MEETING AGENDA
ADVISORY COMMITTEE ON THE MEDICAL USES OF ISOTOPES

March 17-18, 2016
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, March 17, 2016 CLOSED SESSION		
7:30 – 9:30	• **Badging and Enrollment**	**ACMUI**
OPEN SESSION		
9:30 – 11:30	• **Commission Briefing** The ACMUI will participate in a public meeting with the Commission.	**ACMUI**
	• **Group Photo** The ACMUI will take a group photo with the Commission.	**ACMUI**
11:30 – 1:00	**LUNCH**	
1:00 – 2:30	• **Opening Remarks** Mr. Bollock will formally open the meeting and Mr. Collins will provide opening comments.	**D. Bollock, NRC** **D. Collins, NRC**
	• **Old Business** Ms. Holiday will review past ACMUI recommendations and provide NRC responses.	**S. Holiday, NRC**
	• **Open Forum** The ACMUI will identify medical topics of interest for further discussion.	**ACMUI**
	• **Medical Related Events** Dr. Howe will provide the latest update on medical-related events.	**DB. Howe, NRC**
2:30 – 3:00	**BREAK**	
3:00 – 5:00	• **Medical Event Reporting for All Modalities Excluding Permanent Implant Brachytherapy** Dr. Suh will discuss the subcommittee's comments on the reporting of medical events.	**J. Suh, ACMUI**
	• **NUREG-1556, Volume 9 Update** Dr. Tapp will provide an update on the proposed revisions to NUREG-1556, Volume 9, "Consolidated Guidance About Materials Licenses."	**K. Tapp, NRC**
	• **Committee Reporting Structure** Members will discuss the reporting structure of the Committee and provide feedback to NRC staff.	**S. Holiday, NRC**
	• **Status Update for Yttrium-90 Microspheres Brachytherapy Licensing Guidance** Dr. Tapp will provide an update on the proposed revisions to the Y-90 licensing guidance.	**K. Tapp, NRC**
Friday, March 18, 2016 CLOSED SESSION		
7:30 – 8:30	• **Enrollment of HSPD-12 Badges**	**ACMUI**

OPEN SESSION

8:00 – 10:30	• **Staff Response to OIG Audit of NRC's Oversight of Medical Uses of Nuclear Material** Mr. Bollock will discuss staff actions in response to the OIG Audit Report issued on October 08, 2015.	**D. Bollock, NRC**
	• **Leksell Gamma Knife Icon Licensing Guidance** Ms. Holiday and Mr. Perry will provide an overview of the 10 CFR 35.1000 licensing guidance drafted by an NRC/OAS working group.	**S. Holiday, NRC** **E. Perry, KY**
	• **Germanium-68/Gallium-68 Medical Use Generator Update** Dr. Daibes will provide an update on staff's efforts to address the decommissioning funding issues related to the germanium/gallium-68 medical use generator	**S. Daibes, NRC**
	• **Special Presentation to Mr. Mattmuller** Mr. Moore will make a special presentation to Mr. Mattmuller.	**S. Moore, NRC**
	• **Thoughts on Leaving the ACMUI** Mr. Mattmuller will provide his farewell remarks to the Committee and to staff.	**S. Mattmuller, ACMUI**
10:30 – 10:45	**BREAK**	
10:45 – 11:30	• **Open Forum** The ACMUI will discuss medical topics of interest previously identified.	**ACMUI**
	• **Administrative Closing** Ms. Holiday will provide a meeting summary and propose dates for the spring 2016 meeting.	**S. Holiday, NRC**
11:30	**ADJOURN**	

CLOSED SESSION

12:00 – 1:00	• **Training on NRC Rules, Guidance and Generic Communications Development** Ms. Houseman will provide training to the members related to each of these processes.	**E. Houseman, NRC**

Badging and Enrollment

NO HANDOUT

Commission Briefing

NO HANDOUT

Group Photo

NO HANDOUT

Open Forum

NO HANDOUT

	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

	ITEM	DATE	STATUS	
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*

	ITEM	DATE	STATUS	
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*

	ITEM	DATE	STATUS	
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
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

	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	
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

	ITEM	DATE	STATUS		1st/2nd	Vote
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
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	Closed	Guiberteau/Mattmuller	11,0,1

	ITEM	DATE	STATUS		1st/2nd
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	
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	
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	

	ITEM	DATE	STATUS		1st/2nd
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
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
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

	ITEM	DATE	STATUS		1st/2nd
10	ACMUI recommended licensee reporting of out-of-tolerance generator breakthrough results to the NRC	3/12/13	NRC Action	Open	Zanzonico/Weil
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	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
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	
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
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

	ITEM	DATE	STATUS		Assigned	1st/2nd	Vote
6	Dr. Thomadsen formed a subcommittee on May 8, 2014 to provide staff with the background information to justify the recommendation for the regulatory relief from the DFP of Ge-68. The subcommittee is specifically charged with evaluating the cost of a DFP for the use of Ge-68, its effect on the future clinical use of new Ga-68 radiopharmaceuticals and how appropriate regulatory relief may be gained. Subcommittee members include Mr. Mattmuller (chair), Dr. Langhorst, Mr. Costello, Dr. Palestro and Dr. Zanzonico.	5/8/14	ACMUI Action	Open	S. Holiday		
10	The ACMUI recommended that the total treatment activity of yttrium-90 microspheres to be administered should be the required compliance measure for organs and tissues other than the treatment site.	9/29/14	NRC action	Closed	K. Tapp		13,0,0
11	The ACMUI recommended that the implantation of the microsphere brachytherapy sources is considered to be in accordance with the written directive if the total administered/infused activity does not vary from the activity prescribed in the written directive by 20% or more; except in situations in which the activity administered is limited by the termination of procedure due to stasis.	9/29/14	NRC action	Closed	K. Tapp		13,0,0
12	The ACMUI recommended that (a) these recommendations be incorporated into the NRC guidance for yttrium-90 microsphere brachytherapy and that (b) the NRC staff, in consultation with ACMUI, compose and disseminate explanation of these recommended revisions in a manner best suited to both the NRC as well as to AUs and other stakeholders tasked with compliance.	9/29/14	NRC action	Closed	K. Tapp		13,0,0

	ITEM	DATE	STATUS		Assigned	1st/2nd	Vote (Y/N/A)
7	The ACMUI recommended that events reportable under 10 CFR 35.3047 that do not result in harm to the embryo/fetus/or nursing child not be captured as AO's reported to Congress.	03/20/2015	ACMUI Action	Open		Langhorst/Costello	11, 0, 1
9	Dr. Thomadsen created a subcommittee to evaluate if the required 700 hours for training and experience for authorized users of alpha and beta emitters places hardship on the patient community. If so, the subcommittee should make recommendations for potential changes (rulemaking). Subcommittee members include: Dr. Dilsizian, Dr. Ennis, Dr. Langhorst, Dr. Palestro (Chair), Ms. Weil, and Dr. Zanzonico. The subcommittee will present their draft report at the fall 2015 ACMUI Meeting scheduled to take place on October 8-9, 2015, at NRC Headquarters.	06/16/15	ACMUI Action	Closed	S. Holiday		
12	The ACMUI recommended to make the following change to the Patient Intervention Subcommittee Recommendation Issue II: Unintentional Treatment outcome due to anatomic or physiologic anomaly ~~and/or imaging uncertainty~~ falls into the category “the Art of Medical Practice” provided that the standards of medical practice are met.	10/8/15	ACMUI Action	Open	S. Holiday	Alderson/Palestro	10, 0, 1
13	The ACMUI endorsed the Patient Intervention Subcommittee Report with the modification to Issue II (listed in item 12 above).	10/8/15	ACMUI Action	Open	S. Holiday	Costello, Alderson	10, 1, 0
14	Dr. Thomadsen requested that staff provide an update at the Spring 2016 ACMUI Meeting on staff response/action to the Patient Intervention Subcommittee Report.	10/8/15	NRC Action	Open			
15	The ACMUI recommended that staff issue a Generic Communication (i.e. Information Notice or Regulatory Issue Summary) to licensees to inform them of the interpretation of "patient intervention."	10/8/15	NRC Action	Open			

	ITEM	DATE	STATUS		Assigned	1st/2nd	Vote (Y/N/A)
16	Dr. Thomadsen charged the Training and Experience (T&E) for Alpha and Beta Emitters Subcommittee with establishing a recommendation for the total number of hours of T&E for authorized users of such emitters, that is necessary for safety.	10/8/15	ACMUI Action	Open			
17	Dr. Ennis recommended that the individual who implants the source for radioactive seed localization be the authorized user only - and not an individual under the supervision of an authorized user. [*Note: the motion did not pass*]	10/8/15	ACMUI Action	Closed		Ennis, Costello	2, 8, 1
18	The ACMUI recommended that the individual who implants the source for radioactive seed localization procedures can do so under the supervision of an authorized user.	10/8/15	ACMUI Action	Open			
19	The ACMUI endorsed the Radioactive Seed Localization Subcommittee Report.	10/8/15	ACMUI Action	Open			11, 0, 0
20	The ACMUI endorsed the Yttrium-90 Microspheres Subcommittee Report.	10/8/15	ACMUI Action	Closed			11, 0, 0
21	The ACMUI have planned the Spring 2016 Meeting for March 17-18, 2016. The back-up date is March 3-4, 2016.	10/9/15	ACMUI Action	Closed			
22	The ACMUI endorsed the 2015 Abnormal Occurrence Criteria Subcommittee Report with the caveat that the report be amended to include an introductory paragraph that provides the rationale for the recommendations, as well as a summary paragraph to state that the Committee desires that the recommendations be incorporated into this revision of the NRC's Abnormal Occurrence Criteria Policy Statement.	10/9/15	ACMUI Action	Open			10, 1, 0
23	The ACMUI endorsed the NUREG-1556, Volume 9 Subcommittee Report.	10/9/15	ACMUI Action	Open			11, 0, 0

	ITEM	DATE	STATUS		Assigned	1st/2nd	Vote (Y/N/A)
24	Dr. Thomadsen formed a subcommittee to propose the appropriate criteria for Medical Event Reporting for events other than permanent implant brachytherapy. Subcommittee members include: Dr. Dilsizian, Dr. Ennis, Mr. Ouhib, Dr. Palestro, Dr. Suh (Chair), and Dr. Zanzonico. The subcommittee will present its recommendations at the Spring 2016 meeting.	10/9/15	ACMUI Action	Open			

	ITEM	DATE	STATUS		Assigned	1st/2nd	Vote (Y/N/A)
1	The Committee endorsed that component of the current proposed rule re-defining medical events in permanent implant brachytherapy in terms of activity (i.e. source strength) rather than radiation dose).	01/06/2016	NRC Action	Open			10, 0, 0
2	The Committee endorsed, with reservation, designating the current proposed rule re-defining medical events in permanent implant brachytherapy as Compatibility Category C, with activity-based medical event metrics defined as an essential program element.	01/06/2016	NRC Action	Open			10, 0, 0
3	The Committee recommended changing the language for a "wrong-location" medical event in permanent implant brachytherapy from the current proposed language, "Sealed source(s) implanted directly into a location where the radiation from the source(s) will not contribute dose to the treatment site, as defined in the written directive," to **"Sealed source(s) implanted directly into a location discontiguous from the treatment site, as defined in the written directive."**	01/06/2016	NRC Action	Open			10, 0, 0
4	The Committee recommended revising the passage in lines 4182-4186 on page 167 in the Draft Final Rule as follows, thereby eliminating the dose-based criteria for a leaking source" medical event: **"3) An administration that includes the wrong radionuclide; the wrong individual or human research subject; a leaking sealed source; or a sealed source or sources implanted into a location discontiguous from the treatment site, as defined in the written directive."**	01/06/2016	NRC Action	Open			10, 0, 0
5	The Committee endorsed the elimination of the preceptor-statement requirement for Board-certified individuals for an individual seeking regulatory authorization as an authorized user, authorized medical physicist, Radiation Safety Officer, or authorized nuclear pharmacist.	01/06/2016	ACMUI Action	Closed			10, 0, 0

	ITEM	DATE	STATUS		Assigned	1st/2nd	Vote (Y/N/A)
6	With respect to the amended requirements for preceptor attestation for an individual seeking regulatory authorization as an authorized user, authorized medical physicist, Radiation Safety Officer, or authorized nuclear pharmacist through the alternate pathway, the Committee endorsed changing the language for the preceptor attestation from the individual "…has achieved a level of competency to function independently…" for the authorization to **the individual can "…independently fulfill the radiation safety-related duties…" associated with the authorization being requested.**	01/06/2016	NRC Action	Open			10, 0, 0
7	The Sub-Committee recommended that the date of recognition by the NRC of a certifying board should not impact individuals seeking to be named as an authorized user, authorized medical physicist, Radiation Safety Officer, or authorized nuclear pharmacist through the certification pathway. During the discussion, this recommendation was modified in the final report as follows: **The Sub-Committee recommends that NRC Staff consider providing guidance in the NUREG-1556, Volume 9 update to licensees on the ways individuals with board certifications prior to NRC's board recognition date may seek authorization.**	01/06/2016	NRC Action	Open			10, 0, 0
8	The Committee recommended that the NRC adopt the parent-breakthrough limits for radioisotope generators specified in the relevant Food and Drug Administration (FDA)-approved package inserts. During the discussion, the Committee recommended to eliminate this recommendation and instead, revise the general comments section of the report to suggest that NRC consider, in future rulemaking, establishing conformity with the FDA breakthrough-limit regulations.	01/06/2016	NRC Action	Open			9, 1, 0
9	The Committee did not endorse the new requirement in the Draft Final Rule that licensees report to the NRC as well as to the manufacturer/vendor generator elutions with out-of-tolerance parent-breakthrough but, instead, recommends a single reporting requirement to the manufacturer/vendor.	01/06/2016	NRC Action	Open			10, 0, 0

	ITEM	DATE	STATUS		Assigned	1st/2nd	Vote (Y/N/A)
10	The Committee endorsed allowing Associate Radiation Safety Officers (ARSO) to be named on a medical license.	01/06/2016	NRC Action	Open			10, 0, 0
11	The Committee recommended that the designation of a board-certified authorized user, authorized medical physicist, or authorized nuclear pharmacist as the Radiation Safety Officer (RSO) or as an ARSO requires their board certification to include the designation, "RSO Eligible."	01/06/2016	NRC Action	Open			10, 0, 0
12	The Committee did not endorse establishing a separate category of Authorized Users for parenteral administration of alpha-emitting radiopharmaceuticals but, instead, recommends deleting § 35.390(b)(1)(ii)(G)(4) in the current Draft Final Rule and revising the pertinent passage in § 35.390(b)(1)(ii)(G)(3) as follows, **"Parenteral administration of any radioactive drug for which a written directive is required."**	01/06/2016	NRC Action	Open			10, 0, 0
13	The Committee endorsed the elimination of the requirement to submit copies of NRC Form 313, Application for Material License, or a letter containing information required by NRC Form 313 when applying for a license, an amendment, or renewal.	01/06/2016	NRC Action	Open			10, 0, 0

	ITEM	DATE	STATUS		Assigned	1st/2nd	Vote (Y/N/A)
14	The Sub-Committee recommended changing the "medical-events" language in lines 5531-5532 (page 232) of the Draft Final Rule from, "A licensee shall report as a medical event, any administration requiring a written directive, except for an event that results from patient intervention…," back to the language in the current Draft Final Rule, "A licensee shall report any event, except for an event that results from patient intervention…" During the discussion, the recommendation was modified in the final report as follows: **The Sub-Committee recommends changing the "medical-events" language in lines 5531-5532 (page 232) of the current version of the Draft Final Rule from, "A licensee shall report any event, except for an event that results from patient intervention…" back to the language published in the Proposed Rule as presented for public comment,** **"A licensee shall report as a medical event, any administration requiring a written directive, except for an event that results from patient intervention…,"**	01/06/2016	NRC Action	Open			10, 0, 0
15	The Committee endorsed the 2016 Rulemaking Subcommittee Report with modifications as listed above.	01/06/2016	NRC Action	Open			10, 0, 0

Open Forum

NO HANDOUT

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

Status of Medical Events FY 2015

Donna-Beth Howe, Ph.D.
Medical Radiation Safety Team
March 17, 2016

Medical Events

The dose threshold for diagnostic events precludes reportable events most years.

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

Medical Events 2015

- **46 Medical events reported - FY 2014**
- **57 Medical events reported - FY 2015**

	FY14	FY15
35.200	1	3
35.300	3	8
35.400	5	9 (10)
35.600	10	17
35.1000	27	20 (31)

Medical Events 2015

35.200 Medical events **3**

Technetium-99m **2**

- Administered entire 118 mCi multi dose vial to a single patient - 5.6 cGY (rad) whole body.
- Administered entire 160 mCi multi dose vial to a single patient - 7.8 cGY (rad) whole body.

35.200 Medical events (cont.)

Sodium Iodine I-123 1

Administered 136.53 MBq (3.69 mCi) prescribed 11.1 MBq (300 µCi) I-123 for a thyroid uptake study.

- Thyroid exposure of 536 mGy (53.6 rad).
- Physician's asked for correct dosage but Technologist ordered wrong dosage.
- Potential contributor - scheduling diagnostic procedure in therapy time slot contributed.

5

Medical Events 2015

35.300 Medical events 8

Iodine 124 1
Iodine 131 6
Radium 223 1

6

35.300 Medical Events

Iodine-124 1

Administered 1.74 mCi - intended 3.25 mCi.

- Pediatric monoclonal antibody.
- Intravenous connector leaked but not visually obvious.

7

35.300 Medical Events (cont.)

Iodine-131 6

- **Administered 50 mCi instead of 35 mCi.**
  - Patient had low Glomerular filtration Rate score.
  - 2 physicians ordered 2 different dosages both sent to facility wrong one (non-corrected) was selected.
- **Administered 30.8 mCi instead of 3 mCi.**
  - Written directive was wrong - delivered intended dose.
  - Authorized user complete the authorization section in its entirety prior to administration and peer review.

8

35.300 Medical Events (cont.)

- **Administered 1.57 mCi instead of 2 mCi.**
  - Discovered during routine audit.
  - 2 independent measurements and review of dose to ensure it is within 20%.
- **Administered 142 mCi instead of 30 mCi.**
  - Wrong patient – misidentified the patient.
- **Administered 75 mCi instead of 150 mCi.**
  - Dose supplied as 2 capsules only one given.

35.300 Medical Events (cont.)

Ra-223 dichloride 1

- Administered 206 microcuries (µCi) instead of 108 µCi.
- Technologist misread the prescribed dose and injected 2 dosages instead of the 1 prescribed.
- Corrective action - 2 technologists verify patient information and prescribed dose.

Medical Events 2015

35.400 Medical events 9

Tongue	1
Prostate (9 patients)	8

35.400 Medical Events

Tongue Ir-192 1

- 2 ½ hours after linens changed oncologist determined that one strand missing.
- Strand found in the linen basket, recovered, reinserted - tongue received the intended dose.
- Worst-case skin exposure to the patient of 51.75 cSv (rem).

35.400 Medical Events

Prostate (9 patients) 8

Identified during inspection

- **2 patients with Pd-103 implants.**
  - irregularities with one authorized user's (AU's) practices.
  - 37.6% and 66.9% of prescribed dose.
- **73% of prescribed dose.**

13

35.400 Prostate Events (cont.)

Partial Dose intended but full dose given

- **Administered 16,000 cGy (rad) instead of 10,700 cGy (rad), 49.5% greater.**
  - Human error - confirm and document the intended implant dose when the implant is scheduled.

14

35.400 Prostate Events (cont.)

Delivered different from ordered activity

- **Administered 18,432 cGy (rad) instead of 14,400 cGy (rad).**
  - Air kerma ordered but not prescribed in air kerma.
- **Administered 2.95 GBq (79.74 mCi) intended 3.796 GBq (102.6 mCi).**
  - Did not recognize the difference between the delivered and the ordered activity.

15

35.400 Prostate Events (cont.)

Wrong site - poor /uncalibrated ultrasound

- **30% of the seeds were implanted outside the treatment site.**
- **All 53 seeds were implanted into the penile bulb with dose of to this unintended area of 10,800 cGy (rad).**

16

35.400 Prostate Events (cont.)

Wrong site

- **Twenty of the seeds (29% of the total prescribed) were implanted into the bladder.**
  - Enlarged median lobe of prostate protruding into the bladder.
  - Procedure modification and personnel training.

17

Medical Events 2015

35.600 Medical events **17**

HDR 16

- Not specified 1
- Nose 1
- Gynecological 11
- Breast 3

Gamma knife 1(8)

18

35.600 Medical events

HDR **16**

- Wrong Patient 1
- Error/Bad treatment plan 3
- Wrong Site 7
- Source fell out 1
- Physicist error 2
- Equipment problem/failure 2

19

35.600 HDR Events

Not specified **1**

- **Wrong Patient**
  - Treated Patient with another's treatment plan.
  - Patient received 18% less dose than prescribed.
  - Retrained on the requirement to verify the patient's identity prior to treatment.

20

35.600 HDR Events (cont.)

Nose 1

- **Administered 6,850 cGy (rad) instead of 4,000 cGy (rad) 71% higher than written directive.**
  - Junior physicist developed deficient treatment plan.
  - Reviewed by the authorized medical physicist and the authorized user.

35.600 HDR Events (cont.)

Gynecological 11

Wrong site 7

- **Outer vaginal mucosa and upper thigh received entire dose.**
  - Applicator improperly placed and the source placed inferior to the treatment site and exterior to the opening of the vagina.
  - Vaginal burning.

35.600 HDR Events (cont.)

Wrong Site (continued)

- **Outer vaginal mucosa and upper thigh received the entire 2100 cGy - radiation burns.**
  - Source inferior to the treatment site and exterior to the opening of the vagina.
  - Contributor – poor film quality due to obesity - thought it showed proper placement.

35.600 HDR Events (cont.)

Wrong Site (continued)

- **2 skin (0.5 cm wide and 1 cm long) radiation burns on both upper thighs.**
  - patient's skin dose calculated to be 4,000 cGy (rad) at a depth of 0.2 cm.
  - 33% less dose to the intended site than prescribed by the written directive.
  - Either assembled the vaginal cylinder applicator incorrectly or it became loose while in the patient.

35.600 HDR Events (cont.)

Wrong Site (continued)

- **Fractional dose of 450 cGy delivered to wrong site.**
  - Physician had difficulty inserting applicator due to edema and tenderness.
  - Previous weeks post treatment images, showed the applicator was not where it was supposed to be.
  - Approximately 7 cm short of the intended position

25

35.600 HDR Events (cont.)

Wrong Site (continued)

- **260 cGy (rad), the second fractional dose, delivered to 1 cubic centimeter of skin on the right upper thigh.**
  - Close-ended catheter was not fully seated inside the vaginal cylinder.
  - Positioned approximately 15 cm proximal from the prescribed treatment position.
  - Now must verify the position of the cylinder and the length of the transfer tube catheter.

26

35.600 HDR Events (cont.)

Wrong Site (continued)

- **Tissue 3 cm in length inferior to the treatment site received 400 cGy (rad).**
  - Post-treatment imaging revealed the cylinder applicator had come loose from the holder and shifted 3 cm.
  - A resident and physician must now verify applicator immobilization prior to administration and reduce the time from applicator placement in the patient to administration.

27

35.600 HDR Events (cont.)

Wrong Site (continued)

- **Treatment site received 20 % of intended dose.**
  - Inserted the vaginal cylinder 3 cm distal to the vaginal cuff (intended treatment site).
  - Always use all four segments of the treatment cylinder and instructing staff to pay close attention to patient movement.
  - Additional imaging of cylinder placement also to be required.

28

35.600 HDR Events (cont.)

Source fell out 1

- **Administered 1,200 cGy (rad) instead of 1,800 cGy.**
  - Physicist entered room and found the cylinder on the treatment table.
  - Failure to secure the cylinder in place and the inability to view the cylinder on the camera.

35.600 HDR Events (cont.)

Physicist error 2

- **Administered 1,500 cGy (rad) during the three fractions instead of 900 cGy (rad).**
  - Physicist inadvertently selected and delivered an incorrect treatment plan of 900 cGy (rad) per fraction for the third fraction .
  - Skipped “best practice" step of verifying the treatment plan.

35.600 HDR Events (cont.)

Physicist error (cont.)

- **Administered 700 cGy (rad) during one of three fractions instead of 400 cGy (rad).**
  - Physicist loaded the patient’s plan into the treatment control station, but then loaded another patient’s treatment plan for review.
  - The physicist verbally verified the patient’s information from memory, not from the computer screen containing the other patient’s treatment plan.

35.600 HDR Events (cont.)

Equipment problem 1

- **Administered 105 cGy (rad) during second fraction instead of 1050 cGy (rad).**
  - Two AMPs engaged emergency stop, terminated treatment, and retracted the source to the shielded position.
  - On restart, the treatment countdown time was increasing, not decreasing.
  - Console indicated treatment terminated but source extension warning light was activated.

35.600 HDR Events (cont.)

Breast (Savi) 3

- **3,000 cGy (rad) to an unintended site – incision site.**
  - Patient returned with pain and redness at the incision site of the left breast.
  - 21 cubic centimeters of tissue surgically excised.
  - Suspended treatments to investigate.
  - Considering using of a second physicist for independent evaluation of the treatment plan and the a written check-off form.

35.600 HDR Events (cont.)

Breast (Savi) continued

- **Administered 13,000 cGy (rad) to entrance site 3 cm from treatment site - tissue would not heal mastectomy performed.**
  - Dose delivered to connector end and not the tip end.
  - Dwell positions within the applicator were not accurately reconstructed in the treatment planning computer.
  - Difficulty identifying the starting position for multiple catheter HDR treatments within the system.

35.600 HDR Events (cont.)

Breast (Savi) continued

- **Administered 60 cGy (rad) instead of 340 cGy.**
  - Friction event occurred while sending out the check cable in the third channel and the HDR unit was unable to fully retract the check cable.
  - Faulty check cable revealed a fray approximately 0.5 cm behind the welded junction.
  - Total of 3 check cables had similar fraying.

35.600 Medical Events

Gamma knife (Model Type C) 1

- **Administered 8.8 % more to treatment site and 71 cSv (71rem) to wrong site**.
  - 16 gamma knife collimators were placed where there should have been plugs prior to patient treatment.
  - Page three of the written directive which had the plug information was absent during equipment preparation.
  - Move plug use to first page of the written directive.

Medical Events 2015

35.1000 Medical events (31 patients) **20**

Perfexion (8 patients)	**1**
I-125 Seed localization	**1**
Y-90 Microspheres	**18**
Therasphere® (12 patients)	8
SirSphere®	10

37

35.1000 Medical Events

Perfexion (8 patients) 1

- **8 patient administrations meet definition of medical event and may also meet abnormal occurrence criteria.**
  - Approximately 1.87 mm off target misalignment of the patient positioning system due to maintenance/service.
  - Elekta evaluating service issue.

38

35.1000 Medical Events

I-125 Radioactive seed localization 1

- **Administered 83.6 cGy (rad), instead 18.4 cGy (rad).**
  - Due to illness, the patient was unable to return in 5 days and did not have seeds removed until 26 days after implantation.
  - Programmatic review identified other patients did not have their seeds removed until later than the 5 days but did not reach criteria for medical event reporting.

39

35.1000 Medical Events

Y-90 Microspheres (22 patients)	**18**
Therasphere® (12 patients)	**8**
– Multiple patients (5)	1
– Wrong site	1
– Low flow rate –arteries	1
– Kink	1
– Radiation detector	2
– Remained in vial/tubing	2

40

35.1000 Y-90 Events

Therasphere®

- **5 patients administered less than 80% of prescribed dose.**
  - Excess dose found in hub of catheters **- a**ll patients treated with smaller catheters.
- **Administered 874 MBq (23.62 mCi) to wrong lobe of liver.**
  - Intended for left lobe delivered to right lobe.
  - Injected microspheres into wrong artery.

41

35.1000 Y-90 Events (cont.)

Therasphere ® (continued)

- **Administered 588 MBq (15.89 mCi) instead of 763 MBq (20.62 mCi).**
  - Size and physical condition of the patient's arteries caused a low flow condition during treatment.
- **Administered 5,220 cGy (rad) instead of 14,700 cGy (rad) to segment 6 to wrong lobe of liver.**
  - Kinking was noted at the junction of the rigid hub.

42

35.1000 Y-90 Events (cont.)

Therasphere ® (continued)

- **Administered 62% of intended 15,000 cGy (rad).**
  - After "completion of procedure" Rados detector erroneously indicated 0 mR/hour in delivery system.
  - Microspheres left in vial.
- **Administered 60% of intended** 12,000 cGy (rad).
  - Problems with Rados detector contributed to event.
  - Activity concentrated at plunger attached to vial.

43

35.1000 Y-90 Events (cont.)

Therasphere ® (continued)

- **Administered 84 Gy (8,400 rad) instead of 12,500 cGy (rad).**
  - Microspheres were trapped in the vial for an unknown reason.
- **Administered 9,815 cGy (rad) instead of intended 12,000 cGy (rad).**
  - Most of dose remained in D-line tubing with, with lesser amounts in micro-catheter and vial.

44

35.1000 Y-90 Events (cont.)

SirSphere® 10

- Wrong site 4
- Error in Calculation 1
- Delivery system issue 2
- Operator error 1
- Clumping/Occluded 2

35.1000 Y-90 Events (cont.)

SirSphere® Wrong Site 4

- **Kidney – renal artery**
  - Facility's first Y-90 microsphere patient and the manufacturer's representative was present.
  - Dose to the kidney calculated by the manufacturer to be 1,345 Gy (134,500 rad).
  - Formal written checklist completed prior to each administration, additional mapping imagines available for placement of the catheter, and second physician review of the catheter placement.

35.1000 Y-90 Events (cont.)

Wrong Site (continued)

- **Stomach**
  - Administered 1.36 GBq (36.76 mCi) to liver instead of 2.12 GBq (57.4 mCi) but reached stasis.
  - Post-treatment scans indicated microspheres in stomach.
  - Calculations determined that the stomach contained 0.011 GBq (0.3 mCi) of Y-90 for a dose of 54.7 cSv (rem).

35.1000 Y-90 Events (cont.)

Wrong Site (continued)

- **Small Bowel**
  - Intended dose of 7,800 cGy (rad) to the liver.
  - Physician felt that the microspheres were not traveling to the liver and discontinued treatment.
  - Small bowel received a dose of 3,600 cGy (rad).

35.1000 Y-90 Events (cont.)

Wrong Site (continued)

Wrong liver site

- Administered 7,750 cGy (rad), instead 6,450 cGy (rad) posterior portion of the right lobe.
  - Received administration intended for the anterior portion of the right lobe of the liver.
  - Color coding procedure failed to prevent the incident will discontinue use of color coding dual doses.
  - Permit only one dosage of microspheres in the interventional radiology at a time.

35.1000 Y-90 Events (cont.)

Dose calculation error 1

- **Administered 1.37 GBq (37.03 mCi) instead of 1.09 GBq (29.43 mCi).**
  - Physician prescribed activity based on a 20% reduction due to the lung shunt volume.
  - Both the pre-reduction and post-reduction activity values appeared in the written directive.
  - Activity calculations based on the pre-reduction value.

35.1000 Y-90 Events (cont.)

- **Administered 974.95 MBq (26.35 mCi) instead of 1.23 GBq (33.26 mCi).**
  - Administration terminated - air bubbles were collecting in the tubing delivering the microspheres.
  - Microsphere delivery kit was set up incorrectly.
  - Air entered the device from an uncovered needle.
- **Administered 384.8 MBq (10.4 mCi) instead of 658.6 MBq (17.8 mCi).**
  - Administering device came apart during the procedure - microspheres were lost in the apparatus.

35.1000 Y-90 Events (cont.)

- **42% of dose delivered.**
  - During setup, patient's catheter disconnected to flush out potential air bubble.
  - Started administration without realizing that the line was still disconnected.
- **78.1% of dose delivered.**
  - Clumping in the tubing near the 3-way stopcock.
  - Manufacturer determined cause was abnormally high concentration of microspheres being administered.

35.1000 Y-90 Events (cont.)

- **52% of dose delivered.**
  - Physician concluded catheter was clogged when the injection of microspheres through the delivery system met with considerable resistance.
  - Lost some microspheres when catheter disconnected.
  - Manufacturer review of the equipment suggested that blood in the catheter caused the catheter to clog and was an indication that the catheter was not sufficiently flushed prior to infusion.

Acronyms

- AMP – Authorized Medical Physicist
- AU – Authorized User
- cGy – centiGray
- FY – Fiscal Year
- GBq – Giga Becquerel
- HDR – High Dose Rate Remote Afterloader
- I-131 – Iodine-131 I-124 – Iodine-124
- mCi – millicurie µCi – microcurie
- MBq – Mega Becquerel
- Pts - Patients
- Y – Yttrium

QUESTIONS?

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

Medical Event Reporting for All Modalities Except Permanent Implant Brachytherapy

John H. Suh, M.D.
ACMUI

Subcommittee Members

- **Ronald Ennis, M.D.**
- **Vasken Dilsizian, M.D.**
- **Chris Palestro, M.D.**
- **John Suh, M.D. (chair)**
- **Pat Zanzonico, Ph.D.**
- ***Zoubir Ouhib***

Subcommittee Charge

- **To propose the appropriate criteria for ME Reporting for events other than permanent implant brachytherapy**

3

Background

- **On 10/9/15, Dr. Ennis provided the ACMUI with the annual presentation on the previous FY's ME, which remain extremely low**
- **Dr. Thomadsen, outgoing ACMUI Chair, discussed an incident at his institution where there was confusion as to whether or not it was an ME. This led to the formation of this subcommittee.**

4

History of ME Reporting

- **ME Reporting has not changed significantly since the 1970s.**
- **In 1991, ME criteria included a difference between the prescribed and administered doses of >10%.**
- **As a result, the current definition may not be appropriate given the advances and technologies used currently.**
- **10 CFR Part 35, Subpart M – Reports**

§ **35.3045 Report and notification of a medical event**

[68 FR 58805, Oct. 10, 2003; 76 FR 72085, Nov. 22, 2011]

5

Subcommittee Discussions

- **The Subcommittee discussed the current ME Reporting Criteria under 10 CFR 35.3045.**
- **The Subcommittee reviewed different scenarios in which the ME Criteria were ambiguous and therefore required possible modification(s).**
- **Given the spatial precision of modern therapies, a slight shift can result in significant dose to nearby tissues or parts of organs.**

6

§ 35.3045 Report and notification of a medical event

(a) A licensee shall report any event, except for an event that results from patient intervention, in which the administration of byproduct material or radiation from byproduct material results in—

7

§ 35.3045 Report and notification of a medical event

(1) A dose that differs from the prescribed dose or dose that would have resulted from the prescribed dosage by more than 0.05 Sv (5 rem) effective dose equivalent, 0.5 Sv (50 rem) to an organ or tissue, or 0.5 Sv (50 rem) shallow dose equivalent to the skin; and

(i) The total dose delivered differs from the prescribed dose by 20 percent or more;

(ii) The total dosage delivered differs from the prescribed dosage by 20 percent or more or falls outside the prescribed dosage range; or

(iii) The fractionated dose delivered differs from the prescribed dose, for a single fraction, by 50 percent or more.

8

§ 35.3045 Report and notification of a medical event

(2) A dose that exceeds 0.05 Sv (5 rem) effective dose equivalent, 0.5 Sv (50 rem) to an organ or tissue, or 0.5 Sv (50 rem) shallow dose equivalent to the skin from any of the following—

(i) An administration of a wrong radioactive drug containing byproduct material;

(ii) An administration of a radioactive drug containing byproduct material by the wrong route of administration;

(iii) An administration of a dose or dosage to the wrong individual or human research subject;

(iv) An administration of a dose or dosage delivered by the wrong mode of treatment; or

(v) A leaking sealed source.

9

§ 35.3045 Report and notification of a medical event

(3) A dose to the skin or an organ or tissue other than the treatment site that exceeds by 0.5 Sv (50 rem) to an organ or tissue and 50 percent or more of the dose expected from the administration defined in the written directive (excluding, for permanent implants, seeds that were implanted in the correct site but migrated outside the treatment site).

(b) A licensee shall report any event resulting from intervention of a patient or human research subject in which the administration of byproduct material or radiation from byproduct material results or will result in unintended permanent functional damage to an organ or a physiological system, as determined by a physician.

(c) The licensee shall notify by telephone the NRC Operations Center[3] no later than the next calendar day after discovery of the medical event.

10

ME criteria would need to cover a variety of treatment modalities

- Selective Internal Radiation Therapy (SIRT)
- HDR: breast, GYN, lung, prostate, and skin
- Gamma Knife
- ViewRay
- LDR implants (non-prostate)
- LDR meshes
- Unsealed sources
  - Intravenous: Sr-89, Sm-153 and Ra-223
  - Oral: I-131 (capsules or liquids)
- Eye plaques: I-125

11

Defining ME by Modalities

- May be easier for licensee to determine if ME occurred.
- May be easier to inspect and regulate
- May facilitate programs, procedures and education to prevent future events.

Since delivery systems and risks are different, a specific ME for each modality may provide some advantages, but the committee did not favor modality-specific MEs.

12

Recommendations

- **Medical events reporting should allow identification of an ME and provide a forum to discuss how to avoid/reduce the likelihood of such an event.**
- **The definitions of ME reporting need to be broad, simple, and consistent so reports are easily applicable by AU, evaluable by regulators, and process-focused order to eliminate any ambiguity.**

13

Recommendations

- **The subcommittee believes the part of the definition based on "unintended permanent functional damage to an organ or a physiological system, as determined by a physician" needs reconsideration.**
- **The subcommittee believes that the creation of a subsection within the current definition of ME reporting be considered to address the newer radiation oncology modalities that prescribe dose to volumes.**

14

Recommendations

The subcommittee believes that any proposed changes must not encroach on the practice of medicine.

15

Acronyms

- **ACMUI – Advisory Committee on the Medical Uses of Isotopes**
- **AU – Authorized User**
- **CFR – Code of Federal Regulations**
- **FY – Fiscal Year**
- **GYN – Gynecological**
- **HDR – High Dose Rate**
- **LDR – Low Dose Rate**
- **ME – Medical Event**

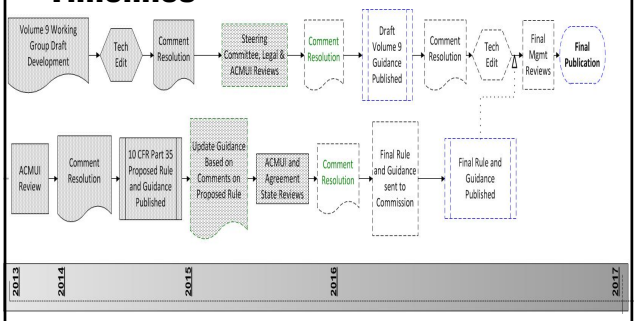
16

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

NUREG-1556, Volume 9 Update

Katie Tapp, Ph.D.
Medical Radiation Safety Team
3/17/16

Timelines



Updates

- **Comments**
  - **Received but not addressed during Revision 2**
  - **New comments from public and NRC and Agreement State staff**
- **ACMUI recommendations**
- **Updates to references and other guidance documents in NUREG-1556, Volume 9**
- **Updates to reflect the general move from hard copy to electronic-based systems**
- **Consistency between NUREG-1556 Volumes**
- **Rulemaking updates**

ACMUI Recommendations

- **Received October 8, 2015**
- **Provided 10 recommendations including:**
  - **Public Comment Period Extension**
  - **Patient Release Guidance**
  - **Addition of Footnote to Clarify "dose"**

Questions?

5

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

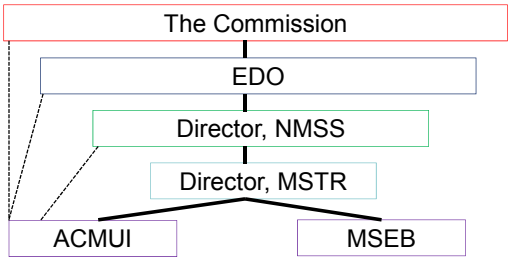
Committee Reporting Structure

Sophie Holiday, ACMUI Coordinator
Medical Radiation Safety Team
March 17, 2016

Outline

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

Current Reporting Structure



Annual Review

- **In September 2012, the ACMUI recommended to have an annual review of reporting structure.**
- **This is the sixth annual review.**

Meetings

Two meetings at Headquarters each year

- **March/April**
- **September/October**

Approximately 2-3 teleconferences (as needed)

5

Discussion

6

Points of Contact

- **Dan Collins – MSTR Director**
  - **301-415-3340; Daniel.Collins@nrc.gov**
- **Douglas Bollock – Designated Federal Officer**
  - **301-415-6609; Douglas.Bollock@nrc.gov**
- **Michael Fuller – Leader, MRST**
  - **301-415-0520; Michael.Fuller@nrc.gov**
- **Sophie Holiday – ACMUI Coordinator**
  - **301-415-7865; Sophie.Holiday@nrc.gov**

7

Acronyms

- **EDO – Executive Director for Operations**
- **NMSS – Office of Nuclear Material Safety and Safeguards**
- **MSTR – Division of Material Safety, States, Tribal and Rulemaking**
- **MSEB – Medical Safety and Event Assessment Branch**

8

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

Yttrium-90 Microspheres Brachytherapy Licensing Guidance

Katie Tapp, Ph.D.
Medical Radiation Safety Team
3/17/16

Outline

- **Revision 9 issued February 12, 2016**
- **NRC and Agreement State Working Group (WG) Considerations for Potential Future Update**

Revision 9 Changes

- **Medical Events: Excludes reporting of events due to**
  - **stasis or emergent patient conditions**
  - **shunting when shunting was evaluated prior to treatment**
- **Shunting Dose/Activity: No longer required to be documented on written directive**

Revision 9 Changes (Continued)

- **Training and Experience: Allow Interventional Radiologists certified by American Osteopathic Board of Radiology to become Authorized Users (AU)**
- **Updated Format**

Future Considerations

- Update to Waste Disposal Issue Section Regarding Long-Lived Impurities
- Autopsy and Cremation Information
- Removal of Pathway 2 in Training and Experience Section

5

Long-Lived Impurities

- Information Notice (IN) 2007-10, "Yttrium-90 TheraSpheres® and SIRSpheres® Impurities"
- Impurities based on Microsphere Manufacturing Process
- WG considering potential updates to the Waste Disposal Section or to the IN

6

Autopsy and Cremation

- Microspheres are Permanent
  - Yttrium-90 has a 64 hour Half Life
  - Considerations for Long-Lived Impurities
- WG considering if information should be be added to license guidance

7

Training and Experience

- Current Licensing Guidance Requires Completion of Training Program provided by either:
  - an AU (Pathway 1), or
  - the Manufacturer (Pathway 2).
- WG evaluating manufacturer pathway

8

Schedule

- Working Group Draft Expected April 2016
- ACMUI Comment Period
- Agreement State Review
- Issue Revision Expected Summer 2016

9

Questions?

10

Acronyms

- AU - Authorized User
- IN - Information Notice
- WG - Working Group

11

Enrollment of HSPD-12 Badges

NO HANDOUT

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

Staff Response to OIG Audit of NRC's Oversight of Medical Uses of Nuclear Material

Douglas Bollock
NMSS/MSTR

Overview

- **Background**
- **Audit Findings**
- **Audit Recommendations**
- **Staff Response**
  - **Path Forward**

Background

Audit objective

- **To determine if NRC's oversight of medical uses of radioactive isotopes adequately protects public health and safety.**

Audit Findings

- **NRC provides adequate oversight of the medical uses of radioactive isotopes to protect public health and safety; however, opportunities for improvement exist with regard to**
  - **Clarification of NRC's medical event reporting requirements.**
  - **Periodic self-assessment of medical event reporting.**
  - **Providing better feedback to ACMUI.**

Audit Recommendations

Recommendation 1

- **Clearly define the purpose of medical event reporting in a publicly available document and clarify the reporting requirements.**

5

Audit Recommendations (cont.)

Recommendation 2

- **Proactively provide all medical licensees with medical event tracking/trending information for lessons-learned purposes.**

6

Audit Recommendations (cont.)

Recommendation 3

- **Develop and implement policy and procedures that require periodic assessments of NRC's approach to medical event reporting. These assessments should include whether**
  - **i. The intended purpose of the reporting requirements is being met.**
  - **ii. The thresholds of the reporting requirements are appropriate.**

7

Audit Recommendations (cont.)

Recommendation 4

- **Develop and implement policy and procedures to guide provision of sufficiently detailed and timely feedback to ACMUI from NRC staff.**

8

Staff Response

Recommendation 1

- Information has been disseminated explaining the purpose of medical event reporting.
  - NRC's website
  - Medical list server
  - 10 CFR Part 35 SOC
  - RCPD Letter to Agreement States

9

Staff Response (cont.)

Recommendation 2

- Medical event tracking and trending initiatives
- Access to ACMUI medical event slides

10

Staff Response (cont.)

Recommendation 3

- An annual self-assessment of the overall effectiveness of NRC's event reporting program will be conducted.

11

Staff Response (cont.)

Recommendation 4

- Staff updated NMSS P&P 2.5 and 6.15 to enhance communications and to better inform ACMUI members of the rationale behind staff's proposed actions.

12

Acronyms

OIG – Office of the Inspector General

ACMUI – Advisory Committee on the Medical Uses of Isotopes

P&P – Policy and Procedures

RCPD – Radiation Control Program Directors

SOC – Statements of Consideration

QUESTIONS?

14

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

Leksell Gamma Knife® Icon ™ 10 CFR 35.1000 Licensing Guidance

Sophie J. Holiday, NRC
Eric D. Perry, KY
March 18, 2016

Outline

- **Working Group**
- **Overview of Icon™ Features**
- **Overview of Licensing Guidance**

Working Group

NRC and OAS formed a joint WG to:

1. **Review and evaluate the Icon™ SS&D Certificate and relevant documents;**
2. **Determine if the Perfexion™ and Icon™ units were similar enough that they could be addressed in a single 10 CFR 35.1000 licensing guidance document;**
3. **Develop the 10 CFR 35.1000 licensing guidance document.**

Working Group

- **Four members on the WG**
- **Kickoff meeting in December 2015**
- **Draft Guidance completed January 2016**

Overview of Icon™ Features

The Icon™ unit differs from the Perfexion™ unit by adding an integrated stereotactic CBCT, IFMM system and the option to use a thermoplastic frameless mask.

5

Overview of Icon™ Features

The frameless option allows for single session treatments, fractionations and/or re-treatment of metastases.

6

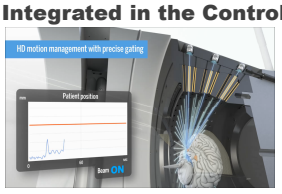
Overview of Icon™ Features

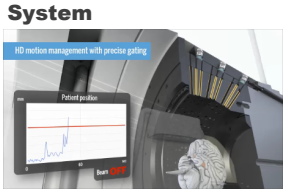
1. Mask & Patient marker 2. Head Support with IR reference markers 3. IR camera 4. IR camera arm

7

Overview of Icon™ Features

- **Infra-red based system tracks reflective reference markers and marker on patient**
- **Continuous monitoring during dose delivery**
- **Movement outside limit will initiate sector off**
- **Integrated in the Control System**





8

Overview of Licensing Guidance

- Current 10 CFR 35.1000 Licensing Guidance for Perfexion™ has been amended in its entirety.
- All requirements for the Perfexion™ unit are applicable to the Icon™ unit.
- There are additional requirements for the Icon™ unit.

9

Status

- The States and the NRC Regions received the draft guidance for comment in February 2016.
- The guidance is expected to be issued in summer 2016.

10

Questions?

11

Acronyms

- CBCT – Cone Beam Computed Tomography
- CFR – Code of Federal Regulations
- IFMM – Intra-Fraction Motion Management
- HDMM- High Definition Motion Management
  - » The terms IFMM and HDMM are used interchangeably
- NRC – US Nuclear Regulatory Commission
- OAS – Organization of Agreement States
- SSDR – Sealed Source and Device Registry
- WG – Working Group

12

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

Germanium/Gallium-68 Medical Use Generator Update

Said Daibes, PhD
Medical Radiation Safety Team
March 17, 2016

Overview

- **Background**
- **Current Status**
- **Regulatory Options**

Ga-68 PET Imaging Background

- **Instrumental for patients with neuroendocrine disease.**
  - **Use expanding in clinical research.**
- **Demonstrated advantages over clinical agents.**
  - **greater sensitivity and specificity.**

Current Status

- **A DFP must be developed by the licensee before it can possess the Ge-68/Ga-68 generator.**
  - **parent radionuclide long half-life**
  - **unsealed radioactive material**

Regulatory Options

- **License Specific Exemption**
  - **Exempting the DFP requirement**
  - **Specific Guidance**
- **Direct Final Rule**
  - **Amend Appendix B (10 CFR 30.35) to include the Ge-68 limit changes.**
  - **This new limit will allow a licensee to use a Ge-68/Ga-68 generator and not trigger the DFP requirement.**

5

Acronyms

DFP – Decommissioning Funding Plan
FDA – Federal Drug Administration
Ga-68 – Gallium-68
Ge-68 – Germanium-68
PET – Positron Emission Tomography

QUESTIONS?

7

Special Presentation to Mr. Mattmuller

NO HANDOUT

Thoughts on Leaving the ACMUI

NO HANDOUT

Open Forum

NO HANDOUT

September 2016

Sunday	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday
				1	2	3
4	5 LABOR DAY	6 X	7	8	9	10
11	12	12	14	15	16	17
18	19	20	21	22 ASNC Annual Meeting	23 ASNC Annual Meeting	24 ASNC Annual Meeting
25 ASNC and ASTRO Annual Meeting	26 ASTRO Annual Meeting	27 ASTRO Annual Meeting	28 ASTRO Annual Meeting	29 X	30 X	1

October 2016

Sunday	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday
2	3 Rosh Hashanah	4 Rosh Hashanah	5	6	7	8
9	10 COLUMBUS DAY	11 X	12 Yom Kippur	13	14	15
16	17 *Sukkot*	18 *Sukkot*	19	20	21	22
23	24 *Sh'mini Atzeret*	25 *Simchat Torah*	26	27	28	29