MEETING AGENDA
ADVISORY COMMITTEE ON THE MEDICAL USES OF ISOTOPES

April 26-27, 2017
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.

Wednesday, April 26, 2017 **CLOSED SESSION**		
7:30 – 8:00	• **Badging and Enrollment**	**ACMUI**
OPEN SESSION		
8:00 – 10:15	• **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. Smethers will review past ACMUI recommendations and provide NRC responses.	**M. Smethers, NRC**
	• **Open Forum** The ACMUI will identify medical topics of interest for further discussion.	**ACMUI**
	• **Physical Presence Requirements** Representatives from Elekta will discuss the physical presence requirements for the Leksell Gamma Knife® Icon™.	**S. Lohman, Elekta**
	• **Status Update on Source Security and Accountability Initiatives** Ms. Wu will provide an overview of source security initiatives and provide a status update on the evaluation of Category 3 source security and accountability.	**I. Wu, NRC**
10:15 – 10:30	**BREAK**	
10:30 – 11:45	• **Medical Related Events** Dr. Howe and Dr. Langhorst will provide an update on recent medical events and events at medical institutions.	**DB. Howe, NRC &** **S. Langhorst, ACMUI**
11:45 – 1:00	**LUNCH**	
1:00 – 2:30	• **Training and Experience for All Modalities** Dr. Palestro will discuss the subcommittee's comments on the training and experience requirements for authorized individuals in 10 CFR Part 35.	**C. Palestro, ACMUI**
	• **Patient Release Project Update** Dr. Howe will provide an update on the patient release project.	**DB. Howe, NRC**
2:30 – 3:00	**BREAK** (Public portion ends)	
3:00 – 5:00	• **ACMUI Working Preparatory Session**	**ACMUI**

Thursday, April 27, 2017 OPEN SESSION		
8:00 – 9:30	• **Medical Event Reporting for All Modalities Excluding Permanent Implant Brachytherapy** Dr. Suh will discuss the subcommittee's final recommendations for the reporting of medical events.	**J. Suh, ACMUI**
	• **Patient Intervention Subcommittee Report** Dr. Dilsizian will discuss the subcommittee's recommendations on the definition of patient intervention.	**V. Dilsizian, ACMUI**
9:30 – 10:00	**BREAK**	
10:00 – 12:00	• **Commission Briefing** The ACMUI will participate in a public meeting with the Commission.	**ACMUI**
	• **Group Photo** The ACMUI will take a group photo with and without the Commission.	**ACMUI**
12:00 – 1:00	**LUNCH**	
1:00 – 2:30	• **10 CFR Part 35 Rulemaking Status** Ms. Taylor will provide an update on the 10 CFR Part 35 rulemaking effort.	**T. Taylor, NRC**
	• **Medical Event Reporting and Impact on Safety Culture** Dr. Langhorst will discuss the subcommittee's report on Medical Event Reporting and Impact on Safety Culture.	**S. Langhorst, ACMUI**
	• **Annual Reporting Structure** Members will discuss the reporting structure of the Committee and provide feedback to NRC staff.	**M. Smethers, NRC**
2:30 – 3:00	**BREAK**	
3:00 – 3:45	• **Open Forum** The ACMUI will discuss medical topics of interest previously identified.	**ACMUI**
	• **Administrative Closing** Ms. Smethers will provide a meeting summary and propose dates for the fall 2017 meeting.	**M. Smethers, NRC**
3:45	**ADJOURN**	

Badging and Enrollment

NO HANDOUT

Opening Statements

NO HANDOUT

2007 ACMUI RECOMMENDATIONS AND ACTION ITEMS

	ITEM	DATE	STATUS	
2	NRC staff should remove the attestation requirement for board certified individuals and rewrite the attestation requirement for individuals seeking authorization under the alternate pathway. The rewritten attestation should not include the word “competency” but should instead read “has met the training and experience requirements.”	6/12/07	Accepted	Open
3	NRC staff should revise the regulations so that board certified individuals, who were certified prior to the effective date of recognition or were certified by previously recognized boards listed in Subpart J of the previous editions of Part 35, are grandfathered.	6/12/07	Accepted	Open
6	NRC staff should add the words “or equivalent” so it is clear that information included in a letter is the same as that which would have been submitted in NRC Form 313A (35.12(c))	6/13/07	Accepted	Open
7	NRC staff should revise 10 CFR 35.50(c)(2) to include AUs, AMPs, or ANPs identified on any license or permit that authorizes similar types of use of byproduct material. Additionally, the AU, AMP, or ANP must have experience with the radiation safety aspects of similar types of use of byproduct material for which the individual is seeking RSO authorization.	6/13/07	Accepted	Open
8	NRC staff should remove the attestation requirement from 10 CFR 35.50(d) for AUs, AMPs, and ANPs seeking RSO status, if the AU, AMP, or ANP seeking RSO status will have responsibilities for similar types of uses for which the individual is authorized.	6/13/07	Accepted	Open

	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*

2008 ACMUI RECOMMENDATIONS AND ACTION ITEMS

	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

	ITEM	DATE	STATUS		1st/2nd	Vote
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

	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	

	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.	3/20/2015	ACMUI Action	Open		Langhorst/Costello	11, 0, 1
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	M. Abogunde	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	M. Abogunde	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	Closed	M. Abogunde		
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	M. Abogunde		
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

	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).	1/6/2016	Accepted	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.	1/6/2016	Accepted	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."**	1/6/2016	Accepted	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."**	1/6/2016	Not Accepted	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.	1/6/2016	Accepted	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.**	1/6/2016	Accepted	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.**	1/6/2016	Accepted	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.	1/6/2016	ACMUI 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.	1/6/2016	Not Accepted	Open			10, 0, 0
10	The Committee endorsed allowing Associate Radiation Safety Officers (ARSO) to be named on a medical license.	1/6/2016	Accepted	Open			10, 0, 0

	ITEM	DATE	STATUS		Assigned	1st/2nd	Vote (Y/N/A)
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."	1/6/2016	Not Accepted	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."**	1/6/2016	Partially Accepted	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.	1/6/2016	Accepted	Open			10, 0, 0
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…,"**	1/6/2016	Not Accepted	Open			10, 0, 0

	ITEM	DATE	STATUS		Assigned	1st/2nd	Vote (Y/N/A)
15	The Committee endorsed the 2016 Rulemaking Subcommittee Report with modifications as listed above.	1/6/2016	NRC Action	Open			10, 0, 0
16	Dr. Alderson formed a subcommittee to review and evaluate the training and experience requirements for all modalities in 10 CFR Part 35. Subcommittee members include: Dr. Langhorst, Dr. Metter, Dr. Palestro (chair), Dr. Suh and Ms. Weil. NRC staff resource: Maryann Abogunde.	2/25/2016	ACMUI Action	Open			
24	The ACMUI will contact their respective professional organizations to request and encourage interactions between the NRC and ACMUI with their organization.	3/18/2016	ACMUI Action	Open			
38	Dr. Alderson requested that the ACMUI discuss the nursing mothers guidelines during the Spring 2017 ACMUI Meeting.	10/6/16	ACMUI Action	Open			
39	The Committee recommended that staff issue a generic communication (information notice) regarding tubing issues (kinking, connection, hub etc.) during the administration of Y-90 microspheres brachytherapy.	10/6/16	NRC Action	Open	Dr. Katie Tapp	Ennis/Costello	9, 0, 1
41	Dr. Alderson re-established the Patient Intervention Subcommittee. The subcommittee's new charge is to make a recommendation on what the definition of "patient intervention" should be. Subcommittee membership include: Mr. Costello, Dr. Dilsizian (Chair), Dr. Ennis, Dr. Suh, and Ms. Weil. Ms. Maryann Abogunde is the NRC resource.	10/6/16	ACMUI Action	Open	Maryann Abogunde		
42	The Committee recommended that the Pathway 2 remain for the Y-90 Microsphere Brachytherapy Licensing Guidance. The NRC/OAS working group should determine what the requirements should be for the proctoring of cases by the manufacturer(s).	10/7/16	NRC Action	Open	Dr. Katie Tapp	Langhorst/Costello	9, 1, 1
43	The Committee recommended to support the update to the waste disposal section and the review of the Y-90 radiation safety issues in autopsy and cremation in the draft revision of the Y-90 Microsphere Brachytherapy Licensing Guidance.	10/7/16	NRC Action	Open	Dr. Katie Tapp	Langhorst/Ennis	11, 0 , 0
44	For the NorthStar Guidance Subcommittee: The Committee recommended that NorthStar provide a video clip of how the system operates in the training module.	10/7/16	NRC Action	Open	Dr. Donna-Beth Howe		10, 0, 0

	ITEM	DATE	STATUS		Assigned	1st/2nd	Vote (Y/N/A)
45	For the NorthStar Guidance Subcommittee: Given the unique design and operation of the NorthStar system, the Committee agreed that NorthStar should have sole responsibility for the content of the training course and certification.	10/7/16	NRC Action	Open			10, 0, 0
46	For the NorthStar Guidance Subcommittee: The Committee stated that it is important to clarify that a System Administrator can be any individual assigned by the AU without a specifically defined educational or training background. Given the unique role of the System Administrator, perhaps that individual should be named on the license.	10/7/16	NRC Action	Open			10, 0, 0
47	For the NorthStar Guidance Subcommittee:The Committee recommended an explicit statement regarding the System Administrator Designee, although it may not have been intended, one could infer from the description of the system administrator designee that there can be only one designee. Presumably, there can, and should, be multiple System Administrator designees.	10/7/16	NRC Action	Open			10, 0, 0
48	For the NorthStar Guidance Subcommittee:The Committee recommended that the appropriate time period allotted for training on the “changes” and the responsibility of the vendor/manufacturer to inform and train the applicants on changes in a timely manner be specified.	10/7/16	NRC Action	Open			10, 0, 0
49	For the NorthStar Guidance Subcommittee: The Committee recommended that the guidance clarify whether the generator will be “non-operational” until ALL individuals handling the generator are trained in the changes, including the AU, RSO, system administrator, etc. or does it require only the AU to be trained on the “changes.” If the latter, once the AU is trained on the “changes”, is the AU then solely responsible for training all others on these changes? This should be stated.	10/7/16	NRC Action	Open			10, 0, 0
50	For the NorthStar Guidance Subcommittee: The Committee recommended using the term, “individual tasks” throughout the document for consistency and to clarify that there is only one protocol and software program with this system.	10/7/16	NRC Action	Open			10, 0, 0
51	For the NorthStar Guidance Subcommittee: The Committee recommended that the manufacturer’s procedures be reviewed and incorporated into the Licensing Guidance itself.	10/7/16	NRC Action	Open			10, 0, 0
52	For the NorthStar Guidance Subcommittee: The Committee recommended that the term “higher than expected” be defined in terms of a maximum specific exposure or exposure-rate limit which a survey meter should be capable of measuring.	10/7/16	NRC Action	Open			10, 0, 0

	ITEM	DATE	STATUS		Assigned	1st/2nd	Vote (Y/N/A)
54	The Committee tentatively scheduled the Spring 2017 Meeting for March 20-21, 2017. The back-up dates are April 25-28, subject to Commission availability.	10/7/16	ACMUI Action	Open			

Open Forum

NO HANDOUT

Leksell Gamma Knife® Icon™ Radiosurgery

Advisory Committee on Medical Use of Isotopes (ACMUI)

Susan Lohman, RN
Clinical Applications Manager, Neuroscience

April 26-27, 2017

Elekta

Agenda

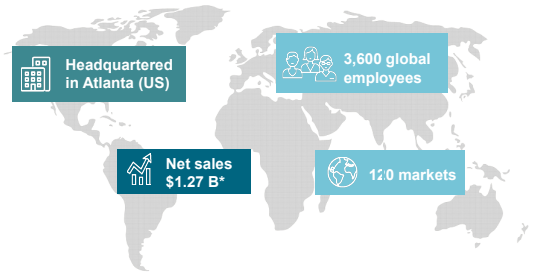
I. Elekta Corporate Overview
II. Evolution of Leksell Gamma Knife
III. Rationale for Modification to the PPR
IV. Requested Modification to the PPR

Elekta

Elekta Corporate Overview

Elekta at-a-glance

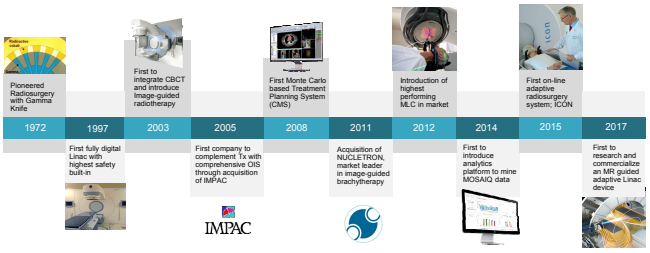
Medical technology company, developing solutions for treating cancer and brain disorders.



*FY2015-2016

Elekta

Elekta has pioneered the development of radiation therapy



Elekta

Elekta is a well established cancer care partner

6,000 Hospitals worldwide

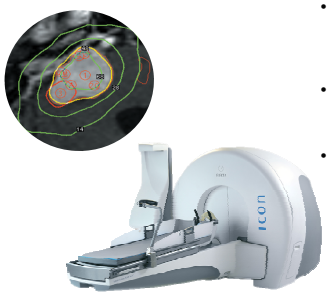
Every year close to **1.5 million** Patients are treated with an Elekta solution

Every day **140,000** Patients receive diagnosis, treatment or follow-up with an Elekta solution

Elekta

Evolution of Leksell Gamma Knife®

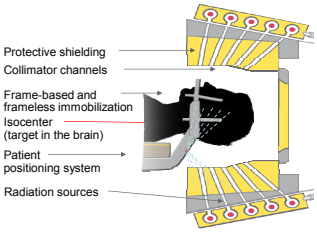
Leksell Gamma Knife®



- Treats critically located brain targets with the highest precision and selectivity
- The delivery of a high dose of irradiation through the intact skull
- Gold standard in radiosurgery

Elekta

Leksell Gamma Knife®



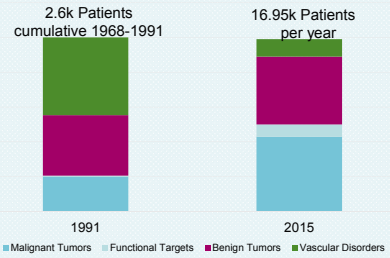
- 192 simultaneous beams converge on a target in the brain
- Steep dose fall-off keeps dose to healthy tissue extremely low
- Few moving parts reduce risk of mechanical error and inaccuracies
- Stable and known output

Elekta

Leksell Gamma Knife®

Expanding Clinical Application

Indications Treated



> 1 million
Patients treated worldwide

> 80,000
Patients treated annually

> 2,500
Peer-reviewed publications

Elekta

Leksell Gamma Knife®

Continuous Innovation

1986 LGK® Model U
1996 LGK® Model B
1999 LGK® Model C
2004 LGK® Model 4C
2006 LGK ® Perfexion™
2016 LGK® Icon™

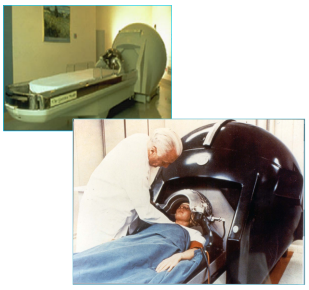
No Automation — **Fully Automated**

Since 1987, the Leksell Gamma Knife has evolved into a fully automated dose delivery system with several on board safety features that ensure the patient receives the lowest dose of radiation to healthy tissue of any system on the market.

Elekta

Leksell Gamma Knife® Model U

A completely manual workflow



- 1987 - First Installation of Model U
- Output of treatment planning computer was printed on a list of instructions
- Clinical staff (neurosurgeon, radiation oncologist, medical physicist, nurse) had to manually treat the patient one shot (isocenter) at a time via the exchange of collimator helmets
- Elaborate radiosurgery treatments lasted up to several hours
- No automation to detect and correct errors in setting stereotactic coordinates by eye at submillimeter level

Elekta

Leksell Gamma Knife® Model B

Second Generation Platform

- New platform from Model U released in 1996
- New innovations but still manual
- Manual change of four different collimator helmets to change collimator size; interaction by operator during treatment session
- Manual plugging by replacing final collimator in helmet with plugs; interaction by operator during treatment session
- Manual setting of shot coordinates using trunnions, pause between each shot to set coordinate; interaction by operator during treatment session

Elekta

Leksell Gamma Knife® Model C

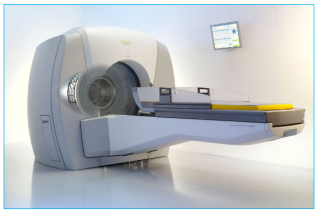
Automation Takes Hold

- Model C released in 1999
- Introduction of Automatic Positioning System (APS), for automated patient positioning to shot coordinates, moving head of patient
- Reduced need for operator interaction during treatment session

Elekta

Leksell Gamma Knife® Perfexion

First Fully Automated Patient Positioning System



- New platform from Model C, released in 2006
- Fully automated collimator system for collimator change and plugging, all built into the radiation unit
- Fully automated, full body, patient positioning system
- GUI guided workflow for complete treatment session
- Simple system accuracy QA with Focus Precision Tool

Elekta

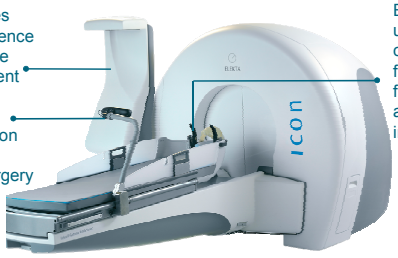
Leksell Gamma Knife® Icon™

Gamma Knife Technology Evolved

Leksell Gamma Knife® Icon™

Addition of cone-beam CT provides stereotactic reference system for precise imaging and patient set up

Provides HD motion management for precision radiosurgery

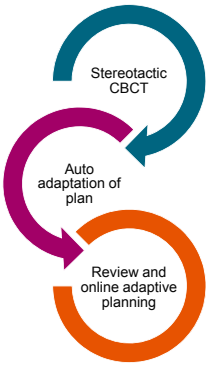


Enables unlimited clinical flexibility for frame-based and frameless immobilization

Elekta

Online Adaptive DoseControl™ for Continuous Quality Control

Ensuring Treatment Consistency



Optimized stereotactic CBCT for accurate geometrical co-registration at time of treatment

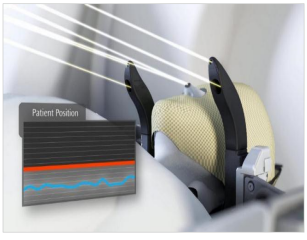
Online automatic treatment plan adaptation to compensate for patient-position changes

Online dose evaluation compares dose to be delivered to planned dose – allowing **online adaptive planning**

Elekta

The Leksell Gamma Knife® Icon™ Frameless SRS Solution

Continuous Patient Monitoring



HD Motion Management + Mask

- Real-time tracking: 20 times/sec
- High-definition: 0.15mm vs. 1mm standard
- Mounted on rigid device close to patient
- Beam off when patient motion is outside limits
- IR-based – no additional dose to patient

Elekta

Leksell Gamma Knife® Icon™

Adds significant patient value

UNLIMITED FLEXIBILITY FOR CRANIAL SRS	Frame/frameless, single-session/fractionation, any intracranial target
HIGHEST PRECISION	The most targeted dose delivery with the highest accuracy – for all workflows
CONTINUOUS QUALITY CONTROL	Through Online Adaptive DoseControl™
SAFETY THROUGH INTEGRATION	Safe, reliable fully integrated system designed and dedicated specifically for the brain

Elekta

Leksell Gamma Knife® Impeccable Safety Record

Key Findings based on review of patients treated October 2006-September 2014

➢ *Review of MER Submissions to NRC under 10 CFR Part 35.3045*

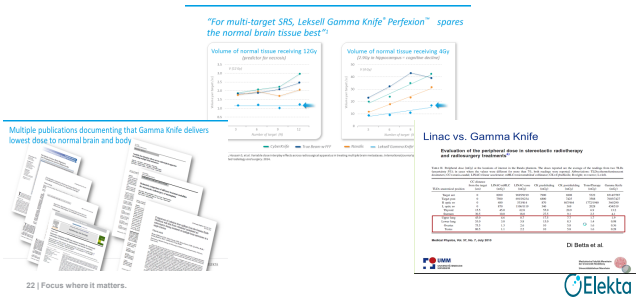
- ~105,000 LGK patients treated in the U.S.
- Only 17 GK-related MERs made of which 1 MER identified during time of patient treatment
- The issue, a planning error, was detected during physician dictation
- "No Adverse Effects are expected as a result of the event"
- *Review of Elekta records reflecting all global reports including U.S.*
- ~300,000 patients treated globally
- 1:25,000 requiring entering the room mid-treatment with sectors in on position

Elekta

Leksell Gamma Knife® Spares More Healthy Tissue

Proven Peer-Reviewed Track Record

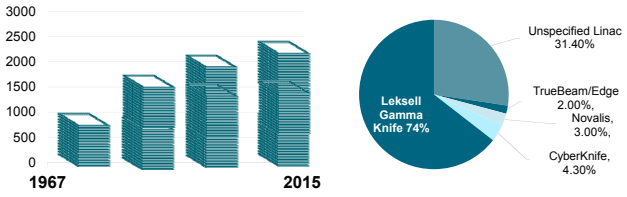
Multiple peer-reviewed publications demonstrate Gamma Knife delivers the lowest dose to healthy brain and body tissues



Elekta

Clinical efficacy reported in over 2,500 peer reviewed publications

Leksell Gamma Knife® represents the majority of clinical publications



Source: Elekta Database with information from PubMed; *Includes AVMs, Gliomas, Meningiomas, Metastatic Tumors, Pituitary Tumors, Trigeminal Neuralgia, Vestibular Schwannoma, Essential Tremor, Glioma papers Linac papers may include some SRT patients. Unspecified linac includes brand name linacs.

Elekta

Requested Modification to PPR

NRC Guidance on Elekta Gamma Knife® Icon

Current

According to 10 CFR 35.615(f) (3)

"a licensee shall…For gamma stereotactic radiosurgery units, require an authorized user and an authorized medical physicist to be physically present throughout all patient treatments involving the unit."

"Physically present" is defined as within hearing distance of normal voice.

Elekta

NRC Guidance on Elekta Gamma Knife® Icon

Proposed

Elekta formally and respectfully requests consideration of amending the licensing guidance for Icon to read as follows:

"We will have an **Authorized User and/or Authorized Medical Physicist physically present during the initiation** of all treatments involving the unit.

We will have an **Authorized Medical Physicist physically present throughout all patient treatments** involving the unit.

We will have an **Authorized User physically present in the department during patient treatment and immediately available** to come to the treatment room to respond to an emergency."

Elekta

Current Requirements vs. Requested Modification

CURRENT	REQUESTED
At the Console	**At the Console**
At Initiation of Treatment Authorized User Authorized Medical Physicist	At Initiation of Treatment Authorized User Authorized Medical Physicist
Throughout Treatment Authorized User Authorized Medical Physicist	Throughout Treatment Authorized Medical Physicist
	Immediately Available in the Department
	Throughout Treatment Authorized User

Elekta

Physical Presence Requirements Compared

Revised language reflects technological evolution and parity

Linear Accelerator SRS*

ViewRay MR-Guided Radiotherapy System

Leksell Gamma Knife® Icon™

Physical Presence Requirements

None — **Restrictive**

Requested PPR Modification

*Not Under NRC Jurisdiction

Elekta

Thank you

Questions?

Acronyms

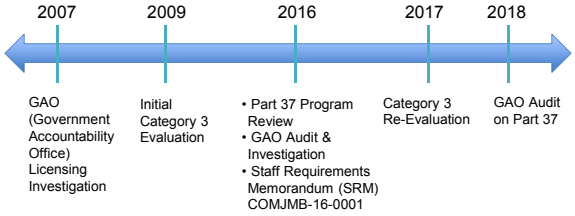
- APS: Automatic Positioning System
- CBCT: Cone-Beam CT
- GUI: Graphical User Interface
- IR: Infrared
- LGK: Leksell Gamma Knife
- MER: Medical Event Report
- PPR: Physical Presence Requirement
- QA: Quality Assurance
- SRS: Stereotactic Radiosurgery

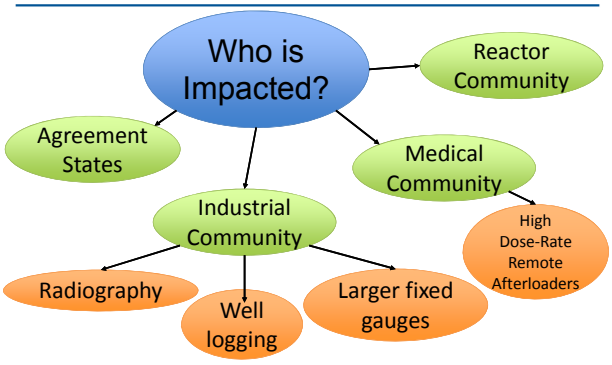
Status Update on Source Security and Accountability Initiatives

Irene Wu
Office of Nuclear Material Safety and Safeguards

Advisory Committee on the Medical Uses of Isotopes
April 26, 2017

How We Got Here



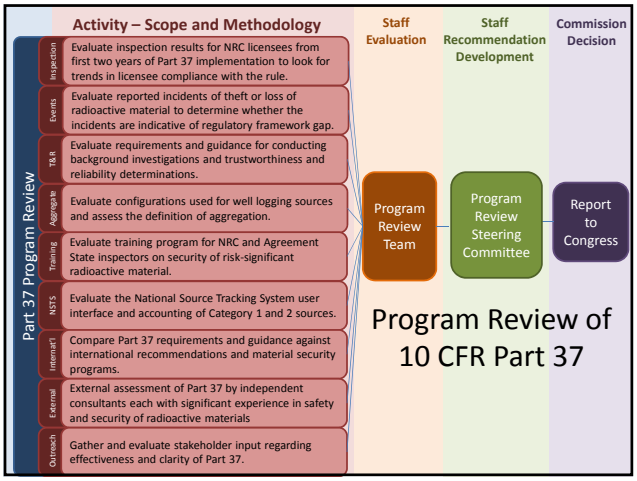


GAO 2007 Licensing Investigation
GAO-07-0138T

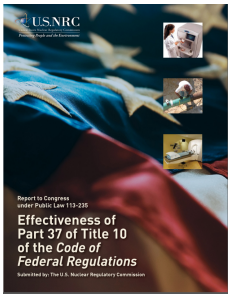
- Obtained valid NRC license for Category 4 quantity of material using fake company
- Withdrew Agreement State application due to State's plans for a site visit
- Ordered sufficient devices to obtain Category 3 quantity of material
- Report and testimony July 12, 2007
- Three recommendations by GAO
  1) Improve guidance for screening new applicants
  2) Conduct periodic oversight of license reviewers
  3) Prevent the counterfeiting of NRC licenses
- NRC considers all the recommendations closed

Initial Category 3 Evaluation

- **January 2009**: Licensees begin reporting Category 1 and 2 sources to the National Source Tracking System (NSTS).
- **January – June 2009**:
  - Staff requested Commission approval to defer rulemaking on expanding the NSTS; this request was not approved
  - Staff requested Commission approval to publish a final rule to amend 10 CFR Parts 20 and 32 to expand reporting to the NSTS to include Category 3 sources; this request was not approved (**Rationale**: Original recommendation lacked adequate technical basis and operating experience for proposed regulatory action)



Report Conclusion



- Report to Congress submitted on December 14, 2016

The analysis […] demonstrated that Part 37 provides a strong regulatory framework to ensure the security of Category 1 and 2 radioactive materials.

ADAMS ML16348A230

GAO 2016 Licensing Audit and Investigation
GAO-16-330

- Obtained valid Agreement State license for Category 3 quantity of material using fake company
- Rented storefront/warehouse space to demonstrate legitimacy
- Unsuccessful in 2 of 3 attempts
- Obtained one license and used it to order two sources (one with valid license and one after altering license)
- Two sources, in aggregate, totaled a Category 2 quantity of material

GAO 2016 Licensing Audit and Investigation
GAO-16-330 (Cont.)

- Three recommendations made by GAO
  1) Take steps needed to include Category 3 sources in NSTS and add Agreement State Category 3 licenses as quickly as reasonably possible.
  2) At least until such time that Category 3 sources can be verified using the License Verification System (LVS), require that transferors of Category 3 quantities confirm the validity of the recipient's license with the appropriate regulatory agency before the transfer until such time such verification can be done using LVS.
  3) Consider requiring that an onsite security review be conducted for all unknown applicants of Category 3 licenses to verify that the applicant is prepared to implement the required security measures before taking possession of licensed radioactive materials.

NRC Response to 2016 GAO Audit and Investigation

- Short and longer term actions performed
  - Self-assessments
  - Communication to Agreement States
  - Refresher training
  - Formation of two NRC/Agreement State working groups

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

Specific Tasks from SRM-COMJMB-16-0001

1. Evaluation of pros and cons of different methods for verification of license's validity
2. Evaluation of pros and cons to include Category 3 sources in NSTS
3. Assessment of any additional options for addressing GAO recommendations on source accountability
4. Vulnerability assessment
5. Regulatory impact analysis of benefits and costs of any recommended changes
6. Discussion on potential actions that do not require regulatory changes and monitoring their implementation through the Integrated Materials Performance Evaluation Program (IMPEP)
7. Assessment of the risk of aggregation of Category 3 sources into Category 2 quantities
8. Collaboration with all affected stakeholders
9. Any other factors to help inform Commission's decision

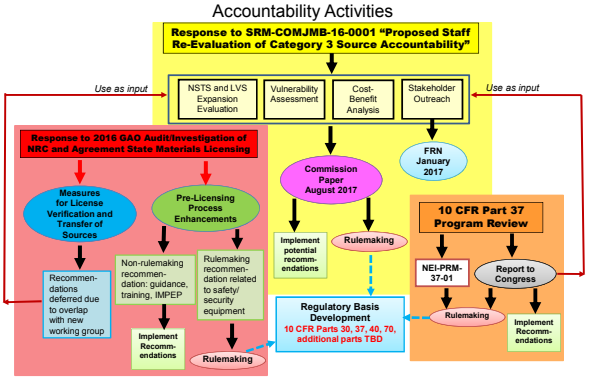
U.S.NRC
United States Nuclear Regulatory Commission
Protecting People and the Environment

Category 3 Source Security and Accountability Working Group

- NRC/Agreement State working group
- Four Principal Activities
  1. Expand on analysis and recommendations developed by License Verification and Transfer of Category 3 Sources Working Group
  2. Perform a vulnerability assessment
  3. Perform a regulatory impact/cost benefit analysis
  4. Solicit feedback from affected communities

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

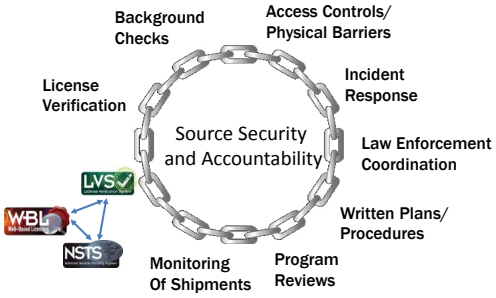
Strategy Diagram of Interrelated Category 3 Source Security and Accountability Activities



Enhancements under Consideration

- Verification of Category 3 licenses through the LVS or the regulatory authority as is done with Category 1 and 2 licenses
- Inclusion of Category 3 sources in the NSTS as is done with Category 1 and 2 sources
- Expanding physical security requirements to include Category 3 quantities of radioactive material along with Category 1 and 2 quantities of radioactive material

Enhancements under Consideration



Outreach

- *Federal Register* notice (FRN) issued, which included specific questions for stakeholders to consider
- Public meetings/webinars to facilitate feedback on the FRN
  - 4 public meetings/webinars
  - 2 webinars
- Presentations to industry groups and professional organizations
- Comment period closed March 10, 2017

FRN Questions/Comments

- Comments received regarding Category 3 license verification
- Comments received regarding Category 3 sources in the NSTS
- Comments received regarding enhanced physical security requirements for Category 3 sources
- Comments received regarding Category 3 sources covered under a general license

Next Steps

- Consolidate stakeholder comments and input
- Identify potential enhancements for consideration
- Complete vulnerability assessment
- Perform regulatory impact and cost benefit analysis
- Determine which recommendations will enhance safety and security

Commission Paper due August 2017

Additional Information on Category 3 website:
https://www.nrc.gov/security/byproduct/category-3-source-security-accountability-reevaluation.html

Questions?

Duncan White
Email: Duncan.White@nrc.gov
Phone: (301) 415-2598

Irene Wu
Email: Irene.Wu@nrc.gov
Phone: (301) 415-1951

Acronyms

- GAO – Government Accountability Office
- LVS – License Verification System
- NRC – Nuclear Regulatory Commission
- NSTS – National Source Tracking System
- SRM – Staff Requirements Memorandum
- T&R – Trustworthiness and Reliability

Status of Medical Events FY 2016

Donna-Beth Howe, Ph.D.
Medical Radiation Safety Team
April 26, 2017

1

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.

2

Medical Events 2011-1312

- **58 Medical events reported - FY 2011**
- **48 Medical events reported - FY 2012**
- **43 Medical events reported - FY 2013**

	FY11	FY12	FY 13
35.200	3	2	0
35.300	6	2	2
35.400	26 (2?)	15	15
35.600	12	13	10
35.1000	11	20	16

3

Medical Events 2014-16

- **46 Medical events reported - FY 2014**
- **57 Medical events reported - FY 2015**
- **50 Medical events reported - FY 2016**

	FY14	FY15	FY16
35.200	1	3	4
35.300	3	8	4
35.400	5	9(10)	6(18)
35.600	10	17	6
35.1000	27	20(31)	30

4

Medical Events 2016

35.200 Medical events 4

Technetium-99m

- Administered entire 128 milliCurie(mCi) multi dose vial to a single patient - 8 centiGray (cGY) (rad) whole body.
  - Staff member failed to verify dosage.
  - Licensee will no longer prepare kits.
- Intra venous port leaked.
  - Skin exposure exceeded 50 centiSievers(cSV)(rem).

5

Medical Events 2016

35.200 Medical events (cont.)

- Failure to verify dosage or type of procedure.
  - Prescribed 18.5 to 37 MegaBequerel (MBq) (0.5 to 1 mCi) filtered sulfur colloid for a lymphoscintigraphy study.
  - Technologist delivered 88.8 MBq (2.4 mCi) unfiltered sulfur colloid for a gastric emptying study.
  - Potential dose of 58.08 to 273.6 cSv (rem) to the skin.
  - Technologist now has to verbally confirm the activity and type of procedure with the doctor prior to administration.

6

Medical Events 2016

35.200 Medical events (cont.)

- Wrong patient and wrong drug.
  - Prescribed interstitial 18.5 MBq (0.5 mCi) Tc-99m for sentinel node scintigraphy.
  - Received interstitial 1,110 MBq (30 mCi) Tc-99m bone.
  - Miscommunication contributed to error.
  - Technologist failed to verify patient identity was same as on the dosage pig

7

Medical Events 2016

35.300 Medical events 4

Samarium 153	1
Radium 223	2
Iodine 131	1

8

35.300 Medical Events

Samarium 153 **1**

- Administered 3.22 GBq (86.9 mCi) – instead of 2.48 GBq (67.13 mCi).
  - Dosage from pharmacy was not correctly calculated for the patient's weight.

9

35.300 Medical Events (cont.)

Ra-223 dichloride **2**

- Administered 119.3 microcuries (µCi) instead of 86.7 (µCi).
  - Wrong patient.
- Administered 99.4 µCi instead of 980 µCi.
  - Failed to observe the difference between the calibrated activity and the prescribed activity.
  - Licensee believes authorized user intended to prescribe 98 µCi a typical dosage.
  - Corrective action - list the activity in µCi, instead of mCi.

10

35.300 Medical Events (cont.)

Iodine-131 **1**

- **Administered 53 mCi instead of 120.8 mCi.**
  - Dosage delivered in two capsules.
  - One capsule returned to the pharmacy.
  - Licensee to revise procedures for transfer of radioactive materials.

11

Medical Events 2016

35.400 Medical events **6**

Gynecological 1

Prostate (18 patients) 5

12

35.400 Medical Events

Gynecological **1**

- Administered 1,500 cGy (rad) - instead of 3,460 cGy (rad) to the treatment site.
  - Crimped applicator tube in lead pig during transport.
  - Incorrectly interpreted resistance during application placement in left side of tandum as indicating source was at end tube.
  - Lower rectum and vaginal areas received more dose than expected.

13

35.400 Medical Events (cont.)

Prostate (18 patients) 5

One licensee 2 event reports 15 patients.

- 2006 - 2011 - **13 patients -** identified by inspectors
  - Administered dose differed by more than 50 cSv (rem) and by 20% or more.
- 2016 – **2 patients** identified by post implant images **)**
  - Administered 8,319 cGy - 66.55% of prescribed dose.
  - Administered 8,906 cGy (rad) - 71.25% of prescribed dose.

14

35.400 Prostate Events (cont.)

- **Ultrasound the images confusing**.
  - No activity administered to the prostate gland.
  - Seeds mistakenly implanted into a mass identified as the prostate gland.

15

35.400 Prostate Events (cont.)

Human error.

- Administered 643.948 MBq (17.404 mCi) for a dose 69.55% to the intended target tissue.
- Administered total seed activity of 26.34 mCi in prostate for dose of 59.79% intended 45.33 mCi.

16

Medical Events 2016

35.600 Medical events	**6**
HDR (8 patients)	6
• Broncus (3 patients)	1
• Mandible	1
• Gynecological	2
• Prostate	2

17

35.600 HDR Events

Bronchus (3 patients) 1

- **Adaptor piece used to determine Dwell positions.**
  - 2 of 3 fractions delivered 4 cm from treatment site- no dose to treatment site for 2 fractions.
  - 3 of 3 fractions delivered to wrong treatment site - received 0%, 43% and 20 % of dose to treatment site.
  - 3 of 3 fractions to wrong treatment site no dose to treatment site.
  - Revise HDR bronchoscopy treatment procedure.
  - ELEKTA update user's manual, put warning sticker on the applicator packaging, and improve user training.

18

35.600 HDR Events (cont.)

Mandible 1

- **Wrong Patient Treatment Plan.**
  - Used treatment plan time for another patient - 8.2 seconds less.
  - "time-out" policy to confirm the patient and treatment information is correct prior to treatment.

19

35.600 HDR Events (cont.)

Gynecological 2

Wrong site.

- **Patient reported to primary care physician with skin burns on leg.**
  - Thought second of three fractions delivered 6,000cGY rad to leg.
  - Human error with the transfer tube/applicator interface.

20

35.600 HDR Events (cont.)

Gynecological cont.

Equipment Problem.

- **Prior to third channel, friction detected in the applicator check cable, the check cable withdrawn, and the treatment stopped**.
  - Prescribed 600 cGy (rad) during the tandem and ovoid treatment.
  - Applicator permanently removed from use.

21

35.600 HDR Events (cont.)

Prostate 2

- **Equipment Failure.**
  - Patient received .16% of intended 1,350 cGy.
  - Error code 4 (friction was detected during source in-drive) on second of 18 catheter sites, the source retracted, unit reset, but problem persisted.
  - Several parts required replacement (opto-pair interface, power supply control board, and stepper motor control board).

22

35.600 HDR Events (cont.)

Prostate continued

- **Equipment Failure.**
  - During second fraction on catheter site 10 of 19 catheter sites, multiple error codes (source had moved from the dwell position and that a reset of the console was required and friction was detected during source in-drive).
  - Console reset but attempts to continue the treatment failed and treatment terminated at 12.5 % of dose.
  - V-block and opto-pair had to be replaced.

23

Medical Events 2015

35.1000 Medical events		**30**
Perfexion	**3**	
I-125 Seed localization	**1**	
Y-90 Microspheres	**26**	
Therasphere ®	13	
SirSphere ®	13	

24

35.1000 Medical Events

Perfexion 2

- **Wrong treatment site - new frame adaptor issue.**
  - Patient was given a break and the frame adapter was observed locked, but in wrong position.
  - Displacement was a maximum of 2 cm in one plane.
- Non-keyed design - frame adaptor could be placed onto the head frame incorrectly.
- Difference in clamping force between the old and new frame adapters.
- Operator did not follow new instructions.

25

35.600 Medical Events

Perfexion cont.

- **Estimated Administerion of 930 cGy (rad) to an unintended cerebral site, with a volume of 0.7 cc.**
  - Treatment stopped after 15 of 16 sites to re-sedate the patient.
  - On site 16, the patient awoke and moved significantly.
  - The frame was out of position when the patient was removed from the unit.
  - Frame could have moved during or after treatment.

26

35.1000 Medical Events

Perfexion cont.

- **Human error – incorrect positioning of isocenter.**
  - Administered 8,500 cGy to left side of the brain instead of right side of brain.
  - Identified as the treatment was completed.
  - Corrective actions - procedure modifications.

27

35.1000 Medical Events

I-125 Radioactive seed localization. 1

- **Seed unable to be removed on schedule.**
  - Surgery was cancelled - patient had a stroke during interim days.
  - Initial estimates of the patient's effective whole body dose are 3.7 cSv (rem) and 73 cGy (rad) to the breast..

28

35.1000 Medical Events

Y-90 Microspheres 26

Therasphere ® 13

- Wrong site 2
- Volume determination 1
- Catheter 1
- Radiation detector 3
- Modified apparatus 1
- Unusual resistance 2
- Remained in waste/delivery 2
- No description/reason 1

29

35.1000 Y-90 Events (cont.)

Therasphere® wrong site 2

- **administered to previously treated segment IV (left lobe) not segments V, VI, VII, and VIII (right lobe).**

- Concluded catheter moved from patient movement or breathing but did not perform fluoroscopic contrast imaging immediately prior to treatment to verify catheter position.
- Medical consultant determined that segment IV received 43,700 cGy (rad) - hepatic and tumor necrosis are anticipated.

30

35.1000 Y-90 Events (cont.)

Therasphere ® wrong site(cont.)

- **Administered 88.6% more than prescribed –dosage intended for another patient the next day.**
  - wrong lobe because of displaced the catheter and failure to verify its position during administration.
  - Inadequate procedures and insufficient training.
  - Additional imaging techniques to verify catheter placement.

31

35.1000 Y-90 Events (cont.)

Therasphere ® volume determination 1

- **Administered 9,400 cGy (rad) instead of intended 12,000 cGy (rad) to entire left lobe of the liver.**
  - Tc-99m image taken prior to the administration showed a smaller liver volume that was used to determine the amount of Y-90 to administer.
  - Change work flow so a second review of the liver volume is performed prior to administration.

32

35.1000 Y-90 Events (cont.)

Therasphere ® catheter 1

- **Administered 0.491 GBq (13.27 mCi) instead of 3.1 GBq (83.78 mCi).**
  - Post apparatus readings were higher than expected.
  - Most of the activity remained within the catheter.
  - Catheter representative thought catheter apparatus may not have been fully extended.
  - Will use a different and newer catheter product.

33

35.1000 Y-90 Events (cont.)

Therasphere ® radiation meter 3

- **Administered 64% of 3,065.45 MBq (82.85 mCi).**
  - Electronic dosimeter attached to the treatment device had fluctuating readings but no low battery warning.
  - Dosimeter readings indicated microspheres were administered but 36% of the activity remained.
  - Dosimeter checked and had low battery warning.
  - Corrective actions - changing batteries in the electronic dosimeter prior to each administration.

34

35.1000 Y-90 Events (cont.)

Therasphere ® radiation meter cont.

- **Administered 71% of 14,000 cGy (rad).**
  - Stasis was not reached, radiation survey meter revealed 0 reading and it was thought the patient received the entire dose.
  - From waste measurements, and calculations 4,000 cGy (rad) were discovered in the waste.

35

35.1000 Y-90 Events (cont.)

Therasphere ® radiation meter cont.

- **Administered 62% of 1.81 GBq (48.92 mCi).**
  - At completion radiation survey revealed 0 mR/hour.
  - Microsphere delivery kit taken to the hot laboratory for further radiation surveys and had 34% of dose in vial.

36

35.1000 Y-90 Events (cont.)

Therasphere ® modified apparatus 1

- **Administered 52% of 819.18 MBq (22.14 mCi).**
  - Authorized user observed air in the delivery system and added a three-way stopcock to the system to collect the air.
  - Radiation surveys revealed 0 mR/hour from the dose vial, but significant activity found in plastic container.
  - Concluded the three-way stopcock interfered with the administration.

35.1000 Y-90 Events (cont.)

Therasphere ® unusual resistance 2

- **Administered 25% of activity during two separate administrations.**
  - Unusual resistance during the both procedures.
  - Unsuccessful attempts to clear the line, efforts to complete the administration were experienced both times and the administrations were terminated.
  - Delivery sets from the same lot and both doses of microspheres came from the same lot.

35.1000 Y-90 Events (cont.)

Therasphere ® unusual resistance cont.

- **Administered 76% of intended 12,500 cGy (rad).**
  - Resistance in the tubing felt during administration .
  - The tubing disconnected, flushed with saline solution, and then reattached.
  - 24% of radioactivity was in the waste.

35.1000 Y-90 Events (cont.)

Therasphere ® waste/delivery 2

- **Administered 50% of activity.**
  - Discovered at completion of dose assessment - primarily in the system waste container.
- **Administered 74% of activity.**
  - Discovered at completion of dose assessment - primarily in delivery equipment.
  - Attributed to human error - corrective actions included providing new training to personnel.

35.1000 Y-90 Events (cont.)

Therasphere ® no description/reason

- **Administered 0.28 GBq (7.57mCi) 15% of intended 1.87 GBq (50.54 mCi).**

41

35.1000 Y-90 Events (cont.)

SirSphere ® 13

- Dose Calculation Error 2
- Wrong site 1
- Apparatus tubing 1
- Catheter Clumping/Occluded 3
- Catheter displaced 1
- Vials 4
- No description/reason 1

42

35.1000 Y-90 Events (cont.)

SirSphere ® Dose calculation error 2

- **Administered 643.8 MBq (17.4 mCi) instead of 499.5 MBq (13.5 mCi).**
  - 29% more than prescribed .
  - Technologist miscalculated the doseage required.
- **Administered 77 % to 78 % of intended dose.**
  - Authorized User forgot to change the lung and liver estimated doses on the pre-calculation worksheet.
  - Instructions to draw slightly more microspheres than prescribed to account for the 74 MBq (2 mCi) in waste.

43

35.1000 Y-90 Events (cont.)

SirSphere ® Wrong Site 1

- **Delivered to left lobe instead of right.**
  - Intended 1,076.7 MBq (29.1 mCi) for right lobe.
  - Administering 868.76 MBq (23.48 mCi) to left.
  - 119.4% of the activity prescribed in the written directive scheduled.
  - Failure to follow procedures.

44

35.1000 Y-90 Events (cont.)

SirSphere ® aparatus tubing 1

Administered 0.74 GBq (20 mCi)instead of 0.95 GBq (25.7 mCi).

- A large amount of microspheres found in the tubing.
- No resistance felt - stasis not reached.
- Long time period between microsphere preparation and patient administration contributed to the cause.
- Will draw 4 to 6% more activity in dose to account for decay and residual activity in the apparatus tubing.

45

35.1000 Y-90 Events (cont.)

SirSphere ® catheter Issues 3

- **Administered 0.04 GBq (1.08 mCi) 3% of intended 1.29 GBq (34.86 mCi).**
  - Encountered back pressure and terminated the procedure.
  - Microsphere clumping.
  - Improper manufacturer preparation of microspheres, occlusion of the micro-catheter used, or collection of air in the three-way stopcock.

46

35.1000 Y-90 Events (cont.)

SirSphere ® catheter displaced

- **Administered 518 MBq (14 mCi) 56% of 925 MBq (25 mCi).**
  - Microspheres ended up in the patient's catheter, chucks, and on the floor**.**
  - Attributed to patient movement that displaced the catheter in the patient and disabling treatment to the desired liver lobe.
  - When patient moves during treatment, will stop the administration.

47

35.1000 Y-90 Events (cont.)

SirSphere ® catheter issues cont.

- **Administered 70% activity.**
  - Concluded caused by a clogged catheter.
- **Administered 144.3 MBq (3.9 mCi) 33% of intended 432.9 MBq (11.7 mCi).**
  - Significant resistance within the Surefire microcatheter**.**
  - Low flow in catheter or target vessels may allow distal accumulation of microspheres in catheter.
  - Use vasodilators will be administered prior to infusion.

48

35.1000 Y-90 Events (cont.)

SirSphere ® vial issues 4

- **Administered 129.5 MBq (3.5 mCi) 44% of intended 296 MBq (8 mCi).**
  - Small plug of microspheres was noticed in the bottom of the dose vial.
  - Lack of experience with microspheres.
  - Mixing the dose as close as possible to the delivery time, routine agitation of vial, adjusting position of the inlet tubing needle to ensure maximum agitation.

49

35.1000 Y-90 Events (cont.)

SirSphere ® vial issues cont.

- **Administered 268.25 MBq (7.25 mCi) 69% of intended 389.98 MBq (10.54 mCi).**
  - Residual activity adhered to top of vial.
  - Either the needle not inserted far enough into the vial or agitation of the vial during the administration caused microspheres to adhere to the top of the vial.
  - Increase orders by 5% to compensate for residual activity that remains in vials and tubing.

50

35.1000 Y-90 Events (cont.)

SirSphere ® vial issues cont.

- **Administered 492.1 MBq (13.3 mCi) 74% of intended 669.7 MBq (18.1 mCi).**
  - Residual activity in the vial.
- **Administered 10 % of intended dose.**
  - Puncture site in V-vial rubber stopper leaking.
  - Could not stop leak with dermabond (manufacturer recommended glue) - aborted procedure.
  - Radiopharmacy to higher gauge, smaller lumen needles.

51

35.1000 Y-90 Events

SirSphere ® no description/reason

Administered 79.5% of their prescribed dose.

- 20.5% of dose found in device/waste.

52

Acronyms

- 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

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QUESTIONS?

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Protecting People and the Environment

Other Medical Byproduct Material Events FY 16

Susan M. Langhorst, Ph.D., CHP
ACMUI
April 26, 2017

Other Medical Byproduct Material Events – identified in FY16

- **NMED event involving medical license or associated license**
- **NMED event associated with medical license, including § 35.3047 events**
- **Does not include § 35.3045 medical events or other patient safety events**

Other Medical Byproduct Material Events – identified in FY16 [FY15]

Categories

- **Miscellaneous – 8 [13]**
- **Leaking sealed sources – 8 [4]**
- **Lost matls/sources (no Cat. 1 or 2) – 17 [24]**
- **Shipping issues – 13 [12]**
- **Landfill alarms – 71 [114]**

Other Events – Miscellaneous FY16 [FY15]

- **Occupational overexposure – (4) 0 [6]**
- **Declared pregnant worker – 2 [0]**
- **§ 35.3047 events – 1 [1]**
- **Suspected public overexposure – 2 [0]**
- **Equipment failures – 1 [3]**
- **Contamination – 2 [2]**
- **Recordkeeping – 0 [1]**

Other Events –
Leaking sealed sources FY16 [FY15]

- **Cs-137 source (<0.3 mCi) – 4 [0]**
- **Ge-68 source – 2 [0]**
- **I-125 source (localization) – 1 [2]**
- **I-125 source (eye plaque) – 0 [1]**
- **Pd-103 source (prostate seed) – 0 [1]**
- **Isotope not given – 1 [0]**

5

Other Events –
Lost materials/sources FY16 [FY15]

- **Lost after procedure (I-125) – 8 [10]**
- **Lost/found/lost and found – 7/0/0 [4/1/0]**
- **Buried pacemaker – 0 [1]**

6

Other Events –
Shipping issues FY16 [FY15]

- **Delivered issue – 3 [4]**
- **Stored in unsecured area – 0 [1]**
- **Accident – 1 [0]**
- **Shipping package issues – 6 [7]**
- **No license approval for receipt – 1 [0]**
- **Lost during shipment – 2 [8]**

7

Other Events –
Landfill alarms FY16 [FY15]

Isotope	Hospital	Residence	Not identified
I-131	1 [6]	0 [10]	41 [58]
In-111	0 [1]	0 [2]	3 [1]
Tc-99m	3 [3]		11 [10]
Tl-201		0 [1]	0 [1]
Not identified			12 [21]

Reports from States or other areas –
10 [18]% AL 86 [81]% CA 0 [1]% DC 0 [1]% FL 4 [0]% TN

8

Acronyms

- **ACMUI** – Advisory Committee on Medical Uses of Isotopes
- **FY** – NRC Fiscal Year (October 1-September 30)

9

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

ACMUI Standing Subcommittee on Training and Experience Requirements for All Modalities

April 26, 2017

Subcommittee Members

- **Dr. Susan Langhorst**
- **Dr. Darlene Metter**
- **Dr. Christopher Palestro (Chair)**
- **Dr. John Suh**
- **Ms Laura Weil**

ACMUI Standing Subcommittee on T&E

- **Established in 2016**
- **Specific charge**
  - **Periodically review T&E requirements currently in effect for all modalities**
  - **Make recommendations for changes as needed**

ACMUI Standing Subcommittee on T&E

- **Review T&E requirements currently in effect for uses of**
  - **Unsealed byproduct materials**
    (10 CFR 35.100, 35.200, 35.300, & 35.1000)
  - **Sealed byproduct materials**
    (10 CFR 35.400, 35.500, 35.600, & 35.1000)

Guiding Principle

- Recommendations regarding training & experience should ensure that
  (1) requirements & provisions in Part 35, which "provide for the radiation safety of workers, the general public, patients, and human research subjects" are satisfied &
  (2) patient access to these procedures is not unnecessarily compromised.

5

Issues to be Addressed by the Subcommittee

- Periodic review
  - T & E requirements
  - Competency
  - Patient access

Periodic Review

- Reasonable review interval
  - 15 years: too long
  - 1 year: impractical
  - 5 years: reasonable/practical
    - More frequently if needed
      - New procedure
      - Increase in ME's
      - Other

Review Template

T & E Requirements for.....

- Classification
  - Appropriate
  - Inappropriate
  - Obsolete
- Evaluation
  - ME's
  - RSE's
  - Patient Access

Classifying T & E Requirements

- **Appropriate**
- **Inappropriate**
  - **Insufficient**
  - **Excessive**
  - **Obsolete**

Classifying T & E Requirements

Appropriate

- **ME's and RSE's**
  - **Few/none**
  - **Constant or trending downward over time**
- **Adequate patient access**

Classifying T & E Requirements

Inappropriate

- **Insufficient**
  - **Frequent/many ME's or RSE's**
  - **Upward trending of ME's or RSE's**

Classifying T & E Requirements

Inappropriate

- **Excessive**
  - **Few or no ME's & RSE's**
  - **No upward trending of ME's or RSE's**
  - **Inadequate patient access**

Classifying T & E Requirements

- **Obsolete**
  - **Procedure(s) no longer performed**
  - **No AU's**

Classification of T & E Requirements

Should be based, at a minimum, on evaluation of

- **ME's**
- **RSE's**
- **Patient Access**

Evaluating T & E Requirements

ME's

- **Number & Trends**
  - **Analysis**
    - **Procedure issue**
    - **Competence issue**
    - **Combination**

Evaluating T & E Requirements

RSE's*

- **Number & Trends**
- **Enforcement actions**
- **Analysis**
  - **Procedure issue**
  - **Competence issue**
  - **Combination**

***high occupational doses, lost sources, improper recordkeeping, lack of instrument checks or calibrations**

Evaluating T & E Requirements

Patient Access*

- Do current/proposed regulations limit patient access to procedures?
- Do current/proposed regulations provide adequate protection from unintended radiation exposure?
- Accessible/reasonable pathways for obtaining AU status?

*including number of procedures performed

Competency

General Definition:

- Ability to do something, especially measured against a standard

Medical Definition:

- Principle of professional practice, identifying ability of a provider to consistently administer safe, reliable care

Determining Competence

Majority of AU's

- Deemed status of various certifying boards (ABNM, ABR, etc.)

Potential Alternative Pathway

- Didactics (with examination) and "hands on" experience with preceptor certification
- Practical examination (independent examining committee)

Review Template Example

10 CFR 35.190 Training for uptake, dilution, and excretion studies.

- Evaluation
  - ME's: None reported over 10 yrs.
  - RSE's: Not available
  - Patient access: No known issues
- Classification
  - Appropriate

Subcommittee

Acknowledges & appreciates

NRC staff input, especially Ms Maryann Ayoade

Encourages continued input from

- **NRC staff**
- **ACMUI**
- **Stakeholders**

Stakeholder Input

- **Informal**
  - **Faster**
  - **Potential for bias**
- **Formal**
  - **Slower**
  - **Broader respondent base**

Acronyms

ACMUI: Advisory Committee on Medical Uses of Isotopes

AU: Authorized user

ME: Medical event

NRC: Nuclear Regulatory Commission

RSE: Radiation safety event

T&E: Training and experience

Nuclear Regulatory Commission (NRC)

Advisory Committee on the Medical Uses of Isotopes (ACMUI)

Standing Subcommittee on Training and Experience Requirements

Subcommittee Status Report

April 26, 2017

SubCommittee Members:

Dr. Susan Langhorst

Dr. Darlene Metter

Dr. Christopher Palestro (Chair)

Dr. John Suh

Ms Laura Weil

NRC staff: Maryann Ayoade

Charge

The specific charge of this standing subcommittee is to periodically review the training and experience requirements currently in effect for all modalities, which includes both unsealed byproduct materials (10 CFR 35.100, 35.200, 35.300, & 35.1000) and sealed byproduct materials (10 CFR 35.400, 35.500, 35.600, & 35.1000) and to make recommendations for changes as needed.

Guiding principle

The subcommittee recognizes that any recommendations for or against changes in training and experience should ensure that the requirements and provisions in Part 35, which "provide for the radiation safety of workers, the general public, patients, and human research subjects" are satisfied, while simultaneously ensuring that patient access to these procedures is not unnecessarily compromised.

Standing Subcommittee Suggestions for Consideration

In order to conduct the reviews in a systematic and consistent fashion, the subcommittee has developed the following review template:

Review Template

For

Training & Experience Requirements for 10 CFR 35---

Classification

Appropriate
Inappropriate
Obsolete

Evaluation

Medical events
Radiation safety events
Patient access

Explanation of Template Items

The subcommittee suggests that current requirements for training and experience be classified as appropriate, inappropriate, or perhaps, obsolete.

Appropriate: There are no, few, or downward trending medical events or radiation safety events, and there are no patient access issues.

Inappropriate:

- Insufficient - there are frequent, many or increasing numbers of medical events or radiation safety events, or
- Excessive - there are few or no upward trending of medical events or radiation safety events, but there are patient access issues

Obsolete: Procedure(s) no longer performed; no authorized users

Classification should be based, at a minimum, on evaluation of medical events, radiation safety events (e.g. high occupational doses, lost sources, sources disposed of in regular waste, improper

recordkeeping, lack of instrument checks or calibrations, inadequate labeling or posting, etc.) and patient access, including the number of procedures performed.

Medical events: Number & trends (increasing/decreasing/stable). If there are many or the numbers are increasing, further analysis is needed. Is there an issue with the procedure itself; is it due to lack of competence, or a combination?

Radiation safety events: Number & trends (increasing/decreasing/stable). If there are many or the numbers are increasing, further analysis is needed. Is there an issue with the procedure itself or is it due to lack of competence, or a combination?

Patient Access: Do current/proposed regulations limit patient access to procedures? Are the pathways for obtaining Authorized User status reasonable and accessible?

The subcommittee has discussed the issue of how to define "periodic review" and agrees that five years is a reasonable, and attainable, goal. The introduction of new procedures, increasing numbers of medical and/or radiation safety events, and patient access issues all could be cause for an accelerated review.

The subcommittee continues to grapple with the complex issue of competence. A general definition of competence is the ability to do something, especially measured against a standard. Medically, competence is defined as a principle of professional practice, identifying the ability of a provider to consistently administer safe, reliable care.

In the majority of cases for Authorized Users, competence is determined through the certification process of a "specialty board" that has been granted "deemed status" by the NRC.

What about "alternative pathways"? How is competence to be determined?

Didactics with examination and "hands on" experience with preceptor certification?

Practical examination by an independent examining committee?

For its initial review the subcommittee chose 10 CFR 35.190, the training and experience requirements for which follow.

10 CFR 35.190 Training for uptake, dilution, and excretion studies.
Except as provided in § 35.57, the licensee shall require an authorized user of unsealed byproduct material for the uses authorized under § 35.100 to be a physician who -
(a) Is certified by a medical specialty board whose certification process has been recognized by the Commission or an Agreement State and who meets the requirements in paragraph (c)(2) of this section. (The names of board certifications which have been recognized by the Commission or an Agreement State will be posted on the NRC's Web page.) To have its certification process recognized, a specialty board shall require all candidates for certification to:
(1) Complete 60 hours of training and experience in basic radionuclide handling techniques and radiation safety applicable to the medical use of unsealed byproduct material for uptake, dilution, and excretion studies as described in paragraphs (c)(1)(i) through (c)(1)(ii)(F) of this section; and
(2) Pass an examination, administered by diplomates of the specialty board, that assesses knowledge and competence in radiation safety, radionuclide handling, and quality control; or

(b) Is an authorized user under §§ 35.290, 35.390, or equivalent Agreement State requirements; or

(c) (1) Has completed 60 hours of training and experience, including a minimum of 8 hours of classroom and laboratory training, in basic radionuclide handling techniques applicable to the medical use of unsealed byproduct material for uptake, dilution, and excretion studies. The training and experience must include -
(i) Classroom and laboratory training in the following areas -
(A) Radiation physics and instrumentation;
(B) Radiation protection;
(C) Mathematics pertaining to the use and measurement of radioactivity;
(D) Chemistry of byproduct material for medical use; and
(E) Radiation biology; and

(ii) Work experience, under the supervision of an authorized user who meets the requirements in §§ 35.57, 35.190, 35.290, 35.390, or equivalent Agreement State requirements, involving -

(A) Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;
(B) Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters;
(C) Calculating, measuring, and safely preparing patient or human research subject dosages;
(D) Using administrative controls to prevent a medical event involving the use of unsealed byproduct material;
(E) Using procedures to contain spilled byproduct material safely and using proper decontamination procedures; and
(F) Administering dosages of radioactive drugs to patients or human research subjects; and

(2) Has obtained written attestation, signed by a preceptor authorized user who meets the requirements in §§ 35.57, 35.190, 35.290, or 35.390, or equivalent Agreement State requirements, that

the individual has satisfactorily completed the requirements in paragraph (a)(1) or (c)(1) of this section and has achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized under § 35.100.

Review Template

For

Training & Experience Requirements for 10 CFR 35.190 Training for uptake, dilution, and excretion studies.

Evaluation

Medical events: None reported over 10 yrs.

Radiation Safety events: Not available

Patient access: No known issues

Classification

Appropriate

The subcommittee acknowledges and appreciates the input of NRC staff, in particular Ms Maryann Ayoade, and continues to encourage ACMUI, NRC, and stakeholder input throughout the process.

Patient Release Project Update

Donna-Beth Howe, Ph.D.
Medical Radiation Safety Team
April 26, 2017

April 28, 2014

STAFF REQUIREMENTS – COMAMM-14-0001/COMWDM-14-0001 – "BACKGROUND AND PROPOSED DIRECTION TO NRC STAFF TO VERIFY ASSUMPTIONS MADE CONCERNING PATIENT RELEASE GUIDANCE"

Commission Direction/ Objectives

Input from wide spectrum of stakeholders - the public, patients, patient groups, physicians, professional societies, licensees, ACMUI, and Agreement States

- Office of Budget and Management Clearance
- Federal Register Notice
- Public Meeting(s)

Part 1 Commission Direction/ Objectives

Focus on obtaining:

- Information that patients believe will help them understand the I-131 treatment procedures,
- Information on physician's or licensee's best practices when making informed decisions on releasing I-131 patients,

Part 1 Commission Direction/ Objectives

Focus on obtaining:

- Information provided to patients on how to reduce radiation doses to others, and
- If patient advocacy, medical professional organizations, licensees, or other individuals have brochures that already contain the information requested.

Part 1 Staff Actions

- Received Office of Management and Budget (OMB), OMB control number 3150-0229, expiration date of October 31, 2018.
- Published Request for Information in the Federal Register November 16, 2015 with 60 day comment period.
- Held 2 public meetings December 2015 and January 2016.

Part 1 Staff Actions

- Received comments from Individual Physicians, Clinics, Hospitals, Professional Societies, Patient Advocacy Groups and Individual Patients.
- Information collected on licensee and patient best practices will be used to develop a Generic communication Summer of 2017
- Two items identified to be included in Part 2 of the Commission's Directive

Part 2 Commission Direction/ Objectives

Evaluate whether significant regulatory changes to the patient release program are warranted.

Explore with the public, licensees, and state partners whether the agency should change 10 CFR Part 35.75 for specific reasons.

Part 2 Commission Direction/ Objectives

Should the Agency change 10 CFR Part 35.75 to:

1. Require an activity-based patient release threshold under which patients would be required to be maintained in a clinic-sponsored facility (e.g., a medical facility or facility under the licensee's control) until the standard for release is met..

2. To clarify the time frame for the current dose limit in 10 CFR 35.75(a) for releasing Individuals?

Part 2 Commission Direction/ Objectives cont.

3. Should the NRC continue to apply the same dose criteria of 5 mSv (0.5 rem), to all members of the general public, including family members, young children, pregnant women, caregivers, hotel workers, and other members of the public when considering the release of patients.

4. Have a new requirement for the release of a patient who is likely to expose young children or pregnant women to doses above the 10 CFR Part 20 public dose limit.

Part 2 Commission Direction/ Objectives Staff addition

5. Have a specific requirement for the licensee to have a patient isolation discussion with patients in sufficient time prior to the administration to provide the patient time to make isolation arrangements or the licensee to make plans to hold the patient, if the patient cannot be immediately released. and

6. Have NRC explicitly include the time frame for providing instructions in the regulations (e.g., the instructions should be given prior to the procedure).

Part 2 Commission Direction/ Objectives Open questions

1. If not making a change, explain why.
2. If making a change, what criterion should the NRC use?
3. If a specific group is involved, specify the group for each criterion.
4. In either case, describe the resulting health and safety benefits, or lack of benefits, to the individual being released, the licensee. and to individual members of the public.

Part 2 Commission Direction/ Objectives Staff activities

- Federal Register Notice requesting comment from the public on these 6 items.
- 60 day public comment period.
- 2 public meetings held at NRC Headquarters with electronic participation from the public in other location.
- Results of public comments will form basis for SECY paper to the Commission on whether to pursue changes to 10 CFR 35.75.

Acronyms

- ACMUI – Advisory Committee on the Medical uses of Isotopes
- CFR – Code of Federal Regulations
- I-131 – Iodine-131
- RAI – Radioactive Iodine
- Reg – Regulatory

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

Medical Event Reporting for All Modalities Except Permanent Implant Brachytherapy

John Suh, M.D.

Subcommittee Members

- Ronald Ennis, M.D.
- Vasken Dilsizian, M.D.
- Chris Palestro, M.D.
- John Suh, M.D. (chair)
- Frank Costello
- ***Zoubir Ouhib, M.S.***

Subcommittee Charge

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

*Permanent implant brachytherapy MEs addressed previously by the ACMUI

Rationale

- Medical event reporting has not changed significantly for many years.
- Given advances in technologies, in particular radiation oncology, the current definition may not be sufficient for AU and regulators.

Number of Medical Events

- **The annual number of reports is extremely low considering the estimated 15,000,000 diagnostic and 150,000 therapeutic procedures performed annually.**

Number of Medical Events

	FY 2013	FY 2014	FY 2015
35.200			4
35.300			7
35.400	16	5	7
35.600	9	11	14
35.1000	15	26	14

ME Events Reporting FY 2015. Oct 6, 2016

Number of Medical Events

- **Does this accurately reflect the true number of cases if the current definition may be ambiguous?**
- **Does the current process, which is perceived as being punitive by some, lead to the desired goal of transparency, education, and adoption of best practices?**

Guiding Principles

- **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 in order to eliminate any ambiguity.**

Guiding Principles

- **The subcommittee believes that any proposed changes should not be overly prescriptive and must not encroach on the practice of medicine.**
- **Focus of ME reporting should be on education and improvement rather than punitive action whenever possible.**

ME criteria would need to cover a variety of treatment modalities

- **HDR brachytherapy**
- **Gamma Knife™**
- **LDR temporary implants**
- **Intraoperative modalities**
- **2D, 3D-CRT, IMRT, SRS, and SBRT**
- **SIRT**

Current Definition of 35.3045

- **Clear ME:** **Wrong drug, route of administration, patient, and mode; or leaking sealed source**
- **Ambiguous ME:**
  - **Total dose to treatment site differs from prescribed dose by 20% or more;**
  - **Single fraction dose to treatment site differs from prescribed dose by 50% or more**
  - **Intervention of patient or human 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.**

35.2 Definition

- **"Treatment site means the anatomical definition of the tissue intended to receive a radiation dose, as described in the written directive."**
- **Since the written directive gives the AU a great deal of flexibility, this can be a potential source of ambiguity as treatment site can have different meanings among AU.**
- **Treatment site is often defined as a volume, which may be source of confusion.**

Recommendations

- Use new definitions for permanent implant brachytherapy.
- Continue to use the current 10 CFR part 35.3045 definition for medical event reporting for all modalities except permanent implant brachytherapy.
- ACMUI is discussing patient intervention at this time.

Recommendations

- Encourage major societies to issue white paper(s) to develop consensus on what should be incorporated into a written directive for various diagnostic and therapeutic modalities.
- Benefits of white paper
  - Will help with inspections and regulations by promoting standardization for identifying ME.
  - Will assist licensees determine if ME has occurred.
  - Assist institutions to develop SOP to prevent future ME.

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
- IMRT – Intensity modulated radiation therapy
- LDR – Low Dose Rate

Acronyms (Cont.)

- ME – Medical Event
- SBRT – Stereotactic body radiation therapy
- SOP – Standard Operating Procedures
- SRS – Stereotactic radiosurgery
- SIRT – Selective internal radiation therapy
- 2D – Two dimensional
- 3D-CRT – Three dimensional conformal radiation therapy

Nuclear Regulatory Commission (NRC)
Advisory Committee on the Medical Use of Isotopes (ACMUI)

Subcommittee on

Medical Event Reporting for All Modalities Except for Permanent Implant Brachytherapy

***Draft* Report**
March 27, 2017

Subcommittee Members:
Frank Costello
Vasken Dilsizian
Chris Palestro
John Suh (Chair)
Zoubir Ouhib (Consultant)

NRC Staff Resource: Katie Tapp

Charge to subcommittee: To propose the appropriate criteria for medical event (ME) reporting for events other than permanent implant brachytherapy.

Subcommittee Process

The subcommittee and its Chair were appointed by ACMUI Chair, Bruce Thomadsen, at the regularly scheduled ACMUI meeting October 9, 2015. Subcommittee discussions and deliberations were conducted by teleconference on February 17, 2016. Its initial recommendations were presented at the ACMUI meeting on March 17, 2016. Subsequent discussions and deliberations were conducted by teleconference on August 15, 2016. The revised recommendations were presented at the ACMUI meeting on October 16, 2016. Since the ACMUI committee believed that having an agreement state representative was important, Frank Costello was added to the subcommittee and Pat Zanzonico was removed at the last ACMUI meeting. Most recently, the subcommittee had additional discussions and deliberations on February 28, 2017. This report summarizes the subcommittee's recommendations, which will be presented on April 27, 2017 to the NRC commissioners.

Summary of subcommittee recommendations

- Use proposed definitions for permanent implant brachytherapy that have been reviewed and submitted by the ACMUI.

- Continue to use 10 CFR35.3045 as written for medical event reporting and notification for all modalities except permanent implant brachytherapy.

- Continue ongoing discussion of whether patient intervention should be considered a medical event.

- Encourage major societies to issue a white paper(s) to develop consensus on what should be incorporated into a written directive for various diagnostic and therapeutic modalities.

Introduction

The safe delivery of diagnostic imaging procedures and therapeutic radiation treatments is the highest priority for caregivers, medical institutions, various agencies, and, ultimately, the patient. Given the many advances in imaging, nuclear medicine, and radiation oncology, various radiation modalities are now used to safely and effectively diagnose and treat cancers in addition to other diseases including non-cancerous tumors and thyroid conditions. Radiation therapy, which is a clinically and technologically complex field, can be a very effective primary, adjunctive or palliative treatment, and has been shown to eradicate cancer, control cancer growth, and palliate symptoms such as pain[1]. Since the use of radiation is not without risk and can result in potential harm, the NRC plays an important regulatory role in the medical uses of radiation.

The NRC requires extensive training requirements for physicians who use radioactive materials or byproducts, such as those used in Gamma Knife radiosurgery, brachytherapy, radiopharmaceuticals, and other forms of radiation. Although proper training is one component of safe and effective delivery of radiation for diagnostic or therapeutic uses, the treatment team needs to adopt a culture of safety and quality with checks and balances at every level to ensure that the safest procedure or treatment is being delivered to patients. Since the NRC issues regulations on the medical uses of isotopes, the balance between protecting the public's safety and facilitating the practice of medicine can be difficult to maintain. Given the approximately 7,000 medical licensees between the NRC and Agreement States, any change in medical event reporting can positively or negatively influence caregivers, medical institutions, patients, and the public. It is important that any change in reporting requirements will not restrict patients' access to medical care.

Medical event reporting has not significantly changed over the past 15 years. Aside from some administrative changes in 10 CFR Part 35, Subpart M – Reports § 35.3045 report [68 FR 58805, Oct. 10, 2003] and notification of a medical event [76 FR 72085, Nov. 22, 2011], there has been little change aside from the proposed permanent implant brachytherapy. Various organizations including the American Society for Radiation Oncology (ASTRO) and the American Association of Physicists in Medicine (AAPM) sponsor the Radiation Oncology Incident Learning System® (RO-ILS) to support patient safety of medical procedures using radiation[2].

The delivery of safe diagnostic and therapeutic radiation that utilizes radioactive materials or byproducts requires a concerted effort of the entire treatment team, including the authorized user. Based on an analysis of radiation therapy medical events which included linear accelerators during 2001-2009 in New York, failure to follow existing policies and procedures contributed to

63.6% of events, inadequate policy and procedures contributed to 15.4% of events, and documentation/communication issues contributed to 23.2% of reported events[3]. In a high reliability organization, which is the goal of every medical center, the objective is to deliver the appropriate treatment to the correct patient as safely as possible[4]. Given the evolution of radiation modalities over the past decade, the appropriate criteria for medical event reporting for events other than permanent implant brachytherapy was examined by the subcommittee.

Background

Using the current definition for medical events for all modalities, the number of medical events is extremely low when viewed in light of the estimated 15,000,000 diagnostic and 150,000 therapeutic procedures performed annually. Unfortunately, medical event reporting has come to be viewed by some as punitive, particularly among providers at those medical centers where medical event reporting is scrutinized by many individuals and/or committees with limited or no knowledge of radiation. In addition to the intense scrutiny, medical event reporting dictates a sense of urgency: expeditious notification by the next calendar day and submission of a written report within 15 days after discovery of the medical event. In addition to timely notification of government agencies, the licensee must notify the referring physician and to the individual who is the subject of the medical event no later than 24 hours after its discovery unless based on medical judgment, informing the individual would be harmful. If the referring physician or the affected individual cannot be reached within 24 hours, the licensee shall notify the individual as soon as possible thereafter. This medical event reporting process places culpability on the licensee even if the event may have minimal or no medical consequence.

The table below summarizes medical event reporting for FY 2013-2015 based on the medical events reported at the Oct 6, 2016 ACMUI meeting.

	FY 2013	FY 2014	FY 2015
35.200			4
35.300			7
35.400	16	5	7
35.600	9	11	14
35.1000	15	26	14

Some questions regarding medical event reporting:

1) Do these reports accurately reflect the true number of medical events if the current definition is ambiguous?
2) Should the definition of medical event be revised and updated to reflect the advancements made in radiation delivery, with respect to both potential and actual harm?

3) Does the current reporting process, which is perceived as being punitive by some, impede the desired goal of transparency, education, and adoption of best practices?
4) Does the current reporting process promulgate the lessons learned after root cause analysis from any medical event or does it focus blame on the individual responsible for the event?
5) Should the model of medical event reporting be more aligned with that of the aviation industry which has a spectacular record of quality and safety?

Guiding principles

Since accurate medical event reporting requires transparency and understanding of what constitutes a medical event, the subcommittee believes that any modification to the current definition needs to be carefully considered.

Medical event reporting should allow for the identification of a medical event and provide a forum to discuss how to avoid or reduce the likelihood of such an event. By fostering a just culture of quality and safety, a meaningful root cause analysis will occur serving to decrease the likelihood of such an event through the development of best practices. Furthermore, the definition of a medical event needs to be broad, simple and consistent. If the definition is too complex or is ambiguous, the reports will not be easily applicable to the authorized user, evaluable by regulators or process-focused. Any change in the medical event definition should accurately capture those cases which may cause serious injury or harm to the patient.

The subcommittee believes that any proposed change should not be overly prescriptive and must not encroach on the practice of medicine, which is rapidly evolving. Overly prescriptive changes may inhibit a physician from providing a certain diagnostic or therapeutic modality given concerns for potential medical event (as presently defined) and the subsequent reporting of same, thereby depriving a patient of an available treatment.

The focus of medical event reporting should be on education and improvement rather than punitive action. Some members of the ACMUI subcommittee have reached out to their respective professional societies to increase dialogue about the NRC's role in regulating medical isotopes, in particular trainees whose understanding can be very limited about medical event reporting. By increasing this dialogue, it is anticipated that medical event reporting will serve to optimize patient care through learning and adopting best practices**.**

Medical Event (ME) criteria for a variety of treatment modalities

Given the advances in diagnostic and therapeutic modalities using radiation, medical event reporting needs to address a number of different treatment modalities including:

1) Selective Internal Radiation Therapy (SIRT), e.g. Y-90
2) High dose rate (HDR) brachytherapy
3) Gamma Knife

4) ViewRay
5) LDR implants (non-prostate)
6) LDR meshes
7) Unsealed sources

The subcommittee considered defining ME based on a particular treatment modality in order to make it easier for licensees to determine whether an ME had occurred. Defining ME by modality may make it easier to inspect and regulate and facilitate programs, procedures, and education, which may prevent future events. Although the different modalities of imaging and therapy may have specific inherent risks associated with its delivery, a modality-specific ME for each modality was not favored by the subcommittee as this deviated from the guiding principle of keeping the definition of a medical event to be broad, simple and consistent.

Another consideration was the creation of subsections within the current definition of ME reporting to address the newer, highly conformal radiation oncology modalities that prescribe doses to volumes rather than to a treatment site. With modern radiation oncology techniques and delivery systems, a slight spatial shift of dose can result in significant dose to nearby tissues or parts of organs, which may have medical implications. Since there is variation among authorized users of what constitutes a treatment site within a radiation prescription, the same spatial shifts of dose may have different implications regarding an ME. As an example, some authorized users may use different margins for treatment planning (1 cm versus 2 cm), which would influence how much of the treatment site received prescribed dose. As a result, the subcommittee also did not favor this approach.

Current ME criteria

The current ME reporting criteria under 10 CFR 35.3045 [68 FR 58805, Oct. 10, 2003; 76 FR 72085, Nov. 22, 2011]

(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—

(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.

(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.

(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 no later than the next calendar day after discovery of the medical event.

The subcommittee believes that the following are clear ME:

(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.

Two areas of the current ME criteria discussed in detail as to whether modifications should be considered were the following:

1) Use of the term 'treatment site' in the definition of ME reporting.
2) 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.

<u>Treatment site</u>

Treatment site is defined by 10 CFR 35.2 as "the anatomical description of the tissue intended to receive a radiation dose, as written in the written directive". Some members of the subcommittee felt that the use of target volume or target site rather than treatment site was more consistent with modern nomenclature used, in particular radiation oncology. CT, PET, and MRI

scans are used to help delineate targets and normal structures. Routinely, the concepts developed from ICRU Report 50[5] and 63[6] to help create gross target volume (GTV), clinical target volume, and planning target volume (PTV) for radiation oncology treatment planning for photons and electrons. Since the current definition of ME does not incorporate volume, this may lead to ambiguity about ME reporting. For example, in the case of trigeminal neuralgia radiosurgery treatment, if only a small portion of the trigeminal nerve received prescription dose, would this be a medical event?

However, use of terms like PTV and GTV would be problematic since there is not even agreement among practitioners within an institution and clinical trials as to what constitutes ideal treatment volumes

Since the current 10 CFR 35.2 allows the authorized user to define the anatomical description and the written directive, it allows the authorized user great flexibility. For instance, the anatomical description in the written directive can be described as a treatment volume. Requiring the use of these terms with the incorporation of a minimum volume coverage threshold (GTV, CTV, and PTV) covered by the prescribed dose was discussed as an alternative ME definition, but was rejected giving the difficulty in defining this among subcommittee members. In fact, the American Association of Physicists in Medicine (AAPM) formed task group (TG263) in July 2014 to develop standardization and consistency in naming of organs and structures, dose volume histogram constraints, and other parameters[7]. Nomenclature names were more straightforward to develop for normal organs compared to targets, which is being developed. As a result, in keeping with the principle that medical event reporting should be broad, simple and consistent, the subcommittee supports the use of treatment site with the caveat that societies be encouraged to issue white paper(s) on what should be treated into a written directive for diagnostic and therapeutic modalities.

Since 10 CFR 35.2 relies on the written directive to describe the treatment site and is used to determine if an ME has occurred, it is important that the written directive contains the necessary information for the staff administering the treatment to know how and where the radiation should be given to satisfy the regulatory requirements. Since authorized users at similar facilities may have different ways to describe the same treatment site, it is important that the respective facilities understand the written directive and delivers the administration per the physician's instruction. The written directive documentation needs to contain sufficient information for regulators to determine if a medical event has occurred in accordance with the applicable regulations.

A recent paper by Evans, which was supported by multiple societies, is an example of a white paper on recommendations for the standardization of several key components of the radiation therapy prescription to facilitate accurate communication among radiation caregivers[8]. The key elements for the prescription for radiation therapy and brachytherapy are include treatment site, method of delivery, dose per fraction, total number of fractions, and total dose. They also make other recommendations such as the use of cGy rather than Gy and minimizing the use of decimal points. Development of white papers focused on the written directive would help with the standardization and be educational for authorized users, medical personnel dealing with radiation, and regulators.

Intervention of a patient or human research subject

Even with the most experienced and well trained authorized user and departmental safeguards, intervention by patient or research subject cannot be avoided. As a result, the subcommittee believes that additional discussions are needed about this section of current ME definition. Another subcommittee is reviewing whether intervention by patient or research subject should be reclassified based on passive versus active intervention.

Summary:

Subcommittee on Medical Event Reporting for All Modalities Except for Permanent Implant Brachytherapy recommends that:

- The new definitions for permanent implant brachytherapy that have been reviewed and submitted by the ACMUI should be finalized as rule making.

- The current 10 CFR 35.3045 regulations for medical event reporting for all modalities except permanent implant brachytherapy, does not require a change at this time.

- Discussion should continue on whether patient intervention should be considered a medical event.

- Major societies are encouraged to issue a white paper(s) to develop consensus on what should be incorporated into a written directive for various diagnostic and therapeutic modalities. The benefits of a white paper include 1) help with inspection and regulations by promoting standardization for identifying ME, 2) assist licensees to determine if a medical that has occurred, and 3) assist institutions in developing best practices such as development of standard operating procedures with the goal of preventing future medical events.

Ideally, medical event reporting would allow the licensee to determine if a medical event occurred, would allow the regulator to inspect and regulate, would not encroach on the practice of medicine, and would facilitate educational programs to prevent future occurrences. It is important that the process of medical event reporting fosters a culture of safety and quality with checks and balances at every level to ensure that the safest and most effective care is delivered to patients while simultaneously protecting the public. Licensees are encouraged to continue to audit and monitor their programs and adopt best practices including a high reliability system approach[9] to mitigate medical events.

Respectfully submitted, March 27, 2017

Subcommittee on Medical Event Reporting for All Modalities Except for Permanent Implant Brachytherapy, Advisory Committee on the Medical Uses of Isotopes (ACMUI), Nuclear Regulatory Commission (NRC)

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ACMUI's "Patient Intervention" Subcommittee Report – PART II

Vasken Dilsizian, M.D.
ACMUI Nuclear Cardiologist
April 27, 2017

Charge

Clarify Issue II recommendation from the October 8, 2015, Advisory Committee on the Medical Uses of Isotopes (ACMUI) presentation of "Unintentional Treatment Outcome" to determine whether the Nuclear Regulatory Commission (NRC) staff can implement the ACMUI recommendation as written.

Subcommittee Members:
Frank Costello; Vasken Dilsizian, M.D. (Chair); Ronald Ennis, M.D.; John Suh, M.D.; and Laura Weil

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10 CFR 35.2

- **"Patient intervention" means actions by the patient or human research subject, whether intentional or unintentional, such as dislodging or removing treatment devices or prematurely termination the administration.**

3

2002 Final Rule

10 CFR 35.3045(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.

4

2014 Proposed Rule

- **No changes related to the reportable medical event that results from intentional/unintentional <u>patient action</u>.**
- **<u>Question:</u>**

  What about unintentional <u>treatment outcome</u> due to anatomic or physiologic anomaly rather than intentional or unintentional action taken by a patient or human research subject? Does that constitute patient intervention? Albeit "passive" rather than "active".

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What Problem Needs Solving?

- **In Mr. Costello's presentation in March 2015, the concern was focused Y-90 microspheres**
  - **Specifically "…the patient's artery contracts and the spheres flow retrograde into the gastrointestinal artery…"**
  - **and, "…If the patient's lung shunt fraction was one value during the work-up and changed for the treatment…"**
- **Yttrium-90 Microsphere Brachytherapy Sources and Devices TheraSphere® and SIR-Spheres® Licensing Guidance, Revision 9, issued on February 12, 2016**
  - **Exception made for shunting when shunting was evaluated prior to the treatment in accordance with the manufacturer's procedures**
  - **Exception made for emergent patient conditions that prevent administration in accordance with the written directive (e.g. artery spasm or sudden change in blood pressure) (Rev 8, June 2012)**

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6

2015 ACMUI Recommendations

Issue II: Relates to ALL Treatments and not limited to Y-90 microspheres

- **Unintentional <u>Treatment outcome</u> 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.**
- **Reporting such unpredictable and unavoidable patient-specific medical events will not help to prevent such events in the future, and therefore cannot be regulated.**

7

What is the Problem that we are trying to Solve?

- **Medical Event is <u>NOT</u> a violation**
- **However, failure to report a medical event <u>IS</u> a violation**
- **Reporting such medical events by a physician may be perceived negatively in most medical centers**
- **Medical "Events" may be interpreted as medical "Errors"**

8

Medical "Event" vs Medical "Error": Should the Reporting be Similar?

Medical "Event"	Medical "Error"
• **Unintentional treatment outcome due to anatomic or physiologic anomaly**	• **Misadministration of the wrong radiopharmaceutical and/or dose in the wrong patient**

9

2017 ACMUI Recommendation

"Registry" of Unintentional Treatment Outcome events: Educational rather than Punitive

- **Tracking**
- **Trending**
- **Identifying the problem**
- **Reporting to the medical community**
- **Corrective action**
- **Feedback loop**
- **Constructive improvement**
- **Learn from the Mistakes**

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QUESTIONS?

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Nuclear Regulatory Commission (NRC)
Advisory Committee on the Medical Use of Isotopes (ACMUI)

Subcommittee on

Patient Intervention Report, Part II

***Draft* Report**
April 27, 2017

Subcommittee Members:
Dr. Vasken Dilsizian (Chair)
Mr. Frank Costello
Dr. Ronald Ennis
Dr. John Suh
Ms. Laura Weil

I. Charge

The ACMUI Chairman, Dr. Alderson, re-established the Patient Intervention Subcommittee on October 6, 2016. The subcommittee's new charge was to clarify Issue II recommendation from the October 8, 2015, Advisory Committee on the Medical Uses of Isotopes (ACMUI) presentation of "Unintentional Treatment Outcome".

II. Introduction

The reportable medical event that results from intentional/unintentional patient action dates back to the 2002 Final Rule - 10 CFR 35.3045(b) – which states that "***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***". On the subsequent 2014 Proposed Rule, no changes were proposed to the reportable medical event that results from intentional/unintentional patient action. However, during the spring of 2015 ACMUI deliberations, the question of "passive" rather than "active" patient intervention was raised. That is, what about unintentional treatment outcome due to anatomic or physiologic anomaly rather than intentional or unintentional action taken by a patient or human research subject? Does that constitute patient intervention?

In the 2015 ACMUI fall meeting, the committee proposed the following 2 sentences (as Issue II) to address the question of "passive" rather than "active" patient intervention. "***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. Reporting such unpredictable and unavoidable patient-specific medical events will not help to prevent such events in the future, and therefore cannot be regulated".***

III. What is the Problem that we are trying to Solve?

The issue of "passive" unintentional treatment outcome was addressed by the NRC staff for Yttrium-90 microsphere brachytherapy sources and devices (TheraSphere® and SIR-Spheres® Licensing Guidance, Revision 9, issued on February 12, 2016) by making an exception for 1) shunting when shunting was evaluated prior to the treatment in accordance with the manufacturer's procedures, and 2) emergent patient conditions that prevent administration in accordance with the written directive (e.g. artery spasm or sudden change in blood pressure) (Rev 8, June 2012). However, these exceptions were limited toYttrium-90 microspheres. The ACMUI committee's intention was to have a broader "passive" unintentional treatment outcome exception that relates to ALL current and future treatments, and not limited to Y-90 microspheres.

IV. Medical "Event" vs Medical "Error": Should the Reporting be Similar?

Unintentional treatment outcome due to anatomic or physiologic anomaly is a "medical event". While a medical event is not a violation, failure to report a medical event is a violation. Misadministration of the wrong radiopharmaceutical and/or dose in the wrong patient is a "medical error". Medical "events" may be interpreted as medical "errors". Because a "medical event" requires reporting to the NRC or Agreement States, it is taken to mean "fault". Reporting such medical events by a physician may be perceived negatively. It captures the attention of most medical centers leadership. It requires reporting to the legal counsel in some institutions, and in reality becomes a big deal (out of proportion to the issue at hand when it comes to patient intervention). NRC needs to think creatively about a term that will not carry with it the same weight as a medical "error".

V. 2017 ACMUI Recommendations and Specific Comments

Establish a "Registry" of unintentional treatment outcome events due to anatomic or physiologic anomaly that is educational rather than punitive in nature, with the goals of 1) Tracking, 2) Trending, 3) Identifying the problem, 4) Reporting it back to the medical community, 5) Taking corrective action, 6) Developing a feedback loop, 7) Suggesting constructive improvement, and 8) Learning from the mistakes. Is there any other registry (alternative reporting systems – ROILS, etc.) that the Authorized Users can use without calling it a medical event?

VI. Concluding Remarks

The idea of reporting an unintentional and /or unavoidable medical event due to anatomic or physiologic anomaly and having punitive consequences is the problem that we are trying to solve. The authorized users are not trying to avoid the reporting process, but rather they are trying to avoid the punitive process of reporting a medical event. The committee's intention for proposing issue II in the 2015 ACMUI fall meeting was to recommend that these "passive" rather than "active" patient interventions should not be considered as reportable medical events. Reporting such unpredictable patient-specific medical events will not help to prevent such events

in the future, and therefore cannot be regulated. Such unintentional treatment outcome exception should apply to ALL current and future treatments, and not limited to Y-90 microspheres.

Respectfully submitted, March 24, 2017
***Subcommittee on* Patient Intervention**
Advisory Committee on the Medical Use of Isotopes (ACMUI),
Nuclear Regulatory Commission (NRC)

Commission Briefing

NO HANDOUT

Group Photo

NO HANDOUT

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

UPDATE ON PART 35 FINAL RULE

TORRE TAYLOR
OFFICE OF NUCLEAR MATERIAL SAFETY AND SAFEGUARDS
April 2016

Outline of Presentation

- **Background**
- **Status**
- **Contacts**
- **Questions**

Background

- **Final rule provided to the Commission on June 17, 2016**
  - **SECY-16-0080**
    - **"Final Rule: Medical Use of Byproduct Material – Medical Event Definitions, Training and Experience, and Clarifying Amendments (RIN 3150-AI63; NRC-2008-0175)**
  - **ADAMS Accession No. ML16123A342**

Status

- **Still under Commission review**
- **Once NRC staff receives a Staff Requirements Memorandum**
  - **Final package prepared**
  - **Review and Approval – OMB**
- **Publication**
  - **Effective date – 180 days from date of publication**
  - **Agreement States – 3 years from the effective date to adopt the final rule**

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Rulemaking Process

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ACRONYMS

- **ADAMS – Agencywide Documents Access and Management System**
- **OMB – Office of Management and Budget**

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

Medical Event Reporting and Impact on Medical Licensee Patient Safety Culture

Susan M. Langhorst, Ph.D., CHP
ACMUI
April 27, 2017

Subcommittee Members

Mr. Francis Costello
Dr. Vasken Dilsizian
Dr. Ronald Ennis
Dr. Susan Langhorst (Chair)
Ms. Laura Weil
Mr. Zoubir Ouhib (Consultant)
Dr. Katherine Tapp (NRC Staff)

Overview

- **Medical use and patient exposure is different**
- **History of medical use regulations**
- **Development of safety culture and patient safety programs and organizations**
- **Exploring need and alternatives to NRC Medical Event reporting**

Fundamental Principles of Radiological Protection

- **Justification – do more good than harm**
- **Optimization of Protection – dose as low as reasonably achievable, taking into account economic and societal factors**
- **Application of Dose Limits – limits set and not exceeded other than medical exposure of patients**

AEC/NRC Medical Use History

1957 – Part 20 first established
1965 – Part 35 first established
1979 – Medical use policy established
1980 – Misadministration reporting
1986 – Training & experience for medical use types

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NRC Medical Use History

1991 – QMP & misadministration reporting changes
1995 – Strategic assessment & rebaselining project; risk-informed, performance-based approached
1997 – Patient release criteria change
2000 – Medical use policy revised

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NRC Medical Use History

2002-2005 – Current major revision of Part 35
2006-present – Continuing discussions for other Part 35 major revisions including changes in medical event reporting criteria

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NRC Nuclear Safety Culture

1996 – Policy on safety-conscious environments and raising safety concerns
2011 – Policy on safety culture where "nuclear safety culture" is defined

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NRC Nuclear Safety Culture Traits

Leadership Safety Values and Actions	**Problem Identification and Resolution**	**Personal Accountability**
Work Processes	**Continuous Learning**	**Environment for Raising Concerns**
Effective Safety Communications	**Respectful Work Environment**	**Questioning Attitude**

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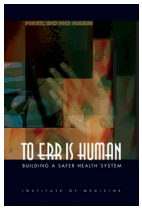
Patient Safety Culture in Healthcare

NAS IOM Reports on Patient Safety



2000

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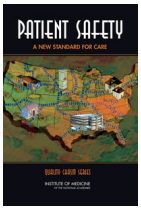

2004

10

Patient Safety – Accrediting Organizations

Medicare Program for Oversight for Accrediting Organizations

The Joint Commission

QUALITY SYSTEM CERTIFICATION DNV·GL ISO 9001

HFAP Healthcare Facilities Accreditation Program

Center for Improvement CIHQ in Healthcare Quality

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Patient Safety Organizations

Patient Safety and Quality Improvement Act of 2005

Department of Health and Human Services – 43 CFR Part 3

RIRAS Radiotherapy Incident Reporting & Analysis System
For patient safety, quality improvement and prevention of errors in Radiation Oncology

RO•ILS RADIATION ONCOLOGY® INCIDENT LEARNING SYSTEM
Sponsored by ASTRO and AAPM

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How Should NRC Support of a Positive Patient Safety Culture?

- **Medical use in early years – NRC "only game in town"**
- **Medical use now – significant and mature patient safety programs options to do professional review of patient events for overall patient safety and process improvement**

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ACMUI Discussion

- **Pros and Cons of NRC Medical Event reporting vs. other patient safety programs**
- **Should the Subcommittee continue exploration of establishing a new way in which the NRC can enhance patient safety culture while maintaining its regulatory authority?**

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Safety Culture

NRC	AOs or PSOs
NRC/AS Safety Culture is narrowly focused on "nuclear safety" and primarily focused on occupational safety and public safety; NRC has challenge dealing with patient safety issues versus interfering with the practice of medicine.	Legislative and regulatory changes have encouraged the development of hospital patient safety culture and formal patient safety programs.

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Initial patient event review

NRC	AOs or PSOs
Licensee required to review event with emphasis on regulatory compliance, but it is unclear if the licensee has more time than by the next calendar day to make this review.	Personnel required to review event and report to hospital patient safety program to determine extent of review and process improvement needed for the event.

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Timing of initial patient event review

NRC	AOs or PSOs
It is unclear if the licensee has more time than by the next calendar day to make this review.	Personnel encouraged to report a patient event or near-miss at the time of the incident to evaluate need for process improvement.

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Patient event reporting

NRC	AOs or PSOs
Medical event reporting is required for NRC regulatory compliance.	Event reporting to AO or PSO is voluntary, but encouraged.

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Reason to report event

NRC	AOs or PSOs
Review NRC regulatory compliance.	Reporting viewed as non-punitive and part of process improvement in support of patient safety.

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Identity

NRC	AOs or PSOs
Reporting information, including licensee identity, is posted on the NRC website and remains even if the event is later determined by the NRC not to be a medical event.	Reporting is anonymous to those outside the hospital, the patient or patient advocate, and the AO or PSO.

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Extent of patient event review

NRC	AOs or PSOs
Only covers NRC regulatory compliance.	Review covers overall patient safety and possible needs for process improvement.

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Type of review

NRC	AOs or PSOs
Review primarily driven by regulatory inspector focused on identifying areas of NRC non-compliance.	Hospital patient safety program includes staff qualified in patient safety, performance improvement, and root cause analysis who assist the medical staff in making and documenting their review.

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Corrective actions

NRC	AOs or PSOs
Focused on NRC regulatory compliance and kept minimal to avoid having additional regulatory compliance requirements imposed in the future.	Review used to encourage a culture of safety and to provide feedback and assistance to effectively minimize patient risk.

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Oversight expertise

NRC	AOs or PSOs
Regulatory inspector trained in identifying NRC regulatory non-compliance.	AO or PSO have staff qualified in medical care, patient safety, performance improvement, and root cause analysis able to assist the hospital patient safety program.

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Information sharing

NRC	AOs or PSOs
Besides posting event report on NRC website, NRC posts inspection reports and notices of violations and licensee responses. If similar events occur, NRC may issue regulatory summary document alerting licensees or may initiate rulemaking to prevent future events.	**AO or PSO provides database to track events, and provide education or tips on tools, best practices to prevent errors, and general patient safety initiatives to improve safety culture.**

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Acronyms

ACMUI – Advisory Committee on Medical Uses of Isotopes
AEC – Atomic Energy Commission
AO – Accrediting Organization
CFR – Code of Federal Regulations
IOM – Institute of Medicine
NAS – National Academies of Science
NRC – Nuclear Regulatory Commission
PSO – Patient Safety Organization
QMP – Quality Management Program

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Advisory Committee on the Medical Use of Isotopes (ACMUI)

Medical Event Reporting and Impact on Medical Licensee Patient Safety Culture

Report Date: April 27, 2017

Subcommittee Members: F. Costello, V. Dilsizian; R. Ennis, S. Langhorst (Chair), and L. Weil; Z. Ouhib (consultant)

Charge: To 1) explore the impact of medical event reporting and its impact on self-reporting (safety culture); 2) identify potential ways to improve effectiveness of self-reporting in support of a culture of safety; and 3) suggest ways to share medical event reports and lessons-learned with the medical community to promote safety.

Recommendations:

- Radiological protection is greatly different for control of patient exposures as opposed to radiological protection for control of occupational exposures and public exposures. To give everyone a common perspective of these differences, the Subcommittee has provided in this report background information on radiological protection differences and on the U.S. regulatory history of medical use of byproduct materials[1].

- The establishment of safety culture standards has grown in recent years with efforts by the Nuclear Regulatory Commission (NRC) and with efforts by other regulators and organizations involved in U.S. healthcare. To give everyone a common perspective of different safety culture standards, the Subcommittee has provided background information on the development of different areas of patient safety standards and self-reporting in support of a culture of patient safety.

- Given the background information provided in this report, the Subcommittee recommends that the ACMUI discuss at its April 2017 meeting the pros and cons of the NRC medical event reporting regulations in support of patient safety culture and as compared with other patient event reporting programs used by U.S. healthcare.

- Based on the April 2017 ACMUI discussion, the Subcommittee asks the ACMUI to decide whether to continue exploration of establishing a new way for the NRC to support patient safety culture and the Subcommittee will work on a report for the Fall 2017 ACMUI meeting to identify specific options the NRC may take to encourage a licensee's patient safety culture, while maintaining its regulatory authority to protect patients treated with byproduct materials.

[1]The Atomic Energy Commission (AEC) and the NRC are described in this report as the regulatory authorities for medical use of byproduct material, but that regulatory authority may have been transferred to States approved as Agreement States - https://www.nrc.gov/about-nrc/state-tribal/agreement-states.html (last accessed 3/27/2017).

I. Background on Radiological Protection and U.S. Regulatory History for Medical Use

Medical use of ionizing radiation is different from every other use of ionizing radiation in that it involves purposely exposing an individual to ionizing radiation to diagnose or treat a medical condition some of which can be a serious or life-threatening illness. This medical exposure is to patients who have been informed by their physicians why the medical procedure is needed along with the potential medical risks, and who have consented to undergo the medical procedure.

For most health physicists, and others who regulate non-medical uses of radioactive materials, purposely exposing an individual to radiation can be a foreign concept. This is why the purposeful exposure of human beings to radiation in the arena of medical care needs to be approached in a special regulatory context. This is particularly true with respect to reporting of medical events and promoting patient safety.

A. Fundamental Principles of Radiological Protection

The International Commission on Radiological Protection (ICRP) published its latest revised recommendations for a system of radiological protection in 2007[2]. The ICRP stated that the primary aim of the recommendations was "to contribute to an appropriate level of protection for people and the environment against the detrimental effects of radiation exposure without unduly limiting the desirable human actions that may be associated with such exposure." The ICRP considers three types of exposure situations – planned exposures, emergency exposures, and existing exposure situations. Medical exposure is a planned exposure. For planned exposures, the ICRP recommends three fundamental principles of radiological protection which were retained from the 1990 ICRP update[3] and remained largely the same as established in the 1977 ICRP update[4] of the radiological protection recommendations. These fundamental principles are:

- The Principle of Justification: Any decision that alters the radiation exposure situation should do more good than harm.
- The Principle of Optimization of Protection: The likelihood of incurring exposure, the number of people exposed, and the magnitude of their individual doses should all be kept as low as reasonably achievable, taking into account economic and societal factors.
- The Principle of Application of Dose Limits: The total dose to any individual from regulated sources in planned exposure situations other than medical exposure of patients should not exceed the appropriate limits specified by the Commission.

[2] ICRP Publication 103, "The 2007 Recommendations of the International Commission on Radiological Protection" – http://www.icrp.org/publication.asp?id=ICRP%20Publication%20103 (last accessed 3/27/2017).
[3] ICRP Publication 60, "1990 Recommendations of the International Commission on Radiological Protection" – http://www.icrp.org/publication.asp?id=ICRP%20Publication%2060 (last accessed 3/27/2017).
[4] ICRP Publication 26, "Recommendations of the ICRP" (1977) – http://www.icrp.org/publication.asp?id=ICRP%20Publication%2026 (last accessed 3/27/2017).

The ICRP distinguishes these exposures between three categories: occupational exposures; public exposures; and medical exposures of patients, comforters, carers, and volunteers in research.

Each of the fundamental principles is meant to be applied differently to each exposure category. The Principle of Justification is easily applied in the case of medical exposure because the patient is the individual who receives the measurable benefit of the exposure and the one who accepts the theoretical risk of that exposure. The Principle of Optimization has been applied to medical exposures in recent years in continuing efforts in improving imaging techniques with reduced ionizing radiation exposures, or more precisely targeting radiation exposure to diseased tissues and protecting healthy tissues. In the case of the Principle of Dose Limits, medical exposure of patients is explicitly excluded from requiring dose limits.

B. NRC Regulatory History - Recognizing Medical Exposures as Different from Other Exposure Categories

From the start of regulatory controls for the use of radioactive materials, the primary exposures categories considered for regulatory controls were occupational exposures and public exposures. Medical exposures were recognized as being different and were taken into consideration. As time has gone by to present day, NRC's recognition that patient exposures are different from occupational or public exposures has become less clear.

1. 1950s – Early 1970s AEC Establish Medical Use Regulations

The Atomic Energy Commission's (AEC) first rule establishing the standards for protection against radiation[5] was published in 1957. Medical use of radiation was addressed in the following sections:

> § 20.104 – "*Medical diagnosis, therapy, and research*. Nothing in the regulations in this part shall be interpreted as limiting the intentional exposure of patients to radiation for the purpose of medical diagnosis or medical therapy."
>
> § 20.204 "*Exceptions from posting requirements...* (b) Rooms or other areas in hospitals 'are not required to be posted with caution signs because of the presence of patients containing byproduct material provided that there are personnel in attendance who shall take the precautions necessary to prevent the exposure-of any individual to radiation or radioactive material in excess of the limits established in the regulations in this part."
>
> § 20.303 "*Disposal by release into sanitary sewerage systems*. Excreta from individuals undergoing medical diagnosis or therapy with radioactive material shall be exempt from any limitations contained in this section."

[5] Atomic Energy Commission, 10 CFR Part 20, 22 FR 548, January 29, 1957 – http://loc.heinonline.org/loc/Page?handle=hein.fedreg/022019&id=1&collection=journals&index=fedreg/022#18 go to page 548 (last accessed 3/27/2017).

The exemption of last section still remains in place today in § 20.2003(b).

The AEC's first rule establishing a specific set of regulations related to medical use of byproduct material[6] was published in 1965. This set of regulations was established to better clarify licensing of individual physicians, medical use of sealed sources, and licensing of medical use in institutions, and to grant general license for medical use of certain byproduct material quantities.

2. 1970s to 1980s - Development of NRC Medical Use Regulations

In 1974, the Nuclear Regulatory Commission (NRC) was established to provide regulatory oversight of the civilian use of nuclear material, including byproduct material[7], and took on rulemaking begun by the AEC to establish additional requirements for medical use of byproduct material. In 1979, the NRC published its first medical use policy statement[8] to inform of the Commission's general intent on regulating medical uses of radioisotopes:

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

A major update of the NRC's medical use regulations was published in 1980 which established the concept of reporting medical misadministrations[9]. The NRC has previously stated[10] that one purpose of the misadministration reporting requirements was to allow NRC to investigate the incident, to determine if there was a violation, to evaluate the licensee's corrective action, and to allow NRC to inform other licensees of the potential problem and to take generic

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[6] Atomic Energy Commission, "Licensing Byproduct Material", includes initial 10 CFR Part 35, 30 FR 8185, June 26, 1965 – http://loc.heinonline.org/loc/Page?handle=hein.fedreg/030123&id=1&collection=journals&index=fedreg/030#5 go to page 8185 (last accessed 3/27/2017).

[7] Energy Reorganization Act of 1974 – https://www.nrc.gov/docs/ML1327/ML13274A489.pdf#page=241 (last accessed 3/27/2017).

[8] Nuclear Regulatory Commission, "Regulation of the Medical Uses of Radioisotopes; Statement of General Policy", 44 FR 8242, February 9, 1979 – http://loc.heinonline.org/loc/Page?handle=hein.fedreg/044029&id=1&collection=journals&index=fedreg/044#16 go to page 8242 (last accessed 3/27/2017).

[9] Nuclear Regulatory Commission, "Misadministration Reporting Requirements", 45 FR 31701, May 14, 1980 – http://loc.heinonline.org/loc/Page?handle=hein.fedreg/045095&id=1&collection=journals&index=fedreg/045#15 go to page 31701 (last accessed 3/27/2017).

[10] Nuclear Regulatory Commission, "Misadministration Reporting Requirements; Proposed Rule", 43 FR 29297, July 7, 1978 – http://loc.heinonline.org/loc/Page?handle=hein.fedreg/043131&id=1&collection=journals&index=fedreg/043#49 go to page 29297 (last accessed 3/27/2017).

corrective action if there is a possibility of other licensees making the same error. The NRC stated[10] another purpose was to inform the patient or the patient's responsible surrogate so that corrective action could be taken, although the Commission was concerned this could represent undue intrusion into the physician-patient relationship[10]. Following a public comment period on the proposed rule, the Commission ultimately decided[9] it believed the misadministration recordkeeping and reporting requirement was necessary to protect patients. The Commission did recognize in the final misadministration rule[9] one medical limitation by excluding extravasation as a misadministration, which was subsequently reviewed and reconfirmed by the ACMUI as appropriate in both diagnostic[11] and therapeutic[12] procedures.

The NRC published another major update of the medical use regulations in 1986 to clarify and consolidate all the requirements in use at that time into the Part 35 regulations[13]. This regulatory change established the different types of medical uses, the required training and experience for individuals involved with medical administration of byproduct materials, and the authority and responsibility for medical use radiation safety programs. The NRC described this Part 35 change as retaining the "current balance between adequate controls and undue interference in medical judgments." The NRC further stated that "too much regulation could result in poorer health care delivery to patients", and that "insufficient regulation could result in the unwarranted or unsafe use of radiation[13]."

3. Early 1990s – Quality Assurance Requirements Added to NRC Medical Use Regulations

In 1991, the NRC amended the Part 35 to require a quality management program for therapeutic administrations and certain uses of radioactive sodium iodide[14]. This change was made to provide high confidence that the byproduct material or radiation from byproduct material will be administered as directed by an authorized user physician. The Commission stated it believed "this performance-based amendment will result in enhanced patient safety in a cost-effective manner while allowing the flexibility necessary to minimize intrusion into medical judgments[14]." Under the discussion of the medical use policy, the NRC stated:

> "The NRC has the authority to regulate the medical use of byproduct material or radiation from byproduct material to protect the health and safety of patients, but also recognizes

[11] Advisory Committee on the Medical Uses of Isotopes, "Infiltration of Therapeutic Radiopharmaceuticals", Cindy Flannery slide presentation, May 8, 2009 – https://www.nrc.gov/docs/ML0914/ML091400100.pdf go to page 79 (last accessed 3/27/2017).

[12] Advisory Committee on the Medical Uses of Isotopes, May 7-8, 2009 Meeting Summary – https://www.nrc.gov/docs/ML0917/ML091730001.pdf (last accessed 3/27/2017).

[13] Nuclear Regulatory Commission, "Medical Use of Byproduct Material; Final Rule", 51 FR 36932, October 16, 1986 – http://loc.heinonline.org/loc/Page?handle=hein.fedreg/051200&id=1&collection=journals&index=fedreg/051#144 go to page 36932 (last accessed 3/27/2017).

[14] Nuclear Regulatory Commission, "Quality Management Program and Misadministrations; Final Rule", 56 FR 34104, July 25, 1991 – http://loc.heinonline.org/loc/Page?handle=hein.fedreg/056143&id=1&collection=journals&index=fedreg/056#110 go to page 34104 (last accessed 3/27/2017).

> that physicians have the primary responsibility for the protection of their patients. NRC regulations are predicated on the assumption that properly trained and adequately informed physicians will make decisions that are in the best interest of their patients."

And in describing their responsibilities, the NRC stated:

> "The NRC distinguishes between the unavoidable risks attendant in purposefully prescribed and properly performed clinical procedures and the unacceptable risks of improper or careless use. The NRC is responsible, as part of its public health and safety charge, to establish and enforce regulations that protect the public from risks of improper procedures or careless use."

In this 1991 final rule, the NRC added dose criteria to the misadministration reporting requirements based on NCRP[15] dose levels described as having a total detriment from stochastic effects as less than one percent. These dose criteria were added to better clarify the definition of a misadministration to rule out diagnostic radiopharmaceutical administrations that were considered to be low-risk. The Commission noted that these dose levels also corresponded to the annual dose limits for occupational workers which are thresholds for reporting overexposures to the NRC, and thus felt it was reasonable to apply these dose criteria to patient exposures[14].

In a separate rulemaking updating Part 20[16] in 1991, the NRC clarified in the definitions that occupational dose and public dose does not include the intentional dose received as a patient from medical practices or from voluntary participation in medical research programs.

4. Late 1990s to present - NRC Strategic Planning for Current Medical Use Regulations

In the 1995, the NRC began a Strategic Assessment and Rebaselining Project to develop an agency-wide strategic plan which included a Direction-Setting Issue Paper[17] to define NRC's future role and scope of NRC's regulations of the medical use of nuclear materials. A key consideration in this direction-setting issue paper was described as "the interpretation that the Commission has adopted and implemented that medical patients are include in the 'public.'" Also discussed were the regulatory options set forth in the Institute of Medicine (IOM) of the National Academy of Sciences independent review and evaluation of the NRC's Medical Use

[15] National Council on Radiation Protection and Measurements, Commentary No. 7, "Misadministration of Radioactive Material in Medicine – Scientific Background" (1991) – https://www.ncrppublications.org/Commentaries/07 (last accessed 3/27/2017).

[16] Nuclear Regulatory Commission, "Standards for Protection Against Radiation; Final Rule", 56 FR 23360, May 21, 1991 – http://loc.heinonline.org/loc/Page?handle=hein.fedreg/056098&id=1&collection=journals&index=fedreg/056#180 go to page 23360 (last accessed 3/27/2017).

[17] Nuclear Regulatory Commission, SECY-01-0057- Enclosure 7; "Strategic Assessment Issue Paper , DSI 7: Materials/Medical Oversight," September 16, 1996, ML010780349 – https://www.nrc.gov/docs/ML0107/ML010780349.pdf (last accessed 3/27/2017).

Program[18]. While the IOM recommended that regulatory authority over medical use of byproduct materials be given to the States, the Commission ultimately decided to continue to regulate medical use of byproduct materials and to utilize a risk-informed performance-based approach to determine which activities in the medical area are low-risk activities for decreased NRC oversight. These Commission directions have shaped the subsequent changes to the Commission's Medical Use Policy and Part 35 regulations.

In 1997, the NRC changed § 35.75[19] to allow patients administered radiopharmaceuticals or permanent implants containing radioactive materials to be released from the licensee's control if dose to any other individual did not exceed 5 mSv (0.5 rem). In the same rulemaking, the Part 20 occupational dose and public dose definitions were again modified to note that dose from patients released under the § 35.75 release criteria is not considered occupational dose or public dose.

The NRC updated the Medical Use Policy Statement[20] in 2000 to guide the NRC's future regulation based on:

1. "NRC will continue to regulate the uses of radionuclides in medicine as necessary to provide for the radiation safety of workers and the general public.
2. NRC will not intrude into medical judgments affecting patients, except as necessary to provide for the radiation safety of workers and the general public.
3. NRC will, when justified by the risk to patients, regulate the radiation safety of patients primarily to assure the use of radionuclides is in accordance with the physician's directions.
4. NRC, in developing a specific regulatory approach, will consider industry and professional standards that define acceptable approaches of achieving radiation safety."

The Commission explained in a report to Congress[21] that a key assumption in the Commission's medical use policy item 3 "…is that a patient, like everyone else who is not exposed as part of their employment functions, is a member of the public to be protected by NRC. The focus of NRC regulation—to protect the patient's health and safety—is primarily to ensure that the authorized user physician's directions are followed as they pertain to the administration of the radionuclide."

[18] Institute of Medicine, "Radiation in Medicine: A Need for Regulatory Reform," National Academy Press (1996) – https://www.nap.edu/catalog/5154/radiation-in-medicine-a-need-for-regulatory-reform (last accessed 3/27/2017).
[19] Nuclear Regulatory Commission, "Criteria for the Release of Individuals Administered Radioactive Material; Final Rule", 62 FR 4120, January 29, 1997 – https://www.gpo.gov/fdsys/pkg/FR-1997-01-29/pdf/97-2166.pdf (last accessed 3/27/2017).
[20] Nuclear Regulatory Commission, "Medical Use of Byproduct Material; Policy Statement, Revision", 65 FR 47654, August 3, 2000 – https://www.gpo.gov/fdsys/pkg/FR-2000-08-03/pdf/00-19573.pdf (last accessed 3/27/2017).
[21] Nuclear Regulatory Commission, "Report to Congress on Part 35", February 11, 2002 – https://www.nrc.gov/docs/ML0135/ML013550321.pdf (last accessed 3/27/2017).

The most recent major update of Part 35 was implemented beginning 2002[22] with completion of its full implementation in 2005[23]. The NRC described[21] the underlying premise of these regulations was that authorized user physicians will understand radiation safety principles and practices and will make decisions that are in the best interests of their patients. The regulations for a quality management program to be submitted to the NRC were removed, but the requirement to provide high confidence that byproduct material will be administered as directed by the authorized user through written procedures for medical administrations requiring a written directive was retained. Reporting of medical events, previously called misadministrations, was retained with the same dose reporting criteria for patient exposures.

Since the current major revision of 10 CFR Part 35 was fully implemented in 2005, the NRC has been working to do additional major updates of the Part 35 regulations, but as of the date of this ACMUI Subcommittee report, the final rule has not been approved. One cause for this delay has been the continuing discussions and disagreements regarding what should be the medical event reporting criteria for permanent brachytherapy implants.

II. Development of Safety Culture and Standards

A. NRC Nuclear Safety Culture Policy

The NRC has encouraged development of what is now known as safety culture in its regulatory framework and encouragement of workers to report to their licensee or to the NRC safety concerns and items of non-compliance. In 1996, the Commission issued a policy statement[24] on "its expectation that licensees and other employers subject to NRC authority will establish and maintain safety-conscious environments in which employees feel free to raise safety concerns, both to their management and to the NRC, without fear of retaliation." And in 2002, NRC staff presented the Commission with policy options and recommendations for revising the NRC's process for handling discrimination issues[25]. The staff recommended that the Commission pursue rulemaking for oversight of a safety conscious work environment, including provisions for handling discrimination complaints. The Commission did not approve the NRC staff recommendation[26] principally because of the subjectivity associated with direct regulation of safety culture and instead directed the staff to develop guidance, in consultation with stakeholders, that would identify best practices to encourage a safety conscious work

[22] Nuclear Regulatory Commission, "Medical Use of Byproduct Material; Final Rule", 67 FR 20250, April 24, 2002 – https://www.gpo.gov/fdsys/pkg/FR-2002-04-24/pdf/02-9663.pdf (last accessed 3/27/2017).
[23] Nuclear Regulatory Commission, "Medical Use of Byproduct Material – Recognition of Specialty Boards; Final Rule", 60 FR 16336, March 30, 2005 – https://www.gpo.gov/fdsys/pkg/FR-2005-03-30/pdf/05-6103.pdf (last accessed 3/27/2017).
[24] Nuclear Regulatory Commission, "Freedom of Employees in the Nuclear Industry to Raise Concerns without Fear of Retaliation; Statement of Policy", 61 FR 24336, May 14, 1996 – https://www.gpo.gov/fdsys/pkg/FR-1996-05-14/pdf/96-12028.pdf go to page 24336 (last accessed 3/27/2017).
[25] Nuclear Regulatory Commission SECY-02-0166, "Policy Options and Recommendations for Revising the NRC's Process for Handling Discrimination Issues", September 12, 2002 – https://www.nrc.gov/docs/ML0221/ML022120479.pdf (last accessed 3/27/2017).
[26] Nuclear Regulatory Commission SRM-SECY-02-0166, "Policy Options and Recommendations for Revising the NRC's Process for Handling Discrimination Issues", March 26, 2003 – https://www.nrc.gov/docs/ML0308/ML030850783.pdf (last accessed 3/27/2017).

environment. As a result, the NRC issued a regulatory issue summary[27] providing guidance on establishing and maintaining a safety conscious work environment.

In 2008, the Commission issued another SRM[28] directing the NRC staff to expand the Commission's policy on safety culture to address the unique aspects of security, considering safety and security interfaces, and to ensure the resulting policy is applicable to all licensees and certificate holders. And with consultation of the NRC's various stakeholders, the Commission issued its final statement of policy[29] in 2011 setting forth its expectation that "individuals and organizations performing or overseeing regulated activities establish and maintain a positive safety culture commensurate with the safety and security significance of their activities and the nature and complexity of their organizations and functions." The NRC policy statement defined "Nuclear Safety Culture" as "the core values and behaviors resulting from a collective commitment by leaders and individuals to emphasize safety over competing goals to ensure protection of people and the environment." NRC noted that safety and security activities are closely intertwined, and their respective activities may complement each other, or there may be instances in which safety and security interests create competing goals. Organizations under the NRC regulatory authority were cautioned to ensure that personnel in the safety and security sectors have an appreciation for the importance of each, emphasizing the need for integration and balance to achieve both safety and security in their activities so as not to diminish or adversely affect either, but to establish mechanisms to identify and resolve these differences.

The NRC safety culture policy[29] also set out certain personal and organizational traits that should be part of a positive safety culture:

(1) Leadership Safety Values and Actions—Leaders demonstrate a commitment to safety in their decisions and behaviors;
(2) Problem Identification and Resolution—Issues potentially impacting safety are promptly identified, fully evaluated, and promptly addressed and corrected commensurate with their significance;
(3) Personal Accountability—All individuals take personal responsibility for safety;
(4) Work Processes—The process of planning and controlling work activities is implemented so that safety is maintained;
(5) Continuous Learning—Opportunities to learn about ways to ensure safety are sought out and implemented;
(6) Environment for Raising Concerns—A safety conscious work environment is maintained where personnel feel free to raise safety concerns without fear of retaliation, intimidation, harassment, or discrimination;
(7) Effective Safety Communication— Communications maintain a focus on safety;
(8) Respectful Work Environment— Trust and respect permeate the organization; and

[27] Nuclear Regulatory Commission "Regulatory Issues Summary 2005-18, Guidance for Establishing and Maintaining a Safety Conscious Work Environment", August 5, 2005 – https://www.nrc.gov/docs/ML0522/ML052220239.pdf (last accessed 3/27/2017).
[28] Nuclear Regulatory Commission SRM–COMGBJ–08–0001, "A Commission Policy Statement on Safety Culture", February 25, 2008 – https://www.nrc.gov/docs/ML1025/ML102500672.pdf (last accessed 3/27/2017).
[29] Nuclear Regulatory Commission, "Final Safety Culture Safety Policy", 76 FR 34773, June 14, 2011 – https://www.gpo.gov/fdsys/pkg/FR-2011-06-14/pdf/2011-14656.pdf (last accessed 3/27/2017).

(9) Questioning Attitude—Individuals avoid complacency and continuously challenge existing conditions and activities in order to identify discrepancies that might result in error or inappropriate action.

The NRC safety culture policy[29] ends with the following statements:

> "It is the Commission's expectation that all individuals and organizations, performing or overseeing regulated activities involving nuclear materials, should take the necessary steps to promote a positive safety culture by fostering these traits as they apply to their organizational environments. The Commission recognizes the diversity of these organizations and acknowledges that some organizations have already spent significant time and resources in the development of a positive safety culture. The Commission will take this into consideration as the regulated community addresses the Statement of Policy."

In order to support licensees in their development and maintenance of a positive nuclear safety culture, the NRC has developed a website[30] devoted to safety culture and provided outreach materials. Unfortunately, the site provides no specific links related to safety culture and medical use of byproduct materials. Safety culture trait educational tools are provided in the NRC's Trait Talk[31] issues, but only one example in the Questioning Attitude Trait Talk mentions a Medical Physicist evaluating equipment and computer software issues for a high dose rate afterloader therapy. The NRC does not address patient safety culture and given the emphasis on the use of the word "nuclear," it is clear that NRC would restrict any discussion on patient safety culture to that small portion of patient safety issues that are under NRC's regulatory authority.

B. Development of Patient Safety Culture in U.S. Healthcare

The development of patient safety culture and patient safety programs has greatly advanced since 2000 with the advent of some key reports published by the National Academies of Science. In addition to NRC regulatory authority, healthcare providers are regulated or otherwise influenced by other organizations which have impacted the providers' fostering a patient safety culture and developing patient safety reporting and review programs.

1. Medicare Program for Oversight of Accrediting Organizations

To be eligible to receive Medicare reimbursement, certain types of health care facilities must demonstrate compliance with the Medicare conditions of participation (CoPs), conditions for coverage (CfCs), or conditions for certification[32]. The health care facilities are allowed to

[30] NRC Safety Culture website – https://www.nrc.gov/about-nrc/safety-culture.html (last accessed 3/27/2017).
[31] NRC Trait Talks – https://www.nrc.gov/about-nrc/safety-culture/sc-outreach-edu-materials.html#sctt (last accessed 3/27/2017).
[32] Centers for Medicare and Medicaid Services, "FY 2015 Report to Congress (RTC): Review of Medicare's Program Oversight of Accrediting Organizations (AOs) and the Clinical Laboratory Improvement Amendments of 1988 (CLIA) Validation Program", January 29, 2016 – https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Downloads/Survey-and-Cert-Letter-16-07.pdf (last accessed 3/27/2017).

demonstrate this compliance through accreditation by a Centers for Medicare & Medicaid Services (CMS)-approved accreditation program of a private, national Accrediting Organization (AO). Beginning in the 1990s, AOs initiated compliance demonstration requirements which have become more focused on issues associated with patient safety[33].

2. NAS IOM Reports on Patient Safety

As the NRC was completing their most recent update of 10 CFR Part 35, the National Academies of Science (NAS) Institute of Medicine (IOM) began releasing a series of reports under the Quality of Health Care in America project[34]. The committee working on this project was directed to:

- "review and synthesize findings in the literature pertaining to the quality of care provided in the health care system;
- develop a communications strategy for raising the awareness of the general public and key stakeholders of quality of care concerns and opportunities for improvement;
- articulate a policy framework that will provide positive incentives to improve quality and foster accountability;
- identify characteristics and factors that enable or encourage providers, health care organizations, health plans and communities to continuously improve the quality of care; and
- develop a research agenda in areas of continued uncertainty."

The purpose of the first report[34] was to focus the Committee's initial attention on quality concerns that fall into the category of medical errors. They stated:

> "In health care, building a safer system means designing processes of care to ensure that patients are safe from accidental injury. When agreement has been reached to pursue a course of medical treatment, patients should have the assurance that it will proceed correctly and safely so they have the best chance possible of achieving the desired outcome."

The second report in the series[35] focused more broadly on how the health system could be reinvented to foster innovation and improve the delivery of care with a comprehensive strategy and action plan for the next decade. The Committee presented six aims for improvement which need to be accepted by health professionals, federal and state policy makers, public and private purchasers of care, regulators, organization managers and governing boards, and consumers for their explicit purpose to continually reduce the burden of illness, injury, and disability, and to

[33] The Joint Commission website history – https://www.jointcommission.org/assets/1/6/TJC-history-timeline_through_20161.PDF (last accessed 3/27/2017).
[34] Institute of Medicine, "To Err is Human: Building a Safer Health System", National Academy Press (2000) – https://www.nap.edu/catalog/9728/to-err-is-human-building-a-safer-health-system (last accessed 3/27/2017).
[35] Institute of Medicine, "Crossing the Quality Chasm: A New Health System for the 21st Century," National Academy Press (2001) – https://www.nap.edu/catalog/10027/crossing-the-quality-chasm-a-new-health-system-for-the (last accessed 3/27/2017).

improve the health and functioning of the people of the United States. The six aims were built around the core need for health care to be:

- Safe: avoiding injuries to patients from the care that is intended to help them.
- Effective: providing services based on scientific knowledge to all who could benefit, and refraining from providing services to those not likely to benefit.
- Patient-centered: providing care that is respectful of and responsive to individual patient preferences, needs, and values, and ensuring that patient values guide all clinical decisions.
- Timely: reducing waits and sometimes harmful delays for both those who receive and those who give care.
- Efficient: avoiding waste, including waste of equipment, supplies, ideas, and energy.
- Equitable: providing care that does not vary in quality because of personal characteristics such as gender, ethnicity, geographic location, and socioeconomic status.

The Committee felt that achieving these aims would ensure patients would experience care that is safer, more reliable, more responsive to their needs, more integrated, and more available, and they could count on receiving the full array of preventive, acute, and chronic services that are likely to prove beneficial. To redesign of the health care system, the Committee formulated ten rules:

1. Care is based on continuous healing relationships. Patients should receive care whenever they need it and in many forms, not just face-to-face visits. This implies that the health care system must be responsive at all times, and access to care should be provided over the Internet, by telephone, and by other means in addition to in-person visits.
2. Care is customized according to patient needs and values. The system should be designed to meet the most common types of needs, but should have the capability to respond to individual patient choices and preferences.
3. The patient is the source of control. Patients should be given the necessary information and opportunity to exercise the degree of control they choose over health care decisions that affect them. The system should be able to accommodate differences in patient preferences and encourage shared decision making.
4. Knowledge is shared and information flows freely. Patients should have unfettered access to their own medical information and to clinical knowledge. Clinicians and patients should communicate effectively and share information.
5. Decision making is evidence-based. Patients should receive care based on the best available scientific knowledge. Care should not vary illogically from clinician to clinician or from place to place.
6. Safety is a system property. Patients should be safe from injury caused by the care system. Reducing risk and ensuring safety require greater attention to systems that help prevent and mitigate errors.
7. Transparency is necessary. The system should make available to patients and their families information that enables them to make informed decisions when selecting a health plan, hospital, or clinical practice, or when choosing among alternative

treatments. This should include information describing the system's performance on safety, evidence-based practice, and patient satisfaction.

8. Needs are anticipated. The system should anticipate patient needs, rather than simply react to events.
9. Waste is continuously decreased. The system should not waste re-sources or patient time.
10. Cooperation among clinicians is a priority. Clinicians and institutions should actively collaborate and communicate to ensure an appropriate exchange of information and coordination of care.

A third report[36] on patient safety was issued in response to a request from the Department of Health and Human Services for the Institute of Medicine to produce a detailed plan to facilitate the development of data standards applicable to the collection, coding, and classification of patient safety information. To achieve an acceptable standard of patient safety, the committee conducting this work recommended that all health care settings establish comprehensive patient safety programs operated by trained personnel within a culture of safety and involving adverse event and near-miss detection and analysis. In addition, the committee recommended that the federal government pursue a robust applied research agenda on patient safety, focused on enhancing knowledge, developing tools, and disseminating results to maximize the impact of patient safety systems. And finally, the committee recommended that a standardized format and terminology be developed for the capture and reporting of data related to medical errors to achieving patient safety as a standard of care.

To date, many more NAS reports have been written to address various aspects of these early key reports.

3. Legislation and Regulatory Development Supporting Patient Safety Culture

In July 2005, Congress passed the Patient Safety Act[37] amending title IX of the Public Health Service Act to provide for the "improvement of patient safety and to reduce the incidence of events that adversely affect patient safety." Elements of the act were similar to the NAS patient safety report recommendations[36]. The Department of Health and Human Services adopted rules[38] in November 2008 to implement certain aspects of the Patient Safety Act. Specifically, the DHHS final rule established a "framework by which hospitals, doctors, and other health care providers may voluntarily report information to Patient Safety Organizations (PSOs), on a privileged and confidential basis, for the aggregation and analysis of patient safety events." But the Act and the final rule recognize that the privileged and confidential protection afforded by reporting to a PSO does not relieve an entity from its obligation to comply with other Federal, State, or local laws pertaining to information that is not privileged and confidential.

[36] Institute of Medicine, "Patient Safety: Achieving a New Standard of Care," National Academy Press (2004) – https://www.nap.edu/catalog/10863/patient-safety-achieving-a-new-standard-for-care (last accessed 3/27/2017).
[37] PUBLIC LAW 109–41—JULY 29, 2005 "Patient Safety and Quality Improvement Act of 2005" – https://www.gpo.gov/fdsys/pkg/PLAW-109publ41/pdf/PLAW-109publ41.pdf (last accessed 3/27/2017).
[38] Department of Health and Human Services, "Patient Safety and Quality Improvement; Final Rule" established 42 CFR 3, 73 FR 70732, November 21, 2008 – https://www.gpo.gov/fdsys/pkg/FR-2008-11-21/pdf/E8-27475.pdf (last accessed 3/27/2017).

As defined in 42 CFR 3.20, patient safety activities carried by or on behalf of a PSO or provider include the following activities:

(1) Efforts to improve patient safety and the quality of health care delivery;
(2) The collection and analysis of patient safety work product;
(3) The development and dissemination of information with respect to improving patient safety, such as recommendations, protocols, or information regarding best practices;
(4) The utilization of patient safety work product for the purposes of encouraging a culture of safety and of providing feedback and assistance to effectively minimize patient risk;
(5) The maintenance of procedures to preserve confidentiality with respect to patient safety work product;
(6) The provision of appropriate security measures with respect to patient safety work product;
(7) The utilization of qualified staff; and
(8) Activities related to the operation of a patient safety evaluation system and to the provision of feedback to participants in a patient safety evaluation system.

III. Current Patient Safety Groups Influencing Medical Use of Byproduct Materials

A. Centers for Medicare & Medicaid Services (CMS)

As noted above, the CMS administers the program to approve and review Accrediting Organizations (AO). The AOs are private, national organizations which have accreditation programs by which health care facilities may demonstrate compliance with the Medicare conditions of participation (CoPs), conditions for coverage (CfCs), or conditions for certification in order to be granted "deemed status" and receive Medicare reimbursement. Health care facilities are not required to seek AO accreditation, but are then subject to assessment of compliance by the applicable State Survey Agency (SA) if the facility seeks Medicare reimbursement.

An AO can provide different types of accreditation for different types of health care facilities. In FY 2014, CMS reported[39] the following types of Medicare-participating accreditation program facilities:

- Hospitals
- Psychiatric hospitals
- Critical access hospitals
- Home health agencies
- Hospices
- Ambulatory surgery centers

[39] Centers for Medicare and Medicaid Services, "FY 2015 Report to Congress (RTC): Review of Medicare's Program Oversight of Accrediting Organizations (AOs) and the Clinical Laboratory Improvement Amendments of 1988 (CLIA) Validation Program", January 29, 2016 – https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Downloads/Survey-and-Cert-Letter-16-07.pdf (last accessed 3/27/2017).

- Outpatient physical therapy and speech-language pathology services
- Rural health clinics

For purpose of this report, the Subcommittee decided to focus discussion on hospitals because these facilities would conduct the majority of medical use of byproduct materials. In FY 2014, the CMS noted[39] that 80% of all Medicare-participating hospitals had deemed status through an AO.

1. The Joint Commission (TJC)

The Joint Commission (TJC) is considered the market leader[40] and was the AO for 88% of the hospitals granted deemed status in FY 2014[39]. TJC first established its Sentinel Event policy in 1996[41] to help their accredited hospitals that experience serious adverse events improve safety and learn from those sentinel events. Sentinel event is defined as a patient safety event that reaches a patient and results in any of the following:

- Death
- Permanent harm
- Severe temporary harm and intervention required to sustain life
- Other event that signals the need for immediate investigation and response[42].

The accredited hospital "is strongly encouraged, but not required, to report sentinel events to" TJC and can benefit from self-reporting in the following ways[41]:

- "The Joint Commission can provide support and expertise during the review of a sentinel event."
- "The opportunity to collaborate with a patient safety expert in The Joint Commission's Sentinel Event Unit of the Office of Quality and Patient Safety."
- "Reporting raises the level of transparency in the organization and promotes a culture of safety."
- "Reporting conveys the health care organization's message to the public that it is doing everything possible, proactively, to prevent similar patient safety events in the future."
- "Further, reporting the event enables "lessons learned" from the event to be added to The Joint Commission's Sentinel Event Database, thereby contributing to the general knowledge about sentinel events and to the reduction of risk for such events."

In 2002, TJC established its first National Patient Safety Goals[43] to help their accredited hospitals address specific areas of concern regarding patient safety. Each year TJC publishes an

[40] V.M. Fennel, "Accreditation options, Selecting an accrediting source ", Becker Hospital Review, September 24, 2014 – http://www.beckershospitalreview.com/quality/accreditation-options-selecting-an-accrediting-source.html (last accessed 3/27/2017).
[41] The Joint Commission, "Sentinel Event policy" – https://www.jointcommission.org/sentinel_event_policy_and_procedures/ (last accessed 3/27/2017).
[42] The Joint Commission, "Sentinel Event policy for hospitals" – https://www.jointcommission.org/assets/1/6/SE_2017_CAMH.pdf (last accessed 3/27/2017).

updated set of safety goals[44]. Another resources developed by TJC is the Patient Safety Systems chapter which describes the relationship between TJC accreditation and patient safety[45]. And, TJC provides access to the National Patient Safety Foundation (NPSF) report[46] on "RCA2: Improving Root Cause Analyses and Actions to Prevent Harm."

2. DNV GL Healthcare[47]

DNV GL-accredited hospitals are described as pioneers in that they commit to annual surveys with the ultimate goal of achieving ISO9001 certification[40]. DNV GL offers the National Integrated Accreditation for Healthcare Organizations (NIAHO®) program which is described as the first integrated accreditation program for hospitals in the United Sates[48]. The CMS reported that DNV GL was the AO for 7.5% of the accredited hospitals in FY 2014[39].

3. Healthcare Facilities Accreditation Program (HFAP)

The Healthcare Facilities Accreditation Program (HFAP) has been described as predictable and may be an AO option preferred by community hospitals[40]. The CMS reported that HFAP was the AO for 4.3% of the accredited hospitals in FY 2014[39]. The HFAP describes itself as meeting or exceeding the standards required by CMS/Medicare to provide accreditation for all hospitals[49] to advance high quality patient care and safety. The HFAP has adopted the 34 Safe Practices[50] established in 2009 by the National Quality Forum (NQF). The NQF is a consensus-based healthcare organization defined by the Office of Management and Budget (OMB) to allow the federal government to rely on NQF-defined measures or healthcare practices as the best, evidence-based approaches to improving care[51].

The HFAP encourage facilities to provide documentation of self-reported patient safety incidents[52]. Once reported, the HFAP requests a copy of the hospital's policy on Root Cause Analysis (RCA) and the actual RCA conducted as a result of the incident be forwarded to HFAP

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[43] The Joint Commission, website history – https://www.jointcommission.org/assets/1/6/TJC-history-timeline_through_20161.PDF (last accessed 3/27/2017).
[44] The Joint Commission, "National Patient Safety Goals Effective January 2017 - Hospital Accreditation Program" – https://www.jointcommission.org/assets/1/6/NPSG_Chapter_HAP_Jan2017.pdf (last accessed 3/27/2017).
[45] The Joint Commission, "Patient Safety Systems", March 3, 2017 – https://www.jointcommission.org/assets/1/18/CAMH_04a_PS.pdf (last accessed 3/27/2017).
[46] National Patient Safety Foundation, "RCA2: Improving Root Cause Analyses and Actions to Prevent Harm" Version 2, January 2016 – https://npsf.site-ym.com/?RCA2 (last accessed 3/27/2017).
[47] DNV GL website – http://dnvglhealthcare.com/ (last accessed 3/27/2017).
[48] DNV GL website, "What We Do" – http://www2.dnvgl.us/l/127291/2016-11-18/21d8t9 (last accessed 3/27/2017).
[49] Healthcare Facilities Accreditation Program, Overview website – http://www.hfap.org/about/overview.aspx (last accessed 3/27/2017).
[50] Healthcare Facilities Accreditation Program, "National Quality Forum (NQF) Endorsed Set of 34 Safe Practices", February 2013 update – http://www.hfap.org/pdf/patient_safety.pdf (last accessed 3/27/2017).
[51] National Quality Forum, history website – http://www.qualityforum.org/about_nqf/history/ (last accessed 3/27/2017).
[52] Healthcare Facilities Accreditation Program, Patient Safety website – http://www.hfap.org/resources/patientsafety.aspx (last accessed 3/27/2017).

for review within 60 days so that the HFAP staff can assess the plan of correction to verify implementation of an effective process and provide guidance if necessary.

4. Center for Improvement in Healthcare Quality (CIHQ)

The Center for Improvement in Healthcare Quality (CIHQ) is described as pragmatic and practical with an approach to accreditation that is straightforward[40]. The CIHQ is the newest AO[53] which accredited 0.2% of the accredited hospitals in FY 2014[39].

B. Patient Safety Organizations Supporting Medical Use of Byproduct Materials

At the October 6, 2016 meeting[54] of the NRC Advisory Committee on the Medical Uses of Isotopes (ACMUI), four groups were invited to brief the ACMUI on development of their event reporting databases in support of patient safety for medical procedures involving ionizing radiation. Two of these groups are registered as PSOs.

1. Radiation Oncology Incident Learning System (RO-ILS)

The American Society for Radiation Oncology (ASTRO) and the American Association of Physicists in Medicine (AAPM) sponsor the Radiation Oncology Incident Learning System® (RO-ILS)[55]. Clarity PSO (DHHS PSO P0015), a division of Clarity Group, Inc., provides PSO services to the radiation oncology practices enrolled in RO-ILS. ASTRO report that more than 250 facilities have joined RO-ILS and receive benefits like:

- Contribute to a national database and collectively improve the field of radiation oncology.
- Track and review internal incidents, near misses, and unsafe conditions.
- Track and analyze internal incidents while contributing to the national database.
- Receive institution-specific summary reports, including aggregate data on events entered throughout the country.
- Receive educational materials such as PSO-sponsored instructional webinars or Tips of the Month about features/tools, best practices to prevent errors, and general patient safety initiatives to improve safety culture.

[53] Center for Improvement in Healthcare Quality, "Welcome to the CIHQ Hospital Accreditation Division" – http://cihq.org/hospital_accreditation_division.asp (last accessed 3/27/2017).

[54] Advisory Committee on the Medical Uses of Isotopes, "October 6-7, 2016 Meeting Agenda" – https://www.nrc.gov/docs/ML1620/ML16209A233.pdf (last accessed 3/27/2017).

[55] "RO-ILS: Radiation Oncology Incident Learning System®," sponsored by American Society for Radiation Oncology and by American Association of Physicists in Medicine – https://www.astro.org/RO-ILS.aspx (last accessed 3/27/2017).

2. Center for the Assessment of Radiological Sciences (CARS)

An organization called the Center for the Assessment of Radiological Sciences (CARS) is a PSO (DHHS PSO P0149) and maintains a radiotherapy incident reporting and analysis system[56]. The CARS provides its clients professional support in completely filing out the reporting database information and in doing root cause analysis for radiotherapy incidents. As with all PSOs, confidentially is maintained of the reported incident, good catch (sometimes called a near miss), or unsafe condition, and of the associated patient safety work product developed in accordance with 42 CFR Part 3 rule. CARS-PSO has been in existence since 2014.

IV. How Should NRC Support of a Positive Patient Safety Culture?

The use of nuclear medicine and radiation therapy began growing into more universal use in the 1970s as the NRC came into existence, and it could be said that the NRC was the "only game in town" in addressing patient safety in its limited regulatory authority over health care. The NRC established its misadministration reporting and quality management program regulations in part due to patient diagnostic and therapeutic procedures which were not correctly administered. The NRC recognized[57] that the misadministration rate for radiopharmaceuticals was much lower than for other drugs, that there was no reporting requirement for misadministrations of cyclotron-produced radiopharmaceuticals[58], x-rays, and nonradioactive drugs, and that the risk to patients, workers, and the public was small. But, their view was that therapy clinical procedures presented greater risk to the public and patients than diagnostic clinical procedures. The NRC concluded that misadministrations which resulted in a dose to the patient greater than a dose to a member of the public permitted under Part 20 should require a report to the NRC and the referring physician[57]. In maintaining the reporting of medical events[59], the NRC believed that the reporting and notification requirements were necessary so that the NRC was aware of the events to determine what actions, if any, needed to be taken to prevent recurrence; so that other licensees could be made aware of generic problems that result in medical events; and so that patients would make timely decisions regarding remedial and prospective health care.

In developing the Nuclear Safety Culture Policy, the NRC cautioned organizations under its regulatory authority to ensure that personnel in safety and security sectors have an appreciation for the importance of each. The NRC emphasized the need for integration and balance to achieve both safety and security in their activities so as not to diminish or adversely affect either, but to establish mechanisms to identify and resolve these differences. The Subcommittee asks the ACMUI and the NRC to consider that there is a similar relationship

[56] "RIRAS: Radiotherapy Incident Reporting & Analysis System" – www.cars-pso.org (last accessed 3/27/2017).
[57] Nuclear Regulatory Commission, "Medical Use of Byproduct Material; Final Rule", 51 FR 36932, October 16, 1986 – http://loc.heinonline.org/loc/Page?handle=hein.fedreg/051200&id=1&collection=journals&index=fedreg/051#144 go to page 36932 (last accessed 3/27/2017).
[58] The NRC later was given regulatory authority of cyclotron-produced radiopharmaceuticals as the result of the Energy Policy Act (EPAct)of 2005 – https://www.nrc.gov/materials/byproduct-mat.html
[59] Nuclear Regulatory Commission, "Medical Use of Byproduct Material; Final Rule", 67 FR 20250, April 24, 2002 – https://www.gpo.gov/fdsys/pkg/FR-2002-04-24/pdf/02-9663.pdf (last accessed 3/27/2017).

between Nuclear Safety Culture and Patient Safety Culture with need to find balance by identifying and resolving the differences between the two safety cultures. We have provided a review of differences between occupational and public exposures as compared to patient exposures, the history of NRC regulatory authority over medical use of byproduct material, recent legislative and regulatory development regarding patient safety, and the establishment various patient safety groups and organizations to further discussions of how the NRC may consider alternatives to medical event reporting that support both their regulatory authority and a medical licensee's safety conscious work environment in regard to patient safety.

The Subcommittee requests that the ACMUI discuss at its April 2017 meeting the pros and cons of the NRC medical event reporting regulations in support of patient safety culture and as compared with other patient event reporting programs used by U.S. healthcare. The Subcommittee suggests example topics here for this discussion.

Example Topic	NRC	AOs or PSOs
Safety Culture	NRC/AS Safety Culture is narrowly focused on "nuclear safety" and primarily focused on occupational safety and public safety; NRC has challenge dealing with patient safety issues versus interfering with the practice of medicine.	Legislative and regulatory changes have encouraged the development of hospital patient safety culture and formal patient safety programs.
Initial patient event review	Licensee required to review event with emphasis on regulatory compliance, but it is unclear if the licensee has more time than by the next calendar day to make this review.	Personnel required to review event and report to hospital patient safety program to determine extent of review and process improvement needed for the event.
Timing of initial patient event review	It is unclear if the licensee has more time than by the next calendar day to make this review.	Personnel encouraged to report a patient event or near-miss at the time of the incident to evaluate need for process improvement.
Patient event reporting	Medical event reporting is required for NRC regulatory compliance.	Event reporting to AO or PSO is voluntary, but encouraged.
Reason to report event	Review NRC regulatory compliance.	Reporting viewed as non-punitive and part of process improvement in support of patient safety.

Example Topic	NRC	AOs or PSOs
Identity	Reporting information, including licensee identity, is posted on the NRC website and remains even if the event is later determined by the NRC not to be a medical event.	Reporting is anonymous to those outside the hospital, the patient or patient advocate, and the AO or PSO.
Extent of patient event review	Only covers NRC regulatory compliance.	Review covers overall patient safety and possible needs for process improvement.
Type of review	Review primarily driven by regulatory inspector focused on identifying areas of NRC non-compliance.	Hospital patient safety program includes staff qualified in patient safety, performance improvement, and root cause analysis who assist the medical staff in making and documenting their review.
Corrective actions	Focused on NRC regulatory compliance and kept minimal to avoid having additional regulatory compliance requirements imposed in the future.	Review used to encourage a culture of safety and to provide feedback and assistance to effectively minimize patient risk
Oversight expertise	Regulatory inspector trained in identifying NRC regulatory non-compliance.	AO or PSO have staff qualified in medical care, patient safety, performance improvement, and root cause analysis able to assist the hospital patient safety program.
Information sharing	Besides posting the event report on the NRC website, the NRC posts the inspection reports and notices of violations and licensee responses. If similar events occur, the NRC may issue a regulatory summary document alerting licensees or may initiate rulemaking to prevent future events.	AO or PSO provides database to track events, and provide education or tips on tools, best practices to prevent errors, and general patient safety initiatives to improve safety culture.

If the ACMUI decides it wants the Subcommittee to continue exploration of establishing a new way in which the NRC can enhance patient safety culture, the Subcommittee will work on a report for the Fall 2017 ACMUI meeting to identify specific options the NRC may take to encourage a licensee's patient safety culture, while maintaining its regulatory authority to protect patients during medical use of byproduct materials.

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

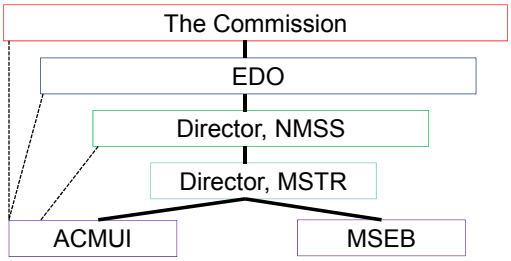
Committee Reporting Structure

Michelle Smethers, ACMUI Coordinator
Medical Radiation Safety Team
April 27, 2017

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 seventh annual review.**

Meetings

Two meetings at Headquarters each year

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

Approximately 2-3 teleconferences (as needed)

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Discussion

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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**
- **Michelle Smethers– ACMUI Coordinator**
  - **301-415-0168; Michelle.Smethers@nrc.gov**

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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**

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Open Forum

NO HANDOUT

September 2017

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

October 2017

Sunday	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday
1	2	3	4 X	5 Sukkot	6 Sukkot	7
8	9 COLUMBUS DAY	10 X	11 X	12 Sh'mini Atzeret	13 Simchat Torah	14
15	16 X	17	18	19	20 X	21
22	23 X	24 X	25 X	26 X	27 X	28
29	30 X	31 X				