MEETING AGENDA
ADVISORY COMMITTEE ON THE MEDICAL USES OF ISOTOPES
April 3-4, 2019

Three White Flint North Building, 11601 Landsdown Street, Room 1-C03/1-C05, North Bethesda, Maryland 20852

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 3, 2019
OPEN SESSION

	1.	**Opening Remarks** Mr. Einberg will formally open the meeting and Ms. Kock will provide opening remarks.	**C. Einberg, NRC** **A. Kock, NRC**
	2.	**Old Business** Ms. Holiday will review past ACMUI recommendations and provide NRC responses.	**S. Holiday, NRC**
8:30 – 10:30	**3.**	**Open Forum** The ACMUI will identify medical topics of interest for further discussion.	**ACMUI**
	4.	**Yttrium-90 Microspheres Brachytherapy Licensing Guidance Subcommittee Report** Dr. O'Hara will discuss the subcommittee's recommendations on the NRC's draft Revision 10 to the Yttrium-90 Microspheres Brachytherapy Licensing Guidance.	**M. O'Hara, ACMUI**
	5.	**Lucerno Dynamic's LARA Infiltration Detection** Mr. Lattanze will provide an overview about a product that can assist with detecting nuclear medicine injection infiltrations.	**R. Lattanze, Lucerno Dynamics**
10:30 – 10:45		**BREAK**	
	6.	**Summary of Changes to 10 CFR Part 35** Ms. Dimmick will discuss the changes to the final rule 10 CFR Part 35 that went into effect January 2019.	**L. Dimmick, NRC**
10:45 – 12:00	**7.**	**Germanium-68/Gallium-68 Subcommittee Report** Ms. Shober will discuss the subcommittee's recommendations on the NRC's draft revision to the Germanium-68/Gallium-68 Pharmacy Grade Generator Licensing Guidance.	**M. Shober, ACMUI**
12:00 – 1:00		**LUNCH**	
	8.	**Medical Related Events** Dr. Howe will provide an update on recent medical events.	**DB. Howe, NRC**
1:00 – 2:45	**9.**	**Appropriateness of Medical Event Reporting Subcommittee Report** Dr. Ennis will discuss the subcommittee's recommendations on the appropriateness of the required medical event reporting in accordance with 10 CFR 35.3045.	**R. Ennis, ACMUI**

2:45 – 3:15	**BREAK** (public portion ends)	
	WEDNESDAY, APRIL 3, 2019 **CLOSED SESSION**	
3:15 – 5:00	**10. ACMUI Working Session: Biennial Evaluations and Commission Meeting Presentation Development**	**ACMUI**
	THURSDAY, APRIL 4, 2019 **OPEN SESSION**	
	11. ACMUI Reporting Structure Members will discuss the reporting structure of the Committee and provide feedback to the NRC staff.	**K. Jamerson, NRC**
8:30 – 9:30	**12. Special Presentation to Ms. Weil** Mr. Moore will make a special presentation to Ms. Laura Weil	**S. Moore, NRC**
	13. Thoughts on Leaving the ACMUI Ms. Weil will share her thoughts on leaving the ACMUI, after serving two full terms (8 years).	**L. Weil, ACMUI**
9:30 – 10:00	**BREAK**	
	14. Commission Meeting with the ACMUI The ACMUI will brief the Commission on various topics in a public meeting.	**ACMUI**
10:00 – 12:15		
	15. Group Photo The ACMUI will take a group photo with and without the Commission.	**ACMUI**
12:15 – 1:15	**LUNCH**	
	16. ACMUI Bylaws Subcommittee Report Ms. Weil will discuss the subcommittee's recommendations for changes to the ACMUI's Bylaws – with particular focus on the ACMUI Chair's role with respect to subcommittees.	**L. Weil, ACMUI**
1:15 – 2:45	**17. Open Forum** The ACMUI will discuss medical topics of interest previously identified.	**ACMUI**
	18. Administrative Closing Ms. Jamerson will provide a meeting summary and propose dates for the fall 2019 meeting.	**K. Jamerson, NRC**
2:45	**ADJOURN**	

Opening Remarks

NO HANDOUT

	ITEM	DATE	STATUS	
33	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*
34	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*

2008 ACMUI RECOMMENDATIONS AND ACTION ITEMS

	ITEM	DATE	STATUS	
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*
26	NRC staff should revise 10 CFR 35.40 to clarify that the AU should sign and date both the pre-implantation and post-implantation portions of the WD for all modalities with two part WDs	10/28/08	Accepted	Open *Delayed*
27	NRC staff should revise 10 CFR 35.40 to clarify that an AU, not the AU, should sign and date both the pre-implantation and post-implantation portions of the WD for all modalities with two part WDs. [Note this allows for one AU to sign the pre-implantation portion of the WD and another AU to sign the post-implantation portion of the WD]	10/28/08	Accepted	Open *Delayed*

	ITEM	DATE	STATUS	
6	ACMUI created an action item to reevaluate its satisfaction with the reporting structure annually.	1/12/11	ACMUI Action	Open indefinitely

	ITEM	DATE	STATUS	
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 Indefinitely
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 Indefinitely
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
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
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
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
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
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

	ITEM	DATE	STATUS	
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
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
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
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
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
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
53	The Committee endorsed the NorthStar Mo-99/Tc-99m Generator (RadioGenix) Subcommittee Report.	10/7/16	ACMUI Action	Open

	ITEM	DATE	STATUS	
1	The Committee requested that the recommendations and actions pertaining to the Part 35 rulemaking be reviewed during the fall 2017 ACMUI meeting and that additional time be provided to review each item.	4/26/2017	NRC Action	Open
13	The ACMUI recommended that the NRC establish a program allowing a medical use licensee to evaluate MEs as described in 10 CFR 35.3045, in NRC 10 CFR 35.1000 licensing guidance, and in 10 CFR 35.3047 with an approved patient safety program.	9/11/2017	NRC Action	Open
14	The ACMUI recommended that NRC licensees with an NRC-approved patient safety program will continue to report medical events as required with the following conditions: (1) The NRC will not include this event notification in the Event Notification Report posted on its website. If this is not possible, the ME notification posted on the website will leave the licensee information and location anonymous. (2) The NRC will not conduct a reactive inspection of the ME unless the event results or will result in death, unintended permanent harm, or unintended significant temporary harm for which medical intervention was or will be required to alleviate the harm or reduce radiation effects. (3) The medical use licensee will write a report available for the next NRC inspection describing the event cause and corrective action taken. (4) NRC will develop, with ACMUI advice, new temporary inspection procedures for NRC review of licensee patient safety event reports, and will evaluate, with ACMUI advice, need to change enforcement manual procedures regarding MEs to support a test of this program.	9/11/2017	NRC Action	Open

15	The ACMUI recommended that NRC should test out this program with two large medical centers, two community hospitals, two rural hospitals, and two patient clinics for a year, evaluating the ME reports with the ACMUI. During this test period, the NRC, with advice from the ACMUI, should do the following: (1) Develop the minimum criteria for patient safety program reviews; (2) Assess how this change in ME reporting impacts the NRC's ability to protect patient health and to minimize danger to the patient's life; and (3) Evaluate the different types of patient safety programs in how lessons learned from their patient safety incident reviews are shared with the medical community.	9/11/2017	NRC Action	Open
16	The ACMUI recommended that after completion of the test year, the NRC should consider opening the program to all NRC medical use licensees who request approval of their patient safety program, and to Agreement States who request to implement the program with their medical licensees.	9/11/2017	NRC Action	Open
17	The ACMUI recommended that the NRC redefine its perspective of patient safety to be different from occupational safety and from public safety.	9/11/2017	NRC Action	Open
18	The ACMUI recommended that NRC partner with the Department of Health and Human Services (HHS), specially the Agency for Healthcare and Research and Quality (AHRQ) , and ACMUI to develop a national database taxonomy specific for reporting patient events involving medical use of byproduct material.	9/11/2017	NRC Action	Open
19	The ACMUI recommended that the NRC Update its Medical Use Policy Statement and 10 CFR 35 event reporting regulations for patient safety programs to verify the active involvement of the licensee's patient safety program review of medical errors and reporting of reviews to the national patient safety database.	9/11/2017	NRC Action	Open
20	The ACMUI endorsed the Medical Event Reporting and Impact on Medical Licensee Patient Safety Culture Draft Report, as amended to support the concept of the pilot program with the total number of sites and duration to be determined at a later date and to include the Patient Intervention Subcommittee recommendations as an addendum .	9/11/2017	ACMUI Action	Open

2018 ACMUI RECOMMENDATIONS AND ACTION ITEMS

	ITEM	DATE	STATUS	
1	The ACMUI recommended that there be no breast feeding cessation for ^{11}C, ^{13}N, ^{15}O, and ^{82}Rb; a 12-hours cessation for ^{18}F-labeled and 68Ga-labeled; a 24-hours cessation for ^{99m}Tc-labeled; 7-days cessation for ^{123}I-NaI and ^{111}In-leukocytes; 14 days cessation for ^{201}-Tl-chloride; 28 days cessation for ^{67}Ga and ^{89}Zr; 35 days for ^{177}Lu, diagnostic; and total stop of breastfeeding for ^{131}I-NaI, ^{177}Lu, therapeutic, ^{223}Ra and all alpha emitters.	2/15/2018	NRC Action	Open
2	The ACMUI endorsed the Nursing Mother Guidelines for the Medical Administration of Radioactive Materials Subcommittee Report, as amended to: (1) include recommended cessation periods for both 100 and 500 mrem limits; (2) acknowledge benefits of breastfeeding; (3) incorporate corrections as needed for gamma ray constants; (4) convert the units from conventional to SI units; and (5) correct references.	2/15/2018	ACMUI Action	Open
3	The ACMUI recommended that the AU be physically present during the initiation of all Leksell Gamma Knife Icon treatments. However, the AU could be present in the department (defined as a two minute walk to the console area) during treatment but is immediately available to come to the treatment room. If there is an interruption of treatment secondary to medical or mechanical issues, the AU must return to the console prior to reinitiation.	2/15/2018	NRC Action	Closed

4	The ACMUI recommended as a best practice that appropriately trained nursing or auxiliary staff be present at the console to respond to any immediate medical needs.	2/15/2018	ACMUI Action	Closed
5	The ACMUI unanimously endorsed the Physical Presence Requirements for the Leksell Gamma Knife Icon Subcommittee Report.	2/15/2018	ACMUI Action	Closed
6	The NRC staff will create an ACMUI Recommendations Web page and post the full ACMUI Recommendations and Actions charts on the ACMUI Web page from 2007 – present	3/7/2018	NRC Action	Open Indefinitely
7	The NRC staff will send out a medical list server announcement to inform subscribers of the availability of ACMUI and NRC ME slides each time that they are posted on the Medical Toolkit.	3/7/2018	NRC Action	Open Indefinitely
9	Dr. Palestro appointed Ms. Megan Shober and Mr. Zoubir Ouhib to the Physical Presence Requirements for the Leksell Gamma Knife Icon Subcommittee. Subcommittee membership includes: Dr. Ennis, Mr. Ouhib, Ms. Shober, Dr. Suh (Chair), and Ms. Weil. NRC POC: Sophie Holiday	7/16/2018	ACMUI Action	Closed
11	The ACMUI endorsed the report of the Subcommittee on the Nursing Mother Guidelines for the Medical Administration of Radioactive Materials with added language that this document reflects the FDA approved radiopharmaceuticals on the market at this time and that licensees are obligated to carefully evaluate radiopharmaceuticals that are not encompassed in this report to keep exposures ALARA to patients, staff, and members of the public. The recommendation passed unanimously.	9/20/2018	ACMUI Action	Open

12	The ACMUI endorsed the Leksell Gamma Knife® PerfexionTM and Leksell Gamma Knife® IconTM Licensing Guidance Subcommittee Report. The recommendation passed unanimously.	9/20/2018	ACMUI Action	Closed
13	The NRC staff will provide the Committee with a copy of the Briefing on Results of the Agency Action Review Meeting presentation slides on Yttrium-90 microspheres; SECY-18-0048, "Annual Report to the Commission on Licensee Performance in the Nuclear Materials and Waste Safety Program Fiscal Year 2017," which includes a discussion on medical events involving Yttrium-90 microsphere brachytherapy; and the Strategic Programmatic Overview of the Fuel Facilities and Nuclear Materials Users Business Lines Commission meeting slides related to Yttrium-90.	9/21/2018	NRC Action	Closed
14	Dr. Palestro amended the membership of the Training and Experience for All Modalities Subcommittee. Subcommittee membership now includes Dr. Metter (chair), Dr. Ennis, Dr. Schleipman, Ms. Weil, Ms. Shober, and Mr. Sheetz. The NRC staff resource continues to be Ms. Maryann Ayoade.	9/20/2018	ACMUI Action	Open

15	Dr. Palestro formed a subcommittee to review the Germanium-68/Gallium-68 Pharmacy Grade Generator Licensing Guidance. Subcommittee membership includes Ms. Shober (chair), Dr. Metter, Mr. Sheetz, and Ms. Martin. The NRC staff resource is Dr. Said Daibes.	9/21/2018	ACMUI Action	Open
16	Dr. Palestro formed a subcommittee to review the revisions to Regulatory Guide 8.39, "Release of Patients Administered Radioactive Material." Subcommittee membership includes Mr. Sheetz (chair), Ms. Shober, Dr. Dilsizian, Dr. Schleipman, Ms. Martin, and Ms. Weil. The NRC staff resource is Dr. Said Daibes.	9/21/2018	ACMUI Action	Open
17	Dr. Palestro formed a subcommittee to review the Yttrium-90 Microspheres Brachytherapy Sources and Devices TheraSphere® and SIR_Spheres® Licensing Guidance. Subcommittee membership includes Dr. O'Hara (chair), Dr. Dilsizian, Mr. Ouhib, Ms. Marin, Dr. Metter, and Dr. Schleipman. The NRC staff resource is Dr. Katie Tapp.	9/21/2018	ACMUI Action	Open
18	Dr. Palestro formed a subcommittee to review and update the ACMUI Bylaws as needed, including a review of the role of the ACMUI Chair and his or her participation on subcommittees. Subcommittee membership includes Ms. Weil (chair), Dr. Schleipman, Ms. Shober, and Mr. Sheetz. The NRC staff resource is Ms. Sophie Holiday.	9/21/2018	ACMUI Action	Open

19	Dr. Palestro formed a subcommittee to review the appropriateness of the required elements of medical event reporting, the adherence to these requirements, and recommend actions to improve reporting. Subcommittee membership includes Dr. Ennis (chair), Ms. Weil, Ms. Martin, Mr. Ouhib, Dr. Dilsizian, and Ms. Shober. The NRC staff resource is Ms. Lisa Dimmick	9/20/2018	ACMUI Action	Open
20	The Committee recommended for the NRC to draft an Information Notice on the best practices that could help prevent medical events.	9/21/2018	NRC Action	Open
21	The Committee requested a list of all the current ACMUI members, their contact information, information regarding each member's term, and the subcommittee(s) they serve on. The Committee also requested that the NRC staff create a web page that lists the active subcommittees and subcommittees that have been sunset, their members with term expiration, NRC staff resource, and the specific charge of the subcommittee.	9/21/18	NRC Action	Closed
22	The Committee tentatively scheduled the spring 2019 meeting for April 15-16, 2019. The alternate meeting dates are April 3-4, 2019, subject to Commission availability.	9/21/18	ACMUI Action	Closed

2019 ACMUI RECOMMENDATIONS AND ACTION ITEMS

	ITEM	DATE	STATUS	
1	The ACMUI recommended adding language into the draft *Training and Experience Requirements for All Modalities Subcommittee report* regarding the Committee's desire to work with the NRC staff to develop a curriculum for limited-scope authorized user pathway.	2/26/2019	ACMUI Action	Open
2	The ACMUI endorsed the *Training and Experience Requirements for All Modalities Subcommittee Report,* and the recommendations included therein.	2/26/2019	ACMUI Action	Open

Open Forum

NO HANDOUT

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

ACMUI Sub-committee on the Draft Y-90 Microspheres Brachytherapy Licensing Guidance, Rev. 10

Michael O'Hara, Ph.D.
ACMUI FDA Representative
April 3, 2019

Sub-Committee Members

- Vasken Dilsizian, M.D.
- Melissa Martin, M.S.
- Darlene Metter, M.D.
- Michael O'Hara, Ph.D. (Chair)
- Zoubir Ouhib, M.S.
- Robert Schleipman, Ph.D.

NRC Resource: Katie Tapp, Ph.D.

Background

- Manual intra-arterial brachytherapy implants with unique properties for 1° and 2° hepatic malignancies
- Regulated under 10 CFR 35.1000 "Other Medical Uses of Byproduct Material or Radiation from Byproduct Material"

Background

- The licensing guidance was published in 2002 and revised in 2004, 2007, 2008, 2011 and 2016.
- In Oct. 2016, the ACMUI provided comments on the initial draft Rev. 10 of the licensing guidance. Specific topics addressed included:
  1. Consider the elimination of Pathway 2 (manufacturer AU training)
  2. Update the waste and disposal section
  3. Review Y-90 radiation safety issues in autopsy and cremation

Background

- In Nov. 2017, the NRC published the draft Rev. 10 of the licensing guidance in the *FR* for public comment. The comment period ended in Jan. 2018.
- In July 2018, the final Part 35 rule, "Medical Use of Byproduct Materials—Medical Event Definitions, Training and Experience, and Clarifying Amendments," was issued. The rule went into effect Jan. 14, 2019 for NRC licensees.

Background

- The NRC/Agreement State WG updated the draft Revision 10 licensing guidance to include the criteria for T&E and medical event reporting, inventory requirement specifications, and waste disposal issues and aligned the guidance with the Part 35 rule.
- After addressing public comments, the 2016 ACMUI comments, and the rule changes, the WG provided the Subcommittee with a revised draft guidance for its review and comment.

Subcommittee Charge

To review the staff's draft Revision 10 of the *Yttrium-90 Microsphere Brachytherapy Sources and Devices TheraSpheres and Sir-Spheres Licensing Guidance* and provide any comments or recommendations for change/acceptance of the guidance.

Comments on the Licensing Guidance

- The Subcommittee believes this is a well written and documented licensing guidance document.
- Subcommittee endorses the draft Revision 10 of the licensing guidance, subject to the following specific changes

Specific Comments on the Licensing Guidance

- **Defining manufacturer's representative**
- **Keeping three hands-on cases for each type of microsphere delivery device. The Y-90 spheres are slightly different (glass or polymeric) and the delivery systems of the two devices have different characteristics**
- **RSO familiarity required with all devices used at the facility**
- **Evaluation of a possible ME for unexpected dose or activity to an organ or tissue other than the treatment site that is caused by catheter placement**

Specific Comments on the Licensing Guidance

- **Delineating the site to be treated more specifically (left hepatic lobe, right hepatic lobe)**
- **Adding activity, date of administration and route of administration**
- **Question whether intervention should be defined in the licensing guidance document**
- **Explicit labeling to include patient name, dose, date and treatment site, if feasible**

Acronyms

ACMUI	Advisory Committee on the Medical Uses of Isotopes
AU	Authorized user
CFR	*Code of Federal Regulations*
FR	*Federal Register*
ME	Medical Event
NRC	U.S. Nuclear Regulatory Commission
RSO	Radiation Safety Officer
T&E	Training and experience
WG	Working Group
Y-90	Yttrium-90

11

U.S. Nuclear Regulatory Commission (NRC)

Advisory Committee on the Medical Use of Isotopes (ACMUI)

Subcommittee on Yttrium-90 Microsphere Brachytherapy Sources and Devices TheraSphere® and Sir-Spheres® Licensing Guidance, Revision 10

Draft Report

Submitted on: March 11, 2019

Subcommittee Charge

The Subcommittee's charge was to review the staff's draft Revision 10 of the *Yttrium-90 Microsphere Brachytherapy Sources and Devices TheraSphere® and Sir-Spheres® Licensing Guidance* and provide any comments or recommendations for change/acceptance of the guidance.

Subcommittee Members

Dr. Vasken Dilsizan
Ms. Melissa Martin
Dr. Darlene Metter
NRC Staff Resource: Dr. Katie Tapp
Mr. Zoubir Ouhib
Dr. Robert Schleipman
Dr. Michael O'Hara (Chair)

Introduction

Yttrium-90, a pure beta emitter, decays to stable zirconium-90 with a physical half-life of 64.1 hours (2.67 days). The average energy of the beta emissions from yttrium-90 is 0.9367 MeV with an average penetration range of 2.5 mm and a maximum range of 11 mm in tissue. Following delivery of the yttrium-90 microspheres in tumorous liver tissue, the microspheres provide an embolic effect and the beta radiation emitted provides a therapeutic effect. The microspheres are delivered into the liver tumor through a catheter placed into the hepatic artery that supplies blood to the tumor. The microspheres, being unable to pass through the vasculature of the liver due to arteriolar capillary blockade, are trapped in the tumor and exert a local radiotherapeutic effect with some concurrent damage to surrounding normal liver tissue. There are currently two Y-90 based microsphere devices that have been reviewed by the FDA. They differ slightly in composition of the spheres and in the patient population for which they are approved.

TheraSphere® consists of insoluble glass microspheres where yttrium-90 is an integral constituent of the glass. A preassembled single use TheraSphere® Administration Set is provided for each dose. Also provided are re-usable accessories including an acrylic box base, top shield, removable side shield, bag hook and a RADOS RAD-60R radiation dosimeter (or equivalent). TheraSphere® is an approved HDE device indicated for use in radiation treatment

or as neoadjuvant to surgery or transplantation in patients with unresectable hepatocellular carcinoma (HCC) who can have placement of appropriately positioned hepatic arterial catheters.

SIR-Spheres® microspheres consist of biocompatible resin microspheres containing yttrium-90 with a size between 20 and 60 microns in diameter. The administration set includes a delivery box (an acrylic box base), delivery set (including all the catheters and connectors), and a V-vial (including the shielding). Sir-sphere are an approved PMA device for the treatment of unresectable metastatic liver tumors from primary colorectal cancer with adjuvant intrahepatic artery chemotherapy (IHAC) of FUDR (Floxuridine).

Background

The "Yttrium-90 Microsphere Brachytherapy Sources and Devices TheraSphere® and Sir-Spheres® Licensing Guidance" was published in 2002 and revised in 2004, 2007, 2008, 2011 and 2016. NRC staff, stakeholders and the ACMUI identified numerous issues that needed to be addressed. NRC staff and Agreement State Representatives formed a working group to address the issues and make any necessary revisions. Revision 10 updated the criteria for training and medical event reporting, inventory requirement specifications, and waste disposal issues and aligned the guidance with the Part 35 rule entitled "Medical Use of Byproduct Materials—Medical Event Definitions, Training and Experience, and Clarifying Amendments" which went into effect on January 14, 2019 for NRC licensees.

Overall, the Subcommittee believes this is a well written and documented licensing guidance document. The Subcommittee endorses the draft Revision 10 of the licensing guidance, subject to the specific changes outlined below.

Specific Changes to the Guidance Considered by the Subcommittee and its Recommendations

Page 8, section iii, line 3: The current section reads…*to support training provided by a Y-90 microsphere manufacturer representative involving*: We suggest defining what manufacturer's representative means. This will help to ensure the manufacturer's trainer has the proper experience.

Page 9, section B, paragraph 2, line 2: This section currently reads… *unsupervised use should include at least 3 hands-on patient cases for each type of Y-90 microsphere requested.* We suggest keeping three hands on cases for each type of microsphere delivery device. The Y-90 spheres are slightly different (glass or polymeric) and the delivery systems of the two devices have different characteristics. This will ensure that the user has documented experience with both device types.

Page 11, section 4.2, line 4: The current sentence reads, "…*An RSO already listed on a license that includes one type of microsphere device does not require additional approval for the other type of microsphere device*…" We suggest adding to the end of the sentence, *"but should be familiar with all devices used at the facility."*

Page 13, section 5.1, paragraph 1, last sentence: The current sentence reads, "… *Unexpected dose or activity to an organ or tissue other than the treatment site that is caused by catheter placement during delivery of the y-90 microspheres is not considered shunting."* We suggest adding *"and should be evaluated as a possible medical event"* to the end of the sentence.

Page 14, section 5.2, paragraph 3, line 2: The current sentence reads, "…*the treatment site, the radionuclide (including the physical form (Y-90 microspheres)); the model of spheres e.g. TheraSpheres® or Sir-Spheres®) or manufacturer, the prescribed dose or activity, and if appropriate for the type of microsphere used, the statement 'or dose or activity delivered at stasis"*. We suggest describing the site to be treated more specifically (left lobe, right lobe)

Page 14, section 5.2, paragraph 3, line 4: The current sentence reads, *"…the treatment site, the radionuclide (including the physical form (Y-90 microspheres)); the model of spheres e.g. TheraSpheres® or Sir-Spheres®) or manufacturer, the prescribed dose or activity, and if appropriate for the type of microsphere used, the statement 'or dose or activity delivered at stasis"*. We suggest adding activity, date of administration and route of administration

Page 14, section 5.2, paragraph 4, line 6: The sentence currently reads, *"…anatomical description of the tissue intended to receive a radiation dose…"* We suggest changing *tissue* to *tissue(s).* Segmented doses may be delivered to various anatomic locations.

Page 15, section 5.3, paragraph 1, line 3: The current sentence reads, *"…as a result from patient intervention, as defined in 10 CFR 35.2..."* We question if the term "intervention" should be defined in the guidance document.

Page 16, section 5.3, paragraph 1, line 1: The sentence currently reads "…*organ or tissue other than the treatment site…"* We suggest that treatment site should be *intended treatment*.

Page 16, section 5.6, paragraph 2, line 2: The current sentence reads *"label syringes and syringe radiation shields with the radioactive drug."* We believe the label should be explicit and include patient name, dose and date, and treatment site, if feasible.

Other Recommendations

There are no other recommendations from the subcommittee.

Respectfully Submitted,

Subcommittee on Yttrium-90 Microsphere Brachytherapy Sources and Devices TheraSphere® and Sir-Spheres® Licensing Guidance, Revision 10
Advisory Committee on the Medical Use of Isotopes
Nuclear Regulatory Commission

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

Nuclear Medicine Injection Infiltrations

Ron Lattanze, Lucerno Dynamics

ACMUI Meeting

April 3, 2019

Infiltration Agenda

- Presentation – Ron Lattanze
  - Overview
  - Incidence
  - Patient implication/impact
  - Solution
  - Request NRC and ACMUI reconsider a 1980 decision regarding infiltrations
- Q&A – Ron Lattanze, Dr. David Townsend, and Dr. Daniel Sullivan

Overview

- Bolus injection quality critical
- Infiltration definition and effects
- Quality Control (QC) for "injected" dose, but not the dose "delivered" into circulation

Overview – NRC and ACMUI Infiltration Position

- **1980** – Misadministration Reporting Requirements Final Rule
  - "infiltrations are virtually impossible to avoid"
- **2002** – "Misadministration" replaced by "Medical Event"
- **2008** – Boston VA reports an infiltration as a Medical Event

Nuclear Medicine Infiltration Rates Are High

- 2006-17 Published data:
  - 15.2% (3% - 23%)
- 2017 Alberta QI, 9 centers:
  - 15.0% (0% - 28%)
  - 20.0% (8% - 44%)
- 2018 Lara QI, 7 centers:
  - 6.2% (2% - 16%)


2018 SNMMI Highlights Lecture: General Nuclear Medicine

Infiltrations Can Matter

50+ references support how diagnostic radiopharmaceutical infiltrations can harm or have harmed patients

~50% of injection sites are outside image FOV

Patient 11490 **MTV** Change

MTV	Day 1	Day 5	Understated
Lesion 1	7.43	11.34	34%
Lesion 2	5.57	10.66	48%
Lesion 3	27.77	41.07	32%
Lesion 4	0.88	2.93	70%

Adversely Affects Treatment Planning

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Infiltrations Can Exceed Reporting Limits

- Reporting Limit – 0.5 Sievert (Sv) effective dose equivalent to the tissue

	Time between injection and imaging	Estimated infiltration activity at time of imaging	Estimated effective dose equivalent to the tissue from injection to reabsorption time
A	57 mins	4.55 mCi	11.5 Sv (~23x limit)
B	107 mins	0.11 mCi	2.26 Sv (~4.5x limit)

Infiltrations Are Avoidable

- 2017 Chemotherapy rates – 0.18%
- 2016 Contrast CT rates – 0.24%
- Monitoring nuclear medicine injection quality can lead to significant and quick improvement

Site	Measure Phase Rate	Standard Error	Improve Phase Rate	Standard Error	Change
A	13.3%	2.1%	2.9%	1.0%	-78%
B	15.7%	4.0%	6.0%	2.6%	-62%
C	12.8%	1.5%	8.7%	1.3%	-32%
D	2.1%	0.6%	1.9%	0.6%	-10%

Identifying, Reporting, and Reducing Infiltrations

Consistent with the goals of:

- NRC
- Nuclear Medicine Societies
- Technologists
- Physicians
- Patients

Request

- Nuclear medicine infiltrations are avoidable
- Some infiltrations can negatively affect patients
- Some infiltrations exceed reporting limits

Requesting the NRC and ACMUI to reconsider the 1980 infiltration decision and, moving forward, require reporting of infiltrations that meet Subpart M criteria.

Discussion and Q&A

Acronyms

- QI – Quality Improvement
- SUV – Standardized Uptake Value
- MTV – Metabolic Tumor Value
- FOV – Field of View
- mCi – Millicurie
- CT – Computed Tomography
- TAC – Time-activity Curve

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10 CFR Parts 30, 32, and 35 FINAL RULE CHANGES

Lisa Dimmick, Team Leader
Medical Radiation Safety Team
April 3, 2019

Objective

- Present a summary of rule changes that became effective January 14, 2019

Major Changes

- Permanent implant brachytherapy medical event reporting & notification
- Name Associate Radiation Safety Officers on a medical license
- Training & Experience (T&E) generic changes for all individuals
- Molybdenum (Mo) breakthrough measurement frequency and reporting of failed generators

General Topics

- Generators
- Associate RSO & Ophthalmic Physicist
- Emerging Technologies
- Notification
- Manual Brachytherapy
- Training & Experience
- Diagnostic Medical Uses
- 10 CFR 35.300 Radiopharma-ceuticals
- Sealed Source & Device Registry
- Vendor Training
- Gamma Knife Source Exchange

Generators: 35.204 & 35.3204

- Breakthrough has to be measured for each elution of Mo-99/Tc-99m generator
- Breakthrough in excess of regulatory limits need to be reported to NRC and the generator distributor
- Information that has to be reported and reporting timeframe is provided

Associate RSO (ARSO) and Ophthalmic Physicist: 35.2 & 35.24

- Associate Radiation Safety Officer Ophthalmic physicist – defined
- Revised the Preceptor definition - add ARSO
- Introduced provisions to appoint an ARSO
- Clarified requirements for licensee, RSO, and ARSO

Associate RSO: 35.50

- Added ARSO
- Permit ARSO to provide written attestation
- Permit new AU to be RSO on new license
- Permit authorized individuals (AU, AMP, ANP) to use authorized status be RSO on a different license for same uses for which the individual is authorized

Ophthalmic Physicist: 35.433

- Added ophthalmic physicist to individuals who are required to perform certain task
- Clarified the training needed to be an ophthalmic physicist
- Clarified expected duties of AMP and ophthalmic physicist for Strontium-90 sources used for ophthalmic

Emerging Technologies: 35.12

- Clarified information required for 10 CFR 35.1000 medical uses application
  - Additional aspects needed for radiation safety not in or different from requirements in the regulations
  - Identification and commitment to meet appropriate existing requirements

Notification: 35.13, 35.14, & 35.15

- Added notification/termination provision for the ophthalmic physicist
- Added amendment requirement before an individual works as an ARSO or before the RSO can assign duties and tasks to an ARSO beyond the current authorization

Notification: 35.13, 35.14, & 35.15

- Added notification provision for certain manual brachytherapy sources
- Removed notification attestation statement
- Exempted Type A broad scope licensees from needing to notify NRC when permitting an ophthalmic physicist to working as an ophthalmic physicist;

Manual Brachytherapy: 35.40

- Clarified permanent implant brachytherapy written directive (WD) components:
  - Still includes AU signature and dating before administration
  - Requiring the total source strength in the pre-implantation portion of the WD

Manual Brachytherapy: 35.40 cont.

- Deleting the total dose from the post-implantation portion of the WD added total number of sources and date
- Deleting the requirement to include dose
- Requiring completion of the post-implantation portion of the WD before the patient leaves post treatment recovery area

Manual Brachytherapy: 35.40

The term **post-treatment recovery area** means the area or place where a patient recovers immediately following the brachytherapy procedure before being released to a hospital intensive care unit or patient room, or in the case of an outpatient treatment, released from the licensee's facility.

Manual Brachytherapy: 35.40

- Revises the definition of an ME for permanent implant brachytherapy:
  - The total source strength for inside and outside the treatment site compared with post-implantation written directive
  - The wrong radionuclide

Manual Brachytherapy: 35.40 cont.

- The wrong individual or human research subject
- Sealed source(s) directly delivered to the wrong treatment site
- A leaking sealed source resulting in a dose that exceeds 0.5 Sv (50 rem) to an organ or tissue

Manual Brachytherapy: 35.40

What does **discontiguous** mean?

- As it relates to the ME criteria in 10 CFR 35.3045 for PIB, discontiguous means a location that is not physically adjacent to or touching the treatment site.

Manual Brachytherapy: 35.41

- All licensees must have procedures to determine if a medical event occurred
- Permanent implant brachytherapy licensees must have procedures to determine within 60 days

Manual Brachytherapy: 35.41 cont.

- The total source strength outside treatment site compared to total source strength in post implant written directive.
- That if a patient was not available within the 60 days, the licensee must document the reason for the unavailability.

Training and Experience (T&E)

- Removed written attestation from board certification pathway requirements
- Revised written attestation statement
  - "…is able to independently fulfill the radiation safety-related duties as …"
- Permits residency program directors to provide written attestation under certain conditions

T&E: 35.51

- Require AMP to be board certified by board recognized under 10 CFR 35.51

T&E: 35.57

- Grandfathered RSO's and AMP's must meet requirements in 10 CFR 35.50(d) or 35.51(c), for materials or uses not authorized earlier
- Grandfathered individuals board certified on or before October 24, 2005 by boards listed in regulation for materials and uses performed before this date

Diagnostic medical uses: 35.65

- Clarified medical use does not include calibration, transmission, and reference sources except as authorized under 10 CFR 35.500
- Bundled or aggregated sources with activities greater than maximum single source activities in 35.65 is not permitted under 10 CFR 35.65

Diagnostic medical uses: 35.65 cont.

- Clarified when sources do not have to be listed on license

Diagnostic medical uses: 35.590

- Authorizes an AU for imaging uses for medical use of sealed sources and medical devices for diagnosis

Radiopharmaceuticals: 35.300, 35.390, & 35.396

- Clarified that 10 CFR 35.300 only applied to materials listed in 10 CFR 35.390
- Revised listing of materials in 10 CFR 35.390 for parenteral uses by the primary emission needed for the particular medical use (i.e., is primarily used for … emission)

Radiopharmaceuticals: 35.300, 35.390, & 35.396

- ***Current Rule* reads**:
  - A licensee may use any unsealed byproduct material prepared for medical use and for which a written directive is required that is—

Radiopharmaceuticals: 35.300, 35.390, & 35.396 cont.

- ***New Rule* reads**:
  - A licensee may use any unsealed byproduct material identified in § 35.390(b)(1)(ii)(G) prepared for medical use and for which a WD is required that is—

Radiopharmaceuticals: 35.300, 35.390, & 35.396

10 CFR 35.390(1)(ii)(G) categories for 3 cases

Current Rule reads:

1. Oral ≤ 1.22 GBq (33 mCi) of NaI I-131 WD;
2. Oral > 1.22 GBq (33 mCi) of NaI I-131 WD;

Radiopharmaceuticals: 35.300, 35.390, & 35.396 cont.

3. Parenteral of any beta emitter, or a photon- emitting radionuclide with a photon energy less than 150 keV, for which a WD is required; and/or

4. Parenteral administration of any other radionuclide, for which a WD is required;

Radiopharmaceuticals: 35.300, 35.390, & 35.396

10 CFR 35.390(1)(ii)(G) categories for 3 cases

New Rule reads:

– A licensee may use any unsealed byproduct material identified in § 35.390(b)(1)(ii)(G) prepared for medical use and for which a WD is required that is —

1) the same as current rule.

Radiopharmaceuticals: 35.300, 35.390, & 35.396 cont.

2) the same as current rule

3) Parenteral administration of any radioactive drug that contains a radionuclide that is primarily used for its electron emission, beta radiation characteristics, alpha radiation characteristics, or photon energy of less than 150 keV, for which a written directive is required

SS&D: 35.400, 35.500, & 35.600

- Clarifies that use includes uses under the appropriate medical use that is not explicitly listed in the Sealed Source and Device Registry (SSDR)
- Requires the use to be in accordance with radiation safety conditions and limitations in SSDR
- Differentiated between use requirements for sources and devices containing sources

Vendor Training: 35.610

- Requires vendor training of 10 CFR 35.600 medical use devices when there are upgrades that affect the operational and safety of the unit
- Vendor training must be by the vendor or someone certified by the vendor

Gamma Knife: 35.655

- Clarifies in the title that the section is addressing full-inspection servicing
- Retains 5 year frequency for teletherapy units
- Changes frequency for gamma stereotactic units to 7 years

Acronyms

- ANP – Authorized Nuclear Pharmacist
- AMP – Authorized Medical Physicist
- ARSO – Associate Radiation Safety Officer
- AU – Authorized User
- Ga – Gallium
- Ge – Germanium
- GBq - Gigabecquerel

Acronyms

- I-131 – Iodide-131
- keV – kiloelectron volts
- mCi - millicurie
- ME – Medical Event
- Mo-99 – Molybdenum-99
- NaI – Sodium Iodide
- PIB – Permanent Implant Brachytherapy
- PRM – Petition for Rulemaking

Acronyms

- Rb - Rubidium
- RSO – Radiation Safety Officer
- Sr – Strontium
- SS&D – Sealed Source and Device
- SSDR – Sealed Source and Device Registry
- T&E – Training and Experience
- Tc-99 – Technetium-99
- WD – written directive

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Subcommittee on Germanium-68/Gallium-68 Generator Licensing Guidance

Megan Shober
Advisory Committee on the Medical Uses of Isotopes
April 3, 2019

Subcommittee Members

- Melissa Martin
- Darlene Metter, M.D.
- Michael Sheetz
- Megan Shober (Chair)

Current Ge-68/Ga-68 Generator Licensing Guidance (2017)

- Expressly names Eckert and Ziegler brand of generator
- Includes specific breakthrough limit
- Describes steps to take if generator has not been eluted within 48 hours
- Requires notification to the NRC Operations Center if an eluate exceeds breakthrough levels
- Requires wipe tests each day of use

Proposed Revision to Ge-68/Ga-68 Generator Licensing Guidance

- Brand neutral
- Removed reconditioning requirements for generators not eluted within 48 hours
- Revised breakthrough reporting requirements ("multiple" failures)

Recommendations

- Subcommittee recommends endorsing the draft guidance with changes as noted:
  1. Add alternate pathway training option for ANP user.
  2. Remove brand-specific breakthrough limit.
  3. Reject proposed breakthrough failure reporting requirement and recommend conformance with 10 CFR 35.3204.

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Recommendations cont'd.

4. Due to the long time period required for breakthrough testing, add guidance on when breakthrough failure is "effective."
5. Revise survey requirements to allow increased flexibility in performance.

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Acronyms

ANP – Authorized Nuclear Pharmacist
CFR – Code of Federal Regulations
Ga-68 – Gallium 68
Ge-68 – Germanium 68
NRC – Nuclear Regulatory Commission

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

Subcommittee Review and Comments on

Germanium-68/Gallium-68 Generator Licensing Guidance, Revision 1

Submitted on: November 30, 2018

Subcommittee Members:
Ms. Melissa Martin
Dr. Darlene Metter
Mr. Michael Sheetz
Ms. Megan Shober (Chair)

NRC Staff Resource: Said Daibes-Figueroa, Ph.D.

Background

The subcommittee and its Chair were appointed by ACMUI Chairman, Christopher Palestro, at the ACMUI meeting on September 21, 2018. The purpose of the subcommittee was to review the NRC staff's draft proposed revision to the licensing guidance for Germanium-68 (Ge-68)/Gallium-68 (Ga-68) generators. The NRC's current licensing guidance for Ge-68/Ga-68 generators (Revision 1) was issued on July 13, 2017. At that time, the only Ge-68/Ga-68 generator approved by the U.S. Food and Drug Administration (FDA) and available on the market was the Eckert and Ziegler GalliaPharm® generator. As such, the NRC tailored its licensing guidance to this specific product. Now that additional Ge-68/Ga-68 generators (IREs [Institute of Radio Elements] Galli Eo™ generator and others) are becoming commercially available, the Ge-68/Ga-68 generator licensing guidance is being revised to eliminate reference to any specific generator manufacturer or product. This document represents the Subcommittee's report on the draft proposed revision of this licensing guidance issued by NRC staff in July 2018.

Changes to Guidance Considered by the Subcommittee and its Recommendations

General Comment: Throughout the document, ensure that font sizing and bullet size and shape are uniform.

Specific Comments

Title: The Subcommittee supports the change to the title of the proposed guidance.

Pg 1, 1st paragraph: Delete the sentence "Future Ge-68/Ga-68 radionuclide generators will be addressed in revisions to the licensing guidance."

Pg 2, Section 4.1, 2nd paragraph: Replace the words "FDA approved" with "if utilizing an FDA-approved kit for radiolabeling."

Pg 3, Authorized Use for commercial nuclear pharmacies: Add "(Form 313 Item 5)" under "Radionuclides," "Chemical/Physical Form," and "Maximum Possession Limit."

Pg 4 Section 4.4, 1st paragraph: Replace "to develop/create Ga-68" with "to elute Ga-68".

Pg 4, Section 4.4: The training for authorized individuals has omitted an "alternate pathway" option for ANPs, similar to 10 CFR 35.55(b), and written attestation signed by a preceptor ANP.

Pg 5 Written attestation requirement: Replace "35.1000 Ge-68 generator use" with "35.1000 Ge-68/Ga-68 generator use."

Pg 5, Section 4.4, last sentence: Replace "Physicians or nuclear pharmacists" with "Other individuals."

Pg 6, 1st bullet: Delete the word "to."

Pg 6, 3rd bullet: Begin the sentence with "Eluting…"

Pg 6, 7th bullet: Remove the value of 0.001 percent, as this is specific to a particular manufacturer. Replace with a generic reference to "the manufacturer's recommended breakthrough limit."

Pg 6, 7th bullet: Delete the sentence "Not knowingly distributing or administering to a patient or human research subject any material containing Ga-68 which is determined to exceed the manufacturer's 0.001 percent breakthrough limit." This topic is covered by the revised 8th bullet, below.

Pg 6, 8th bullet: Revise to read "During the course of breakthrough testing, if the eluate exceeds the manufacturer's breakthrough limits, the eluate will not be distributed or administered to a patient or human research subject;"

Pg 6, 10th bullet: Move this bullet to be the last bullet in the series.

Pg 6, 11th bullet: The criteria for "multiple" and "unusable" are vague. Delete "on multiple occasions rendering the generator unusable in human patients and research subjects." Adopt the language from the new 10 CFR 35.3204 for telephone reports to the NRC Operations Center within 7 days.

Pg 6, 12th bullet: "Center" should be capitalized.

Pg 7, general: Due to the extended time necessary for completing a breakthrough test, the guidance should specify when a generator failure is "effective." The Subcommittee recommends specifying that a generator has "failed" on the date when the breakthrough calculation is

performed. This should be no more than 7 days from the date of the previous breakthrough calculation.

Pg 7, 1st bullet: Remove this bullet. There is no reasonable scenario where a breakthrough failure could cause a reportable medical event due to Ge-68, based on 5 rem effective dose to the whole body or 50 rem dose to an organ.

Pg 7, 2nd bullet: In the first sentence, replace "manufacture's" with "manufacturer's."

Pg 7, 3rd bullet: Revise the sentence to read "Conduct surveys of all areas of licensed material use, including the generator storage and kit preparation areas, for contamination each day of use; and"

Pg 7, 4th bullet: Remove the bullet. This bullet appears to be less stringent than the guidance in NUREG-1556, Vol. 13, Appendix R, which says that areas where licensed material is stored must be surveyed for contamination weekly. What additional survey should be performed every three months that would not be captured in the required weekly surveys?

Pg 8, Section 7.3.2: Distributor (in 2 cases) should be spelled with an "o."

Pg 9, Section 7.4.1, 2nd paragraph: In the last sentence, delete the first "for" to read "…must provide financial assurance for decommissioning…"

Pg 10, Section 8, 1st paragraph: Add "Medical" at the beginning of the first sentence.

Pg 10, Section 8, 2nd paragraph: Delete "also."

Other recommendations

The subcommittee agrees with the remainder of the licensing guidance document.

Respectfully submitted, November 30, 2018,
Subcommittee on Germanium-68/Gallium-68 Generator Licensing Guidance,
Advisory Committee on the Medical Use of Isotopes (ACMUI),
Nuclear Regulatory Commission (NRC)

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Status of Medical Events FY 2018

Donna-Beth Howe, Ph.D.
Medical Radiation Safety Team
April 3, 2019

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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 FY 2013 - 2015

- **43 Medical events reported - FY 2013**
- **46 Medical events reported - FY 2014**
- **57 Medical events reported - FY 2015**

	FY13	FY14	FY15
35.200	0	1	3
35.300	2	3	8
35.400	15	5	9 (10)
35.600	10	10	17
35.1000	16	27	20 (30)

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Medical Events FY 2016 - 2018

- **50 Medical events reported - FY 2016**
- **43 Medical events reported - FY 2016**
- **50 Medical events reported - FY 2018**

	FY16	FY17	FY18
35.200	4	0	0
35.300	4	4	2
35.400	6 (18)	7	13 (15)
35.600	6	8 (14)	10
35.1000	30	24	25 (26)

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Medical Events 2018

35.300 Medical events **2**

Iodine-131 MIBG 1
Radium-223 1

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35.300 Medical Events

Iodine-131 MIBG **1**

- **50,000 to 12,000 cGy skin dose to 15 cm²**
  - Patient was disconnected from infusion pump at Spiros connection to use restroom.
  - At end of procedure, high activity of I-131 on patient's clothing and bed linen.
  - Two days later, patient reported discomfort and reddening of skin on upper right thigh erythematous lesion to desquamation the next day.

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35.300 Medical Events

Iodine-131 MIBG (cont.)

- **50,000 to 120,000 cGy skin dose to 15 cm²**
  - Did not decontaminate patient until signs of erythema.
  - Will only disconnect patient if medical emergency.
  - Will use adsorbent pads under administration line.
  - Will develop patient specific decontamination procedures.

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35.300 Medical Events

Ra-223 dichloride **1**

- **Administered 176.1 µCi instead of 180 µCi**
  - Signed written directive called for oral administration
  - Technologist administered intravenous
  - Will implement new written directive
  - Review current policy and procedures with staff

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Medical Events 2018

35.400 Medical events **13 (15)**

Eye Plaque	1
Unknown procedure	1
Prostate	11 (13)
One licensee, 3 reports	3 (5)
Human error	2
Wrong site	1
Larger than pre-plan or swelling	2

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35.400 Medical Events

Eye Plaque **1**

- **Prescribed 8,600 cGy – received 6,500 cGy**
  - Used new model of eye plaque that differed from old model
  - Isodose curves differed from brachytherapy plan.
  - Dose was deeper than expected

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35.400 Medical Events

Unknown Procedure **1**

- **70% of the intended dose was delivered**

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35.400 Medical Events

Prostate **9 (11)**

One licensee, 3 separate reports, 5 patients

- Report 1 - First patient prescribed 14,000 cGy, but administered 8,990 cGy – 62% of prescribed dose
  - No root cause, but attributed to human error
  - Some seeds may have migrated post-implant
  - Performed historical review after inspection
  - Second Patient prescribed 14,500 cGy, but received 19,200 cGy - 132% of the prescribed dose
  - Third Patient prescribed 14,500 cGy, but received 18,900 cGy - 130% of the prescribed dose

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35.400 Medical Events

One licensee, 3 separate reports, 5 patients (cont.)

- Report 2 - Patient prescribed 14,500 cGy, but received 10,500 cGy – 72.4% of the prescribed dose
- Report 3 - Patient prescribed 14,500 cGy, but received 7,000 cGy - 48% of the prescribed dose

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35.400 Medical Events

- **Patient prescribed 11,000 cGy, but received 5,815 cGy – 53% of dose**
  - Partial seed strand implanted in the bladder
  - Removed errant seeds immediately with cystoscopy
  - Attributed to human error
  - Corrective actions include:
    - New written procedure
    - Use of more needles, more seeds, and less aggressive sparing of the urethra
    - Stop using pre-loaded stranded seeds, so improperly implanted seeds can be individually

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35.400 Medical Events

- **Patient intended 10,800 cGy, but 50% of prostate received no dose**
  - Ultrasound volume of prostate was smaller on ultrasound pre-implant scan than CT post-implant scan
  - Real-time implantation with ultrasound did not permit potential visualization errors
  - Attributed to human error
  - Corrective actions include:
    - Additional training to personnel and improved supervision
    - Terminate the seed implant program due to low patient volume

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35.400 Medical Events

- **Patient prescribed 11,000 cGy, but received 6,215 cGy – 56.5% of dose**
  - Attributed to human error
  - Improve imaging techniques
- **Patient prescribed 14,400 cGy, but received only 73% of dose**
  - Attributed to 18% increase in prostate size compared to pre-plan
  - Planned intentional cooler coverage near rectum
  - Additional training to personnel

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35.400 Medical Events

- **Patient intended 12,500 cGy, but received 1,000 cGy 12.5% of dose (Pd-103 seeds)**
  - Used Foley catheter but inflated balloon in prostate urethra instead of bladder
  - 32 of 54 seeds placed outside prostate and 3 seeds could not be seen
  - Expect risk of radiation damage to rectum and surrounding tissue
  - Failed to locate Foley catheter compounded by using magnification factor of ultrasound device that did not give full view of relevant anatomy

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35.400 Medical Events

- **Patient intended 12,500 cGy, but received 1,000 cGy 12.5% of dose (Pd-103 seeds) [cont.]**
  - Physician and medical physicist will audibly concur on image quality before preceding
  - Manufacturer reset new default magnification value that will initial view of relevant prostate anatomy
  - Once first seed is implanted, fluoroscopic image will be used to verify relative location of seed and Foley catheter is where it is expected to be

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35.400 Medical Events

- **Patient prescribed 12,500 cGy, but received 9,670 cGy – 77% of dose (Pd-103 seeds)**
  - Three seeds from one needle did not remain in place
  - Contributing factors:
    - AU's preference for peripheral loading
    - Potential rotation of the prostate during needle insertion
    - Pressure effects from using hydrogel to separate prostate from rectum
  - Corrective actions:
    - No longer implant needle between urethra and rectum - will use two needles offset on axis
    - Use stabilized needles during surgery

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Medical Events 2018

35.600 Medical events **10**

HDR

- Skin 1
- Breast 2
- Gynecological 7
  - Device malfunction 2
  - Wrong site 3
  - Human mistake 2

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35.600 HDR Events

Skin **1**

- **Patient prescribed 8 fractions of 500 cGy each to temple area, but received 350 cGy on first 2 fractions**
  - First physicist used incorrect setup – forgot to use accuform - second physicist used correct setup
  - Wrong position - gap between treatment device and patient's skin

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35.600 HDR Events

Skin (cont.)

- Lack of policy for custom immobilization devices for skin treatment
- Therapist present at first treatment and any time there is a new physicist
- Photograph set up with and without patient to show accuform
- Barcode scanning to track custom set up devices

22*

35.600 HDR Events

Breast **2**

- **Wrong site - 1,200 cGy to lateral breast skin**
  - Patient contacted oncologist because of skin reaction
  - Physicist used tip end instead of connector end in treatment plan
  - Corrective actions:
    - Additional training to personnel

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35.600 HDR Events

Breast **2**

- **Wrong site - 1 cc volume of skin received 850 cGy instead of intended 256 cGy**
  - Savi applicator – struts 2 and 6 mislabeled - changed orientation of the applicator – direction of radiation
  - Corrective actions:
    - Second physicist to independently verify catheter struts in treatment plan.
    - HDR review checklist – verify digitization of struts in treatment plan
    - Add HDR plan review to monthly audit
    - Additional training to personnel

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35.600 HDR Events

Gynecological 7

- **Device malfunction**
  - Patient to receive 1,500 cGy during 3 fractions in 13 dwell points
  - HDR unit malfunctioned at dwell point 9
  - Treatment adjusted after repair of the HDR unit

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35.600 HDR Events

- **Device malfunction**
  - Device failed to fully retract at completion of treatment fraction
  - Dose of 100 cGY to patient thigh – source was 5 cm from cylinder guide tube connector
  - Source wire was bent near source
  - Delay in removing source from vicinity of patient and reporting the event to RSO

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35.600 HDR Events

- **Catheter movement - connector locking nut too loose, which allowed catheter to slide out**
  - Event discovered by skin reaction progressed to moist desquamation
  - Dose to skin of 5,154 to 8,555 cGy
  - Corrective action:
    - Retrain medical staff and AU
    - AU will double check all connections and placement before and after each treatment
    - Purchased new cylinder with new design

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35.600 HDR Events

- **Prescribed 6 fractions of 350 cGy each – first fraction received 2,100 cGy**
  - Total treatment time incorrectly entered into treatment planning system
  - Human error and poor decision making – started first treatment after hours – second physicist not available
  - Corrective actions:
    - Second physicist has to independently verify treatment plan
    - Physicist to check that plan was exported correctly to the treatment console

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35.600 HDR Events

- **Wrong Site – 587 cGy dose to small intestine and bowel instead of 220 cGy**
- Patient's pelvis had extensive damage from uterine cancel
- Two dwell positions shifted to deliver dose to non-targeted small intestine/bowel in first of 3 fractions
- Treatment plan modified for next 2 fractions
- Licensee thought not reportable - 10 CFR 35.3045(a)(1) and (3); NRC determined reportable - 10 CFR 35.3045(a)(1)(iii) and (a)(3)

29

35.600 HDR Events

- **Wrong site - 5.5 cm outside the treatment site received 500 cGy in 0.5 cm volume**
- Channel 12 digitized twice with no digitization of Channel 13 (Channel 13 digitization included in Channel 12 with no dwell positions for 13)
- Treatment plan displayed expected dose distribution to critical organs and tumor and no dwell positions for Channel 13
- Physician approved the plan

30*

35.600 HDR Events

- **Wrong site - 5.5 cm outside the treatment site received 500 cGy in 0.5 cm volume (cont.)**
- Patient discomfort (full bladder)
- Physicist rushed to complete the plan and export to treatment console - error overlooked
- Corrective action:
  - Second check by physicist that did not prepare the plan
  - Each channel will be carefully reviewed
  - Patient not brought to treatment area until plan has been checked and exported to console

31

35.600 HDR Events

- **Wrong site - 100 cGy outside treatment site Prescribed 1,890 cGy, but received 1,675 cGy**
- In first of three fractions digitize the catheter as linear instead of as a single curved catheter
- Physicist failed to recognize the incorrectly reconstructed catheter shape in planning software
- Treatment length of 15.7 cm instead of 9 cm

32*

35.600 HDR Events (cont.)

- **Wrong site - 100 cGy outside treatment site (cont.)**

– Discovered on second fraction

– Treatment plan was not enlarged so physicist could not see the dwell points overlapping

– Corrective actions:
  - Enlarge each treatment plan in which the physicist signs off
  - Use of a formalized check list

33

Medical Events 2018

35.1000 Medical events	**25**
Perfexion	**1**
Intervascular Brachytherapy	**1**
Radioactive seed localization	**1**
Y-90 Microspheres	**22**
Unidentified	2
Therasphere ®	13
SirSphere ®	7

34

35.1000 Medical Events

Perfexion **1**

- **Device malfunctioned**

– Device recorded an error and backup power was low, so the sources were returned to the shielded position

– One-third of prescribed dose delivered

35

35.1000 Medical Events

Intravascular Brachytherapy **1**

– First extra long delivery catheter – source could not get to treatment site and retracted safely to unit

– Second extra long treatment catheter – source still could not get to treatment site but source could not be returned to IVB unit; all catheters removed

– Hydraulic return mechanism failed to return source.

– No dose to treatment site and 39 cGy to surrounding tissue

– Deformation of delivery catheter confirmed root cause

36

35.1000 Medical Events

Radioactive seed localization **1**

- Expected dose 12 cGy to tissue, but patient received 99 cGy to tissue
- Seed implanted and scheduled for removal 6 days later
- Insurance company rescinded approval after seed was implanted and required 3 medical opinions
- Surgery performed approximately 64 days after implant

37

35.1000 Medical Events

Y-90 Microspheres **25**

Unknown 2

38

35.1000 Unknown Y-90 Events

Unknown **2**

- Prescribed 13,400 cGy to a segment of the liver, but received 10,300 cGy – 77% of intended dose
- Patient received 60% of prescribed dose

39

35.1000 Medical Events

Y-90 Microspheres **25**

Therasphere ® **13 (14)**

- Overdose 1
- Catheter/Obstruction 8
- Bubbles 2
- Backflow to contrast 1
- Human mistake 1

40

35.1000 Y-90 Therasphere® Events

Overdose

- **Prescribed 13,600 cGy, but received 29,400 cGy**
  - Picked up wrong dosage, measured and compared activity to shipping box information and not the written directive
  - Shipping box was for next week's patient
  - Post administration calculations identified the medical event
  - Will add a dose verification step in interventional radiology

41

35.1000 Y-90 Therasphere® Events

Dose in Waste Jar

- **Prescribed 12,000 cGy administered 1,770 cGy – liver volume - 14% of intended dose**
  - Licensee thought equipment did not function as designed
  - Most of the dosage was in the waste jar
  - Manufacturer could not determine root cause

42

35.1000 Y-90 Therasphere® Events

- **Two patients received less dose than prescribed**
  - First patient prescribed 72.6 mCi, but received 15 mCi. Inspector thought expansion tubing resulted in turbulent flow triggering suspension issues
  - Second patient prescribed 72 mCi, but received 36.75 mCi – Inspector thought lack of adequate agitation prior to administration or issues with quality/sizing of microspheres
  - Extension tubing no longer used
  - Manufacturer supported Inspector's findings

43

35.1000 Y-90 Therasphere® Events

- **Prescribed activity 122 mCi – received 46 mCi – 38% of intended activity**
  - From device components sent to manufacturer no cause for the blockage was determined
  - Obstruction/blockage located in microcatheter - obstruction in the outlet tubing at the E junction
  - Manufacturer recommended handling microcatheters with extra care and looking for kinks

44

35.1000 Y-90 Therasphere® Events

- **Prescribed 12,000 cGy – received 2,000 cGy (rad)**
  - Malfunction in the administrative set – significantly less pressure than usual to press syringe
  - Saline accumulating in overflow vial
  - Only returned portion of administration set that infused dosage into patient to manufacturer
  - May have been a kink or obstruction in treatment catheter but not conclusive
  - Will send complete administrative set next time

45

35.1000 Y-90 Therasphere® Events

One licensee – 2 reported medical events

- **Report 1 - Prescribed 64.8 mCi, but received 41 mCi - 65% of activity**
  - Air bubbles noted in overflow tubing connected to the micro-catheter
  - Connected 3-way stopcock between overflow tubing and micro-catheter aspirated bubbles to syringe with stopcock close to patient
  - Resurvey of delivery kit showed residual activity

46*

35.1000 Y-90 Therasphere® Events

- **Report 2 - Prescribed 46 mCi but received 27 mCi – 59% of activity**
  - Used left radial artery with 5-French Sarah Radial catheter with coaxial micro-catheter
  - Nothing unusual was encountered
  - No radioactive contamination of the suite
  - Dose was in catheter, gauze, dose vial and other waste

47

35.1000 Y-90 Therasphere® Events

- **Prescribed 89,200 cGy, but received 57,500 cGy - 64% of dose**
  - Backflow of microspheres into contrast line and syringe
  - Significant contamination in contrast syringe, flushing syringe, contrast tubing, and associated y-adaptor
  - Thought contrasting syringe and tubing were made of materials that bind microspheres more than administration kit - will look for same materials
  - Will use clamp and one-way valve

48

35.1000 Y-90 Therasphere® Events

- **Prescribed 23 mCi, but received 7.4 mCi – 32% of the activity**
  - Blockage occurred in the delivery apparatus
  - Imaged the administration set and saw most of the undelivered activity near where plunger connects to the dose vial
  - Will send administration set and procedure waste to contractor for manufacturer

49

35.1000 Y-90 Therasphere® Events

- **Prescribed 35 mCi, but received 5.4 mCi – 16% of activity**
  - Microspheres were coagulated in the tubing
  - Unexpected activity remained near the Touhy-Borst connector
  - Manufacturer thought caused by issues with the micro-catheter
  - Will flush micro-catheter immediately prior to connecting it to the administration kit

50

35.1000 Y-90 Therasphere® Events

- **Prescribed 13,000 cGy to left lobe of liver, but received 8,490 cGy - 65% of dose**
  - First vial administered without incident
  - Second vial primed and prepped, but saw a train of bubbles in the line between the dose vial and patient
  - AU stopped the procedure; did not want the bubbles to cause the flow to reflux into gastric artery and cause permanent damage to the stomach
  - Could not pinpoint cause of bubbles
  - Limit number of staff trained to prime and do set-up and ensure enough are available on treatment days

51

35.1000 Y-90 Therasphere® Events

- **Prescribed 24,500 cGy, but administered 13,083 cGy - 53% of dose**
  - CT scan verified dose was administered to correct location
  - Remainder of dose hung up in catheter despite flushing
  - Catheter tubing met manufacturer's specifications
  - No root cause identified

52

35.1000 Y-90 Therasphere® Events

- **Prescribed 1,300 cGy to specific part of liver, but received 931 cGy - 71% of dose**
  - Used 3 different written directives to fractionate the delivery
  - Thought the small activity prescribed contributed to under dose because of typical losses in the valve and tubing
  - Order higher dosages for any administration below 10 mCi
  - Amend license to go to different manufacturer

53

35.1000 Medical Events

SirSphere® 7

- Wrong site 2
- Measurement unit error 1
- Written Directive error 1
- High activity clogging 1
- Low activity administration 1

54

35.1000 Y-90 SirSphere® Events

Wrong treatment site **2**

- **Prescribed 38.4 mCi to liver but received about 13 mCi to abdominal wall**
  - Post-treatment scan appeared normal with small uptake in bowel
  - Pain in abdomen with erythema on abdomen – thought dose was above 55 cGy but less than 1,000 cGy
  - Thought one-third of dose migrated up a venous ligament and lodged in abdominal wall

55*

35.1000 Y-90 SirSphere® Events

Wrong treatment site (cont.)

- Difficult visualizing arterial access to the tumor
- Micro-catheter was not advanced far enough into correct artery
- Pre-existing kidney impairment precluded using more contrast
- Add second monitor to refer to original arteriogram without switching tasks and improve confidence of correct location
- Take prophylactic measures for future patients with impaired kidney function

56

35.1000 Y-90 SirSphere® Events

Wrong site

- **Prescribed 4,874 cGy to right lobe of liver, but received 11,080 cGy to left lobe**
  - Human error
  - Placed catheter in left hepatic artery instead of right hepatic artery

57

35.1000 Y-90 SirSphere® Events

Measurement Unit Error

- **Prescribed 0.91 GBq, but received 8.9 mCi**
  - Ordered 0.91 mCi - marked wrong box in computer
  - Did not multiply measured dose value by correction factor of 10
  - Not identify until post-procedure check
  - Worksheet revised to be in SI units
  - Written directive sheet to be in SI units
  - Dose preparation and post-procedure forms to be in SI units

58

35.1000 Y-90 SirSphere® Events

Written Directive Error

- **Prescribed 1,504 cGy to right lobe of liver, but received 1,498 cGy in left lobe**
  - Written directive prepared incorrectly - AU wanted to treat left lobe
  - Identified after completion of the procedure
  - AU did not indicate correct treatment site on written directive; AU did not forward pre-treatment information to the RSO
  - Clinical staff failed to identify discrepancy during patient time-out just before the implantation

59

35.1000 Y-90 SirSphere® Events

High activity clogging 1

- **Prescribed 4,320 cGy, but received 828 cGy – 19% of the dose**
  - Micro-catheter clogging due to unusually large number of microspheres being used
  - Prescribed activity was at high end of the treatment range
  - Patient administration delayed 1 day - 25% increase in number of microspheres were needed to deliver the dose
  - Will use smaller aliquots and/or slower infusion rate

60

35.1000 Y-90 SirSphere® Events

Device malfunctioned 1

- **Prescribed 32.5 mCi but received 8 mCi – 25% of activity**
  - Treatment device malfunctioned and ceased to deliver microspheres
  - Manufacturer's representative was present, but cause of malfunction is unknown
  - Will return delivery device to manufacturer for technical analysis and root cause determination

61

35.1000 Y-90 SirSphere® Events

- **Prescribed 19.6 mCi to left lobe of liver, but received 10 mCi – 51% of activity**
  - Planned to deliver activity in two split dosages
  - Written directive not properly reviewed, so split one dosage in two instead of the total dosage in two
  - Radiation oncologist failed to check the drawn dosages prior to injecting them
  - Identified after injection when the remainder of the dosage was discovered

62*

35.1000 Y-90 SirSphere® Events

- **Prescribed 19.6 mCi to left lobe of liver, but received 10 mCi – 51% of activity (cont.)**
  - Lack of comprehension of dose draw worksheet
  - Miscommunication and failure to review the written directive
  - Failure to perform a safety pause and properly review the dosage to be administered against the written directive prior to the administration

63

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
- IVB – Intravascular Brachytherapy
- Ra-223 – Radium-223
- MBq – Mega Becquerel

64

Acronyms

- µCi – microcurie
- mCi – millicurie
- MIBG - Metaiodobenzylguanidine
- Pd-103 – Palladium-103
- RSO – radiation safety officer
- SI units – International System of Units
- Y-90 – Yttrium-90

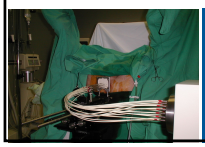
U.S.NRC
United States Nuclear Regulatory Commission
Protecting People and the Environment

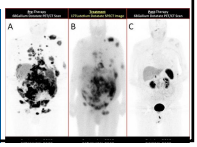
QUESTIONS?

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

Appropriateness of Medical Event Reporting Subcommittee Report

Ronald D. Ennis, M.D.
April 3, 2019



Subcommittee Charge

- To review the appropriateness of the required elements of medical event reporting; the adherence to these requirements; and recommend actions to improve reporting.

Subcommittee Members

- Dr. Dilsizian
- Dr. Ennis (Chair)
- Ms. Martin
- Mr. Ouhib
- Ms. Shober
- Ms. Weil

Purpose of Reporting

- An ME is reported to an Agreement State or NRC per 10 CFR 35.3045 as summarized in "Event Reporting Schedule for Agreement States 7/29/12" and SA-300, "Reporting Material Events" – "The information collected on … medical events … is invaluable in *assessing trends or patterns,* identifying generic issues or generic concerns, and *recognizing any inadequacies or unreliability of specific equipment or procedures.* The reported information is critical for initiating a timely and effective response to security-related events and *will significantly aid in understanding why the event occurred and identifying any actions necessary to improve the effectiveness of NRC and Agreement State regulatory programs."*

Documents Reviewed

- SA-300 - FSME Procedure Approval Reporting Material Events
- SA-105 - Reviewing the Common Performance Indicator, Technical Quality of Incident and Allegation Activities
- Event Reporting for Agreement States of July 29, 2012
- NMED Annual Report of 2017
- OAS Letter 7/2/14 regarding proposal for a public NMED
- Root cause and corrective action pick lists
- NMED content

Nuclear Material Events Database

- Nuclear Material Events Database (NMED)
- Includes data from both Agreement States and NRC
- NMED is managed by NRC's Office of Nuclear Material Safety and Safeguards
- The NMED contractor is responsible for coding and quality control of information with general oversight from the NRC NMED Project Manager
- Access to NMED is limited

NMED Issues

- Frequently, narrative is inadequate for an ACMUI reviewer to understand an event, its cause and contributing factors and the adequacy of the corrective action.
- At times, there appears to be a disconnect between the narrative and the chosen cause from the "cause pick list."
- At times, there appears to be a disconnect between the narrative and the chosen corrective action from the "corrective action pick list."

NMED Issues

- NMED lacks information from some inspections that has been conducted by the NRC region or Agreement State.
- In 23% of MEs from FY 2017-18, either no cause or no corrective action was indicated in NMED report.
- Of all 2017 MEs, 11% are incomplete and an additional 11% are pending additional information.
- Public, including AUs and RSOs, only have access to an NMED annual report.

Recommendations of the Subcommittee

- Root cause and corrective action sections on NMED – In addition to the pick lists, a narrative, searchable, section should be required.
- Require root cause and corrective action sections in NMED, both pick list and narrative sections always be completed.
- Require information gathered from any investigation be added to NMED.
- Require that a report in NMED be completed within 12 months.
- Require ACMUI and NRC staff to promulgate the findings of annual report of the ACMUI Subcommittee on Medical Events to the medical and medical physics communities.

Recommendations under Consideration by this Subcommittee

- Modify how Event Reports are written:
  - Require the report use additional guidelines to be developed by this subcommittee to assure more complete and useful information is provided.
  - Require the report be initially written by the AU and clinical physicists and subsequently reviewed by the inspector.
  - Require the inspector interview all involved in the ME.
  - Require a report from the manufacturer be included if the event involved a device.
  - Corrective action should include medical as well as technical.
  - Require the final report must be signed off by the AU, physicist and inspector.

Conclusion

- Significant opportunities exist to enhance the utility of medical event reporting, the NMED database, and the promulgation of the information to the user community.
- The Subcommittee asks that it be able to continue evaluating these issues in more detail with a goal of creating a set of specific recommendations.

Acronyms

- ACMUI – Advisory Committee on the Medical Use of Isotopes
- AU – Authorized user
- FSME - Office of Federal and State Materials and Environmental Management Programs
- FY – fiscal year
- ME – medical event
- NMED – Nuclear Materials Event Database
- NRC – Nuclear Regulatory Commission
- OAS – Organization of Agreement States
- RSO – Radiation Safety Officer
- SA – State Agreement

ACMUI Working Session

[CLOSED MEETING PORTION]

NO HANDOUT

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Protecting People and the Environment

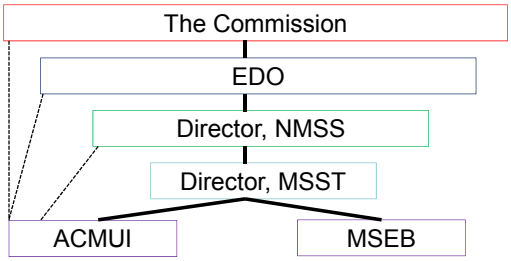
Committee Reporting Structure

Kellee Jamerson, ACMUI Coordinator
Medical Radiation Safety Team
April 4, 2019

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 ninth annual review.**

Meetings

Two meetings at Headquarters each year

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

Approximately 2-3 teleconferences (as needed)

5

Discussion

6

Points of Contact

- **Andrea Kock – MSST Director**
  - **301-415-2368; Andrea.Kock@nrc.gov**
- **Christian Einberg – Designated Federal Officer (DFO), Chief, MSEB**
  - **301-415-5422; Christian.Einberg@nrc.gov**
- **Kellee Jamerson – DFO, ACMUI Coordinator**
  - **301-415-7408; Kellee.Jamerson@nrc.gov**

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Acronyms

- **EDO – Executive Director for Operations**
- **MSST – Division of Materials Safety, Security, States, and Tribal Programs**
- **MSEB – Medical Safety and Events Assessment Branch**
- **NMSS – Office of Nuclear Material Safety and Safeguards**

8

Special Presentation

to

Ms. Laura Weil

NO HANDOUT

Thoughts on Leaving the ACMUI

NO HANDOUT

Commission Meeting with the ACMUI

NO HANDOUT

Group Photo

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U.S.NRC
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Protecting People and the Environment

ACMUI
Bylaws Subcommittee

Laura Weil
April 4, 2019

Subcommittee Members

- Robert Schleipman, M.D.
- Michael Sheetz
- Megan Shober
- Laura Weil (chair)

NRC Staff Resource: Sophie Holiday

Subcommittee Charge

- Review ACMUI Bylaws and recommend updates
- Particular focus on the role of the ACMUI Chairman and his/her participation on subcommittees

Existing Language in the Bylaws

Section 1.3.6 currently states:

"The Chair may take part in the discussion of any subject before the ACMUI and may vote. The Chair should not use the power of the Chair to bias the discussion. Any dispute over the Chair's level of advocacy shall be resolved by a vote on the Chair's continued participation in the discussion of the subject."

Suggested Additional Language

The Subcommittee proposes to add the following language:

In matters where the ACMUI Chair's unique experience and knowledge would be especially informative, the Chair may serve on relevant subcommittees. In these instances, the ACMUI Chair will not chair the subcommittee.

Existing Language – Conduct of Members

Section 4.1 currently states:

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

Suggested Language – Conduct of Members

The Subcommittee proposes to add the following:

Members cannot personally and substantially participate in the review of any particular matter (including general matters such as a rulemaking) that could directly and predictably affect their personal financial interest or the financial interest of:

- Their spouse or minor child
- Their general partner or organization in which they serve as an officer, director, trustee, general partner, or employee
- An organization with which they are negotiating or have an arrangement for prospective employment

Recommendations

- ACMUI Chair should be permitted to serve as a subcommittee member (not chair) when his/her specific expertise is necessary. A specific statement to that effect should be included in the ACMUI Bylaws.
- Explicit language defining financial Conflict of Interest (COI) should be inserted in bylaws.

Acronyms

ACMUI - Advisory Committee on the Medical Uses of Isotopes

COI - Conflict of Interest

DFO - Designated Federal Officer

U.S. Nuclear Regulatory Commission (NRC)
Advisory Committee on the Medical Use of Isotopes (ACMUI)
Subcommittee on ACMUI Bylaws

Draft Report Submitted On: March 3, 2019

Subcommittee Members: Robert Schleipman, Michael Sheetz, Megan Shober, Laura Weil (Chair)
NRC Staff Resource: Sophie Holiday

Subcommittee Charge:
Review ACMUI Bylaws and recommend updates, with particular focus on the question of whether the ACMUI Chair may serve as a member or chair of any ACMUI subcommittee.

Subcommittee process:
The Subcommittee and its Chair were appointed by the ACMUI Chairman, Dr. Chris Palestro, at the fall 2018 ACMUI meeting.

The Subcommittee members reviewed ACMUI Bylaws to determine whether the existing ACMUI Bylaws addressed the issue of Chair participation in subcommittee proceedings. Suggestions for possible revision regarding that question and any other concerns were made. A draft report was crafted by the Subcommittee Chair and was circulated to all Subcommittee members. The draft report was discussed, amended as necessary, and submitted to the full ACMUI for discussion at the spring 2019 meeting April 3-4, 2019.

Issues considered:
1. Should the ACMUI Chair be allowed to participate on subcommittees? If so, in what capacity should the ACMUI Chair participate? What language, if any, should be added to the Bylaws to clarify this question?
2. What other clarifications or additions to the ACMUI Bylaws, if any, should be considered?

Discussion:
1. ACMUI Chair participation on subcommittees

It has been the practice of the NRC to prohibit the participation of the ACMUI Chair in subcommittee deliberations and recommendations. This was recently brought to the attention of the incoming ACMUI Chairman, Dr. Palestro, who was asked to relinquish his position as Chair of an ongoing subcommittee in anticipation of his role as ACMUI Chairman. Dr. Palestro felt that this issue should be investigated by a subcommittee, and an explicit recommendation be made to the ACMUI, with potential clarification in the ACMUI Bylaws. The current ACMUI Chair and Vice Chair would not vote on the recommendations put forth by this Subcommittee.

The ACMUI Bylaws do not address this point, nor does the ACMUI Charter. The documents of our sister NRC Federal Advisory Committee Act (FACA) Committee, Advisory Committee on Reactor Safeguards (ACRS) are also generally silent on this issue, although the ACRS Chair is the designated Chair of a standing subcommittee. The ACMUI has no standing subcommittees, per its charter. There is no discussion of this issue on the FACA website, nor did consulted FACA staff suggest any required position on the issue. Several other FACA committee bylaws and charters were reviewed by the Subcommittee; none had explicit language regarding the potential for Chair membership and participation in subcommittee work. The understood rationale for the existing informal prohibition of the ACMUI Chair on subcommittees is two-fold: a) the role of Chair is onerous and time-consuming. It would be an imposition to expect the Chair to undertake additional subcommittee responsibilities, and b) the Chair might exert undue influence on subcommittee deliberations. Section 1.3.6 of the ACMUI Bylaws explicitly states, "The Chair may take part in the discussion of any subject before the ACMUI and may vote. The Chair should not use the power of the Chair to bias the discussion. Any dispute over the Chair's level of advocacy shall be resolved by a vote on the Chair's continued participation in the discussion of the subject."

Each member of the ACMUI has a specific area of expertise. In some cases, there is no duplication of expertise among the ACMUI members. The Subcommittee felt that all subcommittees should be able to avail themselves of the relevant expertise of any member of the ACMUI. The potential for benefit of specific expertise on any given subcommittee outweighs the potential for undue influence by the position of Chair. The example given was the recent subcommittee relating to gamma stereotactic radiosurgery (GSR) licensing guidance. Only one member of the ACMUI had specific and significant GSR expertise. Had that one member been the ACMUI Chair, and prohibited from subcommittee participation, the subcommittee would have been deprived of essential information and input in its deliberations. Concern was expressed that ACMUI Chair participation on a subcommittee should not overburden or compromise the ability of the Chair to perform the duties of ACMUI Chair; so it is proposed that the ACMUI Chair should not be asked to serve as any subcommittee chair.

The Subcommittee also discussed whether explicit Bylaws language is required to address this question (or whether a formal position expressed and captured at the ACMUI meeting would be adequate). The membership of the ACMUI turns over completely every eight years or sooner, and NRC staff rotate in and out of the medical team with unpredictable frequency. It is challenging to research areas of tradition and practice such as this. The minutes and transcripts of ACMUI meetings, while available, are not indexed by subject. It was felt that there are potential limits to ACMUI institutional memory, such that inclusion of specific language in the Bylaws would be the most efficient way to address this issue. New language is suggested (in bold italics) to be inserted in the existing Bylaws statement regarding ACMUI Chair discussion, participation, and voting rights. Section 1.3.6):

"The Chair may take part in the discussion of any subject before the ACMUI and may vote. The Chair should not use the power of the Chair to bias the discussion. Any dispute over the Chair's level of advocacy shall be resolved by a vote on the Chair's continued participation in the discussion of the subject." ***In matters where the ACMUI Chair's unique experience and knowledge would be especially informative, the Chair may serve on relevant subcommittees. In these instances, the ACMUI Chair will not chair the subcommittee.***

2. Additional Bylaw additions

The Subcommittee felt that the existing language in the Bylaws regarding conflict of interest was vague. The bylaws currently state:

> 4. CONDUCT OF MEMBERS
> 4.1 If a member believes that he or she may have a conflict of interest with regard to an agenda item to be addressed by the ACMUI, this member should divulge it to the Chair and the DFO as soon as possible and before the ACMUI discusses it as an agenda item. ACMUI members must recuse themselves from discussion of any agenda item in which they have a conflict of interest.

It is suggested that the ACMUI Bylaws be amended to include additional language to clarify more completely what constitutes a conflict of interest for ACMUI members. The following language is used in the ACRS Bylaws, Section 10.2-2, defining what constitutes a financial conflict of interest and should be considered for amending the ACMUI Bylaws:

> Members cannot personally and substantially participate in the review of any particular matter (including general matters such as a rulemaking) that could directly and predictably affect their personal financial interest or the financial interest of:
> - Their spouse or minor child
> - Their general partner or organization in which they serve as an officer, director, trustee, general partner, or employee
> - An organization with which they are negotiating or have an arrangement for prospective employment

However, the Subcommittee welcomes staff input on other language that will provide adequate clarification.

Summary of recommendations:

- The Subcommittee recommends that the ACMUI Chair be permitted to serve as subcommittee member (not chair) when his/her specific expertise is necessary. A specific statement to that effect should be included in the ACMUI Bylaws.

- The Subcommittee recommends that more explicit language be included in the ACMUI Bylaws defining conflict of interest with respect to participation of individual ACMUI members in discussion of matters that come before the Committee.

Respectfully submitted.
The ACMUI Bylaws Subcommittee

Open Forum

NO HANDOUT

September 2019

Monday	Tuesday	Wednesday	Thursday	Friday
2	3	4	5	6
Labor Day	X			
9	10	11	12	13
16	17	18	19	20
ASTRO Annual Meeting	ASTRO Annual Meeting	ASTRO Annual Meeting		X
23	24	25	26	27
30				
Rosh Hashana				

October 2019

Monday	Tuesday	Wednesday	Thursday	Friday
	1	2	3	4
	Rosh Hashana			
7	8	9	10	11
X		Yom Kippur		
14	15	16	17	18
Columbus Day Sukkot	Sukkot			
21	22	23	24	25
Shmini Atzeret	Simchat Torah			
28	29	30	31	