ (Eckerman KF, Wolbarst AB, Richardson ACB. *Limiting Values of Radionuclide Intake and Air Concentration and Dose Conversion Factors for Inhalation, Submersion, and Ingestion.* Federal Guidance Report No. 11, U. S. Environmental Protection Agency, Washington, DC, 1988)

Note: NRC recommended a value of 10^{-5} for the assumed fractional intake to account for the most highly exposed individual and to add a degree of conservatism to the calculation. However, no such "highly exposed" individual has been found and there is no documentation to substantiate that this conservative approach is advisable, necessary, or accurate.

Example: Using the ingestion pathway, calculate the maximum internal dose to a person exposed to a patient who has been administered 200 mCi of ^{131}I sodium iodide.

Substituting the appropriate values into Equation 5, the maximum internal dose to the exposed individual is:

$$CEDE = (200\text{ mCi})(10^{-6})(53\text{ rem/mCi}) = 10.6\text{ mrem}$$

In this case, the internal dose is 10.6 mrem; therefore, the external dose to any exposed individual must be no greater than 489.4 mrem (500 mrem - 10.6 mrem). In order to be less than 10% of the external gamma dose and to maintain the TEDE to less than 500 mrem, the CEDE must be less than 45 mrem (even if the maximum observed fractional intake of 4×10^{-6} was used in the calculation, the resulting CEDE of 42.4 mrem is within the 45 mrem limit). Since the internal dose is likely to be less than 10 percent of the external gamma dose it need not be taken into account in the calculations for patient release.

The NCRP addressed the risk of intake of radionuclides from patients' secretions and excreta in NCRP Commentary No. 11, *Dose Limits for Individuals who Receive Exposure from Radionuclide Therapy Patients* and concluded, "Thus, a contamination incident that could lead to a significant intake of radioactive material is very unlikely."

5.4.3 Suggested Procedures for Compliance

Licensees can authorize patient release after radionuclide therapy using the activity and/or dose rate limits given in Table 5.2 for beta-emitting radionuclides and ^{153}Sm and Table 5.3 for ^{131}I sodium iodide for the treatment of hyperthyroidism and thyroid cancer. For the latter patients, a licensee may choose instead to use the more liberal maximum activity and dose rate values for authorizing patient release given in Table 5.4. The values of activity and dose rate in these Tables can be applied to all patients, i.e., the case-specific calculations performed to generate these Tables apply to more than one patient release. The record for a particular patient's release could reference the calculation done for the class of patients. Records must be kept if the basis for authorizing patient release involves Tables 5.3 and 5.4. Records are not required for patients receiving beta-emitting radionuclides or ^{153}Sm EDTMP. Note: Make sure that the appropriate occupancy factor is being used; generally this value can be set at 0.25. If an occupancy factor less than 0.25 is used (e.g., 0.125), it must be justified and recorded. Licensees may use occupancy factors greater than 0.25 (e.g., 0.5), if appropriate for a particular patient's release, without the need for recordkeeping.

Any patients not releasable in accordance with § 35.75 must be hospitalized (see Chapter 5.5).

For ^{131}I sodium iodide as well as other ^{131}I labeled radiopharmaceuticals, the nuclear medicine practitioner may also use the references cited in Chapter 5.4.2.1 as a guide in implementing even more patient-specific release limits, if so desired. The internal dose component does not have to be taken into account; the TEDE is due almost entirely to the external dose component.

Patient instructions, if required (no regulatory requirement to give instructions for patients receiving beta-emitters or ^{153}Sm), may include:

(1) Maintaining distance from other individuals;
(2) Separate sleeping arrangements;
(3) Minimizing time in public places;
(4) Precautions to reduce spread of radioactive contamination (control of body fluid contamination is an important concern for ^{131}I sodium iodide; it is much less problematic for the beta-emitting radionuclides and ^{153}Sm EDTMP);
(5) Precautions to reduce likelihood of radioactive household trash appearing at solid waste landfills (at least until the landfill issue is resolved); and
(6) Length of time each of the instructions should be in effect.

The AU physician must be professionally satisfied that patient compliance with any instructions is highly likely before authorizing patient release.

It is generally best to stop lactation in any patient given ^{131}I sodium iodide. Stopping lactation for 3 weeks is sufficient to ensure cessation of milk production and no extra radiation absorbed dose to the breasts after treatment. In the event that a radiation dose to an infant needs to be calculated because of radioactive breast milk ingestion, we recommend using the publication by Stabin and Breitz (J Nucl Med. 2000; 862-873).

Breast-feeding patients should not receive radionuclide therapy. If the patient is breast-feeding, additional instructions should include appropriate recommendations on whether to interrupt breast-feeding and the length of time to interrupt breast-feeding, or, if necessary, the discontinuation of breast-feeding. The instructions should include information on the consequences, if any, of failure to follow the breast-feeding guidance. Licensees should note that the required instructions are not in any way intended to interfere with the discretion and judgment of the physician in specifying the detailed instructions and recommendations.

5.5 Safety Procedures for Treatment When Patients Are Hospitalized

5.5.1 Pertinent Regulations

1. 10 CFR 20.1301 Dose limits for individual members of the public.

The TEDE to individual members of the public must not exceed 0.1 rem (1 mSv) in a year and the dose in any unrestricted area from external sources must not exceed 2 mrem (0.02 mSv) in any 1 hour. (Note: The yearly dose limit does not include exposure from radionuclide therapy patients who are released in accordance with § 35.75 and these patients are not regarded as "external sources.")

A licensee may permit visitors to an individual who cannot be released, under § 35.75, to receive a radiation dose greater than 0.1 rem (1 mSv) if (1) the radiation dose received does not exceed 0.5 rem (5 mSv); and (2) the authorized user has determined before the visit that it is appropriate.

2. 10 CFR 20.1302 Compliance with dose limits for individual members of the public.

A licensee must make or cause to be made, as appropriate, surveys of radiation levels in unrestricted and controlled areas to demonstrate compliance with the dose limits for individual members of the public in § 20.1301.

3. 10 CFR 20.1501 General.

A licensee must make or cause to be made surveys that (1) may be necessary to comply with applicable Part 20 regulations; and (2) are reasonable under the circumstances to evaluate the magnitude and extent of radiation levels.

4. 10 CFR 35.315 Safety precautions.

For each patient or human research subject who cannot be released under § 35.75, licensees must:

(1) Quarter the patient or human research subject either in:
  (i) A private room with a private sanitary facility; or
  (ii) A room with a private sanitary facility, with another individual who also has received therapy with unsealed byproduct material and who also cannot be released under § 35.75;
(2) Visibly post the individual's room with a "Radioactive Materials" sign.
(3) Note on the door or in the individual's chart where and how long visitors may stay in the room; and
(4) Either monitor material and items removed from the room to determine that their radioactivity cannot be distinguished from natural background levels with a radiation detection survey instrument set on its most sensitive scale and with no interposed shielding, or handle the material and items as radioactive waste.

Licensees must notify the RSO or designee, and the AU as soon as possible if the patient or human research subject has a medical emergency or dies.

5.5.2 Discussion of the Requirements

Certain radionuclide therapy patients may have to be hospitalized for a variety of reasons (e.g., live in a small dwelling with children, not likely to follow instructions). Licensees must develop and implement procedures to ensure that in the event that a radionuclide therapy patient cannot be released in accordance with

§ 35.75, access to treatment rooms can be restricted and exposure rates from confined patients are limited to maintain doses to occupational workers and members of the public within regulatory limits.

Licensees are required under 10 CFR 20.1501 to perform adequate surveys to evaluate the magnitude and extent of radiation levels. Therefore, licensees must evaluate the exposure rates around patients who are hospitalized following the dosage administration (e.g., measured exposure rates, combination of measured and calculated exposure rates). In order to control exposures to individuals in accordance with 10 CFR Part 20, the licensee should also consider: briefing patients on radiation safety procedures, limiting room access and visitor control, notification of medical staff in the event of problems, and other items as applicable and consistent with good medical care. Safety instruction must be given to personnel caring for patients or human research subjects who cannot be released under § 35.75 (see Chapter 5.8).

Regulatory requirements, the ALARA principle, good medical care, and access control should be considered when determining the location of the therapy patient's room. A corner room, for example, will keep dose rate concerns to a minimum in surrounding areas. It may be desirable for the designated therapy rooms to be on the same floor to minimize any potential problems and training efforts.

A licensee cannot legally force a patient who is required to be hospitalized after therapy to remain in the hospital. While not required, the licensee may choose to contact the NRC and/or the appropriate state regulatory agency if the patient leaves against medical advice (AMA).

5.5.3 Suggested Procedures for Compliance

For patients who cannot be released under 10 CFR 35.75, applicants must take the following steps:

- Provide a room with a private sanitary facility for patients treated with a radiopharmaceutical therapy dosage (note: the room may be shared with another radiopharmaceutical therapy patient);
- Visibly post a "Radioactive Materials" sign on the patient's room and note on the door or in the patient's chart where and low long visitors may stay in the patient's room;
- Either monitor material and items removed from the patient's room (e.g., linens, surgical dressings) with a radiation detection survey instrument set on its most sensitive scale with no interposed shielding to determine that their radioactivity cannot be

distinguished from the natural background radiation level or handle them as radioactive waste; and

- Notify the RSO, or their designee, and AU as soon as possible if the patient has a medical emergency or dies.

A licensee may permit visitors to an individual who cannot be released, under § 35.75, to receive a radiation dose greater than 0.1 rem (1 mSv) if (1) the radiation dose received does not exceed 0.5 rem (5 mSv); and (2) the authorized user has determined before the visit that it is appropriate.

Licensees are required to perform adequate surveys to evaluate the magnitude and extent of radiation levels. Therefore, licensees should evaluate the exposure rates around patients who are hospitalized either by measured exposure rates or by combination of measured and calculated exposure rates. The therapy rooms could also be "pre-evaluated" by placing a typical dosage at various locations in the room (e.g., on the empty bed, in the bathroom) and measuring the surrounding area dose rates, thereby alleviating the need to perform surveys for every patient.

Licensees must also perform surveys prior to the release of the room for unrestricted use. Licensees should be cognizant of the requirement to perform surveys to demonstrate that public dose limits are not exceeded. The TEDE to an individual member of the public must not exceed 0.1 rem (1 mSv) in a year and the dose in any unrestricted area from external sources must not exceed 2 mrem (0.02 mSv) in any one hour. The surveys required prior to releasing the hospital room of a confined radionuclide therapy patient for use by other patients must demonstrate compliance with these public dose limits. In order to minimize potential contamination and to facilitate cleanup, if required based on radiation surveys, licensees may wish to cover appropriate areas of the room with absorbent paper, or other suitable covering, prior to patient dosage administration.

Licensees should know what steps to take if a therapy patient undergoes emergency surgery or dies. In this case, it is necessary to ensure the safety of others attending the patient. As long as the patient's body remains unopened, the radiation received by anyone in close proximity is due almost entirely to gamma radiation. The simple principles of time, distance, and shielding can be used to minimize potential exposures. When an operation or autopsy is to be performed, radiation dose to the hands and face is also possible due to beta emissions and avoidance of radiation contamination should be considered. Double thicknesses of surgical gloves or heavy rubber autopsy gloves may be used to reduce hand exposure due to beta emissions. Procedures for emergency surgery or death can be found in Chapter 5 of NCRP Report No. 37, *Precautions in the Management of Patients Who Have Received Therapeutic Amounts of Radionuclides*."

5.6 Records

5.6.1 Pertinent Regulations

1. 10 CFR 35.2040 Records of written directives.

Licensees must retain a copy of each written directive for 3 years.

2. 10 CFR 35.2041 Records for procedures for administrations requiring a written directive.

Licensees must retain a copy of their procedures for administrations requiring a written directive for the duration of the license.

3. 10 CFR 35.2070 Records of surveys for ambient radiation exposure rate.

Records of each survey required by § 35.70 must be retained for 3 years. The records must include the date of the survey, the results of the survey, the instrument used to make the survey, and the name of the individual who performed the survey.

4. 10 CFR 35.2075 Records of the release of individuals containing unsealed byproduct material or implants containing byproduct material.

Records of the basis for authorizing the release of an individual must be retained if the TEDE is calculated by: (1) using the retained activity rather than the activity administered; (2) using an occupancy factor less than 0.25 at 1 meter; (3) using the biological or effective half-life; or (4) considering the shielding by tissue. Records must also be retained, if applicable, indicating that instructions were provided to a breast-feeding female if the radiation dose to the infant or child from continued breast-feeding could result in a TEDE exceeding 0.5 rem (5 mSv). All records must be retained for 3 years after the date of release of the individual.

5. 10 CFR 35.2310 Records of safety instruction.

Records of safety instructions required by § 35.310 must be maintained for 3 years and must include, for each instruction session, a list of the topics covered, the date of the instruction, the name(s) of the attendee(s), and the name(s) of the individuals(s) who provided the instruction.

5.6.2 Discussion of the Requirements

The required records are self-explanatory.

5.6.3 Suggested Procedures for Compliance

Licensees should be able to easily develop forms for each of the required records based on the information in this section. Each required record must be legible throughout the specified retention period. The licensee must maintain adequate safeguards against tampering with and loss of these records.

5.7 Reports

5.7.1 Pertinent Regulations

Reports required pursuant to 10 CFR Parts 35.3045 and 35.3047 were discussed in the SNM/ACNP *Guide for Diagnostic Nuclear Medicine*, but are reproduced here for emphasis.

1. 10 CFR 20.2201 Reports of theft or loss of licensed material.

Licensees must notify the NRC Operation Center by telephone (301-951-0550):

1. Immediately after the occurrence of any lost, stolen, or missing licensed material becomes known in a quantity equal to or greater than 1000 times that specified in Appendix C to Part 20 under such circumstances that it appears to the licensee that an exposure could result to persons in unrestricted areas; or
2. Within 30 days after the occurrence of any lost, stolen, or missing licensed material becomes known in a quantity greater than 10 times that specified in Appendix C to Part 20.

Quantities for the most commonly used radionuclides used in therapeutic nuclear medicine are given in Table 5.5.

Table 5.5
Quantities of Most Common Therapy Radionuclides
to be Reported to NRC if Lost or Stolen

Radionuclide	Quantity (mCi) x1000	Quantity (mCi) x10
^{32}P	10	0.1
^{89}Sr	10	0.1
^{90}Y	10	0.1
^{131}I	1	0.01
^{153}Sm	100	1

Within 30 days after the telephone report, a written report must be made to the administrator of the appropriate NRC Regional Office, containing the following information: description of the licensed material involved, description of the circumstances under which the loss or theft occurred, statement of disposition or probable disposition of licensed material involved, exposures of individuals to radiations, actions that have been taken to recover the material, and procedures that have been adopted to ensure against a recurrence of the loss or theft. Names of individuals who may have received exposure to radiation must be stated in a separate and detachable part of the report.

2. 10 CFR 35.3045 Report and notification of a medical event.

A licensee must report any event, except for an event resulting from patient intervention, in which the administration of licensed material results in:

1. A dose that differs from prescribed dosage by more than 5 rem EDE, 50 rem to an organ or tissue, or 50 rem shallow dose equivalent to the skin; and the total dosage delivered differs from prescribed dosage by 20% or more or falls outside prescribed dosage range; or
2. A dose that exceeds 5 rem EDE, 50 rem to an organ or tissue, or 50 rem shallow dose equivalent to the skin from any of the following: administration of wrong radioactive drug; administration of radioactive drug by wrong route of administration; administration of dosage to wrong individual or human research subject; or a leaking sealed source.

A licensee must report any event resulting from intervention of a patient or human research subject in which the administration of licensed material will result in unintended permanent functional damage to an organ or a physiological system, as determined by a physician. (Patient intervention means actions by the patient or human research subject, whether intentional or unintentional, such as dislodging or removing treatment devices or prematurely terminating the administration.)

A licensee must notify the NRC Operations Center by telephone no later than the next calendar day after discovery of the medical event. A written report must be submitted to the appropriate NRC Regional Office within 15 days and must include: licensee's name; name of prescribing physician; brief description of event; why event occurred; effect, if any, on individual(s) who received the administration; actions taken, if any, to prevent recurrence; and certification that

licensee notified the individual (or responsible relative or guardian), and if not, why not. The report may not contain any information that could lead to identification of the individual. The licensee must also provide an annotated copy of the report to the referring physician no later than 15 days after the discovery of the event with the name of the affected individual and their social security number or other identification number.

A licensee must provide notification of the event to the referring physician and also notify the involved individual no later than 24 hours after discovery of the event, unless the referring physician personally informs the licensee either that he or she will inform the individual or that, based on medical judgment, telling the individual would be harmful. The licensee is not required to notify the individual without first consulting the referring physician. If the referring physician or affected individual cannot be reached within 24 hours, the licensee must notify the individual as soon as possible thereafter (if necessary, notification may be made to responsible relative or guardian). The licensee may not delay any appropriate medical care for the individual. If a verbal notification is made, the licensee must inform the individual that a written description of the event can be obtained upon request.

Aside from notification, nothing in this requirement affects any rights or duties of licensees and physicians in relation to each other, to individuals affected by the medical event, or to that individual's responsible relatives or guardians.

3. 10 CFR 35.3047 Report and notification of a dose to an embryo/fetus or a nursing child.

A licensee must report any dose to an embryo/fetus that is greater than 5 rem dose equivalent that is a result of an administration of byproduct material to a pregnant individual unless the dose was specifically approved, in advance, by the authorized user.

A licensee must report any dose to a nursing child that is a result of an administration of byproduct material to a breast-feeding woman that is greater than 5 rem TEDE or has resulted in unintended permanent functional damage to an organ or a physiological system of the child, as determined by a physician.

Notification consists of first telephoning the NRC Operations Center no later than the next calendar day after discovery of the event followed by a written report to the appropriate NRC Regional Office within 15 days that includes: licensee's name; name of prescribing physician; brief description of event; why event occurred; effect, if any, on embryo/fetus or nursing child; actions taken, if any, to prevent recurrence; and certification that licensee notified pregnant individual or mother (or responsible relative or guardian), and if not, why not. The report must not contain any information that could lead to identification of the individual or child. The licensee must also provide an annotated copy of the report

to the referring physician no later than 15 days after the discovery of the event with the name of the pregnant individual or the nursing child and their social security number or other identification number.

A licensee must provide notification of the event to the referring physician and also notify the pregnant individual or mother (both hereafter referred to as the mother), no later than 24 hours after discovery of the event, unless the referring physician personally informs the licensee either that he or she will inform the mother or that, based on medical judgment, telling the mother would be harmful. The licensee is not required to notify the mother without first consulting with the referring physician. If the referring physician or mother cannot be reached within 24 hours, the licensee must make the appropriate notifications as soon as possible thereafter (if necessary, notification may be made to a responsible relative or guardian). The licensee may not delay any appropriate medical care for the embryo/fetus or for the nursing child. If a verbal notification is made, the licensee must inform the mother that a written description of the event can be obtained upon request.

5.7.2 Discussion of the Requirements

The required reports are self-explanatory. The reporting requirements under § 20.2201 appear to be overly conservative and ambiguous. For example, licensees must notify NRC immediately after discovery that 1 mCi (37 MBq) of ^{131}I is lost, stolen, or missing "under such circumstances that it appears to the licensee that an exposure could result to persons in unrestricted areas." The degree of exposure is not specified. Licensees must also notify NRC within 30 days if 10 μCi (370 kBq) of ^{131}I is lost, stolen, or missing.

5.7.3 Suggested Procedures for Compliance

Licensees should be able to easily develop forms for each of the required reports based on the information in this section. It is anticipated that the reporting of some of these events (e.g., medical events and unauthorized medical exposure of embryo/fetus) will be rare occurrences, but could occur. Permanent functional damage to an organ, i.e., the thyroid, is also highly likely with ^{131}I sodium iodide. A functioning thyroid exists in an embryo/fetus at approximately 12 weeks gestation.

5.8 Safety Instruction for Workers and Personnel

5.8.1 Pertinent Regulations

1. 10 CFR 20.1301 Dose limits for individual members of the public.

(a)(1). TEDE to individual members of the public must not exceed 0.1 rem (1 mSv) in a year.

2. 10 CFR 35.310 Safety instruction.

Licensees must provide radiation safety instruction (and retain a record of individuals receiving instruction), initially and at least annually, to personnel caring for patients or human research subjects who cannot be released under § 35.75. The instruction must be commensurate with the duties of the personnel and include:

1. Patient or human research subject control;
2. Visitor control, including
    a. Routine visitation to hospitalized individuals in accordance with § 20.1301(a)(1); and
    b. Visitation authorized in accordance with § 20.1301(c).
3. Contamination control;
4. Waste control; and
5. Notification of the RSO, or their designee, and the AU if the patient or the human research subject has a medical emergency or dies.

5.8.2 Discussion of the Requirements

For personnel involved in therapeutic nuclear medicine in instances where a treated patient or human research subject cannot be released under § 35.75, safety instruction is required to be provided initially and at least annually. These personnel may be nuclear medicine staff, referring physicians or members of the nursing staff. This safety instruction should be commensurate with the duties of the personnel and include safe handling, patient control, visitor control, contamination control, waste control, and notification of the RSO and AU if the patient has a medical emergency or dies. Part 20 requirements allow licensees to permit visitors to a patient who cannot be released to receive a dose greater than 0.1 rem (1 mSv) provided the dose does not exceed 0.5 rem (5 mSv) and the AU has determined before the visit that it is appropriate.

Licensees might also determine that housekeeping staff, while not likely to receive doses in excess of applicable public dose limits, should be, for example, informed of the nature of the licensed material and the meaning of the radiation symbol, instructed not to touch the licensed material, and told to remain out of the room. Providing minimal instruction to ancillary staff (e.g., housekeeping, security, etc.) may assist in controlling abnormal events.

5.8.3 Suggested Procedures for Compliance

Safety instruction for professional staff (e.g., AU, RSO, nuclear medicine technologist) in diagnostic nuclear medicine has been discussed in the SNM/ACNP *Guide for Diagnostic Nuclear Medicine*. In addition to this instruction, licensees must also provide instruction, initially and at least annually, commensurate with the duties of the personnel, in:

1. Patient or human research subject control;
2. Visitor control;
3. Contamination control;
4. Waste control; and
5. What to do in the event that patient or human research subject has a medical emergency or dies.

As an example, instruction should include authorized visitation exceeding the 0.1 rem (1 mSv) public dose limit if (1) the visitor's radiation dose will not exceed 0.5 rem (5 mSv); and (2) the authorized user has determined before the visit that it is appropriate (see Chapter 5.5). It may be useful to develop a video or readable instructional materials to facilitate the training of new staff before they have to deal with a radionuclide therapy patient.

If staff and procedures have not changed in a given year, the instruction should obviously be minimized. New employees must receive appropriate safety instruction but there should be no requirement to continually train those personnel who are already adequately trained. The requirement of annual instruction to veteran personnel seems overly burdensome. NOTE: Licensees may want to consider applying to the NRC for an exemption to this continual radiation safety instruction requirement as it applies to adequately trained, veteran employees caring for radionuclide therapy patients who are required to be confined to a hospital room.

5.9 Audit Program

5.9.1 Pertinent Regulations

1. 10 CFR 20.1101 Radiation protection programs.

Licensees must, at least annually, review the radiation protection program content and implementation.

2. 10 CFR 20.2102 Records of radiation protection programs.

Licensees must maintain records of audits and other reviews of the radiation protection program content and implementation.

5.9.2 Discussion of the Requirements

Licensees must review and/or audit their radiation protection program's content, implementation, and effectiveness on an annual basis (or sooner, if deficiencies are identified). This is important so that any violations or radiation safety concerns, which may be identified, can be corrected in a timely manner. Not all deficiencies need result in corrective actions as long as appropriate reasons can be given. These reviews may also indicate that certain procedures and/or requirements should be minimized or even eliminated. In this case, the licensee should appropriately alter their radiation protection policies and implementing procedures and/or apply to the NRC for an exemption from the applicable requirements in Parts 19, 20, 30, and 35 as discussed in the SNM/ACNP *Guide for Diagnostic Nuclear Medicine.*

5.9.3 Suggested Procedures for Compliance

All aspects of the licensee's radiation protection program must be reviewed on an annual basis. If any deficiencies are identified sooner, the appropriate areas of the program should be reviewed at that time. The audit should be performed with the following 3 questions in mind:

(1) What can happen?
(2) How likely is it?
(3) What are the consequences?

Form 5.1 contains a list of the items to be checked and can be used for auditing the radiation protection program for therapeutic nuclear medicine licensees.

Note: An audit program was detailed in the *Guide for Diagnostic Nuclear Medicine*. There are additional requirements for therapeutic nuclear medicine and only those are included in the following form for auditing the radiation protection program. Diagnostic and therapeutic nuclear medicine licensees will need to combine Forms 5.1 and 9.1 in the *Guide for Diagnostic Nuclear Medicine* for a comprehensive audit form.

Form 5.1
Radiation Protection Program Audit for Therapeutic Nuclear Medicine

Date of Review: _____ Date of Last Review: _____

Reviewer: _____ Date: _____
(Name and signature)

Management Review: _____ Date: _____
(Name and signature)

Audit History
1. Were previous audits conducted annually (or sooner, if necessary)?
2. Were records of previous audits maintained?
3. Were any deficiencies identified during previous audits?
4. Were corrective actions taken?

Training and Experience
1. Does AU meet NRC training requirements?
2. Does RSO meet NRC training requirements?
   (ANP and AMP meet NRC training requirements?)
3. Is RSO fulfilling all duties?
   If RSO was changed, was license amended?
4. Recentness of training?

Occupational Dose Limits
1. Dose limits for adults maintained?
2. Internal dose monitored, if required?

Radiation Surveys
1. Exposure rate surveys performed at end of each day in all appropriate areas when unsealed byproduct material requiring a written directive was used?

Written Directives
1. Written directive procedures in place?
2. Written directives contain required information?
3. Written directive signed and dated by AU before dosage administration?
4. Patient's or human research subject's identity verified before each dosage administration?
5. Each dosage administration verified to be in accordance with written directive?

6. Proper written revisions, if any, to existing written directives?
7. Supervised individuals instructed in and required to follow written directive procedures?

Release of Individuals Containing Unsealed Byproduct Material
1. Patient release correctly authorized?
2. Appropriate instructions given to released patients?
3. Appropriate instructions given to breast-feeding women?

Safety Procedures for Treatment When Patients Are Hospitalized
1. Are patient rooms adequate?
2. Patient rooms posted with "Radioactive Materials" sign?
3. Adequate visitor control?
4. Appropriate handling of material and items removed from patient's room?
5. Adequate surveys performed during period of confinement and prior to room release for unrestricted use?
6. Proper procedures in place in event of patient medical emergency or death?
7. If emergency or death occurred, were procedures followed?

Records/Reports
1. Appropriate records kept?
2. Appropriate reports written?

Safety Instruction for Workers and Personnel
1. Is adequate safety instruction being given to personnel caring for patients who cannot be released under § 35.75?
2. Is instruction being given at least annually?

Audit Findings
1. Summary of findings:
    a. Any appropriate program changes (any procedures identified that need to be corrected or any that could be minimized or eliminated?)
    b. Any exemptions from applicable requirements that should be requested?
2. Corrective and preventive actions:

6. License Application

6.1 Application Process and License Issuance

To apply for a NRC license in diagnostic and therapeutic nuclear medicine, an applicant must do the following (§ 35.12):

1. File an original and one copy of NRC Form 313, *Application for Material License*, that includes the facility diagram, equipment, and training and experience qualifications of the RSO and authorized user(s) (if applicable, also AMPs and ANPs); and
2. Have applicant or licensee management sign the application.

The submission of written procedures to meet the requirements of the applicable regulations is not required as part of the license application process; however, the applicant must provide a commitment to "develop, document, and implement" these procedures as they will be examined during NRC inspections. The suggested procedures detailed in Chapter 5 and in the SNM/ACNP *Guide for Diagnostic Nuclear Medicine* can be used for this purpose. The applicant must also provide any other information requested by the NRC in its review of the application.

The NRC will issue a license for the medical use of byproduct material if (§ 35.18):

1. The applicant has filed NRC Form 313, *Application for Material License*, in accordance with the instructions in § 35.12;
2. The applicant has paid any applicable fee as provided in 10 CFR Part 170;
3. The Commission finds the applicant equipped and committed to observe the required safety standards established for the protection of the public health and safety; and
4. The applicant meets the requirements of 10 CFR Part 30.

The first step in filing for an NRC materials license is to complete NRC Form 313. The Form consists of 13 items; items 1 through 4, 12, and 13 can be completed on the form itself while items 5-11 require supplementary pages. The following section explains and provides suggested responses, item by item, for all the information requested on NRC Form 313 for therapeutic nuclear medicine facilities seeking a specific license of limited scope to use unsealed byproduct material prepared for medical use for which a written directive is required (i.e., § 35.300 material). It will be assumed for purposes of this license application that

applicants requesting use of § 35.300 materials will also be requesting use of § 35.100 and § 35.200 materials (refer to *Guide for Diagnostic Nuclear Medicine*).

6.1.1 Item 1. License Action Type

Check the box for a new license (for amendments or renewals, see *Guide for Diagnostic Nuclear Medicine*).

6.1.2 Item 2. Applicant's Name and Mailing Address

The legal name of the applicant's facility must be given. This is the entity that has direct control over use of the radioactive material. Nuclear medicine divisions or departments within hospitals may not be listed. The mailing address must also be provided.

Note: The NRC must be notified before control of the license is transferred, whenever bankruptcy proceedings are initiated, or when a licensee decides to permanently cease licensed activities:

Notification of Transfer of Control

Licensees must provide full information and obtain NRC's written consent before transferring control of the license (§ 30.34(b)). A simple name change that does not involve transfer of control of the license or mailing address change only requires written notification with NRC no later than 30 days after the date of the change.

Notification of Bankruptcy Proceedings

Immediately (i.e., within 24 hours) following the filing of a bankruptcy petition, a licensee must notify the NRC. This is because the NRC wants to ensure that there will be no public health and safety concerns. The licensee remains responsible for compliance with all regulatory requirements.

Termination of Activities/License Termination

For diagnostic and therapeutic nuclear medicine licenses, license termination does not require much, because the total inventory of licensed material will not exceed regulatory limits and because the half-lives of the unsealed byproduct materials used are so short. The NRC must be notified, in writing, within 60 days, when the license has expired or a decision has been made to permanently cease licensed activities at the entire site. Licensees must certify the disposition of licensed materials and that the facility is not contaminated to facilitate decommissioning (i.e., release of the site for unrestricted use). For the interested reader, Subpart E to 10 CFR Part 20 describes the radiological criteria for license termination.

6.1.3 Item 3. Address(es) Where Licensed Material Will be Used

The address should specify a street address, not a post office box, because the address must be sufficient to allow NRC inspectors to find the facility location.

6.1.4 Item 4. Contact Person

A person knowledgeable about the application and the facility should be listed as the contact person (typically the proposed RSO), because the NRC will contact this individual if there are questions about the application. The telephone number of this individual must also be included.

6.1.5 Item 5. Radioactive Material

The form specifies: a. element and mass number; b. chemical and/or physical form; and c. maximum amount that will be possessed at any one time. Because this is an application for a specific license of limited scope for the use of § 35.300 material as well as § 35.100 and § 35.200 materials, the applicant should provide the following information:

a. Any byproduct material included in 10 CFR 35.100, 10 CFR 35.200 and 10 CFR 35.300;
b. Any; and
c. "As needed" for § 35.100 and § 35.200 materials and "300 mCi" for § 35.300 materials.

Note that 300 mCi is not required by regulations but suggested by guidance given in NUREG-1556, Vol. 9. For licensees who will treat mainly hyperthyroid patients and an occasional thyroid cancer patient, 300 mCi may be OK. For those licensees who plan to treat multiple thyroid cancer patients at the same time and/or who expect to use other ^{131}I labeled agents, a possession limit of several curies is more appropriate.

6.1.6 Item 6. Purpose(s) For Use of Licensed Material

The applicant can define the purposes of use by providing the following statements:

"Any uptake, dilution, and excretion procedure approved in 10 CFR 35.100";
"Any imaging and localization procedure approved in 10 CFR 35.200"; and
"Any use of unsealed byproduct material in radionuclide therapy approved in 10 CFR 35.300."

6.1.7 Item 7. Individual(s) Responsible for Radiation Safety Program and Their Training and Experience

NRC requires that an applicant be qualified by training and experience to use licensed materials for the purposes requested in such a manner as to protect health and minimize danger to life or property. For diagnostic and therapeutic nuclear medicine licensees, the personnel that typically have a role in the radiation protection program are the RSO and the AU physician(s). Their training and experience (see Chapter 4 for § 35.300 material and *Guide for Diagnostic Nuclear Medicine* for § 35.100 and § 35.200 materials) must be documented in the license application (if ANPs and/or AMPs are involved, their training and experience must also be provided). NRC Form 313A, *Training and Experience and Preceptor Statement*, may be used for this purpose.

Radiation Safety Officer (RSO)

Applicants must provide the name of the proposed RSO and their credentials demonstrating adequate training and experience. In addition, the applicant should supply documentation indicating that management has delegated the authority for the day-to-day oversight of the radiation protection program to the RSO and that the RSO has agreed in writing to be responsible for implementing the radiation protection program.

Authorized Users (AUs)

Applicants must provide the name of the proposed AU(s) and their credentials demonstrating adequate training and experience in the uses requested.

6.1.8 Item 8. Safety Instruction for Individuals Working in Restricted Areas

Individuals working in the vicinity of licensed material must have adequate safety instruction as described in Chapter 5.8 and the *Guide for Diagnostic Nuclear Medicine*. Licensees must have written policies and procedures in place; however, no response is necessary on the license application.

6.1.9 Item 9. Facilities and Equipment

The facilities and equipment must be adequate to protect health and minimize danger to life or property (§ 30.33(a)(2)). According to § 35.12, the application must include a diagram of the facility and describe the equipment necessary for the radiation protection program. Refer to *Guide for Diagnostic Nuclear Medicine* for information on the facility diagram, equipment, and necessary statements to be provided in the application. In addition, applicants should describe the room(s) where patients will be housed if they cannot be released under 10 CFR 35.75. This discussion should include a description of shielding, if applicable.

6.1.10 Item 10. Radiation Protection Program

The radiation protection program has been described in Chapter 5 and in the *Guide for Diagnostic Nuclear Medicine*, along with suggested written radiation protection policies and implementing procedures, to ensure compliance with all applicable NRC regulations. Applicants should provide a statement, such as "We have developed and will document and implement written procedures for a radiation protection program that will ensure compliance with all applicable NRC regulations and the security and safe use of unsealed byproduct material in diagnostic and therapeutic nuclear medicine. The program addresses training and experience requirements for the RSO and AU(s) (and ANP or AMP, if applicable) and each of the following:

1. Occupational dose limits;
2. Dose limits for members of the public;
3. Minimization of contamination/spill procedures;
4. Material receipt and accountability/ordering, receiving, and opening packages;
5. Radiation surveys and calibration of survey instruments;
6. Caution signs and posting requirements;
7. Labeling containers, vials, and syringes;
8. Determining patient dosages;
9. Sealed source inventory and leak testing;
10. Waste disposal and decay-in-storage;
11. Records;
12. Reports;
13. Safety instruction for workers and personnel;
14. Audit program;
15. Mobile diagnostic nuclear medicine services (if applicable);
16. Written directives;
17. Release of individuals containing unsealed byproduct material; and
18. Safety procedures for treatment when patients are hospitalized."

Note: The necessary radiation protection program elements for each of the 18 areas in the above list can be found in both this book and the *Guide for Diagnostic Nuclear Medicine*.

6.1.11 Item 11. Waste Management

Licensed materials must be disposed of in accordance with NRC requirements; these have been described in the *Guide for Diagnostic Nuclear Medicine* and additional suggested procedures are given in Chapter 5.5 for therapeutic applications. Applicants should provide a statement, such as "We have

developed and will document and implement written waste disposal procedures in accordance with the applicable regulations."

6.1.12 Item 12. Fees

Enter the appropriate fee category from 10 CFR 170.31. For specific licenses of limited scope, this is category 7 for medical licenses, subcategory C. The fee amount must be enclosed with the application.

6.1.13 Item 13. Certification

Typically, a representative of the legal entity filing the application should sign and date the application. This individual must be authorized to make binding commitments and to sign official documents on behalf of the applicant. An application for licensing a medical facility must be signed by the applicant's management, because, as previously discussed, signing the application acknowledges management's commitment and responsibilities for the radiation protection program.

Note: It is a criminal offense to make a willful false statement or representation on this application or any other correspondence with the NRC (18 U.S.C. 1001).

REVIEWER COMMENT SHEET

Reviewer: _____(please indicate your name)
Title: *Nuclear Regulatory Commission Regulation of Nuclear Medicine: Compliance Guide for Therapeutic Nuclear Medicine*

Confidential Manuscript Evaluation

1. EVIDENCE
Do the data support the author's conclusions?

Inadequate									*Definitive*
1	2	3	4	5	6	7	8	9	10

2. PRESENTATION
Please evaluate the quality of the presentation.

Confusing									*Logical*
1	2	3	4	5	6	7	8	9	10

3. CONFIRMATORY OR GROUNDBREAKING

Nothing New									*Innovative*
1	2	3	4	5	6	7	8	9	10

4. CONTRIBUTION

Negligible									*Significant*
1	2	3	4	5	6	7	8	9	10

5. OVERALL EVALUATION

Categorical Rejection									*Accept As Is*
1	2	3	4	5	6	7	8	9	10

COMMENTS AND CRITICISMS FOR THE AUTHOR/CONFIDENTIAL NOTES FOR THE EDITOR
In the space below or on a separate page, please write a brief, compelling argument in support of your rating of this manuscript and any other confidential comments to the editor. Please return the completed review by **May 10, 2003**

Please submit your typed comments only (handwritten notes are not acceptable). If you make specific comments please reference the page number and paragraph number, if appropriate. **Do not mark changes on the manuscript directly.**

Please sign here: _____

Complicated Licensing issues

May 2003 ACMUI Meeting

Donna-Beth Howe, Ph.D.

Complicated Licensing Issues

- 1. Sr-90 Eye Applicators
- 2. Intravascular Brachytherapy Physicist
- 3. 35.59 Training and experience > 7 y
- 4. 2 rem for certain Family members
- 5. Physical presence Gamma Knife

Complicated Licensing Issues

- 1. SR90 Eye Applicator Issues
  - Use of SR-90 eye applicator while waiting to send it for calibration.
  - Physicist performing SR-90 decay corrections and calculations.

Complicated Licensing Issues

- **2. Request use of remotely located Intravascular Brachytherapy physicist**
  - **"Consult " in the IVB license condition**
    - **actively participate in the treatment planning and treatment plan verification of each case.**
    - **for complex cases - on-site presence of both the interventional cardiologist and the AMP for needed consultation in each area of expertise.**
  - **Might consider with license authorization restricted to simple proceedures.**
    - **In this case restrict to cases within the limits of the device labelling.**

Complicated Licensing Issues

- **3. Determining adequacy of T&E for board certified individual not meeting 7 year recentness of training requirement in 35.59.**
  - 10 CFR 35.14 does not apply - need amendment
  - NRC (not licensee) determines adequate "related continuing T&E"
  - a case-by-case basis using applicable regulation
  - T & E obtained by the individual in last 7 years, and current level of competency specific to each topics in the applicable regulation

Complicated Licensing Issues

- **4. Request for family members to receive 2 rem while comforting hospitalized child.**
  - The staff's decision to grant the exemption was not generic and only applied to the request submitted by the particular licensee.
  - If other requests recieved staff may consider whether rulemaking is warranted

Complicated Licensing Issues

Request for family members to receive 2 rem while comforting hospitalized child.

* Limited to very specific situation - young children, for whom adult family care may have a direct impact on the clinical outcome.
* Required licensee implement appropriate training and protection controls normally afforded radition workers.
* Small increase in risk and only applied to specific group of individuals (adult family caregivers).

AGENDA TOPIC: REVIEW OF "COMPLICATED" LICENSING ISSUES SINCE 10/24/02

SUMMARY OF TARS ASSOCIATED WITH MEDICAL ISSUES UNDER THE NEW PART 35

1. SR90 Eye Applicator Issues

Use of SR-90 eye applicator while waiting to send it for calibration.

The Authorized user requested an exemption to permit the continued use of the strontium-90 (Sr-90) eye applicator prior to having it calibrated in accordance with 10 CFR 35.432, "Calibration measurements of brachytherapy sources." 10 CFR 35.432(b) requires the license to calibrate the Sr-90 eye applicator brachytherapy source before first medical use on or after October 24, 2002, using measurements provided by the source manufacturer or by a calibration laboratory accredited by the American Association of Physicists in Medicine that are made in accordance with 10 CFR 35.432(a). The authorized user could not send the source for calibration until the calibration laboratory sent a shipping container.

The exemption was granted for the medical use of its strontium-90 eye applicator for a period not to exceed 90 days from the date of the license amendment provided the licensee used the activity value (corrected for decay) provided by the Sr-90 eye applicator brachytherapy 1988 calibration certificate for ophthalmic treatment

Physicist performing SR-90 decay corrections and calculations.

A physicist's training and experience were reviewed to determine if they were sufficient to name the individual as an authorized medical physicist on a medical use license. They were not. Then a request was made for an exemption to 10 CFR 35.961, "Training for an authorized medical physicist" to permit the individual to be authorized to perform the strontium-90 eye applicator decay correction calculations required in 10 CFR 35.433, "Decay of strontium-90 sources for ophthalmic treatment." The ACMUI reviewed and discussed this case in the last meeting.

The following exemption was granted to the medical use licensee:

"Not withstanding the requirements in 10 CFR 35.433 that "only an authorized nuclear physicist shall calculate the activity of each strontium-90 source that is used to determine the treatment times for ophthalmic treatments," (named individual) may calculate the activity of the licensee's strontium-90 sources that is used to determine the treatment times for ophthalmic treatments."

2. Request for use of remotely located Intravascular Brachytherapy physicist

A limited scope medical use licensee with authorization for strontium-90 intravascular (coronary) brachytherapy (IVB) device requested authorization to use a remotely located (8 to 10 hour drive away) qualified intravascular brachytherapy physicist. The physicist could

be available by to consult by telephone, fax, e-mail and visit approximately once or twice per month but would not be either physically present or on the premises during IVB treatments.

Subsequently an on site authorized medical physicist was hired and the issue moot.

Guidance was provided on NRC's meaning of "consult " in the license condition authorizing the conduct of IVB procedures, i.e., these individuals actively participate in the treatment planning and subsequent treatment plan verification of each individual treatment plan. This would require the on-site presence of both the interventional cardiologist and the AMP for more complex treatments to provide the necessary consultation in their respective areas of expertise.

The licensee's request for authorization to perform the unrestricted range of IVB treatments, as presently authorized on its license, without the on-site presence of an authorized medical physicist, is denied; and

If the licensee's authorization for the conduct of IVB treatments was confined to simpler procedures, the licensee's request for continuation of its IVB therapy program without the requirement for the on-site presence of an authorized medical physicist may be granted. However, the licensee's authorization for IVB therapies would have to be amended from its existing IVB license authorization to limit its IVB authorization to the simpler procedures by using the following three proposed license conditions:

(1) Restricting all IVB therapies to the treatment of instent restenosis in native coronary arteries with the Novoste IVB therapy system;

(2) Restricted to treating lesions with lengths that are 10mm shorter than the length of the source train for the device used for the individual treatment; and,

(3) Restricting treatments to vessel diameters greater than or equal to 2.7 mm less than or equal to 4.0 mm.

3. Determining adequacy of training and experience for individual not meeting 7 year recentness of training requirement in 35.59.

A board certified physician was requested to be added by the notification process to a limited specific medical use license for 10 CFR 35.100, 35.200, and 35.300 medical uses. The physician was board certified 26 years earlier and had never been an authorized user on any license. The following issues were identified:

(1) A licensee cannot utilize the notification provisions of 10 CFR 35.14 to permit an individual to work as an authorized user pursuant to § 35.13(b) when the individual did not complete the training and experience within 7 years (i.e., he or she would have had to complete related continuing education and experience).

The licensee must apply for and receive an amendment before permitting a board certified individual whose training and experience was not obtained within the preceding

7 years to work as an authorized user, unless the individual is listed on a license or permit as described in § 35.13(b)(4).

(2) NRC not licensee management has the authority to determine what constitutes adequate "related continuing training and experience" for purposes of complying with 10 CFR 35.59.

The NRC determines, on a case-by-case basis, whether an individual's "related continuing training and experience" is adequate to meet the requirements of § 35.59 when the individual's training and experience (in this case, board certification in accordance with § 35.920) was not obtained within the 7 years preceding the application.

(3) The criteria used to evaluate "related continuing training and experience" under § 35.59, and information should be provided by the licensee to support this evaluation were described as follows:

In evaluating the adequacy of "related continuing training and experience" to determine compliance with § 35.59, the NRC staff will consider whether the continuing training and experience would demonstrate competency in the topics specified in the applicable regulation (e.g., § 35.190(c), § 35.290(c), § 35.920(b)). To support this determination, the licensee should submit information on the training and experience obtained by the individual during the last 7 years and current level of competency specific to each of the topics in the applicable regulation.

(4) The information submitted by the licensee in this case was not adequate to demonstrate that the board certified physician met the recentness of training requirements of § 35.59.

The licensee needed to provide reasonable assurance that this particular physician has current competency in the required NRC radiation safety areas, the licensee needed to document the individual's chemistry and radiation biology training for the medical use radionuclides and radiopharmaceuticals introduced since 1976, as well as the other topics specified in either § 35.290(c)(i) and (ii) and § 35.390(b)(i)and (ii) or in § 35.920(b), § 35.930(b)(2), § 35.932(b), and § 35.934(b). The information provided should be limited to the use of radiopharmaceuticals for the medical uses requested. To facilitate NRC's review, the licensee may also elect to provide a preceptor statement attesting to current competency in the identified radiation safety areas.

4. **Request for family members to receive 2 rem when providing in hospital comfort to their young children.**

The licensee requested an exemption to allow adults providing care to minors undergoing medical treatment with byproduct material during confinement to receive a dose of up to 2 rems (0.02 Sv) provided that the licensee implemented appropriate training and controls. The key points in the staff granting the exemption were:

1. The exemption was requested for a very specific situation, involving young children, for whom adult family care may have a direct impact on the clinical outcome.

2. The benefit afforded by this exemption appeared to outweigh the small increase in risk, from an incremental dose limit higher than allowed to a member of the public, and will only be applied to specific group of individuals (adult family caregivers).

3. The licensee stated that it would provide, to this group of caregivers, the protection and controls normally afforded workers engaged in licensed activities.

The staff's decision to grant the exemption was not generic and only applied to the request submitted by the particular licensee.

In the Memorandum to the Commission the staff clarified that because of the urgent nature of the health care needs associated with these types of aggressive byproduct treatments and the special needs of small children, NRC anticipates that additional exemption requests may be made by other licensees. Should this occur, the staff may consider whether rulemaking is warranted to allow adults providing care to minors undergoing medical treatment with byproduct material during confinement to receive doses in excess of present regulatory limits.

5. **Authorized user and authorized medical physicist physical presence during Gamma Stereotactic surgery.** Three cases discussed by Bob Ayres.

Stereotactic Radiosurgery

Physical Presence Requirements

Robert L. Ayres, Ph.D.
NRC/NMSS

Requirements

- 10 CFR 35.615(f)(3) -
- Requires the physical presence throughout all patient treatments involving GSR of:
  - An authorized user
  - An authorized medical physicist

Requests for Exemptions

- Since Oct. 24, 2002 the NRC staff has received 3 requests for exemptions to the GSR physical presence requirement
  - One request was approved
  - Two requests were denied

§35.19 Specific Exemptions

- The Commission may, upon application of any interested person, grant exemptions from the regulations in Part 35 that it determines are:
  - Authorized by law
  - Will not endanger :
    - Life;
    - Property; or
    - Common defense and security
  - And are otherwise in the public interest

Staff Application of §35.19 Criteria

- In general, to gain approval for an exemption request to 10 CFR Part 35 requirements, the applicant must:
  - Provide an alternative or justification for the requested exemption from the specific requirement(s)
  - Upon review of the request the staff must determine that an equivalent level of protection is provided by the proposed alternative as is provided by the regulatory requirement

Approved Exemption Request

- Licensee will comply with the physical presence requirement of the AMP
- Alternative proposed in lieu of the presence of the AU thoughout all patient treatements
  - Both an AU and neurosurgeon, formally trained in GSR, present at treatment initation
  - GSR trained neurosurgeon will be present after treatment authorization

1st Disapproved Request

- Licensee proposes that, as an alternative, two individuals trained in GSR emergency procedures be physically present during treatment
  - One individual will be either:
    - An AU;
    - An AMP; or,
    - Physician working under the supervision of an AU
  - Second individual will be an unspecified GSR staff member

Problems

- Only 2 of the individuals out of the propsed list of 3 meets the requirements of the rule for the presence of both an AU and a AMP
- The second proposed individual meets neither requirement
- The licensee's proposal does not does not ensure that the cumulative level of training and experience provided will be equivalent to that required by 10 CFR 35.615(f)(3)

2nd Disapproved Request

- Licensee has two GSR units with a central treatment planning room linked to each GSR's control room via a:
  - A remote viewing system;
  - A two-way audio communication system; and,
  - A emergency alarm system
- Licensee requests an exemption to the physical presence requirements to avoid the requirement for four authorized personnel during simultaneous use of both GSR units

Licensee Proposed Alternative

- GSR neurosurgeon (NS) trained and knowledgeable in GSR unit operations and emergency procedures
- To have present at each operating GSR control area either a:
  - AU;
  - AMP; or,
  - NS
- The other required individual (AU, AMP, or NS) would be in the central planning room and provided coverage for both GSR units

Problems

- Only one required individual at the GSR Control Console
  - AU
  - AMP, or
  - GSR trained NS
- Other required individual in central planning room covering two GSRs
- Requirement for physical presence at each GSR not met

Reason for Disapprovals

- Requirement that an AU and AMP both be physically present throughout the treatment is justified on the basis of:
  - The inherent risk of these procedures; and,
  - The importance of a properly trained physician to be available at all times:
    - To respond to an emergency; and,
    - To ensure the correct dose is delivered to the patient

Discussion?

AGENDA TOPIC: PHYSICAL PRESENCE REQUIREMENTS DURING STEREOTACTIC RADIOSURGERY TREATMENTS

February 13, 2003

MEMORANDUM TO: George Pangburn, Director
Division of Nuclear Materials Safety, RI

FROM: Thomas Essig, Chief /RA/MGB for
Materials Safety and Inspection Branch
Division of Industrial and
Medical Nuclear Safety, NMSS

SUBJECT: RESPONSE TO TECHNICAL ASSISTANCE REQUEST DATED JANUARY 3, 2003, UNIVERSITY OF PITTSBURGH , LICENSE NUMBER 37-000245-02

Issue:

By letter dated January 3, 2003, Region I requested technical assistance in responding to a letter dated October 3, 2002, from University of Pittsburgh, requesting an amendment to its license to allow exemptions from 10 CFR 35.615(f)(3) and 10 CFR 35.645(c)(1)(i). 10 CFR 35.615(f)(3) requires that for gamma stereotactic radiosurgery units (GSR), an authorized user (AU) and authorized medical physicist (AMP) must be physically present throughout all patient treatments involving the unit. The licensee is requesting the use of a neurosurgeon in place of an authorized user and to have only one individual present at the GSR consul during the treatments, while a second individual is in a central planning room nearby. 10 CFR 35.645(c)(1)(i) requires that the licensee perform monthly spot checks on the GSR unit which will include assuring the proper operation of the treatment table retraction mechanism, using backup battery power or hydraulic backups with the unit off. The licensee is requesting to perform these spot checks on a semi-annual basis.

Action Not Approved:

The exemption requests are not approved for reasons addressed in the discussion section.

Background:

The licensee has two GSR units in the hospital which are in two different rooms, separated by approximately 50 feet. Both units may be used to treat patients at the same time, which requires the availability of two authorized users and two authorized medical physicists.

CONTACT: Linda M. Psyk
(301) 415-0215

Item 1

The licensee has proposed to link the control rooms from each GSR unit to a central treatment planning room, located adjacent to the one GSR treatment room, with an audio and visual communication system. The system would allow remote viewing of both the patient and GSR control area, along with two-way audio communication (including an emergency alarm) for the two GSR units.

The licensee has requested to have a neurosurgeon, who is knowledgeable in all aspects of the GSR unit operations and emergency response procedures, be approved to be physically present throughout a patient treatment in place of an authorized user.

The licensee has also proposed that, throughout each patient treatment, either an authorized user, neurosurgeon or an authorized medical physicist will be physically present in the GSR control area. The other required individual, either an authorized user, neurosurgeon, or authorized medical physicist, will be in the central treatment planning room.

Item 2

The licensee has requested an exemption from the requirement in 10 CFR 35.645(c)(1)(i) to perform monthly spot checks to assure the proper operation of the treatment table retraction mechanism, using backup battery power or hydraulic backups with the unit off. The licensee requests to perform this check on a semi-annual basis, or after any repair to the retraction mechanism, battery power backup or hydraulic backup. The licensee states that this spot check frequency is recommended by the manufacturer.

Discussion:

The Region should not approve the exemption requests for the licensee. With respect to Item 1, 10 CFR 35.615(f)(3) requires two individuals with a high level of knowledge and experience to be present during the use of a GSR.

In promulgating this regulation, the NRC specifically considered comments suggesting that there was no need for both an AU and AMP to be physically present during the entire GSR treatment. The NRC determined that, notwithstanding these comments, the requirement that an AU and AMP both be physically present throughout the treatment should be retained. The Supplementary Information to the Final Rule states: "We believe that the inherent risk of these procedures justifies the prescriptiveness of this regulation and that it is important for a properly trained physician to be available at all times to respond to an emergency..." and "NRC requires the physical presence of an AU and an AMP throughout all patient gamma stereotactic radiosurgery treatments to ensure appropriate response to an emergency and to ensure that the correct dose is delivered to the patient". 67 FR 20249 at 20314, 20355 (April 24, 2002)

The licensee's proposal does not ensure that two individuals with the knowledge and experience necessary to identify and respond to emergencies will be available, and is not consistent with the requirements of the regulation. Furthermore, the licensee presents no basis for the need for this exemption, except to state that four authorized personnel are required when using the two GSR units simultaneously.

With respect to Item 2, the licensee's request to perform a semi-annual, instead of a monthly, spot check of the treatment table retraction mechanism using backup battery power or hydraulic backups with the unit off, is also denied. The NRC specifically considered the issue of the frequency of spot checks for the GSR units required by 10 CFR 35.645(c)(1)(i) when the final rule regulating the medical use of byproduct material was promulgated. The Supplementary Information to the Final Rule addresses why a monthly spot check was determined to be appropriate and states: "The NRC developed the frequency of the spot checks from recommendations of AAPM Report No. 54, meetings with medical physicists, input from the Therapy Subcommittees of the ACMUI, and NUREG/CR-6324, 'Quality Assurance for Gamma Knives.' ...Therefore, we believe that the frequencies of the spot checks are appropriate." 67 FR 20249 at 20318 (April 24, 2002) In addition, the licensee presents no basis for the need for the exemption, except to state that a semi-annual frequency is recommended by the manufacturer. The licensee's proposal therefore does not afford the Commission an adequate basis for finding that the requested exemptions will not endanger life or property and are in the public interest, as required by 10 CFR 35.19.

AGENDA TOPIC: PHYSICAL PRESENCE REQUIREMENTS DURING STEREOTACTIC RADIOSURVEY TREATMENTS

February 4, 2003

MEMORANDUM TO: Marc Dapas, Acting Director
Division of Nuclear Materials Safety, RIII

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

SUBJECT: RESPONSE TO TECHNICAL ASSISTANCE REQUEST DATED DECEMBER 5, 2002, INDIANA UNIVERSITY SCHOOL OF MEDICINE , LICENSE NUMBER 13-02752-08

Issue:

By letter dated December 5, 2002, Region III requested technical assistance in responding to a letter dated November 8, 2002, from Indiana University School of Medicine, requesting an amendment to its license to allow an exemption from 10 CFR 35.615(f)(3). 10 CFR 35.615(f)(3) requires that for gamma stereotactic radiosurgery units (GSR), an authorized user (AU) and authorized medical physicist (AMP) must be physically present throughout all patient treatments involving the unit. The licensee has proposed that, as an alternative, at least two individuals who have been trained in GSR emergency procedures be physically present at the console during the entire treatment. At least one of these individuals will be either an authorized user, an authorized medical physicist, or a physician working under the supervision of an authorized user. The licensee also indicates that an authorized user trained for GSR emergencies will be physically present in the department (where the GSR is located) during GSR treatments and can respond to an intercom page in the event of an emergency to provide assistance within approximately one minute.

Action Not Approved:

The exemption request is not approved for reasons addressed in the discussion section.

CONTACT: Linda M. Psyk
(301) 415-0215

Background:

The licensee has stated that it has purchased a Model C unit of the Leksell Gamma Knife which utilizes an automated positioning system (APS). The APS allows for all coordinate settings to be input and adjusted automatically, without having to fully extend the couch and adjust the coordinates manually following each segment of the treatment. The coordinate settings would be verified for all shots at the initiation of treatment and the licensee believes this eliminates the potential for errors that existed with the manual system, thus eliminating the need to have a physician AU and AMP physically present during GSR treatments. This would allow physicians to be more available to other patients in the clinic. The licensee feels that only personnel who need to respond to an emergency with the GSR need to be physically present during treatment with an AU immediately available via the department intercom system. The licensee asserts that the emergency response training of AUs and AMPs is no different than that provided to any other GSR staff member, and that, as such, other staff members are equally capable of addressing any emergency situation.

Discussion:

The Region should not approve the exemption request for this licensee. The rule requires two individuals with a high level of knowledge and experience to be present during the use of a GSR: one individual to recognize and respond to emergencies with the machine, the authorized medical physicist; and one individual to recognize and respond to a physiological emergency with the patient, the physician authorized user. The licensee's proposal does not ensure that personnel with the knowledge and experience necessary to identify and respond to physiological emergencies, specifically a physician authorized user, will be physically present during treatments, and is not consistent with the rule.

In promulgating section 35.615(f)(3), the NRC specifically considered comments suggesting that individuals who were not AU's or AMPs but were trained in emergency procedures particular to the unit could be present instead of the AU or AMP during GSR treatments. The NRC determined that, notwithstanding these comments, the requirement that an AU and AMP be physically present throughout such treatments should be retained. The Supplementary Information to the Final Rule states: "We believe that the inherent risk of these procedures justifies the prescriptiveness of this regulation and that it is important for a properly trained physician to be available at all times to respond to an emergency..." and "NRC requires the physical presence of an AU and an AMP throughout all patient gamma stereotactic radiosurgery treatments to ensure appropriate response to an emergency and to ensure that the correct dose is delivered to the patient". 67 FR 20249 at 20314, 20355 (April 24,2002)

The licensee's proposal that "at least one" of these individuals will be either an AU, AMP or physician working under the supervision of an AU, while not specifying who the other individual will be other than indicating this individual will be trained in GSR emergency procedures, does not ensure that the cumulative level of experience and knowledge of individuals present during the GSR treatment will be compatible with that required by 10 CFR 35.615(f)(3). In addition, the licensee's proposal that the AU be "physically present in the department" does not meet the requirement that an AU must be physically present during the treatment. The licensee's proposal therefore does not afford the Commission an adequate basis for finding that this exemption will not endanger life or property and is in the public interest as required by 10 CFR 35.19.

AGENDA TOPIC: PHYSICAL PRESENCE REQUIREMENTS DURING STEREOTACTIC RADIOSURVERY TREATMENTS

January 22, 2003

MEMORANDUM TO: Marc Dapas, Acting Director
Division of Nuclear Materials Safety, RIII

FROM: Thomas Essig, Chief /RA/
Materials Safety and Inspection Branch
Division of Industrial and
Medical Nuclear Safety, NMSS

SUBJECT: RESPONSE TO TECHNICAL ASSISTANCE REQUEST DATED NOVEMBER 12, 2002, RESEARCH MEDICAL CENTER, LICENSE NUMBER 24-17998-02

Issue:

By letter dated November 12, 2002, Region III requested technical assistance in responding to a letter dated September 20, 2002, from Medical Research Center, requesting an amendment to its license to allow an exemption from 10 CFR 35.615(f)(3). 10 CFR 35.615(f)(3) requires that for gamma stereotactic radiosurgery units (GSR), an authorized user and authorized medical physicist must be physically present throughout all patient treatments involving the unit. The licensee has proposed that a neurosurgeon who has received at least one full week of training at a formal training course for GSRs be physically present in place of the authorized user once the treatment has been initiated, provided certain criteria is met.

Action Approved:

Research Medical Center's license may be amended as follows: "Notwithstanding the requirements specified in 10 CFR 35.615(f)(3), a neurosurgeon trained in gamma stereotactic radiosurgery may be physically present during patient treatments involving gamma stereotactic radiosurgery units in place of an authorized user in accordance with the conditions described in the licensee's letter dated September 20, 2002".

CONTACT: Linda M. Psyk
(301) 415-0215

Background:

The licensee indicates that without the exemption to 10 CFR 35.516(f)(3), GSR procedures would have to be periodically interrupted whenever it would be necessary to call the authorized user to attend to other responsibilities in the Radiation Oncology Department, which would not be conducive to timely completion of the procedure. The licensee states further that neurosurgeons are in large part responsible for the care of patients undergoing GSR, have completed the same course in GSR as the authorized users and are fully capable of handling any medical emergency, and are present during at least part of the treatment, and that the Radiation Oncology Department is separated from the GSR by a short enough distance such that an authorized user could respond quickly if necessary.

Discussion:

The licensee has provided an equivalent alternative to the requirements in 10 CFR 35.615(f)(3). The staff believes there is no safety consequence because a neurosurgeon trained in the operation and emergency procedures of the GSR unit would be capable of responding to a medical emergency until an authorized user physician, who is immediately available, arrives. In addition, the licensee has provided adequate limiting parameters for GSR procedures such as having the neurosurgeon substitute for the authorized user for no more than an average of 50% of the treatment time and having the authorized user immediately available to respond to any emergency. The staff has therefore determined that the exemption is in the public interest, authorized by law, and will not endanger life or property.

An environmental assessment and final finding of no significant impact was performed in accordance with 10 CFR 51.32, "Finding of no significant impact." and will published in the Federal Register on or about January 28, 2003. (The Federal Register number will be forwarded to Region III when available.) The gamma stereotactic radiosurgery sources are sealed sources and no material will be released into the environment. All the sources are contained within the unit, as verified by periodic spot checks performed by the licensee. The action does not increase public radiation exposure. There will be no impact on the environment as a result of the action.

Background:

In letter dated September 20, 2002, Research Medical Center of Kansas City, MO, requested an amendment to their license which would allow a neurosurgeon to be physically present in place of the AU once treatment has been initiated involving the GSR. The neurosurgeon would have received at least one full week of training in the GSR, including operation and emergency response, and be under the supervision of the AU. The AU would be immediately available at all times during the treatment with the GSR and would be substituted by the neurosurgeon on average no more than 50% of the treatment time. The authorized medical physicist will be physically present during the entire treatment.

Research Medical Center has asked for consideration for this exemption so they can provide optimum medical treatment to their patients. Gamma stereotactic radiosurgery is considered by many in the medical community as a surgical procedure and many patients are referred for treatment by neurosurgeons. The exemption would allow Research Medical Center to have a neurosurgeon take an active part in a patient's treatment and to be present for at least part of it. Allowing a neurosurgeon to replace an Authorized User will allow that Authorized User to supervise other patients in the Radiation Oncology Department. The requirements in 10 CFR 35.615(f)(3) would result in periodic interruptions of GSR procedures whenever an Authorized User is required in Radiation Oncology.

Discussion:

The licensee has provided an equivalent alternative to the requirements in 10 CFR 35.615(f)(3). There is no safety issue in using a neurosurgeon trained in the operation and emergency procedures of the GSR unit in place of the Authorized User. A neurosurgeon would be capable of responding to the same medical emergency as an Authorized User physician. In addition, the licensee has provided adequate limiting parameters to their proposes procedures for GSR procedures such as having the neurosurgeon substitute the Authorized User for no more than the an average of 50% of the treatment time and having the Authorized user immediately available to respond to any emergency. The staff has therefore determined that the exemption is in the public interest, authorized by law, and will not endanger life or property.

An environmental assessment and final finding of no significant impact was performed in accordance with 10 CFR 51.32, "Finding of no significant impact." and published in the Federal Register on (XX FR XXXXX). The gamma stereotactic radiosurgery sources are sealed sources and no material will be released into the environment. All the sources are contained within the unit, as verified by periodic spot checks performed by the licensee. The action does not increase public radiation exposure. There will be no impact on the environment as a result of the action.

The American Society for Therapeutic Radiology and Oncology (ASTRO)

respectfully submits testimony to the Advisory Committee on the Medical Uses of Isotopes (ACMUI) for the meeting on May 21, 2003, agenda item "Physical Presence Requirements During Stereotactic Radiosurgery Treatments"

Contact information:
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Memorandum In Support of ASTRO's Position on the Inclusion of Radiation Oncologists in All Procedures Governed by 10 CFR § 35

Introduction

The United States Nuclear Regulatory Commission (NRC) is the governing body for the medical use of byproduct material. The principal statutory authority for the NRC's regulation of the medical use of byproduct material rests in the Atomic Energy Act (AEA) of 1954, as amended. The NRC's medical use program includes regulation of the uses of byproduct material in medical diagnosis, therapy, and research.

The commission supervises the administration of byproduct material or radiation from byproduct material in 18 states (hereinafter referred to as Non-agreement States), the District of Columbia, the Commonwealth of Puerto Rico, and various territories throughout the United States. Thirty-two states (hereinafter referred to as Agreement States) have each entered into an agreement with the NRC to regulate the use of byproduct material (as authorized by § 274 of the Atomic Energy Act) within that state. These states issue licenses for certain diagnostic and therapeutic uses of radioactive materials, and currently regulate approximately 4,200 institutions, e.g., hospitals, clinics, or physicians in private practice.[1]

Radiation therapy is one of the major modalities of treatment for cancer and other non-malignant diseases. More than two-thirds of all cancer patients undergo radiation therapy as part of their cancer treatment. Current standards of care that involve multi-modality treatment like concurrent chemotherapy and radiation therapy require sophisticated radiation treatment planning to reduce the risk for potential life-threatening toxicities. Furthermore, radiation therapy has long been used to treat non-malignant diseases such as fibromatosis, keloids, heterotopic ossification, macular degeneration, arterial venous malformation, and coronary artery disease. The application of radiation therapy in the treatment of nonmalignant diseases continues to expand.

Radiation oncologists, by virtue of their training and experience, are medical professionals who receive specific training and board certification for the use radiation therapy to treat cancer and other diseases. Radiation oncology is a separate subspecialty recognized by the American Board of Radiology under the American Board of Medical Specialties (ABMS). Residency training in radiation oncology ranges from five to more than seven years in length. Board certification in radiation oncology through the American Board of Radiology indicates that the physician has passed three distinct parts of a written examination which tests knowledge in radiation biology, radiation physics, radiation safety, and clinical oncology along with an oral examination taken separately focused solely on clinical experience. This program and the board certification process

[1] Nuclear Regulatory Commission, 10 CFR § 20, 32, and 35 (Background: State and Federal Regulations).

provide the radiation oncologist with a specialized and in-depth knowledge of radiation therapy.

Recognizing the complexity of the delivery of radiation, most hospital staff credentialing boards require physicians to be board certified in order to administer radiation. In order for a physician that is not board certified to administer radiation therapy, most credentialing boards require those physicians to be supervised by a board certified radiation oncologist. Consistent with this, the NRC consults board certified radiation oncologists when evaluating the potential consequences of reported errors in the administration of radiation therapy.

The American Society for Therapeutic Radiology and Oncology (ASTRO) represents the largest group of radiation oncologists in the world. The following memorandum cites serious concerns that ASTRO has with the NRC's regulation of byproduct material and the exemptions given involving 10 CFR § 35.

Matter in Question

Under its jurisdictional power, the NRC has the right to grant licensure exemptions to Non-agreement States for medical procedures involving byproduct material; radiation therapy is among those procedures.[2] The NRC periodically exercises this jurisdiction, and has provided licensure exemptions to allow the administration of radiation therapy without the direct supervision of a radiation oncologist.

Thus, the central question becomes whether the physical presence[3] of radiation oncologists is necessary in those radiation therapy treatments governed by 10 CFR § 35?

ASTRO's Position

ASTRO strongly agrees with 10 CFR § 35.615(3):

"For gamma stereotactic radiosurgery units, require an authorized user and an authorized medical physicist to be physically present[4] throughout all patient treatments involving the unit."

ASTRO strongly maintains that only radiation oncologists have the extensive educational training and experience that are necessary to oversee the safe administration and effective delivery of these treatments.

Reasoning

[2] In Agreement States this process is slightly different. In Agreement States, the medical institution seeking a licensure exemption from the mandated state regulations has to obtain permission from that individual Agreement State by applying for a license amendment.
[3] "Physically present" is interpreted by the NRC to mean within hearing distance of a normal voice.
[4] Id

Radiation oncology is the branch of medicine board certified to treat cancer and non-neoplastic conditions with ionizing radiation. Radiation oncologists are recognized and considered an integral part of the multidisciplinary management of the patient.[5] The training and education received by a board certified radiation oncologist is critical in recognizing the potential risk for complications with increasingly complex and aggressive multi-modality cancer treatment, like concurrent chemotherapy and radiation as one example. Sophisticated radiation treatment planning is necessary to reduce potentially life-threatening side effects in these aggressive treatment strategies to minimize the dose of radiation to and the volume of normal tissues in the radiation portal. Knowledge, only gained in radiation oncology residency training, is required to administer specific doses of radiation to specific anatomic locations. This attention to detail in radiation dose administration maximizes the therapeutic effectiveness and minimizes the risk for complications and late consequences of treatment, such as a radiation-induced malignancy. These issues are of critical importance in the treatment of early-stage cancers and non-malignant disease among patients with a prolonged life expectancy.

Furthermore, radiation oncology is the only specialty in medicine that has direct knowledge and clinical experience to evaluate the acute and late toxicities of radiation. Specific to radiation oncology training is an understanding of the radiation treatment portals, radiation energy, and dose-fractionation schedule. Based on this knowledge, acute radiation effects that occur during the course of treatment can only be accurately predicted by radiation oncologists. Therefore, only radiation oncologists are able to determine whether observed acute radiation effects are consistent with what is expected or what is due to a misadministration. With regard to late complications, only a radiation oncologist has the expertise to evaluate late radiation side effects and determine whether the complication, like a tumor or cardiac dysfunction, is radiation-induced by evaluating the location of the abnormality relative to the previous radiation treatment parameters.

The medical use of radioisotopes is a complex and potentially dangerous process that demands the cooperation of a team of trained professionals in order to insure high quality and safe administration to the patient and minimal exposure to medical personnel. The radiation oncologist has the principal responsibility to determine the radiation treatment plan. The specific parameters include the type and total dose of radiation, the radiation dose-fractionation schedule, the treatment volume, the assessment of radiation treatment effects, and monitoring of potential side effects. The radiation oncologist determines whether to continue, modify or abort radiation therapy based on variance with any one of these factors related to the radiation treatment plan, which might impact on patient tolerance and response.

This is particularly critical in radiation treatments given over a few large fractions or in a single setting like brachytherapy or stereotactic radiation. In these cases, every factor that could impact response or toxicity must be accounted for in the radiation treatment plan before and during the administration of the radiation for a number of reasons. First, there is a limited opportunity to correct an error should it occur with these procedures. Radiation complications are directly related to the dose of radiation given

[5] *Graduate Medical Education Directory 2003-2004*, The American Medical Association (2003).

with each fraction and the total dose of radiation. The risk for complications increases exponentially as the dose given with each radiation fraction increases. High total doses of radiation are also associated with a high risk for complications.

Complications and errors in medicine have been widely discussed and the topic of recent reports by the Institute of Medicine. It is widely agreed that individuals who have the most experience and specialty training have better treatment outcomes and perform procedures with lower rates of complications than physicians lacking this specialized training. Consistent with this, we strongly caution the NRC regarding licensure exemptions for radiation therapy procedures.

Resident education in radiation oncology must include five years of accredited, clinically oriented graduate medical education. Four of those five years are spent on focused clinical experience in radiation oncology. The first post-graduate year includes nine months of direct patient care in medical/or surgical specialties other than radiation oncology. No fewer than 36 months of the four-year program must be spent in clinical radiation oncology. There must also be several months allowed for in-depth experience in individually selected areas applicable to radiation oncology.[6]

No other medical program requires such an intimate knowledge of radiation oncology and radiation therapy treatment procedures and their safe administration. The objective of the residency program is to educate and train physicians to be skillful in the practice of radiation oncology, to be caring and compassionate in the treatment of patients, and to be respectful of the potential hazards of radiation to patients and staff. [7] ASTRO believes the current design of the radiation oncology residency program achieves this objective.[8]

In day-to-day practice, the radiation oncologist is responsible for the delivery of radiation to cancer and selected benign disease patients for curative and palliative care. It is the primary responsibility of the radiation oncologist to prescribe, monitor, and maintain the patient's condition while undergoing such treatment. The radiation oncologist also works to identify and treat any side effects from the treatment.

10 CFR § 35.1 explicitly states that its purpose is to "provide for the radiation safety of workers, the general public, patients, and human research subjects." To grant exemptions is in direct conflict with this stated purpose. There is no better way to meet this stated purpose than to ensure that board certified radiation oncologists are involved in the administration of radiation for medical purposes.

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[6] Id.

[7] Id.

[8] The certifying body for radiation oncologists is the American Board of Radiology. Radiation oncologists must complete the above listed requirements and successfully complete both a written and oral examination in order to receive certification from this certifying body. Re-certification is now required at 10 year intervals.

All radiation therapy treatments covered under 10 CFR § 35 require the presence of an "authorized user" throughout the entire procedure. The definition of an "authorized user" is outlined in 10 CFR § 35.2.[9] In addition, 10 CFR § 35, subpart J outlines the current guidelines for training and experience needed for the administration of unsealed byproduct material for therapeutic use. The training and experience that the radiation oncologist possesses far exceeds the requirements of this section. [10]

The training requisites for therapeutic use of unsealed byproduct material, brachytherapy sources, sealed sources for diagnosis, and therapeutic medical devices as described in 10 CFR § 35.930, 35.940, 35.950, and 35.960 states that the authorized user is required to be a physician who is certified by the American Board of Radiology in radiology, therapeutic radiology, or radiation oncology. The American Board of Radiology certifies radiation oncologists who complete the requirements of accredited institutional programs. Residency training programs are accredited through the Accreditation Council of Graduate Medical Education's (ACGME) Radiation Oncology Residency Review Committee (RRC). The RRC has developed explicit requirements that must be adhered to by each residency-training program. The RRC periodically surveys each program to insure that it is in compliance with these requirements. The American Board of Radiology requires satisfactory completion of an accredited program before taking the certifying exam.

Furthermore, the regulations set forth requisites for classroom and laboratory training in basic radioisotope handling techniques as applicable to the use of radiopharmaceuticals, brachytherapy sources, and a sealed source in a therapeutic medical device.[11] All of these requisites are essential components of the radiation oncology residency program. The clinical curriculum of the radiation oncology residency program must provide the resident with an in-depth knowledge of clinical radiation oncology, including the indications for irradiation and special therapeutic considerations unique to each site and stage of the disease. The resident must be trained in standard radiation techniques as well as in the use of treatment aids and treatment planning to optimize the distribution of the radiation dose to target tissue with minimal dose to normal tissue. [12]

Additionally, the curriculum must specifically provide instruction in the physics, cancer biology, radiation safety, and clinical applicability of the following areas: radio-surgery, intra-operative radiation therapy, three-dimensional conformal treatment planning and delivery, radioimmunotherapy, unsealed sources, total body irradiation as used in stem cell transplantation, total skin irradiation, high- and low-dose-rate brachytherapy, hyperthermia, kilovoltage irradiation, plaque therapy, particle therapy,

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[9] A board certified radiation oncologist is deemed an authorized user as defined in 10 CFR Part 35.2.

[10] The Society is aware that the NRC is in the process of rulemaking related to the mechanisms by which training and experience requirements may be satisfied and some related parts of subpart J are due to expire in October 2004.

[11] See 10 CFR § 35.930, 35.940, 35.950 and 35.960 for a complete listing of training and experience requirements.

[12] *Graduate Medical Education Directory 2003-2004*, The American Medical Association (2003).

intravascular brachytherapy, and any others that may be developed as they apply to the core curriculum.[13]

The resident also must be trained in the use of external beam modalities, including photon, x-ray, and particulate beam megavoltage irradiation, simulation using conventional CT and/or PET/CT simulators to localize anatomy, and computerized treatment planning. The faculty must also ensure that the resident personally performs technical procedures, including treatment setups as well as intracavitary and interstitial placement of radiation sources.[14]

To insure consistent quality health care and high-level competency, state law mandates that radiation oncologists to undergo continuing medical education courses.[15] These courses are mandatory for license re-registration each year. These courses allow radiation oncologists to refresh their skills as well as learn new and innovative techniques in radiation therapy.

This level of training is available, only, in a radiation oncology program that is certified by the ACGME. Although other residency programs may provide some information on the use of radiation therapy, the level of information is limited and does not match the depth of knowledge required by a board certified radiation oncology training program. It also is acknowledged that radiation oncology training programs require knowledge about other aspects of multi-disciplinary care, including medical oncology, surgical oncology, neurology, urology, and cardiology.

Checking treatment parameters by multiple professionals with complimentary experience and knowledge in radiation biology, radiation safety and medical physics is critical to minimizing errors in radiation therapy. Medical radiation physicists are a critical part of this team, along with the radiation oncologists, to ensure patient safety during these potentially dangerous treatments. The medical physicist is trained to handle radiation emergencies that may occur during the procedure. The radiation oncologists specify the total radiation dose and oversee the delivery and dose schedule to be delivered for a particular disease site while the medical physicist insures this dose and schedule is being accurately delivered by calibration of the treatment units and weekly assessment of the delivery schedule.

The treatment that a radiation oncologist gives to its patient is distinctly unique. The radiation oncologist approaches radiation therapy through a multi-tiered team approach. The radiation oncologist works closely with the medical radiation physicist, radiation therapist, dosimetrist, radiation oncology nurse, social worker, and dietitian to ensure high quality patient care and safety. In particular, the radiation oncologist has formed a complex and extremely efficient working relationship with the medical

[13] Id.
[14] Id.
[15] According to the American Medical Association, continuing medical education credit hours vary from 12 to 50 hours per year for license re-registration.

radiation physicist to oversee the work of the dosimetrist and to help insure that complicated treatments are properly tailored for each patient.

Ensuring that the dose prescription is being adhered to is paramount to patient safety in this regard. The interaction between the medical radiation physicist and radiation oncologist has developed and increased over time due to the increased complexity of radiation therapy medical interventions and the necessity to ensure the safe delivery of radiation treatment. Whether in stereotactic treatment of malignant disease or non-malignant disease, this team is instrumental in minimizing irretrievable errors in the delivery of these extremely high doses of radiation.

Conclusion

Clearly, only authorized users, such as the radiation oncologist, meet the requirements set forth in 10 CFR § 35. It is even more evident that only these individuals possess the specialized training and experience that is vital to carrying out all procedures governed by the regulations. The educational and training program as set forth by the ACGME ensures that radiation oncologists are thoroughly indoctrinated on all aspects of radiation therapy treatments.

Therefore, it is imperative that the NRC not allow state licensure exemptions that exclude radiation oncologists from the above stated procedures. To date, there is no other specialty that possesses the skill, knowledge, or expertise in the comprehensive implementation and safe application in the totality of radiation therapy procedures that is currently held by radiation oncologists.

The public impact of such licensure exemptions could prove to be detrimental. The allowance of such exemptions could result in poor quality healthcare, inappropriate radiation exposure, unsafe working conditions, and a significant increase in the probability of medical errors. Accordingly, it is in the best interest of public health and safety that a consistent policy be applied. Physicians who are trained in this particular specialty should be the primary care givers.

Radiation oncologists are specially trained in the medical application of radioisotopes and related radiation therapy procedures. Therefore, they should be physically present in all medical procedures in which byproduct materials are used for radiation therapy procedures to ensure the radiation safety of workers, the general public, patients, and human research subjects.

ASTRO would like to commend the NRC on its efforts to revise 10 CFR § 35, and the Society appreciates the opportunity to comment on rulemaking policy. It is our hope that we can stay involved in this process, and we look forward to working with the Commission toward one common goal, guaranteeing the safe and proper medical use of byproduct material for all Americans.[16]

[16] Prepared by ASTRO, May 13, 2003.

From: <Gibbus1234@aol.com>
To: <arw@nrc.gov>
Date: 5/13/03 2:59PM
Subject: ACMUI recommendations for rad onc

Dear Ms. Williamson:
I am the Director of the Cardiac Catheterization Laboratory at Washington Adventist Hospital in Takoma Park MD. We have an active brachytherapy program that is successful and highly beneficial for our patients. In order to provide this service to all patients in need, we need to have expanded coverage with the radiation oncology department. A firm requirement to have the radiation oncologistphysically present as authorized user will reduce by at least 25% the availability of this necessary therapeutic procedure. The license guidance statement in the past that allowed for either the authorized user or authorized medical physicist to be present was a wise policy allowing flexibility. The guidelines permitted the radiation oncologist to authorize the medical phyisicist to be supervised as the authorized user in the case that the oncologist is unavailable. The procedure is still supervised by a highly trained professional who is knowledgeable in all aspects of the procedure (i.e. the physicist). The dosimetry of the procedure with the Novoste device is actually determined by the interventional cardiologist who assesses vessel diameter and injury length. The radiation oncologist or physicist is needed to maintain and provide the source, to assist in the preparation of the transfer device, and to deliver the source when needed. The interventionalist can easily "push" the source and prepare the delivery catheter. The maintenance of the source and oversight of all safety issues can be performed by the physicist.

Please consider continuing the status quo, requiring the authorized user or physicist to be present during the procedure. The flexibility is needed to assure full access of patients to this treatment when radiation oncologists are not available or are in short supply.

Thank you for your consideration of this email.

Sincerely,
David M. Brill, M.D.
Director, Cardiac Catheterization Laboratory
Washington Adventist Hospital
Takoma Park, MD 20912

CC: <gfarnan@novoste.com>

From: "Albert E. Raizner" <araizner@houston.rr.com>
To: "Angela R. Williamson" <arw@nrc.gov>
Date: 5/13/03 2:10AM

Angela R. Williamson,
Office of Nuclear Materials Safety and Safeguards,
U.S. Nuclear Regulatory Commission, Mail Stop T-8F5,
Washington, DC 20555-0001.

Dear Ms. Williamson

I am the Medical Director of the Methodist-DeBakey Heart Center, Houston, Texas, and an interventional cardiologist. Our institution has had a very active program in vascular brachytherapy for the treatment of in-stent restenosis. Patients are transferred to us 24/7 for vascular brachytherapy. Despite the excellent cooperation, enthusiasm, and support of our outstanding group of radiation oncologists, a major concern remains the lack of immediate availability of our radiation oncology colleagues. Not infrequently, a sick and unstable patient is found to have in-stent restenosis and requires immediate angioplasty and brachytherapy. To delay the procedure until the radiation oncologist is physically available poses a serious potential safety risk to the patient.
Consequently, we strongly support the current Guidance that allows VBT to be preformed under the supervision of the Authorized User with the presence of the Authorized User or Authorized Medical Physicist. In our institution, the Authorized User's use of a Written Directive has not been overused or abused, but is an option that may be life-saving in infrequent emergency situations. Changing the classification of VBT to an HDL class would require the RO's physical presence at ALL brachytherapy procedures, including the unexpected emergency procedures, and thereby impose such a safety risk to the patient and potential liability to the doctors and hospital. We consequently oppose such a change in VBT classification.

Respectfully,

Albert E. Raizner, M.D.
Medical Director
Methodist-DeBakey Heart Center
Houston, Texas

CC: "Farnan, Gail" <gfarnan@novoste.com>

From: "Spencer King" <sking@acrionline.org>
To: <arw@nrc.gov>
Date: 5/13/03 6:08PM

Angela R Williams
Office of Nuclear Materials and Safeguards
US Nuclear Regulatory Commission Mail Stop T-8F5
Washington DC 200555 0001

I am writing to support the current guidence from NRC that allows VBT to be performed under the supervision of an authorised user with the persance of the authorised user or authorized medical physicists. This system is working well allowing this effective therapy to be offered to patients suffering in-stent restenosis. There are not enough available radiation oncologists to provide this service. If this guidence is changed the care of many patients will be seriously impacted.

Spencer King MD MACC
Fuqua Chair of Cardiology
The Fuqua Heart Center
Clinical Professor of Medicine Emory University

Arizona Oncology Services

May 14, 2003

Angela R. Williamson,
Office of Nuclear Materials Safety and Safeguards,
U.S. Nuclear Regulatory Commission, Mail Stop T-8F5,
Washington, DC 20555-0001.

Dear Ms. Williamson,

I am a Radiation Oncologist at St. Joseph's Hospital and Medical Center in Phoenix, AZ and I would like to have this written statement entered into the public record of the NRC's Advisory Committee on the Medical Uses of Isotopes meeting scheduled for May 20-21, 2003.

Our Radiation Oncology group supports several active Vascular Brachytherapy programs in the Phoenix area for the treatment of in-stent restenosis. We believe that Vascular Brachytherapy is a valuable technology that needs to be provided to patients and have seen the clinical benefit to those patients who have received the treatment for in-stent restenosis. Our challenge has been physically covering these ad hoc cases on any given day across the city of Phoenix, while managing an active Radiation Oncology program. Since we strongly believe in the technology and feel that the Vascular Brachytherapy Systems are simple to use, we have worked with our multidisciplinary team to develop a "Supervised User Vascular Brachytherapy Program" to allow open access to patients requiring Vascular Brachytherapy in those instances that a Radiation Oncologist is not physically able to attend a procedure. All procedures are conducted under the supervision of the Authorized User, who consults with the Interventional Cardiologist and Medical Physicist prior to initiating the treatment and provides a Written Directive. All procedures are conducted in the physical presence of the Authorized User (when available) or Medical Physicist. We also developed and implemented additional emergency training procedures for the Vascular Brachytherapy team.

It is our opinion that Vascular Brachytherapy can safely be administered under the supervision of the Authorized User without requiring his/her physical presence during the procedure and strongly oppose any proposed change to the NRC guidance that would return the mandatory requirement for the Authorized User to be physically present for all Vascular Brachytherapy procedures. This proposed change would significantly impact patient's ability to access this clinically proven technology AND may impose a safety risk to patients and a potential liability to the doctors and hospital.

Sincerely,

Burton L. Speiser, MD, MS, FACR, FACRO
Medical Director

BLS/lat

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Modification for Use of Novoste Device for Coronary Brachytherapy #1

1. The Radiation Oncologist will do a consultation. The Radiation Oncologist, who is the AUTHORIZED USER, will write the prescription for the treatment.
2. The Physicist will be present in the Cath Lab throughout the use of the device.
3. The Cardiovascular Technician will be trained to prepare the Novoste Device in a sterile setting. They will also perform the check of the device and catheter with the Medical Physicist.

Modification for Use of Novoste Device for Coronary Brachytherapy #1

4. The information concerning the location of the In Stent Restenosis (ISR), the Reference Vessel Diameter (RVD) and length of the injured artery will be transmitted to the Radiation Oncologist. The Radiation Oncologist will verify the dose prescription to include the dose, dose to specific depth, length of vessel to be treated, and location of treatment to the Physicist.
5. The Cardiovascular Technician trained on this device will then bring the Novoste device in a sterile condition to the patient and assist the Interventional Cardiologist in the placement in the Novoste Beta Cath delivery catheter.

Modification for Use of Novoste Device for Coronary Brachytherapy #1

6. The Cardiovascular Technician will hydraulically send the active sources to the treatment site.
7. The Physicist will time the start of treatment and notify the Cardiovascular Technician when the sources are to be removed. They will also perform dose measurements while the source is out of the device.
8. The Cardiovascular Technician will be return the sources to the device when the Physicist indicates that the treatment time has expired. The Cardiovascular Technician will then remove the device and delivery catheter to the preparation table.

Modification for Use of Novoste Device for Coronary Brachytherapy #1

9. The Physicist will check to ensure that there is no radiation present other than the sources within the "safe position" in the Novoste Device.
10. The Physicist will secure the device, perform a radiation survey and fill out all pertinent paperwork necessary for: a) Compliance with Arizona Radiation Regulatory Agency; b) As mandated for medical/clinical purposes.

Modification for Use of Novoste Device for Coronary Brachytherapy #2

1. The Radiation Oncologist will do a consultation. The Radiation Oncologist, who is the AUTHORIZED USER, will write the prescription for the treatment.
2. The Physicist will be present in the Cath Lab throughout the use of the device.
3. The Physicist will attach the non-sterile portion of the XL catheter to the device (the device is on a non-sterile field, the catheter – sterile portion is in a sterile holder on a sterile field). The Physicist performs the catheter/device check.

Modification for Use of Novoste Device for Coronary Brachytherapy #2

4. When In Stent Restenosis (ISR) is confirmed, the Radiation Oncologist is called to the Cath Lab.
5. The Radiation Oncologist is in scrubs, but not sterile gown.
6. The Beta Cath device (non-sterile) is placed on a mayo stand (non-sterile) at the foot of the procedure table and the sterile portion of the catheter is placed on the sterile field by the Cardiovascular Technician.
7. The Cardiovascular Technician will assist the Cardiologist in placing the delivery catheter.

Modification for Use of Novoste Device for Coronary Brachytherapy #2

8. When in place, the Radiation Oncologist will "send" the sources to the treatment site and will retract the sources when notified by the Physicist who is keeping the elapsed time.
9. The device and catheter is returned to the set-up table for the Physicist. The Physicist will check to ensure that there is no radiation present other than the sources within the "safe position" in the Novoste Device.
10. The Physicist will secure the device, perform a radiation survey and fill out all pertinent paperwork necessary for: a) Compliance with Arizona Radiation Regulatory Agency; b) As mandated for medical/clinical purposes.

DISCUSSION: THE LISTING OF CERTAIN PRACTITIONERS IN 35.1000

NO HANDOUT PROVIDED

Interpretation of 10 CFR 35.61(b), Conditions for Use of Survey Instruments

R. E. Zelac

ACMUI Meeting
May 21, 2003

Specific Requirement

- Use of a survey instrument is prohibited if the difference between the indicated exposure rate and the calculated exposure rate from the calibration source is more than 20%

Changes from Previous Requirement

- Clear statement (previously implied) that instruments which are out of calibration are not to be used
- Acceptable response range for in-calibration (without mandatory correction table or chart) broadened to +/- 20%

Rationale for Current Requirement

- General consistency with calibration acceptability in a national performance standard*

*ANSI-N323A-1997, "Radiation Protection Instrumentation Test and Calibration-Portable Survey Instruments"

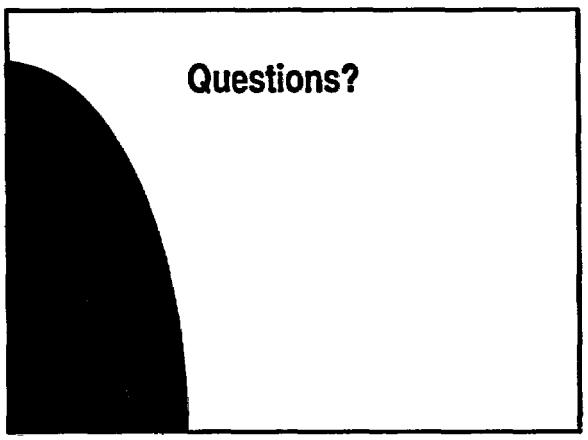
Preferred approach*

- For instrument calibration, a source should be used that has approximately the same photon energy as that in the environment to be assessed

*Per ANSI-N323A-1997

In Practice

- Survey instrument calibrations are usually done with a high energy source, regardless of average energies of photons in fields being assessed
- Many energy-dependent instruments calibrated with a high energy source should respond within the +/- 20 % limit when used in a low energy field (often reading high)
- Note that energy mismatch is not an issue for medical use instruments with essentially energy-independent response (ion chamber type)


Questions?

Medical Area Operating and Enforcement Experience

Roberto J. Torres
NMSS Regional Coordinator
U.S. Nuclear Regulatory Commission

May 21, 2003

Events in Non Agreement States

- Misadministrations:
  - 2000 - 10 events
  - 2001 - 16 events
  - 2002 - 7 events (1/1/02 - 10/24/02)
- Medical Events:
  - 2002 - 1 event (10/25/02 - 12/31/02)
  - 2003 - 8 events (1/1/03 - 4/18/03)

Types of misadministrations and escalated enforcement actions - Year 2000

- Diagnostic nuclear medicine - 2 events
  - Authorized user did not prepare written directive
  - Physician error when administering I-131 capsules
- Therapeutic nuclear medicine - 1 event
  - Failure from technologist to verify written directive
    - SL III, multiple failures to implement QMP
- High Dose Rate remote afterloaders - 2 events
  - Step size increase error by person entering the data
  - Operator error when digitizing film data

Types of misadministrations and escalated enforcement actions - Year 2000

- Gamma Stereotactic Radiosurgery - 1 event
  - X, Z coordinates transposed
- Manual brachytherapy - 4 events
  - Applicator not manually secured
    - SL III, failure to have written procedure in QMP
  - Physician error - Glia Site
  - Equipment failure, Sr-90 Theraspheres
  - Calculation mistake in conversion equation
    - SL III, failure to have written procedure in QMP

Types of misadministrations and escalated enforcement actions - Year 2001

- Diagnostic nuclear medicine - No events
- Therapeutic nuclear medicine - 4 events
  - Failure to verify written directive in 2 events
  - Technologist failed to administer full dosage
  - Sm-153 underdosages to 61 patients (9 hospitals)
    - SL III, failure of radiopharmacy to dispense correct doses
- Gamma Stereotactic Radiosurgery - 2 events
  - Use of wrong patient's treatmemt plan
  - Incorrect entry of treatment time

Types of misadministrations and escalated enforcement actions - Year 2001

- High Dose Rate remote afterloaders - 5 events
  - Software inadvertently altered step size
  - Failure of physician to transcribe the revised treatment plan to the treatment worksheet
  - Incorrect entry of dwell index
  - Catheter stopped short from intended site -IVB
  - Failure to follow procedures - IVB

Types of misadministrations and escalated enforcement actions - Year 2001

- Manual brachytherapy - 5 events
  - Technologist incorrectly measured data points
  - Improper insertion of needle into vial, Y-90
  - Overpressurization of vial caused leak, Y-90
  - Implantation of leaking I-125 seeds
  - Dose less than prescribed after seed implantation

Types of misadministrations and escalated enforcement actions - Year 2002 (until 10/24/02)

- Diagnostic & therapeutic nuclear medicine - No events
- Gamma Stereotactic Radiosurgery - No events
- High Dose Rate remote afterloaders - 4 events
  - IVB, equipment failure
  - IVB, use of different cardiac catheter
  - IVB, catheter did not reach intended treatment site
  - IVB, catheter did not reach intended treatment site

Types of misadministrations and escalated enforcement actions - Year 2002 (until 10/24/02)

- Manual brachytherapy - 3 events
  - Lack of independent review of treatment plan and independent verification of source strength
  - Patient moved abruptly dislodging the applicator
  - Authorized user dropped the source when inserting/loading the applicator
    - SL III, failure to have a procedure to ensure that all sources are implanted according to a written directive and failure to perform surveys after implanting sources

Types of medical events and escalated enforcement actions Year 2002 (10/25/02 through 12/31/02)

- Manual brachytherapy - 1 event
  - Sr-90 ophthalmic treatment involving 36 patients that received doses 32% greater than prescribed when incorrect data was used in treatment planning
    - Pending evaluation from medical consultant
    - Pending determination of enforcement action, if any

Types of medical events and escalated enforcement actions -Year 2003 (until 4/18/03)

- Diagnostic nuclear medicine - 1 event
  - Nine year old patient received 400 microcuries of I-131 instead of the prescribed 4 microcuries
    - Pending evaluation from medical consultant
    - Pending determination of enforcement action, if any
- Therapeutic nuclear medicine - 1 event
  - Technologist failed to administer complete dosage as prescribed by the physician
    - Pending determination of enforcement action, if any

Types of medical events and escalated enforcement actions - Year 2003 (until 4/18/03)

- Gamma Stereotactic Radiosurgery - No events
- High Dose Rate remote afterloaders - 4 events
  - Inadequate procedures/training for the use of the unit
  - Wrong data entered for dwell positions
  - IVB, failure of staff to follow modified written directive from the authorized user
  - IVB, sources did not reach full position
    - Pending determination of enforcement actions for the previous four events, if any

Types of medical events and escalated enforcement actions - Year 2003 (until 4/18/03)

- Manual brachytherapy - 2 events
  - Forty I-125 seeds implanted in unintended area, less than half dose given to intended site
  - Forty-two I-125 seeds implanted in unintended area, 100% given to unintended site
    - Pending OGC decision to classify these two events as medical event or not
    - Pending determination of enforcement actions for the previous two events, if any

Events in Agreement States

- Misadministrations:
  - 2000 - 19 events
  - 2001 - 24 events
  - 2002 - 19 events (1/1/02 - 10/24/02)
- Misadministrations or Medical Events:
  - 2002 - 4 events (10/25/02 - 12/31/02)
  - 2003 - 4 events (1/1/03 - 4/18/03)

Agreement States Adoption of Revised Part 35

- Adopted revised Part 35
  - Iowa
- Final rule in place
  - Wisconsin (Agreement State 7/03)
- Proposed rule
  - Minnesota (Agreement State sometime in 2004)
  - Maine

AGENDA TOPIC: RECOMMENDATIONS FROM FALL 2002 MEETING

MEMORANDUM TO: Manuel D. Cerqueira, M.D., Chairman
Advisory Committee on the
Medical Uses of Isotopes

THRU: Donald A. Cool, Director
Division of Industrial and
Medical Nuclear Safety, NMSS

FROM: Thomas H. Essig, Chief
Materials Safety and Inspection Branch
Division of Industrial and Medical
Nuclear Safety, NMSS

SUBJECT: RESPONSE TO RECOMMENDATIONS FROM THE OCTOBER 28, 2002 MEETING OF THE ADVISORY COMMITTEE ON THE MEDICAL USES OF ISOTOPES

Below are the recommendations from the October 28, 2002 meeting of the Advisory Committee on the Medical Uses of Isotopes (ACMUI). Following each recommendation is the U.S. Nuclear Regulatory Commission (NRC) staff's position.

Status: ACMUI-formulated Training and Experience Recommendations to Amend the Revised 10 CFR Part 35, Medical Use of Byproduct Material

ACMUI recommendation: The ACMUI recommends that the Chairman, ACMUI, contact the NRC Chairman to inquire about the status of the training and experience (T&E) recommendations the ACMUI subcommittee formulated to amend the T&E in the revised 10 CFR Part 35, Medical Use of Byproduct Material.

Staff response: This recommendation does not require action by NRC staff. However, staff will monitor the resolution of the T&E issue and keep the ACMUI informed.

Contact: Angela Williamson, NMSS/IMNS
(301) 415-5030

Review Licensing Guidance for Emerging Technologies

ACMUI recommendation: The ACMUI recommends that the Chairman, ACMUI, form a standing subcommittee to review 10 CFR 35.1000 licensing guidance as it is developed by NRC staff.

Staff response: Staff supports this proposal and plans to utilize the ACMUI subcommittee when it is formed.

Sealed Source Model Numbers as License Conditions on NRC Licenses

ACMUI recommendation: The ACMUI recommends that NRC initiate a rulemaking process to modify 10 CFR Part 35 to override 10 CFR Part 30.32(g)(1), to allow more generic listing of interstitial seeds and sources on NRC licenses.

Staff response: Staff believes that a rulemaking initiative to modify 10 CFR Part 35 to override 10 CFR Part 30.32(g)(1), for the purpose stated, may ultimately reduce radioactive source accountability.

Title 10 CFR Part 30.32 (g)(1), which requires the listing of all sources or devices by manufacturer and model number, was implemented to ensure that licensees maintain full accountability of the sources/devices under their care. Staff believes that identification of all sources/devices by manufacturer and model number is a reasonable measure to ensure that accountability is maintained. Such accountability aids licensees in keeping an accurate inventory of sources, which helps prevent loss of radioactive material, thereby protecting public health and safety.

Furthermore, staff does not believe it to be prudent to reduce accountability of radioactive material in an environment of heightened public awareness and sensitivity, brought on by the terrorist events of September 11, 2001.

For these reasons, staff is unable to support the stated rulemaking initiative.

Approaching ACMUI Vacancies

ACMUI recommendation: The ACMUI recommends that NRC initiate replacement of the approaching Nuclear Cardiologist, Patient Advocate, and State Representative vacancies. Inherent in this recommendation is the replacement of a Chair, since the current Nuclear Cardiologist is also the Chair of the ACMUI.

Staff response: Staff agrees with this recommendation. Furthermore, staff discussed these approaching vacancies before bringing this issue to the October 28, 2002, ACMUI meeting as an agenda topic, and had already made the decision to pursue this matter expeditiously, to minimize disruption of ACMUI's service to the staff.

Moreover, the Commission formally approved - via issuance of a staff requirements memorandum dated December 17, 2002 - the staff's request to launch the replacement process. Although the process includes the routine step of soliciting resumes in the Federal Register, staff will also contact several professional societies (per Commission instruction) so that the solicitation of resumes is broadly announced.

Development of Questions and Answers (Q&As) for Part 35

R. E. Zelac

ACMUI Meeting
May 21, 2003

Objectives

- Develop, for Agency-wide and public use, standard answers to questions of general applicability
- Post Q&As on the NRC website, for broad access on demand

Sources of Questions

- Agency staff training sessions
- Public workshops on implementation
- Calls, e-mails, letters to NRC staff from stakeholders
- Implementation issues identified by NRC staff

Process

- IMNS's Medical Projects Working Group develops draft Answers (As), etc., as required
- Agency-wide Part 35 Q&A Review Group comments on draft Q&As; adjustments, as appropriate

Process (cont.)

- Office of General Counsel comments on adjusted draft Q&As; further adjustments, as appropriate
- IMNS management reviews further-adjusted draft Q&As to declare, after possible added adjustment, as final

Process (cont.)

- Final As provided to questioners, if requested
- Final Q&As posted on the NRC Part 35 website*

*www.nrc.gov/materials/miau/miau-reg-initiatives/

Current Status

- 78 Q&As final and web-posted
- 168 Q&As in various stages of review process

Questions?

35.1000 Licensing Guidance

May 2003
ACMUI Meeting

Donna-Beth Howe, Ph.D.
Robert Ayres, Ph.D

35.1000 Licensing Guidance

- Microsphere Brachytherapy Sources and Devices
- Liquid Brachytherapy Sources and Devices
- Intravascular Brachytherapy

35.1000 Licensing Guidance

Standard characteristics
Unique characteristics
Safety problems
Potential Regulatory problems
Licensing Guidance

35.1000 Licensing Guidance

Microsphere Brachytherapy Sources and Devices

Standard characteristics
- sealed sources
- permanent implant brachytherapy

Unique characteristics of Microspheres:
- Small size 10-25 micron diameter
- Large number per treatment 250,000 -1,000,000
- Special delivery system
- TheraSphere Humanitarian device exemption approval

35.1000 Licensing Guidance

Microsphere Brachytherapy Sources and Devices

Safety problems
- Unable to deliver microspheres to patient resulting in medical events
- Spread of removable contamination

Potential Regulatory problems
- Shunting may be common - to treat individual patient is medical decision
- Treatment end point for SIRSpheres is visual backflow using fluoroscopy

35.1000 Licensing Guidance

Liquid Brachytherapy Sources and Devices

I-125 Iotrex™ Liquid Brachytherapy Source in Proxima GliaSite® Radiation Therapy System:

Standard characteristics
- I-125 source
- Temporary implant brachytherapy

35.1000 Licensing Guidance

Liquid Brachytherapy Sources and Devices

Unique characteristics :

- Liquid contained source
- Special containment system
- Earlier surgical implantation of containment system
- Containment leakage test
- Source labeling
- Small amount of disassociated I-125 moves across catheter barrier

35.1000 Licensing Guidance

Liquid Brachytherapy Sources and Devices

Safety problems

- **Leaking source in patient requires different expertise than normal use**
- **Saline and radiopaque dye visually indistinguishable resulting in medical event**
- **Normal handling may result in contamination**

AGENDA TOPIC: 35.1000 LICENSING GUIDANCE

Microsphere Brachytherapy Sources and Devices

TheraSphere and SIRSphere Yttrium-90 Microspheres

Standard characteristics

sealed sources
permanent implant brachytherapy

Unique characteristics of Microspheres:

Small size 10-25 micron diameter
Large number per treatment 250,000
Special delivery system
TheraSphere Humanitarian device exemption approval
SIRSphere

Safety problems

Unable to deliver microspheres to patient resulting in medical events
Removable contamination

Potential Regulatory problems

Shunting may be common - to treat individual patient is medical decision
Treatment end point for SIRSpheres visual backflow on fluoroscopy

Microsphere Brachytherapy Sources and Devices

Licensing Guidance - TheraSphere and SIRSphere Yttrium-90 Microspheres

Y-90 microspheres are manual brachytherapy sources used for permanent brachytherapy implantation therapy.

Authorized users must meet the training and experience requirements of either 10 CFR 35.490 or, until October 25, 2004, 10 CFR 35.940 as well as the specific vendor training in the use of the microspheres and the microsphere delivery system.

Leak tests are not required because the activity per microsphere (the sealed source) meets the criteria in 10 CFR 35.67(f) for relieving the licensee from the requirements to perform such tests. The licensee shall follow all the requirements in 10 CFR Part 35 for brachytherapy sources and manual brachytherapy use except where the following license conditions provide regulatory relief:

For Y-90 microspheres, "prescribed dose" means the total dose documented in the written directive.

The written directive should include: (1) prior to implantation: the treatment site, the radionuclide (including the chemical/physical form (Y-90 microspheres)), and dose; and (2) after implantation but prior to completion of the procedure: the radionuclide (including the chemical /physical form (Y-90 microspheres)), treatment site, and the total dose.

The written directive should specify the maximum dose that would be acceptable for a specified site (or sites) outside the primary treatment site to which the microspheres could be shunted (such as the lung and gastrointestinal tract).

Procedures for administrations requiring a written directive should, for Y-90 microsphere administrations, describe how to quantify the total dose to the treatment site as well as the total dose to other sites upon completion of the administration to confirm that the administration is in accordance with the written directive.

The quarterly physical inventory of sealed sources and brachytherapy sources should include the individual aggregates of the microspheres identifying the radioisotope, the container the aggregate is in, the total activity of the aggregate, and the location of the container.

Procedures should describe measures taken to ensure that the bremstrahlung emissions from each patient or human research subject permits his/her release in accordance with 10 CFR 35.75.

The following additional guidance applies when the Y-90 microspheres are placed in vials, syringes, or radiation shields that are not labeled by the manufacturer:

Label vials and vial radiation shields with radioisotope and form (i.e., Y-90 microspheres).

Label syringes and syringe radiation shields with the radioisotope, form, and therapeutic procedure (i.e., Y-90 microspheres, brachytherapy).

Notes to Licensees

Change in physical conditions of use.

If the physical conditions of use exceed those reported in the SSD certificate, the limited specific medical use licensee should request an amendment for the new conditions, and broad scope licensee should perform its own engineering and radiation safety evaluation addressing those differences.

Use of other Y-90 microspheres.

The SSDR safety evaluation for a specific manufacturer's Y-90 microspheres does not cover the use of any other Y-90 microspheres, including the preparation of Y-90 on other microspheres by a commercial nuclear pharmacy, the medical use licensee's authorized nuclear pharmacist, or a physician authorized user qualified to prepare radioactive drugs. The medical use of such a source will require a new SSD certificate (or safety evaluation by the broad scope medical use licensee) that addresses the conditions of use, safety of the new Y-90 microspheres, and compatibility of the new microspheres with microsphere delivery system(s).

The SSDR safety evaluation for a manufacturer's Y-90 microsphere delivery system does not cover the use of any other delivery system with the Y-90 microsphere brachytherapy device. Prior to authorization, the medical use of such a delivery system will require a new SSD certificate (or safety evaluation by the broad scope medical use licensee) that addresses the conditions of use, safety of the microsphere delivery system, and compatibility of the new delivery system with the Y-90 microspheres.

TheraSphere use outside Humanitarian Device Exemption (HDE) restrictions.

The MDS Nordion Y-90 TheraSphere® microspheres are currently approved by the U.S. Food and Drug Administration (FDA) under the provisions of a "Humanitarian Device Exemption" (HDE No H9800006)), which includes unique restrictions on the medical use of the devices. Nothing in the NRC license relieves the licensee from complying with those FDA requirements.

If the Institutional Review Board that is required to approve and monitor the use of the MDS Nordion TheraSphere® determines that the particular use of the TheraSphere® is for research purposes, the licensee must meet the requirements in 10 CFR 35.6, "Provisions for research involving human subjects." (Note: One of the conditions of approval for an HDE is that there be an Institutional Review Board initial review and approval before a humanitarian use device is used at a facility, as well as, continuing review of its use.)

Liquid Brachytherapy Sources and Devices

I-125 Iotrex™ Liquid Brachytherapy Source in Proxima GliaSite® Radiation Therapy System:

Standard characteristics

I-125 source
Temporary implant brachytherapy

Unique characteristics of Proxima GliaSite® Radiation Therapy System:

Liquid contained source
Special containment system
Containment leakage test
Source labeling
Small amount of disassociated I-125 moves across catheter barrier

Safety problems

Leaking source in patient requires different expertise than normal use
Saline and Radiopaque dye visually indistinguishable resulting in medical events
Normal handling may result in contamination

Liquid Brachytherapy Sources and Devices

Licensing Guidance - I-125 Iotrex™ Liquid Brachytherapy Source in Proxima GliaSite® Radiation Therapy System:

I-125 Iotrex™ liquid brachytherapy sources are manual brachytherapy sources used for temporary brachytherapy implantation therapy in the Proxima Therapeutics' GliaSite® Radiotherapy system.

The Proxima Therapeutics' GliaSite® Radiotherapy system (RTS) consists of the Proxima Therapeutics' GliaSite® Radiotherapy system balloon catheter and Iotrex™ liquid brachytherapy source.

Required training and experience for authorized users is specified in 10 CFR 35.490 or, until October 25, 2004, 10 CFR 35.940 for use with materials governed by 10 CFR 35.400, as well as vendor training in use of the Proxima Therapeutics' GliaSite® RTS.

An authorized user with experience in radiopharmaceutical therapy procedures should be on call to provide guidance in case of leakage of the implanted device.

The licensee shall follow all of the requirements in 10 CFR Part 35 for brachytherapy sources and manual brachytherapy use, except where the following license conditions provide regulatory relief:

For brachytherapy using Proxima Therapeutics' GliaSite® RTS, "prescribed dose" means the total dose documented in the written directive.

The written directive should include: (1) prior to implantation: the treatment site, the radionuclide (including the chemical/physical form (Iotrex™)), and dose; and (2) after implantation but prior to completion of the procedure: the radionuclide (including the chemical /physical form (Iotrex™)), treatment site, and the total dose.

Procedures should specify how to confirm that the balloon does not leak prior to injection of the Iotrex™ or while Iotrex™ is implanted in the patient or human research subject.

"Source leakage" for the Iotrex™ implanted in the GliaSite® RTS means leakage of I-125 that results in a dose that exceeds 0.5 Sv (50 rem) dose equivalent to any individual organ other than the treatment site (based on definition of a medical event).

The licensee shall retain a record of the leak test for 3 years (the period that 10 CFR 35.2067 requires for brachytherapy sources).

The licensee shall report a leaking source to the NRC within 5 days of the leakage test to the locations specified and provide the information identified in 10 CFR 35.3067.

The licensee shall provide instructions on how to safely handle contamination of unsealed materials, in addition to the instructions required by 10 CFR 35.410, "Safety instruc

The following additional guidance applies when Iotrex™ is placed in vials, syringes, or radiation shields that are not labeled by the manufacturer:

Label syringes and syringe radiation shields with the radioisotope, form, and therapeutic procedure (i.e., I-125 Iotrex™ for brain brachytherapy).

Label vials and vial radiation shields with the radioisotope and form (i.e., I-125 Iotrex™).

Notes to Licensees:

Change in physical conditions of use.

If the physical conditions of use exceed those reported in the SSD certificate, the limited specific medical use licensee should request an amendment for the new conditions, and broad scope licensee should perform its own engineering and radiation safety evaluation addressing those differences.

Use of other I-125 liquid brachytherapy sources or balloon treatment catheters.

The SSDR safety evaluation for the Iotrex™ does not cover the use of any other I-125 source, including the preparation of NA-3-[I-125]iodo-4hydroxybenzenesulfonate by a commercial nuclear pharmacy, the medical use licensee's authorized nuclear pharmacist, or physician authorized user qualified to prepare radioactive drugs. Prior to authorization, the medical use of such a source will require a new SSD certificate (or safety evaluation by the broad scope medical use licensee) that addresses the conditions of use, safety of the new liquid brachytherapy source, and compatibility of the new source with the containment vessel.

The SSDR safety evaluation for the GliaSite® RTS balloon catheter does not cover the use of any other balloon catheter to contain a liquid brachytherapy source. Prior to authorization, the medical use of such a balloon catheter will require a new SSD certificate (or safety evaluation by the broad scope medical use licensee) that addresses the conditions of use, safety of the new liquid brachytherapy source container, and compatibility of the new container with the liquid brachytherapy source.

Use of fluids that can reduce the effective dose delivered:

10 CFR 35.41 requires the licensee to develop, implement, and maintain written procedures to confirm that each administration is in accordance with the written directive. If any fluid used during inflation, imaging, or afterloading of the GliaSite® RTS, etc., (when mixed with prescribed activity of Iotrex™ in the GliaSite® RTS) can cause an effective dose reduction of greater than 20 percent, the required procedures should describe how the licensee ensures that the fluid is not present when the Iotrex™ and

saline are added to the catheter or measures the activity of the Iotrex™ upon removal of the Iotrex™ from the patient.

The licensee should try to avoid the human errors that lead to most medical events (i.e., mislabeling syringes, color code syringe/vial labeling errors, and picking up the wrong syringe because it is within reach of the intended syringes).

Note: Proxima Therapeutics has determined that when a radiopaque dye with 330 milligrams of iodine per millimole of solution is diluted to a 25 percent strength solution, the GliaSite® balloon can still be imaged and the diluted dye will absorb less than 20 percent of the I-125 dose from the Iotrex.™ Therefore, if the licensee follows Proxima Therapeutics directions and dilutes the radiopaque dye every time the GliaSite® balloon is imaged, the licensee will not have to measure the activity of the Iotrex™ upon its removal from the patient. In this case, the volumetric measurement of the removed Iotrex™ can be used to determine whether the administration was in accordance with the written directive. The licensee should contact Proxima Therapeutics to determine the appropriate dilution factor for use with other radiopaque dyes or fluids that could cause an effective dose reduction of greater than 20 percent if mixed with Iotrex™ during treatment.

10 CFR 35.1000 Licensing Guidance

Guidance for
Intravascular Brachytherapy

Robert L. Ayres, Ph.D.
NRC/NMSS

Background

- IVB is a new technology not covered in either §35.400 or §35.600
- IVB devices deliver high dose rates (>12 Gray) at the prescription point

Conditions Common to All IVB Systems

- Condition of use limited to Intravascular Brachytherapy
- Procedures conducted under supervision of AU
  - AU to consult with:
    - Interventional Cardiologist
    - AMP
  - Physical presence of AU or AMP

Common Conditions - 2

- Training and experience for AUs as set forth in:
  - 10 CFR 35.690
  - 10 CFR 35.940
- Vendor training for AU, AMP, and Interventional Cardiologist
- AMP to perform independent measurement of source output
  - 11 vendor calibration errors reported

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Common Conditions - 3

- Written directive will, prior to treatment, specify:
  - Treatment site
  - Radionuclide
  - Dose
- Written emergency procedures for:
  - Stuck sources
    - 28 events reported
  - Detached sources
- Patient survey after treatment (§35.404)

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Cordis Specific Conditions

- Source trains not to be uses after "use by" date
- Sources stepping permitted provided appropriate written procedures developed
- Reminder to submit calculations or measurements demonstrating Part 20 compliance on dose limits
- 35 mCi per seed max activity in ribbons of 6, 10, or 14 seeds

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Novoste Specific Conditions -1

- Use of an introducer sheath unless contraindicated for an individual patient
  - Blocked source events reported
    - 15 on source return after treatment
    - 11 on source insertion
- Use of a dual syringe system
  - 2 reported events due to fluid exhaustion
- Sources stepping permitted provided appropriate written procedures developed

Novoste Specific Conditions - 2

- Locked storage of device in secure location
- Device inspected and service at manufacturer recommended intervals
- 5 mCi sources, 800 mCi total for A1000 series models
- Reminder that source separations during treatment are to be reported as possible medical events

Guidant Specific Conditions - 1

- Source assembly/cartridge use limited to 60 days or 650 cycles, whichever comes first
- Locked storage of device and source assembly and control of console key
- Device inspected and service at manufacturer recommended intervals

Guidant Specific Conditions - 2

- 600 mCi per source assembly,; 2 source assemblies
- Daily system checks prior to patient treatment to include:
  - Console operational checks
  - Indicator lamps
  - Source status indicators
  - Visual inspection of catheters and connectors
  - Source positioning accuracy

Guidant Specific Conditions - 3

- At source exchange:
  - Source uniformity
  - Source positioning accuracy within +/- 1 mm
  - Battery backup
  - Source transit time
  - Timer accuracy and linearity
- Stepping or pullback procedures authorized per FDA PMA

Discussion?

10 CFR 35.1000 SUBCOMMITTEE WORKING MEETING

NO HANDOUTS PROVIDED

DISCUSSION: 10 CFR PART 35.1000 SUBCOMMITTEE

NO HANDOUT PROVIDED

SUMMARY MINUTES FOR THE MEETING OF THE ADVISORY COMMITTEE ON THE MEDICAL USES OF ISOTOPES
October 28, 2002

The Advisory Committee on the Medical Uses of Isotopes (ACMUI) held its semiannual meeting at the U.S. Nuclear Regulatory Commission (NRC) in Rockville, Maryland, on October 28, 2002.

ACMUI members present at the meeting were:

Manuel Cerqueira, MD	Nuclear cardiologist, ACMUI Chairman
Jeffrey A. Brinker, MD	Interventional cardiologist (designee)
David A. Diamond, MD	Radiation oncologist
Douglas F. Eggli, MD	Nuclear medicine physician (designee)
Nekita Hobson	Patients' rights advocate
Ralph Lieto	Medical physicist
Leon Malmud, MD	Healthcare administrator
Ruth McBurney	State representative
Subir Nag, MD	Radiation oncologist
Sally W. Schwarz	Nuclear pharmacist
Richard J. Vetter, PhD	Radiation safety officer
Jeffrey F. Williamson, PhD	Radiation therapy physicist

Staff from various NRC Offices, Divisions, and Branches participated in the meeting. Office representation included the Office of State and Tribal Programs (OSTP), and the Office of Nuclear Material Safety and Safeguards (NMSS). Division representation included Industrial and Medical Nuclear Safety (IMNS), and Branch representation included the Material Safety and Inspection Branch (MSIB), and the Rulemaking and Guidance Branch (RGB). Specific participating staff members are listed below:

Lloyd Bolling	OSTP
Frederick Brown	NMSS/IMNS/MSIB
Thomas H. Essig	NMSS/IMNS/MSIB, Designated Federal Official
Paul Lohaus	OSTP
Angela Williamson	NMSS/IMNS/MSIB
Thomas Young	NMSS/IMNS/RGB

Invited guest present at the meeting: Ryan T. Coles, Government Accounting Office

The meeting came to order at 10:03 a.m.

OPENING REMARKS

Dr. Manuel Cerqueira welcomed everyone to the meeting, and Thomas Essig, Designated Federal Official, made opening remarks.

REVIEW OF DOMESTIC REGULATION OF NUCLEAR MATERIAL

Mr. Ryan T. Coles of the U.S. Government Accounting Office (GAO), made a presentation on this topic. This topic was not an agenda item, but was included at the last minute at the request of the GAO.

Mr. Coles explained that the GAO is conducting an investigation into the accountability of radiation sources worldwide, and is doing so at the request of Senator Daniel Akaka, Chairman of the Subcommittee on International Security, Proliferation, and Federal Services; Senate Committee on Governmental Affairs. Mr. Coles stated that GAO believed it was worthwhile to brief ACMUI on this subject because they represent major stakeholders that use radioactive material.

Mr. Coles explained that GAO divided this investigation into three broad sections. These sections are: 1) a review of radioactive material used domestically; 2) a review of radioactive material used internationally; and, 3) an "aeroscope" review of the U.S. Department of Energy's Offsite Source Recovery Program. Mr. Coles then discussed GAO's planned review of radioactive material used domestically, and spoke specifically of their focus on byproduct material use.

Regarding the review of radioactive material used domestically, Mr. Coles relayed three questions GAO is attempting to answer. The first question is "What is the extent of (radioactive) material usage (specifically, types of material, number of licensees, maximum activities used, and uses of this material)?" The second question is "How effective is the current Federal and State regulatory framework?" The third question is "What actions have the NRC and/or the States taken since September 11, 2001, to improve/modify the regulation of nuclear materials in the United States?"

Mr. Coles went on to explain the approach GAO will use in their attempt to answer these questions. The approach involves the use of three investigative devices. These are: 1) the use of surveys that GAO will send to NRC regions and the Agreement States; 2) GAO interviews of Agreement States licensees; and 3) GAO observation of NRC during their Integrated Materials Performance Evaluation Program reviews of the Agreement States and NRC regions.

Mr. Coles ended his presentation by recounting the outcomes GAO will attempt to achieve. They are:

- As a neutral third party, educate Congress on the regulation of nuclear materials.
- Provide the Bush Administration with a list of Federal/State best practices that can be applied to other industries (e.g., chemical facilities).
- Identify the successes and challenges of the current regulatory system, and provide recommendations, if warranted.
- Examine the need for legislative changes, e.g., amending the Atomic Energy Act to allow NRC regulation of accelerator-produced material.

This presentation begins on page 85 of the meeting transcript.

UPDATE: ACMUI TRAINING AND EXPERIENCE RECOMMENDATIONS TO THE REVISED 10 CFR PART 35

Thomas Essig, NRC/NMSS, provided the update on this topic. Mr. Essig informed ACMUI that the recommendations they drafted to modify the training and experience (T&E) requirements contained within the revised 10 CFR Part 35 were forwarded to the Commission in a paper drafted by the staff called an "options paper." He explained that the options paper consisted of three options for Commission consideration, and that their T&E recommendations were one of the options. ACMUI expressed concern that they had not been kept informed about the options paper. Subsequent to the meeting, a pre-decisional copy was distributed to the advisory committee members.

This presentation begins on Page 98 of the meeting transcript.

AGREEMENT STATE COMPLIANCE WITH 10 CFR PART 35

Lloyd Bolling, NRC/OSTP, briefed ACMUI on this agenda topic. He began his presentation by providing a brief overview of Section 274 of the Atomic Energy Act, which allows states to become Agreement States. Next, Mr. Bolling outlined the status of Agreement State activities to adopt a rule compatible with the revised 10 CFR Part 35.

With respect to training and experience, Mr. Bolling explained that the training and experience sections of the revised 10 CFR Part 35 were at the Category B level, so that State rules had to be essentially identical. Mr. Bolling also explained that Agreement States have 3 years to adopt rules compatible with NRC's rules, but if any State has difficulty in meeting the 3-year time limit because of its rule promulgation process, it may use "Legally Binding Requirements" (such as orders and/or license conditions as interim measures) until the promulgation process is completed and compatible medical rules become effective.

Mr. Bolling finished his presentation by providing ACMUI with the time table Agreement States would need to adopt rules compatible with the revised 10 CFR Part 35. He also shared the results of a survey of the Agreement States that showed all Agreement States indicating they would have a compatible rule by the due date.

This presentation begins on Page 111 of the meeting transcript.

DISCUSSION OF THE NATIONAL MATERIALS PROGRAM

Paul Lohaus, NRC/OSTP, made a presentation on this topic. Mr. Lohaus began his presentation by informing ACMUI that a National Materials Program (NMP) is in place, and that it is a program that has evolved and will continue to evolve. Then he briefly outlined the background documents that helped shape the evolution of the NMP:

- ✓ SECY 01-0112, in which NRC staff provided a copy of the NMP Working Group report presenting options for an NMP;
- ✓ SECY 02-0074, in which the staff provided the Commission with five pilot projects that can be used to provide a further base of information on how the states and NRC can work together to implement the Alliance Option, the option the NMP Working Group recommended;

✓ SECY 02-0107, an addendum to SECY 02-0074, in which staff and the Organization of Agreement States and the Conference of Radiation Control Program Directors provided the Commission with a recommendation to use a blending of the "Current Program" with the Alliance Option for carrying out the pilot projects.

Mr. Lohaus went on to inform ACMUI that the Commission approved the use of blending of the Current Program with the Alliance Option for the pilot projects.

Regarding the status of the NMP today, Mr. Lohaus informed ACMUI that the Agency is working toward moving more of the shared responsibility for development of rules and guidance to the Agreement States, given the larger proportion of Agreement State licensees versus NRC licensees. However, Mr. Lohaus clearly stated that in terms of evaluating Agreement State program performance, NRC will always have lead responsibility, as that responsibility is a legislative mandate that cannot be delegated. Regarding ACMUI input, Mr. Lohaus requested comments from the ACMUI on the pilot projects outlined in SECY 02-0074 and feedback on other NMP issues.

This discussion begins on Page 130 of the meeting transcript.

Follow-up: in response to Mr. Lohaus's request that ACMUI review SECY 02-0074 and provide feedback, as well as general feedback on any issue or area, ACMUI reviewed the National Materials Program Working Group report that staff forwarded to the Commission in May of 2001. In their two-page response entitled, "Summary Statement on the National Materials Program," ACMUI highlighted several concerns. These concerns include:

- NRC's possible regulation of naturally occurring and accelerator-produced radioactive material (NARM). ACMUI is concerned that NRC regulation of NARM will result in increased regulatory burden and cost to the Agreement States without significant improvement in safety.

- Lowering of standards. ACMUI believes that Agreement States with existing strong programs may be forced to lower their standards, so as to be in harmony with Agreement States that have weaker programs.

- Funding issues. ACMUI is concerned that any change in NRC regulatory authority will necessitate a change in the current funding mechanism, an issue they stated that the NMP Working Group report did not address.

- Maintaining expertise in the Agreement States. ACMUI believes that the assumption that the Alliance Option will work, with its requirement that the Agreement States maintain a level of technical and regulatory expertise equal to or better than that of the NRC, may not be a realistic expectation.

To review the ACMUI's "Summary Statement on the National Materials Program, " refer to the enclosure to these minutes.

HEALTH AND HUMAN SERVICES DATABASE

Frederick Brown, NRC/NMSS, made a presentation on this topic. In his presentation, which was presented to the ACMUI primarily for information purposes, he discussed the Health

Integrity and Protection (HIPDB) database. He explained that a goal of the database was to maintain a multi-jurisdictional record of health care providers found guilty of major infractions.

During the heart of his discussion, Mr. Brown informed ACMUI that certain sections of Title 45, Part 61, of the Health and Human Services regulations, require all Federal agencies, as well as the Agreement States, to provide reports to the HIPDB. He explained that NRC limits reports to the database to actions that are final, publicly available, relate to medical practice, and are subject to an adjudicatory process.

Members of the ACMUI expressed concern that being reported to HIPDB would be "punitive." With regard to fair treatment, they also believed there would be disparities between NRC licensees, subject to escalated enforcement action, versus Agreement States licensees, not subject to enforcement action.

Although Mr. Brown indicated that he presented this information to the ACMUI mainly for information purposes, he also indicated that he was willing to accept ACMUI feedback on the management directive the Agency will use to implement the action of reporting to the database. He committed to provide the Committee members with additional background information on the applicable requirements.

This discussion begins on Page 173 of the meeting transcript.

STATUS OF IMPLEMENTATION OF REVISED RULE

Update on Revised Inspection Guidance

Thomas Young, NRC/NMSS, gave a presentation on this agenda topic. In this presentation, Mr. Young informed the ACMUI on the status of the medical inspection procedures that are being updated to support the new requirements in the revised 10 CFR Part 35.

Mr. Young began by explaining that NRC's inspection program is documented in Manual Chapter 2800, which is publicly available at NRC's website. He explained that the new medical inspection procedures are being implemented under a pilot program, and they are designed to streamline the inspection administrative procedures outlined in Manual Chapter 2800. Further, these inspection procedures have been adjusted to direct the inspectors' focus toward more risk-informed activities.

Mr. Young summarized his presentation by pointing out that the procedures have been reduced in size and reformatted, with an emphasis placed on risk-informed activities.

In response, one ACMUI member, Dr. Vetter, relayed his own recent experience with an inspection done under the revised inspection procedures at his organization. He informed the staff that the inspection was risk informed, with very little time spent reviewing records. He characterized the inspection as very professional and very well conducted.

This presentation begins on Page 196 of the meeting transcript.

Update on NUREG-1556, Volume 9

Frederick Brown led the discussion on this agenda topic. He began by giving a brief overview of actions staff previously took to finalize NUREG-1556, Volume 9. These were: the March 2002 draft Volume 9 the staff issued for public comment; staff work to address the comments; staff review and revision of the incorporated comments; and staff approval of the revised Volume 9.

Mr. Brown explained that during the review process, staff kept in mind certain concerns that must be observed while developing a guidance document. Foremost was that the document be written in such a way as not to become de facto regulation. The other concerns that staff carefully observed were that Volume 9 be worded to impose no unnecessary burden on licensees, and would also be a document that had clarity and simplicity, while not compromising safety. Next, Mr. Brown informed the ACMUI that NUREG-1556, Volume 9 is finalized and available.

In response, Committee members expressed a desire that staff regard NUREG-1556, Vol. 9 as a work in progress. They believed staff should continue to engage ACMUI in discussions of Vol. 9 (for instance, areas where the committee members disagree with the staff, such as patient release calculations.)

This discussion begins on Page 205 of the meeting transcript.

Implementation Issues and Release of a Regulatory Issue Summary

Mr. Brown informed ACMUI of two issues that arose out of the stakeholder workshops that NRC held on the new rule.

The first issue revolves around a 10 CFR 35.2432 recordkeeping requirement that brachytherapy seed calibrations be signed by an AMP. Although the rule does not require that an AMP perform the calibration, the requirement that licensees have an AMP on staff may be implicit in the requirement that an AMP sign the calibration. This situation will likely lead to difficulties in licensees' ability to secure an AMP. As Mr. Brown explained, this was not the intent of the procedural part of the rule (10 CFR 35.432), and staff was taking action to address the problem.

The second issue relates to the Strontium-90 (Sr-90) eye applicator calculation of treatment times. Mr. Brown explained that 10 CFR 35.433 does not clearly outline the type of qualifications an AMP who does those calculations must meet. The question was: Is it feasible to introduce a "limited" AMP (one that has not met all the T&E for an AMP) who nonetheless possesses demonstrated credentials that prove (s)he can perform decay corrections for Sr-90 opthalmic treatments?

ACMUI indicated they were uncomfortable with the creation of a "sub" AMP, created just for the purpose of performing Sr-90 decay corrections. Furthermore, Committee members believed AMP involvement in the licensed activity was important. The Committee indicated they were more comfortable reviewing, on a case-by-case basis, the credentials of those individuals who are not AMPs, but who desired to perform this function.

Finally, Mr. Brown presented ACMUI with a Regulatory Issue Summary (RIS), dated October 21, 2002. He informed them that staff released this RIS to notify licensees that three specific new modalities will be regulated under 10 CFR 35.1000.

After reviewing the RIS, ACMUI indicated that 10 CFR 35.1000 covers emerging technologies that could straddle the boundary between radiation oncology and nuclear medicine.

They suggested that the best strategy for addressing these modalities would be to form a standing subcommittee to review 10 CFR 35.1000 licensing guidance and provide NRC staff with recommendations. Toward that end, ACMUI made the following recommendation:

ACMUI recommends that the Chairman, ACMUI, form a standing subcommittee to review 35.1000 licensing guidance as it is developed by NRC staff.

This discussion begins on page 236 of the meeting transcript.

SEALED SOURCE MODEL NUMBERS AS LICENSE CONDITIONS ON NRC LICENSES

Frederick Brown, NRC/NMSS, led the discussion on this topic. Mr. Brown quickly summarized the issue: 10 CFR Part 35 has no requirement for licensees to list individual sources on licenses. However, 10 CFR Part 30 does. Title 10 CFR Part 30 governs over 10 CFR Part 35, unless 10 CFR Part 35 has a more restrictive requirement.

Regarding listing sources on licenses, 10 CFR Part 30 governs. This creates a situation where licensees are required to list, by manufacturer and model number, all of their individual sources, or in the case of multiple sources in a single device, they must list the device. This new requirement is more burdensome than what was previously required.

With respect to listing multiple sources, Mr. Brown offered an example of how existing licensees have tackled this issue. The strategy used was to register multiple sources for use in one device that is then listed in the license. This way, the licensee does not need to update the license every time a new source comes out; the licensee would simply update the Sealed Source and Device Registry to reflect the use of the new source. ACMUI then discussed practical problems they encounter when trying to list a device (rapid change in manufacturers, for instance). ACMUI believed that the basis of this issue is the 10 CFR Part 30 overriding requirement that devices must be listed by manufacturer and model number. They believed that a change in 10 CFR Part 35 would resolve this issue.

The following recommendation was made:

ACMUI recommends that a rule making process be initiated to modify 10 CFR Part 35 to override 10 CFR Part 30.32(g)(1) to allow more generic listing of interstitial seeds and sources.

This discussion begins on Page 255 of the meeting transcript.

PRACTICAL ISSUES ASSOCIATED WITH MANUAL BRACHYTHERAPY SEED IMPLANT

Frederick Brown, NRC/NMSS, led the discussion on this topic. Mr. Brown explained that during a stakeholder meeting, staff identified some licensee concerns in the ability to determine "medical events" associated with manual brachytherapy. For example, during prostate

implantation, which requires the use of a needle that must travel through the patient's body, at what point is the source in the prostate versus the area of the prostate? Mr. Brown asked whether further guidance was necessary. ACMUI discussed the issues identified at the stakeholder meeting, then concluded that there was not a need for additional guidance at this time.

This discussion begins on Page 267 of the meeting transcript.

IMPLICATIONS OF INTERMEDIATE PACKAGING AND STERILIZATION OF BRACHYTHERAPY SEEDS

Frederick Brown, NRC/NMSS, led the discussion on this topic. Mr. Brown began by explaining that NRC requires vendors and distributors to have registration for a seed that is new or modified. He explained that NRC also requires device reviews if the packaging of the seed could affect the spacing of the seed (as it is placed into the patient), or if packaging could cause temperature or manual pressure stresses that would adversely affect the integrity of the seed. He also pointed out that the new 10 CFR 35.432 calibration requirements could not be performed after seeds were packaged in strands or devices by intermediate distributors.

Mr. Brown asked ACMUI to provide feedback on whether individual seeds received in bulk and then handled individually represent more or less of a safety problem than do pre-loaded, pre-sterilized seeds packaged by an intermediate distributor. Also, he requested that ACMUI provide an opinion as to whether spacing, temperature, and/or mechanical pressure on seeds was a significant issue.

After discussion, the ACMUI indicated that the loading of seeds by intermediate distributors was not of major concern. However, they recommended that licensees who use prepackaged seeds establish traceability programs in which they can demonstrate that the seeds are properly calibrated.

This discussion begins on Page 285 of the meeting transcript.

UPDATE: RECOMMENDATIONS FROM SPRING 2002 MEETING

Angela Williamson, NRC/NMSS, led the discussion on this topic under which she reviewed the disposition of the two recommendations, both related to T&E, that ACMUI made to staff at the Spring 2002 meeting.

Ms. Williamson reiterated that the T&E recommendations the ACMUI subcommittee developed had been forwarded to the Commission (earlier in this meeting, Thomas Essig informed them of this under the agenda topic "Update: ACMUI Training and Experience Recommendations to the Revised 10 CFR Part 35"). ACMUI then asked Ms. Williamson to provide a specific date when the Commission will render a decision. NRC staff informed the ACMUI that a definite date could not be given. ACMUI then expressed a desire to be immediately informed of the Commission's decision once it is made, and toward that end, made a recommendation.

The ACMUI's recommendation is as follows:

The ACMUI recommends that the ACMUI Chairman contact the Chairman, NRC to inquire about the status of the training and experience recommendations ACMUI composed to amend the T&E in the revised 10 CFR Part 35.

UPDATE: ACMUI VACANCIES

Angela Williamson, NRC/NMSS, led the discussion on this topic. Ms. Williamson informed the ACMUI that three members were due to rotate off the Committee in 2004. They are Dr. Manuel Cerqueira, nuclear cardiologist and ACMUI Chairman; Ms. Ruth McBurney, State Representative; and Ms. Nekita Hobson, Patient Advocate.

ACMUI made the following recommendation:

Regarding replacement of ACMUI members due to rotate off the Committee, ACMUI recommended that NRC staff initiate the replacement process.

This discussion begins on Page 310 of the meeting transcript.

The meeting concluded at 5:09 p.m.

UNITED STATES NUCLEAR REGULATORY COMMISSION CHARTER FOR THE ADVISORY COMMITTEE ON MEDICAL USES OF ISOTOPES
(Pursuant to Section 9 of Public Law 92-463)

1. **Committee's Official Designation:**

   Advisory Committee on the Medical Uses of Isotopes

2. **Committee's objectives, scope of activities and duties are as follows:**

   The Committee provides advice, as requested by the Director, Division of Industrial and Medical Nuclear Safety, Office of Nuclear Materials Safety and Safeguards, on policy and technical issues that arise in regulating the medical use of byproduct material for diagnosis and therapy.

3. **Time period (duration of this Committee):**

   From March 20, 2002 to March 20, 2004

4. **Official to whom this Committee reports:**

   Donald A. Cool, Director
   Division of Industrial and Medical Nuclear Safety
   Office of Nuclear Materials Safety and Safeguards
   U.S. Nuclear Regulatory Commission
   Washington, DC 20555

5. **Agency responsible for providing necessary support to this Committee:**

   U.S. Nuclear Regulatory Commission

6. **The duties of the Committee are set forth in Item 2 above.**

7. **Estimated annual direct cost of this Committee:**

   a. $160,000.000 (includes travel, per diem, and compensation)

   b. Total staff-year of support: 1.5 FTE

8. **Estimated number of meetins per year:**

   Three meetings per year except when active rulemaking is conducted, then five meetings per year.

Charter, ACMUI

9. **The Committee's termination date.**

April 4, 2002

10. **Filing date:**

March 20, 2002

//s//

Andrew L. Bates
Advisory Committee Management
Officer
Office of the Secretary of the
Commission

ACMUI
February 20, 2002

U.S. NUCLEAR REGULATORY COMMISSION

OFFICE OF NUCLEAR MATERIALS SAFETY AND SAFEGUARDS

ADVISORY COMMITTEE ON MEDICAL USES OF ISOTOPES

BYLAWS

CONTENTS

PREAMBLE

These bylaws describe the procedures to be used by the Advisory Committee on the Medical Uses of Isotopes (ACMUI), established pursuant to Section 161a of the Atomic Energy Act of 1954, as amended, in performing its duties, and the responsibilities of the members. For parliamentary matters not explicitly addressed in the bylaws, Robert's Rules of Order will govern.

These bylaws have as their purpose fulfillment of the Committee's responsibility to provide objective and independent advice to the Commission through the Office of Nuclear Material Safety and Safeguards, with respect to the development of standards and criteria for regulating and licensing medical uses of byproduct material. The procedures are intended to ensure that such advice is fairly and adequately obtained and considered, that the members and the affected parties have an adequate chance to be heard, tand that the resulting reports represent, to the extend possible, the best of which the Committee is capable. Any ambiguities in the following should be resolved in such a way as to support those objectives.

BYLAWS-ADVISORY COMMITTEE ON THE MEDICAL USES OF ISOTOPES

1. Scheduling and Conduct of Meetings

The scheduling and conduct of ACMUI meetings shall be in accordance with the requirements of the Federal Advisory Committee Act (FACA), as amended, 10 CFR Part 7, and other implementing instructions and regulatins as appropriate.

1.1 Scheduling of Meetings:

1.111 Meetings must be approved or called by the Designated Federal Officer. At least two regular meetings of the Committee will be scheduled each year. A spring meeting will be scheduled in April-May, and a fall meeting will be scheduled in October-November. Additionally, the Committee will meet with the Commission each year in the first or second quarter of each year.

1.1.2 Special meetings will be open to the public, except for those meetings or portions of meetings in which matters are discussed that are exempt from public disclosure under FACA or other appropriate rules or statutes.

1.1.3 ACMUI meetings will be open to the public, except for those meetings or portions of meetings in which matters are discussed that are exempt from public disclosure under FACA or other appropriate rules or statutes.

1.1.4 All meetings of the Committee will be transcribed. During those portions of the meeting that are open to the public, electronic recording of the proceedings by members of the public will be permitted. Television recording of the meeting will be permitted, to the extent that it does not interfere with Committee business, or with the rights of the attending public.

1.2 Meeting Agenda:

The agenda for regularly scheduled ACMUI meetings will be prepared by the Chair of the Committee (referred to below as "the Chair") in consultation with the Nuclear Materials Safety and Safeguards (NMSS) staff. The Designated Federal Officer must approve the agenda. The Chair will query committee members for agenda items prior to agenda preparation. A draft agenda will be provided to committee members not later than thirty days before a scheduled meeting. The final agenda will be provided to members not later than seven days before a scheduled meeting.

Before the meeting, the Chair and the Designated Federal Officer for the committee will review the findings of the Office of the General Counsel regarding

possible conflicts of interest of members in relation to agenda items. Members will be recused from discussion of those agenda items with respect to which they have a conflict.

1.3 Conduct of the Meeting:

1.3.1 All meetings will be held in full compliance with the Federal Advisory Committee Act. Questions concerning compliance will be directed to the NRC Office of the General Counsel.

1.3.2 The Chair will preside over the meeting. The Designated Federal Officer will preside if the Chair is absent, if the Chair is recused from participating from discussion of a particular agenda item, or if directed to do so by the Commission.

1.3.3 A majority of the current membership of the Committee will be required to constitute a quorum for the conduct of business at a committee meeting.

1.3.4 The Chair has both the authority and the responsibility to maintain order and decorum, and may, at his or her option, recess the meeting if these are threatened. The Designated Federal Officer will adjourn a meeting when adjournment is in the public interest.

1.3.5 The Chair may take part in the discussion of any subject before the committee, and may vote. The Chair should not use the power of the Chair to bias the discussion. Any dispute over the Chair's level of advocacy shall be resolved by a vote on the Chair's continued participation in the discussion of the subject. The decision shall be by a majority vote of those members present and voting, with a tie permitting continued participation of the Chair in the discussion.

1.3.6 When a consensus appears to have developed on a matter under consideration, the Chair will summarize the results for the record. Any members who disagree with the consensus shall be asked to state their dissenting views for the record. Any committee member may request that any consensus statement be put before the ACMUI as a formal motion subject to affirmation by a formal vote. No committee position will be final until it has been formally adopted by consensus or formal vote, and the minutes written and certified.

2. MINUTES

2.1 The Chair will prepare detailed minutes of each ACMUI meeting (excepting meetings with the Commission for which transcripts are prepared) based on the transcripts of the meeting.

2.2 A draft of the minutes will be prepared by the Chair, assisted by NRC staff, and made available as soon as practicable to the other members. After receiving corrections to the draft minutes from the committee members, the Chair will certify the minutes. By certifying the minutes, the Chair attests to the best of his or her knowledge to the completeness and technical accuracy of the minutes.

2.3 Copies of the certified minutes will be distributed to the ACMUI members. The staff will then forward the minutes to the Public Document Room, with only deletions authorized or required by law.

3. APPOINTMENT OF MEMBERS

3.1 The members of the committee are appointed by the Commission, which determines the size of the committee. The NRC will solicit nominations by notice in the Federal Register and by such other means as are approved by the Commission. Evaluation of candidates shall be by such procedures as are approved by the Commission. The Commission has the final authority for selection. The term of an appointment to the committee is three years, and the Commission has determined that no member may serve more than 2 consecutive terms (6 years).

3.2 The Chair will be appointed by the Commission. The Chair will serve for a period of two years, and will be eligible for reappointment by the Commission for two additional two-year terms.

4. CONDUCT OF MEMBERS

4.1 If a member feels that he or she may have a conflict of interest with regard to an agenda item to be addressed by the committee, he or she should divulge it to the Chair and the Designated Federal Officer as soon as possible, but in any case before the committee discusses it as an agenda item. Committee members must recuse themselves from discussion of any agenda item with respect to which they have a conflict of interest.

4.2 Upon completing their tenure on the committee, members will return any privileged documents and accountable equipment (as so designated by the NRC) provided for their use in connection with ACMUI activities, unless directed to dispose of these documents or equipment.

4.3 Members of the ACMUI are expected to conform to all applicable NRC rules and regulations.

5. ADOPTION AND AMENDMENTS

5.1 Adoption of these bylaws shall require a vote of two-thirds of the current ACMUI membership and the concurrence of the Director of the Office of Nuclear Material Safety and Safeguards.

5.2 Any member of the committee or NRC may propose an amendment to these bylaws. The proposed amendment will be distributed to the members by the Chair and scheduled for discussion at the next regular committee meeting.

5.3 The final proposed amendment may be voted on not earlier than the first regular meeting after it has been discussed at a committee meeting pursuant to Paragraph 5.2.

5.4 A vote of two-thirds of the current ACMUI membership and the concurrence of the Director of the Office of Nuclear Material Safety and Safeguards shall be required to approve an amendment.

5.5 Any conflicts regarding interpretation of the bylaws shall be decided by majority vote of the current membership of the committee.

Persons who do not have access to ADAMS or who encounter problems in accessing the documents located in ADAMS, should contact the NRC PDR Reference staff by telephone at 1–800–397–4209, or 301–415–4737 or by e-mail to *pdr@nrc.gov*.

Dated at Rockville, Maryland, this 18th day of March 2003.

For the Nuclear Regulatory Commission.

Karen R. Cotton,

Project Manager, Section 1, Project Directorate II, Division of Licensing Project Management, Office of Nuclear Reactor Regulation.

[FR Doc. 03–6951 Filed 3–21–03; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

[Docket No. 04008155]

Finding of No Significant Impact Related to H.C. Starck, Inc.'s Amendment Request To Authorize Decommissioning of Its Coldwater, Michigan Facilities

I. Introduction

The U.S. Nuclear Regulatory Commission (NRC) is issuing a license amendment of Source Material License No. STB–1161 to authorize decommissioning of the H.C. Starck, Inc. facilities in Coldwater, Michigan, and has prepared an Environmental Assessment in support of this action. Based upon the Environmental Assessment, the NRC has concluded that a Finding of No Significant Impact is appropriate, and therefore, an Environmental Statement is unnecessary.

II. EA Summary

The EA was prepared to evaluate the environmental impacts of the proposed amendment to H.C. Starck, Inc. Source Material No. STB–1161, to authorize H.C. Starck to remediate residual thorium contamination resulting from licensed activities at their facilities at 460 Jay Street, Coldwater, Michigan. H.C. Starck, Inc. has been licensed for the possession and use of thorium-232 at their facilities in Coldwater, Michigan, since 1973. The H.C. Starck facilities consist of six primary structures: A main production plant, Jolter Building, Former Polymer Building, a wastewater pretreatment building, and two pole-barn storage buildings. The facility is in a rural area of southern Michigan about two miles southwest of downtown Coldwater. Branch County is largely agricultural with farms occupying 70 percent of the land. Non-residential land use in the vicinity of the Starck site primarily consists of agricultural, industrial, commercial, and retail facilities. The nearest residence is within 1,000 feet of the H.C. Starck facility. Soil sampling conducted by H.C. Starck indicates that no radiological contamination has migrated outside the buildings. In addition, there is no evidence that any onsite burial of radiological material ever occurred. Because no remediation is required outside of the buildings, decontamination activities are not expected to have any impact on the environment. Furthermore, no long-term environmental monitoring is expected to be necessary as a result of licensed activities. Because H.C. Starck will continue to operate the facility at the same staffing levels following termination of licensed operations, no socioeconomic impact is anticipated on the employees or within the community. It is anticipated that the total amount of dry solid low level radioactive waste (LLRW) generated from decommissioning activities will be less than 1,000 cubic feet. Waste may be stored onsite in the radioactive waste storage vault or other appropriate secure location while it is being consolidated for shipment to Envirocare of Utah. Any liquid waste generated during decommissioning will be sampled, and the results will be compared to current discharge limits prior to disposal directly into the facility effluent stream or to the facility treatment plant. No radiological dose is expected to a member of the public as a result of the decommissioning activities. For occupational dose estimates, H.C. Starck will employ properly trained and experienced personnel who will apply industry accepted ALARA (as-low-as-reasonably-achievable) principals to minimize exposures during decontamination activities. Decontamination workers are not expected to receive a dose greater than 10 millirem during the expected 6 to 8 weeks of decommissioning activities. Dose assessments were performed to estimate the potential dose to a future site occupant working at the H.C. Starck facility. This average member of the critically exposed group would be exposed to post-decontamination levels of natural thorium contamination. The modeling results determined that a maximum dose rate to a future occupant is 23 millirem/year. This dose rate decreases to about 2 millirem/year after 2.8 years based on the source lifetime for the residual removable contamination on the walls, floor and ceiling. Accordingly, it has been determined that a Finding of No Significant Impact is appropriate.

H.C. Starck's request for the proposed action was previously noticed in the **Federal Register** on October 11, 2002 (67 FR 63457), along with a notice of an opportunity to request a hearing and an opportunity to provide public comment on the action and its environmental impacts.

III. Finding of No Significant Impact

Based on this EA, as summarized above, the NRC has concluded that this licensing action would not have any significant effect on the quality of the human environment, and therefore, an environmental impact statement is unnecessary.

IV. Further Information

Any questions with respect to this action should be referred to Mr. William Snell, Division of Nuclear Materials Safety, U.S. Nuclear Regulatory Commission, Region III, 801 Warrenville Road, Lisle, Illinois 60532–4351; telephone (630) 829–9871 or by email at *wgs@nrc.gov*.

H.C. Starck's request for the proposed action (ADAMS Accession No. ML022550372) and the NRC's complete Environmental Assessment (ADAMS Accession No. ML030660370) are available for inspection and copying for a fee in the U.S. Nuclear Regulatory Commission, Region III, 801 Warrenville Rd., Lisle, Illinois. The documents, along with most others referenced in the EA, are available for public review through ADAMS at NRC's Public Electronic Reading Room at *http://www.nrc.gov/reading-rm/adams.html*.

Dated in Lisle, Illinois, this 12th day of March, 2003.

Christopher G. Miller,

Chief, Decommissioning Branch, Division of Nuclear Material Safety, RIII.

[FR Doc. 03–6950 Filed 3–21–03; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

Advisory Committee on the Medical Uses of Isotopes: Meeting Notice

AGENCY: Nuclear Regulatory Commission.

ACTION: Notice of meeting.

SUMMARY: The U.S. Nuclear Regulatory Commission will convene a meeting of the Advisory Committee on the Medical Uses of Isotopes (ACMUI) on May 20–21, 2003. The meeting will take place at the address provided below. All sessions of the meeting will be open to

the public with the exception of the first session, which will be closed to conduct administrative business related to internal personnel rules and/or practices of ACMUI members. A sample of agenda topics for discussion in the public session includes: (1) Follow-up discussion of the ACMUI's recommendations to the training and experience requirements to the revised title 10, Code of Federal Regulations, part 35; (2) written directives as they pertain to certain uses of brachytherapy; (3) the ACMUI's Subcommittee activities to address the medical uses of byproduct material under title 10, Code of Federal Regulations, part 35.1000; (4) an update to the Government Accounting Office review of the domestic use of byproduct material; (5) the National Materials Program pilot project on operating experience evaluation; and, (6) physical presence requirements during stereotactic radiosurgery treatments.

DATES: The public meeting will be held on Tuesday May 20, 2003, from 1 p.m. to 5 p.m, and Wednesday, May 21, 2003, from 8 a.m. to 5 p.m. The closed session will be held from 8 a.m. to 12 p.m. on May 20.

ADDRESSES: U.S. Nuclear Regulatory Commission, Two White Flint North Building, Conference Room T2B3, 11545 Rockville Pike, Rockville, MD 20852–2738.

FOR FURTHER INFORMATION CONTACT: Angela R. Williamson, telephone (301) 415–5030; e-mail arw@nrc.gov of the Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001.

Conduct of the Meeting

Manuel D. Cerqueira, M.D., ACMUI Chairman, will chair the meeting. Dr. Cerqueira will manage the meeting in a manner that will facilitate the orderly conduct of business. The following procedures apply to public participation in the meeting:

1. Persons who wish to provide a written statement should submit a reproducible copy to Angela R. Williamson, U.S. Nuclear Regulatory Commission, Two White Flint North, Mail Stop T8F5, Washington, DC 20555–0001. Alternately, the statement may be e-mailed to Angela R. Williamson at *arw@nrc.gov*. Submittals must be postmarked by May 13, 2003, and must pertain to the topics on the agenda for the meeting.

2. Questions from members of the public will be permitted during the meeting, at the discretion of the Chairman.

3. The transcript and written comments will be available for inspection on NRC's Web site (www.nrc.gov) and at the NRC Public Document Room, 11555 Rockville Pike, Rockville, MD 20852–2738, telephone (800) 397–4209, on or about July 21, 2003. Minutes of the meeting will be available on or about August 20, 2003.

This meeting will be held in accordance with the Atomic Energy Act of 1954, as amended (primarily section 161a); the Federal Advisory Committee Act (5 U.S.C. App); and the Commission's regulations in title 10, U.S. Code of Federal Regulations, part 7.

Dated: March 17, 2003.

Andrew L. Bates,

Advisory Committee Management Officer.

[FR Doc. 03–6954 Filed 3–21–03; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

Peer Review Committee for Source Term Modeling; Notice of Meeting

The Peer Review Committee For Source Term Modeling will hold a closed meeting on April 8–9, 2003, at Sandia National Laboratories (SNL), Albuquerque, NM.

The entire meeting will be closed to public attendance to protect information classified as national security information pursuant to 5 U.S.C. 552b(c)(1).

The agenda for the subject meeting shall be as follows:

Tuesday, April 8 and Wednesday, April 9, 2003—8:30 a.m. Until the Conclusion of Business

The Committee will review SNL activities and aid SNL in development of guidance documents on source terms that will assist the NRC in evaluations of the impact of specific terrorist activities targeted at a range of spent fuel storage casks and radioactive material (RAM) transport packages including those for spent fuel.

Further information contact: Andrew L. Bates, (telephone 301–415–1963) or Dr. Charles G. Interrante (telephone 301–415–3967) between 7:30 a.m. and 4:15 p.m. (e.t.).

Dated: March 17, 2003.

Andrew L. Bates,

Advisory Committee Management Officer.

[FR Doc. 03–6955 Filed 3–21–03; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

Sunshine Act; Meetings

DATE: Weeks of March 24, 31, April 7, 14, 21, 28, 2003.

PLACE: Commissioner's Conference Room, 11555 Rockville Pike, Rockville, Maryland.

STATUS: Public and closed.

MATTERS TO BE CONSIDERED:

Week of March 24, 2003

Thursday, March 27, 2003

10 a.m. Briefing on status of Office of Nuclear Regulatory Research (RES) programs, performance, and plans.

This meeting will be webcast live at the Web address—*www.nrc.gov.*

Week of March 31, 2003—Tentative

There are no meetings scheduled for the week of March 31, 2003.

Week of April 7, 2003—Tentative

Friday, April 11, 2003

9 a.m. Meeting with Advisory Committee on Reactor Safeguards (ACRS) (public meeting) (contact: John Larkins, 301–415–7360).

This meeting will be webcast live at the Web address—*www.nrc.gov.*

12:30 p.m. Discussion of management issues (closed—Ex. 2).

Week of April 14, 2003—Tentative

There are no meetings scheduled for the week of April 14, 2003.

Week of April 21, 2003—Tentative

There are no meetings scheduled for the week of April 21, 2003.

Week of April 28, 2003—Tentative

There are no meetings scheduled for the week of April 28, 2003.

* The schedule for Commission meetings is subject to changes on short notice. To verify the status of meetings call (recording)—(301) 415–1292. Contact person for more information: David Louis Gamberoni (301) 415–1651.

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Additional Information: "Briefing on Status of Office of Nuclear Security and Incident Response (NSIR) Programs, Performance, and Plans (Closed—Ex. 1)," scheduled for March 20, 2003, was canceled.

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The NRC Commission meeting schedule can be found on the Internet at: *www.nrc.gov/what-we-do/policy-making/schedule.html.*

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This notice is distributed by mail to several hundred subscribers; if you no

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ACMUI Members
Updated: March 5, 2003

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ACMUI Members
Updated: March 5, 2003

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