MEETING AGENDA
ADVISORY COMMITTEE ON THE MEDICAL USES OF ISOTOPES

May 8-9, 2014
Two White Flint North Building (T2-B3), Rockville, Maryland

NOTE: Sessions of the meeting may be closed pursuant to 5 U.S.C. 552(b) to discuss organizational and personnel matters that relate solely to internal personnel rules and practices of the ACMUI; information the release of which would constitute a clearly unwarranted invasion of personal privacy; information the premature disclosure of which would be likely to significantly frustrate implementation of a proposed agency action; and disclosure of information which would risk circumvention of an agency regulation or statute.

Thursday, May 08, 2014
CLOSED SESSION

7:30 – 8:30	**1.**	**Badging and Enrollment**	**S. Holiday, NRC**

OPEN SESSION

8:30 – 8:45	**2.**	**Opening Statements** Mr. Fuller will formally open the meeting and Ms. Dudes will provide opening comments.	**M. Fuller, NRC** **L. Dudes, NRC**
8:45 – 9:00	**3.**	**Old Business** Ms. Holiday will review past ACMUI recommendations and provide NRC responses.	**S. Holiday, NRC**
9:00 – 9:45	**4.**	**Commission Direction on Part 35 Rulemaking Activities** Dr. Howe will discuss the tasking from the Commission related to the 10 CFR Part 35 Rulemaking.	**DB. Howe, NRC**
9:45 – 10:00		**B R E A K**	
10:00 – 11:00	**5.**	**NRC Medical Policy Statement** Dr. Thomadsen and Ms. Cockerham will lead discussions about whether or not the NRC should revise the Medical Policy Statement.	**A. Cockerham, NRC** **B. Thomadsen, ACMUI**
11:00 – 11:45	**6.**	**Medical Related Events** Dr. Howe will provide the latest update on medical-related events	**DB. Howe, NRC**
11:45 – 12:00	**7.**	**Update on Ga-68 Generators** Mr. Mattmuller will provide an update on the developments associated with the Ge-68/Ga-68 generators.	**S. Mattmuller, ACMUI**
12:00 – 1:30		**L U N C H**	
1:30 – 3:00	**8.**	**Amendments to the ACMUI Bylaws** Dr. Zanzonico will discuss the amendments to the ACMUI Bylaws	**P. Zanzonico, ACMUI**
3:00 – 3:30		**B R E A K**	

CLOSED SESSION

3:30 – 5:30	**9.**	**ACMUI Subcommittee Meeting**	**ACMUI**

Friday, May 09, 2014
CLOSED SESSION

7:30 – 8:00 **10. Security Briefing**
8:00 – 9:00 **11. Escort Training**

OPEN SESSION

9:00 – 11:00 **12. Commission Briefing** **ACMUI**
The ACMUI will brief the Commission on various topics in the Commissioners Hearing Room.

11:00 – 11:30 **13. Group Photo**
The ACMUI will take a group photo.

11:30 – 1:00 **L U N C H**

1:00 – 2:00 **14. Research on the Release of Patients Following Iodine-131 Administration** **M. Saba, NRC** **P. Zanzonico, ACMUI**
Mr. Saba will provide a status update on the research being conducted for patients who are released following the administration of iodine-131. Dr. Zanzonico will discuss the presentation given during the Commission Meeting.

2:00 – 2:45 **15. NNSA's Efforts on Reducing HEU in Molybdenum-99 Production** **R. Hamilton, NNSA** **P. Staples, NNSA**
Dr. Staples and Ms. Hamilton will provide a status update on NNSA's efforts to reduce HEU during the production of molybdenum-99.

2:45 – 3:00 **16. Administrative Closing** **S. Holiday, NRC**
Ms. Holiday will provide a meeting summary and propose dates for the Fall 2014 meeting.

3:00 – 3:30 **B R E A K**

CLOSED SESSION

3:30 – 3:45 **17. eTravel Training** **S. Holiday, NRC**
3:45 – 4:00 **18. HRMS Training** **S. Holiday, NRC**

4:00 **A D J O U R N**

Badging and Enrollment

NO HANDOUT

Opening Statements

NO HANDOUT

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 *Delayed*
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 *Delayed*
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	
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
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	ACMUI 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

2011 ACMUI RECOMMENDATIONS AND ACTION ITEMS

	ITEM	DATE	STATUS		1st/2nd
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	Pending	Open	Langhorst/Gilley
6	ACMUI created an action item to reevaluate its satisfaction with the reporting structure annually.	1/12/11	ACMUI Action	Open indefinitely	Welsh/Zanzonico
11	(1) ACMUI feels ASTRO's approach to Permanent Implant Brachytherapy (handout) is correct approach for patient welfare (2) ACMUI recommends that the NRC require Post-Implant dosimetry following brachytherapy treatment (3) ACMUI believes that prostate brachytherapy is a unique subset of brachytherapy and should therefore require a separate set of rules from non-prostate brachytherapy.	4/11/11	Partially Accepted	Open	Welsh/Mattmuller
13	ACMUI recommends to eliminate the written attestation for board certification pathway, regardless of date of certification	4/12/11	Accepted	Open	Zanzonico/Guiberteau
14	ACMUI recommends the attestation to be revised to say … has received the requisite training and experience in order to fulfill the radiation safety duties required by the licensee	4/12/11	Accepted	Open	Langhorst/Thomadsen
15	ACMUI supports the statement that residency program directors can sign attestation letters, representing consensus of residency program faculties, if at least one member of the faculty is an AU in the same category as that designated by the applicant seeking authorized status, and that AU did not disagree with the approval.	4/12/11	Accepted	Open	Thomadsen/Welsh
16	ACMUI continues to assert that the current regulations are based on a per release limit. ACMUI does not recommend any change to the regulation and does not recommend the NRC consider this topic during the current rulemaking process, as there is no clinical advantage or advantage to members of the public for using an annual limit.	4/12/11	Pending	Open	Langhorst/Welsh

2012 ACMUI RECOMMENDATIONS AND ACTION ITEMS

	ITEM	DATE	STATUS	
9	ACMUI requested that reporting structure reviews remain on an annual basis.	9/20/12	Accepted	Open

2013 ACMUI RECOMMENDATIONS AND ACTION ITEMS

	ITEM	DATE	STATUS		1st/2nd	Vote
1	ACMUI recommended NRC staff allow use of total source strength as a substitute for total dose for determining medical events for permanent implant brachytherapy until the Part 35 rulemaking is complete.	3/5/13	NRC Action	Open		11, 0, 0
2	ACMUI recommended that NRC staff solicit feedback from stakeholders, in Supplementary Information section IV.D, on whether the proposed ME definition for permanent implant brachytherapy would discourage licensees from using this form of therapy. This recommendation was modified the caveat that NRC may utilize the language that they think is appropriate for gaining this type of information from its stakeholders	3/5/13	NRC Action	Open	Zanzonico/Langhorst	
3	ACMUI recommended the draft rule re-defining medical events in permanent implant brachytherapy be designated as Compatibility Category B.	3/5/13 3/12/13	NRC Action	Open		11, 1, 0
4	ACMUI recommended replacing the phrasing in the literature in terms of support for the 5 cubic centimeters of contiguous normal tissue provision of the ME definition, to the specific reference cited as, Nag, et al 2004	3/5/13	NRC Action	Open		
5	ACMUI recommended that licensees approved to use generator systems show specific training on the requirement now listed under 35.290 (c)(1)(ii)(G) for those individuals (Authorized Users and others) who are responsible for proper operation and testing of the generator as part of their license conditions. ACMUI further recommended that Authorized Nuclear Pharmacists who have the adequate training and experience (T&E) are able to provide the supervised work experience for Authorized Users on the elution of generators.	3/5/13	NRC Action	Open		
6	ACMUI endorsed the language in the proposed rule for preceptor attestations that states a candidate is able to independently fulfill the radiation safety related duties for which authorization is being sought.	3/5/13	NRC Action	Open		
7	ACMUI recommended that the work experience for parenteral administrations under Sections 35.390 (b)(1)(2)(g), and 35.396 not be separated between parenteral administrations of a beta gamma emitting radiopharmaceutical versus an alpha emitting radiopharmaceutical, as proposed in the proposed rule.	3/12/13	NRC Action	Open	Zanzonico/Guiberteau	11, 0, 1
8	ACMUI recommended that the date of recognition of a certifying board should not impact individuals seeking to be named as an Authorized User, Authorized Radiation Safety Officer, Authorized Medical Physicist, or Authorized Nuclear Pharmacist through the certification pathway.	3/12/13	NRC Action	Open	Zanzonico/Thomadsen	12, 0, 0

2013 ACMUI RECOMMENDATIONS AND ACTION ITEMS

	ITEM	DATE	STATUS		1st/2nd	Vote
9	ACMUI recommended that the NRC adopt the FDA approved package insert for breakthrough limits for radioisotope generators	3/12/13	NRC Action	Open	Zanzonico/Mattmuller	12, 0, 0
10	ACMUI recommended licensee reporting of out-of-tolerance generator breakthrough results to the NRC	3/12/13	NRC Action	Open	Zanzonico/Weil	5, 7, 0
11	ACMUI recommended requiring testing of molybdenum breakthrough on every elution of a molybdenum-technetium generator, rather than after only the first elution.	3/12/13	NRC Action	Open		12, 0, 0
12	ACMUI recommended that the addition of Associate Radiation Safety Officers (ARSOs), and Temporary RSOs also be included in these exemptions in the same manner as AUs, ANPs, and AMPs.	3/12/13	NRC Action	Open	Zanzonico/Langhorst	12, 0, 0
13	In reference to the plain language requirement, the ACMUI suggested that the rule "could be shortened and improved by eliminating redundancies and consolidating related sections and eliminating identical or nearly identical passages appearing multiple times throughout the draft rule. A further improvement would be the inclusion of a detailed "executive summary"-style section summarizing, perhaps in a bullet format, the key changes introduced in the draft rule."	3/12/13	NRC Action	Open		12, 0, 0
15	The ACMUI recommended tabling the discussion of amendments to the ACMUI Bylaws to the Fall 2013 ACMUI Meeting.	4/15/13	NRC Action	Closed		
21	The ACMUI recommended that NRC provides regulatory relief from the decommissioning funding plan requirements for the use of a Germanium-68/Gallium-68 generator.	4/16/13	NRC action	Open	Mattmuller/Zanzonico	8, 0, 4
23	Dr. Thomadsen added Dr. Christopher Palestro to the Medical Events Subcommittee. Dr. Palestro will review the I-131 medical events. Subcommittee Members: Welsh (Chair), Langhorst, Mattmuller, Suh, Suleiman, Thomadsen	9/9/13	ACMUI Action	Open		

2013 ACMUI RECOMMENDATIONS AND ACTION ITEMS

	ITEM	DATE	STATUS		1st/2nd	Vote
24	Dr. Thomadsen created a subcommittee to review the Proposed Amendments to the ACMUI Bylaws. The recommendations will be presentation in the spring 2014 meeting. Subcommittee members include: Dr. Chris Palestro, Dr. John Suh, Dr. Orhan Suleiman, Ms. Laura Weil, and Dr. Pat Zanzonico (chair).	9/9/13	ACMUI Action	Open		
25	The ACMUI recommended to reestablish the Rulemaking Subcommittee to review and address staff's response to the subcommittee's recommendations for the draft proposed expanded 10 CFR Part 35 Rulemaking.	9/10/13	ACMUI Action	Open	Mattmuller/Zanzonico	12, 0, 0
26	Dr. Thomadsen added Mr. Steve Mattmuller to the ACMUI Bylaws Subcommittee	9/10/13	ACMUI Action	Open		
27	Dr. Thomadsen added the following additional charges to the ACMUI Bylaws Subcommittee: 1) Discuss, address and make a recommendation for the reporting structure (to the MSSA Director versus the Commission); 2) Discuss, address, and make a recommendation for the consideration of budgeting for an additional face-to-face meeting at Headquarters; 3) Consider the feasibility of conducting meetings using the Go-To-Meeting or Go-To-Webinar function.	9/10/13	ACMUI Action	Open		
29	Dr. Welsh recommended to add the topic of physical presence requirements of Authorized Users for the Gamma Knife and Perfexion for discussion at the spring 2014 meeting.	9/10/13	ACMUI Action	Delayed	Welsh/Langhorst	10, 0, 0
30	The ACMUI planned the spring 2014 meeting for May 8-9, 2013. The back-up dates are May 12-13, 2013.	9/10/13	ACMUI Action	Closed		

2014 ACMUI RECOMMENDATIONS AND ACTION ITEMS

	ITEM	DATE	STATUS		Assigned	1st/2nd	Vote
1	Dr. Thomadsen created a subcommittee to review the NRC Medical Policy Statement. The subcommittee was charged with determining if the Policy Statement needed revision(s). In addition, the subcommittee was asked to address the following two questions: 1) Stakeholders in the medical community have suggested that physicians are not performing permanent implant brachytherapy procedures because of NRC's current regulations in 10 CFR Part 35. Does the subcommittee believe this to be true; and 2) Does the subcommittee believe the regulations in 10 CFR Part 35, as amended in the proposed rule, address this real or perceived issue? Subcommittee members include: Dr. Thomadsen (chair), Dr. Guiberteau, Dr. Palestro, Dr. Suh, and Dr. Welsh.	1/30/14	ACMUI Action	Open			
2	Dr. Thomadsen added Dr. Philip Alderson to the Medical Policy Statement Subcommittee.	3/24/14	ACMUI Action	Open			

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Commission Direction on Part 35 Rulemaking Activities

Donna-Beth Howe, Ph.D.
Medical Radiation Safety Team
May 8, 2014

1

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STAFF REQUIREMENTS – SECY-13-0084

- The Commission approved publication of the proposed rule for public comment subject to the its comments and changes.

Staff revised both the Federal Register Notice containing the Proposed Rule and the Draft Guidance per Commission direction

2

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STAFF REQUIREMENTS – SECY-13-0084

Staff was further directed to:

- Update the NRC's Memorandum of Understanding with the U.S. Food and Drug Administration; and
- Provide the Commission with the staff's recommendation on whether to update the policy statement on Medical Uses of Byproduct Material.

3

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QUESTIONS?

4

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NRC Medical Policy Statement

Ashley Cockerham
Medical Radiation Safety Team

Purpose

- **Brief history of current and previous Medical Use Policy Statements**
- **Seek ACMUI feedback on potential revisions to current policy statement**

2

Background

- NRC publishes policy statements to cover broad areas where radiation safety is a concern
  - Examples
- What policy statements do/don't do
  - Rules/regulations vs clarifying policy

3

1979 Medical Policy Statement

- Regulate medical use of isotopes to provide for radiation safety of workers and public
- Regulate radiation safety of patients based on risk
- *Minimize intrusion* into medical judgments affecting patients (practice of medicine)

4

2000 Medical Policy Statement

- **Regulate medical use of isotopes to provide for radiation safety of workers and public**
- **Regulate radiation safety of patients based on risk *with focus that use is in accordance with physician directions***
- ***Will not intrude* into medical judgments affecting patients (practice of medicine)**
- ***Consider industry and professional standards***

5

NRC Staff Recommendation

- **No change to current policy**
  - **Effective and flexible**
  - **Part 35 rulemaking addresses issues under scope of current policy**
  - **Resources**

6

Path Forward

- **Summer 2014 - Incorporate ACMUI position/recommendations**
- **Fall 2014 - Finalize Commission Paper**

7

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ACMUI Views on Revision to the NRC's Medical Uses Policy Statement

Bruce Thomadsen, Ph.D.
ACMUI Chairman
May 09, 2014

ACMUI Comments

- **The ACMUI was asked to consider if the NRC should look into revisions to the policy on medical uses of byproduct materials.**
- **A subcommittee was formed to study the issue.**

Subcommittee Membership

- Philip Alderson, M.D.
- Milton Guiberteau, M.D.
- Chris Palestro, M.D.
- John Suh, M.D.
- James Welsh, M.D.
- Bruce Thomadsen, Ph.D., Chair

3

A Brief History of the Policy: 1979

1. The NRC will continue to regulate the medical uses of radioisotopes as necessary to provide for the radiation safety of workers and the general public.

4

A Brief History of the Policy: 1979

2. The NRC will regulate the radiation safety of patients where justified by the risk to patients and where voluntary standards, or compliance with these standards are inadequate.

5

A Brief History of the Policy: 1979

3. The NRC will minimize intrusion into medical judgments affecting patients and into other areas traditionally considered to be a part of the practice of medicine.

6

A Brief History of the Policy: 2000

1. The NRC will continue to regulate the uses of radioisotopes in medicine as necessary to provide for the radiation safety of workers and the general public.

7

A Brief History of the Policy: 2000

2. NRC will not intrude into medical judgments affecting patients, except as necessary to provide for the radiation safety of workers and the general public.

8

A Brief History of the Policy: 2000

3. NRC will, when justified by the risk to patients, regulate the radiation safety of patients primarily to assure the use of radionuclides is in accordance with the physician's directions.

9

A Brief History of the Policy: 2000

4. NRC, in developing a specific regulatory approach, will consider industry and professional standards that define acceptable approaches of achieving radiation safety.

10

Some Concerns (1)

There have been some concerns that some rules, for example involving the definition of medical events and training and experience, may have unduly affected medical practice without increasing safety.

11

Some Concerns (2)

The revision of Part 35 seems to have alleviated these concerns and brought the rules into line with the policy.

12

ACMUI's Recommendation

The ACMUI feels that the current statement provides for medical uses of radionuclides safely for patients, subjects, staff and the general public while avoiding intrusion into the practice of medicine, and no revision is warranted at this time.

13

Acronyms

ACMUI – The Advisory Committee on Medical Uses of Isotopes

NRC – U.S. Nuclear Regulatory Commission

14

Advisory Committee on Medical Uses of Isotopes
NRC Medical Uses Policy Statement Subcommittee Report
April 03, 2014

Subcommittee members:
Philip Alderson, M.D.
Milton Guiberteau, M.D.
Chris Palestro, M.D.
John Suh, M.D.
James Welsh, M.D.
Bruce Thomadsen, Ph.D., Chair

***Subcommittee charge*:**
To consider if the Nuclear Regulatory Commission's policy statement on medical uses of byproduct materials should be revised.

Background
The NRC has the responsibility to ensure that the use of radioactive materials under its control is safe for all persons involved with that use as well as the general public. At the same time, the regulations should not be so onerous as to discourage beneficial medical uses. To help balance these potentially conflicting goals, the NRC has established a guidance policy on medical uses of radionuclides. The earliest official policy available to this subcommittee which was developed in 1979, had three principles:

1. The NRC will continue to regulate the medical uses of radioisotopes as necessary to provide for the radiation safety of workers and the general public.
2. The NRC will regulate the radiation safety of patients where justified by the risk to patients and where voluntary standards, or compliance with these standards, are inadequate.
3. The NRC will minimize intrusion into medical judgments affecting patients and into other areas traditionally considered to be a part of the practice of medicine.

In 2000, the revised policy included four principles:

1. The NRC will continue to regulate the uses of radioisotopes in medicine as necessary to provide for the radiation safety of workers and the general public.
2. NRC will not intrude into medical judgments affecting patients, except as necessary to provide for the radiation safety of workers and the general public.

3. NRC will, when justified by the risk to patients, regulate the radiation safety of patients primarily to assure the use of radionuclides is in accordance with the physician's directions.
4. NRC, in developing a specific regulatory approach, will consider industry and professional standards that define acceptable approaches of achieving radiation safety.

The changes in 2000 clarified that regulations were designed to ensure that a physician's directions are executed correctly and safely and that the development of regulations takes into account professional and industrial standards.

In the middle the past decade it became clear that some aspects of the regulations in 10 CFR 35 were causing problems with medical practice. One example was the definition of a medical event. The definition worked well for external-beam treatment and temporary brachytherapy but was ambiguous and difficult to apply to permanent implants, leading to some conflict between clinicians and regulators. Another problem was the attestation related to preceptor statements, which led some preceptors to refuse to sign the forms required for their trainees to obtain authorization (authorized user status).

This background led to the question of whether the policy on medical uses should be revised.

Subcommittee conclusion

The subcommittee studied the policies from 1979 and 2000 along with the discussions leading to those policies and other proposed policy items. The subcommittee also considered whether or not the current policy fails in either protecting persons or preventing infringement on medical practice.

The subcommittee concluded that the problems encountered with 10 CFR 35 were due to a failure of the regulations to follow the policy, and that the revision of Part 35 brings the regulations into compliance with the policy and eliminates the problems the conflict with policy created. The subcommittee felt that the current policy on medical uses of radionuclides provides effective guidance.

Subcommittee recommendation

The ACMUI feels that the current policy statement provides for the safe medical use of radionuclides for patients, subjects, staff and the general public while avoiding intrusion into the practice of medicine, and no therefore revision is warranted at this time.

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Status of Medical Events FY 2013

Donna-Beth Howe, Ph.D.
Medical Radiation Safety Team
May 8, 2014

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Medical Events 2013

- **48 Medical events reported - FY 2012**
- **43 Medical events reported - FY 2013**

	FY12	FY13
35.200	2	0
35.300	2	2
35.400	15	15
35.600	13	10
35.1000	20	16

Medical Events 2013

Each year there are approximately 15,000,000 diagnostic and 150,000 therapeutic procedures performed utilizing radioactive materials.

3

Medical Events 2013

35.300 Medical events	**2**
Yttrium-90 Zevelin®	1

- Intended activity exceeded package insert
  - 1.18 GBq (32 mCi) intended
  - 0.85 GBq (23 mCi) accidently put in written directive
  - Delivered 1.18 GBq (32 mCi)

4

35.300 Medical Events

I-131 1

- Authorized User referred patient for thyroid ablation (100 to 150 mCi), but put NaI-131 for a whole body scan (5 mci) on the referral paper form
  - Licensee has a new electronic medical record and verification system
  - Transcriber put whole body scan into system
  - Patient was administered 5 mCi

5

Medical Events 2013

35.400 Medical events **15** (18 pts)

Gynecological 2

Prostate 13 (16pts)

6

35.400 Medical Events

Gynecological Cs-135 2

- 450 cGy (rad) to skin – packing came out for final 3 hr of 40 hr treatment
- 1 of 2 sources fell out of applicator discovered 12 hours later – nurse extremity dose 130 mSv (13 rem)

7

35.400 Medical Events

Prostate (16 Patients) **13**

Multiple Medical Events 2

- 3 patients - under doses
  - Very few seeds implanted outside planning margin
  - Changes were made intraoperatively to account for implant difficulties and clinical factors
- 2 patients – under doses reported 1.5 years later
  - Authorized User not aware they were medical events

8

35.400 Medical Events

Pubic Arch Issues 2

- 5 seeds of 106 implanted
  - Corrective Actions included verification that there are no anatomical obstructions to needle placement during treatment planning
- Some needles were bent during the implant of 14 seeds for 65% of intended dose

9

35.400 Medical Events

Treatment Planning Error 1

- Patient to receive 4,500 cGy (rad) from intensity modulated therapy (IMT) and 11,000 cGy (rad) from seeds
  - Medical physicist created treatment based on 14,500 cGy (rad) from seeds (normal non-IMT dose)
  - Corrective actions included modification of default settings for treatment planning system

10

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35.400 Medical Events

Seeds Outside The Treatment Volume 7

- 16 seeds “migrated” towards top of prostate
- 3 seeds recovered in operating room – thought all were distributed in prostate - 2 more passed at home – 9 more “migrated” out of prostate and slightly inferior
- Seeds “migrated” outside treatment volume will use prostate stabilizers and modify ultrasound imaging techniques

11

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35.400 Medical Events

- 6 seeds implanted into perineum – inadequate ultrasound image visualization, urology resident, and tension adjustment issue with applicator
- 19 of 67 seeds in bladder – many seeds not visible on the ultrasound
- All 63 seeds 3.5 cm from site – incorrectly identified target area
- 60% of intended dose – organ shift or incorrect needle depth – insert transrectal ultrasound probe to identify base plane

12

Medical Events 2013

35.600 Medical events **10**

HDR

- Wrong Site 6
- Wrong Patient 3
- Stuck Source 1

13

35.600 Medical Events

HDR Wrong Site 6

- Possible rectal wall thickening, urethral stricture (185 cGy (rad)), ulceration of anterior wall of rectum, skin of inner thigh (1500 cGy (rad))
  - Tip and end of treatment catheters inverted in planning system auto-locate tool – dwell positions below target and outside body
  - Discovered 9 months later when transferring electronic treatment planning records to new system

14

35.600 Medical Events

- 1600 cGy (rad) to unintended site – small bowel near bladder in second of six fractions
  - Error in catheter lengths entered in treatment planning system
  - Dose delivered 5.4 cm superior to treatment volume

15

35.600 Medical Events

- 1,607 cGy (rad) mean dose to the urethra received for the four fractions - 1,849 cGy (rad) maximum dose to 1 cc of the urethra
  - Treatment site (cervix) received 27 % intended dose
  - Physicist selected wrong length source guide tube (132 cm instead of 119 cm)

16

35.600 Medical Events

- 630 cGy (rad) to the distal colon and upper rectum received during the first fraction - 700 cGy (rad) to the sacrum received during the second fraction.
  - Source intended for the cervical area had “dog legged” into the bowel area and was discovered before third fraction.
  - Corrective actions included review and approval of treatment catheter placement/ position by two attending physicians.

17

35.600 Medical Events

- 292 cGy (rad) more than intended to wrong site 4 cm inferior to treatment site on first of three fractions
  - Catheter from a tandem was mistakenly used on the cylinder and 4 cm longer than intended catheter.
  - Corrective actions included the marking of catheters for their intended use.

18

35.600 Medical Events

Mammosite®

- 160 -170 cGy (rad) dose to breast skin
  - Entered wrong indexer length –
  - Faulty source position simulator (ruler)

19

35.600 Medical Events

HDR Wrong Patient 3

- Patient received another patient's procedure.
- Two patients were scheduled on the same day - the second patient received the first patient's treatment plan.
- Administered a 700 cGy (rad) fractional dose prepared for another patient - instead of the prescribed 500 cGy (rad).

20

35.600 Medical Events

HDR Stuck Source 1

- 10.62 cGy (rad) to the thigh and an estimated whole body dose of 4.24 mSv (424 mrem).
  - Source became stuck before reaching the patient.
    - The manufacturer's engineer was unable to dislodge the source from the transfer tube.

21

Medical Events 2013

35.1000 Medical events	**16**
I-125 Seed localization	**1**
Y-90 Microspheres	**14**
SirSphere®	10
Therasphere®	4
Perfexion®	**1**

22

35.1000 Medical Events

I-125 Seed localization 1

- 2,290 cGy (rad) tissue dose at 0.5 cm from the 8.33 MBq (225.14 uCi) I-125 seed (negligible dose at 6 cm)
  - Seed migrated deeper into patient and scarring from previous node removal, mastectomy, and reconstructive surgery prevented safe extraction
  - Under ultrasound guidance, the tumor and lymph node were removed

23

35.1000 Medical Events

Y-90 Microspheres	**14**
SirSphere®	**10**
– Wrong site	2
– Wrong dose	1
– Operator error	1
– Leaking vial	2
– Occluded catheters	4
Therasphere®	**4**
– Occluded catheters	4

24

35.1000 Medical Events

SirSphere® Wrong Site 2

- 6,200 cGy (rad) to the gastric duodenum stomach 9,000 cGy (rad).
  - Complaint of abdominal pain during procedure and stomach pain 5 months later; endoscopy revealed ulcers in the potentially affected areas.
  - Shunt not identified at time of procedure.

25

35.1000 Medical Events

- Treated the right lobe instead of the left lobe of the liver (629 MBq (17mCi)
  - The nuclear medicine authorized user had prescribed 629 MBq (17 mCi) to the left lobe and 1.26 GBq (34 mCi) to the right lobe of liver.
  - The interventional radiologist decided based on more tumor blood flow to treat the right lobe first without consulting the authorized user.

26

35.1000 Medical Events

SirSphere® Wrong Dose 1

- Prescribed 651.2 MBq (17.6 mCi), but only received 473.6 MBq (12.8 mCi), a dose that is 27.3% less than prescribed
  - Physician recorded the wrong administered dose on the written directive form

27

35.1000 Medical Events

SirSphere® Operator Error 1

- 28.2% less dose than prescribed
  - The delivery needle had not been placed in the center of the shielded V-shaped dose vial and thus, did not reach the lowest point in the vial and extract all of its content.

28

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35.1000 Medical Events

SirSphere® Leaking Vial 2

- Prescribed 1.11 GBq (30 mCi) of Y-90 microspheres, received 0.71 GBq (19.26 mCi).
  - Caused by leaking dose vial
  - Corrective actions included the application of derma bond seal

29

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35.1000 Medical Events

- Prescribed 910.2 MBq (24.6 mCi) - received 133.2 MBq (3.6 mCi) of Y-90 microspheres -14 %.
  - Resistance encountered when flushing the catheter following the initial microsphere dose - found an occlusion in the catheter.
  - Stopped second measured dose when evidence of a microsphere leak was discovered between the vial and the catheter

30

35.1000 Medical Events

SirSphere® Microcatheter Occlusions 4

- Delivered 55% of dose – replaced catheters
- Delivered 13.2% of dose – delivery system clogged – thought air bubble combined with the saline flushes, allowed the microspheres to clump and clog the line.
- Delivered 69% and 74% (2 separate medical events reported by same licensee one month apart) microspheres remained in delivery system - elevated delivery system more and increased agitation.

31

35.1000 Medical Events

TheraSphere® Occlusions 4

- 69% of dose - buildup of microspheres in the delivery catheter - greatest activity in the proximal portion of the catheter, with little to no activity in the tip
- 69 % of dose received – rest in outlet tubing and microcatheter of delivery system

32

35.1000 Medical Events

- 9.5% of dose to radial artery in the arm, the angiocatheter was too short and required extension tubing - the microspheres remained in the extension tubing
- 53% of dose - the catheter became plugged during the procedure
  - Corrective actions included looking at catheter hub

33

35.1000 Medical Events

Perfexion® **1**

- 77% of dose delivered for treatment of three lesions
  - First two lesions treated as planned
  - Third lesion treatment was interrupted because of a mechanical failure. A sensor failure occurred, which caused the patient couch to retract and the shielding doors to close.

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Acronyms

- FY – Fiscal Year
- HDR – High Dose Rate Remote Afterloader
- Pts - Patients
- Y – Yttrium
- I-131 – Iodine-131

35

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QUESTIONS?

36

Germanium-68/Gallium-68

Update on Clinical Uses and Regulatory Issues

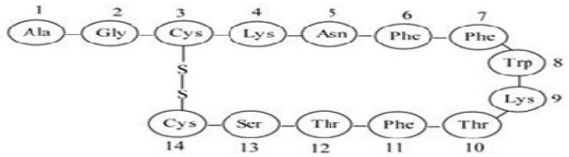
Steve Mattmuller

Advisory Committee
on the Medical Uses of Isotopes
May 8-9, 2014

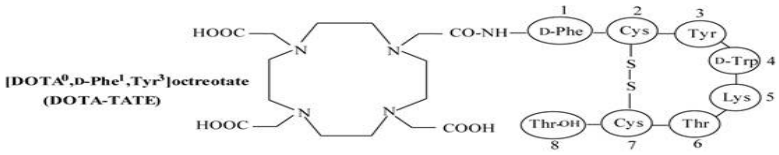
Germanium-68/Gallium-68

- Receptor Imaging
- Ge-68/Ga-68 Generator
- Ga-68 Radiopharmaceuticals
  - New modules and “kits”
  - FDA Orphan Drug Status
- Regulatory Issues

Receptor Imaging



Somatostatin-14

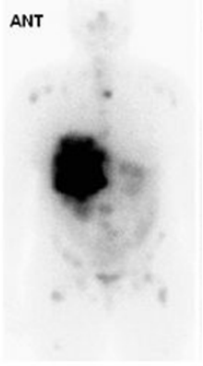


[DOTA^0,D-Phe^1,Tyr^3]octreotate
(DOTA-TATE)

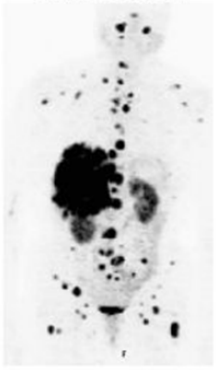
3

Receptor Imaging

^{111}In-DTPA-Octreotide



^{68}Ga-DOTA-TOC



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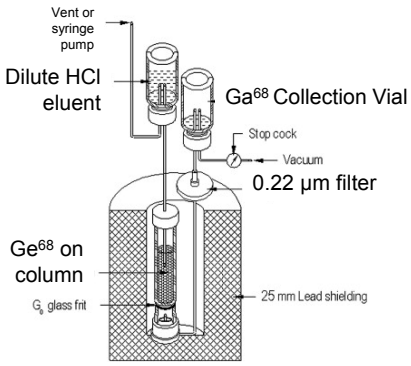
Ge-68/Ga-68 Generator



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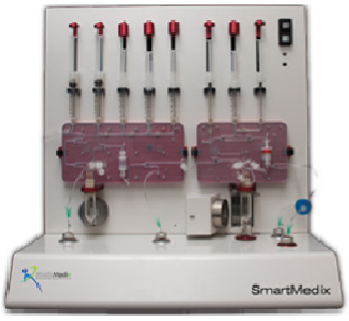
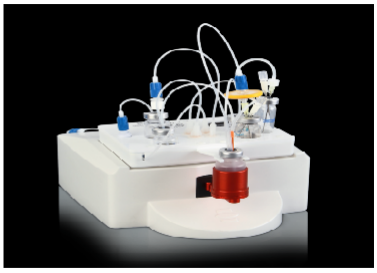
Ga-68 Radiopharmaceuticals

Synthesis Modules: 2nd Generation





Modular-Lab eazy

6

FDA Orphan Drug Program

The FDA Office of Orphan Products Development (OOPD) Mission is to advance the evaluation and development of products (drugs, biologics, devices, or medical foods) that demonstrate promise for the diagnosis and/or treatment of rare diseases or conditions that affect fewer than 200,000.

- Fewer subjects needed in pivotal trial
- Application fees are waived
- Eligible for FDA grant funding

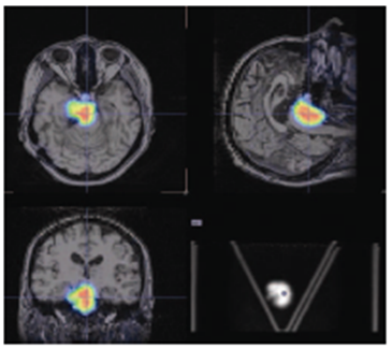
7

Orphan Drug Designation!
Ga-68 Radiopharmaceuticals

SSTR - Based agents

Ga-68 DOTATOC
SNMMI

Ga-68 DOTATATE
RadioMedix



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Ge-68/Ga-68 Regulatory Issue

§ 30.35 Financial Assurance and recordkeeping for decommissioning.

(a)(1) Each applicant for a specific license authorizing the possession and use of **unsealed** byproduct material of half-life greater than **120 days** and in quantities exceeding **10^5 times** the applicable quantities set forth in **appendix B** to part 30 shall submit a decommissioning funding plan as described in paragraph (e) of this section.

9

Ge-68/Ga-68 Regulatory Issues

- Current regulatory status of Ge-68 is hampering its use.
  - Unintentional, as Ge-68 may have fallen through the regulatory cracks.
  - DFP is a very onerous, expensive process
- Wide range of experiences by licensees
  - Some who already have a DFP or meet financial test, no problem
  - Some who had Ge-68 gave it up in 2005
  - But those who don't have a DFP; a real barrier to being licensed for Ge-68.

10

Ge-68/Ga-68 Regulatory Relief (?)

- The Ge-68 in a ~~generator~~/device/source exists as a solid on a solid column sealed in a container.
- Ge-68 stays doesn't leave ("sealed"), the Ga-68 does leave ("unsealed").
- Ga-68 is not a radiopharmaceutical, but a radiopharmaceutical component.

11

Ge-68/Ga-68 Regulatory Relief(?)

§ 32.74 Manufacture and distribution of sources or devices containing byproduct material for medical use.

(a) An application for a specific license to manufacture and distribute sources and devices containing byproduct material to persons licensed under part 35 of this chapter for use as a calibration, transmission, or reference source **or** for the uses listed in § § 35.400, 35.500, 35.600, and **35.1000** of this chapter will be approved if:

(1) The applicant satisfies the general requirements in § 30.33 of this chapter;

(2) The applicant submits sufficient information regarding each type of source or device pertinent to an evaluation of its radiation safety, including:

(i) The byproduct material contained, its chemical and physical form, and amount;

(ii) Details of design and construction of the source or device;

(iii) Procedures for, and results of, prototype tests to demonstrate that the source or device will maintain its integrity under stresses likely to be encountered in normal use and accidents;

12

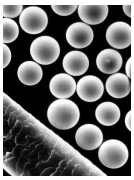
Ge-68/Ga-68 Regulatory Relief (?)

NUREG- 1556: Vol. 3: Consolidated Guidance About Materials Licenses: Applications for Sealed Source and Device Evaluation and Registration April 2004

4.9 SEALED SOURCES AND DEVICES FOR MEDICAL USE

But needs proof of FDA approval:

- Premarket Notification (510(k))
- Premarket Approval (PMA)
- **Humanitarian Device Exemption (HDE)**



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Ge-68/Ga-68 Regulatory Relief (?)

NUREG- 1556: 5.1.3 CUSTOM SEALED SOURCES OR DEVICES

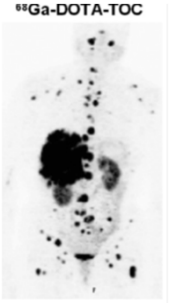
- Sealed sources or devices containing sealed sources built to the unique specifications of a given user (**custom**) need not be sent to NRC or the Agreement State for registration if:
  - (a) they contain less than 7.4 GBq (**200 mCi**) of radioactive material or less than 740 GBq (20 Ci) of tritium, and
  - (b) the licensing reviewer has made a determination that the applicant is qualified by training and experience and has adequate facilities and equipment to safely use and handle the requested quantity of radioactive material in **unsealed** form.

14

Regulatory Relief is Needed…

ACMUI has a recommendation that the NRC provide regulatory relief, still needed…

- The burden of a DFP can stifle the use of an important radionuclide.
- Interest in Ga-68 is high, especially now with Orphan status for two radiopharmaceuticals.
- The Ge-68/Ga-68 "generator" may represent a new "device" or "source" to be regulated.



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Acronyms

DFP	Decommissioning Funding Plan
DOTA-TATE	DOTA-[Tyr3]-Octreotate
DOTA-TOC	DOTA-[Tyr3]-Octreotide
Ga-68	Gallium-68
Ge-68	Germanium-68
SSTR	Somatostatin Receptor
SNMMI	Society of Nuclear Medicine and Molecular Imaging

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Amendments to the ACMUI Bylaws

Pat Zanzonico, PhD, DABR
ACMUI

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Bylaws Sub-Committee Members

- **Steven Mattmuller**
- **Christopher Palestro, MD**
- **John Suh, MD**
- **Orhan Suleiman, PhD**
- **Laura Weil**
- **Pat Zanzonico, PhD (Chair)**

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Sub-Committee Tasks

1. Review and identify additional amendments to amended ACMUI Bylaws, 9/13
2. Discuss and make recommendations for ACMUI reporting structure
3. Discuss and make recommendations for possible budgeting for additional face-to-face meeting
4. Consider feasibility of conducting web-based meetings

3

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Task 1
Amended ACMUI Bylaws

- NRC Legal Counsel review
  - Review required to resolve certain issues
- Webcasting of meetings
  - Proceed with meetings even if webcasting not technically do-able?
- Biasing of discussions by ACMUI Chair
  - Avoid disenfranchising Chair
  - Leave language in § 1.3.5 as is
- Term limits for ACMUI members
  - Two 4-year terms
  - Exemptions may be granted

4

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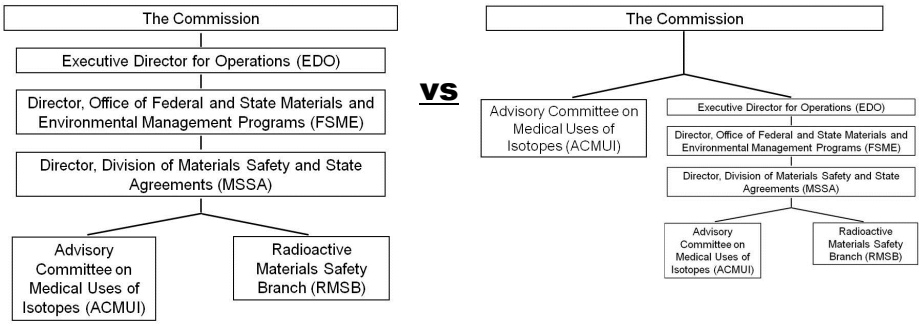
Task 2
ACMUI Reporting Structure



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Task 2
ACMUI Reporting Structure
cont

- **Reporting directly to Commissioners**
  - **Greater time and effort commitment**
  - **No tangible benefit - at present**
- **Maintain current reporting structure**
  - **With annual - Commissioners' Briefing**
    - Review of reporting structure

6

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Task 3
Additional Face-to-Face Meetings

- **Maintain current schedule of 2 face-to-face meetings per year at HQ**
  - **Ample time for uninterrupted discussion**
  - **Timely attention to new issues**
  - **Promotes cooperation among Committee members and between ACMUI and staff**

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Task 4
Web-Based Conferencing
(eg Webex™, Go-To-Meeting™)

- **A mature, reliable, inexpensive, universally available, and easy-to-use technology**
- **All desktop and mobile platforms**
- **Superior to audio-only teleconferencing**
- **Use web-based conferencing as needed**
  - **as a complement to, but <u>not</u> replacement for, face-to-face meetings**

8

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Abbreviations and Acronyms

- **ACMUI:** **Advisory Committee on Medical Uses of Isotopes**
- **EDO:** **Executive Director for Operations**
- **FSME:** **Office of Federal and State Materials and Environmental Management Programs**
- **HQ:** **Headquarters**
- **MSSA:** **Division of Material Safety and State Agreements**
- **NRC :** **Nuclear Regulatory Commission**
- **RMSB:** **Radioactive Materials Safety Branch**

9

Report of
Sub-Committee on Proposed Amendments to ACMUI Bylaws
Advisory Committee on Medical Uses of Isotopes (ACMUI)

Subcommittee Members:
Steven Mattmuller, Christopher Palestro, John Suh,
Orhan Suleiman, Laura Weil, and Pat Zanzonico (Chair)

April 11, 2014

Introduction

The Sub-Committee on Proposed Amendments to Bylaws of the Advisory Committee on Medical Uses of Isotopes (ACMUI) to the Nuclear Regulatory Commission (NRC) was charged with the following tasks:

1. Discuss, address, review and identify any additional amendments to the amended ACMUI Bylaws originally proposed in September 2013;

2. Discuss, address, and make a recommendation for the ACMUI reporting structure (MSSA director versus the Commission);

3. Discuss, address, and make a recommendation for the consideration of budgeting for an additional face-to-face meeting at Headquarters; and

4. Consider the feasibility of conducting meetings using the Go-To-Meeting™ or Go-To-Webinar function™.

These tasks are addressed in numerical order below.

1. Discuss, address, review and identify any additional amendments to the ACMUI Bylaws

The Bylaws describe the procedures to be used by the ACMUI in carrying out its duties and the responsibilities of the Committee members. These duties are as follows: "…to provide objective and independent advice to the NRC staff in the Division of Materials Safety and State Agreements, Office of Federal and State Materials and Environmental Management Programs (FSME), with respect to the development of standards and criteria for regulating and licensing medical uses of byproduct material." The proposed Bylaws largely duplicate the previous version of the ACMUI Bylaws, dated October 24, 2006.

General Comments

a. NRC Legal Counsel review

Some issues that are considered in the Bylaws and, more generally, that may come before the ACMUI have legal implications and may, as recommended by NRC staff, require input from Legal Counsel for their ultimate resolution. It would helpful to include an explicit statement to this effect somewhere in the Bylaws, perhaps in the Preamble.

b. § 1.1.5: Webcasting of public portions of ACMUI meetings

Section § 1.1.5 states that. "Portions of ACMUI meetings that are open to the public will be webcast…" Should this be generalized to include all electronic-dissemination modalities by,

for example, changing the term, "webcast," to, "broadcast or otherwise electronically disseminated (eg webcast)"? More importantly, the use of the word, "will," implies that an ACMUI meeting could not proceed even if webcasting or other electronic dissemination were not possible. A provision should be considered to allow an ACMUI meeting to proceed even if webcasting or other electronic dissemination were not technically do-able. Perhaps § 1.1.5 should be revised as follows, "Portions of ACMUI meetings that are open to the public will be webcast whenever possible, with closed captioning in accordance with the Americans with Disabilities Act.

c. § 3.1: Term limits of ACMUI members

The immediate past ACMUI Chair, Dr. Leon Malmud, served three terms, so a mechanism for granting an exemption from the two-term limit is in place. The Sub-Committee therefore recommends including a statement in Section § 3.1 noting that exemptions to the two-term limit may be granted.

Specific Comments

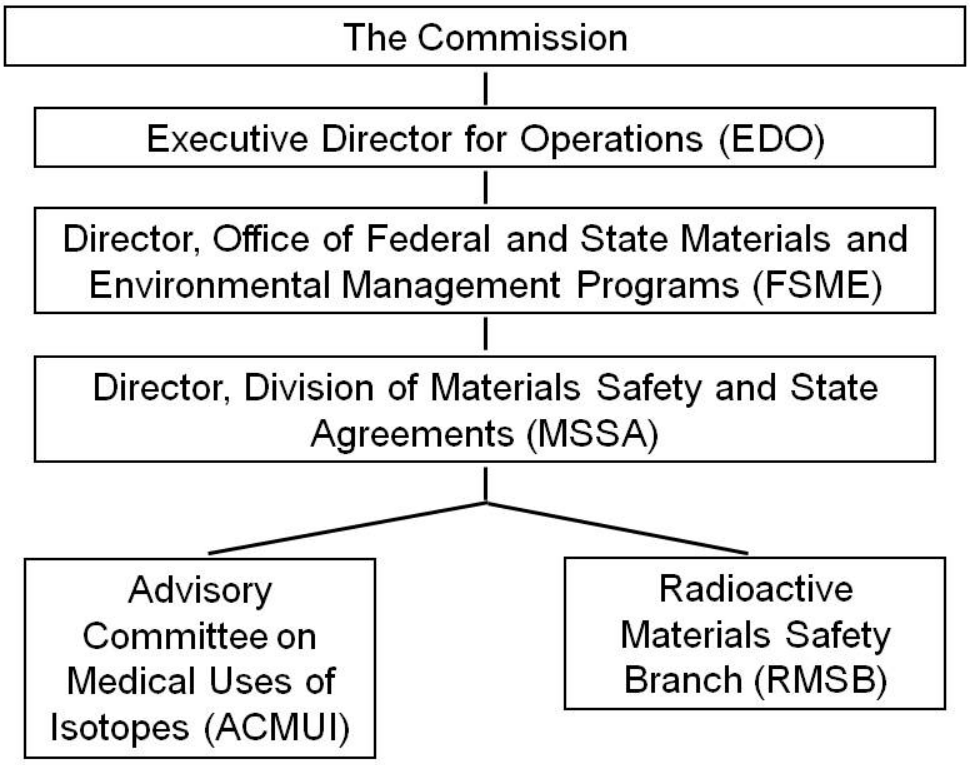
Pg 2, § 1.1.1		There is some concern that, as written, this provision potentially allows arbitrary cancellation of the annual meeting between the Commission and the ACMUI. Language specifying the circumstances under which these meetings can be cancelled should be included, therefore.
Pg 2, § 1.1.1	**Line 5**	The phrase, "…of the ACMUI…," should be inserted between the words, "Chair" and "declines."
Pg 2, § 1.1.3		Are all ACMUI meetings and all portions of meetings transcribed/recorded or only those portions of meetings open to the public? This point should be addressed explicitly in the Bylaws.
Pg 2, § 1.1.6	**Line 1**	We suggest changing the phrase, "All meeting handouts will be electronically transmitted…," to, "All available meeting handouts should be electronically transmitted…" This suggested change would potentially avoid cancellation of a scheduled ACMUI meeting in the event that not all handouts were available for distribution two weeks prior to the meeting.
Pg 2, § 1.1.7	**Line 1**	For the same reason for the suggested revisions to § 1.1.6, we suggest the word, "will," be changed to, "should."
Pp 2-3, § 1.2	**Lines 6 and 7**	For the same reason for the suggested revisions to § 1.1.6, and 1.1.7, we suggest the word, "will," be changed to, "should."
Pg 3, § 1.3.1	**Line 1**	The phrase, "All ACMUI meetings…," should be changed to, ""All ACMUI meetings and ACMUI Sub-Committee meetings…"

Pg 5, § 4.2 **Lines 3-4** This section states that. "The hours shall be transmitted via email to the time resource inbox at ACMUI_MedConsultTime.Resource@nrc.gov." Identification of a specific hyperlink for submission of work hours seems unnecessarily restrictive and potentially problematic (eg in the event the hyperlink is changed). It is suggested, therefore, that this statement be revised as follows, "The hours shall be transmitted to the NRC in the manner specified by staff."

2. Discuss, address, and make a recommendation for the ACMUI reporting structure (MSSA director versus the Commission)[1]

At its teleconference of January 12, 2011 and its semi-annual meeting of September 20, 2012, the ACMUI recommended an annual review of its reporting structure. The current ACMUI reporting structure is summarized in the figure below (provided by Ms. Sophie Holiday, ACMUI Coordinator, Office of Federal and State Materials and Environmental Management Programs (FSME)). The key issue remains whether there is a significant benefit to be derived by the ACMUI reporting directly to the Commission rather than through the Office of Materials Safety and State Agreements (MSSA), the FSME, and the Executive Director for Operations (EDO). The consensus opinion of the ACMUI was that there was perhaps a "theoretical" advantage for reporting of the ACMUI to the Commission (eg unfiltered transmission of opinions from the ACMUI to the Commission). However, the working relationship between the NRC and ACMUI remains excellent, the reporting structure through NRC staff (see figure below) continues to function effectively, and the associated logistical "overhead" associated with direct reporting to the Commission (eg the need for more frequent meetings) did not and does not now justify any change in the ACMUI's reporting structure. This recommendation is predicated on the annual Commission Briefing by the ACMUI and the annual review of its reporting structure remaining in place.

[1] Relevant information is provided in Federal and State Materials and Environmental Management Programs (FSME) Policy and Procedures (P&P) 2-5, Revision 0 (January 12, 2011), entitled, "FSME Procedure for Interacting with the Advisory Committee on the Medical Uses of Isotopes During Development of Major Medical Issues." This P&P defines and documents FSME staff guidance and procedures for interfacing with the ACMUI during the development of major medical policy issues including medical rulemakings that will be reviewed by the Commission.



3. <u>Discuss, address, and make a recommendation for the consideration of budgeting for an additional face-to-face meeting at Headquarters</u>

At the present time, the ACMUI holds two face-to-face meetings annually at NRC Headquarters, one in the spring and one in the fall. This schedule provides ample opportunity for timely and in-depth discussion of issues within the purview of the ACMUI. Additional face-to-face meetings (ie more than two meetings annually) are therefore probably unnecessary. On the other hand, the two-day Agendas of the ACMUI face-to-face meetings are typically full, so eliminating one such meeting per year would be counterproductive and impractical (especially considering recurring administrative tasks such as annual ethics and security training required of the Committee membership). Further, holding regularly scheduled meetings at 6-month intervals serves to maintain the timeliness of ACMUI deliberations; less frequent meetings (ie once a year) would likely result in new and pressing issues remaining unaddressed for a considerable period of time. (An example of just such an issue was the CardioGen-82 rubidium-82 generator breakthrough issue in 2011.) Another option, of course, is to replace one or both face-to-face meetings at Headquarters with web-based conferences (through Webex™ or Go-to-Meeting™, for example). This, too, would undermine the effectiveness of the Committee. The ACMUI membership consists of individuals with many time-critical day-to-day responsibilities at their respective institutions. It is difficult, if not impossible, to completely divest one's self of those responsibilities for several days at a time when physically present at one's home institution. Inevitably, participants in such a web-based conference would be diverted from the meeting at some point to attend to some pressing local issue. Furthermore, in contrast to face-to-face meetings, it is difficult in a web-based scenario to promote the spirit of collegiality and camaraderie among the participants that, in turn, promotes frank, constructive discussion. This is especially important for newer ACMUI members. It is logistically difficult as well to promote such discussion, since the Chair may

not be able to recognize Committee members wishing to speak in a timely manner, for example. The Sub-Committee therefore recommends maintaining the current ACMUI schedule of two face-to-face meetings annually at NRC Headquarters.

4. Consider the feasibility of conducting meetings using the Go-To-Meeting™ or Go-To-Webinar™ function

Web-based conferencing (through Webex™ or Go-to-Meeting™, for example) is now a mature, reliable, universally available, inexpensive, and easy-to-use technology. It is adaptable not only to desk and laptop PCs but also all mobile devices. Web-based conferencing provides the obvious advantages of direct, real-time audio and video communication among multiple individuals throughout the world, dramatic savings in time and money with respect to travel, convenience, and flexible scheduling. It not only allows display of any one of the attendee's computer screen to all other attendees of a conference but also remote control by any one of the attendees of another attendee's computer and its display. It is therefore far superior to conventional teleconferencing, which is restricted, of course, to audio communication, and is especially useful for real-time editing of documents through its common-display functionality. Web-based conferencing is therefore a potentially important complement to face-to-face meetings. As discussed above, however, it is not a viable replacement altogether for face-to face meetings. Inevitably, prolonged, dedicated (ie interrupted) discussion is required to address the complex issues which often confront the ACMUI, and such discussion is not realistically achievable via web-based conferencing. The Sub-Committee therefore endorses the use of web-based conferences as needed as a supplement to, but not as a replacement for, face-to-face meetings.

ACMUI
~~OCTOBER 24, 2006~~
~~SEPTEMBER XX, 2013~~MAY XX, 2014

U.S. NUCLEAR REGULATORY COMMISSION

OFFICE OF FEDERAL AND STATE MATERIALS AND ENVIRONMENTAL MANAGEMENT PROGRAMS

ADVISORY COMMITTEE ON MEDICAL USES OF ISOTOPES

BYLAWS

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CONTENTS

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PREAMBLE

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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 ACMUI's responsibility to provide objective and independent advice to the ~~Commission through the~~NRC staff in the Division of Materials Safety and State Agreements, Office of Federal and State Materials and Environmental Management Programs~~,~~ (FSME), 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 ACMUI members and the affected parties have an adequate chance to be heard, and that the resulting reports represent, to the extent possible, the best of which the ACMUI 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

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1. Scheduling and Conduct of Meetings

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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 regulations as appropriate.

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1.1 Scheduling of Meetings:

Field Code Changed

1.1.1 ~~Meetings~~ ACMUI meetings must be approved or called by the Designated Federal Officer~~.~~ (DFO). At least two regular meetings of the ACMUI will be scheduled each year, one in the ~~Spring~~spring and one in the ~~Fall~~fall. Additionally, the ACMUI will meet with the Commission annually, unless the Chair or designated Chair of the ACMUI declines or the Commission declines.

1.1.2 ~~Special~~ACMUI meetings ~~(e.g.,~~, including teleconferences and subcommittee 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~~3 All ACMUI meetings, open or closed, ~~of the ACMUI~~ 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 ACMUI business~~,~~ or with the rights of the attending public.

1.1.5 Portions of ACMUI meetings that are open to the public will be webcast whenever possible, with closed captioning in accordance with the Americans with Disabilities Act.

1.1.6 All available meeting handouts ~~will~~should be electronically transmitted to the ACMUI members no later than two weeks prior to the meeting.

1.1.7 All publicly available meeting handouts ~~will~~should be posted on the ACMUI public website no later than three business days prior to the meeting.

1.2 Meeting Agenda:

The agenda for regularly scheduled ACMUI meetings will be prepared by the Chair of the ACMUI (referred to below as "the Chair") in consultation with ~~the Office of Federal and State Materials and Environmental Management Programs (FSME)~~ staff. The ~~Designated Federal Officer~~DFO must approve the agenda. The Chair, with the ~~FSME~~ staff's assistance, will query ACMUI members for agenda items prior to agenda preparation. A draft agenda ~~will~~ should be provided to ACMUI members ~~not~~no later than thirty days ~~before~~prior to a scheduled meeting. The final agenda ~~will~~ should be provided to members ~~not~~no later than seven days ~~before~~prior to a scheduled meeting.

Field Code Changed

Before the meeting, the Chair and the ~~Designated Federal Officer for the ACMUI~~DFO 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.

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1.3 Conduct of the Meeting:

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1.3.1 All ACMUI meetings and ACMUI Sub-Committee 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 Vice Chair will preside if the Chair is absent or if the Chair is recused from participating in the discussion ~~of a particular agenda item.~~. The ~~Designated Federal Officer~~DFO will preside when both the Chair and the Vice Chair are absent and/or recused from the discussion~~,~~ or when directed to do so by the Commission.

1.3.3 A majority of the current membership of the ACMUI will be required to constitute a quorum for the conduct of business at an ACMUI 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~~DFO 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 ACMUI, and may vote.~~ Decisions shall be by a majority vote of those members present and voting.

1.3.6 The Chair may take part in the discussion of any subject before the ACMUI 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 ACMUI member may request that any consensus statement be put before the ACMUI as a formal motion subject to affirmation by a formal vote. No ACMUI position will be final until it has been formally adopted by consensus or formal vote~~,~~ and the ~~minutes/~~transcript written and certified.

2. ~~MINUTES/~~TRANSCRIPTS

2.1 ~~Minutes/transcripts~~Transcripts of each meeting will be prepared by the ACMUI Chair~~,~~ with assistance from the FSME staff~~,~~ in accordance with the requirements in 10 CFR Part 7. The Commission staff will prepare ~~minutes/~~transcripts of ACMUI meetings with the Commission.

2.2 ~~The~~ In accordance with 10 CFR Part 7.13(c), the ACMUI Chair will certify the ~~minutes/~~transcripts.

2.3 Copies of the certified transcripts ~~in accordance with 10 CFR Part 7~~will be made available to the ACMUI members and to the public no later than 90 days after the meeting.

2.~~3~~4 In accordance with the requirements of the NRC's Operating Plan, FSME staff will prepare a meeting summary~~. The FSME staff~~, which will ~~e-mail the meeting summary document or web link~~be made available to ~~the~~ ACMUI members~~.~~ and to the public no later than 30 business days after the meeting

~~2.4 Copies of the certified minutes/transcripts will be made available to the ACMUI members, and to the public, not later than 90 days after the meeting.~~

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3. APPOINTMENT OF MEMBERS

3.1 ~~The~~ACMUI members ~~of the ACMUI~~ are appointed by the Director, FSME, after consultation with the Commission. The Commission determines the size of the ACMUI. 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 Director, FSME. The term of an appointment to the ACMUI is four years, and the Commission has determined that no member may serve more than ~~2~~two consecutive terms ~~(8~~for a total of eight years~~).~~.

3.2 The Chair will be appointed by the Director, FSME, from the membership of the ACMUI. The Chair will serve at the discretion of the Director, FSME.

3.3 The Vice Chair will be appointed by the Director, FSME, from the membership of the ACMUI. The Vice Chair will serve at the discretion of the Director, FSME.

4. CONDUCT OF MEMBERS

4.1 If a member believes that he or she may have a conflict of interest with regard to an agenda item to be addressed by the ACMUI, this member should divulge it to the Chair and the ~~Designated Federal Officer~~DFO as soon as possible~~, but in any case~~ and before the ACMUI discusses it as an agenda item. ACMUI members must recuse themselves from discussion of any agenda item ~~with respect to~~in which they have a conflict of interest.

~~4.2~~

4.2 ACMUI members should submit their hours of work, as they relate to official ACMUI business, on the Thursday prior to the close of the pay period, unless notified otherwise. The hours shall be transmitted ~~via email to the time resource inbox at ACMUI_MedConsultTime.Resource@nrc.gov.~~to the NRC in the manner specified by staff.

4.3 For meetings requiring travel, ACMUI members should submit travel authorizations in the eTravel system no later than three weeks prior to the meeting date. ACMUI members should ~~to~~ submit vouchers for reimbursement in the eTravel system no later than 10 business days after the meeting.

4.4 Upon completing their tenure on the ACMUI, 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.

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4.3 ~~Members of the~~ 5. ACMUI members should to conform to all applicable NRC rules and regulations~~,~~ and are expected to attend meetings regularly and perform all assigned duties.

5. ADOPTION AND AMENDMENTS

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5.1 Adoption or approval of an amendment of these bylaws shall require an affirmative vote of two-thirds of the current ACMUI membership and the concurrence of the Director ~~of the Office of Federal and State Materials and Environmental Management Programs~~, FSME.

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5.2 Any member of the ACMUI or FSME staff 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 ACMUI meeting.

5.3 The proposed amendment(s) may be voted on as early as the next ACMUI meeting after distribution to the members.

5.4 The ACMUI shall consult with the Office of the General Counsel regarding conflicts that arise from the interpretation of the bylaws. After consultation, the ACMUI shall resolve interpretation issues by a majority vote of the current membership of the ACMUI.

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ACMUI Subcommittee Meeting

NO HANDOUT

Security Briefing

NO HANDOUT

Escort Training

NO HANDOUT

Commission Briefing

Webcast: video.nrc.gov

NO HANDOUT

Group Photo

NO HANDOUT

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Protecting People and the Environment

STATUS OF PATIENT RELEASE STUDY

Mohammad Saba
Office of Regulatory Research
Advisory Committee on the Medical Uses of Isotopes
May 9, 2014

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Old Rule:

The measured dose rate from the patient or human research subject is less than 5 millirems per hour at a distance of 1 meter; or the activity in the patient or the human research subject is less than 30 millicuries.

Current Rule:

Is based on, the total effective dose equivalent to any other individual is not likely to exceed 5 mSv (0.5 rem).

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The Commission directed NRC staff:

- to review publicly available data on doses being received by members of the public as a result of application of the 10 CFR Part 35.75 release criteria.
- performance of measurements in areas where data is sparse or unavailable. Assessment of the rule itself is not within the scope of this work.
- The objective is to see how well patient release practices are working and the extent to which the dose criterion is being met.

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Current Status of Work

- Completed Review of the Technical Literature
- NRC Completed Dose Calculations for Some Situations Not Found in the Literature
- Field Work Will be Completed in Three Years

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Review of Literature

RES staff has performed an extensive review of the following:

- Technical Journals (Domestic and International)
- NCRP Publications
- ICRP Publications
- IAEA safety Series
- European Commission

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Review of Literature (cont.)

The review focused on the following areas:

- Internal Dose
- External Dose
- Effective Half Life
- Dose Calculations in Regulatory Guide 8.39

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NRC Dose Calculations

NRC has conduced calculations using state-of-the-art anthropomorphic phantoms, the new ICRP biokinetic model, and Monte Carlo calculations to represent the patient, the target and to calculate doses for various situations, such as:

- Public Transportation (e.g. buses and airplanes)
- Hotels
- Nursing Homes

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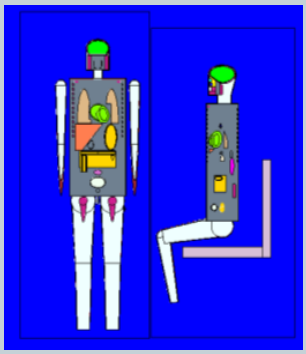
Public Transportation Scenario

Patient standing beside a seated member of the public



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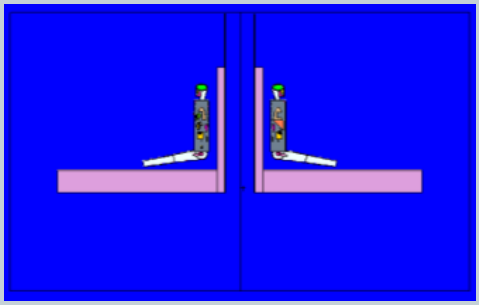
Hotel Scenario

Patient seated in the hotel room bed back-to-back with adjacent room guest



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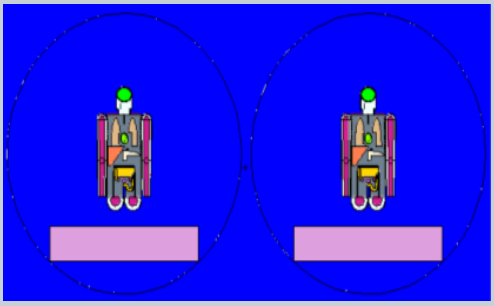
Nursing Home Scenario

Patient in bed and the Nursing Home Caregiver is seated 30 cm adjacent to the bed



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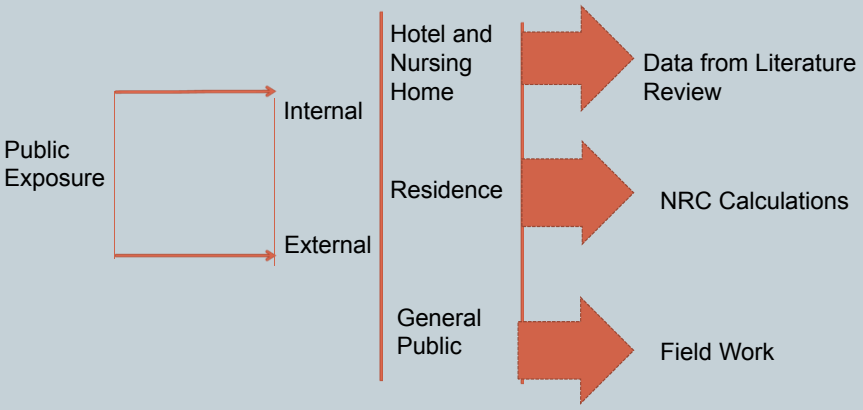
Process for the Review



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Field Work

- Assess where patients reside following their release.
- Measure doses to members of the public (if possible).
- Laboratory measurements and modeling (if data collection is not possible).

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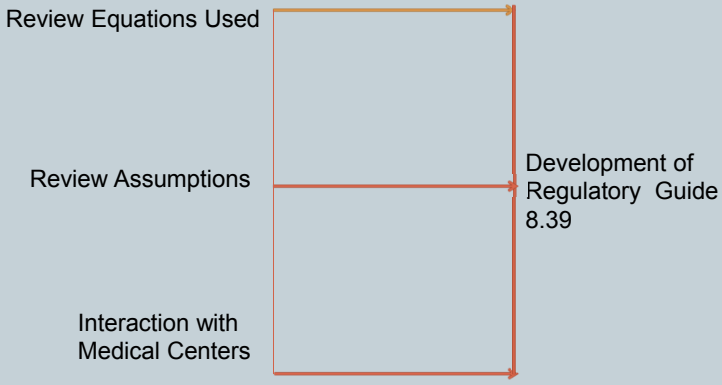
Potential Update to Reg. Guide 8.39



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Next Steps

- Finalize the literature review
- Complete the field work
- Provide recommendations to the Commission

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Back Up Slides

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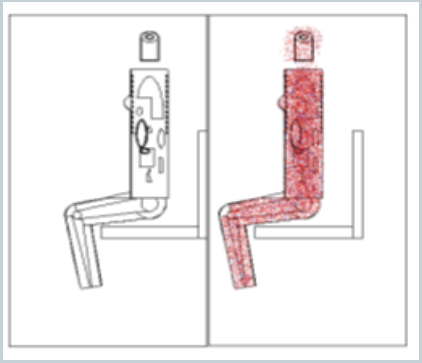
Public Transportation Scenario (2)

Patient seated behind a member of the public



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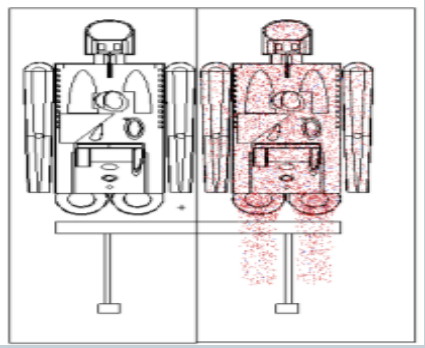
Public Transportation Scenario (3)

Patient seated beside a member of the public



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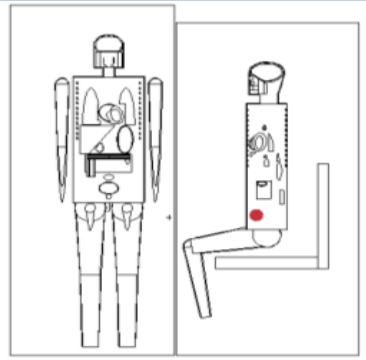
Public Transportation Scenario (4)

Patient seated beside a standing member of the public



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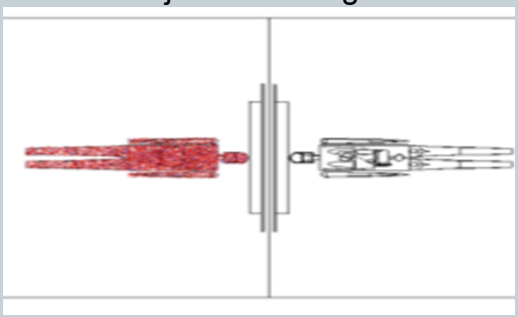
Hotel Scenario (2)

Patient lying down in the hotel room bed back-to-back with adjacent room guest



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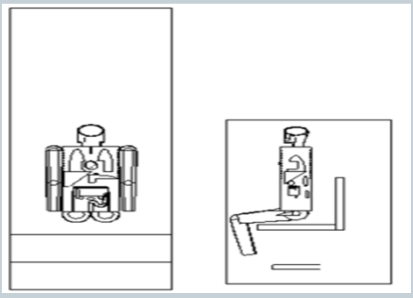
Nursing Home Scenario (2)

Nursing Home Caregiver is seated 30 cm from the patient in the bed



U.S. DEPARTMENT OF ENERGY

Global Threat Reduction Initiative

National Nuclear Security Administration
Defense Nuclear Nonproliferation

Ensuring Reliable Supplies of Molybdenum-99 Produced without Highly Enriched Uranium

Dr. Parrish Staples | May 9th, 2014
Advisory Committee on the Medical Uses of Isotopes

U.S. DEPARTMENT OF ENERGY

National Nuclear Security Administration
Defense Nuclear Nonproliferation

GTRI Mission & Program Goals

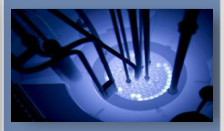
MISSION

REDUCE AND PROTECT VULNERABLE NUCLEAR AND RADIOLOGICAL MATERIAL LOCATED AT CIVILIAN SITES WORLDWIDE

GOALS

1. CONVERT
2. REMOVE
3. PROTECT

CONVERT



CONVERT RESEARCH REACTORS AND ISOTOPE PRODUCTION FACILITIES FROM THE USE OF HIGHLY ENRICHED URANIUM (HEU) TO LOW ENRICHED URANIUM (LEU)

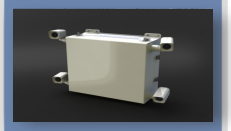
THESE EFFORTS RESULT IN PERMANENT THREAT REDUCTION BY ELIMINATING WHEN TO THE EXTENT POSSIBLE, ELIMINATING THE NEED FOR HEU IN CIVILIAN APPLICATIONS – EACH REACTOR CONVERTED OR SHUT DOWN ELIMINATES A SOURCE OF BOMB MATERIAL

REMOVE

REMOVE AND DISPOSE OF EXCESS NUCLEAR AND RADIOLOGICAL MATERIALS

THESE EFFORTS RESULT IN PERMANENT THREAT REDUCTION BY ELIMINATING BOMB MATERIAL AT CIVILIAN SITES – EACH KILOGRAM OF CORE OF THIS DANGEROUS MATERIAL THAT IS REMOVED REDUCES THE RISK OF A TERRORIST BOMB

PROTECT



PROTECT HIGH PRIORITY NUCLEAR AND RADIOLOGICAL MATERIALS FROM THEFT AND SABOTAGE

THESE EFFORTS RESULT IN THREAT REDUCTION BY INFORMING RESPONSE TO THE BOMB MATERIAL REMAINING AT CIVILIAN SITES – EACH VULNERABLE BUILDING THAT IS PROTECTED REDUCES THE RISK UNTIL A PERMANENT THREAT REDUCTION SOLUTION CAN BE IMPLEMENTED

U.S. DEPARTMENT OF ENERGY

National Nuclear Security Administration
Defense Nuclear Nonproliferation

GTRI & Mo-99

Strategy for Reliable Non-HEU-Based Mo-99 Supply

Global Mo-99 Market – Major Producers

HEU | Non-HEU

ANSTO (Australia)	NTP Radioisotopes (South Africa)	Mallinckrodt (Netherlands)	IRE (Belgium)	AECL-Nordion (Canada)
ANSTO (Australia)	NTP Radioisotopes (South Africa)	Mallinckrodt (Netherlands)	IRE (Belgium)	AECL-Nordion (Canada)
ANSTO (Australia)	NTP Radioisotopes (South Africa)	Mallinckrodt (Netherlands)	IRE (Belgium)	2016

U.S. Domestic Mo-99 Projects

1 2 3 4

3

U.S. DEPARTMENT OF ENERGY

National Nuclear Security Administration
Defense Nuclear Nonproliferation

GTRI's Mo-99 Objective and Strategy

Objective: Accelerate the establishment of reliable supplies of the medical isotope molybdenum-99 produced without highly enriched uranium

GTRI's strategy seeks to address weaknesses in the current Mo-99 supply chain:

- The current supply chain uses HEU to produce Mo-99
- Most Mo-99 production in today's marketplace is subsidized by foreign governments
- The current supply chain does not always have enough reserve capacity to ensure a reliable supply when one or more producers are out of operation
- The current supply chain is primarily dependent on aging facilities
- The current supply chain relies on one technology to produce Mo-99

A long-term, reliable supply of Mo-99 requires that global production of Mo-99 transition to a full-cost recovery, non-HEU-based industry

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U.S. DEPARTMENT OF ENERGY

NNSA National Nuclear Security Administration
Defense Nuclear Nonproliferation

U.S. Government Public Statement

Encouraging Reliable Supplies of Molydenum-99 Produced without Highly Enriched Uranium

- **Calling upon the Mo-99 industry to voluntarily establish a unique product code or similar identifying markers for Mo-99-based radiopharmaceutical products that are produced without the use of HEU;**
  In January 2013, the U.S. Mo-99 industry began to uniquely identify, or "label", Mo-99-based radiopharmaceuticals that are produced without HEU.

- **Preferentially procuring, through certain U.S. government entities, Mo-99-based products produced without the use of HEU, whenever they are available, and in a manner consistent with U.S. obligations under international trade agreements;**
  On January 3, 2014, the Department of Veteran's Affairs issued a policy memorandum that calls for Veterans Health Administration facilities to begin preferentially procuring non-HEU-based Mo-99/Tc-99m radiopharmaceutical products as they become commercially available.

- **Examining potential health-insurance payment options that might promote a sustainable non-HEU supply of Mo-99;**
  On January 1, 2013, the U.S. Centers for Medicaid and Medicare (CMS) issued a new rule that offers a $10 premium payment to any medical procedure that uses Mo-99-based radiopharmaceutical products produced without HEU. This rule is now in its second year of implementation.

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- **Taking steps to further reduce exports of HEU that will be used for medical isotope production when sufficient supplies of non-HEU-produced Mo-99 are available to the global marketplace;**
  Exports of HEU for medical isotope production are made on an annual basis and exports of HEU will be reduced as sufficient supplies of non-HEU-based Mo-99 become available.

- **Continuing to encourage domestic commercial entities in their efforts to produce Mo-99 without HEU during the transition of the Mo-99 industry to full-cost-recovery, and directing those resources to the projects with the greatest demonstrated progress; and**
  NNSA intends to continue to support its domestic commercial partners to produce Mo-99 without the use of HEU in the United States.

- **Continuing to provide support to international producers to assist in the conversion of Mo-99 production facilities from HEU to LEU.**
  Consistent with long-standing HEU minimization and international commitments, NNSA intends to continue to provide support to convert existing Mo-99 producers to LEU targets.

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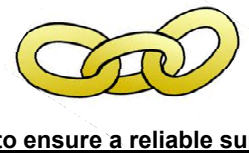
Ensuring Reliable Supplies of Mo-99/Tc-99m

Government subsidies have undermined reinvestment in infrastructure, which has led to the reliance on aging facilities, jeopardizing the reliability of Mo-99/Tc-99m supply.

Non-HEU based, full cost recovery Mo-99/Tc-99m



Reliable Mo-99/ Tc-99m supply

What can be done now to ensure a reliable supply:

- Ask for the non-HEU based Mo-99/Tc-99m available today
- Encourage private payers to adopt the $10 add-on payment consistent with CMS rule
- Educate your customers that non-HEU based Mo-99 = reliable supply for their patients
- Report costs of non-HEU based LEU to CMS

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Myths and Facts (1)

Myth: Patients are paying for the HEU to LEU conversion effort. Conversion to LEU is jeopardizing efforts to provide reliable supplies of Mo-99.

Facts:

- The U.S. objectives remain consistent.
  - Ensure reliable supply of Mo-99 for 30 million worldwide patients annually, including 15 million in the United States
  - Eliminate the use of HEU in Mo-99 production
  - Help transition global Mo-99 production to full cost recovery to establish an economically-sound industry for the long term
- Patients are not paying for the conversion of isotope production facilities from HEU targets to LEU targets.
- The real issue is reliability of Mo-99 supply.
- The conversion to LEU is considered an "externality" on an isotope production facility. Governments have committed to support these conversion efforts.
- Under the CMS $10 add-on reimbursement, non-HEU-based Mo-99 is a "proxy" for both non-HEU *and* reliable, full-cost recovery sources of Mo-99.

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Myths and Facts (2)

Myth: In order to supply hospitals with LEU doses qualified to receive the CMS $10 add-on reimbursement, radiopharmacies would need to segregate LEU generators, thereby increasing costs.

Facts:

- Segregating dispensing lines is a business decision, and is an administrative overhead cost that is shared by both the HEU and the LEU. There are other ways to overcome this.
- If a radiopharmacy makes the decision to segregate dispensing lines, it would only be until there is no longer HEU-based Mo-99 produced.
- If a radiopharmacy makes the decision to segregate dispensing lines and therefore incurs additional costs, those are operating costs passed on to customers and reimbursed by standard payments.
- The $10 add-on payment exists solely to reimburse for the added production costs associated with full cost recovery, non-HEU sources of Mo-99/Tc-99m.

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Myths and Facts (3)

Myth: To receive the CMS $10 add-on reimbursement, hospitals would need to segregate CMS patients, thereby increasing costs.

Facts:

- Hospitals do not need to segregate patients. It is not unusual for Medicaid and private payers to follow CMS payment rates.
- The $10 add-on payment reimburses for the added cost attributable to Medicare beneficiaries when they receive non-HEU-based Mo-99/Tc-99m.

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Myths and Facts (4)

Myth: The $10 add-on reimbursement has not had an effect on the uptake of LEU Mo-99.

Facts:

- According to SNMMI and CMS data, end-users are utilizing the $10 add-on reimbursement at levels consistent with CMS's uptake projections for 2013-14, and consistent with the current availability of LEU-based Mo-99 on the market today.

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Myths and Facts (5)

Myth: There isn't enough LEU Mo-99 on the market to take full advantage of the CMS add-on reimbursement.

Facts:

- There are two large-scale global producers that currently use LEU targets. One producer can increase its volume of LEU-based production. The CMS payment does not cause conversion to LEU, as conversion to LEU will happen regardless.
- The payment exists so that, as supplies of non-HEU Mo-99 increase, the increased cost will not be a barrier.

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Myths and Facts (6)

Myth: The $10 add-on reimbursement is actually only $8.

Facts:

- The $10 reimbursement to hospitals is made up of $8 from CMS, and $2 patient copay. The total reimbursement to hospitals is $10.
- This is consistent with the Medicare benefit that pays 80% of outpatient procedures, and 20% is the patient's responsibility. By law, hospitals should be collecting the $2 copay from the patient unless copays are waived for indigent patients based on need.

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Myths and Facts (7)

Myth: Hospitals receive the $10 add-on payment, not the rest of the Mo-99 supply chain.

Facts:

- The additional costs attributable to full cost recovery, non-HEU-based Mo-99 should be reflected in the costs that each supplier charges for its product.
- The $10 per-dose reimbursement is paid so that the hospital can cover the appropriately priced Mo-99.
  - The hospital receives an additional $10 to pay for an increase in price from the pharmacy,
  - due to an increase in price from the generator manufacturer,
  - due to an increase in price from the producer (reactor/processor),
  - due an increase in production costs associated with full cost recovery, non-HEU-based sources.

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Myths and Facts (8)

Myth: NNSA needs to provide more funding to the domestic projects to avoid a shortage.

Facts:

- Consistent with OECD-NEA guidelines, $25M in government support to these commercial projects helps to accelerate these projects, without negatively impacting/subsidizing the commercial Mo-99 market in the long-term.
- Commercial industry needs to invest in these projects to ensure they are successful in order to avoid widespread shortages.

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Acronyms

AECL	Atomic Energy of Canada Limited
ANSTO	Australian Nuclear Science and Technology Organization
CMS	U.S. Centers for Medicaid and Medicare
HEU	Highly enriched uranium
IRE	Institute National des Radioéléments
GTRI	Global Threat Reduction Initiative
LEU	Low enriched uranium
Mo-99	Molybdenum-99
NNSA	National Nuclear Security Administration
OECD-NEA	Organization for Economic Cooperation and Development – Nuclear Energy Agency
SNMMI	Society of Nuclear Medicine and Molecular Imaging
Tc-99m	Technicium-99 metastable

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September 2014

Sunday	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday
	1 Labor Day	2 X	3 X	4 X	5 X	6 X
7	8 Palestro, Langhorst	9	10 X	11 X	12 X	13 X
14 ASTRO Annual Meeting	15 ASTRO Annual Meeting	16 ASTRO Annual Meeting	17 ASTRO Annual Meeting	18 ASTRO Annual Meeting	19 X	20 X
21 X	22 X	23 X	24 Rosh Hashanah	25 Rosh Hashanah	26 Rosh Hashanah	27 X
28 X	29	30				

October 2014

Sunday	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday
			1 X	2 X	3 Yom Kippur	4 Yom Kippur
5 X	6 X	7 X	8 Sukkot	9 Sukkot	10 Sukkot	11 Sukkot
12 Sukkot	13 Columbus Day and Sukkot	14 Sukkot	15 Shemini Atzeret & Simchat Torah	16 Shemini Atzeret & Simchat Torah	17 Shemini Atzeret & Simchat Torah	18 X
19	20	21	22 X	23	24	25 X
26 X	27	28	29 X	30	31	