U.S.NRC
United States Nuclear Regulatory Commission
Protecting People and the Environment

Ritenour Petition Rulemaking Issue

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Background

- Part 35 was revised in 2002
- There were issues with the training and experience (T&E) requirements
- T&E requirements were finalized in 2005
- To provide continuity, Subpart J of the "old regulations" was effective until October 2005

Pathways for Authorization

1. An individual may be certified by a "recognized board"
2. Approval based on an individual's T&E (alternate pathway)
3. Identification of an individual on an NRC or AS license (petitioner referred to it as the "grandfathered" pathway) [10 CFR 35.57(a)]

Petitioner's Concern

- **2005 T&E regulations have inadvertently affected a group of board certified professionals**
- **These individuals must now apply through the "alternate" pathway**
- **Alternate pathway places an undue burden and could result in a shortage of AMPs and RSOs**

Ritenour Petition Resolution (PRM-35-20)

- NRC resolved the petition in May 2008 and concluded that 2005 revision may have adversely affected some board-certified professionals, including authorized users
- Issues raised in the petition will be considered for rulemaking if a technical basis can be developed

Technical Basis Development

- In October 2008, NRC staff asked certifying boards to survey their Diplomates who are or may be affected by the 2005 T&E revision
- Responses were received from 5 of the 9 contacted boards
- Approximately 10,000 individuals may potentially be affected

Preceptor Attestations for the "affected individuals"

The petitioner requested to amend 35.57

-to recognize board certified medical physicists for the modalities they practiced as of October 24, 2005

- to recognize all diplomates for RSOs, providing the appropriate preceptor statement

Discussion

- **In the Part 35 expanded rulemaking, removal of the attestation requirement for board certified individuals is under consideration**
- **However, the staff proposes to maintain attestation requirements for "grandfathered" individuals**

SUPPLEMENTAL INFORMATION

10 CFR 35.57 (a)

Currently under 35.57(a)

---an individual identified as an RSO, a medical or teletherapy physicist, or a nuclear pharmacist on an NRC or AS license before October 24, 2002 need not comply with the T&E requirements in 10 CFR 35.50, 35.51, or 35.55, respectively

10 CFR 35.57 (a) contd.

--- an individual identified as an RSO, an authorized medical physicist (AMP), or an authorized nuclear pharmacist on an NRC or AS license between October 24, 2002 and April 29, 2005 need not comply with the T&E requirements in 10 CFR 35.50, 35.51, or 35.55 respectively

Survey Result: Response Rate

- ABHP---------- 44 %
- ABMP---------- 90 %
- ABR
  - Radiologists-------- 36 %
  - Oncologists--------- 42 %
  - Physicists---------- 52 %
- AOBR (radiologists)------- 47 %
- AOBR (oncologists)------ 50 %

Individuals Potentially Affected

- **ABHP---------- 848**
- **ABMP---------- 148**
- **ABR**
  - **Radiologists------- 7900**
  - **Oncologists--------- 260**
  - **Physicists---------- 415**
- **AOBR (radiologists)------- 77**
- **AOBR (oncologists)------ 0**

Boards That Did Not Respond

- American Board of Nuclear Medicine
- American Board of Science in Nuclear Medicine
- American Osteopathic Board of Nuclear Medicine
- Board of Pharmaceutical Specialties

Acronyms

- **ABHP: American Board of Health Physicists**
- **ABMP: American Board of Medical Physicists**
- **ABR: American Board of Radiologists**
- **AMP: Authorized Medical Physicists**
- **AOBR: American Osteopathic Board of Radiology**

Acronyms Cont'd

- **AS: Agreement States**
- **RSO: Radiation Safety Officer**

Training and Experience Attestations

Donna-Beth Howe, Ph.D.

April 11, 2011

T & E Attestations

2002 Final Part 35 Rule

- **Introduced statements for all pathways certifying completion of T & E and individuals were competent to function independently as authorized individual**

T & E Attestations

2005 Revision of Part 35

- **Retained statements for all pathways but removed statement from certification process and revised statement to be an attestation**

T & E Attestations

Requires *each individual* have a written attestation, signed by a preceptor authorized …, that the individual has *satisfactorily completed* the board or alternate pathway T & E requirements in …, and *achieved a level of competency sufficient to function independently* as an authorized ….

April 29, 2008 ACMUI Commission Meeting

- **Does *each individual* have to have a written attestation?**
- **Does each attestation have to be *signed by a preceptor authorized individual*?**
- **Does each attestation have to attest that the individual has *achieved a level of competency sufficient to function independently* as an authorized …?**

Commission Direction

- **SRM M080429, May 15, 2008:**

  Coordinate with ACMUI & AS to amend preceptor requirements in 10 CFR 35
- **SECY-08-0179, November 20, 2008:**

  Recommendations on amending preceptor attestation requirements
- **SRM SECY-08-0179, January 16, 2009: Approved recommendations**

Conceptually…

- **Eliminate written attestation for board certification pathway**
- **Revise the attestation to say… has demonstrated the ability to function independently to fulfill the radiation safety related duties required by the licensee**
- **Residency program directors can sign attestations if …**

Discussion

- Comment on the conceptual direction
- Potential Rulemaking Challenges
  - Unintended consequences
  - The certification program may not adequately cover NRC's regulated modalities
  - Perceived relaxation of safety requirements?

Supplemental Information

T & E Attestations

- **10 CFR 35.50, 35.51, 35.55, 35.190, 35.290, 35.390, 35.392, 35.394, 35.396, 35.490, 35.690**

Supplemental Information

SRM M080429, May 15, 2008

- **Staff should work with ACMUI and Agreement States on amending NRC's requirements for preceptor attestation for both board certified individuals and for individuals seeking authorization via the alternate pathway**

Supplemental Information

SECY-08-0179, November 20, 2008

- **Recommendations on Amending Preceptor Attestation Requirements in 10 CFR Part 35 Medical Use of Byproduct material**

Supplemental Information

SRM SECY-08-0179, January 16, 2009

- **Commission approved recommendation for amending the preceptor attestation requirements**

Acronyms

- **ACMUI: Advisory Committee on the Medical Uses of Isotopes**
- **AS: Agreement States**
- **CFR: Code of Federal Regulations**
- **SECY: Office of the Secretary**
- **SRM: Staff Requirements Memorandum**
- **T & E: Training and Experience**

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Patient Release Public Dose Limits
Per Annum vs. Per Episode

James G. Luehman

Deputy Director

Division of Materials Safety and State Agreements

April 11, 2011

Background

- **NRC's current regulations are silent on the issue of per annum vs. per episode**
- **RIS-08-07 (Mar 2008) states: "NRC intends to pursue rulemaking to clarify the 5 mSv (0.5 rem) limit in 10 CFR 35.75 as an annual, rather than a per release limit"**

Background (con't)

- **The Statements of Consideration support the NRC determination that the regulation as it is currently written intended an annual dose Limit based on presumptions appropriate at the time the regulation was developed**

Background (con't)

- **During the January 5, 2011, the ACMUI recommended that NRC pursue rulemaking to clarify the criteria, and endorsed a per episode limit.**

Discussion

- **Is there a solution that appropriately balances the ACMUI's recommendation with the NRC's current position ?**

Acronyms

- **ACMUI: Advisory Committee on the Medical Uses of Isotopes**
- **CFR: Code of Federal Regulations**
- **mSv: millisievert**

NO HANDOUT

September 2011

Sunday	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday
				1	2	3
4	5 Labor Day	6	7 X	8 Annual Scientific Session of the ASNC	9 Annual Scientific Session of the ASNC	10 Annual Scientific Session of the ASNC
11 Annual Scientific Session of the ASNC	12	13	14 X	15	16	17
18	19	20	21 X	22	23	24
25	26	27	28 Rosh Hashana	29 Rosh Hashana	30 Rosh Hashana	

October 2011

Sunday	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday
						1
2 ASTRO Annual Meeting	3 ASTRO Annual Meeting	4 ASTRO Annual Meeting	5 ASTRO Annual Meeting	6 ASTRO Annual Meeting	7 AAPM 2011 CT Dose Summit	8 AAPM 2011 CT Dose Summit
9	10 Columbus Day	11	12 X	13 Sukkot	14 Sukkot	15 Sukkot
16 National Radon Training Conference	17 National Radon Training Conference	18 National Radon Training Conference	19 National Radon Training Conference	20 Shmini Atzeret	21 Simchat Torah	22
23	24	25	26 X	27	28	29
30	31	1 November	2 November X			

2007 ACMUI RECOMMENDATIONS AND ACTION ITEMS

ITEM		DATE	STATUS	
2	NRC staff should remove the attestation requirement for board certified individuals and rewrite the attestation requirement for individuals seeking authorization under the alternate pathway. The rewritten attestation should not include the word “competency” but should instead read “has met the training and experience requirements.”	6/12/07	Accepted	Open
3	NRC staff should revise the regulations so that board certified individuals, who were certified prior to the effective date of recognition or were certified by previously recognized boards listed in Subpart J of the previous editions of Part 35, are grandfathered.	6/12/07	Accepted	Open
6	NRC staff should add the words “or equivalent” so it is clear that information included in a letter is the same as that which would have been submitted in NRC Form 313A (35.12(c))	6/13/07	Accepted	Open
7	NRC staff should revise 10 CFR 35.50(c)(2) to include AUs, AMPs, or ANPs identified on any license or permit that authorizes similar types of use of byproduct material. Additionally, the AU, AMP, or ANP must have experience with the radiation safety aspects of similar types of use of byproduct material for which the individual is seeking RSO authorization.	6/13/07	Accepted	Open
8	NRC staff should remove the attestation requirement from 10 CFR 35.50(d) for AUs, AMPs, and ANPs seeking RSO status, if the AU, AMP, or ANP seeking RSO status will have responsibilities for similar types of uses for which the individual is authorized.	6/13/07	Accepted	Open
10	a) NRC staff should allow more than one RSO on a license with a designation of one RSO as the individual in charge. b) NRC should create a Regulatory Issue Summary (RIS) to inform the regulated community of NRC’s interpretation. The RIS should be sent to ACMUI and the Agreement States for review and comment.	6/13/07	a) Accepted b) Accepted	a) Open b) Closed
25	NRC staff should revise the current regulations to include Canadian trained individuals who have passed the ABNM certification exam.	8/16/07	Accepted	Open
30	The Elekta Perfexion® should be regulated under 10 CFR 35.1000 until 10 CFR 35.600 is modified to be performance-based, which would allow the Perfexion® to be regulated under 10 CFR 35.600.	10/22/07	Accepted	Open *Delayed*
31	NRC staff should require experienced RSOs and AMPs to receive additional training, if the individual is seeking authorization or responsibility for new uses.	10/22/07	Accepted	Open
32	NRC staff should not require experienced RSOs to obtain written attestation to become authorized or have responsibility for new uses.	10/22/07	Accepted	Open
34	NRC staff should modify 10 CFR 35.491(b)(2) to specify 'superficial’ ophthalmic treatments. Additionally, NRC staff should change the title of 10 CFR 35.491 to specify ‘superficial’ ophthalmic treatments.	10/22/07	Accepted	Open *Delayed*
35	NRC staff should not revise 10 CFR 35.491 (intended for ophthalmologists) to include training and experience for the new intraocular device. Instead, NRC staff should regulate the new intraocular device under 10 CFR 35.490.	10/22/07	Partially Accepted	Open *Delayed*
36	NRC staff should not require medical licensees regulated under 10 CFR 35.400, 500, or 600, as applicable, to only use the sealed sources and devices for the principle use as approved in the SSDR.	10/22/07	Accepted	Open
37	NRC staff should revise 10 CFR 35.290 to allow physicians to receive training and experience in the elution of generators and preparation of kits under the supervision of an ANP.	10/22/07	Accepted	Open

2008 ACMUI RECOMMENDATIONS AND ACTION ITEMS

	ITEM	DATE	STATUS	
2	NRC staff should pursue rulemaking to allow more than one RSO on a medical use license with the indication of one RSO as the individual in charge.	4/28/08	Accepted	Open
5	NRC staff should incorporate the subcommittee's recommendations for the Gamma Knife® Elekta Perfexion™ in future rulemaking.	4/28/08	Accepted	Open
9	NRC staff should revise the AO criteria to read, "A medical event that results in: 1) death; or 2) a significant impact on patient health that would result in permanent functional damage or a significant adverse health effect that would not have been expected from the treatment regimen, as determined by an NRC or Agreement State designated consultant physician."	4/28/08	Pending	Open
19	NRC staff should accept the six recommendations of the Permanent Implant Brachytherapy Subcommittee report with one modification. Recommendation six should be modified to read, "When a Written Directive (WD) is required, administrations without a prior WD are to be reported as regulatory violations and may or may not constitute an ME."	10/27/08	Pending	Open *Delayed*
22	ACMUI encouraged NRC staff to begin the rulemaking process to move the medical use of Y-90 microspheres from 10 CFR 35.1000 to another section of the regulations, so that the training and experience requirements for AUs can be vetted though the public review process instead of residing in guidance space.	10/27/08	Partially accepted	Open
26	NRC staff should revise 10 CFR 35.40 to clarify that the AU should sign and date both the pre-implantation and post-implantation portions of the WD for all modalities with two part WDs	10/28/08	Accepted	Open *Delayed*
27	NRC staff should revise 10 CFR 35.40 to clarify that an AU, not the AU, should sign and date both the pre-implantation and post-implantation portions of the WD for all modalities with two part WDs. [Note this allows for one AU to sign the pre-implantation portion of the WD and another AU to sign the post-implantation portion of the WD]	10/28/08	Accepted	Open *Delayed*
28	NRC staff should revise 10 CFR 35.65 to clarify it does not apply to sources used for medical use; however, NRC should not require licensees to list the transmission sources as a line item on the license. NRC staff should also revise 10 CFR 35.590 to permit the use of transmission sources under 10 CFR 35.500 by AUs meeting the training and experience requirements of 10 CFR 35.590 or 35.290.	10/28/08	Accepted	Open
29	NRC staff should revise 10 CFR 35.204(b) to require a licensee that uses Mo 99/Tc-99m generators for preparing a Tc-99m radiopharmaceutical to measure the Mo-99 concentration of each eluate after receipt of a generator to demonstrate compliance with not administering to humans more than 0.15 microcurie Mo-99 per millicurie Tc-99m.	10/28/08	Accepted	Open
30	NRC staff should require licensees to report to the NRC events in which licensees measure molybdenum breakthrough that exceeds the regulatory limits.	10/28/08	Accepted	Open

2009 ACMUI RECOMMENDATIONS AND ACTION ITEMS

	ITEM	DATE	STATUS	
1	NRC staff should allow IRs to become AUs for Y-90 microspheres with: 1) 80 hours training in: a) radiation physics & 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 2) work experience under the supervision of an Authorized User involving: a) ordering, receiving, & unpacking radioactive materials safely & performing the related radiation surveys; b) checking survey meters for proper operation; c) examination of each individual; d) calculating, measuring, & safely preparing patient or human research subject dosages; e) using administrative controls to prevent a medical event involving the use of byproduct material; f) using procedures to control and to contain spilled byproduct material safely & using proper decontamination procedures; g) follow up and review of each patient's or human research subject's case history; and h) the operation of and quality management for dose calibrators; and 3) board certification in diagnostic radiology with a subspeciality in interventional radiology or three years supervised clinical experience in diagnostic radiology with one year in interventional radiology	5/7/09	Accepted	Closed 1/26/11
2	NRC staff should revise 35.390(b)(1)(ii)(G)(3) to read "parenteral administration requiring a written directive for any radionuclide that is being used primarily because of its beta emission, or low energy photo-emission, or auger electron; and/or" and revise 35.390(b)(1)(ii)(G)(4) to read "parenteral administration requiring a written directive for any radionuclide that is being used primarily because of its alpha particle emission"	5/7/09	Accepted	Open
3	NRC staff should revise 10 CFR 35.490 & 690 as proposed with one exception. Delete "private practice." The regulation should read "500 hours of work experience, under the supervision of an Authorized User who meets the requirements in [35.490 or 35.690] or equivalent Agreement State requirements at a medical institution or clinic..."	5/7/09	Superseded by item 10	Closed
4	To prevent reccurrence of events like those at the VA, ACMUI recommends: 1) Every brachytherapy quality assurance program include peer review as published by the American Brachytherapy Society and 2) Authorized Users should perform post-implant dosimetry	5/7/09	No NRC action	Tabled
5	ACMUI will create a subcommittee that includes three members to review ICRP Report 103 and get back to Dr. Don Cool	5/8/09	ACMUI Action	Closed
6	a) ACMUI came to a consensus on NCRP report 160, which is believed to be scientifically sound and well-written b) ACMUI believes NRC and Agreement States should collect and maintain dose records and keep ACMUI aware of the issues but should continue a policy of not intervening with medical practice c) ACMUI supports the medical principle of "First do no harm" and expressed continued concern about exposure to children d) ACMUI's current belief is that the benefit of medical procedures involving radiation outweighs the risk	5/8/09	No NRC action	Closed
7	ACMUI endorsed the subcommittee report for American Board of Radiology candidates who may experience a delay between the completion of Training and Experience and receipt of board certification	5/8/09	No NRC action	Closed
8	NRC staff should not require licensees to report therapeutic infiltrations as Medical Events.	5/8/09	*Not Accepted*	Closed
9	Dr. Malmud added three temporary members to the medical events subcommittee: Dr. Welsh (chair), Dr. Langhorst, Mr. Mattmuller. Existing subcommittee members inlcude: Ms. Gilley, Dr. Suleiman, and Dr. Thomadsen.	10/19/09	No NRC action	Open
10	ACMUI recommends NRC staff delete the phrase "at a medical institution" from 10 CFR 35.2, 35.490(b)(1)(ii), 35.491(b)(2) and 35.690(b)(1)(ii).	10/19/09	Accepted	Open
11	ACMUI recommends NRC staff revise 10 CFR 35.41(a) by adding "(3) If the administration is not in accordance with the written directive, a determination of whether it resulted in a reportable medical event will be made in a timely manner."	10/19/09	Motion did not pass	Closed

2010 ACMUI RECOMMENDATIONS AND ACTION ITEMS

	ITEM	DATE	STATUS		1st/2nd	Vote
1	Dr. Thomadsen created a subcommittee to evaluate patient release issues; to objectively review and analyze available data, which may include state regulations and guidance and international recommendations; to provide a statement on the issue; and to provide recommendations for improvements to existing NRC rules and guidance, if necessary, which should include the issue of patient release to hotels. Subcommitte members include: Dr. Darrell Fisher, Ms. Debbie Gilley, Dr. Susan Langhorst (chair), Mr. Steve Mattmuller, Dr. Orhan Suleiman, Dr. Bruce Thomadsen, Dr. James Welsh, Dr. Pat Zanzonico. The subcommitte should report to the full ACMUI at the fall meeting.	5/24/10	ACMUI Action	Closed 12/13/10	Welsh/Fisher	8, 0, 0
2	The Permanent Implant Brachytherapy subcommittee will revise the draft subcommittee report and resubmit it to the full ACMUI for an email vote. The ACMUI will submit a final subcommittee report to the NRC.	5/24/10	ACMUI Action	Open	Zanzonico/Gilley	8, 0, 0
4	NRC staff should revise the Y-90 microsphere brachytherapy guidance to delete "but before the patient or human research subject leaves the post-prodecural recovery area" under item 2 of the written directive section.	5/25/10	Partially accepted	Closed 1/26/11	Welsh/Zanzonico	8, 0, 0
5	NRC staff should revise the Y-90 microsphere brachytherapy guidance to read (under 1 for written directives) "and, if the procedure was not performed in accordance with the pre-adminstration written directive", then 2) "after administration and within 48 hours of the procedure, the signature of an AU."	5/25/10	Partially accepted	Closed 1/26/11	Welsh/Zanzonico	8, 0, 0
6	NRC staff should consider the necessity and evaluate options to collect or obtain data for the denominator for medical events to improve the overall value of the medical events subcommitte report.	5/25/10	Accepted	Closed 3/1/11	Lewis	
9	ACMUI endorses the permanent implant brachytehrapy subcommittee report with the caveat that this is an interim report that may be revised in the future to consider additional input such as that received from stakeholders at public workshops.	10/20/10	Accepted	Closed 12/22/10	Welsh/Gilley	10, 0, 0
10	ACMUI endorses the draft version of FSME Policy and Procedures 2-5, Revision 0 presented at the meeting.	10/21/10	Accepted	Closed 1/21/11	Langhorst/Fisher	10, 0, 0
11	Dr. Thomadsen created a subcommittee to prepare a document to guide the December discussion on 10 CFR Part 37. Debbie Gilley (chair), Susan Langhorst, Darrell Fisher.	10/21/10	ACMUI Action	Closed 1/5/11	Thomadsen	
12	ACMUI will incorporate the comments made during the meeting to revise the patient release subcommittee report. The committee will vote to finalize the report via email and will resubmit it to NRC in the near future.	10/21/10	ACMUI Action	Closed 12/13/10	Thomadsen	
13	Steve Mattmuller, Bruce Thomadsen, and Susan Langhorst offered to provide support to respond to the letter dated October 20, 2010, to Chairman Jaczko from Congressman Markey regarding patient release.	10/21/10	ACMUI Action	Open	Thomadsen	
14	ACMUI planned a teleconference to discuss 10 CFR Part 37 rulemaking and safety culture on Monday, December 13, 2010, from 1:00 pm to 3:00 pm Eastern. The backup time/date is Wednesday, December 15, 2010 from 11:00 am to 1:00 pm Eastern.	10/21/10	ACMUI Action	Closed 12/13/10	Thomadsen	
15	ACMUI endorsed draft Policy and Procedure 2-5 with comments, as reflected in the meeting handout.	12/13/10	Partially accepted	Closed 1/12/11	Thomadsen/Gilley	10, 0, 0

2010 ACMUI RECOMMENDATIONS AND ACTION ITEMS

	ITEM	DATE	STATUS		1st/2nd	Vote
16	ACMUI approved the Patient Release Subcommittee Report, as reflected in the meeting handout.	12/13/10	Accepted	Closed 12/13/10	Welsh/Fisher	10, 0, 0
17	ACMUI will provide a list of action items for NRC staff based on the recommendations provided in the Patient Release Subcommittee Report.	12/13/10	ACMUI Action	Open	Lewis	
18	ACMUI deferred their discussion on the draft final safety culture policy statement to the January 2011 teleconference.	12/13/10	ACMUI Action	Closed 1/5/11	Guiberteau/Gilley	10, 0, 0
19	The ACMUI will develop a draft document on rulemaking and implementation guidance for physical protection of byproduct material for further discussion at a January 2011 teleconference.	12/13/10	ACMUI Action	Closed 1/5/11	Gilley	

2011 ACMUI RECOMMENDATIONS AND ACTION ITEMS

	ITEM	DATE	STATUS		1st/2nd	Vote
1	ACMUI endorsed the draft response to NRC comments, as reflected in the meeting handout (ML110600249). ACMUI agreed if NRC believes the release criteria should be changed from a per release criteria to an annual criteria, this change would require new rulemaking, as stated in Regulatory Issue Summary (RIS) 2008-07. ACMUI recommended rulemaking to clarify that the release under 10 CFR 35.75 is per release and not per year	1/5/11	NRC action	Open	Langhorst/Gilley	9, 1, 0
2	ACMUI recommended NRC staff maintain the current reporting structure for the Committee; however, the motion was tabled for further discussion at the January 12, 2011 ACMUI Teleconference	1/5/11	ACMUI Action	Closed 1/12/11	Welsh/Zanzonico	
3	ACMUI endorsed the draft comments on proposed 10 CFR Part 37, as reflected in the meeting handout (ML110600261)	1/5/11	NRC action	Open	Gilley/Suh	10, 0, 0
4	ACMUI endorsed the Draft Final Safety Culture Policy Statement	1/5/11	Accepted	Closed 1/26/11	Thomadsen/Fisher	9, 1, 0
5	ACMUI recommended NRC staff maintain the current reporting structure for the ACMUI with enhancements in communication as described in FSME Policy and Procedure 2-5 and increased technical and administrative support staff.	1/12/11	Accepted	Open	Guiberteau/Langhorst	10, 0, 0
6	ACMUI created an action item to reevaluate its satisfaction with the reporting structure annually.	1/12/11	ACMUI Action	Open indefinitely	Welsh/Zanzonico	
7						
8						
9						
10						
11						
12						
13						

Byproduct Material Events Subcommittee Report April 2011

James Welsh

Debbie Gilley, Susan Langhorst, Steve Mattmuller, Orhan Suleiman,

Bruce Thomadsen

Total number of procedures

- **(N = 1,098.8K)**
- **External Beam with SRS (Cranial Stereotactic Radiosurgery - Includes Gamma Knife Treatments) (2.9%)**
- **Brachytherapy - High Dose Rate Temporary Afterloading (3.0%)**
- **All other Cobalt Therapy <0.1% (<1%)**

Total number of procedures

- **Brachytherapy (LDR) Permanent Prostate Implants 1.9% (32%)**
- **Brachytherapy (LDR) Temporary Afterloading 0.4% (10%)**
- **Brachytherapy - High Dose Rate Temporary Afterloading 3.0% (34%)**
- **Radionuclide Therapy* 0.6% (17%)**

10 CFR 35.400

- **Brachytherapy - 25,272**

- **Permanent implant 20,877**
- **Prostate implant 20,877**
- **Other implant - -**
- **Temporary implant 4,395**

10 CFR 35.600

- **N = 42,587**
- **HDR** **32,964**
- **Teletherapy** **1,099**
- **GammaKnife** **8,524**

10 CFR 35.200

- **Diagnostic Imaging 15,220,000**

Radionuclide w/ written directive [10 CFR 35.300]

- IMV Nuclear Medicine Report 537,400
- IMV Radiation Therapy Report 6,593
- Total 543,993
- I-131 w/ written directive 531,700
- I-131 thyroid imaging 445,000
- I-131 thyroid therapy 56,200

Radionuclide w/ written directive [10 CFR 35.300]

- **I-131 other therapy** **30,500**
- **Sm-153 w/ written directive** **1,900**
- **Sr-89 w/ written directive** **1,100**
- **Other w/ written directive[2]** **2,700**

Medical Events for Radiopharmaceuticals Requiring a Written Directive

- **Part §35.300 – 4 Medical Events**
  - **Radionuclide**
    - **I-131 (thyroid patients) - 3**
    - **I-131 MIBG (neuroblastoma patients) -1**

IMV Data 2007

- **Patients Treated with Radionuclide Therapy in Responding Departments**
  - **92,400**
- **Error Rate = 0.0000432**

§35.400 (2009)

- **Total = 26 Events (27 patients)**
  - **Contrasts with 10 Events involving 114 patients between 10/1/07 – 9/30/08**
  - **Y-90 microspheres: 9**
  - **Permanent prostate brachytherapy: 17 (one event from 2005 at DVA LA)**

§35.400 (2010)

- **Total = 26 Events (75 patients)**
  - **Y-90 microspheres: 5 (1 with 2 events in same pt); 4 others underdosed**
  - **1 Cs-137 vaginal cylinder came out very early (76 rem to thigh)**
  - **Permanent prostate brachytherapy: 69 pts**

§35.400 (2010)

- **Total = 26 Events (75 patients)**
  - **Permanent prostate brachytherapy: 69 pts**
    - **8 Overdoses; 1 excess dose to normal tissues; 1 incorrect seed activity**
      - **One overdose retracted based on repeat post-implant dosimetry**

§35.400 (2010)

- Rest were underdoses
  - 2 underdoses retracted since not deemed to be true medical events
  - Gland swelled and upon re-evaluation, final dose was within 20%

§35.400 (2010)

- One D90 <1% but NOT a real ME since 39/41 seeds within target – all implanted within a few mm of "isoline".
- "could have been placed in better location"
- Due to poor image quality

35.400 Comments

- **Majority based on dose (e.g. D90) and number of seeds outside prostate**
  - **Would these be medical events if we used activity or source strength?**
  - **Many from earlier times but reported in this period**
    - ***MANY* more next year expected!**

35.400 Comments

- **Total permanent implant brachytherapy ~ 25,272**
- **26 Events (75 patients) in 2010**
- **75/25,272 = 0.002967 (0.297%)**
- **Permanent prostate brachytherapy: 69 pts**
- **Total ~20,877**
- **69/ 20,877 = 0.0033 (0.33%)**

Medical Events - §35.600 Remote Afterloaders & Teletherapy

	FY2009	FY2010
All §35.600	14	12
All HDR	7	9
MammoSite	2	2
Vaginal Cylinder	2	2
LDR remote afterloader	0	0
Gamma Knife	7	3
Teletherapy	0	0

§35.600 - HDR Medical Events

- **Nucletron HDR - 4 events**
  (M=Breast intracavitary)

  - **Wrong catheter length entered (2M)**
  - **Software failure**
  - **Incorrect treatment-unit mode**
  - **Incorrect contours entered**

§35.600 - HDR Medical Events

- **Varian HDR – VariSource 4 events (N=Needles or Catheters; C=Cylinders)**
  - **Wrong length (N)**
  - **“Patient moved” more likely wrong lenth (C)**
  - **Cylinder shifted (C)**
  - **No information**

Medical Events - §35.600 Gamma Knife

- Gamma Knife - 3 events
  - Incorrect coordinates (data entry)
  - Helmet moved
  - Frame not fastened tightly
- Perfexion – 2 events (Part 1000)
  - Wrong side
  - Hard-drive failure

Medical Events - §35.600 Observations

- Only one type of HDR error stood out:
  - Wrong length (3 of 4).
- Compared with the number of procedures:
  - HDR
    - 9 failures/33,000 procedures = 0.027%

Medical Events - §35.600 Observations

- GammaKnife
  - 3 failures/20,000 procedures = 0.015%
- Teletherapy
  - 0 failure / ~1000 procedures

§35.1000 Events Observations

- **Perfexion – 2 events discussed above**
- **Microspheres – 4 events / 1400 treatments**

  = 0.3%

  - **TheraSphere® – 2**
  - **SIR-Spheres® - 2**
- **Coronary – 1**

In Search of a Common Denominator

- **Problems with use of IMV surveys**
  - **IMV focus is a business perspective (includes FTE, etc)**
  - **Doesn't collect data by regulatory section, i.e. §35.300**
  - **IMV collects data based on practice site vs. a procedure**

In Search of a Common Denominator

- **Problems with use of IMV surveys**
  - **Not clear where I-131 NaI (2-4mCi) for a diagnostic metascan procedure or where I-131 Bexxar therapy is listed**
  - **Radiopharmaceutical therapy data was a composite of two years, 2007 (2008 Dx report) and 2009 (2010 Tx report).**

In Search of a Common Denominator

- **IMV data is valuable in providing a denominator that is "close enough" for demonstrating where we should focus further attention**
- **Unless there is a rash of similar events, further reviews should focus on §35.400-35.1000 only**

Brachytherapy in the USA is Very Safe but…

2004

- **192,102 prostate cancer treatments**
- **41,790 prostate cancer treatments with permanent prostate implants (22%)**

Brachytherapy in the USA is Very Safe but…

2009

- **219,760 prostate cancer treatments**
- **17,490 prostate cancer treatments with permanent prostate implants (8%)**

Brachytherapy in the USA is Very Safe but…

- **Sources:**
- **IMV Radiation Therapy Benchmark Report 2004**
- **IMV Radiation Therapy Benchmark Report October 2010**

U.S.NRC
United States Nuclear Regulatory Commission
Protecting People and the Environment

April 2011 ACMUI Meeting Purpose of Meeting

Michael Fuller

Team Leader

Medical Radiation Safety Team

April 11, 2011

Meeting Purpose

- **In SRM-SECY-10-0062, the Commission directed the staff to hold a series of stakeholder workshops**
- **In SECY-11-0035, staff informed the Commission that it planned to devote this meeting to 10 CFR Part 35 rulemaking activities. This is part 1 of workshop series; 2 more to follow**

Meeting Purpose

- **Over the course of the next two days, the ACMUI members and members of the public will have the opportunity to provide the staff with their comments, concerns, and insights on key topics**
- **Staff's primary objective for this meeting is to listen**

Acronyms

- **ACMUI: Advisory Committee on the Medical Uses of Isotopes**
- **SECY: Office of the Secretary**
- **SRM: Staff Requirements Memorandum**

Part 35 Expanded Rulemaking

Neelam Bhalla and Ed Lohr
Rulemaking Branch B
DILR/FSME

Background Part 35 Rulemakings

- Revised in its entirety in 2002
- Training and Experience regulations in 2005
- 3 additional rulemakings in 2007 and 2009

Part 35 Expanded Rulemaking

- **Items identified through implementation of Part 35, ACMUI recommendations, and a petition for rulemaking**
- **A total of 28 specific items/issues in the expanded Part 35 rulemaking**
- **The potential changes have been presented at past ACMUI meetings**

Expanded Rulemaking Would Consider:

- **Amendment of preceptor attestations**
- **Ritenour Petition (AAPM) regarding T&E requirements**
- **Frequency of Molybdenum-99m testing**
- **Naming Associate RSOs on a medical use license**

Part 35 - Medical Event Definitions Proposed Rule

- Proposed Rule published in FR Aug 6, 2008
- Reproposed rule provided to Commission June 2010
- Commission disapproved publication of the reproposed rule August 2010

Part 35 Expanded Rulemaking

- **The working group (NRC, OAS, and CRCPD) is developing the proposed rule**
- **ME workshops scheduled for June 2011 to include major issues from the expanded rulemaking**

Part 35 Expanded Rulemaking

Questions?

SUPPLEMENTAL INFORMATION

Part 35 - Medical Event Definitions Proposed Rule

- **Proposed Rule published in FR Aug 6, 2008**
- **Large number of ME's reported in Summer-Fall 2008 caused reevaluation of the proposed rule**

Part 35 - Medical Event Definitions Proposed Rule

- **Based on public comments and the circumstances involving a large number of ME's, the proposed rule was revised significantly**
- **Reproposed rule provided to Commission June 2010**

Part 35 - Medical Event Definitions Proposed Rule

- Commission disapproved publication of the reproposed rule August 2010
- Commission directed the staff to conduct a series of stakeholder meetings
- Stakeholder meetings scheduled for June 2011

Impacts on Schedule

- **Current**

  -Proposed Rule: March 2012

  -Final Rule: September 2013

- **Incorporation of ACMUI P&P 2-5, ME rule, and expanded comment periods**

  -Proposed Rule: December 2012

  -Final Rule: October 2014

Acronyms

- **AAPM: American Association of Physicists in Medicine**
- **ACMUI: Advisory Committee on the Medical Uses of Isotopes**
- **CRCPD: Conference of Radiation Control Program Directors**
- **FR: Federal Register**

Acronyms Cont'd

- **ME: Medical Events**
- **OAS: Organization of Agreement States**
- **T&E: Training and Experience**

Part 35 Section Amendments

Item Number	Section to be amended	Brief Description
1	35.12(c)	Information for license amendment renewal
2	35.12(d)	Content of applications, 35.1000 uses
3	35.13	Notification of new brachy source model
4	35.14	Notification of new brachy source model
5	35.50(c)(2)	Intended individual as RSO
6	35.50(d)	Not to require preceptor RSO attestation for AUs, AMPs, and ANPs
7	35.57 (a) and 35.57(b)	Limiting grandfathering authorized individuals as RSOs, only approved uses
8	35.57(a)	No attestation for experienced RSO, only complete training
9	35.51(a)(2)(i)	Revising certification requirement for supervising MP
10	35.57(a) and 35.57(b)	Expand grandfathering of certified individuals (Ritenour Petition)
11	Subparts B, D-F, and G	Amend preceptor attestation requirements
12	Subparts A, B, and L	Allow Assistant RSOs to be named on the license
13	35.65(a)-(d)	Limit quantity on aggregated sources
14	35.65(a)-(d)	Move transmission sources to Subpart G
15	35.204(b)	Increase frequency of molybdenum-99 (Mo-99) tests
16	35.204(e) and Subpart M	Require reporting of failed Mo-99 tests
17	35.290(b)(ii(G)	Supervision for generator elution training
18	35.390(b)(1)	Accept Canadian work experience for AUs
19	35.390(b)(1)(ii)(G)	Work experience for alpha emitters
20	35.400, 500, 600	Sealed sources usage and SSDR listings
21	35.490(b)(1)(ii)	Change site requirements for AU work experience
22	35.433(a)	List AMP tasks for strontium-90 (Sr-90) eye applicators
23	35.433(a)	AMP training and experience for Sr-90 eye applicators
24	35.491(b)(3)	Correct attestation requirements for AUs
25	35.610(d)	Training for therapy unit operators
26	35.655(a)	Gamma knife inspection at source exchange

27	35.690(b)(1)(i)	Change site requirements for AU work experience
28	35.3045(a)(2)	Report a medical event if wrong radionuclide is administered for a brachytherapy procedure

Acronyms

AMP	Authorized Medical Physicist
ANP	Authorized Nuclear Pharmacist
AU	Authorized User
MP	Medical Physicist
RSO	Radiation Safety Officer
SSDR	Sealed Source and Device Registry

Permanent Implant Brachytherapy Medical Event Definition

Michael Fuller

Team Leader

Medical Radiation Safety Team

April 11, 2011

Background

- **In SECY-05-0234, the Staff recommended for all Permanent Implant Brachytherapy, medical events should be defined in terms of total source strength, not absorbed dose**
- **In SRM-SECY-05-0234, the Commission approved Staff's recommendation**

Background (con't)

- **In SECY-08-0080, the Staff provided the commission with the proposed modified rule for the use of total activity rather than absorbed dose**
- **In SRM-SECY-08-0080, the Commission approved the proposed rule**

Background (con't)

- **In SECY-10-0062, the Staff provided the Commission with a reproposed rule that added activity-based criteria for the definition of a ME for Permanent Implant Brachytherapy, plus requirements for training, and other requirements**

Background (con't)

- **In SRM-SECY-10-0062, the Commission disapproved the re-proposed rule and directed the Staff to hold a series of public stakeholder workshops**

Discussion

- **How do we appropriately balance between the medical community's desire to define a medical event in terms of clinical significance with NRC's need to have mistakes in the process reported, even if there is no actual negative consequence to the patient?**

Acronyms

- **ME: Medical Events**
- **SECY: Office of the Secretary**
- **SRM: Staff Requirements Memorandum**

Statement of
Danny Song, MD
Associate Professor and Clinical Director
Department of Radiation Oncology and Molecular Radiation Sciences
Johns Hopkins University School of Medicine
On Behalf of the American Society for Radiation Oncology (ASTRO)
Before the Nuclear Regulatory Commission's Advisory Committee on the Medical Use of Isotopes
April 11, 2011

Thank you for the opportunity to make this statement on behalf of the American Society for Radiation Oncology. I am Dr. Danny Song, an Associate Professor and Clinical Director for the Department of Radiation Oncology and Molecular Radiation Sciences at Johns Hopkins University School of Medicine. I am also director of brachytherapy services at Johns Hopkins and have over 7 years' experience in performing prostate as well as endobronchial brachytherapy, and maintain an active brachytherapy service as well as a federally funded research program in prostate brachytherapy.

ASTRO is the largest radiation oncology society in the world, with more than 10,000 members who specialize in treating patients with radiation therapies. As the leading organization in radiation oncology, biology and physics, the Society is dedicated to improving patient care through education, clinical practice, advancement of science and advocacy. ASTRO's highest priority has always been ensuring patients receive the safest, most effective treatments.

ASTRO believes that the current definition of medical event for permanent implant brachytherapy – one that relies on absorbed dose – is peculiarly problematic and requires practitioners to report events that may very well fall within the range of what is considered to be medically acceptable.

As you know, radiation therapy is the use of various forms of ionizing and in some cases, non-ionizing radiation to safely and effectively treat cancer and other diseases. Radiation Oncologists use radiation therapy to eradicate cancer, to control the growth of the cancer or to relieve symptoms, such as pain. Patients receive radiation therapy in one of two ways: externally or internally. During external beam radiation, a beam of radiation is directed to the tumor and immediate surrounding area in order to destroy the tumor and any nearby cancer cells. Internal radiation or brachytherapy is the placement of radioactive sources in or next to a tumor.

Permanent Implant Brachytherapy and Prostate Cancer

Brachytherapy is a highly effective way of delivering radiation tailored to the shape of the tumor while sparing surrounding normal tissues. Over the last 15 years, sophisticated computerized treatment planning and advances in medical imaging have helped to achieve increased accuracy and superior, optimized dose distribution for cancer patients.

The benefits of brachytherapy vary depending on the patient, their age and diagnosis, stage and preferences. Permanent implant brachytherapy is a cost-effective, minimally invasive outpatient procedure that avoids hospitalization and allows the patient a rapid recovery and rapid return to normal activity. It produces excellent 10-year outcomes with relatively low morbidity. The benefits of using this form of brachytherapy in the treatment of early stage prostate cancer are quite pronounced and include a lower incidence of impotence and incontinence than is commonly

reported with a radical prostatectomy. The high degree of accuracy achievable in prostate implants is partly due to technological improvements, but quality implants still require skill, adequate training, and attention to detail.

Brachytherapy Clinical Practice Guidelines

Permanent prostate brachytherapy, is given by inserting small seeds of radioactive iodine, cesium or palladium directly into the prostate gland. These radioactive sources have relatively low energy levels and half lives of between 10 and 60 days. Patients are under spinal or general anesthesia during this outpatient surgical procedure. The seeds are temporarily radioactive and deliver the radiation to the prostate over several weeks to months. After losing their radioactivity, the seeds remain in the prostate. The seeds are then harmless and should not bother the patient.

It is essential that post-implant dosimetry be performed on all patients undergoing permanent prostate brachytherapy as a quality assessment measure. It is recognized that the dose distributions following implantation are never exactly the same for each patient as those planned prior to the implant because the prostate gland swells and or changes shape during and after the procedure. Because the dose distributions may differ, it is important to document the actual dose that the prostate and normal adjacent tissues will receive over the life of the implant. This can only be determined if a post-implant dosimetric assessment is performed.

The information obtained from post-implant dosimetry is essential for optimal patient care. Significant over-dosing of the prostate may increase the risk of side-effects. Significant under-dosing of the prostate can lead to treatment failure. The latter can potentially be rectified using supplemental external beam radiation therapy or additional seed implants. While the timing may vary in part due to the half-life of the particular isotope involved, post-implant dosimetry scans are generally obtained at intervals varying from one day to one month post-implant.

At the conclusion of the course of treatment, a written summary of the treatment delivery parameters is generated, including the total prescribed dose of brachytherapy and the total dose of external beam therapy if given, treatment technique, treatment volume, acute side effects, clinical course, and patient disposition. Patients treated with brachytherapy should be evaluated after treatment at regular intervals by the radiation oncologist for response and, early and late effects on normal tissues.

Definition of Medical Event

Under Part 35 section 35.3045 it is deemed to be a medical event if “the total dose delivered differs from the prescribed dose by 20 percent or more.” However, ASTRO believes that such a rule is not appropriate for permanent implant brachytherapy. If the NRC definition is rigidly applied, many medically acceptable and appropriate implants will be deemed to be medical events, creating unnecessary patient apprehension. Further, we are concerned the dose-based measure is medically inappropriate and encumbers regulatory bodies (such as the NRC) and the licensees with clinically irrelevant and costly investigations. Hence, a dose-based definition of medical event is not suitable for permanent implant brachytherapy.

One key reason for this is that during the time interval between the initial or preplan volume study and the end of the implant, there are several changes that occur in the treatment volume (e.g., the prostate gland) and the relative position of the radioactive sources within the treatment site which affect the final calculated dose. Further, the prostate volume and therefore the resultant calculated absorbed dose varies upon the post-implant imaging modality used (CT or MRI), observer variability in prostate contouring. An ASTRO working group found that the current definition of medical events was not suitable for permanent implant brachytherapy because the prostate volume (and hence the resultant calculated prostate absorbed dose) depends upon many factors including a) the timing of the imaging; b) the imaging modality

selected; c) the observer variability in prostate contouring (both inter-observer and intra-observer); and d) the planning margins used. If the current dose-based medical event definition remains in force, many properly executed implants would be improperly classified as a medical event leading to a detrimental effect on brachytherapy.

Instead of a rule based on absorbed dose, ASTRO strongly recommends using an activity (i.e., source strength) based rule (>20 percent of source strength implanted outside the treatment site) to define medical events for regulatory purposes. This is because the total source strength implanted within and around the prostate is under control of the authorized user, but the subsequent prostate volume and the resultant dose to the prostate is not. The actual dose and the dosimetric parameters will vary considerably depending upon when and how the images were obtained, how the prostate was contoured, and the amount of swelling or edema. A source strength based criterion, (>20 percent of source strength implanted outside the planning target volume) will correctly identify as medical events cases in which a large number of sources have been improperly implanted outside the treatment site but be less likely to generate spurious medical events than a dose based definition. ASTRO recommends using the source strength-based rule for regulatory purposes.

ASTRO acknowledges one scenario where a source strength-based criterion would not adequately identify a medical event. This would be when all or most of the sources are erroneously implanted within a small region of the target volume, leaving a substantial portion of the treatment site uncovered. Under this circumstance some of the target will be over-dosed and other areas under-dosed. To address this rare event, ASTRO recommends that the authorized user be required to affirm in writing on the written directive, after the implant is completed, that the distribution of the sources within the treatment site was as intended per the pre-implant written directive.

The investigation of the permanent implant brachytherapy procedures at the Philadelphia Veterans Administration has brought attention to this issue, and a Blue Ribbon Panel was assembled to review the cases to determine if the implants were medically inappropriate. This panel found that many of those implants, previously considered to be medical events under the current definition, were, in fact, medically acceptable and proper. Thus, ASTRO is very concerned that if the current dose-based definition for permanent implant brachytherapy medical events remains, many properly executed and medically acceptable implants will erroneously be labeled as medical events.

In the absence of reforming the definition of medical event that relies on dose-based rules, it is difficult to accurately predict exactly how many medically acceptable implants in this country will be mislabeled as medical events. Such a situation would be harmful to the public welfare as it will create undue apprehension in patients and the general public about this safe and effective medical procedure, and it would likely continue to occupy the NRC, state regulatory bodies and the licensees with thousands of man-hours of unnecessary and clinically irrelevant costly investigations. Enforcement of this rule would also lead to decreased patient access to what is well-accepted as a successful and cost-effective treatment which will not be in our patients' best interest.

Written Directive

Another factor compounding the definition of medical event is the revision of medical directives. It is very important that the definition of medical event and the rules surrounding written directives take into account clinical practice realities so that certain medically acceptable implants are not labeled as medical events. Current regulations require that revisions to the written directive be made before implantation begins. The reason the pre-implantation written directive cannot be changed is that the pre-implantation written directive serves as the basis for determining if a medical event has occurred. ASTRO would like to emphasize that many authorized users perform real-time, adaptive, interactive planning, whereby the written directive and the source strength to be implanted are based on the actual volume dynamically determined during the procedure rather than based on the pre-implant volume. ASTRO believes

that real-time planning is a more accurate method of implantation because it takes into account any alterations in the prostate volume and shape. While real-time planning is most developed and most commonly used in the prostate, it can also be used in other brachytherapy procedures as long as the organ is easily imaged in real time.

For those performing real-time adaptive planning implantation, the total source strength to be implanted is determined intraoperatively during the implantation procedure and not pre-implant. Further, even those performing permanent brachytherapy using preplanned techniques will often modify their plan if intraoperatively they find major discrepancies in the gland or organ volume from the volumes determined during the pre-plan. Allowing flexibility to deal with real life clinical situations that become apparent during the operation improves clinical outcomes.

Accordingly, ASTRO recommends that the written directive refer to the total source strength implanted after administration, but before the patient leaves the post-treatment recovery area rather than an arbitrary pre-implantation written directive.

Conclusion

We appreciate both the ACMUI and NRC's deliberations on this issue and look forward to working with the NRC to revise this definition so that patients have access to safe, medically appropriate procedures.

Proposed Definition for Prostate Implant Medical Events

For the Target

- D_{90}<70% of the clinical target volume (CTV)

AND

- Less than 5% of sources occupy any octant of the PTV, except by design (e.g. for preservation of normal tissue or escalated treatment to a particular region), as specified in the written directive.

For Normal Tissues

1. For the bladder and rectum, the D_{5cc} on post-implant dosimetry exceeds 150% of the prescription dose

OR

2. For the urethra, the D_{5cc} on post-implant dosimetry exceeds 150% of its value on the planned, approved dose distribution.

Features of the Definition

- This definition WOULD catch an event where all the sources are bunched.
- It would *not* signify as a Medical Event an implant with the sources missing an octant provided the dose coverage is above 70%.

Features of the Definition

- The D90<70% is based on the RTOG 0232 where minor deviations are 90%<D90<80%.
- Obviously, an event is worse than a minor deviation, but a criterion of D90<60 seems unrealistic.

Features of the Definition

- For the normal tissue, the D_{5cc} avoids the high variation in dose sometimes seen in point doses and has literature to support it being an relevant quantity for toxicity.