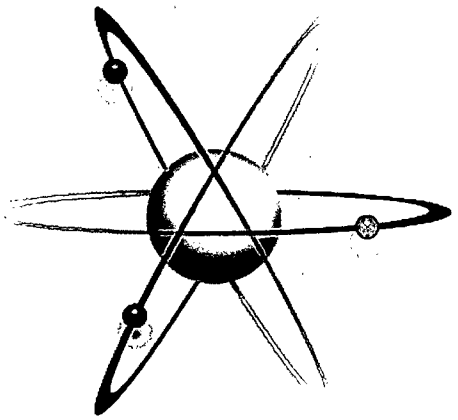

United States Nuclear Regulatory Commission

Advisory Committee on the Medical Uses of Isotopes

October 19-20, 2009

ADAMS

MEETING AGENDA
ADVISORY COMMITTEE ON THE MEDICAL USES OF ISOTOPES

OCTOBER 19-20, 2009
Executive Boulevard Building (EBB01-B13/15), Rockville, Maryland

Monday, October 19, 2009
CLOSED SESSION

8:00 – 8:15 **1.** **Opening Statements** **R. Lewis, NRC**
Mr. Lewis will welcome the ACMUI members.

8:15 – 8:45 **2.** **Ethics Training** **J. Szabo, NRC**
Mr. Szabo will provide annual ethics training for Committee members.

8:45 – 9:30 **3.** **Information Security (INFOSEC) Training** **S. Abrahams, NRC**
Ms. Abrahams will provide annual INFOSEC training for Committee members.

9:30 – 9:45 **4.** **Allegations Training** **ACMUI**
ACMUI members will complete annual allegations training.

9:45 – 10:15 **5.** **2009 Evaluations** **A. Cockerham, NRC**
Ms. Cockerham will review the 2009 staff and self-evaluations.

NOTE: The above session 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.

10:15 – 10:30 **BREAK**

Monday, October 19, 2009
OPEN SESSION

10:30 – 10:45 **6.** **Opening Statements** **C. Einberg, NRC**
Mr. Einberg will formally open the meeting.

10:45 – 11:30 **7.** **Old Business** **A. Cockerham, NRC**
Ms. Cockerham will review past ACMUI recommendations and provide NRC responses.

11:30 – 12:00 **8.** **Summary of the Enforcement Process and Enforcement Actions Against Medical Licensees** **S. Woods, NRC**
Ms. Woods will provide an overview of the enforcement process and give statistics of enforcement actions involving medical licensees.

12:00 – 1:00 **LUNCH**

1:00 – 2:00 **9.** **Update on Medical Isotope Shortage** **S. Mattmuller, ACMUI**
Mr. Mattmuller will provide updated information on the results of the Society of Nuclear Medicine (SNM) surveys on the impact of the medical isotope shortage.

2:00 – 2:30 **10.** **Medical Related Events** **DB. Howe, NRC**
Dr. Howe will provide a summary of recent medical-related events and seek Committee advice, recommendations, and insights.

2:30 – 2:45 **BREAK**

2:45 – 3:45	**11.**	**Update on Permanent Prostate Brachytherapy Medical Events** NRC staff will provide an update on the medical events that occurred at the Veteran's Affairs Medical Centers.	**D. Wiedeman, NRC** **C. Frazier, NRC**
3:45 – 4:45	**12.**	**International Commission on Radiological Protection (ICRP) Publication 103 Subcommittee Report and Discussion** Dr. Thomadsen will discuss the ACMUI subcommittee report on ICRP Publication 103.	**B. Thomadsen, ACMUI**

Tuesday, October 20, 2009
OPEN SESSION

8:00 – 8:45	**13.**	**New Security Regulations - 10 CFR Part 37** Ms. Horn will provide an overview of the new regulations under 10 CFR Part 37.	**M. Horn, NRC**
8:45 – 9:30	**14.**	**Potential Changes to 10 CFR Part 35** Dr. Howe will propose changes to 10 CFR Part 35 and seek Committee advice.	**DB. Howe, NRC**
9:30 – 10:00	**15.**	**Medical Uses of Radium-223** Dr. Welsh will discuss the medical uses of Ra-223.	**J. Welsh, ACMUI**
10:00 – 10:15		**B R E A K**	
10:15 – 10:45	**16.**	**Regulatory Responsibilities of the US Food and Drug Administration (FDA)** Dr. Suleiman will provide a brief overview of the role of the FDA.	**O. Suleiman, ACMUI**
10:45 –11:00	**17.**	**Outgoing Member Presentation** Dr. Eggli will provide final words about his experience on the ACMUI.	**D. Eggli, ACMUI**
11:00 – 11:30	**18.**	**Administrative Closing** Ms. Cockerham will provide a meeting summary and propose dates for the next meeting.	**A. Cockerham, NRC**

Advisory Committee on the Medical Uses of Isotopes October 2009 Meeting
Attendance List

NRC

1. Charles Miller, PhD – Director, Office of Federal and State Materials and Environmental Management Programs
2. Rob Lewis – Director, Division of Materials Safety & State Agreements
3. Jim Luehman – Deputy Director, Division of Materials Safety & State Agreements
4. Chris Einberg – Branch Chief, Radioactive Materials Safety Branch
5. Cindy Flannery – Team Leader, Medical Radiation Safety Team
6. Ashley Cockerham
7. Ron Zelac, Ph.D.
8. Donna-Beth Howe, Ph.D.
9. Gretchen Rivera-Capella
10. Glenda Villamar

ACMUI

1. Douglas Eggli, M.D. – Nuclear Medicine Physician
2. Darrell Fisher, Ph.D. – Patients' Rights Advocate
3. Debbie Gilley – State Government Representative
4. Milton Guiberteau, M.D. – Diagnostic Radiologist (representative)
5. Sue Langhorst, Ph.D. – Radiation Safety Officer
6. Leon Malmud, M.D. – Health Care Administrator, Chairman
7. Steve Mattmuller – Nuclear Pharmacist
8. Orhan Suleiman, Ph.D. – FDA Representative
9. Bruce Thomadsen, Ph.D. – Therapy Medical Physicist, Vice Chairman
10. William Van Decker, M.D. – Nuclear Cardiologist
11. James Welsh, M.D. – Radiation Oncologist

PLEASE DO NOT REMOVE FROM AUDITORIUM

ACMUI VISITOR LIST

October 19, 2009

NAME	ORGANIZATION	SIGNATURE
Burton, David	Walter Reed AMC	David Burton
Dodoo-Amoo, David	AMP	
Fairobent, Lynne	AAPM	Lynne Fairobent
Furlow, Bryant		
Gardner, Emily		
Martin, Melissa	AAPM	Melissa Martin
Martin, Richard	ASTRO	
Massey, Robert		
Michaud, Paul		
Peters, Michael		
Quang, Eiping	WRAMC	
Romanelli, Gloria	ACR	
Stefun, George		
Tomlinson, Cindy	SNM	Cindy Tomlinson
Mary Moore	VA	Mary E Moore
Sandy Gabriel	NRC Region I	Sandra Gabriel
Ossy Font	NRR	
Stuart Sussman	FSME	
Josh Goldstein	NRC/OGC	
Michael Zeitler	NRC/OIG	
Carrie Safford	NRC/OGC	Carrie Safford
Pauline Moore	Beveridge & Diamond	
George Wesley	VA OIG	
R.G. SNOW	VA OIG	
N. Bhalla	NRC/HQ	N Bhalla
J. Goldstein	FMSD	
P. Turko	VA NHPP	
Lin Clegg	VAOIG	Clegg
Virgil Dickson	FDA News	

Andrew Bramnik	NRC/Rgn III	Andrew M Bramnik
Darrell Wiedeman	NRC/Region III	
Cassandra Frazier	NRC/Region III	

PLEASE DO NOT REMOVE FROM AUDITORIUM

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October 20, 2009

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Burton, David	WRAMC	David Burton
Dodoo-Amoo, David		
Fairobent, Lynne	AAPM	Lynne Fairobent
Furlow, Bryant		
Gardner, Emily		
Martin, Melissa	AAPM	Melissa Martin
Martin, Richard	ASTRO	
Massey, Robert	WRAMC	Robt Massey
Michaud, Paul		
Peters, Michael		
Quang, Eiping	WRAMC	
Romanelli, Gloria		
Stefun, George		
Tomlinson, Cindy		
Jennifer Rand	NRC	Jennifer Rand
Merri Horn	NRC	Merri Horn
Curtis Anderson	MELE	Curtis Anderson
John Creasy		John T. Creasy
Jenny Weil	NRC	
N Bhalla	NRC	
Sandy Gabriel	NRC	Sandra Gabriel

NO HANDOUT

NO HANDOUT

NO HANDOUT

NO HANDOUT

NO HANDOUT

NO HANDOUT

2009 ACMUI RECOMMENDATIONS AND ACTION ITEMS

	ITEM	DATE	STATUS	
1	NRC staff should allow IRs to become AUs for Y-90 microspheres with: 1) 80 hours training in: a) radiation physics & instrumentation; b) radiation protection; c) mathematics pertaining to the use and measurement of radioactivity; d) chemistry of byproduct material for medical use; and e) radiation biology; and 2) work experience under the supervision of an Authorized User involving: a) ordering, receiving, & unpacking radioactive materials safely & performing the related radiation surveys; b) checking survey meters for proper operation; c) examination of each individual; d) calculating, measureing, & safely preparing patient or human research subject dosages; e) using administratitve controls to prevent a medical event involving the use of byproduct material; f) using procedures to control and to contain spilled byproduct material safely & using proper decontamination procedures; g) follow up and review of each patient's or human research subject's case history; and h) the operation of and quality management for dose calibrators; and 3) board certification in diagnostic radiology with a subspeciality in interventional radiology or	5/7/09	Pending	Open
2	NRC staff should revise 35.390(b)(1)(ii)(G)(3) to read "parenteral administration requiring a written directive for any radionuclide that is being used primarily because of its beta emission, or low energy photo-emission, or auger electron; and/or" and revise 35.390(b)(1)(ii)(G)(4) to read "parenteral administration requiring a written directive for any radionuclide that is being used primarily because of its alpha particle emission"	5/7/09	Accepted	Open
3	NRC staff should revise 10 CFR 35.490 & 690 as proposed with one exception. Delete "private practice." The regulation should read "500 hours of work experience, under the supervision of an Authorized User who meets the requirements in [35.490 or 35.690] or equivalent Agreement State requirements at a medical institution or clinic..."	5/7/09	*Pending*	Open
4	To prevent reccurrence of events like those at the VA, ACMUI recommends: 1) Every brachytherapy quality assurance program include peer review as published by the American Brachytherapy Society and 2) Authorized Users should perform post-implant dosimetry	5/7/09	No NRC action	Tabled
5	ACMUI will create a subcommittee that includes three members to review ICRP Report 103 and get back to Dr. Don Cool	5/8/09	In progress	Open
6	a) ACMUI came to a consensus on NCRP report 160, which is believed to be scientifically sound and well-written b) ACMUI believes NRC and Agreement States should collect and maintain dose records and keep ACMUI aware of the issues but should continue a policy of not intervening with medical practice c) ACMUI supports the medical principle of "First do no harm" and expressed continued concern about exposure to children d) ACMUI's current belief is that the benefit of medical procedures involving radiation outweighs the risk	5/8/09	No NRC action	Closed
7	ACMUI endorsed the subcommittee report for American Board of Radiology candidates who may experience a delay between the completion of Training and Experience and receipt of board certification	5/8/09	No NRC action	Closed
8	NRC staff should not require licensees to report therapeutic infiltrations as Medical Events.	5/8/09	*Not Accepted*	Closed

2008 ACMUI RECOMMENDATIONS AND ACTION ITEMS

	ITEM	DATE	STATUS	
2	NRC staff should pursue rulemaking to allow more than one RSO on a medical use license with the indication of one RSO as the individual in charge.	4/28/08	Accepted	Open
5	NRC staff should incorporate the subcommittee's recommendations for the Gamma Knife® Elekta Perfexion™ in future rulemaking.	4/28/08	Accepted	Open
9	NRC staff should revise the AO criteria to read, "A medical event that results in: 1) death; or 2) a significant impact on patient health that would result in permanent functional damage or a significant adverse health effect that would not have been expected from the treatment regimen, as determined by an NRC or Agreement State designated consultant physician."	4/28/08	Pending	Open
18	NRC staff agreed to consider incorporating the subcommittee's recommendations from the August 1, 2008 Fingerprinting Subcommittee Report in NRC's Questions and Answers with Regards to Fingerprinting and Criminal History Records Checks or use another appropriate method of communication to transmit the information to licensees.	10/27/08	Pending	Open
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
21	The ACMUI formed a subcommittee to draft a set of proposed qualifications that IRs must satisfy to become AUs for Y-90 microspheres. The subcommittee includes: Dr. Bruce Thomadsen (chair), Dr. Douglas Eggli, Dr. Subir Nag, Dr. James Welsh, and Mr. Steve Mattmuller.	10/27/08	No NRC action	Closed 5/8/09
22	ACMUI encouraged NRC staff to begin the rulemaking process to move the medical use of Y-90 microspheres from 10 CFR 35.1000 to another section of the regulations, so that the training and experience requirements for AUs can be vetted though the public review process instead of residing in guidance space.	10/27/08	Partially accepted	Open
24	ACMUI formed a subcommittee to develop a solution that satisfies both the training needs of the residency program and the NRC requirements for achieving AU status using the board certification pathway. The subcommittee should create a recommendation to be discussed at a future teleconference prior to the spring 2008 ACMUI meeting. The subcommittee includes: Dr. Douglas Eggli (chair), Dr. Subir Nag, Dr. William Van Decker, and Dr. Mickey Guiberteau (technical assistance).	10/28/08	No NRC action	Closed 5/8/09
25	NRC staff should revise 10 CFR 30.35(b) to allow licensees to exceed the limits short term (e.g. 60 days) during source exchange.	10/28/08	Accepted	Open
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
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
28	NRC staff should revise 10 CFR 35.65 to clarify it does not apply to sources used for medical use; however, NRC should not require licensees to list the transmission sources as a line item on the license. NRC staff should also revise 10 CFR 35.590 to permit the use of transmission sources under 10 CFR 35.500 by AUs meeting the training and experience requirements of 10 CFR 35.590 or 35.290.	10/28/08	Pending	Open

2008 ACMUI RECOMMENDATIONS AND ACTION ITEMS

	ITEM	DATE	STATUS	
29	NRC staff should revise 10 CFR 35.204(b) to require a licensee that uses Mo 99/Tc-99m generators for preparing a Tc-99m radiopharmaceutical to measure the Mo-99 concentration of each eluate after receipt of a generator to demonstrate compliance with not administering to humans more than 0.15 microcurie Mo-99 per millicurie Tc-99m.	10/28/08	Accepted	Open
30	NRC staff should require licensees to report to the NRC events in which licensees measure molybdenum breakthrough that exceeds the regulatory limits.	10/28/08	Accepted	Open
31	NRC staff should pursue a change to allow "grandfathered" AUs to be supervisors and preceptors.	10/28/08	Accepted	Closed 9/28/09
32	The standing ACMUI medical nuclear materials events subcommittee should review events and provide an analysis to the full committee annually in the spring instead of the fall.	10/28/08	No NRC action	Ongoing

2007 ACMUI RECOMMENDATIONS AND ACTION ITEMS

	ITEM	DATE	STATUS	
1	NRC staff should issue an (IN), which describes errors previously made and provides examples of best practices with regards units of AKS vs. apparent activity (mCi) for brachytherapy sources. The IN should be done in collaboration with the American Association of Physicists in Medicine (AAPM) and coordinated with Agreement States.	6/12/07	Accepted	Closed 9/9/09
2	NRC staff should remove the attestation requirement for board certified individuals and rewrite the attestation requirement for individuals seeking authorization under the alternate pathway. The rewritten attestation should not include the word "competency" but should instead read "has met the training and experience requirements."	6/12/07	Accepted	Open
3	NRC staff should revise the regulations so that board certified individuals, who were certified prior to the effective date of recognition or were certified by previously recognized boards listed in Subpart J of the previous editions of Part 35, are grandfathered.	6/12/07	Pending	Open
6	NRC staff should add the words "or equivalent" so it is clear that information included in a letter is the same as that which would have been submitted in NRC Form 313A.	6/13/07	Accepted	Open
7	NRC staff should revise 10 CFR 35.50(c)(2) to include AUs, AMPs, or ANPs identified on any license or permit that authorizes similar types of use of byproduct material. Additionally, the AU, AMP, or ANP must have experience with the radiation safety aspects of similar types of use of byproduct material for which the individual is seeking RSO authorization.	6/13/07	Accepted	Open
8	NRC staff should remove the attestation requirement from 10 CFR 35.50(d) for AUs, AMPs, and ANPs seeking RSO status, if the AU, AMP, or ANP seeking RSO status will have responsibilities for similar types of uses for which the individual is authorized.	6/13/07	Accepted	Open
10	NRC staff should allow more than one RSO on a license with a designation of one RSO as the individual in charge. NRC should create a Regulatory Issue Summary (RIS) to inform the regulated community of NRC's interpretation. The RIS should be sent to ACMUI and the Agreement States for review and comment.	6/13/07	Accepted	Open
25	NRC staff should revise the current regulations to include Canadian trained individuals who have passed the ABNM certification exam.	8/16/07	Accepted	Open
30	The Elekta Perfexion® should be regulated under 10 CFR 35.1000 until 10 CFR 35.600 is modified to be performance-based, which would allow the Perfexion® to be regulated under 10 CFR 35.600.	10/22/07	Accepted	Open
31	NRC staff should require experienced RSOs and AMPs to receive additional training, if the individual is seeking authorization or responsibility for new uses.	10/22/07	Accepted	Open
32	NRC staff should not require experienced RSOs to obtain written attestation to become authorized or have responsibility for new uses.	10/22/07	Accepted	Open
34	NRC staff should modify 10 CFR 35.491(b)(2) to specify 'superficial' ophthalmic treatments. Additionally, NRC staff should change the title of 10 CFR 35.491 to specify 'superficial' ophthalmic treatments.	10/22/07	Accepted	Open
35	NRC staff should not revise 10 CFR 35.491 (intended for ophthalmologists) to include training and experience for the new intraocular device. Instead, NRC staff should regulate the new intraocular device under 10 CFR 35.490.	10/22/07	Partially accepted	Open
36	NRC staff should not require medical licensees regulated under 10 CFR 35.400, 500, or 600, as applicable, to only use the sealed sources and devices for the principle use as approved in the SSDR.	10/22/07	Accepted	Open
37	NRC staff should revise 10 CFR 35.290 to allow physicians to receive training and experience in the elution of generators and preparation of kits under the supervision of an ANP.	10/22/07	Accepted	Open

2007 ACMUI RECOMMENDATIONS AND ACTION ITEMS

	ITEM	DATE	STATUS	
49	ACMUI should form a subcommittee to annually review byproduct material events, perform analysis, and report to the full Committee. NMED data should continue to be presented to ACMUI at the fall meetings, and the subcommittee should analyze the data presented at the fall meeting in order to provide a full report at the spring meeting. The subcommittee includes: Mr. Lieto (chair), Dr. Nag, Dr. Thomadsen, and Dr. Suleiman. The subcommittee will consult with an Agreement State representative, Ms. Gilley, and designated NRC staff, as appropriate.	10/23/07	Ongoing	Open
50	ACMUI byproduct material events subcommittee should publish reports, as necessary, to ensure end-users receive the message.	10/23/07	Ongoing	Open

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

NRC Enforcement: Overview

Susanne Woods
Office of Enforcement
October 19, 2009

1

U.S.NRC

Outline

- Enforcement Process

  Provides for:
  - -Communication
  - -Accuracy
  - -Consistency/Fairness
  - -Messages/Corrections

- Medical Enforcement

2

U.S.NRC

Materials Enforcement Process

- Inspection and/or investigation
- NRC review and licensee meeting (exit)
- Inspection report and apparent violations
- Enforcement panel (escalated)
- Predecisional enforcement conference (PEC)
- NRC reviews all information
- Agency decision

3

U.S.NRC

Escalated Enforcement

1. Enforcement Panel
   -Review Information, 360° look, develop a strategy and path forward

2. Licensee asked to provide:
   -Their perspective and considerations
   -Corrections to information
   -Identification and corrective actions

   Letter or PEC

4

U.S.NRC

Escalated Enforcement

3. NRC reviews ALL information

4. Decisions:
   -Violation(s) occurred?
   -Significance (Severity Level)?
   -Enforcement action warranted? Type?
   -Civil Penalty warranted? Amount?

5

U.S.NRC

Possible Process Outcomes

No action

Notice of Violation (NOV)

NOV with Civil Penalty

Order (example: corrective action)

Criminal Penalty (Department of Justice)

6

Significance Decisions

SEVERITY LEVEL – I
(most significant regulatory concern)

SEVERITY LEVEL – II
(very significant regulatory concern)

SEVERITY LEVEL – III
(significant regulatory concern)

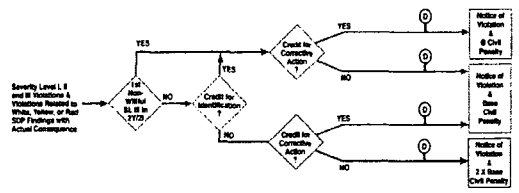
(Escalated Enforcement)

(Non-Escalated Enforcement)

SEVERITY LEVEL – IV
(less significant concern, but more than minor)

7

Civil Penalty Decisions



8

Escalated Enforcement Actions

- Discretion - escalate/mitigate penalty
- Public Information
- Challenges and appeal rights
- Enforcement Policy

9

Willful Violations

Investigation

Panel

PEC and/or Dispute Resolution

Position, Safety Significance, Motivation, Benefit, Other

Outcome: Close-out letter NOV; Order

10

Alternative Dispute Resolution

- Post-investigation
- Voluntary participation
- Mediated
- Between licensee and NRC
- Offer begins early in the enforcement process

11

Recent Medical Enforcement

- Enforcement Statistics
- Increased Control Enforcement Statistics

12

Issues

- Related to 10 CFR Violations
- Related to the Increased Control Orders

13

14

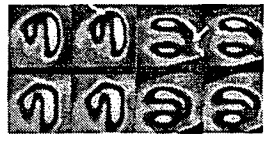
Update on Medical Isotope Shortages

October 19, 2009

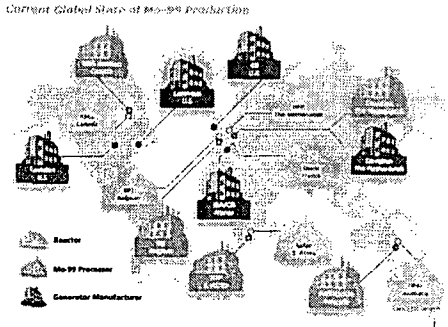
Advisory Committee on the Medical Uses of Isotopes

Steve Mattmuller MS, RPh, BCNP

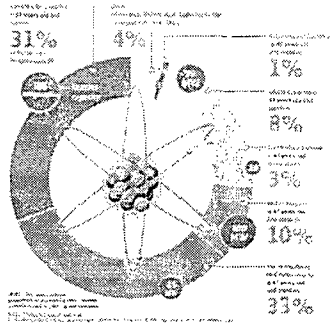
Need: Patient Care



Causes: Fragile Supply



Causes: Fragile Supply



Effects: Diminished Patient Care

Question 2. Is your practice / facility impacted by the current molybdenum-99 (Mo99) shortage?

Yes:	569
No:	27
N/A:	7
Total respondents for Question 2:	603

94.3% of the departments impacted

Effects: Diminished Patient Care

Question 4. If you access to an alternate technetium generator source, what is it?
(30% of the departments had alternate sources)

Another hospital (1):	**2.9%**
Another commercial pharmacy:	**60.0%**
Another manufacturer (2):	**28.0%**
Other (3):	**8.9%**

(1) Remote hospital departments have shared generators.
(2) Another manufacturer, generator
(3) Other ???

Effects: Diminished Patient Care

Question 5. At what percentage of your normal full capacity are you currently able to operate?

0-25 %:	5.8%
26-50 %:	19.2%
52-75 %:	37.7%
76-100 %:	37.1%

62.7% are at less than 75% of their normal full capacity

SNM 7

Effects: Diminished Patient Care

Question 7. Please indicate any and all changes that have been made regarding patient care in response to this shortage.

Postponement of procedure:	80.6%
Cancellation of procedure:	47.2%
Change in procedure:	57.3%
Change in isotope used:	59.6%
Transfer of patient to another facility:	11.1%
Other:	8.5%

SNM 8

Effects: Diminished Patient Care

Question 7. Comparison to past shortages

	2008	June 09	August 09
Postponement of procedure	49%	60.5%	80.6%
Cancellation of procedure	19%	32.3%	47.2%
Change in procedure	25%	43.8%	57.3%
Change in isotope used	(1)	50.9%	59.6%
Transfer patient to another facility	(1)	4.8%	11.1%
Other	(1)	15.0%	8.5%

(1) Data was not collected in this survey

SNM 9

Effects: Diminished Patient Care

Question 8. If you answered "postponement of procedure" to Question 7, how long the procedure has been postponed.

Less than 1 week:	34.6%
Between 1-2 weeks:	44.1%
Between 2-3 weeks:	10.1%
Between 3-4 weeks:	5.9%
One month or more:	5.0%

Over 65.1% of the postponements are for a week or more.

SNM 10

Effects: Diminished Patient Care

Question 9. If you answered "change in procedure" to Question 7, please indicate the procedures that have been substituted:

Thallium-201 for Technectium-99m :	53.94%
Fluorine-18 fluoride for bone scan :	3.66%
Rubidium-82 for Technetium-99m:	2.96%
Other non-nuclear procedure:	26.34%

The 26.34% changed to non-nuclear procedures are the most troublesome for patient care, these would provide different information, i.e., anatomical vs. physiological.

SNM 11

Effects: Diminished Patient Care

Question 12. Approximately how many patients per week are receiving nuclear medicine scans/ procedures at your facility, relative to the shortage?

	Prior	Now
0-100:	66.0%	81.6%
101-200:	22.1%	8.7%
201-300:	4.7%	4.0%
301-400:	2.9%	1.8%
401-500:	1.4%	1.8%
500-1000:	1.8%	1.5%
More than 1000:	1.1%	0.5%

SNM 12

Effects: Diminished Patient Care

Question 12. Approximately how many patients per week are receiving nuclear medicine scans/procedures at your facility, relative to the shortage?

	> 1000	501-1000	401-500	301-400	201-300	101-200	0-100
Prior	1.5%	1.8%	1.4%	2.9%	4.7%	22.1	66.0%
Now	0.5%	1.5%	1.8%	1.8%	4.0%	8.7%	81.6%

SNM 13

Effects: Pharmacy Perspective

Question 6. Please indicate any and all changes that have been made in response to this shortage.

Reschedule of patient orders to another day or time (1):	76.3%
Cancellation of orders:	65.0%
Change in radiopharmaceutical used:	82.5%
Decrease in dosage (2):	81.4%
Cancelled backup doses:	71.1%
No bulk orders (3):	81.4%
Eliminate all contingency doses:	63.9%

SNM 14

Effects: Pharmacy Perspective

Question 6. Please indicate any and all changes that have been made in response to this shortage.

Changed delivery schedules (4):	71.1%
Eliminated standing order:	68.0%
Shifted dosing times:	58.8%
Eluting older generators more often:	84.5%
Modified preparation:	34.0%
Sent doses with later calibration times:	21.7%
Delay and divide deliveries:	66.0%
Other:	8.3%

SNM 15

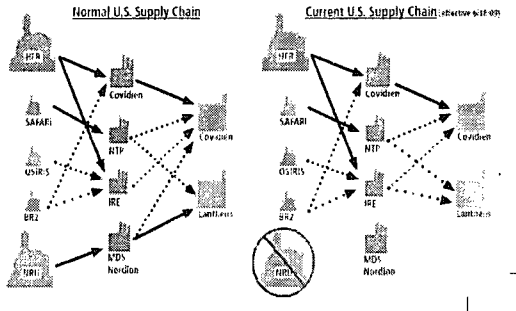
Diminished Patient Care

Referring physicians are frustrated by these interruptions and some have chosen alternate procedures.

- inferior in accuracy
- don't provide physiologic information
- usually more expensive
- may have a higher radiation dose

16

Effects: Manufacture Response



17

Effects: Manufacture Response

Covidien Supply Estimates: 6-10-09

Current standing generator orders are expected to be met, with some extra supply likely, minimal Tc-99m UD impact

Current standing generator orders are expected to be met, but no extra; some Tc-99m impact and UD reductions

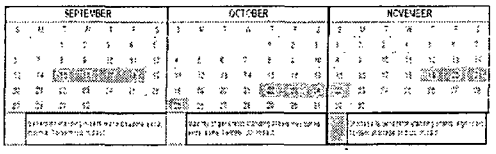
Shortages expected to current standing generator orders, significant Tc-99m shortage and UD impact

Note: Daily projections are based on current information and are subject to change

18

Effects: Manufacture Response

Covidien Supply Estimates: 9-22-09

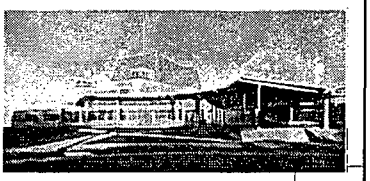


NOTE: Daily projections are based on current information and are subject to change.

19

Solution: New Mo99 Producers:

Australian Nuclear Science and Technology Organization (ANSTO)



20

Solution: New Mo99 Producers:

Missouri University Research Reactor MURR

- **U.S. producer**
- **Low-enriched uranium (LEU) fuel conversion project is underway**

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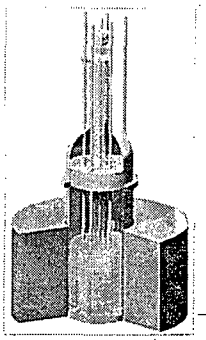
Solution: New Mo99 Producers:

Babcock and Wilcox B&W

- Project includes building several small multiple isotope production system (MIPS)
- Aqueous Homogenous Reactor (AHR) 200 kW
- Liquid LEU fuel and target



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Solutions: American Medical Isotopes Production Act of 2009

111th CONGRESS
1st Session
H. R. 3276

To promote the production of molybdenum-99 in the United States for medical isotope production, and to condition and phase out the export of highly enriched uranium for the production of medical isotopes.

IN THE HOUSE OF REPRESENTATIVES
July 21, 2009

Mr. MARKEY of Massachusetts (for himself and Mr. UPTON) introduced the following bill; which was referred to the Committee on Energy and Commerce

23

Shortages of Other Medical Isotopes

Iodine-131 (I131)

National Research Universal (NRU) reactor and South African (SAFARI) reactor produce it via (n, γ) nuclear reaction from Tellurium-130

Nordion needs (n, γ) I131 for the manufacturer's Food and Drug Administration's (FDA) new drug application (NDA).

The National Institute for Radioelements (IRE), Belgium reactor material is (n, fission) I131

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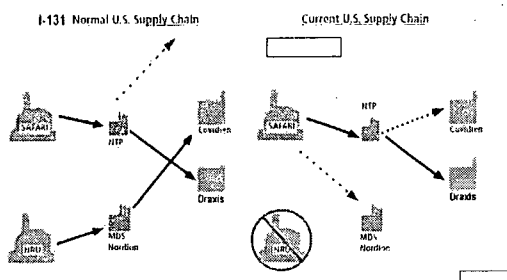
Shortages of Other Medical Isotopes



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Acronyms

AHR	Aqueous Homogenous Reactor
ANSTO	Australian Nuclear Science and Technology Organization
B&W	Babcock & Wilcox
DOE	Department of Energy
FDA	Food and Drug Administration
HEU	Highly Enriched Uranium (≥20%)
IRE	National Institute for Radioelements
LEU	Low Enriched Uranium (<20%)
MIPS	Medical Isotope Production System
MURR	Missouri University Research Reactor
NNSA	National Nuclear Security Administration
NTP	Nuclear Technology Products

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SNM
Advancing Molecular Imaging and Therapy

Isotope Shortage Survey Final Results
June 2009

The Society of Nuclear Medicine (SNM) conducted this survey with the intent of collecting anecdotal information from those impacted by the shortage of Mo-99 caused by the June 2009 shutdown of the National Research Universal (NRU) Reactor in Chalk River Canada. In particular, we were looking for information from those who may be experiencing reduced, or no shipment of generators during the shutdown. This information will be used to help SNM develop strategies as we begin to approach decision makers about the impact of this problem. Total respondents: 1217

Please indicate your primary place of practice.

Hospital: 56.29 %
Outpatient imaging facility: 27.94%
Commercial pharmacy: 7.64%
Hospital pharmacy: 0.74%
Other: 9.2%

Has or is your practice/facility impacted by the molybdenum-99 shortage?

Yes: 90.71%
No: 7.98%
N/A: 0.58%

Do you have access to an alternate technetium generator source?

Yes: 29.66%
No: 64.17%
N/A: 6.41%

If you answered "yes", what is your alternate technetium generator source?

Another hospital: 0.49%
Another commercial pharmacy: 18.08%
Another manufacturer: 11.5%
Other: 2.79%

What percentages of your normal full capacity are you currently able to operate?

0-25%: 6.66%
26-50%: 19.56%
52-75%: 35.66%
76-100%: 38.21%

When, if ever, do you think you will be down to zero percent capacity during this shortage?

Within a week: 4.6%
Within two weeks: 6.33%
Within three weeks: 4.93%
Within a month: 12.57%
Longer than one month: 7.64%
Never: 61.71%

If you answered "longer than one month", please indicate how much longer you anticipate being down to zero capacity? (109 responses)

2-6 Months: 29.35%
6-12 Months: 3.66%
12+Months: 6.42%
Unsure/Don't know: 60.55%

Approximately how many patients per week receive nuclear medicine scans/procedures before August 2008 at your facility?

0-250: 87.9%
251-500: 3.91%
501-1000: 1.52%
1000+: 3.53%

Approximately how many patients are now receiving nuclear medicine scans/procedures at your facility?

0-250: 90.4%
251-500: 3.03%
501-1000: 1.89%
1000+: 1.7%

Please indicate any and all changes that were made regarding patient care in response to this shortage?

Postponement of procedure: 60.48%
Cancellation of procedure: 32.29%
Change in procedure: 43.8%
Change in isotope used: 50.94%
Transfer of patient to another facility: 4.77%
Other: 15.04%

If you answered "postponement of procedure" to the last question, please indicate how long the procedure was postponed? (717 responses)

Less than 1 week: 36.54%
1-2 weeks: 44.7%
2-4 weeks: 6.55%
More than four weeks: 2.51%

If you answered "change in procedure", please indicate the procedures that were substituted. (967 responses)

Tl-201 for Tc: 48.97%
F-18 Fluoride for bone scan: 4.11%
Rb-82 for Tc: 2.38%
Other non-nuclear procedure: 15.94%
Other: 8.05%

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Advancing Molecular Imaging and Therapy

Isotope Shortage Survey Final Results
August 10, 2009

With help from the National Association of Nuclear Pharmacies[1] (NANP), SNM conducted this survey with the intent of collecting anecdotal information from centralized nuclear pharmacies and nuclear pharmacists relating to the current shortage of Mo-99 caused, in part, by the current shutdown of the National Research Universal (NRU) Reactor in Chalk River Canada, along with the High Flux Reactor (HFR), in Petten, The Netherlands. In particular, we were looking to collect information from centralized nuclear pharmacies and pharmacists who are experiencing reduced, or no shipment of generators during the current shutdown. This information will be used to help SNM develop strategies as we begin to approach decision makers about the impact of this problem.
Total Respondents: 97

Q1. Is your pharmacy impacted by the current molybdenum-99 shortage?
Yes: 59.77%
No: 1.15%
Do not use 99Mo/99mTc generators: 2.3%

Q2. Do you have access to an alternate source of 99Mo/99mTc generators?
Yes: 29.31%
No: 33.91%

Q3. If you answered yes to the above question, what is your alternate source of 99Mo/99mTc generators?
Different manufacturer: 21.84%
Sharing resources with other pharmacies: 6.32%
Keeping larger generators on hand: 0%
Other: 2.87%

Q4. What percentage of prescriptions for 99mTc-radiopharmaceuticals have you been able to fill during the shortage?
0-25%: 6.32%
26-50%: 14.37%
52-75%: 20.69%
76-100%: 18.97%

Q5. If you have been unable to fill all prescriptions for 99Mo/99mTc radiopharmaceuticals, how long do you anticipate the interruption to last?
One week: 7.47%
Two weeks: 3.45%
Three weeks: 2.3%
One month: 2.3%
Longer than one month: 36.21%

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[1] The National Association of Nuclear Pharmacies (NANP) is a non-profit trade association founded in 1984, comprised of over 400 hundred nuclear pharmacies and includes the majority of the pharmacies that prepare and distribute radiopharmaceuticals in the United States. NANP differs from other "nuclear" organizations because it represents "pharmacies," rather than pharmacy professionals, manufacturers, or physicians. This enables NANP to focus on the specific business, regulatory, and professional issues that affect nuclear pharmacies. More information is available at http://www.nanp.net. NANP's goal is to represent the unique interests of nuclear pharmacies. Since its inception, NANP has focused on three main areas: legislative and regulatory activities, education, and member services.

Q6. Please indicate any and all changes that have been made in response to this shortage.
Reschedule of patient orders to another day or time 76.29%
Cancellation of orders: 64.95%
Change in radiopharmaceutical used: 82.47%
Decrease in dosage: 81.44%
Cancelled backup doses: 71.13%
No bulk orders: 81.44%
Changed delivery schedules: 71.13%
Eliminated standing order: 68.04%
Shifted dosing times: 58.76%
Eluting older generators more often: 84.54%
Modified preparation: 34.02%
Sent doses with later calibration times: 21.65%
Delay and divide deliveries: 65.98%
Eliminate all contingency doses: 63.92%
Other: 8.25%

Q7. If you answered "change in radiopharmaceutical used", please indicate which isotopes/radiopharmaceuticals have been substituted.
Tl-201 instead of Tc-99m agents for cardiac imaging: 82.47%
In-111 Oxine: 5.15%
FDG for bone imaging: 6.19%
Ga-67: 2.06%
N-13 ammonia: 1.03%
F-18 NaF: 9.28%
Other: 5.15%

Q8. Approximately how many prescriptions for 99Mo/99mTc radiopharmaceuticals did the pharmacy in which you work fill during the week of August 3, 2009?
0-500: 14.94%
501-1000: 16.67%
1001-1500: 6.9%
1501-2000: 6.32%
2001-2500: 2.87%
>2501: 3.45%

Q9. Have you seen a shift from Tc sestamibi and other Tc labeled heart agents to Tl-201?
Yes: 40.23%
No: 14.37%

Q10. If you answered yes to Question 9, how much has the utilization of Tl increased?
0-20%: 12.07%
21-40%: 9.2%
41-60%: 6.9%
61-80%: 3.45%
81-100%: 8.62%

Q11. As a follow up, what percentage of the cardiac unit doses has shifted from Tc to Tl imaging?
0-20%: 21.84%
21-40% :9.2%
41-60%: 8.05%
61-80%: 5.75%
81-100%: 2.3%

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Isotope Shortage Survey Final Results
August 10, 2009

The Society of Nuclear Medicine (SNM) conducted this survey to collect anecdotal information relating to the current shortage of Mo-99 caused, in part, by the current shutdown of the National Research Universal (NRU) Reactor in Chalk River Canada, along with the High Flux Reactor (HFR), in Petten, The Netherlands. In particular, we were looking for information from those who may be experiencing reduced, or no shipment of generators during the shutdown. This information will be used to help SNM develop strategies as we begin to approach decision makers about the impact of this problem. **Total Respondents: 710.**

Q1. Please indicate your primary place of practice.
Hospital: 54.05%
Outpatient Imaging facility: 23.76%
Commercial pharmacy: 2.25%
Hospital pharmacy: 0.45%
Other: 5.07%

Q2. Is your practice / facility impacted by the current molybdenum-99 shortage?
Yes: 80.18%
No: 3.83%
N/A: 1.01%

Q3. Do you have access to an alternate technetium generator source?
Yes: 23.54%
No: 53.83%
N/A:7.77%

Q4. If you answered yes to the above question, what is your alternate technetium generator source?
Another hospital: 0.99%
Another commercial pharmacy:19.86%
Another manufacturer: 9.3%
Other : 2.96%

Q5. At what percentage of your normal full capacity are you currently able to operate?
0-25 %: 4.95%
26-50 %: 16.22%
52-75 %: 31.87%
76-100 %: 31.31%

Q6. When, if ever, do you believe you will be down to zero percent capacity during this shortage?
Within a week: 4.28%
Within two weeks: 3.38%
Within three weeks: 1.91%
Within a month: 6.53%
Longer than one month: 15.54%
Never: 50.68%

SNM
Advancing Molecular Imaging and Therapy

Q7. Please indicate any and all changes that have been made regarding patient care in response to this shortage.
Postponement of procedure: 80.56%
Cancellation of procedure: 47.18%
Change in procedure: 57.32%
Change in isotope used: 59.58%
Transfer of patient to another facility: 11.13%
Other: 8.45%

Q8. If you answered "postponement of procedure" to Question 7, how long the procedure has been postponed.
Less than 1 week: 22.75%
Between 1-2 weeks: 28.15%
Between 2-3 weeks: 6.53%
Between 3-4 weeks: 3.83%
One month or more: 3.27%

Q9. If you answered "change in procedure" to Question 7, please indicate the procedures that have been substituted:
Tl-201 for Tc: 53.94%
F-18 flouride for bone scan: 3.66%
Rb-82 for Tc: 2.96%
Other non-nuclear procedure: 26.34%

Q10. If you answered "change in isotope used" to Question 7, please indicate what isotopes have been substituted.
T Tl-201 instead of Tc-99m agents for cardiac imaging: 58.03%
In-111 Oxine: 7.04%
FDG for bone imaging: 1.41%
Ga-67: 4.93%
N-13 ammonia: 1.27%
F-18 NaF: 2.96%
Other: 3.52%

Q11. Approximately how many patients per week received nuclear medicine scans/procedures prior to the current Tc-99m generator shortage?
0-100: 51.69%
101-200: 17.34%
201-300: 3.6%
301-400: 2.25%
401-500: 1.13%
500-1000: 1.35%
More than 1000: 0.79%

Q12. Approximately how many patients per week are now receiving nuclear medicine scans/procedures at your facility?
0-100: 63.29%
101-200: 6.76%
201-300: 3.04%
301-400: 1.46%
401-500: 1.35%
500-1000: 1.13%
More than 1000: 0.45%

Status of Medical Events & Other Reported Events

ACMUI Meeting
October 19, 2009

Donna-Beth Howe, Ph.D.
Office of Federal and State Materials
Division of Materials Safety and State Agreements

Status of Medical Events 2009

40 Medical Events reported – FY2007
31 Medical Events reported - FY 2008

35.200	1	3
35.300	6	4
35.400	10	10
35.600	15	10
High Dose Rate (HDR) Remote Afterloader	13	8
MAMMOSITE	(4)	(3)
Gamma Knife	2	1
Teletherapy	0	1
35.1000 Y-90 Microspheres	8	4

Status of Medical Events

- 46 Medical Events Reported – FY 2009

	FY 2009	Change
35.200	1	- 2
35.300	5	+ 1
35.400	17	+ 7
• Eye Applicator 1		
• Prostrate 16		
35.600	13	+ 3
• HDR 7	- 1	
• Breast Balloon (2)	(- 1)	
• Gamma Knife 7	+ 6	
• Teletherapy 0	- 1	
35.1000	9	+ 5
• Y-90 Microspheres 9	+ 5	
• IVB 1	+ 1	

Diagnostic Medical Events

35.200 1

Multiple Communication errors
- Intended I-123 but gave I-131
- Referring physician verbal order for I-123
- Secretary scheduled whole body I-131
- Tech took patient history
- Noted patient had a thyroid (should not have been a candidate for whole body I-131 scan)

Therapy Medical Events

35.300 3

1 I-125 Monoclonal Antibody
Failed to deliver dose in the port

4 NaI-131

- 790 rads unintended dose to esophagus when capsule lodged in patient's throat
- 80 mCi (or 194 mCi) remained in feeding tube
- Requested wrong activity - 29 % over dose
- Prescribed 4 mCi gave 100 mCi marked therapeutic instead of diagnostic

Brachytherapy Medical Events

35.400 17

1 Eye Applicator
Did not remove filter and cap

16 PROSTATE (109 patients)
- 5- Department of Veterans Affairs final reports
- 2- Over dose- human error and did not use correction factor
- 4- improper positioning – none in prostate, most outside prostrate, 1/3 in bladder,
- 1- all in prostate but clumped,
- 3- under doses - no reason given
- 1 – Air kerma used for dose calculation instead of millicuries

HDR Medical Events

35.600 HDR **6**

5 Wrong site:

- **Programmed incorrectly - source stopped 10 cm short of treatment site**
- **tandem not fully inserted into cylinder**
- **CT interpretation error gave wrong distance,**
- **catheter too long,**
- **Source tube movement positioning error**

HDR Medical Events cont.

35.600 HDR Continued

2 MammoSite

- **Source Position error - source was not fully inserted into the balloon - it was 3 cm from intended treatment site**
- **Source failed to retract**

Gamma Knife Medical Events

Gamma Knife **7**

2 Wrong side
marked planning sheet wrong
cause not given
1 Wrong site – set up for wrong nerve
2 Equipment malfunction
fiduciary marker box used to register CT images was misaligned
Automatic positioning system one axis off
1 Written directive was for one site - treated two
1 Used wrong collimator

IVB Medical Event

35.1000 Intravascular Brachytherapy **1**

Source train did not go into position could not retract source train into device

Y-90 Microsphere Medical Events

35.1000 Y-90 Microspheres **8**

- **Prescribed 25mCi administered 46 mCi**

SirSpheres
- Over-pressurized three-way valve gave way
- Treatment catheter became occluded
- Cause not provided

TheraSphere
- Fluid leakage from outflow line and needle insertion
- 3 cases of over 20% of the dose adhered to dose vile septum
- Not identified
- Leaking septum v-vile

Other Reported Events

Involving Patients 3

- 3.5 mCi I-131 written directive but intended Tc-99m
- Gave 6 of prescribed 88 seeds revised written directive
- HDR endobroncial treatment conflicting observations

DEPARTMENT OF VETERANS AFFAIRS MEDICAL CENTER – PHILADELPHIA MULTIPLE MEDICAL EVENTS INVOLVING PROSTATE BRACHYTHERAPY TREATMENTS UPDATE

Darrel Wiederman, Senior Health Physicist, Region III
Cassandra Frazier, Senior Health Physicist, Region III
Advisory Committee on the Medical Uses of Isotopes Meeting
October 19, 2009

Background

- At the last Advisory Committee on the Medical Uses of Isotopes (ACMUI) meeting the Department of Veterans Affairs (DVA) reported 92 Medical Events.
- On August 12, 2009, the DVA reported an additional 6 Medical Events.
- To date the DVA has reported 98 Medical Events.

98 Total Medical Events

- 63 Medical Events due to a dose less than 80% of the prescribed dose (underdose)
- 35 Medical Events due to a dose to the skin or an organ or tissue other than the treatment site that exceeds 0.5 sievert (Sv) (50 rem) (over doses to rectum, bladder wall or surrounding tissue)

Update

- March 30, 2009, U.S. Nuclear Regulatory Commission (NRC) Special Inspection Report was issued.
- Six apparent violations of NRC requirements were identified by the inspectors.
- Several areas of concerns were identified that involved inadequate management oversight and lack of safety culture.

Update

- May 26, 2009, NRC issued a Demand for Information to Dr. Kao to obtain specific commitments regarding his current and future use of Byproduct Materials.
- NRC conducted additional on-site inspection activities on June 22-26, 2009 and August 27-28, 2009, to evaluate dose information generated for all 114 patients. Inspection remains open.
- NRC is evaluating medical events against Abnormal Occurrence (AO) criteria.

Update

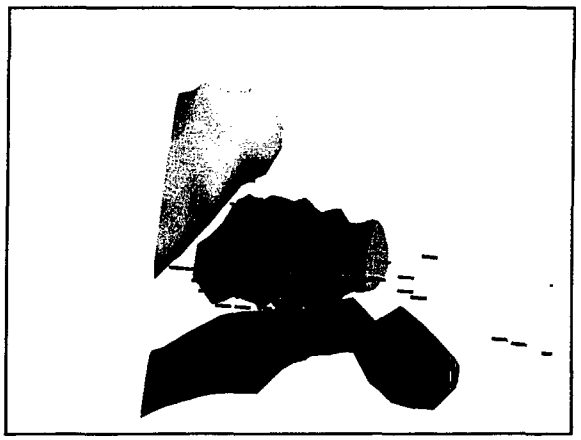
- Eight patients were sent to Seattle Veterans Affairs (VA) and re-implanted.
- Ten patients had recurrence of cancer of the prostate.
- Seed Patterns were inferior to the prostate.
- On August 27-28, 2009, NRC Medical Consultant reviewed an additional 14 Medical Events. The consultant report is pending.

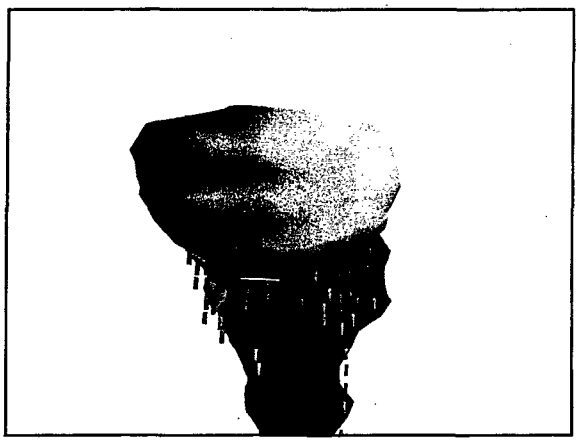
Update

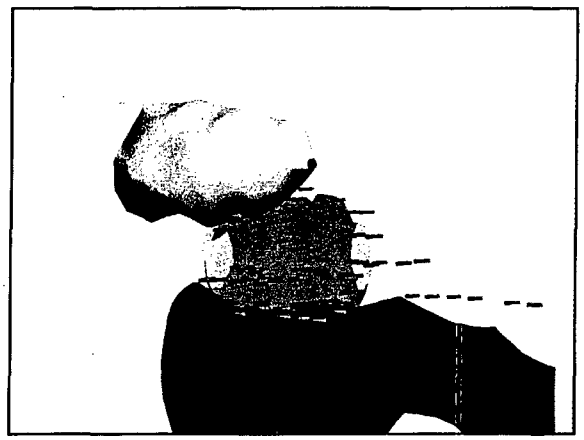
- NRC will issue an inspection report regarding the results of the June and August inspection results in the near future.
- Pre-decisional enforcement conference to be scheduled in the near future.

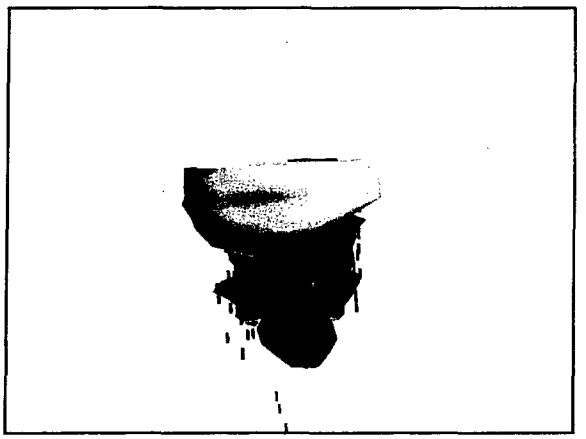
Current Status

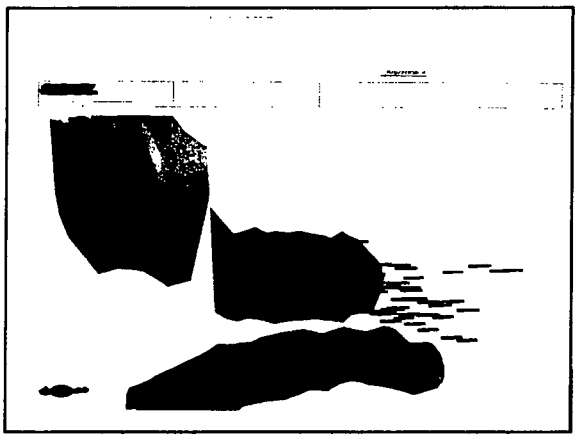
- The Philadelphia Veterans Affairs Medical Center (PVAMC) prostate brachytherapy program remains suspended
- The PVAMC is re-evaluating all implant cases to determine exact dose to treatment sites and adjacent organs or tissues.
- The PVAMC retained the services of an outside medical physicist to review all pre-treatment and post treatment plans.

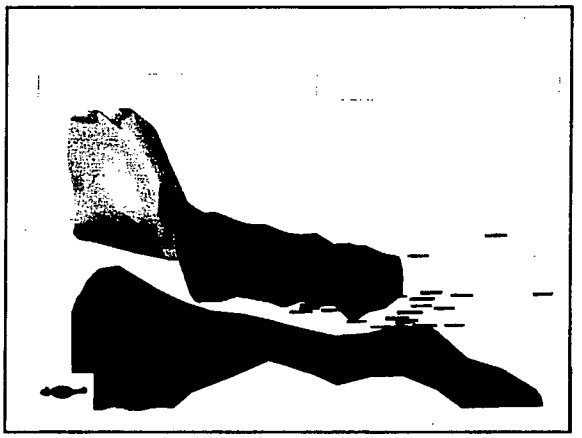


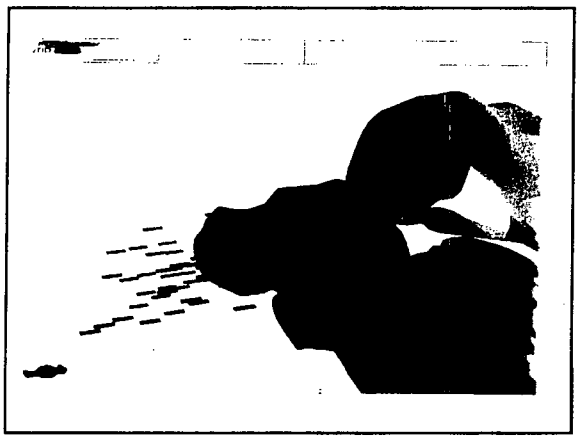












Causes of Medical Events

- Incorrect Placement of Seeds
- Inadequate Procedures
- Inadequate Training and Limited Experience
- Poor Management Oversight
- No Peer Review
- Lack of Safety Culture

Corrective Actions Taken

For patient care, the licensee:

1) Performed verification computed tomography (CT) scans on all patients that received prostate implants;
2) Re-evaluated the dose delivered to the treatment area;
3) Re-implanted brachytherapy seeds at a different VA facility for at least eight individuals; and
4) Removed at least one individual from performing brachytherapy treatments at the VA.

Questions ?

U.S.NRC

International Commission on Radiological Protection Publication 103 Subcommittee

October 19, 2009

Bruce Thomadsen, PhD (Chair)
Debbie Gilley
William Van Decker, MD

Subcommittee Charge

1. Review SECY-08-0197 and its enclosures
2. Review International Commission on Radiological Protection (ICRP) Publication 103
3. Discuss options, consider the cost-benefit, and formulate views associated with revising the radiation protection framework as presented by Dr. Cool (presentation attached for reference) including revisions to:
   a. Effective Dose terminology;
   b. Numerical Values (tissue and radiation weighting factors);
   c. Occupational Dose Limits;
   d. Dose Limit for Embryo/Fetus;
   e. Constraints.
4. Identify other 10 Code of Federal Regulation (CFR) Part 20 issues, which would be important from the Advisory Committee on the Medical Uses of Isotopes (ACMUI) standpoint.
5. Provide a subcommittee report at the October 19-20, 2009 ACMUI meeting.

2

Quantities and Terminology

- Terminology in radiation protection has been confusing for a long time, in part, because of occasional slight changes in the names of quantities with little differences in their names.
- Moving to effective dose (rather than total effective dose) would simplify both the name and quantity, with the qualifications to follow.

3

Effective Dose

- With the move to effective dose, it would be expected that licensees could calculate that. For the most part, they cannot.
- To demonstrate compliance, the badge readings must suffice.
- To do this, the regulation must recognize methods to convert reading to effective dose, such as National Council on Radiation Protection and Measurements (NCRP) Report 122*.

* Use of Personal Monitors to Estimate Effective Dose Equivalent and Effective Dose to workers for External Exposure to Low-LET Radiation

4

Weighting Factors

- The changes in weighting factors should affect medical applications little.
- The use of effective dose replaces the organ-specific dose limits:
  - For a single-organ irradiation, most often an increase in allowed exposure,
  - But there seldom is a single-organ irradiation and for multiple-organ exposure, it's a decrease.

5

Weighting Factors

The subcommittee further supports moving the values for the weighting factors, both the numerical values for the items and the items themselves, out of regulations and into some format that is easier to change.

6

Values for limits - Occupational

- The occupational limits would change from 50 millisievert/year (mSv/y) to 20 mSv/y*.
- This would not be a problem for the medical community given the following:

*Actually, 20 mSv/y averaged over 5 years and <50 mSv in any year. Most likely this would be simplified.

7

Occupational Limit Change not a Problem in Medicine IF:

- Badge readings were converted to effective dose, as noted before, using a method such as NCRP 122.
- The As Low As Reasonably Achievable (ALARA) levels (to be called dose constraints) practically remain at 5 mSv/y and *not* move to 2 mSv/y, & be effective dose. ICRP 103 only says they should be ≤20 mSv/y.
- It is clear that badge change frequency depended on the expected reading, and
- Investigation levels should vary with application.

8

Further Condition Regarding Occupational Limit

Shielding not be retrofitted to meet the new limits, grandfathering exiting installations*.

- Shielding likely will satisfy the new limits anyway due to conservative assumptions usually used.
- The rationale for the reduced limits is not strong enough to mandate additional shielding given the cost.

*General Population limits do not change so most shielding will not be affected.

9

Dose Limits for the Embryo or Fetus

- This would decrease the limit for pregnant works from 5 to 1 mSv/term.
- This would have a great effect in medical settings, requiring removing staff for service at times, depriving patients of expertise.
- *IF* this change occurred, it would have to be clear that a badge under a lead apron would apply, not a badge outside.

10

Dose Limits for the Embryo or Fetus

SECY-08-0197 gives three options:

1. Limit to 1 mSv after the declaration. That was discussed on the previous slide.
2. Limit to 0.5 mSv after declaration to keep below 1 mSv total. See note for next option.
3. Make no change in rules. See next slide.

11

Notes: Dose Limits for the Embryo or Fetus

1. 0.11 mSv/m (11 millirem/month) is at the edge of badge's ability to measure.
2. 1 mSv is less than background.
3. 1 mSv is less than the variation in background.
4. There is no evidence of detriment at the current level.

12

Potential Exposures

The NRC should not adopt the concept of potential exposure.

- The benefit is not clear,
- The principle is not well supported,
- Assigning variability and making assumptions to guess at potential exposures will be a very difficult to onerous burden on the licensee,
- The considerable costs would not be offset by benefits,
- Compliance would be hard to assess.

13

Emergency Exposures

- The ICRP gives little guidance on emergency exposures, but if rewriting the NRC rules, now might be a good time to consider the issue.
- Keep the language to allow increased exposure for caregivers and family of radioactive patients.

14

Final Points

- Any changes in the rules must not be onerous or compliance will suffer (for example, not wearing a dosimeter).
- The ICRP recommendations are based on studies that have been criticized for ignoring oppositional data and studies (e.g., B. Cohen), leaving suggested lower limits poorly supported.

15

U.S.NRC *Protecting People and the Environment*

Options to Revise Radiation Protection Regulations

SECY-08-0197

Advisory Committee on Medical Uses of Isotopes
May 8, 2009

Donald A. Cool, Ph.D.
Office of Federal and State Materials and Environmental Management Programs

Background

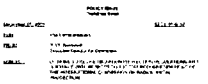
- Most recent rulemaking to incorporate the recommendations of the ICRP into 10 CFR 20 was completed in 1991, and was based primarily on ICRP Publications 26 (1977)
- Regulations that contained explicit dose criteria, rather than cross-references to Part 20, were not updated in 1991, and remain based primarily on ICRP Publications 1 (1958) and 2 (1959)

Background

- NRC staff recommended in 2001 that the Commission wait for next set of ICRP recommendations, and begin Technical Basis development
- Commission agreed in April, 2002, but did not approve Technical Basis efforts
- ICRP Recommendations published in December, 2007 as Publication 103, following considerable public consultation

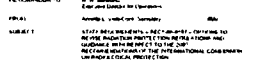
SECY-08-0197

- Policy Issue Notation Vote paper provided to Commission on December 18, 2008
- Provided Options for next steps regarding NRC radiation protection standards
- Provided Background on technical issues in 10 CFR Part 20 and 10 CFR Part 50
- Recommended Commission approval for staff to undertake stakeholder dialogue and technical basis development



SRM-SECY-08-1097

- Commission approved staff recommendation to move forward with stakeholder dialogue and technical basis development, April 2, 2009
- Objective is to explore implications, as appropriate and where scientifically justified, of greater alignment with ICRP Publication 103.
- Given adequate protection, discussion is to focus on discerning the benefits and burdens associated with revising the radiation protection regulatory framework



Technical Issues for Part 20

- Total Effective Dose
- Dose limits
  - Occupational
  - Public
  - Embryo/fetus of Declared Pre
- Constraints
  - Occupational Exposure
  - Public Exposure
- Numerical values

Occupational Dose Limits

- ICRP Recommendation is 10 rem over 5 years, with a maximum of 5 rem in any one year.
- Part 20 limit is 5 rem per year.
- Options:
  - No change: 5 rem per year
  - ICRP recommendation
  - 2 rem per year
- Implications:
  - Impacts of reduced values?
  - Impacts of increased recordkeeping?

7

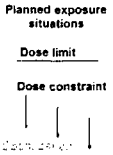
Dose Limit for Embryo/Fetus

- ICRP recommendation is 100 mrem after notification of pregnancy.
- 10 CFR 20.1208 is 500 mrem over gestation period
- Options:
  - No Change
  - ICRP Recommendation
  - *Other single value, such as 50 mrem, after declaration*
- Implications:
  - Impacts of reduced values?
  - Impacts of increased recordkeeping?

8

Constraints (1)

- ICRP recommends the consistent application of constraints as a tool in optimization of protection.
- Constraints are not to be limits.
- Part 20 already as a constraint for public exposure from airborne radionuclides from materials facilities.
- Many large licensees already use planning values in ALARA programs.



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Constraints (2)

- Options:
  - No Change?
  - Require a licensee to use constraints as part of radiation protection program?
  - *Specify a numeric value licensee is not to exceed?*
- Implications:
  - Impacts to Programs?
  - *Benefits in protection seen?*
  - Relationship to Dose Limit?
  - Appropriate insertion of regulatory requirement?

10

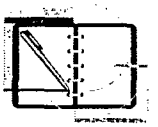
Moving Forward

- NRC staff is looking to engage stakeholders on the technical issues and options for resolution
  - What are YOUR thoughts on the technical issues?
  - What are the impacts of different options?
  - Are there other options that should be considered?
  - What other issues need to be put on the table?
  - What information is needed to make decisions?

11

Schedule

- Spring – Summer 2009: Initial discussions and awareness presentations
- Fall 2009: Initiate detailed discussions, including possible workshops, on options and impacts
- 2010: Continued development and refinement of information, options, and impacts
- Ongoing: Background analysis and technical basis development



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Planned Interactions

- Web page under development
- Email Address: regs4rp@nrc.gov
- Press Release: April 27, 2009
- Scheduled Presentations
  - CRCPD, May 2009
  - SNM, June 2009
  - HPS, July 2009
  - State Liaison Officers, August 2009

13

How Can We Work Together?

- NRC Staff would like to work with, and through, ACMUI and its members to engage the medical communities
- What suggestions do you have for meetings we can make presentations to?
- What arrangement (subcommittee?) can we utilize for ongoing interactions with ACMUI?

14

Questions?

Questions?

15

Background Materials

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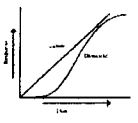
ICRP Publication 103

- Consolidated material from ICRP Publication 60 and subsequent publications
- Maintained fundamental principles of:
  Justification, Optimization, and Limitation
- Radiation risk remains as ~ 5 x 10^{-4} per rem
- LNT for prospective radiation control programs



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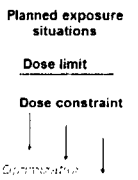
ICRP Publication 103

- Moved to a "situation" based framework
  - Planned Exposure Situations
  - Emergency Exposure Situations
  - Existing Exposure Situations
- Emphasized Optimization using Dose Constraints
- Retained Dose Limits and values
  - Occupational Exposure: 10 rem / 5 years, max of 5 rem in any one year
  - Public Exposure: 100 mrem
  - Embryo/Fetus: 100 mrem



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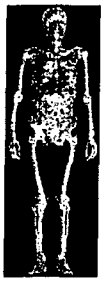
ICRP Continuing Work

- Assessment of new scientific information has resulted in new tissue and radiation weighting factors
- Efforts now underway to calculate new dose conversion factors using updated models and information
- *Commonly used radionuclides to be* available in 2011 ... Complete set 2014



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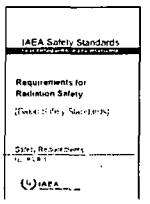
International Standards Work

- IAEA continuing revision of Basic Safety Standards.
  - Draft reviewed by RASSC in November
  - Additional drafting in topical meetings
  - Further review at RASSC in June, 2009
  - *Eventual Member State comment*
- Draft moves to adopt ICRP Recommendations



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International Standards Work

- Revision of Euratom Basic Safety Standards
  - Revision of BSS Directive 96/29
  - Incorporate new ICRP recommendations
  - Consolidate all existing legislation
  - Integration of natural and artificial sources
  - *Protection of the Environment*
- Draft to Article 31 Group of Experts Plenary October, 2009

21

Technical Issues Part 50, App I

- Align App. I criteria concepts with Part 20
- Reconsider criteria in Sect. II.A, II.B, and II.C
- Update definition of dose receptors in Sect. II and IV
- Update cost-benefit criteria in Sect. II.D
- Assess whether Sect. I and V need qualifiers, i.e., existing fleet of reactors vs. new plants

22

Technical Issues Part 50, App I

- Revise Sect. I in differentiating applicability between LWR, Non-LWR, and NGNP
- Redefine compliance requirements for "licensed operation" for sites with multiple licensees
- Assess whether compliance with 40 CFR Part 190 needs further elaboration in Part 20 or guidance

23

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

Physical Protection of Byproduct Material – Proposed Rule

Merri Horn
Senior Project Manager
October 20, 2009

1

U.S.NRC
Protecting People and the Environment

Rule Objective

- Provide reasonable assurance of preventing the theft or diversion of category 1 and category 2 quantities of radioactive material for malevolent use

2

U.S.NRC
Protecting People and the Environment

Proposed Rule

- Create new 10 Code of Federal Regulations (CFR) Part 37 for security of byproduct material
  - Category 1 and Category 2
  - Irradiated fuel (<100 grams)
- Conforming changes to 10 CFR Parts 30, 32, 33, 34, 35, 36, 39, 51, 71, 73, and 150

3

U.S.NRC
Protecting People and the Environment

Major Provisions

- Access Authorization Program
  - Background investigations
  - Anyone with unescorted access to Category 1 or 2 quantities of radioactive material
- Security Plans
  - Procedures, training, security zones
  - Monitoring, detection, response
- Transportation Security
  - Preplanning and coordination, advance notification
  - Surveillance, communications
  - License verification

4

U.S.NRC
Protecting People and the Environment

10 CFR Part 37 - Timeline

- Preliminary language posted for comment - complete
- Proposed rule to Commission - fall 2009
- Publication for public comment – winter/spring 2010 (120 days)
- Public workshop on guidance during rule comment period
- Final rule to Commission - winter 2010-11

5

Potential Changes to 10 CFR Part 35

Donna-Beth Howe, Ph.D.
Office of Federal and State Materials and Environmental Management Programs

October 19, 2009

Medical Institution

Last ACMUI Meeting

- ACMUI was asked if the requirement in 10 CFR 35.490(b)(1)(ii) and 35.690(b)(1)(ii) that the 500 hours of work experience obtained under the supervision of an appropriate authorized user at a medical institution should be revised to include supervised training at other types of medical facilities.
- ACMUI recommended adding clinic but not private practice.

SLIDE PRESENTED IN MAY 2009

Problem: Both 10 CFR 35.490(b)(1)(ii) and 35.690(b)(1)(ii) require 500 hours of work experience, under the supervision of an appropriate authorized user at a medical institution.

Medical practice has changed. Now medical practices outside of medical institutions (e.g., in clinics, private practices) treat patients with manual brachytherapy, photon emitting remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units.

The individual seeking authorized user status is still required to complete three years of radiation oncology residency training that will provide training and experience with diverse brachytherapy procedures and therapy devices.

SLIDE PRESENTED IN MAY 2009

Questions: Is a stand alone clinic (that only conducts one NRC-regulated activity) an appropriate place to receive training? Does training obtained at a stand alone clinic have the oversight and validation that it could receive from an institution with programs and support staff in place? If deemed adequate, then 35.490(b)(1)(ii) and 35.690(b)(1)(ii) could be revised to clarify the supervised work experience does not limit experience to be obtained in only a medical institution.

Example

(ii) 500 hours of work experience, under the supervision of an authorized user who meets the requirements in [35.490 or 35.690] or equivalent Agreement State requirements at a medical institution, **clinic, or private practice**, involving--

Medical Institution

This ACMUI meeting

- Should NRC delete the definition of medical institution from 10 CFR 35.2 and the phrase "medical institution" in 35.490, 35.491, and 35.690?
- The term only appears in these 4 places in the regulations

Medical Institution

- Revise 10 CFR 35.490(b)(1)(ii) from

  500 hours of work experience, under the supervision of an authorized user who meets the requirements in § 35.490 or equivalent Agreement State requirements at a medical institution, involving–

To read:

500 hours of work experience, under the supervision of an authorized user who meets the requirements in § 35.490 or equivalent Agreement State requirements, involving--

10 CFR 35.41

Problem: NRC licensee written procedures in a number of cases are not only inadequate to provide high confidence that administrations are in accordance with written directives but also are inadequate to identify medical events and identify them in a timely manner.

7

10 CFR 35.41

Case:

A licensee implanted manual brachytherapy seeds incorrectly – none of the seeds went into the prostate.

- **Two CT scans were performed approximately a month later. A radiologist read the first scan and notified the licensee's urologist immediately that the seeds were not in the prostate.**
- **This information was not shared with the AU.**
- **The second CT scan was performed 3 days after the first CT scan and the AU read it immediately and identified *mispositioning of the seeds and determined external beam* treatment would be needed.**
- **This information was not shared with the AMP.**
- **The medical physicist performed the post implant dosimetery *a month after the AU read the CT scan and recognized no* seeds were in the prostate.**
- **The medical event was not reported until the AMP performed the dosimetry.**

8

10 CFR 35.41

Possible solution: Revise 10 CFR 35.41 (a) to include a criterion that there will be high confidence that, if the administration was not in accordance with the written directive, a determination of whether the administration resulted in a reportable medical event will be made in a timely manner.

9

10 CFR 35.41

Revise 10 CFR 35.41(a) to read:

(a) For any administration requiring a written directive, the licensee shall develop, implement, and maintain written procedures to provide high confidence that:

(1) The patient's or human research subject's identity is verified before each administration;

(2) Each administration is in accordance with the written directive; and

(3) If the administration is not in accordance with the written directive, a determination of whether it resulted in a reportable medical event will be made in a timely manner.

10

U.S.NRC

Radium-223
A Possible New Radioisotope for Palliative Therapy in the United States?

James S. Welsh, MS, MD
Advisory Committee on the Medical Uses of Isotopes

October 20, 2009

Radium

- Heaviest of the alkaline earth elements
- Chemistry similar to barium
  - Thus the extraction of barium by Otto Hahn and Fritz Strassmann when expecting radium
- Discovered in 1898
  - Gustave Bemont, Pierre and Marie Curie
- Less than a gram of radium from about 10 tons of pitchblend

Pitchblende

- Amorphous, black, pitchy form of the crystalline mineral uraninite (uranium oxide, UO_2)
- One of the primary mineral ores of uranium, containing 50–80% of that element.
- Three chemical elements were first discovered in pitchblende:
  - uranium by the German chemist Martin Klaproth in 1789,
  - Polonium and
  - Radium

Radium Basics

- One gram of radium-226 undergoes 3.7×10^{10} disintegrations per second
- Thirty-three isotopes of radium
  - all radioactive
- Half-lives, with the exceptions of radium-226 (1,600 years) and radium-228 (5.8 years), are less than a few weeks.

Radium Basics

- Radium occurs naturally only as a disintegration product in the three natural radioactive-decay series
  - thorium
  - uranium
  - and actinium series
- Radium-226 is a member of the uranium-decay series.
- The long-lived radium-226 is found in nature as a result of its continuous formation from uranium-238 decay
  - Its parent is thorium-230 and its daughter radon-222.

Biological effects

- Radium dermatitis
- Only 2 years after its discovery, A. Henri Becquerel developed a skin ulcer after carrying an ampule in his pocket for six hours
- Marie Curie developed a skin ulcer after a few days following 10 hours of direct contact with a tiny sample

The Radium Craze

- In 1903 numerous commercially available products became available to the public
  - Cosmos Bag for arthritis
  - Liquid Sunshine
  - Radiathor
- The sad case of Eben Byers ended the era upon his death in 1932
  - He consumed an estimated 1400 bottles of Radiathor
  - *The Wall Street Journal* article "The Radium Water Worked Fine until His Jaw Came Off" says it all

7

The Radium Girls

- U.S. Radium Corporation
- Watch dial luminous paint containing 70 μg/g of paint
- The paint consisted of RaBr and ZnS (which *glows after alpha irradiation*)
- Of 800 employees from 1917 to 1924, 48 developed radiation sickness (including mandibular necrosis) and 18 died (including cases of osteosarcoma)

8

So why is there interest in Radium today???

- Radium-226 is part of the Uranium Series beginning with uranium-238 and ending with lead-206 (i.e. the 4n+2 series)
- In the thorium series (aka 4n series), two radium isotopes occur and are found naturally in the mineral monazite
  - radium-228 (5.75-year half-life)
  - radium-224 (3.64-day half-life).
  - A fourth isotope, ***radium-223*** (11.4-day half-life), occurs in the actinium-decay series (i.e. the 4n + 3 series)

9

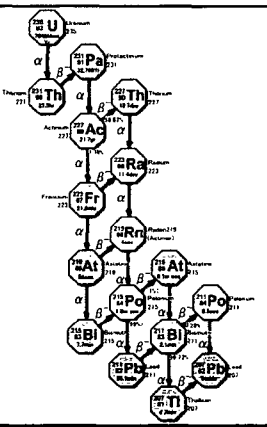
Radium-223

- Radium-223 is the isotope of interest presently
- It has radiological properties that make it well suited for radiopharmaceutical applications
- Some compelling clinical data has emerged recently regarding its potential in palliation of bone metastases

10

Isotopes of radium

isotope	half-life	Decay Mode	Decay Energy (MeV)	Daughter Product
^{223}Ra	***11.43 d***	***alpha***	***5.99***	***^{219}Rn***
^{224}Ra	3.6319 d	*alpha*	5.789	^{220}Rn
^{226}Ra	1602 y	alpha	4.871	^{222}Rn
^{228}Ra	6.7 y	beta-	0.046	^{228}Ac



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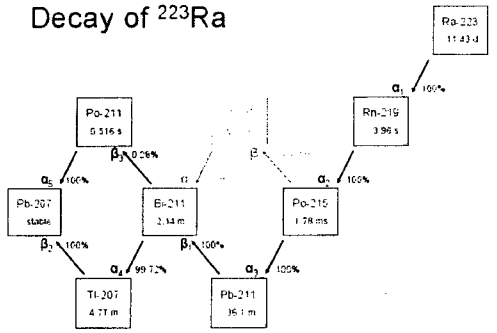
Decay of ^{223}Ra



Radium-223

- Bone seeking radioisotope
- Mouse studies showed a bio-distribution similar to strontium-89
  - Accumulation in skeletal matrix with retention in osteoblastic lesions
- Dose modeling suggests a significant reduction in marrow irradiation compared to strontium-89 (Hendriksen et al J Nucl Med 2003)

Radium-223

- Bone seeking like the beta emitters strontium-89 and samarium-153 Ethylene Diamine Tetramethylene Phosphonate (EDTMP)
- These are effective but clinically hampered by myelosuppression
  - Perhaps underutilized because of the reputation for interfering with further chemotherapy administration
- Radium-223 is a high Linear Energy Transfer (LET) alpha emitter
- In principle:
  - potentially more effective at killing tumor cells and
  - less myelosuppressive due to range <100 μm of alpha particles

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Radium-223

- Radium-223 has a suitable half-life for therapeutic applications (11.4 days)
- Rapidly decays to stable lead-207
- Emits some photons suitable for imaging

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Radium-223

- Hendriksen et al 2002 showed effective anti-tumor effect in a rodent model of metastatic breast cancer without myelosupression
- At 67 days:
  - 2/5 treated with ≥ 100kBq/kg radium-223 survived whereas non of the controls did

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Radium-223

- In a Phase I trial (Nilsson et al Clinical Cancer Research 2005)
- One IV administration of activities from 50-250 kBq/kg in 25 pts with bone metastases secondary to breast (n=10) or prostate (n=15)
- Only 3 with Common Terminology Criteria for Adverse Events (CTCAE) grade 3 leukopenia
- Zero with grade ≥2 thrombocytopenia
- Improved pain scores seen across all doses
- Alkaline phosphatase reduced also at all doses
- 50kBq/kg thus selected for future studies

18

Radium-223

- Phase II Randomized, multicenter, palcebo controlled study (Nilsson et al Lancet Oncology 2007)
- 64 pts with hormone-refractory metastatic prostate cancer
  - 31 in placebo group
  - 33 in Ra-223 group
- 50kBq/kg q 4 wks

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Nilsson et al (Lancet Oncology 2007)

- Primary endpoints
- Bone alkaline phosphatase (ALP)
- Skeletal related events (SRE's)
- Secondary endpoints
  - Toxicity
  - Time to Prostate-Specific Antigen (PSA) progression
  - Overall survival

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Nilsson et al (Lancet Oncology 2007)

- Highly significant reduction in median relative change in ALP
  - -65.6% vs +9.3%
- No difference in toxicity
- Median time to PSA progression significantly altered
  - 26 weeks vs 8 weeks (p=0.048)
- Hazard ratio for overall survival 2.12 (p=0.02)

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Future in the U.S.?

- Algeta has selected radium-223 for its lead product, Alpharadin, which is in phase III clinical development as a potential treatment of bone metastases in patients with hormone refractory prostate cancer.
- Algeta has developed a generator system based for the production of radium-223
- Algeta announced last week (9/8/09) an up to $800 million agreement with Bayer for Alpharadin, currently in late-stage clinical trials in men with hormone-refractory prostate cancer that has spread to the bone.

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U.S. Food and Drug Administration
Protecting and Promoting Public Health
www.fda.gov

FDA's Radiation Associated Regulatory Responsibilities

Presented to the Nuclear Regulatory Commission's Advisory Committee on Medical Use of Isotopes (October 20, 2009)

Orhan H. Suleiman MS, PhD, FAAPM
Senior Science Policy Advisor
Office of Oncology Drug Products
Center for Drug Evaluation and Research

1

U.S. Food and Drug Administration
Protecting and Promoting Public Health
www.fda.gov

Food, Drug and Cosmetic Act (FDCA) - 1906

- Law has been amended many times over the last century.
- Subsequent laws have been incorporated into the FDCA, e.g. Radiation Control for Health and Safety Act 1968, and Medical Device laws (1976), Medical Device laws (1976), FDAMA (1997), FDAAA (2007)

2

U.S. Food and Drug Administration
Protecting and Promoting Public Health
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FDA consists of many Centers

- Center for Drug Evaluation and Research (CDER) – Radiopharmaceuticals
- Center for Devices and Radiological Health (CDRH) – Medical Devices – accelerators, brachytherapy sources, etc.
- Center for Biologics Evaluation and Research (CBER) – Blood Irradiators
- Center for Food Safety and Nutrition (CFSAN) – Food irradiators

3

U.S. Food and Drug Administration
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www.fda.gov

Other FDA Components

- Center for Veterinary Medicine
- National Center for Toxicological Research
- Office of Regulatory Affairs – FDA's field operations
- Office of the Commissioner- Office of Crisis Management (Emergency Operations)

4

U.S. Food and Drug Administration
Protecting and Promoting Public Health
www.fda.gov

Center for Devices and Radiological Health

Regulates most radiation products

- Medical Devices – regulated by Office of Device Evaluation (ODE) -analogous to CDER's Office of New Drugs (OND)
- Radiation emitting electronic products- regulated by Office of Communication, Education, and Radiation (OCER)
- Mammography- also regulated by OCER

5

U.S. Food and Drug Administration
Protecting and Promoting Public Health
www.fda.gov

Three different Statutes

- Electronic Products- 1968
- Medical Devices – 1976
- Mammography - 1992

6

Radiation Emitting Electronic Products (Radiation Control for Health and Safety Act of 1968)*

- Mandatory Emission Performance Standards
- Consumer and Medical Products
- Microwave ovens, lasers
- X-rays (medical and security products)

* Center for Devices and Radiological Health

7

Medical Device Act of 1976*

- 510 (k) – predicate device, substantial equivalency
- Class I – Minimal controls
- Class II- *Special controls*
- Class III
  - High risk devices
  - May require clinical trials for premarket *approval* (PMA).
  - *Center for Devices and Radiological Health

8

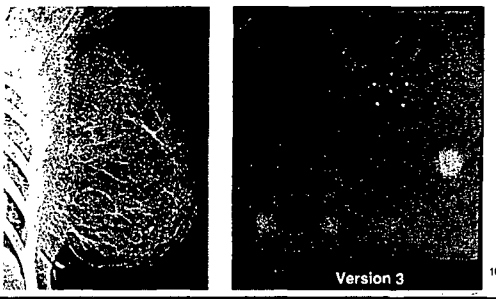
Mammography Quality Standards Act of 1992*

- Assures quality by establishing standards and regulating:
  - Quality control of equipment
  - Personnel
  - Image quality (Imaging and dosimetry phantom)

* Center for Devices and Radiological Health

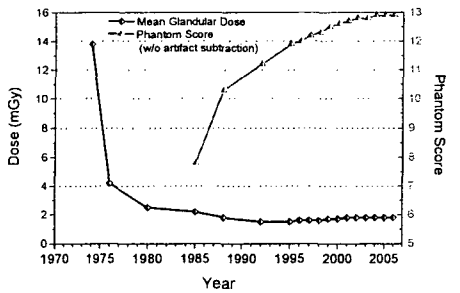
9

In order to detect change clinically, you need to assure the standard image remains constant.



10

Dose and Image Quality Trends in Mammography



11

Medical Isotopes (Radiopharmaceuticals)

- Center for Drug Evaluation and Research (CDER)
- Center for Biologics Evaluation and Research (CBER)

12

U.S. Food and Drug Administration
Protecting and Promoting Public Health
www.fda.gov

What does it take to get a drug approved? Research Phase

- Clinical Research under an Investigational New Drug (IND) Application
  - Phase I- Safety "n ~ 20 – 80"
  - Phase II- Efficacy "n < several hundred"
  - Phase III- Large scale studies for benefit – risk, dosing, and physician labeling information "n ~ several hundred to several thousand"

13

U.S. Food and Drug Administration
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www.fda.gov

What does it take to get a drug approved? Manufacturing Standards

- Quality and purity of product
  Good Manufacturing Practice (GMP) and Chemistry Manufacturing Control (CMC)

14

U.S. Food and Drug Administration
Protecting and Promoting Public Health
www.fda.gov

What does it take to get a drug approved?- Application process – New Drug Application

- NDA Process:
  http://www.fda.gov/cder/regulatory/applications/nda.htm#Related%20Topics:
- Application Fee for NDA ~ $1 M+

15

U.S. Food and Drug Administration
Protecting and Promoting Public Health
www.fda.gov

Radioactive Drug Research Committee Research

(non-IND human research)

- Established in 1975
- Formally codified in 21 CFR 361.1
- Allows human research with radioactive drugs without an IND when:
  - Research is basic
  - RDRC approves
  - There is no clinically detectable pharmacologic effect from the administered
  - and radiation dose limits as specified are met

16

U.S. Food and Drug Administration
Protecting and Promoting Public Health
www.fda.gov

Manufacturing Responsibilities for medical isotope production?

Pharmaceuticals: Good Manufacturing Practice (GMP) – 21 CFR Parts 210, 211, 212 (proposed), 600-680

Medical Devices: Quality System (QS) regulations – 21 CFR Part 820

Guidance for Industry and FDA Current Good Manufacturing Practice for Combination Products
http://www.fda.gov/cder/guidance/QCLove1dft.htm

17

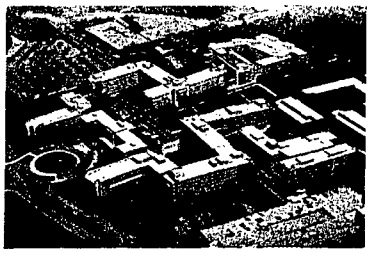
U.S. Food and Drug Administration
Protecting and Promoting Public Health
www.fda.gov

Licensing

- FDA does not license radioactive materials
- Radioactive materials licensed by the Nuclear Regulatory Commission (NRC) or
- Radioactive materials licensed by Agreement States (36 states with formal "agreements" with the NRC
- FDA approves biological products via the Biological Licensing Application (BLA)
- FDA approves radiolabeled drugs via the New Drug Application (NDA)
- www.fda.gov/cder/guidance/5645fnl.htm

18

10903 New Hampshire Ave
Silver Spring, Maryland



NO HANDOUT

Please check your 2010 calendar for possible conflicts with the spring ACMUI meeting. Be prepared to choose one of the dates circled on the calendars enclosed.

Ashley

Calendar for April 2010 (United States)

April

Sun	Mon	Tue	Wed	Thu	Fri	Sat
				1	2	3
4	5	6	7	8	9	10
11	12	13	14	15	16	17
18	19	20	21	22	23	24
25	26	27	28	29	30	

Phases of the moon: 6:◑ 14:● 21:◐ 28:○

Holidays and Observances: 4: Easter Sunday

Calendar generated on www.timeanddate.com/calendar

Calendar for May 2010 (United States)

May

Sun	Mon	Tue	Wed	Thu	Fri	Sat
						1
2	3	4	5	6	7	8
9	10	11	12	13	14	15
16	17	18	19	20	21	22
23	24	25	26	27	28	29
30	31 HOLIDAY					

Phases of the moon: 6:◑ 13:● 20:◐ 27:○

Holidays and Observances: 9: Mother's Day, 31: Memorial Day

Calendar generated on www.timeanddate.com/calendar

UNITED STATES NUCLEAR REGULATORY COMMISSION
CHARTER FOR THE ADVISORY COMMITTEE ON MEDICAL USES OF ISOTOPES

1. **Committee's Official Designation**:

   Advisory Committee on the Medical Uses of Isotopes

   Established Pursuant to Section 9 of Public Law 92-463 as an NRC discretionary committee.

2. **Committee's objectives, scope of activities and duties are as follows:**

   The Committee provides advice, as requested by the Director, Division of Materials Safety and State Agreements (MSSA), Office of Federal and State Materials and Environmental Management Programs (FSME), on policy and technical issues that arise in regulating the medical use of byproduct material for diagnosis and therapy. The Committee may provide consulting services as requested by the Director, MSSA.

3. **Time period (duration of this Committee):**

   Continuing Committee.

4. **Official to whom this Committee reports:**

   Director, Division of Materials Safety and State Agreements
   Office of Federal and State Materials and Environmental Management Programs
   U.S. Nuclear Regulatory Commission
   Washington, DC 20555

5. **Agency responsible for providing necessary support to this Committee:**

   U.S. Nuclear Regulatory Commission.

6. **The duties of the Committee are set forth in Item 2 above.**

7. **Estimated annual direct cost of this Committee:**

   Members are appointed by the Director, Office of Federal and State Materials and Environmental Management Programs as Special Government Employees (SGEs). Approximately 12 members utilize 1 FTE (includes approximately 0.6 FTE for NRC staff and 0.4 FTE for ACMUI member compensation and travel).

8. **Estimated number of meetings per year:**

Five meetings per year, three of which are teleconferences.

9. ***The Committee's termination date.***

Continuing Committee subject to Charter renewal on March 17, 2010.

10. **Filing date:** March 17, 2008

/RA/

Andrew L. Bates
Advisory Committee Management Officer
Office of the Secretary of the Commission

ACMUI
OCTOBER 24, 2006

U.S. NUCLEAR REGULATORY COMMISSION

OFFICE OF FEDERAL AND STATE MATERIALS AND ENVIRONMENTAL MANAGEMENT PROGRAMS

ADVISORY COMMITTEE ON MEDICAL USES OF ISOTOPES

BYLAWS

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PREAMBLE

These bylaws describe the procedures to be used by the Advisory Committee on the Medical Uses of Isotopes (ACMUI), established pursuant to Section 161a of the Atomic Energy Act of 1954, as amended, in performing its duties, and the responsibilities of the members. For parliamentary matters not explicitly addressed in the bylaws, Robert's Rules of Order will govern.

These bylaws have as their purpose fulfillment of the ACMUI's responsibility to provide objective and independent advice to the Commission through the Office of Federal and State Materials and Environmental Management Programs, with respect to the development of standards and criteria for regulating and licensing medical uses of byproduct material. The procedures are intended to ensure that such advice is fairly and adequately obtained and considered, that the members and the affected parties have an adequate chance to be heard, and that the resulting reports represent, to the extent possible, the best of which the ACMUI is capable. Any ambiguities in the following should be resolved in such a way as to support those objectives.

1. Scheduling and Conduct of Meetings

The scheduling and conduct of ACMUI meetings shall be in accordance with the requirements of the Federal Advisory Committee Act (FACA), as amended, 10 CFR Part 7, and other implementing instructions and regulations as appropriate.

1.1 Scheduling of Meetings:

1.1.1 Meetings must be approved or called by the Designated Federal Officer. At least two regular meetings of the ACMUI will be scheduled each year, one in the Spring and one in the Fall. Additionally, the ACMUI will meet with the Commission, unless the Chair or designated Chair declines or the Commission declines.

1.1.2 Special meetings (e.g., teleconferences and subcommittee meetings) will be open to the public, except for those meetings or portions of meetings in which matters are discussed that are exempt from public disclosure under FACA or other appropriate rules or statutes.

1.1.3 ACMUI meetings will be open to the public, except for those meetings or portions of meetings in which matters are discussed that are exempt from public disclosure under FACA or other appropriate rules or statutes.

1.1.4 All meetings of the ACMUI will be transcribed. During those portions of the meeting that are open to the public, electronic recording of the proceedings by members of the public will be permitted. Television recording of the meeting will be permitted, to the extent that it does not interfere with ACMUI business, or with the rights of the attending public.

1.2 Meeting Agenda:

The agenda for regularly scheduled ACMUI meetings will be prepared by the Chair of the ACMUI (referred to below as "the Chair") in consultation with the Office of Federal and State Materials and Environmental Management Programs (FSME) staff. The Designated Federal Officer must approve the agenda. The Chair, with the FSME staff's assistance, will query ACMUI members for agenda items prior to agenda preparation. A draft agenda will be provided to ACMUI members not later than thirty days before a scheduled meeting. The final agenda will be provided to members not later than seven days before a scheduled meeting.

Before the meeting, the Chair and the Designated Federal Officer for the ACMUI will review the findings of the Office of the General Counsel regarding possible conflicts of interest of members in relation to agenda items. Members will be recused from discussion of those agenda items with respect to which they have a conflict.

1.3 Conduct of the Meeting:

1.3.1 All meetings will be held in full compliance with the Federal Advisory Committee Act. Questions concerning compliance will be directed to the NRC Office of the General Counsel.

1.3.2 The Chair will preside over the meeting. The Vice Chair will preside if the Chair is absent or if the Chair is recused from participating in the discussion of a particular agenda item. The Designated Federal Officer will preside when both the Chair and the Vice Chair are absent and/or recused from the discussion, or when directed to do so by the Commission.

1.3.3 A majority of the current membership of the ACMUI will be required to constitute a quorum for the conduct of business at an ACMUI meeting.

1.3.4 The Chair has both the authority and the responsibility to maintain order and decorum, and may, at his or her option, recess the meeting if these are threatened. The Designated Federal Officer will adjourn a meeting when adjournment is in the public interest.

1.3.5 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. The decision shall be by a majority vote of those members present and voting, with a tie permitting continued participation of the Chair in the discussion.

1.3.6 When a consensus appears to have developed on a matter under consideration, the Chair will summarize the results for the record. Any members who disagree with the consensus shall be asked to state their dissenting views for the record. Any ACMUI member may request that any consensus statement be put before the ACMUI as a formal motion subject to affirmation by a formal vote. No ACMUI position will be final until it has been formally adopted by consensus or formal vote, and the minutes/transcript written and certified.

2. MINUTES/TRANSCRIPTS

2.1 Minutes/transcripts of each meeting will be prepared by the ACMUI Chair, with assistance from the FSME staff, in accordance with the requirements in 10 CFR Part 7. The Commission staff will prepare minutes/transcripts of ACMUI meetings with the Commission.

2.2 The ACMUI Chair will certify the minutes/transcripts in accordance with 10 CFR Part 7.

2.3 In accordance with the requirements of the NRC's Operating Plan, FSME staff will prepare a meeting summary. The FSME staff will e-mail the meeting summary document or web link to the ACMUI members.

2.4 Copies of the certified minutes/transcripts will be made available to the ACMUI members, and to the public, not later than 90 days after the meeting.

3. APPOINTMENT OF MEMBERS

3.1 The members of the ACMUI are appointed by the Director, FSME, after consultation with the Commission. The Commission determines the size of the ACMUI. The NRC will solicit nominations by notice in the Federal Register and by such other means as are approved by the Commission. Evaluation of candidates shall be by such procedures as are approved by the Director, FSME. The term of an appointment to the ACMUI is four years, and the Commission has determined that no member may serve more than 2 consecutive terms (8 years).

3.2 The Chair will be appointed by the Director, FSME, from the membership of the ACMUI. The Chair will serve at the discretion of the Director, FSME.

3.3 The Vice Chair will be appointed by the Director, FSME, from the membership of the ACMUI. The Vice Chair will serve at the discretion of the Director, FSME.

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 Designated Federal Officer as soon as possible, but in any case before the ACMUI discusses it as an agenda item. ACMUI members must recuse themselves from discussion of any agenda item with respect to which they have a conflict of interest.

4.2 Upon completing their tenure on the ACMUI, members will return any privileged documents and accountable equipment (as so designated by the NRC) provided for their use in connection with ACMUI activities, unless directed to dispose of these documents or equipment.

4.3 Members of the ACMUI are expected to conform to all applicable NRC rules and regulations, and are expected to attend meetings regularly and perform all assigned duties.

5. ADOPTION AND AMENDMENTS

5.1 Adoption or approval of an amendment of these bylaws shall require an affirmative vote of two-thirds of the current ACMUI membership and the concurrence of the Director of the Office of Federal and State Materials and Environmental Management Programs.

5.2 Any member of the ACMUI or FSME staff may propose an amendment to these bylaws. The proposed amendment will be distributed to the members by the Chair and scheduled for discussion at the next regular ACMUI meeting.

5.3 The proposed amendment may be voted on as early as the next ACMUI meeting after distribution to the members.

5.4 The ACMUI shall consult with the Office of the General Counsel regarding conflicts that arise from the interpretation of the bylaws. After consultation, the ACMUI shall resolve interpretation issues by a majority vote of the current membership of the ACMUI.

ADVISORY COMMITTEE ON THE MEDICAL USES OF ISOTOPES SPECIALTIES AND FUNCTIONS	
Food and Drug Administration (FDA) Representative	The FDA representative provides advice on current FDA requirements, as they relate to radiation safety and U.S. Nuclear Regulatory Commission (NRC) medical-use policy issues. This individual is appointed by the FDA and is familiar with NRC-regulated byproduct material and devices.
Health Care Administrator	The Health Care Administrator provides advice on a broad perspective of various interests, to include, patients' interests, physicians' interests, and hospitals' interests, as they apply to radiation safety, the treatment of patients, and NRC medical-use policy. This individual is appointed based on his or her educational background, certification(s), work experience, involvement and/or leadership in professional society activities, and other information obtained in letters or during the selection process.
Medical Physicist, Nuclear Medicine	The nuclear medicine physicist provides advice on issues associated with nuclear medicine applications of byproduct material. This advice includes recommendations on the training and experience requirements for Authorized Medical Physicists and other nuclear medicine issues as they relate to radiation safety and NRC medical-use policy. This individual is appointed based on his or her educational background, certification(s), work experience, involvement and/or leadership in professional society activities, and other information obtained in letters or during the selection process.
Medical Physicist, Therapy	The therapy physicist provides advice on issues associated with therapeutic applications of byproduct material. This advice includes recommendations on the training and experience requirements for Authorized Medical Physicists and other therapeutic issues as they relate to radiation safety and NRC medical-use policy. This individual is appointed based on his or her educational background, certification(s), work experience, involvement and/or leadership in professional society activities, and other information obtained in letters or during the selection process.
Nuclear Cardiology Physician	The nuclear cardiology physician provides advice on issues associated with diagnostic applications of byproduct material in cardiology. This advice includes recommendations on the training and experience requirements for physicians specializing in diagnostic nuclear cardiology and other nuclear medicine issues as they relate to radiation safety and NRC medical-use policy. This individual is appointed based on his or her educational background, certification(s), work experience, involvement and/or leadership in professional society activities, and other information obtained in letters or during the selection process.

Nuclear Medicine Physician	The nuclear medicine physician provides advice on issues associated with diagnostic and therapeutic applications of byproduct material. This advice includes recommendations on the training and experience requirements for physicians specializing in diagnostic and therapeutic nuclear medicine, identification of medical events associated with these uses, and other nuclear medicine issues as they relate to radiation safety and NRC medical-use policy. This individual is appointed based on his or her educational background, certification(s), work experience, involvement and/or leadership in professional society activities, and other information obtained in letters or during the selection process.
Nuclear Pharmacist	The nuclear pharmacist provides advice on issues associated with nuclear pharmacy applications of byproduct material. This advice includes recommendations on the training and experience requirements for Authorized Nuclear Pharmacists and other issues as they relate to radiopharmaceuticals, radiation safety and NRC medical-use policy. This individual is appointed based on his or her educational background, certification(s), work experience, involvement and/or leadership in professional society activities, and other information obtained in letters or during the selection process.
Patients' Rights Advocate	The patients' rights advocate provides advice on patients' issues associated with medical applications of byproduct material. This advice includes ensuring patients' rights are represented during the development and implementation of NRC medical-use policy. This individual is appointed based on his or her professional and personal experience with and/or knowledge about patient advocacy, involvement and/or leadership with patient advocacy organizations, and other information obtained in letters or during the selection process.
Radiation Oncology Physician, Brachytherapy	The brachytherapy radiation oncology physician provides advice on issues associated with radiation oncology applications of byproduct material, such as permanent implant brachytherapy and high dose-rate brachytherapy. This advice includes recommendations on the training and experience requirements for physicians specializing in these uses, identification of medical events associated with these uses, and other radiation oncology issues as they relate to radiation safety and NRC medical-use policy. This individual is appointed based on his or her educational background, certification(s), work experience, involvement and/or leadership in professional society activities, and other information obtained in letters or during the selection process.

Radiation Oncology Physician, Gamma Stereotactic Radiosurgery (GSR)	The GSR radiation oncology physician provides advice on issues associated with radiation oncology applications of byproduct material, such as GSR. This advice includes recommendations on the training and experience requirements for physicians specializing in this use, identification of medical events associated with this use, and other radiation oncology issues as they relate to radiation safety and NRC medical-use policy. This individual is appointed based on his or her educational background, certification(s), work experience, involvement and/or leadership in professional society activities, and other information obtained in letters or during the selection process.
Radiation Safety Officer (RSO)	The RSO provides advice on health physics issues associated with medical applications of byproduct material. This advice includes recommendations on the training and experience of RSOs, identification of medical events, security of byproduct material used in medical and research facilities, and other issues as they relate to radiation safety and NRC medical-use policy. This individual is appointed based on his or her educational background, certification(s), work experience, involvement and/or leadership in professional society activities, and other information obtained in letters or during the selection process.
State Government Representative	The state government representative provides advice on regulatory issues associated with medical applications of byproduct material. This advice includes recommendations on the training and experience requirements for all specialties, compatibility of federal and state regulations, and other issues as they relate to radiation safety and NRC medical-use policy. This individual is appointed based on his or her educational background, certification(s), work experience, involvement and/or leadership in professional society activities, and other information obtained in letters or during the selection process.

ADVISORY COMMITTEE ON THE MEDICAL USES OF ISOTOPES

Position	Name	Phone	Email	Title	Address	Fax	Assistant
Nuclear Medicine Physician	**Douglas F. Eggli, M.D.**	(717) 531-8940	deggli@psu.edu	Dept of Radiology, H066, Penn State Univ Hospital, The Milton S. Hershey Med Center	Room HG300B, PO Box 850, 500 University Dr., Hershey, PA 17033 Home: redacted	(717) 531-5596	Debra Pavone (717) 531-5341 dpavone@psu.edu
Patient Advocate	**Darrell R. Fisher, Ph.D.**	(509) 373-2000 redacted cell	dr.fisher@pnl.gov	Sr Scientist, Radioisotopes Program, Pacific Northwest National Lab	Home: redacted 902 Battelle Blvd., P7-27, Richland, WA 99354	(509) 373-2001	
State Government Representative	**Debbie B. Gilley**	(850) 245-4266 redacted cell	debbie_gilley@doh.state.fl.us	Dept of Health, Bureau of Rad. Control, Environmental Mgr, Dir. of Training & QA	Bureau of Radiation Control, 4052 Bald Cypress Way, Bin C21, Tallahassee, FL 32399-1741 Home: redacted	(850) 487-0435	Nancy Houston (850) 245-4266 nansalary_houston@doh.state.fl.us
Diagnostic Radiologist Representative	**Milton S. Guiberteau, M.D.**	(713) 757-7467	mjgmd@aol.com		Home: redacted	(713) 756-5048	
Radiation Safety Officer	**Susan M. Langhorst, Ph.D.**	(314) 362-2988 redacted cell	langhors@wustl.edu	Dir & RSOr, Dept of Env Hlth & Sfty, Rad Sfty Div, WUSTL	724 S. Euclid Avenue, Rm 2240, St. Louis, MO 63110 Home: redacted	(314) 362-6666	Tracey Whitfield (314) 362-3333 twhitfield@wustl.edu
Health Care Administrator	**Leon S. Malmud, M.D.** CHAIRMAN	(215) 707-7074 (215) 885-0756	malmudls@tuhs.temple.edu	Dean Emeritus, Temple Univ School of Med, Temple Univ Health System	3401 N. Broad St., Philadelphia, PA 19140 Home: redacted	(215) 707-3261	Wanda Holmes (215) 707-7078 wanda.holmes@tuhs.temple.edu
Nuclear Pharmacist	**Steve Mattmuller**	(937) 298-3399 x57682 redacted cell	Steve.Mattmuller@kmcnetwork.org	Chief Nuclear Pharmacist, Dept of Nuc Med/PET, Kettering Memorial Hospital	3535 Southern Blvd., Kettering, OH 45429		
FDA Representative	**Orhan H. Suleiman, Ph.D.**	(301) 796-1471 redacted cell	orhan.suleiman@fda.hhs.gov	Senior Science Policy Advisor, Office of Oncology Drug Products, Office of New Drugs, Center for Drug Evaluation and Research (CDER), FDA	USFDA, White Oak Building 22, Room 2206, 1093 New Hampshire Ave., Silver Spring, MD 20993	(301) 796-9909	
Medical Physicist Therapy	**Bruce R. Thomadsen, Ph.D**	(608) 263-4183 (608) 263-8500 redacted cell	thomadsen@humonc.wisc.edu	University of Wisconsin-Madison, University of Wisconsin Medical School, Associate Professor	L1-1005 Wisconsin Institutes for Med Research 1111 Highland Ave Madison, WI 53705-2275 Home: redacted	(608) 262-2413	
Nuclear Cardiologist	**William A. Van Decker, M.D.**	(215) 707-3347 (215) 707-9857	vandecwa@tuhs.temple.edu	Dir of Nuc Card and Assoc Prof of Med, Temple Univ School of Med	Home: redacted 3401 N. Broad St. 945 Parkinson Pavilion Philadelphia, PA 19140	(215) 707-3946	Tanya Santiago 215-707-9587 tanya.santiago@tuhs.temple.edu
Radiation Oncologist	**James S. Welsh, M.D.**	(715) 422-7725 redacted cell	welsh@humonc.wisc.edu	Med Dir, UW Cancer Center, Riverview	410 Dewey St., P.O. Box 8080, Wisconsin Rapids, WI 54495-8080 Home: redacted	(715) 421-7408	Barbara Schmalz (715) 422-7725 schmba@rhahealthcare.org
Radiation Oncologist Gamma Knife	**VACANT**						
Medical Physicist Nuclear Medicine	**VACANT**						

1.183, "Alternative Radiological Source Terms for Evaluating Design Basis Accidents at Nuclear Power Reactors," dated July 2000.

Therefore, the separation of the MS Pathway from the other containment leakage pathways is warranted because a separate radiological consequence term has been provided for these pathways. The revised design-basis radiological consequences analyses address these pathways as individual factors, exclusive of the primary containment leakage. Therefore, the NRC staff finds the proposed exemption from Appendix J, to separate MS leakage from other containment leakage, to be acceptable.

3.0 Discussion

Pursuant to 10 CFR 50.12, the Commission may, upon application by any interested person or upon its own initiative, grant exemptions from the requirements of 10 CFR Part 50 when (1) the exemptions are authorized by law, will not present an undue risk to public health or safety, and are consistent with the common defense and security; and (2) when special circumstances are present. The licensee's exemption request was submitted with a license amendment request to use the alternative source term methodology for use in calculating the dose consequences of the design-basis loss-of-coolant accident analysis. The NRC staff will issue the proposed amendment in conjunction with the exemption. The exemption and amendment together would implement the alternative source term methodology. The special circumstances associated with the MS Pathway leakage testing are fully described in the licensee's application dated October 13, 2008, as supplemented by letters dated April 8, May 29, June 12, and September 1, 2009, and discussed below.

Authorized by Law

This exemption would permit exclusion of the MS Pathway leakage contribution from the overall integrated leakage rate Type A test measurement and from the sum of the leakage rates from Type B and Type C tests. As stated above, 10 CFR 50.12 allows the NRC to grant exemptions from the requirements of 10 CFR Part 50. The NRC staff has determined that granting of the licensee's proposed exemption will not result in a violation of the Atomic Energy Act of 1954, as amended, or the Commission's regulations. Therefore, the exemption is authorized by law.

No Undue Risk to Public Health and Safety

The underlying purposes of 10 CFR Part 50, Appendix J, Option B, Sections III.A and III.B are to ensure that containment leak-tight integrity is maintained (a) as tight as reasonably achievable and (b) sufficiently tight so as to limit effluent release to values bounded by the analyses of radiological consequences of design-basis accidents. Based on the above, no new accident precursors are created by exclusion of the MS Pathway leakage contribution from the overall integrated leakage rate Type A test measurement and from the sum of the leakage rates from Type B and Type C tests, thus, the probability of postulated accidents is not increased. Also, based on the above, the consequences of postulated accidents are not increased. Therefore, there is no undue risk to public health and safety.

Consistent With Common Defense and Security

The proposed exemption would exclude the MS Pathway leakage contribution from the overall integrated leakage rate Type A test measurement and from the sum of the leakage rates from Type B and Type C tests. This change to the operation of the plant has no relation to security issues. Therefore, the common defense and security is not impacted by this exemption.

Special Circumstances

Special circumstances include, in part, the special circumstances defined in 10 CFR 50.12(a)(2)(ii), which states, "Application of the regulation in the particular circumstances would not serve the underlying purpose of the rule or is not necessary to achieve the underlying purpose of the rule."

The underlying purpose of 10 CFR Part 50, Appendix J, is to ensure that containment leak-tight integrity is maintained as tight as reasonably achievable and sufficiently tight so as to limit effluent release to values bounded by the analyses of radiological consequences of design-basis accidents. The intent of the rule is not compromised by the licensee's proposed action because the containment leak rates will continue to be limited by CNS's TSs. The proposed action will appropriately permit ALT pathway leakage to be independently grouped with its unique leakage limits and maintain the accident dose analyses consequences within the acceptance criteria of 10 CFR 50.67.

Therefore, since the underlying purposes of 10 CFR Part 50, Appendix J, is achieved, the special circumstances required by 10 CFR 50.12(a)(2)(ii) for the granting of an exemption from 10 CFR Part 50, Appendix J, Option B, Sections III.A and III.B exist.

4.0 Conclusion

Accordingly, the Commission has determined that, pursuant to 10 CFR 50.12, the exemption is authorized by law, will not present an undue risk to the public health and safety, and is consistent with the common defense and security. Also, special circumstances are present. Therefore, the Commission hereby grants NPPD an exemption (1) from the requirements of 10 CFR Part 50, Appendix J, Option B, Section III.A, to allow exclusion of the MS Pathway leakage from the overall integrated leakage rate measured when performing a Type A test; and (2) from the requirements of 10 CFR Part 50, Appendix J, Option B, Section III.B, to allow exclusion of the MS Pathway leakage from the combined leakage rate of all penetrations and valves subject to Type B and C tests for CNS.

Pursuant to 10 CFR 51.32, the Commission has determined that the granting of this exemption will not have a significant effect on the quality of the human environment (74 FR 47030; September 14, 2009).

This exemption is effective upon issuance.

Dated at Rockville, Maryland, this 14th day of September 2009.

For the Nuclear Regulatory Commission.

Joseph G. Giitter,

Director, Division of Operating Reactor Licensing, Office of Nuclear Reactor Regulation.

[FR Doc. E9–22600 Filed 9–18–09; 8:45 am]

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NUCLEAR REGULATORY COMMISSION

Advisory Committee on the Medical Uses of Isotopes: Meeting Notice

AGENCY: U.S. Nuclear Regulatory Commission.

ACTION: Notice of meeting.

SUMMARY: NRC will convene a meeting of the Advisory Committee on the Medical Uses of Isotopes (ACMUI) on October 19–20, 2009. A sample of agenda items to be discussed during the public session includes: (1) International Commission on Radiological Protection (ICRP) Publication103 subcommittee report and discussion; (2) update on permanent prostate brachytherapy medical events; (3) update on results from the Society of Nuclear Medicine

(SNM) on the medical isotope shortage; (4) new security regulations in 10 Code of Federal Regulations (CFR) part 37; (5) potential changes to 10 CFR part 35; (6) medical uses of radium-223; (7) information on the regulatory responsibilities of the U.S. Food and Drug Administration; (8) summary of the enforcement process and enforcement actions against medical licensees; and (9) medical-related events. A copy of the agenda will be available at *http://www.nrc.gov/reading-rm/doc-collections/acmui/agenda* or by e-mailing Ms. Ashley Cockerham at the contact information below.

Purpose: Discuss issues related to 10 CFR part 35 Medical Use of Byproduct Material.

Date and Time for Closed Session: October 19, 2009, from 8 a.m. to 10 a.m. This session will be closed so that ACMUI can review and discuss evaluations, receive annual training, and discuss internal Committee business.

Date and Time for Open Sessions: October 19, 2009, from 10:15 a.m. to 4:45 p.m. and October 20, 2009, from 8 a.m. to 12 p.m.

Address for Public Meeting: U.S. Nuclear Regulatory Commission, Executive Boulevard Building (EBB01–B13/15), 6003 Executive Boulevard, Rockville, Maryland 20852.

Public Participation: Any member of the public who wishes to participate in the meeting should contact Ms. Cockerham using the information below.

Contact Information: Ashley M. Cockerham, e-mail: *ashley.cockerham@nrc.gov*, telephone: (240) 888–7129.

Conduct of the Meeting

Leon S. Malmud, M.D., will chair the meeting. Dr. Malmud will conduct the meeting in a manner that will facilitate the orderly conduct of business. The following procedures apply to public participation in the meeting:

1. Persons who wish to provide a written statement should submit an electronic copy to Ms. Cockerham at the contact information listed above. All submittals must be received by October 9, 2009, and must pertain to the topic on the agenda for the meeting.

2. Questions and comments from members of the public will be permitted during the meeting, at the discretion of the Chairman.

3. The draft transcript will be available on ACMUI's Web site (*http://www.nrc.gov/reading-rm/doc-collections/acmui/tr/*) on or about November 23, 2009. A meeting summary will be available on ACMUI's Web site (*http://www.nrc.gov/reading-rm/doc-collections/acmui/meeting-summaries/*) on or about December 2, 2009.

4. Persons who require special services, such as those for the hearing impaired, should notify Ms. Cockerham of their planned attendance.

This meeting will be held in accordance with the Atomic Energy Act of 1954, as amended (primarily section 161a); the Federal Advisory Committee Act (5 U.S.C. App); and the Commission's regulations in Title 10, *U.S. Code of Federal Regulations*, part 7.

Dated: September 16, 2009.

Andrew L. Bates,

Advisory Committee Management Officer.

[FR Doc. E9–22599 Filed 9–18–09; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

Sunshine Federal Register Notice

AGENCY HOLDING THE MEETINGS: Nuclear Regulatory Commission.

DATES: Week of September 21, 2009.

PLACE: Commissioners' Conference Room, 11555 Rockville Pike; Rockville, Maryland.

STATUS: Public and Closed.

ADDITIONAL ITEMS TO BE CONSIDERED:

Week of September 21, 2009

Tuesday, September 22, 2009

9:25 a.m. Affirmation Session (Public Meeting) (Tentative). b. Final Rule Related to Alternate Fracture Toughness Requirements for Protection Against Pressurized Thermal Shock Events (10 CFR 50.61a) (RIN 3150–A101) (Tentative).

This meeting will be Webcast live at the Web address—*http://www.nrc.gov.*

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The schedule for Commission meetings is subject to change on short notice. To verify the status of meetings, call (recording)—(301) 415–1292. Contact person for more information: Rochelle Bavol, (301) 415–1651.

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The NRC Commission Meeting Schedule can be found on the Internet at: *http://www.nrc.gov/about-nrc/policy-making/schedule.html.*

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The NRC provides reasonable accommodation to individuals with disabilities where appropriate. If you need a reasonable accommodation to participate in these public meetings, or need this meeting notice or the transcript or other information from the public meetings in another format (e.g. braille, large print), please notify the NRC's Disability Program Coordinator, Rohn Brown, at 301–492–2279, TDD: 301–415–2100, or by e-mail at *rohn.brown@nrc.gov*. Determinations on requests for reasonable accommodation will be made on a case-by-case basis.

* * * * *

This notice is distributed electronically to subscribers. If you no longer wish to receive it, or would like to be added to the distribution, please contact the Office of the Secretary, Washington, DC 20555 (301–415–1969), or send an e-mail to *darlene.wright@nrc.gov.*

Dated: September 15, 2009.

Rochelle C. Bavol,

Office of the Secretary.

[FR Doc. E9–22775 Filed 9–17–09; 4:15 pm]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

[NRC–2009–0414]

Withdrawal of Regulatory Guide 7.2

AGENCY: Nuclear Regulatory Commission.

ACTION: Withdrawal of Regulatory Guide 7.2

FOR FURTHER INFORMATION CONTACT: Thomas J. Herrity, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, telephone: 301–251–7447 or e-mail to *Thomas.Herrity@nrc.gov.*

SUPPLEMENTARY INFORMATION:

I. Introduction

The U.S. Nuclear Regulatory Commission (NRC) is withdrawing Regulatory Guide (RG) 7.2, "Packaging and Transportation of Radioactively Contaminated Biological Materials." Regulatory Guide 7.2 was published in June 1974. It provides guidance on meeting the Department of Transportation (DOT) requirements for Type A shipments of radioactively contaminated biological materials. It also recommends appropriate packaging and limits on the radioactive contents for any single package of this type of material, marking and labeling of packages, and limitations on storage of the packaged material before, during, and after transport. The NRC is withdrawing RG 7.2 because the guidance it provides is outdated.

The regulations for transport of hazardous materials are currently in 49 CFR Part 173 Subpart I. The DOT's