MEETING AGENDA
ADVISORY COMMITTEE ON THE MEDICAL USES OF ISOTOPES
September 21-22, 2020
WEBEX

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

Monday, September 21, 2020
OPEN SESSION

	1. Opening Remarks Mr. Einberg will formally open the meeting and provide opening remarks.	**C. Einberg, NRC**
10:00 – 11:30	**2. Old Business** Ms. Jamerson will review past ACMUI actions and recommendations and provide NRC responses.	**K. Jamerson, NRC**
	3. Open Forum The ACMUI will identify medical topics of interest for further discussion.	**ACMUI**
	4. Medical Events Subcommittee Report Dr. Ennis will provide an analysis of FY19 medical events.	**R. Ennis, ACMUI**
11:30 – 12:15	**BREAK / LUNCH**	
	5. Non-Medical Events Mr. Sheetz will provide an analysis of FY19 non-medical events reported by medical use facilities and commercial pharmacies.	**M. Sheetz, ACMUI**
12:15 – 2:00	**6. New Drug Development and Labeling** Mr. Lutterodt will discuss the U.S. Food and Drug Administration's regulatory process for new drug development and labeling.	**F. Lutterodt, FDA**
	7. Dosimetry Methodology Update for Regulatory Guide 8.39, Phase 2 Revision Dr. Hamby will discuss the dosimetry methodology update for the Regulatory Guide 8.39, Phase 2 revision.	**D. Hamby, RCD Radiation Protection Assoc.**
2:00	**ADJOURN FOR THE DAY**	

Tuesday, September 22, 2020
CLOSED SESSION

10:00 – 12:00	**8. INFOSEC Training**	**R. Norman, NRC**
	9. Ethics Training	**C. Safford, NRC**
	10. Allegations Training	**S. Hawkins, NRC**

12:00 – 12:15	**BREAK**	
	Tuesday, September 22, 2020 **OPEN SESSION**	
	11. Medical Team Updates Ms. Dimmick will provide an update on Medical Radiation Safety Team activities.	**L. Dimmick, NRC**
12:15 – 1:45	**12. Open Forum** The ACMUI will discuss medical topics of interest previously identified.	**ACMUI**
	13. Administrative Closing Ms. Jamerson will provide a meeting summary and propose dates for the spring 2021 meeting.	**K. Jamerson, NRC**
1:45	**ADJOURN**	

	ITEM	DATE	STATUS		Target Completion Date for NRC Action
17	The ACMUI endorsed the Appropriateness of Medical Event Reporting Subcommittee report and the recommendations provided therein.	9/10/2019	ACMUI Action	Open	Spring 2021
18	The ACMUI endorsed the Evaluation of Extravasations Subcommittee Report, as amended, to note that under future revisions to Part 35 rulemakings, extravasations be captured as a type of passive patient intervention in the definition of patient intervention.	9/10/2019	ACMUI Action	Open	Spring 2021
20	The ACMUI endorsed the Institutional Memory Subcommittee Report, as amended, to include the recommendation that a complete list of ACMUI members be updated and added to the webpage. The Subcommittee membership was amended to add Dr. Wolkov.	9/11/2019	ACMUI Action	Open*	09/14/2020
	*Action completed via the September 14, 2020 NRC Response Memorandum (ADAMS Accession No. ML20254A179) - pending formal closure by the ACMUI at the fall 2020 meeting.				

	ITEM	DATE	STATUS		Target Completion Date for NRC Action
1	The ACMUI endorsed the Regulatory Guide (RG) 8.39, "Release of Patients Administered Radioactive Material" Subcommittee report and the recommendations provided therein regarding the draft final RG 8.39, Revision 1, Phase 1.	3/11/2020	*Accepted*	Open*	09/14/2020
2	Dr. Metter formed a subcommittee to review the impacts that COVID-19 could have or is having on the medical use community and determine if potential impacts could help the NRC prepare for any regulatory impacts. Subcommittee membership includes: Dr. Vasken Dilsizian, Mr. Richard Green, Dr. Hossein Jadvar (chair), Ms. Melissa Martin, Ms. Megan Shober, and Dr. Harvey Wolkov. Non-voting subcommittee consultants include: Mr. Gary Bloom and Mr. Zoubir Ouhib. NRC staff resource: Ms. Lisa Dimmick	03/30/2020	*Accepted*	Open*	09/14/2020
3	Dr. Metter amended the membership of the Training and Experience Requirements Subcommittee. Subcommittee membership now includes: Dr. Ronald Ennis, Dr. Hossein Jadvar, Dr. Darlene Metter, Dr. Robert Schleipman (chair), Mr. Michael Sheetz, and Ms. Megan Shober. Mr. Gary Bloom will serve as a non-voting subcommittee consultant.	03/30/2020	*Accepted*	Open*	09/14/2020
4	The ACMUI endorsed the Patient Intervention subcommittee report, as presented, and the recommendations provided therein.	03/30/2020	*Accepted*	Open	Spring 2021

5	The ACMUI endorsed the Bylaws Subcommittee report, as presented, and the recommendations provided therein.	03/30/2020	*Accepted*	Open*	09/14/2020
6	Dr. Metter formed a subcommittee to review the abnormal occurrence criteria, with the following in mind: (1) define patient harm in AO; (2) reassess current AO criteria; (3) define goals of AO criteria and reporting; and (4) are current AO criteria sufficient in regards to public health? Subcommittee membership includes: Mr. Gary Bloom, Dr. Ronald Ennis, Dr. Hossein Jadvar, Mr. Zoubir Ouhib, Mr. Michael Sheetz, and Ms. Megan Shober. NRC staff resource: Dr. Katie Tapp. (subcommittee on hold until further notice from staff)	03/30/2020	*Accepted*	Open*	09/14/2020
7	The ACMUI endorsed the Interventional Radiologist Subcommitee report, as presented, and its recommendations provided therein.	03/30/2020	*Accepted*	Open*	09/14/2020
8	The ACMUI tentatively scheduled its fall 2020meeting for September 21-22, 2020. The alternate date is September14-15, 2020.	03/30/2020	*Accepted*	Open*	09/14/2020
9	The ACMUI endorsed the COVID-19 Subcommittee report, as presented, and its recommendations provided therein. (4/30/20)	4/30/20	*Accepted*	Open*	09/14/2020
	*Action completed via the September 14, 2020 NRC Response Memorandum (ADAMS Accession No. ML20254A179) - pending formal closure by the ACMUI at the fall 2020 meeting.				

OPEN FORUM

NO HANDOUT

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

Medical Events Subcommittee Report

Ronald D. Ennis, M.D.

Advisory Committee on the Medical Uses of Isotopes

September 21, 2020

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Protecting People and the Environment

Subcommittee Members

- Ronald D. Ennis, M.D. (Chair)
- Richard Green
- Darlene Metter, M.D.
- Michael O'Hara, Ph.D.
- Michael Sheetz
- Harvey Wolkov, M.D.

NRC Staff Resource: Donna-Beth Howe, Ph.D.

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Process

- As begun in 2018, every two years the Medical Events Subcommittee will report on our review of events over the last 4 years to discern common themes within each section of 10 CFR Part 35 and across the sections, to inform a discussion of possible ways to decrease medical events (MEs).
- The Subcommittee reviewed the medical events for FYs 2016-2019.

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Summary

- Two overarching themes remained
  - Performance of a “time out” immediately prior to administration of radioactive byproduct material, as is done in surgery and other settings, could have prevented some MEs
  - Lack of recent or frequent performance of the specific administration appears to be a contributing factor in a number of cases
- One new issue identified
  - Increase complexity of unsealed source administrations of newer agents may be leading to more equipment related MEs

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35.200 Use of Unsealed Byproduct Material for Imaging and Localization

Medical Events Summary

	2016	2017	2018	2019	Total
Cause					
Wrong drug	0	0	0	0	0
Wrong dosage	0	2	0	0	2
Wrong patient	0	1	0	0	1
Extravasation	0	1	0	0	1
Human error	0	0	0	1 (8 patients)	1 (8 patients)
Total	0	4	0	1	5

3/5 possibly preventable by "time out"

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35.300 Use of Unsealed Byproduct Material, Written Directive Required

Medical Events Summary

	2016	2017	2018	2019	Total
WD not done or incorrectly	1	2	1	2	6
Error in delivery (# capsules)	1	1	0	1	3
Wrong dose	1	0	0	0	1
Equipment	0	0	1	4	5
Human Error	1	0	0	1	2
Wrong patient	1	1	0	1	3
Total	4	4	2	9	19

"Time out" could prevent 13/19 = 68%
Emerging increase in equipment issues 5/19 = 26% compared to 10% in last review

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35.400 Manual Brachytherapy

Medical Events Summary

	2016	2017	2018	2019	Total
Applicator issue (e.g. movement during implant	1	0	0	0	1
Wrong site implanted (e.g. penile bulb)	1	1	1	1	4
Activity/prescription error (e.g. air kerma vs mCi, enter wrong activity in planning software)	0	1	0	1	2
Prostate Dose	18	5	11	3*	37
New device	0	0	1	0	1
Total	20	7	13	5	45

*Still using dose-based criteria

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35.400 Manual Brachytherapy

Medical Events Summary

	2016	2017	2018	2019	Total
Total MEs	20	7	13	5	45
"Time out" may have prevented ME	0	1	0	1	2
Lack of experience may have played a role	1	1	1	1	4

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35.400 Manual Brachytherapy

- Many MEs in this category are no longer categorized as MEs due to change from dose to activity-based definition, although even in 2019, this definition continued to be used for some MEs.
- Lack of experience possibly plays a role in the true MEs of this type, but hard to assess to what degree in each case.
- In approximately 13% (down from 25% in last review) of cases, a “time-out” or enhanced retraining prior to performance of an uncommon procedure might have prevented the ME.

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35.600 Use of a sealed source in a remote afterloader unit, teletherapy unit, or gamma stereotactic unit

Medical Events Summary

	2016	2017	2018	2019	Total
Cause					
Wrong position	1	2	3	4	10
Wrong reference length	0	2	1	4	7
Wrong plan	1	0	2	0	3
Wrong dose/source strength	0	0	1	0	1
Machine malfunction	3	2	3	1	9
Software failure	0	2 (9 pts)	0	1	3
Total	5	8 (14 pts)	10	10	33

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35.600 Use of a sealed source in a remote afterloader unit, teletherapy unit, or gamma stereotactic unit

Medical Events Summary

	2016	2017	2018	2019
Location				
Breast	0	0	1	0
Gynecological	2	7 (14 pts)	7	8
Skin	1	0	1	0
Bronchus	0	0	0	0
Prostate	2	0	0	0
Brain	0	1	1	2
Total	5	8 (14 pts)	10	10

GYN tumors were most common site of ME.

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35.600 Use of a sealed source in a remote afterloader unit, teletherapy unit, or gamma stereotactic unit

MEs that may have been prevented by "timeout" (wrong plans or dose)

- 2016 1/5 events
- 2017 0/8 events
- 2018 3/10 events
- 2019 3/10 events

Total: 7/33 (21.2%) compared to 16% on last review

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35.600 Use of a sealed source in a remote afterloader unit, teletherapy unit, or gamma stereotactic unit

MEs caused by "infrequent user"

This is difficult to determine based on information in NMED. If assumption is made about wrong position as surrogate for "infrequent" user.

- 2016 1/5 events
- 2017 2/8 events
- 2018 1/10 events
- 2019 1/10 events

Total: 5/33 (15.2%) compared to 32% on last review

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35.1000 Radioactive Seed Localization

Medical Events Summary

	2016	2017	2018	2019
Total Medical Events	1	0	1	0
Cause:				
Delayed seed removal (patient intervention)	1		1	
Lost seed				0
Wrong implant site				0

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35.1000 Intravenous Cardiac Brachytherapy

Medical Events Summary

	2016	2017	2018	2019	Total
Did not follow proper procedure	0	0	0	1	1
Tortuous vessel anatomy	0	0	1	1*	2
Catheter issue	0	0	1	0	1
Total	0	0	2	1	4

*AU felt this is “patient intervention”
No time out issues
Difficult to assess the unfamiliarity issue, but possibly played a role in some

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35.1000 Gamma Knife® Perfexion™ and Icon™

Medical Events Summary

	2016	2017	2018	2019
Total Medical Events	3	0	1	0
Cause:	0	0	0	0
Back-up battery power source failure	0	0	1	0
Patient setup error	2	0	0	0
Patient movement	1	0	0	2
Wrong site (treatment plan)	0	0	0	0

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35.1000 Y-90 Theraspheres

Medical Events Summary

	2016	2017	2018	2019	Total
Total Medical Events	13	15	14	15	57
Cause:					
> 20% residual activity remaining in delivery device	9	7	11	9	36
Delivery device setup error	1	2	2	1	6
Wrong dose (treatment plan calculation error)	1	4	0	1	6
Wrong site (catheter placement error)	2	2	0	0	4
Wrong dose vial selected			1	4	5

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35.1000 Y-90 SirSpheres

Medical Events Summary

	2016	2017	2018	2019	Total
Total Medical Events	13	8	7	11	39
Cause:					
> 20% residual activity remaining in delivery device not due to stasis	9	7	2	8	26
Wrong dose (treatment plan calculation error)	2	0	2	0	4
Wrong site (catheter placement error)	2	1	2	2	7
Wrong site (WD error)	0	0	1	1	2

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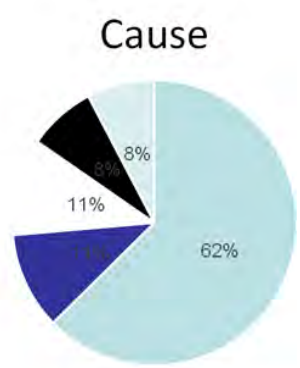
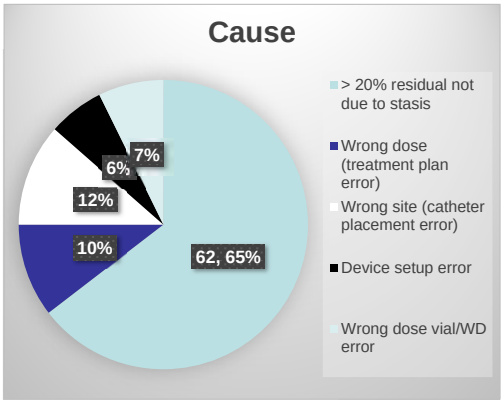
Overview Y-90 Microsphere MEs

FY2014 – 2017 N=91



FY2016 – 2019 N=96



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Actions to Prevent 35.1000 Y-90 Microsphere Medical Events

- Review mechanics of Y-90 microsphere delivery device and setup procedures
- Confirm all data and calculations in treatment plan
- Perform “Time Out” to assure all elements of treatment are in accordance with Written Directive

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35.1000 Medical Events That May Have Been Prevented by "Time Out"

	RSL	Perfexion/Icon	Y-90 Microspheres
2016	0/1	2/3	3/26
2017	0	0	3/23
2018	0/1	0/1	4/21
2019	0	0/2	7/26
Total	0/2	2/6 (33%)	17/96 (18%)

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35.1000 Medical Events That May Have Been Attributed to Lack of Experience or Infrequent User

	RSL	Perfexion/Icon	Y-90 Microspheres
2016	0/1	2/3	1/26
2017	0	0	2/23
2018	0/1	0/1	2/21
2019	0	0/2	1/26
Total	0/2 (0%)	2/6 (33%)	6/96 (6%)

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Possible Elements of a "Time Out"

- Identity of patient via two identifiers (e.g., name and DOB)
- Procedure to be performed
- Isotope
- Activity
- Dosage – second check of dosage calculation and that the WD and dosage to be delivered are identical

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Possible Elements of a "Time Out" cont'd.

- Others, as applicable
  - units of activity (LDR prostate)
  - anatomic location
  - patient name on treatment plan
  - treatment plan independent second check has been performed
  - reference length (HDR)
  - implant site location (RSL)

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Subcommittee Response to Findings

- The subcommittee recommended that the NRC staff issue an Information Notice alerting Authorized Users to the themes identified herein.
- IN-19-07, Methods to Prevent Medical Events, was published on August 26, 2019. (ADAMS Accession No. ML19240A450)

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Acronyms

- 10 CFR – Title 10 of the *Code of Federal Regulations*
- AUs – authorized users
- FY – Fiscal Year
- gyn – gynecological
- HDR – high dose-rate
- LDR – low dose rate
- mCi – milliCurie
- ME – Medical Event
- RSL – radioactive seed localization
- Y-90 – yttrium-90

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U.S. Nuclear Regulatory Commission

Advisory Committee on the Medical Uses of Isotopes

Subcommittee on Medical Events

Draft Report

Submitted On: August 11, 2020

Subcommittee Members: Mr. Richard Green, Dr. Ronald D. Ennis (Chair), M.D., Dr. Darlene F. Metter, Mr. Michael Sheetz, and Dr. Harvey Wolkov

NRC Staff Resource: Dr. Donna-Beth Howe

Charge

The specific charge of this subcommittee is to annually review the medical events (MEs) with an eye to advising the ACMUI and NRC about emerging trends needing regulatory attention.

Background

At the Fall 2018 ACMUI meeting this subcommittee initiated a new approach to reporting on MEs such that every 2 years the subcommittee will review medical events (MEs) occurring in the previous 4 years with the goal of identifying common themes within each section of 10 CFR Part 35 and discuss possible ways to prevent these MEs. The report herein is the second such in-depth 4-year review of MEs.

Findings

The Subcommittee on Medical Events reviewed the Medical Events from FY 2016-19. Events from each section were reviewed in detail by a subcommittee member with expertise in the area. In the subcommittee's review two years ago, we noted that a significant proportion of MEs might be prevented by the universal implementation of a time out prior to the procedure/treatment. In addition, we noted that a considerable number of events seemed to occur in situations in which the authorized user and team were performing a procedure/treatment with which they do not have much recent experience.

In the current review, the subcommittee found that the number of MEs, the types and the proportion possibly preventable by a time out and the proportion related to lack of experience, were about the same.

One new emerging trend was noted. In the delivery of unsealed byproduct material for which a written directive is required (10 CFR 35.300), there was an increase in the number of MEs related to equipment (e.g., catheter) issues. This is thought to be attributable to the increasing use of agents with more complex delivery (e.g., Lu-177 dotatate). The subcommittee anticipates this

trend will continue and warrants close observation. However, no specific intervention by NRC staff is recommended at this time.

A new Y-90 microsphere delivery device has been introduced by Sirtex. We will be watching for trends in MEs related to this problematic area with the introduction of this new device.

Concluding Remarks

The subcommittee looks forward to performing an in-depth trend analysis in 2022 and next year will perform a focused one-year review of FY2020.

The subcommittee welcomes any comments and/or suggestions.

Respectfully Submitted,
The Medical Event Subcommittee
Ronald Ennis, MD, Chair

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

Non-Medical Byproduct Material Events: FY18 and FY19

Michael Sheetz

Advisory Committee on the Medical Uses of Isotopes

September 21, 2020

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Non-Medical Events Reported by Medical Licensees

- NMED event reported by medical licensee
- Does not include medical events under 10 CFR 35.3045 or 35.3047
- Includes events reported under:
  - 10 CFR 35.3067 (leaking source)
  - 10 CFR 20.2201 (lost or stolen material)
  - 10 CFR 20.2202 (over exposures)
  - 10 CFR 30.50 (contamination)
  - 49 CFR 171.15 (transportation incidents)

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Non-Medical Event Categories

Identified in FY18 and FY19

Category	FY18	FY19
Lost, Abandoned, or Stolen Sources	9	18
Leaking Sealed Source	9	4
Transportation of Radioactive Material	5	3
Radiation Overexposure	5	3
Radioactive Contamination	3	3
Equipment Malfunction	1	4
Total	**32**	**35**

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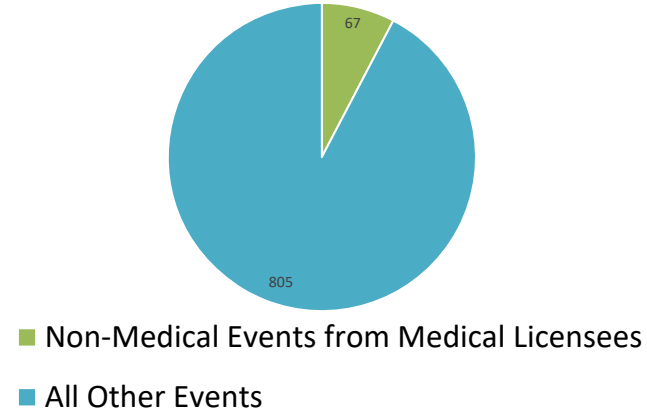
Total NMED Events (All Categories)

FY18 and FY19



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Lost, Abandoned, or Stolen Sources

FY18 and FY19

- Lost I-125 RSL seed – 9
- Lost RAM shipment – 6
- Missing I-125/Pd-103 brachy seeds – 3
- Temporary loss and recovery of RAM – 3
- Abandoned calibration sources – 2
- Lost Cs-137 dose calibrator source – 1
- Patient removal of I-125 brachy seeds – 1
- Ir-192 source delivery to wrong location – 1
- Incomplete shipment of Lu-177 – 1

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Leaking Sealed Source

FY18 and FY19

- Ir-192 HDR source – 4
- Cs-137 dose calibrator vial – 3
- I-125 RSL seed – 2
- Co-57 dose calibrator vial – 1
- Sr-90 intravascular brachytherapy device – 1
- Co-57 calibration rod – 1
- Ge-68 phantom – 1

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Transportation of Radioactive Material

FY18 and FY19

- Contaminated package – 4
- Vehicle accident – 2
- Damaged package – 1
- High exposure rate – 1

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Radiation Overexposure

FY18 and FY19

- PET radiopharmaceutical production – 3
  - (50 mSv DDE, 690 mSv SDE, 600 mSv SDE)
- Nuclear medicine procedures – 2
  - (130 mSv DDE, 580 mSv SDE)
- Cyclotron repair – 1
  - (720 mSv SDE)
- C-11 and F-18 animal research – 1
  - (130 mSv DDE)
- Interventional radiology using Y-90 microspheres – 1
  - (530 mSv SDE)

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Radioactive Contamination

FY18 and FY19

- Contamination of hospital room from patient receiving previous I-131 therapy – 2
- Contamination of veterinary clinic from I-131 treatment of cat – 2
- Patient contamination from administration of F-18 – 1
- Contamination of hot lab following breakage of Tc-99m vial – 1

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Equipment Malfunction

FY18 and FY19

- Sr-90 IVB device source retraction failure – 2
- Defective HDR transfer guide tube – 1
- HDR device premature termination of treatment – 1
- Rb-82 generator Sr-82/85 breakthrough limits exceeded – 1

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Other Events – Landfill Alarms

- Detection of short-lived medical isotopes in municipal waste
- No standard reporting requirement
- Declining number of events

FY14	FY15	FY16	FY17	FY18	FY19
113	114	71	18	17	6

- Can result in significant response effort

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Conclusions

- Relatively small number of Non-Medical events
- Type of events occurring have minimal health and safety impact
- Declining number of landfill alarm responses reduces burden on both regulators and licensees

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Acronyms

- C-11 – carbon-11
- CFR – Code of Federal Regulations
- Co-57 – cobalt-57
- Cs-137 – cesium-137
- DDE – Deep Dose Equivalent
- F-18 – flourine-18
- FY – Fiscal Year
- Ge-68 – germanium-68
- HDR – high dose rate

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Acronyms

- I-125/I-131 – iodine-125/131
- IR-192 – iridium-192
- IR – Interventional Radiology
- IVB – Intravascular Brachytherapy
- Lu-177 – lutetium-177
- mSv – milliSievert
- NMED – Nuclear Material Events Database
- Pd-103 – palladium-103
- PET – Positron Emission Tomography

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Acronyms

- RAM – Radioactive Material
- Rb-82 – rubidium-82
- RSL – Radioactive Seed Localization
- SDE – Shallow Dose Equivalent
- Sr-82/85/90 – strontium-82/85/90
- Tc-99m – technetium-99 metastable
- Y-90 – yittruim-90

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New Drug Development and Labeling

Frank Lutterodt, M.S., MSDRA
Division of Imaging and Radiation Medicine
Division of Regulatory Operations—Specialty Medicine

Office of Regulatory Operations
Center for Drug Evaluation and Research

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Outline

- Overview Drug Development Process
- Regulating the Use of Radioactive Drugs in Basic Research
- Pre-Clinical Phase
- Clinical Phase
- New Drug Application Review and Labeling

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Drug Development Process

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Regulating Radioactive Drugs in Basic Research

- Radioactive Drug Research Committee (RDRC) (*21 CFR 361.1*)
- For basic science research
- Not for use for immediate therapeutic, diagnostic or similar purpose
- No intent to determine safety or effectiveness for clinical use

https://www.fda.gov/drugs/science-and-research-drugs/radioactive-drug-research-committee-rdrc-program

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New Drug Development Process

Pre-Clinical Research

- Synthesis and purification
  - Target affinity
  - Selectivity etc.
- Animal Testing
  - PK
  - Proof of concept
  - Toxicity
  - Translation to humans
- Meetings with FDA

https://www.fda.gov/media/109951/download

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New Drug Development Process

Clinical Phase

Phase 1

Phase 1 approaches involve Investigational New Drug Application (IND) and may involve:

1. Exploratory IND
2. Traditional IND

- *INDs are governed by 21 CFR 312.21*
- *INDs are used to establish the safety or effectiveness of a drug to support the approval of a new use*

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New Drug Development Process
Clinical Phase
Phase 1 (Exploratory IND)

An exploratory IND study is a clinical trial that

- is conducted early in phase 1,
- involves very limited human exposure, and
- has no therapeutic or diagnostic intent.

The main purpose of this approach is to find promising drug candidates to enable the sponsor to proceed efficiently with the most promising drug.

https://www.fda.gov/media/72325/download

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New Drug Development Process
Clinical Phase
Phase 1 (Traditional IND)

- Traditional Phase 1 trials usually involve healthy volunteers to determine the drug's most frequent and serious adverse events, and often, how the drug is metabolized and excreted by the body
- Involve a small number of participants, generally in the range of 20 to 80 subjects

https://clinicaltrials.gov/ct2/about-studies/glossary
21 CFR312.21 https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=312.21

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New Drug Development Process
Clinical Phase
Phase 2

- Phase 2 clinical trial gathers more information about a drug's safety and effectiveness in the condition/disease being studied
- Larger group of subjects/participants are enrolled
- Subjects/participants receiving the drug may be compared with others receiving placebo
- Safety and short-term adverse reactions continue to be evaluated

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New Drug Development Process
Clinical Phase
Phase 3

- During Phase 3, more information is gathered about a drug's safety and effectiveness by studying different populations and different dosages and by using the drug in combination with other drugs
- Studies typically involve more participants and efficacy endpoints are assessed
- If safety and efficacy are adequately confirmed, clinical testing may end at this step and a New Drug Application (NDA) may be submitted

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NDA Review

- Preclinical data (Pharmacology/Toxicology, Chemistry Manufacturing and Controls), and data from the clinical trials are reviewed to assist FDA in making a benefit/risk assessment
- A favorable benefit/risk assessment culminates in the review and approval of the drug labeling

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New Drug Label and Labeling

Label

Any display of written, printed, or graphic matter ***on the immediate container*** of any article, or any such matter affixed to any consumer commodity or affixed to or appearing upon a package containing any consumer commodity

21CFR1.3 (b) / FD&C Act section 201(k)

Labeling

All labels, as well as other written, printed, or graphic matter ***accompanying the product***.

21CFR1.3 (a) /FD&C Act section 201(m)

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Labeling

- Carton and Container Labels
- Prescribing Information (PI) "Package Insert"
- Patient Labeling
  - Patient Instructions for Use, Patient Information, Medication Guide
- Operator Guide (User Manual)

Prescribing Information

- Physician Labeling Rule (PLR) Format was implemented in 2006

- Contents of the Prescribing Information (PI)
  - **Highlights**
  - **Table of Contents**
  - Full Prescribing Information (FPI)
    - Pregnancy and Lactation Labeling Rule (PLLR)

21 CFR 201.56 and 201.57
Physician's Labeling Rule Requirements for Prescribing Information
http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/LawsActsandRules/ucm084159.htm

PLLR

- Label ***format change*** to reflect an integrated assessment of known risks relevant to pregnancy, lactation, and infertility based on available information/data

Draft Guidance for Industry: Pregnancy, Lactation, and Reproductive Potential: Labeling for Human Prescription Drug and Biological Products — Content and Format
http://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm425398.pdf

Pregnancy and Lactation Labeling Final Rule
http://www.fda.gov/Drugs/DevelopmentApprovalProcess/DevelopmentResources/Labeling/ucm093307.htm

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General Table of Contents in FPI

BOXED WARNING

1 INDICATIONS AND USAGE
2 DOSAGE AND ADMINISTRATION
3 DOSAGE FORMS AND STRENGTHS
4 CONTRAINDICATIONS
5 WARNINGS AND PRECAUTIONS
6 ADVERSE REACTIONS
7 DRUG INTERACTIONS
8 USE IN SPECIFIC POPULATIONS
8.1 Pregnancy
8.2 Lactation
8.3 Females and Males of Reproductive Potential
8.4 Pediatric Use
8.5 Geriatric Use
9 DRUG ABUSE AND DEPENDENCE
10 OVERDOSAGE
11 DESCRIPTION
12 CLINICAL PHARMACOLOGY
12.1 Mechanism of Action
12.2 Pharmacodynamics
12.3 Pharmacokinetics
13 NONCLINICAL TOXICOLOGY
13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility
13.2 Animal Toxicology and/or Pharmacology
14 CLINICAL STUDIES
15 REFERENCES
16 HOW SUPPLIED/STORAGE AND HANDLING
17 PATIENT COUNSELING INFORMATION

16

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Post-Market Activity

- Supplemental applications
- INDs
- Drug Advertising
- Manufacturer Inspections
- Active Surveillance
- Safety Reports

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Examples of Radiological Drugs Regulated at CDER

- Positron Emission Tomography Generators
- Scintigraphic Agents
- Magnetic Resonance Imaging Media
- Ultrasound Contrast Media
- Ionic Iodinated Contrast Media
- Non-Ionic Iodinated Contrast Media
- Non-iodinated Contrast Media

18

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Conclusion

- The discovery and development of new drugs can be long and complicated
- From conception to the marketing of a drug, FDA encourages sponsors/applicants to meet early in development
- Radiopharmaceutical and PET drugs are regulated by both NDA and labeling regulations (21 CFR 314, *21 CFR 201.56 and 201.57)*

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U.S. FOOD & DRUG ADMINISTRATION

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Backup Slides

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New Drug Development Process Links

- https://www.fda.gov/patients/learn-about-drug-and-device-approvals/drug-development-process

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Labeling for Radiopharmaceuticals and PET Products

- Imaging instructions are placed in the "Dosage and Administration" sections

IMAGING INSTRUCTIONS

- Image Acquisition Guidelines
  - Timing and Duration
  - Location (head, body)
  - Patient Instructions (voiding)
  - Device Parameters (e.g. 2D or 3D PET, software reconstruction)
- Image Display
  - Orientation
  - Coloring Display
- Image Interpretation
  - "Positive" vs. "Negative"

DOSIMETRY METHODOLOGY UPDATE FOR REGULATORY GUIDE 8.39, PHASE 2

SEPTEMBER 21, 2020

RCD RADIATION PROTECTION ASSOCIATES
David M. Hamby, PhD

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OVERVIEW

- Phase 2 revisions to Regulatory Guide (RG) 8.39 are intended to update the dosimetry methodology
- Proposed direction will provide a versatile, realistically-conservative threshold for dosimetry
- The ease of basic thresholds and, if necessary, the ability to create patient-specific thresholds
- Thresholds are based on maximum bystander equivalent dose of 5 mSv and 1 mSv
- Breastfeeding infants are protected to the same level and the method is simplified
- Emerging technologies are easily supported with the new methodology

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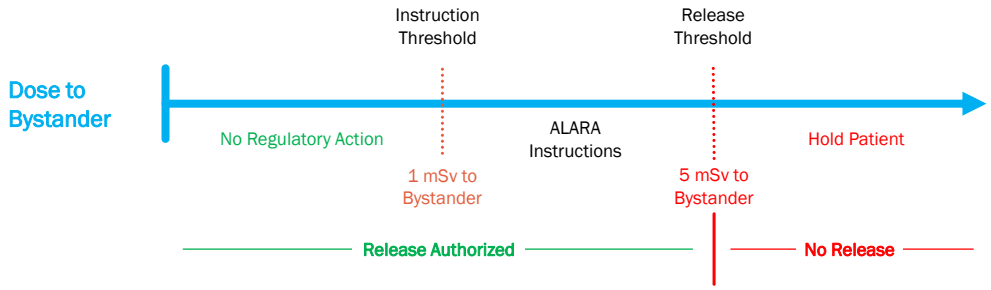
BASIC THRESHOLD PHILOSOPHY

10 CFR 35.75: release is authorized if bystander TEDE < 5 mSv
written instructions required if bystander TEDE > 1 mSv



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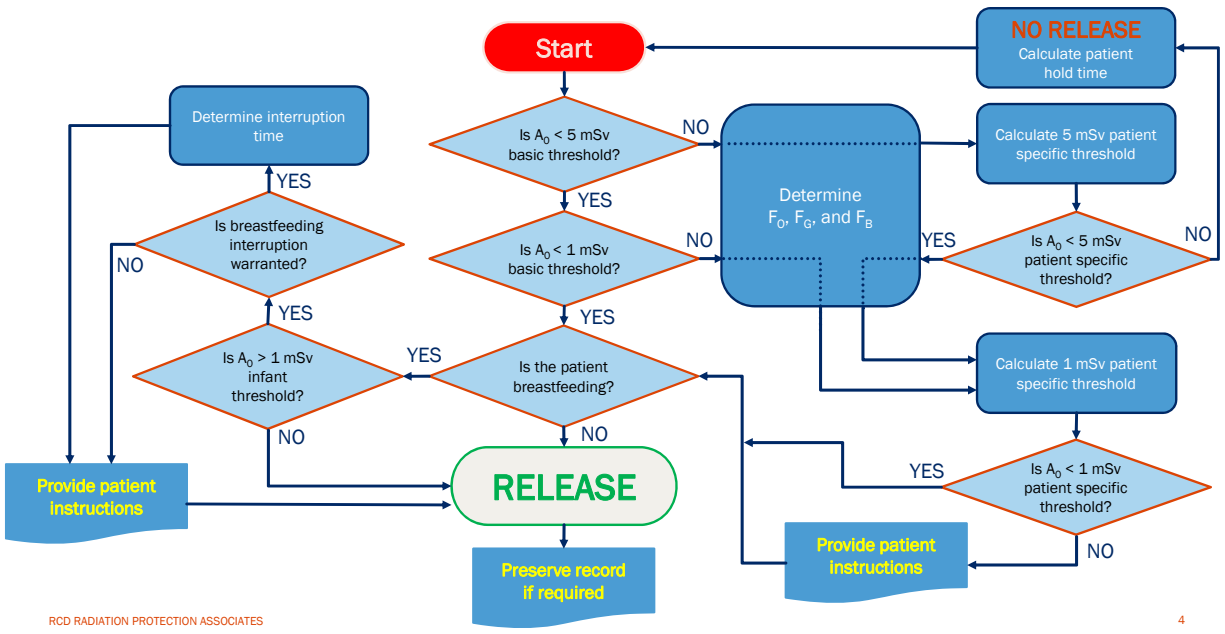

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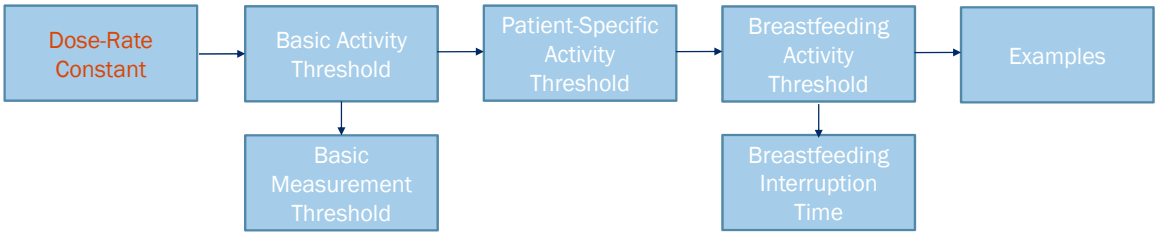

THE DOSE-RATE CONSTANT

5

THE CURRENT METHOD …

(SIMPLISTIC AND CONSERVATIVE WITH ONLY MINOR PATIENT-SPECIFIC INPUTS)

The estimated external time-integrated ($t = 0 \rightarrow \infty$) effective dose equivalent is:

$$\widetilde{D}(\infty) = k\,\frac{\Gamma\, A_o\, (1.44\, T_r)\, E}{r^2}$$

k = conversion constant
Γ = exposure rate constant
A_0 = administered activity
T_r = radiological half-life
E = occupancy factor
r = point/point distance

In RG 8.39 Rev 0, gamma exposure constants come from several different sources without a consistent method of calculation. Additionally, point geometry is mandated, occupancy is overly simplistic, and pharmacokinetics can be applied if biological studies are available (but there's quite a bit of question here).

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STANDARDIZED DOSE-RATE CONSTANT, Δ_{pr}

- The purpose of standardizing the "gamma constant" is:
  - to provide a consistent method of calculation, specifically for patient release;
  - to develop a tissue dose constant ("point kernel") as opposed to an exposure constant;
  - to use the ICRP 107 nuclear decay database with an energy threshold of 10 keV;
  - to include primary photons, as well as bremsstrahlung from conversion & Auger electrons and beta emission;
  - to surround the source in a 2 cm tissue sphere (attenuation/buildup); and
  - to encapsulate implants in 50 μm of titanium.

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COMPARISON OF DOSE-RATE CONSTANTS

all values in units of [mSv m^2 GBq^{-1} h^{-1}]

Nuclide	Γ Rev 0	Δ_{pr} (ICRP 107)	Smith & Stabin 2012	Peplow 2020
^{67}Ga	0.0203	0.0234	0.0217	0.0225
^{90}Y	-	0.000798	-	0.000000362
^{99m}Tc	0.0204	0.0196	0.0215	0.0184
^{111}In	0.0867	0.0736	0.0934	0.0615
^{123}I	0.0435	0.0394	0.0481	0.0285
^{125}I	0.0383	0.0301	0.0473	0.0125
^{131}I	0.0594	0.0582	0.0594	0.0548
^{177}Lu	-	0.00548	0.00489	0.00518
^{192}Ir*	0.124[a]	0.122[b]	0.124[c]	0.117[c]

*Encapsulation: [a]200 μm steel; [b]50 μm titanium; [c]none

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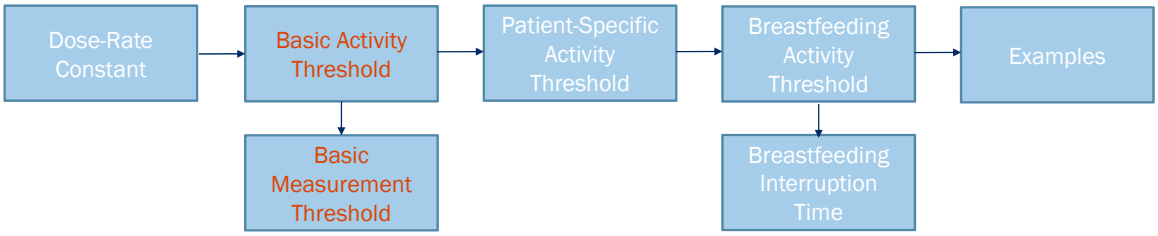

THE BASIC ACTIVITY & MEASUREMENT THRESHOLDS

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CALCULATION OF THE BASIC ACTIVITY THRESHOLD, Q_0

$$Q_0(\tilde{D}) = \frac{\tilde{D} \cdot r^2}{\Delta_{pr} \cdot 1.44 \cdot T_r}$$

$\tilde{D}$ = integrated dose limitation
r = distance between patient and bystander
Δ_{pr} = dose-rate constant (point kernel)
T_r = physical (radiological) half-life

Therefore, the basic activity threshold for release at 1 meter (point-to-point) for ^{99m}Tc is:

$$Q_0(5) = \frac{5\ [mSv] \cdot 1\ [m^2]}{0.0196 \left[\frac{mSv\ m^2}{GBq\ h}\right] \cdot 1.44 \cdot 6.02\ [h]} = 29\ GBq$$

$$Q_0(1) = 5.8\ GBq$$

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CALCULATION OF THE BASIC MEASUREMENT THRESHOLD, M_0

$$M_0 = \frac{Q_0 \cdot \Delta_{pr}}{r^2}$$

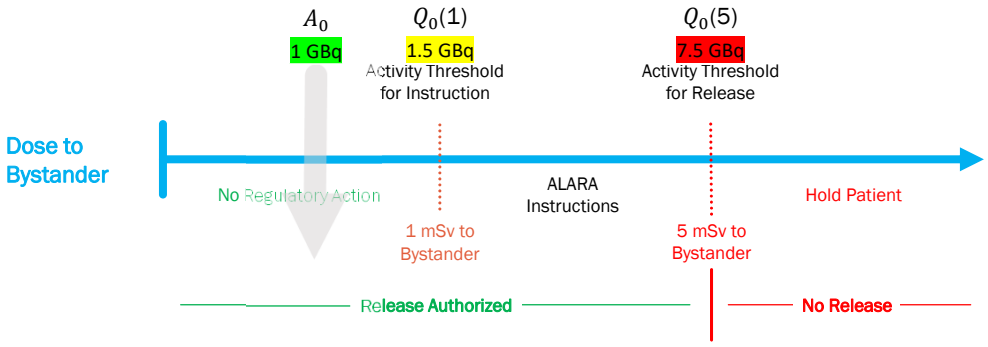
Q_0 = basic activity threshold
Δ_{pr} = dose-rate constant (point kernel)
r = distance from source to instrumentation

Therefore, the basic measurement threshold for release at 1 meter (point-to-point) for ^{99m}Tc is:

$$M_0(5) = \frac{29\ [GBq] \cdot 0.0196 \left[\frac{mSv\ m^2}{GBq\ h}\right]}{1^2\ [m^2]} = 0.58\ \frac{mSv}{h}$$

11

Assume a given radionuclide has the basic instruction and release thresholds as shown and suppose 1 GBq of that nuclide has been administered. The activity is less than the basic thresholds for release and for instruction.



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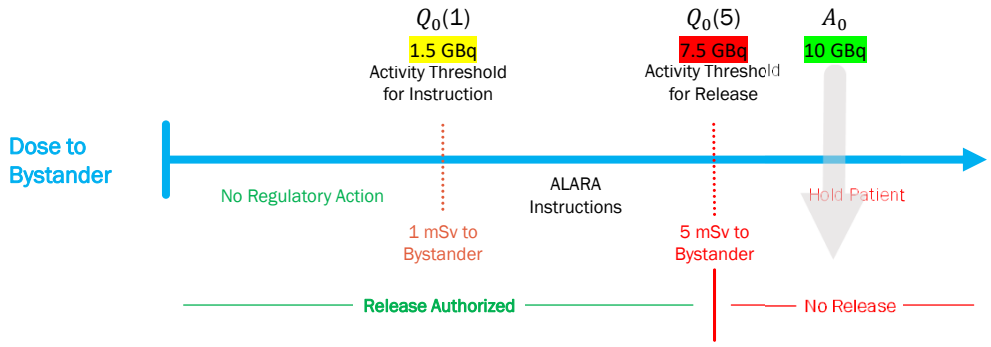
Now suppose 10 GBq of that same nuclide has been administered to a different patient. This time the administered activity exceeds the basic threshold for instruction and for release.



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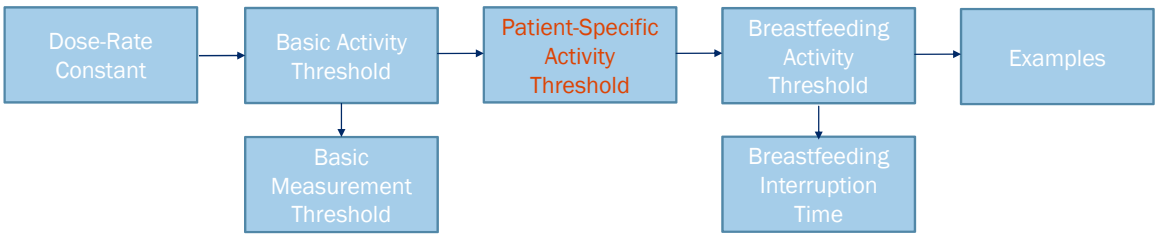

THE PATIENT-SPECIFIC ACTIVITY THRESHOLD

PATIENT-SPECIFIC MODIFYING FACTORS APPLIED TO THE BASIC THRESHOLD

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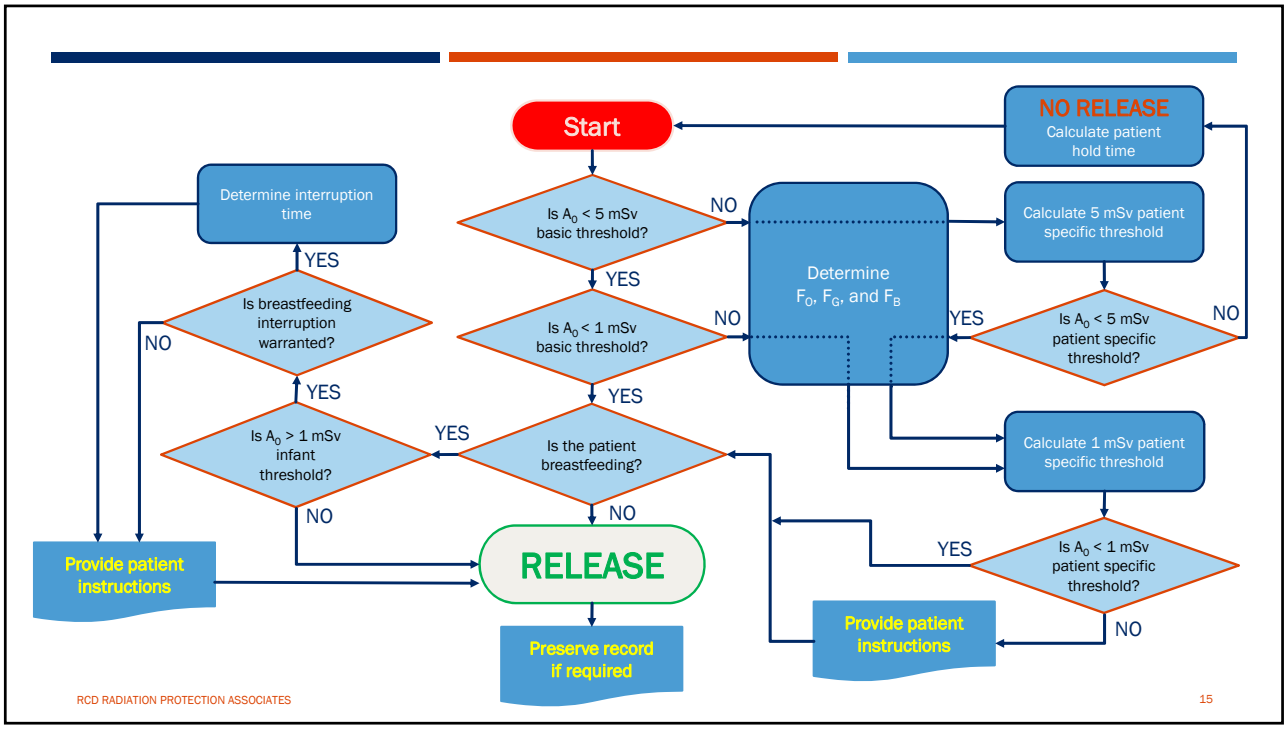

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THE PATIENT-SPECIFIC ACTIVITY THRESHOLD, Q_M

$$Q_M = \frac{Q_0}{F_O \cdot F_G \cdot F_B}$$

Q_0 = basic activity threshold
F_O = occupancy factor
F_G = geometry factor
F_B = biokinetic factor

To provide realism, the licensee justifies that the patient-specific occupancy factor is 0.80, the geometry factor is 0.94, and the biokinetic factor is 0.84. Therefore, with a basic release threshold of 7.5 GBq, the patient-specific threshold for release, $Q_M(5)$, is:

$$Q_M(5) = \frac{7.5\ [GBq]}{0.80 \cdot 0.94 \cdot 0.84} = 12\ [GBq]$$

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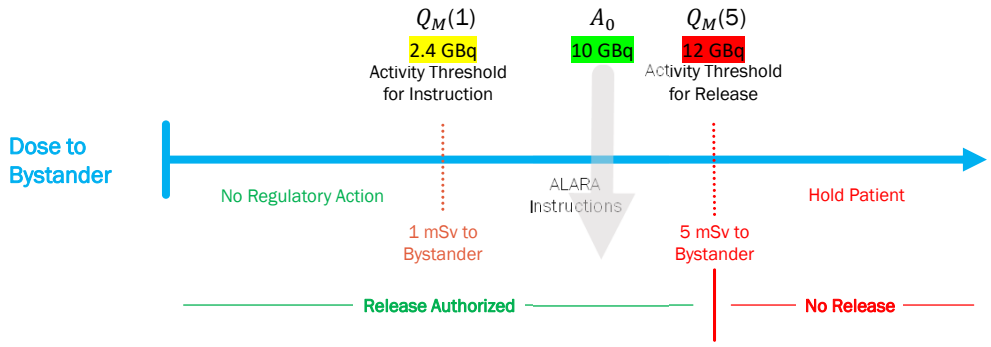
Using the patient-specific thresholds, and still considering the 10 GBq administered activity, the patient can be released with instruction.



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THE OCCUPANCY FACTOR, F_0

$$Q_M = \frac{Q_0}{F_O \cdot F_G \cdot F_B}$$

The licensee draws from a comprehensive patient survey to determine occupancy factor, F_0.

Sample questions					
Do you have children?	Yes				No
Are you breastfeeding?	Yes				No
You'll return home using which form of transportation?	Plane	Bus	Train	Subway	Private
Will family members travel with you?	Yes				No
How many others live in your home?	4	3	2	1	0
Do you normally sleep with someone in the same bed?	Yes				No
What is the total time (hours) of your return trip?	>10	8	6	4	<2
Will your return trip require a hotel stay?	Yes				No

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DEVELOPMENT OF THE OCCUPANCY FACTOR

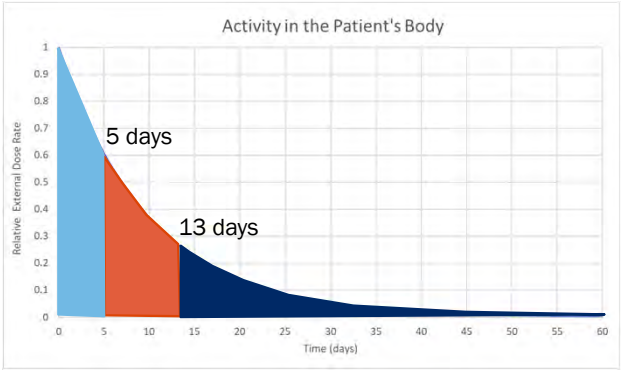
Radiopharmaceutical

Total Dose is Divided into Thirds

The patient survey indicates that two individuals are candidates for the maximum bystander:

(1) the patient's driver (8-hour trip)

(2) the patient's co-worker (half-time; starting day 10)



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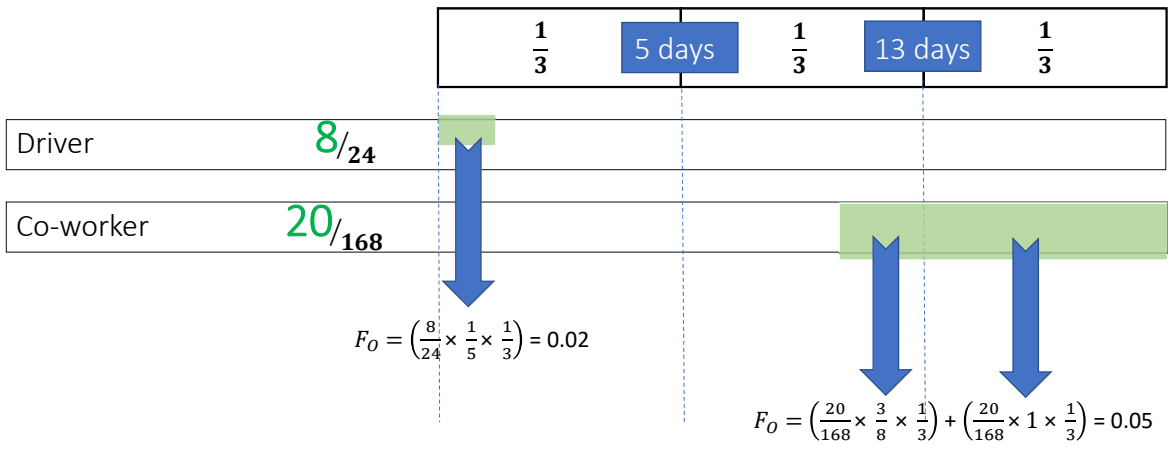

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	Fraction of time in the vicinity of patient	$\frac{1}{3}$	X days	$\frac{1}{3}$	Y days	$\frac{1}{3}$
Co-travelers	$/_{24}$					
Caregivers	$/_{24}$					
Family members Co-habitants Roommates	$/_{24}$ $/_{24}$					
Co-workers	$/_{168}$					

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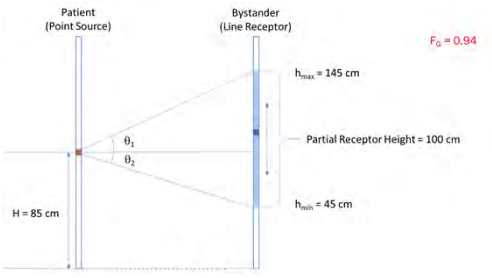
THE GEOMETRY FACTOR, F_G

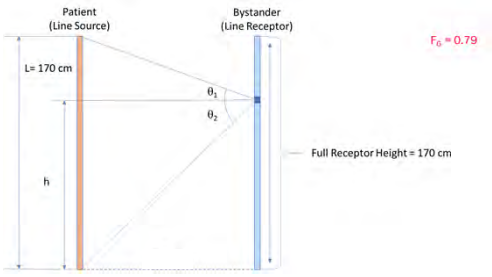
The geometry factor accounts for more realistic (less conservative) photon flux originating in the patient and impacting the bystander.

The assumption of a point source with a point receptor is no longer required.

F_G is a function of both source/receptor geometry and distance between the two.

$$Q_M = \frac{Q_0}{F_O \cdot F_G \cdot F_B}$$





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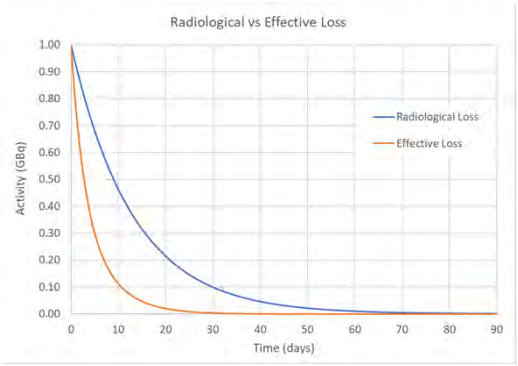
THE BIOKINETIC FACTOR, F_B

$$Q_M = \frac{Q_0}{F_O \cdot F_G \cdot F_B}$$

- A unitless surrogate for the "residence time" of a radionuclide in the body
- Retention functions are specific to the chemical form of an administered agent and, therefore, F_B is different for each pharmaceutical (and likely, each person)
- We define F_B as the ratio of integrated activity considering effective loss to that considering only radiological loss:

$$F_B \equiv \frac{\int_{t_1}^{t_2} R(t)dt}{\int_0^{\infty} e^{-\lambda_r t}\, dt} = \lambda_r \int_{t_1}^{t_2} R(t)dt$$



CALCULATION OF THE BIOKINETIC FACTOR

$$F_B = \lambda_r \int_0^{\infty} R(t)dt$$

Single-exponential retention function:

$$R(t) = e^{-\lambda_e t}$$

$$F_B = \lambda_r \int_0^{\infty} R(t)dt = \frac{T_e}{T_r}$$

Double-exponential retention function:

$$R(t) = f_1 e^{-\lambda_{e1} t} + f_2 e^{-\lambda_{e2} t}$$

$$F_B = \lambda_r \int_0^{\infty} R(t)dt = \frac{f_1 T_{e1} + f_2 T_{e2}}{T_r}$$

COMPARISON OF F_B USING DIFFERENT MODELS

... demonstrating the variability in F_B for $Na^{131}I$ retention.

	τ [h]	$^*E_1$	$^*E_2$	f_1	T_{e1} [h]	f_2	T_{e2} [h]	F_B
Single exponential	-	-	-	-	-	1.0	100	0.52
Hyperthyroidism	-	-	-	0.20	7.68	0.80	125	0.53
	-	-	-	0.20	7.68	0.80	106	0.45
	-	-	-	0.165	6.73	0.835	191	0.84
	1	0.25	0.75	0.20	7.68	0.80	125	0.40
	8	0.75	0.25	0.20	7.68	0.80	125	0.15
Thyroid cancer	-	-	-	0.95	7.68	0.05	175	0.084
	1	0.25	0.75	0.95	7.68	0.05	175	0.063
	8	0.75	0.25	0.95	7.68	0.05	175	0.037

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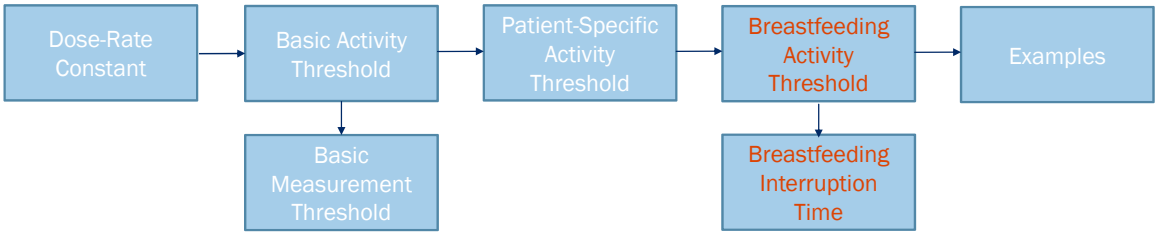

THE BREASTFEEDING ACTIVITY THRESHOLD

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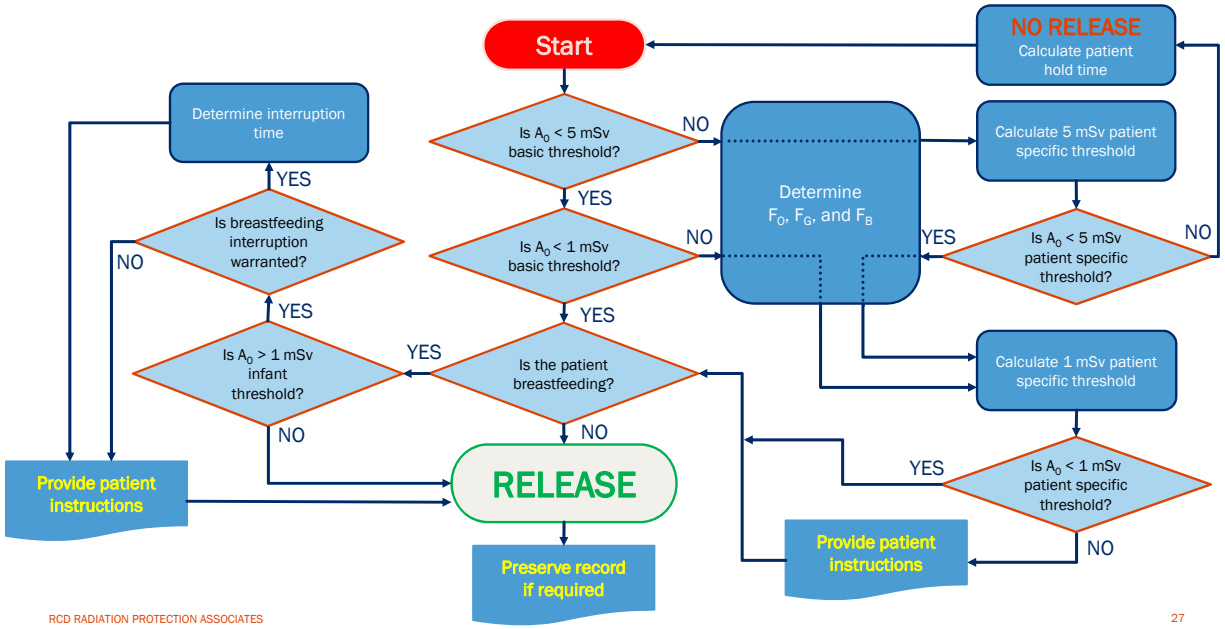

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PROPOSED METHOD AND ASSUMPTIONS

- Infant dose from external exposure (to body and to breast) and internal exposure from breastmilk consumption
  - two geometry factors (F_G) with associated distance (r) for the external exposures
- Pharmaceutical retention, $R(t)$, describes activity over time in the mother's body and the derived concentration in breastmilk
- Biokinetic factor: $F_B = \lambda_r \int R(t)\, dt$
- Occupancy factor for breastfeeding: F_O = 0.17
  - e.g., 30-minute duration every 3 hours
- Maximum breastmilk concentration assumed at t_{max} hours after administration
  - unless there is interruption, the time of first feeding is assumed at t_{max} (currently 3 hours)
- Breastmilk consumption rate: 40 mL/hr
- Infant absorption fraction: f_1 = 1
- Infant dose coefficients taken from ICRP 128, RADAR, literature, etc.

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COMPARISON OF BREASTFEEDING INTERRUPTION TIMES

Radiopharmaceutical	*RG 8.39 Rev 0*	*ACMUI 2019*	*NUREG 1556 Rev 3*	*ICRP 106 2007*	*ICRP 128 2015*	*Stabin & Breitz 2000*	*Sloan Kettering 2017*
^{67}Ga citrate	28 d	31 d	1 mo	> 3 wk	> 3 wk	cessation	21 d
^{99m}Tc DTPA aerosol	none	24 h	none	none	-	none	24 h
^{99m}Tc RBC *in vivo*	24 h	24 h	6 h	12 h	12 h	12 h	24 h
^{111}In WBC	6 d	5.7 d	7 d	none	none	none	7 d
^{123}I NaI	3 d	2.7 d	none	> 3 wk	> 3 wk	cessation	7 d
^{123}I MIBG	24 h	none	24 h	> 3 wk	> 3 wk	48 h	7 d
^{131}I NaI	cessation	32 d	cessation	> 3 wk	> 3 wk	cessation	cessation

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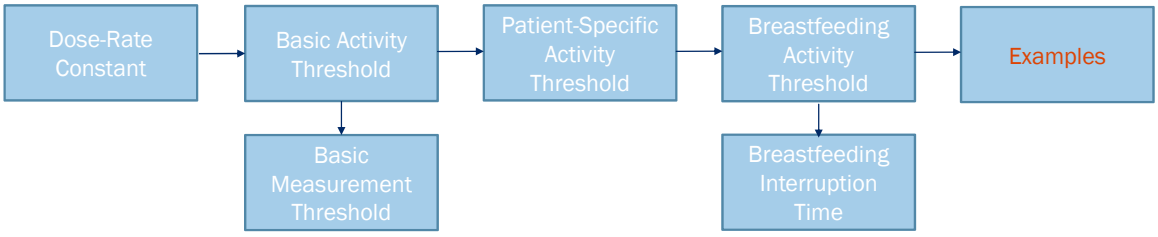

EXAMPLES DEMONSTRATING THE METHODOLOGY

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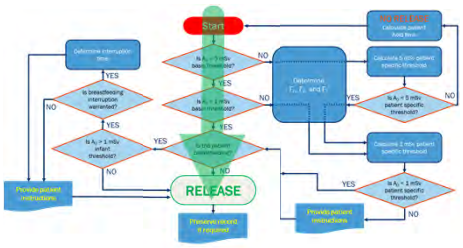
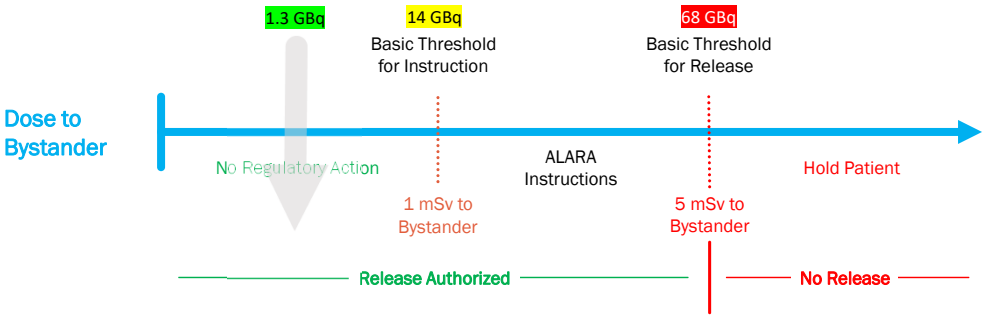
Y-90 MICROSPHERES

- 56 yo female administered 1.3 GBq ^{90}Y resin microspheres
- For the treatment of hepatocellular carcinoma





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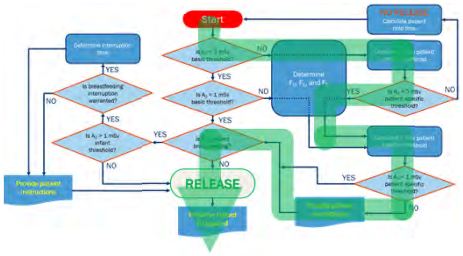
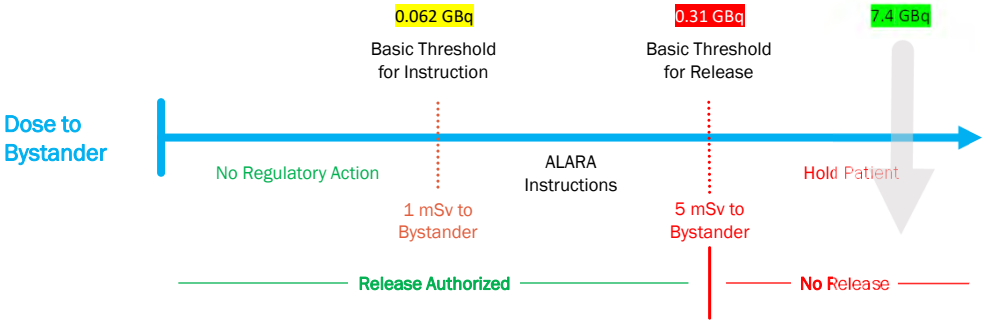
I-131 FOR THYROID CANCER

- 40 yo male administered 7.4 GBq ^{131}I as NaI
- For the treatment of thyroid remnants and metastases





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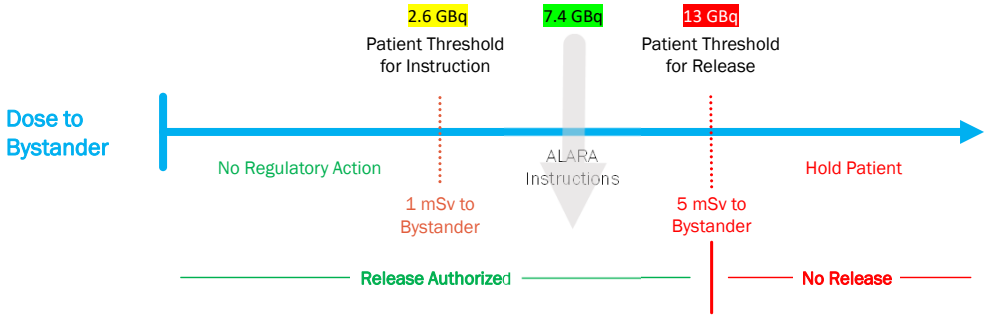
I-131 FOR THYROID CANCER

- 40 yo male administered 7.4 GBq ^{131}I as NaI
- For the treatment of thyroid remnants and metastases

$$Q_M(5) = \frac{0.31}{(0.40)(0.72)(0.084)} = 13$$

$$Q_M(1) = \frac{0.062}{(0.40)(0.72)(0.084)} = 2.6$$



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ACMUI Training

September 22, 2020

[CLOSED MEETING PORTION]

NO HANDOUT

Updates from the Medical Radiation Safety Team

September 22, 2020

Lisa Dimmick, Team Leader, Medical Radiation Safety
Medical Safety and Events Assessment Branch
Division of Materials Safety, Security,
State, and Tribal Programs
Office of Nuclear Material Safety and Safeguards

1

COVID-19

- NRC Preparation for Temporary Regulatory Relief Requests
  - Developed guide and a template to quickly process anticipated exemption requests.
- Public meetings
  - April 22, 2020 meeting to gather stakeholder input (meeting summary available at ML20122A253)
  - April 30, 2020 ACMUI COVID-19 Subcommittee meeting (subcommittee report available at ML20125A148)
  - May 13, 2020 SNMMI Town Hall
- May 5, 2020 Letter to NRC Medical Licensees
  - Enclosure contains a table of 10 CFR Parts 19, 20, 30, and 35 requirements for which the NRC may consider expedited requests for temporary exemption.
  - ML20126G385 and https://www.nrc.gov/materials/miau/med-use-toolkit.html

2

COVID-19

- Updated the table for expedited exemptions during COVID-19, August 2020 (ML20233B145)
  - Continually reviewing information received from medical professional societies and medical licensees regarding the impact of the COVID-19 emergency.
- Virtual training/training modification requests
  - CBNC
  - ASNC, SNMMI, ACR, ASTRO
  - Elekta
  - NorthStar

Authorized User Training and Experience

- SECY-20-0005, "Rulemaking Plan for Training and Experience Requirements for Unsealed Byproduct Material," January 13, 2020 (ML19217A318)
- Recommended rulemaking: (1) remove prescriptive training and experience (T&E) requirements, (2) NRC and Agreement States no longer review and approve T&E, (3) authorized users must be credentialed by a recognized medical specialty board, and (4) maintain high-level board recognition criteria.
- Recent letters to the Commission from urologists supporting the recommended rulemaking.
- SECY-20-0005 is still being reviewed by the Commission.

Patient Release

- SECY-18-0015, “Staff Evaluation of the U.S. Nuclear Regulatory Commission's Program Regulating Patient Release After Radioisotope Therapy,” January 29, 2018 (ML17279B139)
- Brochure – “What You Should Know About Treatments With Radioactive Drugs,” May 2019 (ML19121A242)
- Phase 1 update of Regulatory Guide 8.39 Rev 1, “Release of Patients Administered Radioactive Material,” April 2020 (ML19232A081)

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Patient Release

- Notice of Docketing for the Peter Crane petition was published in the *Federal Register* on April 13, 2020 and subsequently withdrawn by the petitioner on July 10, 2020
- What’s next?
  - Patient Release video—target release: November 2020
  - Phase 2 update Regulatory Guide 8.39—target release: spring 2022

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New Process for Reviewing Emerging Medical Technologies

- The Medical Team is transforming its process for reviewing emerging medical technologies (EMTs). The benefits of this new process are that it:
  - Streamlines the review process and license guidance development
  - Provides a cost savings in both time and staff resources;
  - Remains inclusive of NRC regional, Agreement State, and ACMUI contribution to license guidance development; and
  - Ensures consistency and a more uniform approach to license guidance development.

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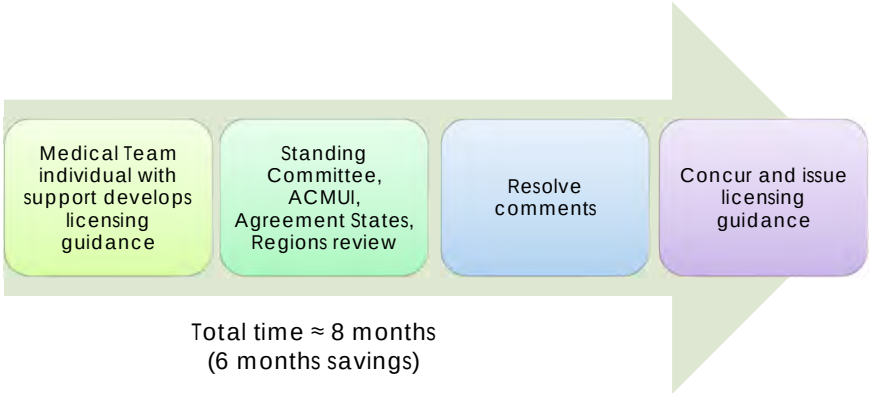
New Process for Reviewing Emerging Medical Technologies



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Rulemaking Plan: Emerging Medical Technologies

- Rulemaking plan will provide options to codify licensing requirements for EMTs and address calibration and dose measurement issues for Rb-82 generators.
  - Rulemaking options range from only addressing Rb-82 generators, codifying requirements for only certain EMTs, or codifying more performance-based licensing requirements for EMTs across most of 10 CFR Part 35
- Rulemaking plan will go to the Commission in December 2020.
- ACMUI will receive a courtesy copy of the draft rulemaking plan in October 2020.

Extravasation

- House and Senate FY20 appropriation bills required a report on updates to injection quality monitoring, classification, and reporting requirements regarding extravasations.
  - Congressional report submitted on March 17, 2020 (ML20050W302)

Extravasation

- Petition for rulemaking PRM-35-22, "Reporting Nuclear Medicine Injection Extravasations as Medical Events," was submitted to the NRC on May 18, 2020
  - Find more information on the petition on the Federal rulemaking website, https://www.regulations.gov, by searching Docket ID **NRC-2020-0141**
  - Public comment period on the petition will run from September through November 2020

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Extravasation

- Medical Team staff is coordinating their evaluation of whether extravasations should be reported as medical events with the petition review working group.
- Medical Team will hold a public meeting for medical community input on extravasations and medical event reporting. (Tentatively scheduled for December 8, 2020)
- Medical Team will seek ACMUI review of their preliminary recommendations in early March 2021.
- A decision on whether to accept the petition for rulemaking will be made by June 2021.

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Veterinary Release

- Medical Team is evaluating a request to release dogs following treatment of osteoarthritis using a Sn-117m colloid.
- Veterinary release is subject to 10 CFR Part 20 limits for members of the general public, which are:
  - 100 mrem per year
  - 2 mrem in any one hour
- The proposed release procedure contains a pre-screening questionnaire to determine the need to modify or stop any typical interactions (e.g., co-sleeping) for a duration of time after release.
- Staff is still reviewing this request.

Upcoming Meetings

- FDA-NRC Workshop Enhancing Development of Emerging Technologies: Radiopharmaceuticals and Radiological Devices, October 14, 2020, 8am-5pm. https://www.fda.gov/drugs/news-events-human-drugs/fda-nrc-workshop-enhancing-development-emerging-technologies-radiopharmaceuticals-and-radiological
- AAHP and Medical Health Physics Section Special Session—Therapy Patient Release Issues, October 15, 2020, 2-5 pm.
- International Conference on Radiation Safety: Improving Radiation Protection in Practice. IAEA, November 9-20, 2020. https://www.iaea.org/newscenter/news/coming-up-fully-virtual-iaea-radiation-safety-conference
- Commission Meeting with the Advisory Committee on the Medical Uses of Isotopes (ACMUI), November 18, 2020, 10am – 12pm
- Extravasation public meeting, December 8, 2020. Meeting details to be provided at a later date.

Acronyms

- AAHP—American Academy of Health Physics
- ACMUI—Advisory Committee on Medical Uses of Isotopes
- ACR—American College of Radiology
- ASNC—American Society of Nuclear Cardiology
- ASTRO—American Society for Radiation Oncology
- CBNC—Certification Board of Nuclear Cardiology
- EMT—Emerging Medical Technology
- FDA—U.S. Food and Drug Administration
- FY—Fiscal Year
- IAEA—International Atomic Energy Agency

Acronyms

- Mrem - millirem
- Rb-82—rubidium-82
- Sn-117m—tin-117m
- SNMMI—Society of Nuclear Medicine and Molecular Imaging
- T&E – training and experience

OPEN FORUM

NO HANDOUT

March 2021

Sunday	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday
28	1	2	3	4	5	6
7	8	9 NRC RIC	10 NRC RIC	11 NRC RIC	12 APhA Annual Meeting	13 APhA Annual Meeting
14 APhA Annual Meeting	15 APhA Annual Meeting	16	17	18	19	20
21	22	23	24	25	26	27
28 PESASH	29 PESACH	30	31	1	2	3
4	5	Notes NRC's Regulatory Information Conference - March 9-11 American Pharmacists Association (APhA) Annual Mtg. - March 12-15 Passover (Pesach) begins March 28 - April 4 (work permitted March 30-April 2 with restrictions)				

April 2021

Sunday	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday
28	29	30	31	1	2	3 PESACH
4 EASTER PESACH	5	6	7	8	9	10
11	12	13	14	15	16	17 AAPM Clinical
18 AAPM Clinical	19 AAPM Clinical NCRP	20 AAPM Clinical NCRP	21 CIRMS	22 CIRMS	23 CIRMS	24
25	26	27	28	29	30	1
2	3	Notes American Association of Physicists in Medicine (AAPM) Spring Clinical Meeting - April 17-20 National Council on Radiation Protection & Measurements (NCRP) Annual Meeting - April 19-20 Council on Ionizing Radiation Measurements & Standards (CIRMS) Annual Meeting - April 21-23				