MEETING AGENDA
ADVISORY COMMITTEE ON THE MEDICAL USES OF ISOTOPES

September 9-10, 2013
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.

Monday, September 09, 2013
CLOSED SESSION

8:00 – 8:30	**1.**	**Amendments to the ACMUI Bylaws**	**S. Holiday, NRC**
8:30 – 9:30	**2.**	**Ethics Training**	**M. Clark & J. Suttenberg, NRC**
9:30 – 10:00	**3.**	**Information Security Training**	**B. Stapleton, NRC**
10:00 – 10:30	**4.**	**Allegations Training**	**T. Powell, NRC**
10:30 – 11:00		**B R E A K**	

OPEN SESSION

11:00 – 11:15	**5.**	**Opening Statements** Mr. Einberg will formally open the meeting and Mr. McDermott will provide opening comments.	**C. Einberg, NRC** **B. McDermott, NRC**
11:15 – 11:30	**6.**	**Old Business** Ms. Holiday will review past ACMUI recommendations and provide NRC responses.	**S. Holiday, NRC**
11:30 – 12:00	**7.**	**What is the ACMUI?** Ms. Cockerham will provide an overview of the ACMUI and its history.	**A. Cockerham, NRC**
12:00 – 12:15	**8.**	**Group Photo** The ACMUI will take a group photo.	**AV-Photo, NRC**
12:15 – 1:30		**L U N C H**	
1:30 – 1:45	**9.**	**10 CFR Part 35 Rulemaking Update** Ms. Bhalla and Mr. Lohr will provide an update on the status of rulemaking for 10 CFR Part 35.	**N. Bhalla & E. Lohr, NRC**
1:45 – 2:15	**10.**	**NRC and Safety Culture** Dr. Thomadsen will discuss safety culture principles as they apply to the interactions between the NRC and its licensees.	**B. Thomadsen, ACMUI**
2:15 – 2:45	**11.**	**Interim Enforcement Policy for Permanent Implant Brachytherapy Programs** Dr. Zelac will discuss the NRC's interim enforcement policy for permanent implant brachytherapy programs.	**R. Zelac, NRC**
2:45 – 3:15	**12.**	**Enforcement Guidance Memorandum for Rb-82 Generators** Dr. Howe will discuss the NRC's enforcement guidance memorandum for rubidium-82 generators.	**DB. Howe, NRC**
3:15 – 3:30		**B R E A K**	
3:30 – 4:30	**13.**	**Medical Events Subcommittee Report** Dr. Welsh will discuss the subcommittee report on medical events for fiscal year 2012.	**J. Welsh, ACMUI**

Tuesday, September 10, 2013
CLOSED SESSION

8:30 – 10:30 **14. Commission Briefing Preparation** **ACMUI**
The ACMUI will prepare for the October Commission Briefing.

Tuesday, September 10, 2013
OPEN SESSION

10:30 – 11:00 **15. ACMUI Reporting Structure** **S. Holiday, NRC**
Members will discuss the reporting structure of the Committee and provide feedback to NRC staff.

11:00 – 11:30 **16. ViewRay™ System Licensing Guidance** **C. Frazier, NRC**
Ms. Frazier and Ms. Shober will discuss the joint NRC/OAS licensing guidance for the ViewRay™ System for Radiation Therapy. **M. Shober, WI**

11:30 – 12:00 **17. Iodine - 123 mIBG Imaging : New Frontiers in Nuclear Cardiology With Cardiac Sympathetic Innervation Imaging** **W. Van Decker, ACMUI**
Dr. Van Decker will discuss the use of iodine-123 mIBG as a diagnostic option for cardiac patients.

12:00 – 1:30 **L U N C H**

1:30 – 2:00 **18. Regulatory Aspects of Germanium-68/Gallium-68 Generators** **P. Zanzonico, ACMUI**
Dr. Zanzonico will discuss the regulatory aspects and regulation of germanium-68/gallium-68 generators.

2:00 – 3:00 **19. Status Update of 10 CFR Part 20** **D. Cool, NRC**
Dr. Cool will provide a status update of the revisions to 10 CFR Part 20.

3:00 – 3:15 **B R E A K**

3:15 – 3:45 **20. Status of Revisions to NUREG-1556, Volume 9** **A. Cockerham, NRC**
Ms. Cockerham and Dr. Howe will provide a status update of the revisions to NUREG-1556, Volume 9. **DB Howe, NRC**

3:45 – 4:15 **21. Special Presentation to Dr. Van Decker** **B. McDermott, NRC**
Mr. McDermott will recognize Dr. Van Decker for his service to the ACMUI.

4:15 – 4:45 **22. Administrative Closing** **S. Holiday, NRC**
Ms. Holiday will provide a meeting summary and propose dates for the next meeting.

4:45 **A D J O U R N**

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*
9	NRC staff should revise the AO criteria to read, "A medical event that results in: 1) death; or 2) a significant impact on patient health that would result in permanent functional damage or a significant adverse health effect that would not have been expected from the treatment regimen, as determined by an NRC or Agreement State designated consultant physician."	4/28/08	Accepted	Closed
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	No NRC action	Open
10	ACMUI recommends NRC staff delete the phrase "at a medical institution" from 10 CFR 35.2, 35.490(b)(1)(ii), 35.491(b)(2) and 35.690(b)(1)(ii).	10/19/09	Accepted	Open

2011 ACMUI RECOMMENDATIONS AND ACTION ITEMS

	ITEM	DATE	STATUS		1st/2nd	Vote
1	ACMUI endorsed the draft response to NRC comments, as reflected in the meeting handout (ML110600249). ACMUI agreed if NRC believes the release criteria should be changed from a per release criteria to an annual criteria, this change would require new rulemaking, as stated in Regulatory Issue Summary (RIS) 2008-07. ACMUI recommended rulemaking to clarify that the release under 10 CFR 35.75 is per release and not per year	1/5/11	Pending	Open	Langhorst/Gilley	9, 1, 0
6	ACMUI created an action item to reevaluate its satisfaction with the reporting structure annually.	1/12/11	ACMUI Action	Open indefinitely	Welsh/Zanzonico	
7	Dr. Malmud will serve as a reviewer to screen I-131 cases for the ACMUI Medical Event Subcommittee	4/11/11	ACMUI Action	Open indefinitely		
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	11, 0, 0
13	ACMUI recommends to eliminate the written attestation for board certification pathway, regardless of date of certification	4/12/11	Accepted	Open	Zanzonico/Guiberteau	11, 0, 0
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	11, 0, 0
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	11, 0, 0
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	11, 0, 0
19	Steve Mattmuller asked that NRC Staff add ACMUI to the organizational chart on the FSME website.	9/22/11	Accepted	Closed	Mattmuller	
20	Dr. Langhorst requested that NRC staff 1) place historical documents on the ACMUI website that would give everyone a better understanding of the ACMUI organization and how it got to where it is today and 2) NRC add past ACMUI membersip information on the ACMUI Website.	9/22/11	Accepted	Open	Langhorst	
32	ACMUI reaffirms the 2008 AO Criteria as stated in the handout with the amendment that (s) be added to the end of physician, to read "consultant physician(s)"	12/15/11	Accepted	Open	Guiberteau/Mattmuller	11,0,1

2012 ACMUI RECOMMENDATIONS AND ACTION ITEMS

	ITEM	DATE	STATUS		1st/2nd	Vote
3	Dr. Thomadsen created a subcommittee to provide a recommendation on licensing for alpha-emitters, including Ra-223, The subcommittee will submit its report by 6/15/12. Subcommittee members include: Dr. Zanzonico (chair), Ms. Bailey, Dr. Langhorst, Mr. Mattmuller, Dr. Palestro, Dr. Suleiman, Dr. Thomadsen, Dr. Welsh. The NRC Staff resource person will be Ms. Ashley Cockerham.	4/17/12	ACMUI Action	Closed		
5	ACMUI approved the Draft Subcommitee Report on Licensing Ra-223 Chloride with minor modifications to be made.	7/9/12	ACMUI Action	Closed		11, 0, 0
6	Dr. Malmud asked NRC staff to find data on events in which the radiopharmacy has dispensed the incorrect amount of a radiopharmaceutical or the incorrect radiopharmaceutical.	9/20/12	NRC Action	Closed		
7	ACMUI recommends licensing of Ra-223 dichloride under 10 CFR 35.300 and recommends (but does not recommend *requiring*) direct measurement of activity before/after administration.	9/20/12	ACMUI Recommendation	Closed	Zanzonico/Langhorst	12,0,0
8	ACMUI endorses the subcommittee report submitted on July 16, 2012 with the following changes: 1) recommend licensing of Ra-223 dichloride under 10 CFR 35.300 and recommend (but not require) direct measurement of activity before/after administration; 2) remove statement regarding applicability of report for all future alpha-emitting particles; and 3) remove statement regarding Ra-223 dichloride significantly prolonging survivial. ACMUI will submit a report to NRC staff with the aforementioned changes.	9/20/12	ACMUI Action	Closed	Zanzonico/Welsh	12, 0, 0
9	ACMUI requested that reporting structure reviews remain on an annual basis.	9/20/12	NRC Action	Accepted		
10	Dr. Malmud created a subcommittee to review the refined Abnormal Occurrence criteria and provide recommendations to NRC staff. The subcommittee includes: Dr. Langhorst (chair), Ms. Bailey, Ms. Weil, Dr. Palestro, Dr. Welsh, Dr. Thomadsen, and Mr. Mattmuller. NRC staff resource will be Angela McIntosh.	9/21/12	ACMUI Action	Closed		
11	Dr. Langhorst asked NRC staff to provide direction as to whether or not the trigger criteria needs to be a part of the Abnormal Occurrence criteria or if the trigger criteria could be used separately	9/21/12	NRC Action	Closed		
12	ACMUI proposed the next meeting be on April 15-16, 2013 with a backup date of April 29-30, 2013. The ACMUI will meet separately with the Commission, if requested.	9/21/12	NRC Action	Closed		
13						

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 the 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 th 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
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
14	ACMUI recommended approval of the Second Draft ACMUI Rulemaking Subcommittee Report (ML13071A690) with the caveat that all modifications discussed during the teleconference would be incorporated before submission to NRC staff.	3/12/13	NRC Action	Closed	Zanzonico/Guiberteau	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		

2013 ACMUI RECOMMENDATIONS AND ACTION ITEMS

	ITEM	DATE	STATUS		1st/2nd	Vote
16	Dr. Langhorst requested if NRC staff could add the Draft Guidance for the Draft Expanded Part 35 Rulemaking into the same docket number as the Rulemaking document. If this is not possible, she requests that the location (docket number) of the draft guidance be clearly identified in the Draft Expanded Part 35 Rulemaking docket and vice versa.	4/15/13	NRC Action	Open		
17	The ACMUI have planned to hold a summer teleconference to discuss the Medical Events Subcommittee analysis of Yttrium-90 microspheres medical events. The dates are June 18, 2013 from 2-4pm EDT or June 20, 2013 from 2-4pm EDT (back-up).	4/15/13	ACMUI Action	Closed		
18	The ACMUI endorsed the Abnormal Occurrence Criteria Subcommittee Report.	4/15/13	ACMUI Action	Closed	Langhorst/Palestro	12, 0, 0
19	The ACMUI have planned to hold the Fall 2013 ACMUI Meeting at NRC Headquarters on September 9-10, 2013 or September 16-17, 2013 (back-up).	4/16/13	ACMUI Action	Closed		
20	Dr. Guiberteau requested that NRC staff provide a link to the abstract cited in Ms. Weil's ThyCa presentation to the full ACMUI.	4/16/13	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
22	The ACMUI endorsed the Draft ACMUI Yttrium-90 Microsphere Brachytherapy Medical Events Analysis Report (ML13162A113).	6/18/13	ACMUI Action	Closed	Welsh/Langhorst	9, 0, 0

What is the ACMUI?

September 9, 2013

Ashley Cockerham, Health Physicist
Medical Radiation Safety Team

Advisory Committee on the Medical Uses of Isotopes

Overview

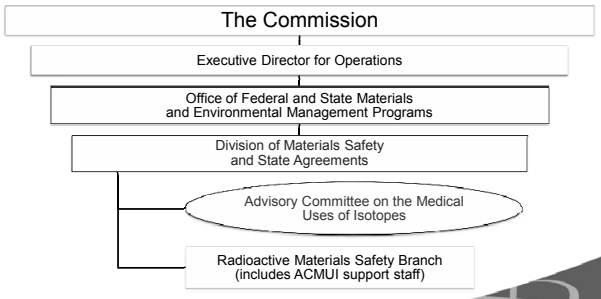
- History
- Organization
- Purpose
- Membership
- Meetings
- Subcommittees
- ACMUI Online
- Contacts

History

- Advisory Committee on the Medical Uses of Isotopes (ACMUI)
  - 1946 Manhattan Project
  - 1947 Atomic Energy Commission
  - 1959 ACMUI named
  - 1974 Nuclear Regulatory Commission

http://www.hss.doe.gov/healthsafety/ohre/roadmap/achre/chap6.html

Organization Chart



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Purpose

- Advise NRC staff on policy
- Provide technical assistance
- Raise key issues
- Serve as medical consultants

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Membership Selection

- Formal Nomination Process
  - *Federal Register* Notice
  - Panel Review, Recommendation
  - Appointed by FSME Director
- Serve 4 year terms
  - Eligible for reappointment
- Special Government Employees

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Membership Positions

- Health Care Administrator
- Nuclear Medicine Physician
- Radiation Oncologist (2)
- Nuclear Cardiologist
- Diagnostic Radiologist
- Medical Physicist (2)
- Nuclear Pharmacist
- Radiation Safety Officer
- Patients' Rights Advocate
- Agreement State Representative
- U.S. FDA Representative

8

Membership Expertise

- Diagnostic
- Therapeutic
- Research
- Patients' Rights
- Co-regulators
  - Agreement States
  - U.S. Food and Drug Administration

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Members

- L→R: [Dr. Leon Malmud], Dr. James Welsh, Dr. William Van Decker, Dr. Orhan Suleiman, Mr. Steve Mattmuller, Ms. Laura Weil, Dr. Susan Langhorst, [Ms. Darice Bailey], Dr. Christopher Palestro, Dr. Pat Zanzonico, Dr. Bruce Thomadsen (Chair), Dr. Milton Guiberteau (Vice Chair), Dr. John Suh

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Meetings

- Public Meeting at NRC Headquarters
  - 2x year
  - 2 days
- Teleconferences
  - As needed (1-3x year)
  - 1–2 hours
- Annual Commission Briefing

11

Subcommittees

- Created as needed
- Topic or issue specific
- Generate reports
- Reports endorsed by committee
- Submitted to NRC staff

12

Subcommittee Topics

- 2002 – Training and Experience Recommendations
- 2003 – Novoste Medical Events Root Cause Analysis
- 2008 – Fingerprint Efficiency
- 2008 – Cesium-137 Chloride Irradiators
- 2009 – Board Certification Pathway
- 2010 – Patient Release
- 2008, 2010, 2011, 2012 – Permanent Implant Brachytherapy
- 2012 – Electronic Signatures
- 2012 – Radium-223 Dichloride
- 2013 – Abnormal Occurrence Criteria
- 2013 – Expanded Part 35 Rulemaking
- 2013 – Yttrium-90 Microsphere Brachytherapy Medical Events
- Ongoing – Medical Events

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Links

- Main ACMUI webpage

http://www.nrc.gov/about-nrc/regulatory/advisory/acmui.html

  - Membership information & biographies
  - History & historical membership
  - ACMUI charter
  - Subcommittee reports
  - Meeting information
  - Contact submission form

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Contacts

- Chris Einberg, Radioactive Materials Safety Branch Chief
  - Christian.Einberg@nrc.gov
  - (301) 415-5422
- Michael Fuller, Medical Radiation Safety Team Leader
  - Michael.Fuller@nrc.gov
  - (301) 415-0520
- Sophie Holiday, ACMUI Coordinator
  - Sophie.Holiday@nrc.gov
  - (301) 415-7865

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Group Photo

NO HANDOUT

Part 35 Proposed Rule Status Update

Neelam Bhalla and Ed Lohr
Rulemaking and Project Management Branch
DILR/FSME

Current Status

- SECY-13-0084 dated August 8, 2013, conveyed the proposed rule to the Commission
- The package (SECY paper and the enclosures) is available in Agencywide Documents Access and Management System (ADAMS) under ML13178A124

Next Steps

- A Commission meeting has been scheduled for October 18, 2013 to discuss the proposed rule
- Commission votes on the rule
- Pending Commission approval, the proposed rule will be published in the Federal Register

Federal Register Notification

- Comment Period: 90 days or as directed by the Commission
- Medical community will be informed about the FRN publication
- Agreement States will be informed about the FRN publication

Posting of Comments

NRC will be posting any comments received at the following Website:

www.regulations.gov

under the docket number NRC-2008-0175

5

Tentative Schedule for the Final Rule

Currently the final rule is due to the Commission at the end of 2014

6

The Nuclear Regulatory Commission and Safety Culture

Bruce Thomadsen, Ph.D.
ACMUI Chairman

Characteristics from Statement

1. Leadership Safety Values and Actions
2. Problem Identification and Resolution
3. Personal Accountability
4. Work Processes

Characteristics from Statement

5. Continuous Learning
6. *Environment for Raising Concerns*
7. Effective Safety Communications
8. Respectful Work Environment
9. Questioning Attitude

6. Environment for Raising Concerns

NRC defines *chilled work environment*: "…employees perceive that raising safety concerns to their employer or to the NRC is being suppressed or is discouraged…" - Inspection Manual

Example Given at HPS Meeting

- Workers at facility did not report a problem.
- Speaker hypothesized they may have been afraid of retaliation: a chilled work environment.

5

Example Given at HPS Meeting

- I more often hear, not of fear of what employers will do, but of what regulators will do.
- Maybe the workers were afraid of what the NRC would do (and did).
- This forms a chilled work environment.

6

What is the Goal?

- To learn about issues
- To fix the issues before they cause problems
- All the research supports open, non-punitive reporting – viz. item 6 is in the safety culture list

7

How to Best Achieve the Goal?

- Follow the NRC guidance to avoid a chilled workplace by not punishing facilities that identify and report problems.
- Possibly use a reporting system like the Federal Aviation Administration.

8

How to Best Achieve the Goal?

- This could lead to more detail, and more correct detail, given during an investigation, and better information in NMED.
- Openness could facilitate concentrating on solutions.

9

Summary

Following the practices of a good safety culture could be beneficial to the NRC and the medical community.

10

Acronym

HPS – Health Physics Society

NMED – Nuclear Materials Events Database

NRC – U.S. Nuclear Regulatory Commission

11

Interim Enforcement Policy for Permanent Implant Brachytherapy Programs

Ronald Zelac, Ph.D., FSME/MSSA
ACMUI Meeting
9-9-13

Basis for Staff Action

- STAFF REQUIREMENTS – SECY-12-0053 – RECOMMENDATIONS ON REGULATORY CHANGES FOR PERMANENT IMPLANT BRACHYTHERAPY PROGRAMS
- Issued August 13, 2012

Interim Enforcement Policy (IEP) - Objective

- Allows staff enforcement discretion for both existing and future specific violations of current 10 CFR 35.3045 (reporting medical events)

Interim Enforcement Policy (IEP) - Status

- Published in the Federal Register and effective on 7/9/13

IEP - Specific Enforcement Discretions

1. Allow licensee use of total source strength and treatment time for determining the existence of a treatment site medical event (ME)

5

IEP - Specific Enforcement Discretions (cont.)

2. Allow the total dose to the treatment site to exceed 120 percent of the prescribed dose

6

IEP – Rationale for Applying Discretion 1 (source strength)

- The two dose criteria for a treatment site medical event in 10 CFR 35.3045(a)(1) are linked – exceeding the percent dose variation threshold means that the absorbed dose variation threshold is also exceeded.

7

IEP – Rationale for Applying Discretion 2 (dose >120 %)

- Permanent implant therapies have the objective of delivering as much radiation dose as possible to the treatment site without exceeding medically-recognized dose limits for nearby normal tissues and structures.

8

IEP – Conditions for Applying Discretion 1 (source strength)

a. Licensee's required documented procedures (10 CFR 35.41) must specify total source strength and exposure time as the regulatory evaluation values for treatment site dose comparisons (prescribed to delivered).

9

IEP – Conditions for Applying Discretion 1 (cont.)

b. The licensee entered both the prescribed dose and the delivered dose into the written directive as total source strength and exposure time.

10

IEP – Conditions for Applying Discretion 1 (cont.)

c. To evaluate the medical administration, the licensee uses total source strength and exposure time to compare the dose delivered to the treatment site with the prescribed dose.

11

IEP – Conditions for Applying Discretion 1 (cont.)

d. The licensee timely reported, per § 35.3045, the event based on that comparison, if applicable.

12

IEP – Conditions for Applying Discretion 1 (cont.)

e. The use of these values does not result in the misapplication of byproduct material by the licensee.

13

IEP – Condition for Applying Discretion 2 (dose >120%)

a. Licensees are using absorbed dose to compare the dose delivered to the treatment site with the prescribed dose

14

IEP – Condition for Applying Discretion 2 (cont.)

b. Doses to normal tissues and structures do not exceed the regulatory dose limits for reporting medical events in the current § 35.3045(a)(3).

15

IEP – Condition for Applying Discretion 2 (cont.)

c. The total dose for the treatment site was expressed in the written directive as absorbed dose.

16

QUESTIONS?

17

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ENFORCEMENT GUIDANCE MEMORANDUM EGM-13-003 Issued April 13, 2013

Donna-Beth Howe, Ph.D.
Medical Radiation Safety Team
September 09, 2013

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

EGM-13-003

Enforcement Guidance Memorandum - Interim Guidance for Dispositioning Violations Involving 10 CFR 35.60 And 10 CFR 35.63 for the Calibration of Instrumentation to Measure the Activity of Rubidium-82 and the Determination of Rubidium-82 Patient Dosages

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

EGM-13-003

- Problem: The short half-life (76 seconds)
- Result: The administration of the Rb-82 chloride is eluted **directly** from the generator system **into the patient**. This **precludes pre-measurement** before administration and measurement of the dosage in a **dose calibrator** prior to administration.

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EGM-13-003

- **10 CFR 35.60** requires a licensee to calibrate the instrument used to measure the activity of the dosage administered to each patient or human research subject. This calibration may either be performed in accordance with nationally recognized standards or calibration instructions provided by the manufacturer.

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EGM-13-003

- There are currently neither nationally recognized standards nor specific calibration procedures for calibrating detectors in a dynamic mode (*i.e.*, while liquids are flowing by the detector). Until such standards or procedures are developed, compliance with 10 CFR 35.60 is not possible.

5

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EGM-13-003

- **10 CFR 35.63** requires a licensee to determine the activity of each dosage administered before medical use.
- Due to the 76 second half-life of Rb-82 and direct infusion into the patient, users of this generator system are unable to measure patient dosages of Rb-82 **prior** to administration

6

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EGM-13-003

When using Rb-82 Cl, it is not possible for licensees to meet the current NRC regulatory requirements:

(1) the medical use calibration requirements for the radiation detectors associated with Rb-82 generator systems and

(2) the inability of users of those systems to determine the dosage of the Rb-82 before medical use.

7

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EGM-13-003

Use of ENFORCEMENT DISCRETION to not issue a violation for failure to comply with requirements for Rb-82 generator systems, in accordance with 10 CFR 35.60 or 10 CFR 35.63, if **all three** of the following criteria are met:

8

Test Procedures

1)The licensee must have **written test procedures** to ensure that the infusion pump flow rate is consistent and accurate, and that the radiation detector meets the manufacturer's specifications. The licensee must **perform the tests**, at least every twelve months (and repeated after repair or replacement), and **maintain records** documenting the performance of and results of these tests.

9

Test Procedures (cont.)

The radiation detector specifications are compared to the values obtained during tests of the **detector's electronics** and the response of the **radiation response** to a radiation source in the static mode. The licensee may use documentation of the infusion cart maintenance **performed by the manufacturer** to document the completion and results of the infusion rate and radiation detector test.

10

Test Procedures (cont.)

[Note: If in the future the manufacturer were to develop a calibration procedure (*i.e.*, accuracy, linearity and geometry evaluations of the detector), then such calibration must be performed for the detector as opposed to the electronic and radiation function tests, as currently used.]

11

Training

2. All **authorized user(s**) (AU) for medical uses under 10 CFR Part 35.200 who are using Rb-82 chloride, as well as the **Radiation Safety Officer** for that facility, must have **successfully completed training** specific to the manufacturer and model of generator and infusion cart being used. The licensee must maintain **documentation**.

12

Training (cont.)

- The training must include: (1) **elution and quality control procedures** needed to determine Rb-82 activity and the Sr-82 and Sr-85 breakthrough levels; (2) **dose calibrator calibration** procedures; and (3) **safety procedures** for the clinical use of Rb-82 chloride.

Training (cont.)

- Until the generator manufacturer develops static or dynamic calibration procedures for calibrating the radiation detector in the infusion cart, the quality control procedures must include: (1) performance of the **Rb-82 activity constancy check** comparison with Rb-82 measured in a calibrated dose calibrator; (2) how to **adjust the infusion cart readout** setting; and (3) **when** these tests are required by the manufacturer.

Dosage

3.The licensee must record the activity of each dosage administered, as provided by the infusion cart.

EGM-13-003

QUESTIONS?

U.S.NRC
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Medical Events Report FY 2012

James S. Welsh, MD

Advisory Committee for the
Medical Uses of Isotopes

September, 2013

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

Subcommittee members

- Susan Langhorst, Ph.D.
- Steve Mattmuller
- John Suh, M.D.
- Orhan Suleiman, Ph.D.
- Bruce Thomadsen, Ph.D.
- James Welsh, M.D. (Chair)

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Fiscal Year 2012
(As itemized in NMED under "Advanced Search" Medical Event Details menu - Therapeutic Procedure)
Total = 69

- Eye applicator brachytherapy: 0
- Intravascular brachytherapy: 0
- Manual afterloader brachytherapy: 0 (1 in Nov 2012 and 2 in 2010 and 1 in 2007)
- Manual implant brachytherapy: 32
- HDR remote afterloader: 16
- LDR remote afterloader: 0
- Brachytherapy, type not reported: 0
- Gamma Knife: 2

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Fiscal Year 2012
(As itemized in NMED under "Advanced Search" Medical Event Details menu - Therapeutic Procedure)
Total = 69

- Linear accelerator: 0 (last one listed in 2009 - a stereotactic radiosurgery case)
- NA: 14
- NR: 1
- Radiolabeled antibodies: 0
- Radiopharmaceutical D: 0 (Nothing since 2004)
- Radiopharmaceutical T: 2 (Zevalin, a radiolabeled antibody and Sm-153 EDTMP)
- Radioiodine-A: 1

Fiscal Year 2012
(As itemized in NMED under "Advanced Search" Medical Event Details menu - Therapeutic Procedure)
Total = 69

- Radioiodine-D: 0 (last one in 2008)
- Radioiodine-T: 1
- Teletherapy: 0 (last one in 2008)
- X-ray: 0 (last one in 2000 – a stereotactic radiosurgery case)

5

Some comments/observations

- Some nebulous categories are listed in the menu:
  - Linac
  - X-ray
  - NA

6

Some comments/observations

- Zevalin has its own category but Bexxar does not
- "Radiolabeled antibodies" is another category
- Some events from many years back get logged during the period in question
- Some events from the period in question are not entered for many months

7

Some comments/observations

- The only really practical way to conduct a search efficiently is to focus on the dates actually listed as REPORTED during the fiscal year in question
- It would be nice if the database were organized by Subparts consistent with 10 CFR 35 but…
- Gamma Knife stereotactic radiosurgery ME's can be difficult given some are § 35.600 and others § 35.1000
  - Same for manual brachytherapy – Y-90 microspheres are § 35.1000
- So organizing according to 10 CFR 35 parts could be challenging as things move in and out of subparts

8

Medical Events 2012

From Dr. Howe
(Spring 2013 ACMUI meeting):

35.400 Medical events	**11**
– Brachy-mesh	1
– Prostate (22 patients)	10

§ 35.400 Medical Events (per BRACHY, MANUAL IMPLANT)

- 32 found in "Advanced Search" in NMED
- But Dr. Howe's presentation said: 2012 § 35.400 Medical events = 11
- Why the discrepancy???
- Further investigation warranted

Some comments/observations

- NMED database is not in chronological order!
  - Event 130374 was the very LAST entry in the manual implant brachytherapy section yet refers to Event Date 11/03/2011
  - Event 130359 (third from last) - Event Date in Sept 2012
- For an adequate search one must look at pages well beyond the year in question!

Medical events Fiscal Year 2012

(As itemized in NMED under Advanced Search menu; Medical event Details - Therapeutic Procedure)

- Searching this way leads to a total of 69 "items" for the period in question
- Not all are truly medical events (just events listed in NMED)
- Some are retracted
- Some may be added after your search has been done

Medical events Fiscal Year 2012 (As itemized in NMED under Advanced Search menu; Medical event Details - Therapeutic Procedure)

- NMED is not organized along § 35 lines
  - e.g. 32 items are found in "Advanced Search menu/Medical event Details/Therapeutic Procedure/BRACHY, MANUAL IMPLANT"
  - But includes Y-90 microspheres (§ 35.1000) as well as manual brachytherapy that is under § 35.400

13

NMED Items and Medical Events 2012

- **BOTTOM LINE:**
- **Different total tallies at Spring meeting vs Fall**

	FY12 (Spring)	FY12 (Fall)
§ 35.200	2	2
§ 35.300	2	2
§ 35.400	15	20
§ 35.600	13	17
§ 35.1000	20	20
Total	**52**	**61**

14

Diagnostic Medical Events (§ 35.200)

- 2 ME's (4 patients)
- Pharmacy filled vial labeled gallium with thallium
  - 6.2 rem - 1 patient
- Sr-82/Sr-85 breakthrough exceeded limits over 5 rem – 3 patients

15

Medical Events - § 35.300 Use of Unsealed Byproduct Material

2 ME's

Especially interesting was NMED Item Number 120548

"Written Directives in an Electronic Medical Record World…"

35.400 Medical Events (per BRACHY, MANUAL IMPLANT)

Of 20 ME's found:

- 18 prostate permanent seed implants involving 32 pts:
  - EN100567 = 2 pts
  - EN120432 = 13 pts
  - EN120687 = 2 pts
  - All others were one patient apiece

17

35.400 Medical Events (per BRACHY, MANUAL IMPLANT)

- Focusing on these prostate implants:
- I-125 = 13
- Pd-103 = 2
- Cs-131 = 2
- Unspecified = 1

18

35.400 Medical Events (per BRACHY, MANUAL IMPLANT)

- Focusing on these prostate implants:
- 3 involved multiple patients (two with 2 pts, one with 13 pts)
- 23 (of 32) individual patient cases were underdoses to treatment site
- 11 had overdoses to normal tissues
- Of the underdoses where normal tissue was not overdoses several subsequently had either additional seed placed or supplemental external beam radiotherapy

19

35.400 Medical Events (per BRACHY, MANUAL IMPLANT)

- Specific cases of interest:
- EN120341
- All 65 seeds placed inferior to prostate based on Day Zero CT
- Penile bulb mistaken for prostate in OR based on ultrasound - Human error
- Corrective action: Will use fluoroscopy to verify position of needles

20

35.400 Medical Events (per BRACHY, MANUAL IMPLANT)

- Specific cases of interest:
- EN120689 and EN120690
- Similarly seeds were placed inferior to prostate
- In EN120689, seeds were systematically misplaced ~1 cm inferior to prostate
- In EN120690, seeds were up to 3.5 cm inferior to prostate with only 25% of target getting prescribed dose of 144Gy

21

35.400 Medical Events (per BRACHY, MANUAL IMPLANT)

EN120393

- Survey of packing material showed elevated reading suggesting leaking seed(s)
- Urine bioassays and thyroid counts revealed (suggested) I-125 uptake:
  - 3.7 MBq (0.1 mCi), thyroid dose ~330cGy, whole body dose ~12cSv (rem)
- Manufacturing error vs damage in transit or on site
- Hospital switched to different seed manufacturer

22

35.400 Medical Events (per BRACHY, MANUAL IMPLANT)

EN120406

- Patient passed two strands of seed (total of 15 seeds)
- One flushed into septic system, other to be brought into hospital for proper disposal
- Pt had TURP (transurethral resection of prostate) over 15 years ago

23

35.400 Medical Events (per BRACHY, MANUAL IMPLANT)

EN110625

- Wrong patient – back to back procedures on two consecutive days and written directives were confused
- First patient received proper treatment
- Second patient received same seed placement procedure as the first
- 27% underdose based on D90 and overdose to urethra
- Additional seeds placed to improve coverage

24

35.400 Medical Events (per BRACHY, MANUAL IMPLANT)

EN120432

- WI Dept of Health Services inspection of all cases since 2001
  - 13 patient cases identified between 7/15/05 to 5/20/12)
  - One prostate overdose
  - Seven prostate underdoses (two with overdoses to rectum)
  - Five with rectum overdoses
- Hospital had not reviewed cases against medical event criteria = Human error
- Corrective action: AU now places all needles (whereas in past urologist and AU alternated on placing needles)

35.400 Medical Events (per BRACHY, MANUAL IMPLANT)

EN110567

- Two patients underdosed in Jan and Aug 2011
- Review subsequently found an additional 14 pts who might have gotten <80% of prescribed dose in prior 3 years
- Attributed to prostate swelling between implant and 15 day scan
- All seed implant procedures suspended during policy & procedure revision
  - Later determined these were NOT ME's since administered dose was not truly off by >20%

Prostate implant ME retractions

In addition to EN110567 being found not to be a true ME:

- EN120166 and EN120694 were both treatment site underdoses that were subsequently retracted
  - One did not meet CT State activity-based ME criteria
  - Other was initially an underdose based on outside expert claiming that 21 of 52 seeds were outside the prostate
  - AU disagreed and felt that outside expert's contours did not account for prostate anatomical asymmetry
  - NRC inspection 3/19/12
  - ME retracted after conclusion that dose not off by >20%

§ 35.400 NON-prostate manual implants:

EN120492: Lung I-125 mesh implant performed 5/31/12

- Chest x-ray 7/7/12: Only 38 of implanted 50 seeds visible
  - CT 7/9/12: 35 in chest; 3 in abdomen
  - 7/17/12: 25 in lung; 9 in abdomen
  - 7/18/12: 13 in lung; 17 in abdomen
  - 8/4/12: 6 in lung; 8 in abdomen
  - 8/9/12: ONE in lung; ZERO in abdomen
- Concluded that pt coughed up loose seeds and swallowed them
- Failure of device reported to manufacturer and FDA

§ 35.400
NON-prostate manual implants:

EN120610: Cs-137 temporary implant (Fletcher-Suit ovoids)
- 30 Gy to each ovary prescribed
- At completion of 26.5 hr procedure, source was missing on left
- Found on IV monitor stand

- Determined that only one source was correctly placed, the other fell onto bed where nurse found it 12 hrs later and put it on stand (by hand)
- Pt subsequently treated to left side
- Nurse extremity dose ~ 13 rem
- Human error, inadequate training

§ 35.600
Remote Afterloaders, Teletherapy

	FY2011	FY2012
All § 35.600	8	17
All HDR	7	16
LDR remote afterloader	1	0
Gamma Knife	--	1*
Teletherapy	0	0

HDR Brachytherapy Sites

Event Site	Number of Events
Breast	4
Cervix	3
Uterus	2
Sarcoma	1
Endobronchial	1
Endoesophageal	1
Vagina	1
Intraoperative Sacrum	1
Skin	1
Bile duct	1

§ 35.600 HDR Brachytherapy Observations

As with 2011, no frequent problems

- 5 Length problems: 2 Catheter not fully inserted in tandem, 1 Endobronchial used transfer tube instead of adaptor, 1 Wrong distance used, 1 Not stated
- 4 Treatment-planning errors
- 1 Wire drift during tandem treatment
- 1 Marker in NG tube mistaken for source location
- 1 Incorrect adjustment for catheter slippage
- 1 Wrong patient's plan
- 2 Hardware or software failure

§ 35.600 HDR Brachytherapy Observations

- 2 cases noted that QA was not performed.
- Imaging before treatment with the actual connectors or transfer tubes used with full-length markers could have uncovered several of the problems.

§ 35.600 GammaKnife Events

- Mechanical Failure - Latch fastener failure

§ 35.1000 Events

	FY2011	FY2012
All § 35.1000	11	20
Microspheres	11	19
SIR-Spheres	3 (1 pt related)	8
TheraSphere	8	11
LDR remote afterloader	0	0
Perfexxion	0	1
Coronary	0	0

§ 35.1000 Events

8 SIR-Spheres

- 2 Spheres stuck to septum
- 1 Wrong patient's dose
- 1 Retrograde flow
- 1 Settling due to slow delivery
- 1 Wrong artery
- 1 Wrong dose drawn
- 1 No information

§ 35.1000 Events

11 TheraSpheres

- 6 Slow flow
  - 1 from clamp-deformed tube
  - 1 clamp not fully opened
  - 1 due to small arteries
  - 1 because increased difficulty with syringe
  - 1 piece of septum impeded flow
  - 1 reason not specified
- 1 Needle-in-vial problem
- 1 Wrong patient's dose

§ 35.1000 Events

11 TheraSpheres - Continued

- 6 Slow flow
- 1 Needle-in-vial problem
- 1 Wrong patient's dose
- 1 Stasis – should not have been an event
- 2 No information

§ 35.1000 - Perfexion GammaKnife Event

Computer failure after reapplying frame, although listed as human error

General observation

Many of the events have little useful information in the NMED reports.

IMV data 2010

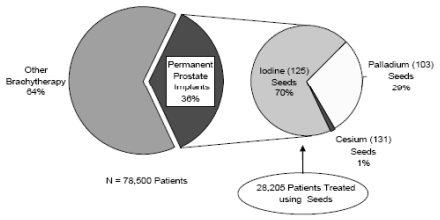
Radiation Therapy Treatment Method	% Distribution of Courses of Treatment, by Treatment Method (N = 924.1K)	% of Sites Performing Method (N = 2,290)
Brachytherapy (LDR) Permanent Prostate Implants	2.7%	31%
Brachytherapy (LDR) Temporary Afterloading	0.4%	9%
Brachytherapy - High Dose Rate Temporary Afterloading	4.5%	39%
Radionuclide Therapy*	0.7%	15%
	Total = 8.5%	

Denominators (2010 from IMV)

- ~675 radiation therapy sites reported treating an estimated 28,205 prostate cancer patients with permanent prostate implants
- 70% (19,605 patients) I-125 seeds
- 29% (8,175 patients) Pd-103 seeds
- 1% Cs-131 seeds

IMV 2011 Benchmark Report: Radiation Therapy

PERCENT MIX OF BRACHYTHERAPY AGENTS
USED IN PERMANENT PROSTATE IMPLANTS, 2010



General questions and comments

- Is quality control being done on the database?
- How is NMED ME information being used by Agreement States and others?
- Are other ME reporting systems being used or developed?
- How can an ME database be used to support licensee safety culture development and help improve patient care?
- What comes in from the states is voluntary - so is NMED possibly incomplete..?

General questions and comments

- The numbers are too small for meaningful, statistically confident, conclusions…. However….
- Many of the ME's are still due to failure to perform some basic QA
  - e.g. lack of (or sloppy) verification - be they calculation or imaging based (e.g. counting seeds)
- These should be ingrained in the community
- Agreement State consistency
  - How does the NRC assure that agreements states are consistent with the NRC with regard to ME's?

QUESTIONS?

Acronyms

- cGy (rad) –centiGray
- cm - centimeter
- FY – Fiscal Year
- GYN - gynecological
- HDR – High dose-rate
- LDR – Low dose-rate
- mCi – millicurie

Acronyms

- ME – Medical Event
- NMED - Nuclear Material Events Database
- Pt - Patient
- QA - Quality Assurance
- rem - roentgen equivalent in man
- Sr – Strontium
- Y- Yttrium

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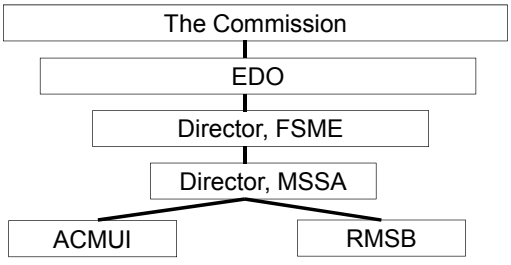
ACMUI
Reporting Structure

Sophie Holiday, ACMUI Coordinator
Medical Radiation Safety Team
Office of Federal and State Materials and Environmental Management Programs

Outline

- **Current Reporting Structure**
- **Annual Review**
- **Meetings**
- **Discussion**

Current Reporting Structure



Current Reporting Structure

January 5, 2011 Teleconference

- **Recommendation to maintain current reporting structure**

Annual Review

Jan. 12, 2011 Teleconference and Sept. 20, 2012 Meeting

- **Recommendation by ACMUI to have an annual review of reporting structure**

5

Meetings

Two meetings at Headquarters each year

- **April/May**
- **September/October**

Approximately 2-3 teleconferences (as needed)

6

Discussion

7

Acronyms

- **EDO – Executive Director for Operations**
- **FSME – Office of Federal and State Materials and Environmental Management Programs**
- **MSSA – Division of Materials Safety and State Agreements**
- **RMSB – Radioactive Materials Safety Branch**

8

Licensing Guidance for ViewRay ™ System

September 10, 2013

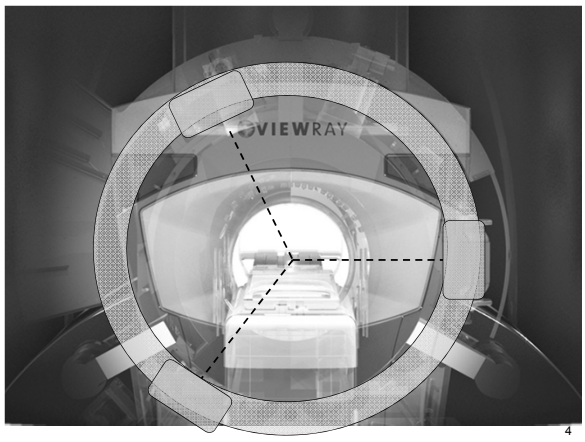
Cassandra Frazier (NRC) and Megan Shober (WI)
Co-chairs, NRC/OAS Working Group on
Computerized Teletherapy Units

Outline

- Overview
- Working group tasks
- Decision to use 10 CFR 35.1000
- Features of the guidance

Working Group History

- Three NRC staff and three State representatives
- Evaluate two new radiation therapy devices



Working Group Tasks

- Can the device meet the requirements in 10 CFR 35.600?
- Are any safety issues with the device not adequately addressed by the regulations?

✓Guidance published in Medical Toolkit July 24, 2013

5

10 CFR 35.1000

- ViewRay cannot meet teletherapy requirements in 10 CFR 35.600

- Examples
  - 10 CFR 35.632(b)(2)
  - 10 CFR 35.642(d)(2)

6

10 CFR 35.1000

- Safety issues not adequately addressed

- Examples
  - Multiple treatment heads
  - MR imaging during treatment
  - Gated treatment delivery
  - Weekly and daily QA tests

7

Physical presence

- Wide range of opinions
- Need to consider unique device characteristics
- Allow for an acceptable health and safety risk

8

Authorized individuals

AU	AMP	RSO
35.690	35.51	35.50
Hands-on device training		Emergency procedures

9

Next steps

- The guidance will be revised as clinical experience is gained.
- If you have specific concerns, contact your regulator.

10

Acronyms

- AU – Authorized User
- AMP – Authorized Medical Physicist
- MR – Magnetic Resonance
- OAS – Organization of Agreement States
- RSO – Radiation Safety Officer
- QA – Quality Assurance

11

Questions?

12

Iodine-123 mIBG Imaging: New Frontiers In Nuclear Cardiology With Cardiac Sympathetic Innervation Imaging

William A. Van Decker, M.D.
Nuclear Cardiologist
ACMUI

Nuclear Cardiology, 2013 Spectrum

- Myocardial Perfusion Imaging
- - Thallium
- - Technetium Sestamibi
- - Technetium Tetrofosmin
- - Rubidium
- Myocardial Function Myocardial Viability

Research Interests:

-Infarct Avid Imaging
- Apoptosis Imaging
- Metabolism Imaging (I-123 IPPA, I-123 BMIPP)
-Autonomic nervous system imaging (I123 mIBG)

I-123 mIBG

- Congestive Heart Failure
- I-123 mIBG is indicated for the scintigraphic assessment of sympathetic innervation of the myocardium by measurement of the heart to mediastinal (H/M) ratio of radioactive uptake in patients with NYHA Class II or Class III heart failure and LVEF < 35%. Among these patients, the radiopharmaceutical may be used to help identify patients with lower one and two year mortality risks.

Iodine – 123

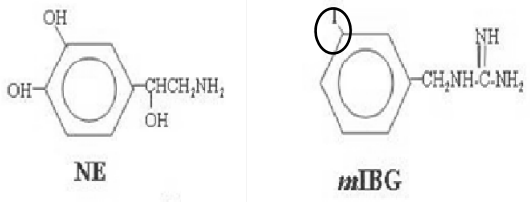
- Cyclotron produced
- Decays to Te-123 by electron capture
- Physical half life about 13.2 hours
- Gamma radiation, 159 keV
- Half value layer lead (Pb) is 0.04 cm
- Commonly used isotope in the 35.200 class , radiation safety knowledge similar as for other 35.200 isotopes , and able to be utilized by physicians trained under 35.290 requirements.
- Imaged with SPECT crystals.

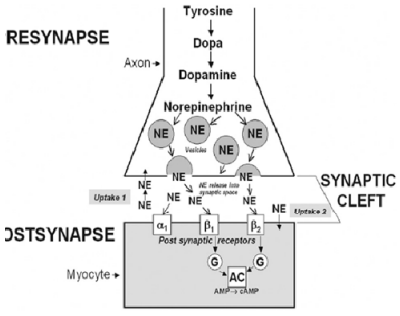
I-123- mIBG

- Renal excreted
- Effective Dose 5.07 mSv for a 10 mCi dose
- Organs with highest dosing by ICRP calculations and biodistribution kinetics are liver and urinary bladder wall

^{123}I-*m*IBG (*meta*-iodobenzylguanidine)

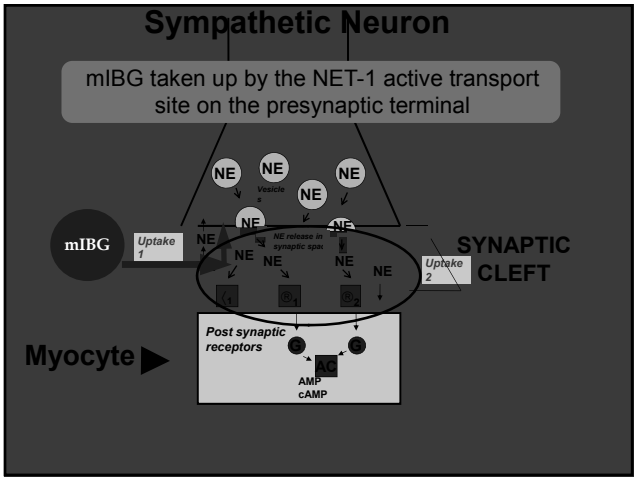
A Physiologic Analog of the Sympathetic Nervous System Neurotransmitter Norepinephrine (NE)





Catecholamines and the Heart

Chirumamilla et al. Sem Nucl Med 2011.



CATECHOLAMINES IN HEART FAILURE

- Inciting event: reduction in cardiac pump function by ischemic or non ischemic cause
- Up regulation of renin-angiotensin-aldosterone system and sympathetic nervous system
- Initial increased release of NE into synaptic cleft
- Chronic stimulation of sympathetic nervous system causes depletion of NE at the synaptic terminal
- Down regulation of NE reuptake transporter in response to chronic stimulation
- This accounts for global decrease in H/M ratio

Radiotracers and synaptic action

Table 13. Radiotracers used for neurotransmitter imaging

	Presynaptic terminals	Postsynaptic terminals
Sympathetic nerves	*I-123 MIBG*	*I-125 iodocyanopindolol*
	C-11 HED	C-11 practolol
	C-11 epinephrine	C-11 CGP 12177
	C-11 phenylephrine	C-11 prazosin
	F-18 fluorobenzylguanidine	
	F-18 fluorodopamine	
	F-18 fluoronorepinephrine	
	F-18 metaraminol	
Parasympathetic nerves	*I-125 iodobenzoversamicol*	*I-123 quinuclidinyl benzylate*
	F-18 fluorobenzyl-benzovesamicol	C-11 methyl-quinuclidinyl benzylate
	F-18 fluoroethoxybenzovesamicol	

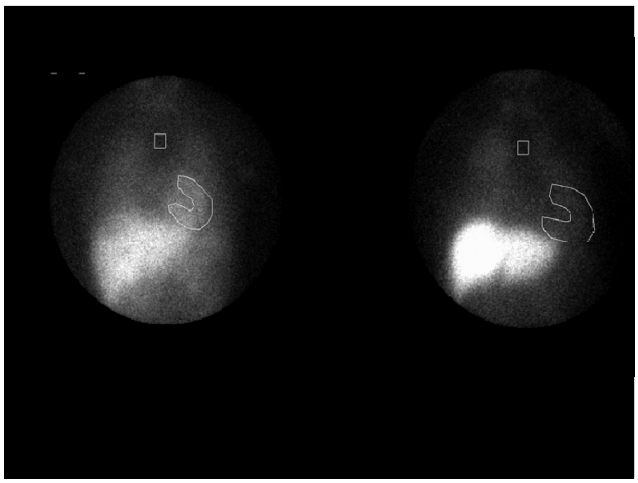
Italics denote SPECT radiotracers only. The remaining radiotracers are used in PET.

mIBG

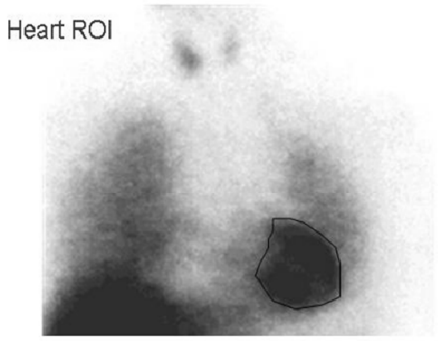
- Meta-iodobenzylguanidine : an analog of guanethidine
- Guanethidine is similar in structure to norepinephrine
- Once taken up into pre synaptic nerve terminal it competes for entry into vesicles
- Guanethidine – false neurotransmitter
- mIBG does not undergo metabolism

Heart to Myocardium ratio

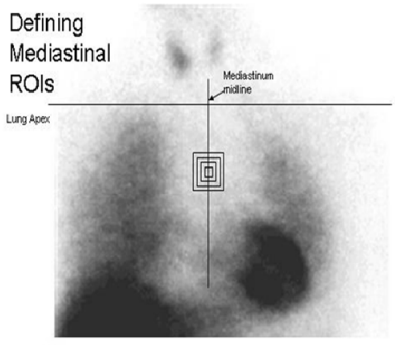
- Region of interests are drawn over the heart and the upper mediastinum in anterior image
- Mean counts in the mediastinum and the heart are calculated
- Ratio is derived from above
- Normal mean value is 2.2+/ 0.3
- What does it mean: reflects receptor density, integrity of presynaptic nerve terminals, ability to take up norepinephrine
- Normally ratio is high
- Lower ratio signifies disease (down regulation), clinical or subclinical



ADMIRE H/M protocol



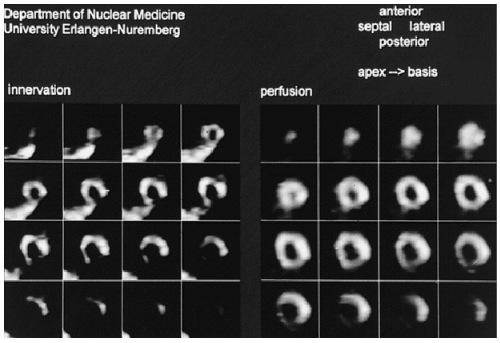
ADMIRE H/M protocol



Regional mIBG distribution and regional distribution of standard tracer

- **2 sets of images obtained**
- **SPECT mIBG images – extent and severity scored**
- **Either matched – denervation and perfusion images**
- **Or mismatched – denervation and perfusion**
- **Mismatched pattern could indicate more extensive denervation beyond perfusion**
- **Such areas shown to be more sensitive to catecholamines and may be prone to arrhythmias**

Innervation and perfusion images



□ Druschky et al. Journal of Autonomic nervous system 1999Z

ADMIRE-HF: Adreview Myocardial Imaging for Risk Evaluation in Heart Failure (MBG 311/312)

- □ **2 multicenter studies involving a total of 57 centers in USA, 35 centers in Europe, 4 centers in Canada (over 2-2½ yrs)**
  - **961 CHF patients available for analysis. MIMG enrollment 39**
- □ **Phase III trial to investigate clinical utility of ^{123}I-MIBG imaging in patients with Class II-III CHF, EF δ 35%.**

Jacobson et al. *J Nucl Cardiol* 2009;16:113-21.
Jacobson AF, Senior R, Cerqueira MD, Wong ND, Thomas GS, Lopez VA, Agostini D, Weiland F, Chandna H, Narula J. *JACC*; 2010 55(20):2212-21.

ADMIRE-HF: Adreview Myocardial Imaging for Risk Evaluation in Heart Failure (MBG 311/312) Cont'd

- □ **Primary endpoint**
  - **Correlate abnormally low H/M ratio (< 1.6) with adverse cardiac events:**
    - **Heart failure progression (II to III or IV, III to IV)**
    - **Potentially life-threatening arrhythmia (sustained VT, ICD discharge, aborted arrest)**
    - **Cardiac death**

Jacobson et al. *J Nucl Cardiol* 2009;16:113-21.
Jacobson AF, Senior R, Cerqueira MD, Wong ND, Thomas GS, Lopez VA, Agostini D, Weiland F, Chandna H, Narula J. *JACC*; 2010 55(20):2212-21.

ADMIRE-HF

- **Studies of mIBG H/M ratio have used**
  - **–early planar imaging**
  - **–late imaging - 4 hours**
  - **–washout or**
  - **–all three as endpoints**
- **As this was a phase 3 trial one key measurement was needed**
- **ADMIRE investigators selected the 4 hour endpoint which allows not only the assessment of mIBG by measuring the H/M ratio at 4 hours but also incorporates washout**
- **A normal washout is ≈ 9%. Thus, as washout increases the 4 hour H/M ratio will decrease**

Imaging Protocol

- 15 – 25 minutes: Anterior planar image (10')
- 25 minutes: SPECT (20')
- 3 hr 50 min – 4 hrs: Anterior planar image (10')
  Primary endpoint
- 4 hours: SPECT (20')
- On a different day: SPECT tetrofosmin perfusion
- 10 mCi I-123 MIBG administered over 1 – 2 minutes

Jacobson AF, Senior R, Cerqueira MD, Wong ND, Thomas GS, Lopez VA, Agostini D, Weiland F, Chandna H, Narula J. *JACC*; 2010 55(20):2212-21.

ADMIRE-HF trial

- Largest trial to date looking at Heart failure and MIBG
- Prospective evaluation of Heart failure patients to identify risk of cardiac events
- 961 patients with NYHA class II-III, LVEF < 35%, underwent initial MIBG imaging followed for a period of 2 years
- Time to progression of NYHA class, life threatening arrhythmia and cardiac death were end points
- 237 patients experienced events. Out of these patients, H/M ratio of 1.6 was used as cut off for stratifying events
- Two year composite event rate was 15% in the group with H/M ratio >1.6 and 37% in those with H/M ratio <1.6%
- 2 year probability of cardiac death 11.2% vs 1.8%
- 2 year probability of all cause mortality 16.1% vs 3%

Demographics and Clinical Characteristics

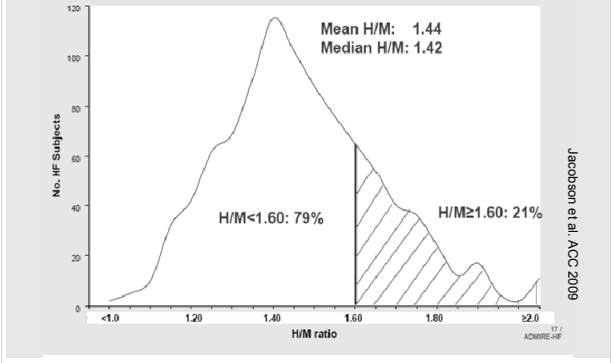
964 HF subjects were evaluable for efficacy.

Variable	Data	Range
Mean Age (yr)	62.4	20-90
Gender (M/F) (%)	80/20	-
Race (W/B/O) (%)	75/14/11	-
NYHA II/III (%)	83/17	-
HF Etiology (I/NI*) (%)	66/34	-
Mean LVEF (%)	27	5-35
Median Follow-up (mo)	17	0.1-27
2-year mortality rate (%)	12.8	-

*I=Ischemic; NI=Non-ischemic

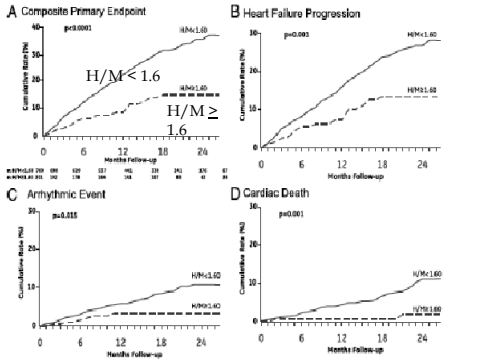
Jacobson et al. ACC 2009 ADMIRE-HF

Distribution of H/M ratios



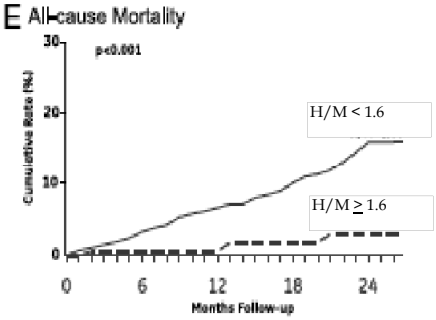
Jacobson et al. ACC 2009

ADMIRE-HF results



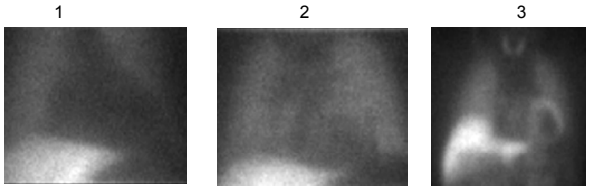
Jacobson AF, Senior R, Cerqueira MD, Wong ND, Thomas GS, Lopez VA, Agostini D, Weiland F, Chandna H, Narula J. JACC 2010;55(20):2212-21.

ADMIRE-HF all cause mortality



Jacobson AF, Senior R, Cerqueira MD, Wong ND, Thomas GS, Lopez VA, Agostini D, Weiland F, Chandna H, Narula J. JACC 2010;55(20):2212-21.

Three Patients with NYHA Class II HF and LVEF between 20 and 25%. Patient 1 has highly elevated BNP (>1000). BNP in patients 2 and 3 is normal (<100).



1	2	3
H/M=0.96	H/M=1.38	H/M=1.67
Died at 8 mo HF Progression	Died at 8 mo, SCD (No ICD)	No event

Based upon the results of ADMIRE-HF, 2-year cardiac mortality risk for patient 1 is 10 times that of patient 3.

ADMIRE-HF
Jacobson et al. ACC 2009

NC Community Preparation

- Acquisition and Reporting Standards
- Appropriate Use Criteria
- Lab Accreditation
- Educational Seminars
  - Clinical
  - Radiopharmaceutical

Acronyms

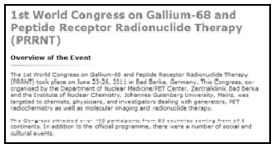
ADMIRE HF: adreview myocardial imaging for risk evaluation in heart failure
CHF: congestive heart failure
EF: ejection fraction
H/M: heart to mediastinal
I-123 BMIPP: iodine-123 labeled beta-methyl-p-iodophenyl-pentadecanoic acid
I-123 IPPA: iodine-123-phenylpentadecanoic acid
ICD: implantable cardioverter defibrillator
ICRP: International Commission on Radiological Protection
LVEF: left ventricular ejection fraction
mIBG: meta-iodobenzylguanidine
NE: norepinephrine
NET-1: norepinephrine transporter 1
NC: nuclear cardiology
NYHA: New York Heart Association
SPECT: single-photon emission computed tomography
VT: ventricular tachycardia

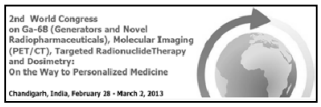
Germanium-68/Gallium-68 Generators

Pat Zanzonico, PhD, DABR
ACMUI

Acknowledgment: **Steven Mattmuller, ACMUI**

Germanium-68 (^{68}Ge)/Gallium-68 (^{68}Ga) Generators





Widespread growth in clinical applications of ^{68}Ga and of radionuclide Tx of SSTR-over expressing tumors - largely outside US

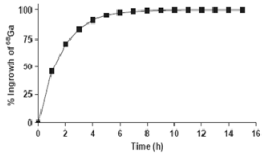
Outline

- **Physical properties**
- **Radiochemistry**
- **Clinical applications**
- **Radiation safety**
- **Regulatory issues**
- **Concluding remarks**

Physical Properties

Secular equilibrium:

^{68}Ge - $T_{1/2}$: 287 d; Decay mode: EC (100%) + <10-keV x-rays →
^{68}Ga - T1/2: 68.1 m; Decay mode: β+ (89%) + ~1-MeV γs (3%)

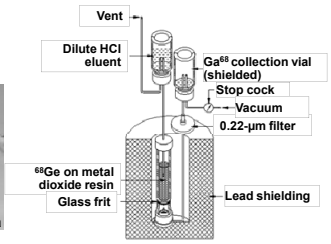


- **10-50 mCi ^{68}Ge per generator**
- **No-carrier-added ^{68}Ga → High-specific activity (low-mass dose) tracers**
- **2-10 patients per day**
  - **5 mCi per patient**
  - **2 elutions per day**
  - **50% radiochemical yield**

  $5-10 per patient
- **~2-year useful life**
- **~$30K**

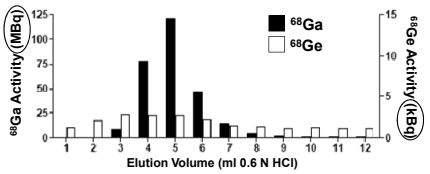
Physical Properties cont

Extra shielding for ^{68}Ga 511-keV annihilation γs + ~1-MeV γs (3%)



Physical Properties cont

^{68}Ga Elution



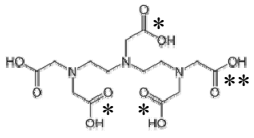
In 4-6 ml elutant:
- **~90% of ^{68}Ga**
- **~0.0025% ^{68}Ge breakthrough**
  - ***Radioassay of elutant 1-2 d post-elution***
  - ***Cation exchange chromatography immediately post-elution***

Breeman et al. Eur J Nucl Med Mol Imaging 32: 478, 2005

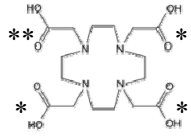
Radiochemistry

- **Gallium: Trivalent (+3) metal ≈ Indium**
- **Stably bound by bifunctional polydentate chelates**

** Protein/peptide binding
* Metal binding



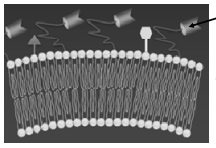
DTPA: Linear (open) chelate



DOTA: Cyclic (closed) chelate

Radiochemistry cont

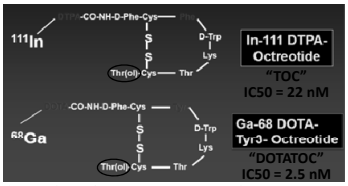
Overexpressed on neuroendocrine tumors, neuroblastomas etc



Tumor-cell membrane

O'Dorisio. Society of Nuclear Medicine, 1/25/13, New Orleans, LA

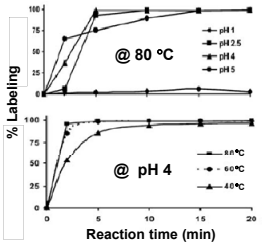
Radiochemistry cont



O'Dorisio. Society of Nuclear Medicine, 1/25/13, New Orleans, LA
Reubi et al. Eur J Nucl Med 27: 273, 2000

DOTATATE = DOTA + Octreotate

C-terminal threoninol replaced w/ threonine



Breeman et al. Eur J Nucl Med Mol Imaging 32: 478, 2005

Radiochemistry cont

Radiochemical Synthesis Modules

Rapid, automated preparation of ^{68}Ga radiopharmaceuticals

Clinical Applications : Detection & Characterization and Staging

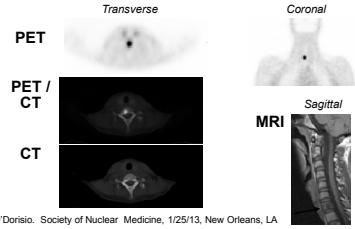
Sensitivity: 97% *
Specificity: 92%
Accuracy: 96%

vs 63% for ^{18}F-FDG PET

"^{68}Ga-DOTATOC-PET showed a significantly higher detection rate compared with conventional somatostatin receptor scintigraphy (OctreoScan) and diagnostic CT with clinical impact in a considerable number of patients."

Gabriel et al. J Nucl Med 48: 508, 2007

Re-staging 16 yo with small-bowel NET using ^{68}Ga-DOTATOC PET/CT and MRI



O'Dorisio. Society of Nuclear Medicine, 1/25/13, New Orleans, LA

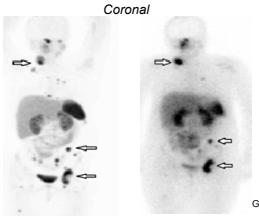
Clinical Applications cont: Personalized Medicine - Theranostics and Tx Planning

Child w/ Relapsed Neuroblastoma

Dx

^{68}Ga-DOTATATE PET

- **ID treatable tumors**
- **Lesion dosimetry**



Tx

^{177}Lu-DOTATATE SPECT

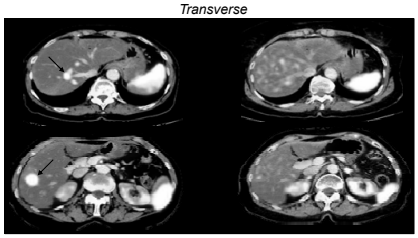
200 mCi

Gains et al. J Nucl Med 52: 1041, 2011

Clinical Applications cont: Tx Monitoring

^{68}Ga-DOTATATE PET/CT

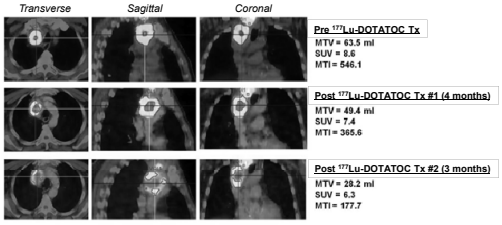
Transverse



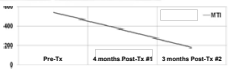
Courtesy of Dr. Wolfgang Weber

Clinical Applications cont : Quantitiative Tx Monitoring

^{68}Ga-DOTATOC PET/CT



Molecular Tumor Index (MTI) = Standard Uptake Value (SUV) x Molecular Tumor Volume (MTV)



Baum and Kilkarni. Theranostics 2: 437, 2012

Clinical Applications cont

Comparison of ^{111}In-DTPA-TOC and ^{68}Ga-DOTA-TOC

	^{111}In-DTPA-TOC	^{68}Ga-DOTA-TOC
Modality	**SPECT**	**PET**
Spatial Resolution	**15 mm**	**5 mm**
Activity Quantitation	**Semi-quantitative**	**Accurate**
Binding Affinity, IC50	**22 nM**	**2.5 nM**
Radiation Dose to Patient	**2.6 rem**	**0.4 rem**
Logistics	**2-day procedure, multiple visits**	**1-day procedure, single visit**

Clinical Applications cont - ^{68}Ga Radiopharmaceuticals

Radiopharmaceutical	1st Use in Man	Mechanism	Clinical Application
DOTATOC etc	7/2004	SSTR targeting	NETs, neuroblastomas etc
Gastrin	12/2006	Gastrin peptide targeting	Medullary carcinoma of thyroid
AMBA	8/2006	Bombesin analog - GRP & NMB receptor targeting	Breast, prostate, & colon cancer
Tyrosine	8/2008	Amino acid uptake	Gliomas
BPAMD	2/2009	Bisphosphonate - Binding to bone crystal	Skeletal metastases
MAA	9/2008	Pulmonary perfusion – Embolic trapping	Pulmonary emboli
Glucose	5/2009	Tumor hypermetabolism	FDG-avid tumors
Demobesin	7/2009	GRP receptor targeting	Breast, prostate, & colon cancer
MSH	5/2009	Melanocyte cell-surface receptor targeting	Melanoma
Sarabesin-6	8/2011	GRP receptor targeting	Breast, prostate, & colon cancer
RGD	9/2011	$\alpha_v\beta_3$-Integrin targeting	Neoangiogenesis - Various tumors
Her2 affibody	12/2005	HER-2 targeting	Breast cancer
SHAL	5/2010	Selective high-affinity ligand	B-cell Lymphoma

Baum and Kilkarni. Theranostics 2: 437, 2012

Radiation Safety

- **^{68}Ge/^{68}Ga already widely used for PET QC and calibration - as 10- to 20-mCi sealed sources**
- **Generators: 10 to 50 mCi** vs ~1,000 mCi for ^{99}Mo-^{99m}Tc generators
- **Exposure rate @ surface: 0.5 mR/h per mCi ^{68}Ge (shielded) 10 mR/h for 20-mCi generator**
- **Transport Index: ≤ Yellow II**

Radiation Safety cont

- **"Heavy" additional shielding important**
- **Patients: ~5 mCi administered activity, <1 rem effective dose** } **< ^{18}F-FDG**
- **^{68}Ga $T_{1/2}$ ≈ 1 h → Contamination issues minimal**

∴ **Manageable in manner consistent with radiation safety practices in typical Nuclear Medicine and PET facilities**

Regulatory Considerations - Disposal / De-commissioning, 10 CFR 30 (2010)

§ 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 (DFP) as described in paragraph (e) of this section.

Appendix B to Part 30

- ^{68}Ge *not* listed
- Any radionuclide other than alpha emitting radionuclides not listed…0.1 μCi
- 10^5 x 0.1 μCi = 10^4 μCi = 10 mCi → ≥ 10-mCi ^{68}Ge / ^{68}Ga generator requires DFP

Regulatory Considerations - Disposal / De-commissioning cont

§ 30.35 (e) Each DFP must contain a cost estimate for de-commissioning and a description of the methods of assuring funds for de-commissioning…

- Surety method 1: Pre-payment (CD), Bond, Line of credit etc
- Surety method 2: Self-guarantee → Financial-test criteria *eg* Net worth ≥ $50M *or* 30X total de-commissioning cost for university w/o bonds
- Not problematic for large hospitals, universities; Potentially onerous for smaller facilities
- Regulatory relief

Concluding Remarks

- Generator-produced ^{68}Ga and chelation chemistry may extend applicability of PET far more widely
  - ^{68}Ge/^{68}Ga generator (^{68}Ge $T_{1/2}$: 287 d; ^{68}Ga $T_{1/2}$: 68.1 m) can be used for up to 2 y and eluted every 4 h
  - Ready supply of inexpensive, rapidly produced, high-specific activity PET tracers
  - Short ^{68}Ga $T_{1/2}$ compatible w/ targeting kinetics of peptides and other small-molecule tracers and w/ favorable patient dosimetry
- ^{68}Ga radiopharmaceuticals important in Dx and personalized Tx of NETs and, potentially, many other cancers

Concluding Remarks cont

- Radiation safety issues for ^{68}Ge/^{68}Ga generators and ^{68}Ga radiopharmaceuticals manageable w/ current best practices
- Regulatory relief for smaller facilities from onerous financial requirements related to generator disposal/de-commissioning
  → Expand Appendix B to Part 30: ≥ 1-μCi entry for ^{68}Ge
  ∴ DFP *not* required for up to 100-mCi ^{68}Ge/^{68}Ga generator

Abbreviations and Acronyms

AMBA	DO3A-CH_2CO-G-[4-amino-benzoyl]-QWAVGHLM-NH_2
ACMUI	Advisory Committee on Medical Uses of Isotopes
BPAMD	Bisphosphonate
C	Carbon
CD	Certificate of deposit
CFR	Code of Federal Regulations
CT	Computed tomography
D	Day
DFP	De-commissioning funding plan
DOTA	Tetraazacyclododecane-tetraacetic acid
DOTANOC	DOTA-1-Nal^3-octreotide
DOTATATE	Tetraazacyclododecane-tetraacetic acid octreotate
DOTATOC	Tetraazacyclododecane-tetraacetic acid-octreotide
DTPA	Diethylene triamine pentaacetic acid
Dx	Diagnosis
EC	Electron capture
eg	For example
^{18}F	Fluorine-18
FDG	Fluoro-deoxyglucose
^{68}Ga	Gallium-68
^{68}Ge	Germanium-68
GRP	Gastrin-releasing peptide
H	Hour
HCl	Hydrochloric acid
HER2	Human epidermal growth factor receptor 2
IC50	50% Inhibitory concentration
M	Minutes
MAA	Macroaggregated albumen
^{99}Mo	Molybdenum-99
MRI	Magnetic resonance imaging
MSH	Melanocyte-stimulating hormone
NMB	Neuromedin B
NET	Neuroendocrine tumor
NRC	Nuclear Regulatory Commission
PET	Positron emission tomography
QC	Quality control
RGD	Arginylglycylaspartic acid
SHAL	Selective high-affinity ligand
S&P	Standard & Poor's
SPECT	Single-photon emission computed tomography
SST	Somatostatin
SSTR	Somatostatin receptor
^{99m}Tc	Technetium-99m
TOC	Octreotide
Tx	Therapy
Y	Year
yo	Year-old

Next Steps towards Revising Radiation Protection Regulations

Don Cool, Ph.D.
FSME/DILR

September 10, 2013

History

- ICRP Recommendations announced December, 2007
- Initial Staff Recommendations – SECY-08-0197, December 2008
- Staff Recommendations for direction – SECY-12-0064, April 25, 2012
- Commission Direction SRM-SECY-12-0064, December 17, 2012
- The Commission approved in part, and disapproved in part, the staff's recommendations

Areas of Work

- Updated Methodology and Terminology
- Part 20 (Standards for Protection Against Ionizing Radiation) Technical Issues
- Part 50, Appendix I (Numerical Guidelines for Design Objectives to meet ALARA) Technical Issues
- Conforming Changes to other portions of the Regulations

Overarching Questions to Address

- Cumulative effects of regulation
- Regulatory impact
- State implementation

Updated Methodology and Terminology

- Commission Direction:
  - Develop a regulatory basis for a revision to 10 CFR Part 20 to align with the most recent methodology and terminology for dose assessment.
- Proposal:
  - TEDE becomes TED
  - New W_T and W_R values incorporated into definitions
  - Appendix B revised with new ALI and DAC values

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Updated Methodology and Terminology

- Issues:
  - Mathematical vs. Voxel Phantoms
    - Coherence of EPA, DOE, NRC approaches
  - Calculation for "member of the public" using age and gender weighted composite
  - Target dose for effluents at 0.5 mSv (50 mrem) or change?
  - Time frame for calculations to be available

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Updated Methodology and Terminology

- Key Questions:
  - What are the implications of terminology change? Specific costs?
  - What would be an appropriate implementation time frame and approach to transition of terminology?
  - How should the calculations of effluent concentration be modified to reflect advances in modeling that are now available? Views on age and gender weighted composite?
  - What dose level should used for effluent concentrations to demonstrate compliance?

7

Individual Protection - ALARA

- Commission Direction:
  - TEDE limit to remain at 50 mSv (5 rem)
  - Continue discussions with stakeholders on alternative approaches to deal with individual protection at or near the current effective dose limit.
  - Improve ALARA guidance
- Objective:
  - Regulatory Requirements and guidance that will ensure that cumulative exposures are examined, and that progressive restrictions can be taken as cumulative exposures increase.

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Individual Protection Proposals

- Require ALARA planning
- Require mechanism(s)s to examine cumulative exposure, and take progressive restrictions on the occupational exposure allowed as cumulative exposures increase.
  - Require licensees to establish one or more administrative control levels (ACL) as part of their radiation protection program and to establish specific procedures for individual protection.
- Require licensees be provided with record of all other concurrent sources of occupational exposure

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Acceptable Approaches

- ACL 20 mSv per year
- ACL average 20 mSv over 5 year period (ICRP-103)
- ACL 10 (mSv) x N (age) (NCRP-116)
- ACL to restrict individuals to 20 mSv if cumulative exposure exceeds xxx mSv
- Other Options

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Individual Protection Questions

- What are the implications of a more structured framework for ALARA planning and implementation in the regulations? What changes to programs would be anticipated?
- How might each approach work for different classes of licensed use?
- Should licensees be allowed to establish different ACL's for different groups of individuals?
- How do the different options for guidance support, or impact, the ability of licensees to best address protection within their programs. Are there other options that could be considered?

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Individual Protection Questions

- Are there other mechanisms to look at cumulative exposures?
- What would be the impact of clarifying amendments to ensure that occupationally exposed individuals provide their exposure to each licensee under which they may be concurrently receiving exposure?
- Should States be allowed to use more restrictive or prescriptive requirements if NRC decides to use performance based approach?

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Lens of the Eye

- Commission Direction:
  - Continue discussions with stakeholders regarding possible revisions to the dose limit (150 mSv (15 rem)) for the lens of the eye
- Proposal:
  - Reduction to 50 mSv (5 rem) LDE

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Lens of the Eye

- Key Questions:
  - Is the proposal appropriate given the information available?
  - Are there alternatives to keep cumulative exposure below threshold?
  - Viewpoints on the relative importance of health endpoint?
  - What methods should be allowed for measurement or assessment?
  - What methods should be allowed for recording dose when eye is protected?
  - What is impact on licensee activities? State regulatory programs?

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Embryo/Fetus

- Commission Direction:
  - Continue discussions with stakeholders regarding possible revisions to the dose limit (5 mSv (0.5 rem)) for embryo/fetus
- Proposal:
  - Reduction to 1 mSv (0.1 rem)

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Embryo/Fetus

- Key Questions:
  - Apply to post declaration or entire gestation period?
  - What should be done if 1 mSv has already been reached at declaration?
  - Continue to require efforts to avoid substantial variation above a uniform monthly exposure rate?
  - What methods should be allowed for measurement or assessment?
  - What is impact on licensee activities? State regulatory programs?

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Traditional vs. SI Units

- Commission Direction:
  - Disapproved the elimination of traditional units from NRC regulations. Both traditional and SI units should be maintained.
- Proposal:
  - Implement Commission Policy Statement – SI first, traditional in parenthesis

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Traditional vs. SI Units

- Key Questions:
  - What is the impact of changing order of presentation to SI first, traditional in parentheses?
  - Should Appendix B be given in SI, or traditional, or both?
  - Should licensees be allowed to report in SI?
  - How do we avoid confusion?
  - What is impact on licensee activities? State regulatory programs?

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Reporting of Occupational Exposure

- Commission Direction:
  - Improve reporting of occupational exposure by NRC and Agreement State licensees, some of which do not currently submit reports.
- Proposal:
  - Add categories of licensed use: e.g., Part 35
  - Modify requirements for compatibility
  - Explore mechanisms for central repository of data for all to use.

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Reporting of Occupational Exposure

- Key Questions:
  - Are the reasons for reporting now valid for other categories of licensees?
  - What categories should be added, and why?
  - What are health and safety, and/or trans-boundary considerations?
  - Should Agreement States be required to adopt reporting requirements? Rationale? Adequacy and Compatibility level?
  - How might States incorporate exposure from machine produced radiations?
  - What is impact on licensee activities? State regulatory programs?

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Next Steps

- **Engage Federal Agencies, States, licensees, and with public stakeholders on each of the topics.**
- **Develop Federal Register Notice with specific proposed options and questions.**
  - **Plan to publish for input**
  - **Possibility of webinar(s)**
  - **All comments to be docketed**
  - **Further opportunities for comment with more specific proposals.**

http://www.nrc.gov/about-nrc/regulatory/rulemaking/potential-rulemaking/opt-revise.html

Status of Revisions to NUREG-1556, Volume 9

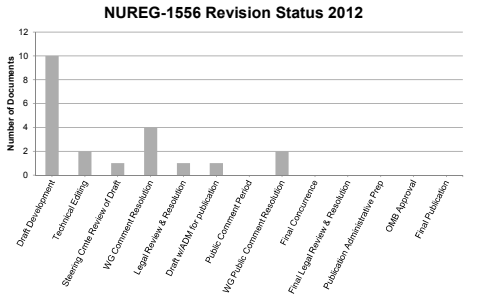
Consolidated Guidance About Materials Licenses
Program-Specific Guidance About Medical Use Licenses

September 10, 2013

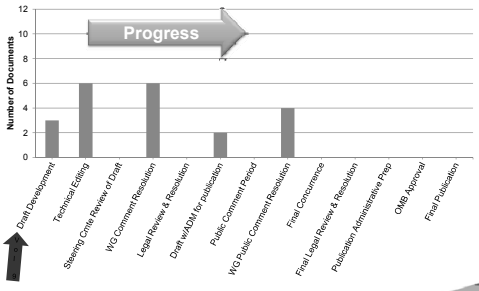
Ashley Cockerham, Health Physicist
Donna-Beth Howe, Ph.D., Health Physicist
Medical Radiation Safety Team

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

NUREG 1556 Updates



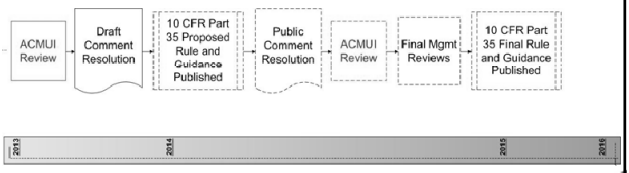
NUREG 1556 Updates



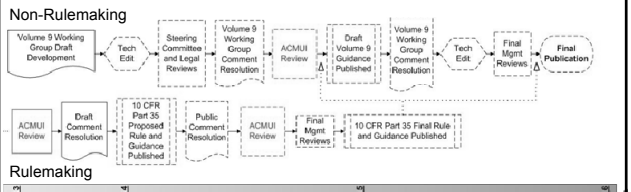
Working Groups

- Volume 9 (Non-Rulemaking)
  - Mary Burkhart
  - Ashley Cockerham
  - Jackie Cook
  - Penny Lanzisera
  - Toye Simmons
- Volume 9 Rulemaking
  - Said Daibes
  - Sandra Gabriel
  - Donna-Beth Howe
  - Ronald Zelac

Volume 9 Rulemaking Timeline



Volume 9 Combined Timeline



Questions?

Special Presentation to Dr. Van Decker

NO HANDOUT

April 2014

Sunday	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday
		1 X	2 X	3 X	4 X	5 X
6 X	7 X	8 X	9 X	10 X	11 X	12 X
13 X	14 X	15 Pesach (Passover)	16 Pesach (Passover)	17 Pesach (Passover)	18 Pesach (Passover)	19 Pesach (Passover)
20 Pesach (Passover)	21 Pesach (Passover)	22 Pesach (Passover)	23 X	24 X	25 X	26 ACR Annual Meeting
27 ACR Annual Meeting	28 ACR Annual Meeting	29 ACR Annual Meeting	30 ACR Annual Meeting			

May 2014

Sunday	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday
				1 X	2 X	3 X
4 X	5	6	7	8	9	10 X
11 X	12	13	14 X	15 X	16 X	17 X
18 X	19 46th National Conference on Radiation Control	20 46th National Conference on Radiation Control	21 46th National Conference on Radiation Control	22 46th National Conference on Radiation Control	23 X	24 X
25 X	26 Memorial Day	27 X	28 X	29 X	30 X	31 X