

United States Nuclear Regulatory Commission

# Advisory Committee on the Medical Uses of Isotopes

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October 20-21, 2010

**ADAMS**



**Thursday, October 21, 2010  
CLOSED SESSION**

- 8:00 – 8:30 **12. Allegation Training** **A. Cockerham, NRC**  
Ms. Cockerham will provide annual allegations training for Committee members.
- 8:30 – 9:00 **13. Information Security (INFOSEC) Awareness Training** **R. Norman, NRC**  
Mr. Norman will provide annual INFOSEC training for Committee members.
- 9:00 – 9:15 **14. Ethics Training** **J. Szabo, NRC**  
Mr. Szabo will provide annual ethics training for Committee members.
- 9:15 – 9:30 **15. Escort Training** **M. Rodriguez, NRC**  
Mr. Rodriguez will provide escort training for Committee members.
- 9:30 – 10:30 **16. ACMUI Badges** **A. Cockerham, NRC**  
ACMUI members will enroll for and activate new NRC badges.
- 10:30 – 11:00 **17. Policy & Procedure – ACMUI** **DB. Howe & N. Bhalla, NRC**  
**Interactions with Staff For Major Medical Policy**  
Dr. Howe and Ms. Bhalla will discuss the draft procedure for ACMUI interactions with staff for major medical policy.

**OPEN SESSION**

- 11:00 – 11:15 **18. 10 CFR Part 37 Rulemaking & Guidance** **M. Horn, NRC**  
Ms. Horn will provide updates on the Part 37 rulemaking and guidance.
- 11:15 – 11:45 **19. Overview of the NRC's Initiatives on the Use of Cesium-137 Chloride Radiation Sources** **J. Jankovich, NRC**  
Mr. Jankovich will provide information on the draft policy statement regarding the protection of cesium chloride radiation sources.
- 11:45 – 12:45 **LUNCH**
- 12:45 – 2:15 **20. Patient Release Subcommittee Report** **S. Langhorst, ACMUI**  
Dr. Langhorst will present the subcommittee's views on patient release issues.
- 2:15 – 2:45 **BREAK**
- 2:45 – 3:30 **21. Medical Related Events** **DB. Howe, NRC**  
Dr. Howe will provide the latest information on medical related events.
- 3:30 – 4:00 **22. Further Considerations on Options to Revise Radiation Protection Regulations & Guidance** **D. Cool, NRC**  
Dr. Cool will discuss the next steps for potential changes to 10 CFR Parts 20 and 50.
- 4:00 – 4:30 **23. Safety Culture Policy Statement** **M. Schwartz & K. Thompson, NRC**  
NRC staff will provide the revised draft policy statement on Safety Culture and will discuss plans for developing the final policy statement
- 4:30 – 5:00 **24. Administrative Closing** **A. Cockerham, NRC**  
Ms. Cockerham will provide a meeting summary and propose dates for the next meeting.

5:00

**ADJOURN**

**Advisory Committee on the Medical Uses of Isotopes October 2010 Meeting  
Attendance List**

**NRC**

1. Rob Lewis Director, Division of Materials Safety and State Agreements
2. Chris Einberg Branch Chief, Radioactive Materials Safety Branch
3. Ashley Cockerham ACMUI Coordinator
4. Kimyata Morgan Butler, Ph.D. NRC staff
5. Andrea Cock NRC staff
6. Mark Banks NRC staff
7. Neelam Bhalla NRC staff
8. Marc Ferdas NRC staff
9. James Firth NRC staff
10. Michael Fuller NRC staff
11. Patricia Holahan, Ph.D. NRC staff
12. Vincent Holahan, Ph.D. NRC staff
13. Sophie Holiday NRC staff
14. Donna-Beth Howe, Ph.D. NRC staff
15. John Jankovich, Ph.D. NRC staff
16. Varughese Kurian NRC staff
17. Jose Ibarra NRC staff
18. Robert Norman NRC staff
19. Kevin O'Sullivan NRC staff
20. Patricia Pelke NRC staff
21. Michael Rodriguez NRC staff
22. Maria Schwartz NRC staff
23. John Szabo NRC staff
24. Catherine Thompson, Ph.D. NRC staff
25. Ron Zelac, Ph.D. NRC staff

**ACMUI**

1. Darrell Fisher, Ph.D. Member
2. Debbie B. Gilley Member
3. Milton S. Guiberteau, M.D. Representative
4. Susan M. Langhorst, Ph.D. Member
5. Steve R. Mattmuller Member
6. Christopher J. Palestro, M.D. Member
7. John H. Suh, M.D. Member
8. Orhan H. Suleiman, Ph.D. Member
9. Bruce R. Thomadsen Ph.D. Vice Chairman, acting Chair
10. William A. Van Decker, M.D. Member
11. James S. Welsh, M.D. Member
12. Pat Zanzonico, Ph.D. Member

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ACMUI VISITOR LIST

OCTOBER 20, 2010

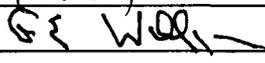
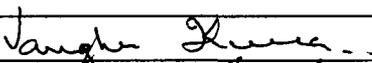
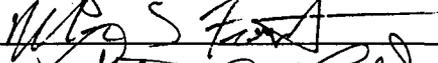
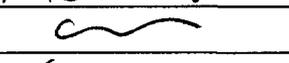
NAME	ORGANIZATION	SIGNATURE
Acevedo, Andre	Johns Hopkins	
Adler, Dave	ASTRO	(attended)
Browder, Rachel	NRC RIV	
Brown, Roy	CORAR	
Bukovcan, Janet	MDS Nordion	
Chidakel, Susan	NRC/OGC	
Choi, Simon	FDA	
Colangeli, Grace	Johns Hopkins	
Crane, Peter		
Dansereau, Robert	NY	
Davidson, Will	University of Pennsylvania	
Deye, James A.	NIH	(attended)
Ditch, Calvin	Johns Hopkins	
Flannery, Cindy	NRC/FSME	
Florian, Carol	Symetosphere	
Gabriel, Sandy	NRC RI	
Green, Heather	Johns Hopkins	
Katanic, Janine	NRC RIV	
Lloyd, Jessica	SNM	(attended)
Martin, Richard J.	ASTRO	
Morgan, Mary	Johns Hopkins	
Nance, Jim	Symetosphere	
Peters, Michael	ACR	
Phung, Nguyen	Johns Hopkins	
Potters, Louis	NSUH and LIJ Medical Center	
Puka, Jacob	Johns Hopkins	



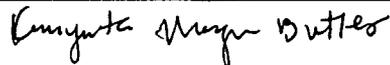
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Choi, Simon	FDA	
Crane, Peter		(attended)
Dansereau, Robert	NY	
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Florian, Carol	Symetosphere	
Gabriel, Sandy	NRC RI	
Katanic, Janine	NRC RIV	
Langley, Karen	Univ of UT	
Lloyd, Jessica	SNM	(attended)
Martin, Richard J.	ASTRO	
Nance, Jim	Symetosphere	
Peters, Michael	ACR	
Potters, Louis	NSUH and LIJ Medical Center	
Romanelli, Gloria	ACR	(attended)
Soltycki, Eric	AEHN	(attended)
Sutlief, Steven G.	VA	
Warbick-Cerone, Ann	MDS Nordion	(attended)
Weber, Mike	NRC/OEDO	
Wilkes, Jenna M.	ASNC	(attended)
Williams, Gary E.	VA NHPP	
Wilson, Emily	ASTRO	
Wolff, Sandy J.	Sentara	
KUR, AN, VARUGHESE	NRC	
Ferdas, Marc	NRC, RI	
PELKE, FRANCIS	NRC RTI	
Mark Banks	NRC OIG	
Andres Kocel	NRC/OCM	

Kimyata Morgan Butler NRC/FSME







## **Patient Event Database**

**Promises and Challenges**  
**Bruce Thomadsen**  
**Ben-Tzion Karsh**

### **Radiotherapy Database Needs**

- 1. Consolidation of event databases**
  - Obviously to reduce redundant effort.
  - To increase information on events.
  - To facilitate research on prevention.
  - To get a better estimate of numbers
- 2. A unified taxonomy.**

### **Radiotherapy Database Needs**

- Require cooperation among groups
- Experts who have worked on database taxonomies.
- A poor taxonomy, such as used in *all* the existing databases *greatly* reduces the utility of the data.
- There is a multi-institutional group working on this now, but unofficial

### **Radiotherapy Database Needs**

- 3. A carefully crafted, smart data entry method designed by experts AND users. (Nothing kills a reporting system faster than a bad interface.)**
- 4. Carefully chosen data**
  - Many types of information are necessary to address problems.

### **Nuclear Regulatory Commission Database**

- For looking at things that the regulators need.
- Entered by the NRC investigator, who often does not understand the clinical or physical aspects of the case well.
- The licensee may not be completely forthcoming.

### **Where is NMED Lacking?**

- All of the procedural information is in the free text, which is not useful, is incomplete and often inaccurate.
- There is little information on the case and confounding circumstances.
- There *is* the general description of the type of treatment approach (e.g. HDR afterloader.)

### **Radiotherapy Database Needs**

#### **5. Regulations that allow and require reporting.**

- **Currently, most states have laws that prohibit release of any information on events that will have a RCA performed, which would be many events that should be entered into this database.**

### **Radiotherapy Database Needs**

#### **6. Incentive.**

- **The airlines crafted a method to exempt from discipline those involved in incidents and hazardous activities *if* they report to the database immediately.**
- **This worked very well and improved safety greatly.**

### **Incentive**

- **The incentives are absences of punishment.**
- **This would take a change in culture among regulatory bodies preferring patient safety to punishment.**

### **Conclusion**

- **Radiotherapy needs a discipline-wide, consolidated reporting system.**
- **The system needs a carefully drafted taxonomy and data-entry methodology.**
- **The regulatory culture needs to shift focus from punishing errors to making radiotherapy safer.**



## Byproduct Material Events Subcommittee Report Oct 2010

James Welsh  
Debbie Gilley, Susan Langhorst,  
Steve Mattmuller, Orhan Suliman,  
Bruce Thomadsen

### Background

- The subcommittee has reviewed the NMED database and tabulated the medical events
- The Subcommittee understands the desired aims of:
  - Identifying trends and causes
  - Coming up with possible solutions

2

### Subcommittee Findings:

- However this admirable goal is not truly possible with only the raw data in NMED
- An obvious limitation is the absence of denominators
- As an extreme example:
  - Events from procedure  $x = 10$  per year
  - Events from procedure  $y = 5$  per year
  - Therefore  $x=2y$
  - But there are 1,000,000  $x$  procedures and 100  $y$  procedures annually...

3

### Subcommittee Findings:

- So unless the denominators are available, trends can't be accurately identified
- Educated guesses can be made by clinicians and estimates can be made based on data from 2006
  - But these are only educated estimates and could be quite far off
  - Accurate figures can be obtained through IMV and maybe others (e.g. CORAR, Arlington)
  - But at a price! Question: How do THEY get this?

4

### Subcommittee Findings:

- Can NRC and the Agreement States obtain this data?
  - Initially it might seem very easy to just ask the licensees to simply provide the numbers of procedures done per year
  - But the fact is that licensees will likely NOT provide these numbers unless required (not everyone was sure of this statement)
  - Is regulatory requirement the best use of resources?

5

### Subcommittee Findings:

- The debate regarding how and at what cost it might be to obtain the denominators so that true incidence rates can be obtained
  - What do we truly gain from this?
  - Is it worth a thousand dollars?
  - Will this really help achieve our goals?
  - If we learn something and reduce the number of Medical Events next year by just one... it might be worth it!

6

### Subcommittee Findings:

- Additionally, true incidence rates can help in allocation of resources and training dollars
- For example if we learn that the incidence of Medical Events from procedure *x* was far higher than procedure *y*, States might be able to direct training from *y* to *x* with justification based on actual data

7

### Subcommittee Findings:

- But if the cost in manpower and dollars is more, resources might be better spent differently
  - e.g. assuring that written directives are followed through some validated tool (which of course would also cost a bit in terms of manpower and cash)
- Will things become far easier when everyone moves to full electronic records?
- Should we position ourselves now for when that day comes?
- Many not be as hard as we think...?

8

### Subcommittee Findings:

- One member identified a possible trend in radiopharmaceuticals of failure to carefully and systematically verify that the amount of radiation to be administered just prior to administration
- A suggestion was made that written directives include a checkbox to verify that the amount of radioactivity about to be administered is indeed correct
- Other simple ideas to reduce medical events were suggested such as checklists
  - But should such advice become regulation?

9

### Nuclear Medicine Byproduct Events (Reported Between 10/1/08-9/30/09)

- Diagnostic: 2
- Therapeutic (35.300): 5 (down from 15 in 2008 and 7 in 2007)
  - I-131: 4 (vs 7 in 2008)
  - Sm-153: 0 (vs 8 in 2008)
  - Y-90: 0
  - Sr-89: 0
  - I-125 monoclonal antibody: 1
- Shipment Reports: 13

10

**35.600 n=13 (n=10 in FY08; 17 in 07)**

- HDR Brachytherapy: 7 (vs 8 in FY 08)
  - “Wrong location” = 3
  - “Wrong site” = 3
  - Low dose = 1
- Comments: ALL were in fact probably wrong location
- Two involved cylinders, confirming that this “simple” procedure is in fact challenging

11

**35.600**

- Gamma Knife: 6 total (vs 1 in previous period)
  - Wrong side: 2
  - Wrong location: 2 (one was secondary to mechanical failure but team decided to proceed anyway)
  - Locator box slippage: 1
  - Wrong collimator: 1
- Overall comments: Lack of proper oversight
  - No Teletherapy, Intravascular or others (1 teletherapy in FY2008)

12

### 35.400

- **Total = 26 Events (27 patients)**
  - **Contrasts with 10 Events involving 114 patients between 10/1/07 – 9/30/08**
  - **Y-90 microspheres: 9**
  - **Permanent prostate brachytherapy: 17 (one event from 2005 at DVA LA reported in this period involved two patients with seeds located outside target)**

13

### 35.400 Comments

- **Some based on dose (e.g. D90) and number of seeds outside prostate**
  - **Would these be medical events if we used activity or source strength?**

14

### 35.400 Comments

- **Majority (8/9) of Y-90 microsphere medical events were under dosings**
  - **Causes included technical failures**
    - (e.g. 3-way stopcock leakage, catheter occlusion due to a blood clot, leakage at puncture site of the vial septum)
- **Several due to microspheres not getting into patient because they adhered to vial septum after inversion (including during transport)**
  - **Manufacturer suggested shaking and tapping if vial was inverted and microspheres could be adherent to rubber septum**

15

### Conclusions

- **Subcommittee suggests that further improvements to NMED searching be made to make it more efficient**
- **To achieve the real goals of drawing conclusions about trends, identifying truly high-risk procedures, providing meaningful feedback to NRC and users, etc, dominators are needed**
  - **Without this, the value of this exercise is questionable**

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# Medical Isotope Shortage: Update

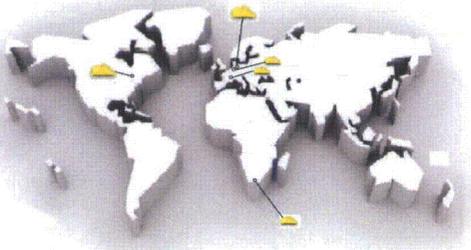
Steve Mattmuller, MS, RPh, BCNP

## Need: Patient Care



2

## Fragile Mo-99 Supply



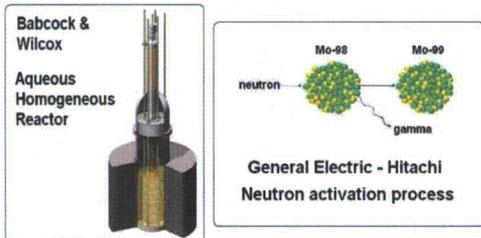
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## Affect on Patients



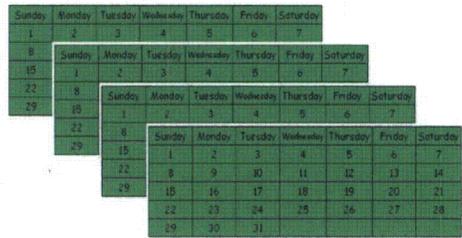
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## Long Term Solution



5

## Goal: Optimal Patient Care



6



## **Briefing on Review of Patient Release Issues 10 CFR 35.75**

**October 20, 2010**

**Susan M. Langhorst, Ph.D.**

Advisory Committee on the Medical Uses of Isotopes

## **Subcommittee Charge**

### **Evaluate patient release issues**

- Objectively review and analyze data, regulations/guidance, and international recommendations
- Provide statement on issues, including -
  - Release to other than private residence
  - Per-release limit vs. annual limit
- Recommend needed changes/improvements

2

## **Statement**

### **Dose to other individuals is safely and cost-effectively controlled by -**

- Current 10 CFR 35.75 release criteria
- Scientifically developed, dose-based release calculation methods and physician assessment of patient release suitability
- Patients' and caregivers' understanding of and adherence to release instructions on maintaining dose to others ALARA

3

## **Fundamental principles for use of radioactive materials**

- Justification
- Optimization of Protection (ALARA) - account for economic and societal as well as medical factors
- Application of Dose Limits

4

## **Statements**

### **Current release criteria appropriately balance safety, access to treatment and cost**

- Consistent with national and international recommendations in principle/practice
  - 5 mSv/episode for caregivers/relatives
  - 1 mSv/y for child/pregnant woman/public
- Apply to single releases - not annual limit
- Focus on patient precautions to maintain dose to others ALARA

5

## **Statements**

### **Concerning a return to previous NRC patient release criteria - "30 mCi rule"**

- Has no identifiable scientific basis
- Excessive for some radionuclides and inadequate for other radionuclides
- Does not account for patient actions
- Specifically not recommended as sole release criterion by ICRP and IAEA
- Inappropriate for NRC regulations

6

## Recommendations

### NRC guidance on patient release dose calculation

- Update with current information and realistic assumptions
- Support development of computer-based calculation tools available to licensees
- Address different patient living and other release situations

7

## Recommendations

### NRC guidance on patient release instructions

- Incorporate new release calculation information, use new communication tools
- Support research efforts to advance understanding and communication of circumstances that impact patient release decisions, instructions and perceptions

8

## Conclusions

- Medical use is important – benefits millions of patient lives each year
- 10 CFR 35.75 should not be changed
- NRC should focus on providing
  - Appropriate/realistic guidance for licensees and patients
  - Research support for understanding and communication of the real-world issues impacting patient care and public safety

9

## Acronyms

- ALARA – As low as reasonably achievable
- CFR – Code of Federal Regulations
- IAEA – International Atomic Energy Agency
- ICRP – International Council on Radiological Protection
- 1 mSv – 1 millisievert = 100 mrem
- NRC – Nuclear Regulatory Commission
- Patient – includes clinical patients and human research subjects

Acknowledgements: D. Fisher, D. Gilley, S. Mattmuller, O. Suleiman, B. Thomadsen, J. Welsh, P. Zanzonico

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Johns Hopkins University Hospital, Nuclear Medicine-Outpatient Center

Topic: Medical Isotope Shortages and Release of Patients Treated with I-131

**Tony Seibert**, Ph.D., FAAPM, President-Elect American Association of Physicists in Medicine, Radiology Department of UC Davis Medical Center **5 mins.\***

Center

Topics: Medical Event Data Reporting, Part 35 Updates, and Medical Isotope Shortages

**Commission Q & A** **30 mins.**

**Break** **5 mins.**

**NRC Staff** **30 mins.\***

**Bill Borchardt**, Executive Director for Operations

**Josephine Piccone**, Ph.D., Director, Division of Intergovernmental Liaison and Rulemaking, FSME

**James Luehman**, Deputy Director, Licensing and Inspection Support Directorate, Division of Materials Safety and State Agreements, FSME

Also at the table- not making presentations, but to answer questions:

**Neelam Bhalla**, Sr. Project Manager, Division of Intergovernmental Liaison and Rulemaking, FSME

**Ronald Zelac**, Ph.D., Sr. Health Physicist, Division of Materials Safety and State Agreements, FSME

Topics:

- Part 35 Rulemaking Issues (modify training and experience attestation requirements; expand grandfathering to authorized status for selected board-certified individuals who were not named on a license before 10/25/05; Assistant Radiation Safety Officers, etc.)
- Staff Perspective on Patient Release

**Commission Q & A** **30 mins.**

**Discussion – Wrap-up** **5 mins.**

\*For presentation only and does not include time for Commission Q & A's

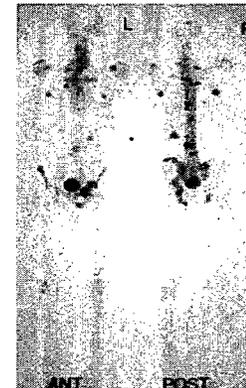


# **Medical Isotope Shortage: Update**

**October 20, 2010**

**Steve Mattmuller, MS, RPh, BCNP**

## **Need: Patient Care**



## Fragile Mo-99 Supply



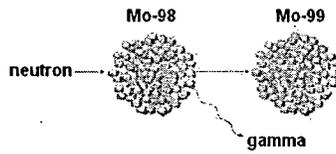
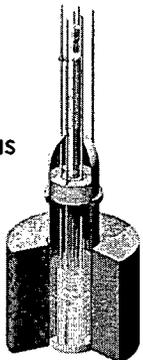
## Effect on Patients

JUNE 2009							OCTOBER 2009							FEBRUARY 2010							JUNE 2010						
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12	13	14	15	16	17	18	15	16	17	18	19	20	21	14	15	16	17	18	19	20	11	X	13	X	15	16	17
19	20	21	22	23	24	25	22	23	24	25	26	27	28	21	X	23	X	25	X	27	18	X	20	X	22	X	24
26	27	28	29	30	31		29	30						28	29	30	31				25	X	27	29	30	31	
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16	17	18	19	20	21	22	13	14	15	16	17	18	19	11	12	13	14	15	16	17	15	16	17	18	19	20	21
23	24	25	26	27	28	29	20	21	22	23	24	25	26	18	19	20	21	22	23	24	22	X	24	X	26	27	28
30	31						27	28	29	30	31		25	26	27	28	29	30	29	X	31						
SEPTEMBER 2009							JANUARY 2010							MAY 2010							SEPTEMBER 2010						
S	M	T	W	T	F	S	S	M	T	W	T	F	S	S	M	T	W	T	F	S	S	M	T	W	T	F	S
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20	21	22	23	24	25	26	17	18	19	20	21	22	23	16	X	18	X	1	X	20	19	20	21	22	23	24	25
27	28	29	30				24	25	26	27	28	29	30	23	X	25	26	1	X	20	26	27	28	29	30		
							31							30	X												

## Long Term Solution

Babcock & Wilcox

Aqueous Homogeneous Reactor



General Electric - Hitachi  
Neutron activation process

## Goal: Optimal Patient Care

Sunday	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday		
1	2	3	4	5	6	7		
8	Sunday	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday	
15	1	2	3	4	5	6	7	
22	8	Sunday	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday
29	15	1	2	3	4	5	6	7
22	8	Sunday	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday
29	15	1	2	3	4	5	6	7
22	8	9	10	11	12	13	14	
29	15	16	17	18	19	20	21	
22	23	24	25	26	27	28		
29	30	31						



**Briefing on Review of  
Patient Release Issues  
10 CFR 35.75**

**October 20, 2010**

**Susan M. Langhorst, Ph.D.**

**Advisory Committee on the Medical Uses of Isotopes**

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  - Release to other than private residence
  - Per-release limit vs. annual limit
- Recommend needed changes/improvements

## **Statement**

**Dose to other individuals is safely and cost-effectively controlled by –**

- Current 10 CFR 35.75 release criteria**
- Scientifically developed, dose-based release calculation methods and physician assessment of patient release suitability**
- Patients' and caregivers' understanding of and adherence to release instructions on maintaining dose to others ALARA**

3

## **Fundamental principles for use of radioactive materials**

- Justification**
- Optimization of Protection (ALARA) – account for economic and societal as well as medical factors**
- Application of Dose Limits**

4

## **Statements**

**Current release criteria appropriately balance safety, access to treatment and cost**

- **Consistent with national and international recommendations in principle/practice**
  - **5 mSv/episode for caregivers/relatives**
  - **1 mSv/y for child/pregnant woman/public**
- **Apply to single releases - not annual limit**
- **Focus on patient precautions to maintain dose to others ALARA**

5

## **Statements**

**Concerning a return to previous NRC patient release criteria – “30 mCi rule”**

- **Has no identifiable scientific basis**
- **Excessive for some radionuclides and inadequate for other radionuclides**
- **Does not account for patient actions**
- **Specifically not recommended as sole release criterion by ICRP and IAEA**
- **Inappropriate for NRC regulations**

6

## **Recommendations**

### **NRC guidance on patient release dose calculation**

- **Update with current information and realistic assumptions**
- **Support development of computer-based calculation tools available to licensees**
- **Address different patient living and other release situations**

## **Recommendations**

### **NRC guidance on patient release instructions**

- **Incorporate new release calculation information, use new communication tools**
- **Support research efforts to advance understanding and communication of circumstances that impact patient release decisions, instructions and perceptions**

## Conclusions

- **Medical use is important – benefits millions of patient lives each year**
- **10 CFR 35.75 should not be changed**
- **NRC should focus on providing**
  - **Appropriate/realistic guidance for licensees and patients**
  - **Research support for understanding and communication of the real-world issues impacting patient care and public safety**

## Acronyms

- **ALARA – As low as reasonably achievable**
- **CFR – Code of Federal Regulations**
- **IAEA – International Atomic Energy Agency**
- **ICRP – International Council on Radiological Protection**
- **mCi - millicurie**
- **1 mSv – 1 millisievert = 100 mrem**
- **NRC – Nuclear Regulatory Commission**
- **Patient – includes clinical patients and human research subjects**

**Acknowledgements: D. Fisher, D. Gilley, S. Mattmuller, O. Suleiman, B. Thomadsen, J. Welsh, P. Zanzonico**



**Physical Protection of  
Byproduct Material:  
Proposed Rule  
10 CFR Part 37**

**October 20, 2010**

**Debbie Bray Gilley**

**Advisory Committee on the Medical  
Uses of Isotopes (ACMUI)**

**Concerns with the Physical  
Protection Proposed Rules**

- **Impact on access to healthcare**
- **Justification of additional regulatory requirements beyond IC Orders**
- **Additional cost to licensee**
- **Implementation obstacles may impact regulatory compliance**

## **Primary Sections of Concern**

**Part 37.25 Background Checks**

**Part 37.41 Security Plans**

**Part 37.45 Coordination with Law  
Enforcement**

## **37.25 Background Investigations**

- **Reviewing Official –**
- **Collection/evaluation of personal background information**
- **Credit and criminal history information**

## April 2008 ACMUI

### Direct:

**Fingerprinting costs for one licensee:**

- Local fingerprinting: <\$50
- NRC/FBI costs: \$36
- Total per employee <\$90
- 400 employees: \$36,000

Indirect : \$40,000

**Total cost:** \$76,000

5

## Proposed Background Review Costs

### Direct

- Credit Bureau
- Local Background Checks:
- 400 employees @ \$150: \$60,000

### Indirect

\$40,000

**Proposed cost** \$100,000

6

### **37.41 Security Program Justification**

- **Security creep to Category 3 sources**
- **More medical licensees impacted**
  - **Expansion from sealed to all sources**
  - **Access program required for physical accumulation**
  - **Security program based on possession limits for prevention of co-location/aggregation of sources**

7

### **37.45 Local Law Enforcement Agency Coordination and Notification**

- **Regulatory compliance**
- **Licensees can not control LLEA activities**
- **LLEA are not likely to contact the licensees when their ability to response has been compromised**
- **Regulatory burden of frequent notifications**

8

## **ACMUI Discussion**

- **Should the regulations codify the orders?**
- **Are the proposed expanded regulatory requirements reasonable?**
- **Are the regulations understandable and flexible to continue to use the material?**
- **Do the regulations impede access to medical care or research?**

## **Acronyms**

- **ACMUI – Advisory Committee on the Medical Uses of Isotopes**
- **CFR – Code of Federal Register**
- **FBI – Federal Bureau of Investigation**
- **IC – Increased Controls**
- **LLEA – Local Law Enforcement Agency**
- **NMED – Nuclear Materials Events Database**
- **NRC – Nuclear Regulatory Commission**

## **Acknowledgement**

**Susan Langhorst, Ph.D.**



## **Byproduct Material Events Subcommittee Report**

**James Welsh  
Oct 20, 2010**

### **Background**

- **The subcommittee has reviewed the NMED database and tabulated the medical events**
- **The Subcommittee understands the desired aims of:**
  - **Identifying trends and causes**
  - **Coming up with solutions**

### **Subcommittee Findings:**

- **However this admirable goal is not possible with the raw data in NMED**
- **An obvious limitation is the absence of denominators**

3

### **Subcommittee Findings:**

- **So unless the denominators are available, trends can't be accurately identified**
- **Educated guesses can be made and estimates can be made based on data from 2006**
- **Accurate figures can be obtained**

4

### **Subcommittee Findings:**

- **Can NRC and the Agreement States obtain this data?**
- **Just ask the licensees provide the numbers**
- **Licensees will likely NOT provide these numbers unless required**
- **Is regulatory requirement the best use of resources?**

5

### **Subcommittee Findings:**

- **A possible trend in ME's involving radiopharmaceuticals: failure to verify the amount to be administered**
- **A suggestion: WD could include a checkbox**

6

## **Nuclear Medicine Byproduct Events**

- **Diagnostic: 2**
- **Therapeutic (35.300): 5 (down from 15 in 2008 and 7 in 2007)**
- **Shipment Reports: 13**

7

**35.600**

- **HDR Brachytherapy: 7 (vs 8 in FY 08): “Wrong location” = 3; “Wrong site” = 3; Low dose = 1**
- **Gamma Knife: 6 total (vs 1 in previous period)**
- **No Teletherapy, Intravascular or others (1 teletherapy in FY2008)**

8

**35.400**

- **26 Events (27 patients)**
- **(Contrasts with 10 Events involving 114 patients between 10/1/07 – 9/30/08)**
- **Y-90 microspheres: 9**
- **Prostate: 17**

9

## **Conclusions**

- **Recommend further improvements to NMED**
- **Denominators are needed**
- **Without this, the value of this exercise is questionable**

10

## **Acknowledgements**

- **Debbie Gilley, Susan Langhorst,  
Steve Mattmuller, Orhan Suliman,  
Bruce Thomadsen**

## **Acronyms**

**FY – Fiscal Year**

**HDR – High Dose Rate**

**ME – Medical Event**

**NMED – Nuclear Materials Events  
Database**

**NRC – Nuclear Regulatory Commission**

**WD – Written Directive**

**Y-90 – yttrium 90**



# **Patient Event Database**

## **Promises and Challenges**

**Bruce Thomadsen, PhD**  
**Advisory Committee on the Medical Uses**  
**of Isotopes**

## **Radiotherapy Database Needs**

- 1. Consolidation of event databases**
  - **Obviously to reduce redundant effort.**
  - **To increase information on events.**
  - **To facilitate research on prevention.**
  - **To get a better estimate of numbers**
- 2. A unified taxonomy**

## **Radiotherapy Database Needs**

- **Require cooperation among groups**
- **Experts who have worked on database taxonomies.**
- **A poor taxonomy, such as used in *all* the existing databases *greatly* reduces the utility of the data.**
- **There is a multi-institutional group working on this now, but unofficial**

3

## **Radiotherapy Database Needs**

- 3. A carefully crafted, smart data entry method designed by experts AND users. (Nothing kills a reporting system faster than a bad interface.)**
- 4. Carefully chosen data**
  - **Many types of information are necessary to address problems.**

4

## **Nuclear Regulatory Commission Database**

- **For looking at things that the regulators need.**
- **Entered by the NRC investigator, who often does not understand the clinical or physical aspects of the case well.**
- **The licensee may not be completely forthcoming.**

5

## **Where is NMED Lacking?**

- **All of the procedural information is in the free text, which is not useful, is incomplete and often inaccurate.**
- **There is little information on the case and confounding circumstances.**
- **There *is* the general description of the type of treatment approach (e.g. HDR afterloader.)**

6

## **Radiotherapy Database Needs**

- 5. Regulations that allow and require reporting.**
- **Currently, most states have laws that prohibit release of any information on events that will have a RCA performed, which would be many events that should be entered into this database.**

7

## **Radiotherapy Database Needs**

- 6. Incentive.**
- **The airlines crafted a method to exempt from discipline those involved in incidents and hazardous activities *if* they report to the database immediately.**
  - **This worked very well and improved safety greatly.**

8

## **Incentive**

- **The incentives are absences of punishment.**
- **This would take a change in culture among regulatory bodies preferring patient safety to punishment.**

## **Conclusion**

- **Radiotherapy needs a discipline-wide, consolidated reporting system.**
- **The system needs a carefully drafted taxonomy and data-entry methodology.**
- **The regulatory culture needs to shift focus from punishing errors to making radiotherapy safer.**

## **Acronyms**

**HDR – High Dose Rate**

**NMED – Nuclear Materials Events  
Database**

**NRC – Nuclear Regulatory  
Commission**

**RCA – Root Cause Analysis**



## **CRCPD H-38 Committee on Radiation Medical Events**

**October 20, 2010  
Jennifer Elee, Chair**

1

## **Why is CRCPD interested in Medical Events?**

- **CRCPD represents state and local radiation programs and can host national database of medical events**
- **State programs already receive and evaluate reports of medical events**
- **State Programs license/approve physicists, therapists, physicians**
- **State programs track compliance with QA as part of the regulatory inspection**

2

## **What have we done?**

- **Initial Survey of States**
- **Special Interest Meeting**
- **Follow-up survey of state and local radiation programs regarding radiation medical events**

3

## **Initial Survey Results**

- **Responses from 29 states**
- **79.3% have adopted regulations similar to Suggested State Regulations developed by CRCPD for Radiation Safety Requirements for Linear Accelerators (Part I)**
- **70% have adopted regulations similar to SSR's for Medical Therapy (part X)**

4

## **Special Interest Meeting**

- **What would states and/or facilities be willing to report?**
- **How do current databases coincide (NMED, FDA, State) or- Single National Database?**
- **Would we be collecting for regulatory or best practice purposes?**

5

## **Follow up Survey**

- **37 responses from states, LA county and New York City**
- **97% have regulations for either RAM or machine based radiation medical event reporting**
- **92% have reporting for RAM based therapy radiation medical event reporting**
- **81% have reporting for RAM based diagnostic medical event reporting**

6

## **Follow up Survey**

- **83% have reporting for machine based therapy radiation event reporting**
  - **~130 events reported since Jan, 2009 (26 responses)**
  - **Regulations fairly consistent to SSR's**

7

## **Follow up Survey**

- **43% have reporting for machine based diagnostic x-ray radiation event reporting**
  - **~53 events reported since Jan, 2009 (12 responses)**
  - **Regulations not as consistent**

8

## **Follow up Survey**

- **Of the states and local entities responding 30% make the events easily available to the general public**
  - **Posted on the state website**
  - **Annual summary report**
- **Other states do have methods in place for the records of the events to be requested through FOIA, etc.**

9

## **Where are we?**

- **Developed a definition for a machine based radiation which includes therapy and diagnostic**
- **Held one face to face meeting and several conference calls**
- **Participated in many meetings and round tables concerning medical events**

10

## **Where are we going?**

- **Development of a reporting form for all radiation medical events**
- **Creating/expanding the definition of RAM radiation medical events especially in the diagnostic area**
- **Investigating what will it take for CRCPD to house a radiation medical events database**

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## **Summary**

- **CRCPD wants to provide a single point for states and facilities to enter events**
- **CRCPD will work with the states, federal partners, and other experts to analyze the data**
- **CRCPD will provide summaries and timely notices**

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## **ACRONYMS**

- **CRCPD-Conference of Radiation Control Program Directors**
- **QA-Quality Assurance**
- **SSR-Suggested State Regulations**
- **NMED-Nuclear Materials Events Database**
- **FDA-Food and Drug Administration**

## **ACRONYMS**

- **RAM-Radioactive Material**
- **FOIA-Freedom of Information Act**

**Gary Bloom, Executive Director,  
ThyCa: Thyroid Cancer  
Survivors' Association, Inc.  
([www.thyca.org](http://www.thyca.org))  
October 20, 2010**

- Executive Director of ThyCa: Thyroid Cancer Survivors' Association (ThyCa), a non-profit patient organization, representing more than 22,000 people.
- Thyroid cancer survivor who had 5 treatment doses of Radioactive Iodine within a 3 year period.

Thanks to James Luehman, one of this morning's speakers, who participated at this year's 13<sup>th</sup> International Thyroid Cancer Survivors' Conference on behalf of the NRC.

[www.thyca.org](http://www.thyca.org)

Why am I here?

[www.thyca.org](http://www.thyca.org)

Consider the following questions:

- What instructions are the patients given, oral and/or written?
- How does the dosing hospital determine who is safe to discharge after dosing?
- Who is released after radioactive iodine, how quickly, and after what dose?
- Do patients drive themselves home or take public transportation, exposing others?
- Do they go home or to a hotel?

[www.thyca.org](http://www.thyca.org)

What resolution would ThyCa like?

[www.thyca.org](http://www.thyca.org)

ThyCa does not advocate that everyone treated with Radioactive Iodine need be isolated for 1, 2 or 3 nights.

- Facilities need to adhere to standard instructions/questionnaires in evaluating who can or can't be released from the dosing facility.
- Facilities need to address the issues of private housing and transportation versus commercial.

[www.thyca.org](http://www.thyca.org)

ThyCa recently developed an online survey with regards to RAI issues.

- presented to 15,000 survivors
- 2,421 participants responded
- 1,551 had one or more outpatient RAI
- 147 of the 1,483 who answered had vomiting (9.95%)
- 67 participants (4.5%), reported vomiting within the first 4 hours of I-131

[www.thyca.org](http://www.thyca.org)

Compromise between immediate release and overnight (or longer) isolation is holding people for a period of hours before release to insure no nausea and/or vomiting. For most patients, holding the patient for 3-4 hours will ensure that the RAI has been absorbed. NCRP 155 addressed this very option.

[www.thyca.org](http://www.thyca.org)

It is time for action!

- Update standard written instructions to be easier to read, and understand
- Make instructions available in a number of languages for the same reason
- Develop a script for oral instructions. This redundant effort is necessary.
- Consider different languages, and level of understanding (keeping in mind the patient may be extremely hypothyroid).

[www.thyca.org](http://www.thyca.org)

I invite all of you to join us at next year's 14<sup>th</sup>  
International Thyroid Cancer Survivors'  
Conference:

Los Angeles, California

October 14-16, 2011

Interested in attending? Contact me at:  
[gbloom@thyca.org](mailto:gbloom@thyca.org), or 301-943-5419.

[www.thyca.org](http://www.thyca.org)



***Medical Isotope Shortage,  
Patient Release &  
Occupational Exposure  
Criteria***

***October 20, 2010***

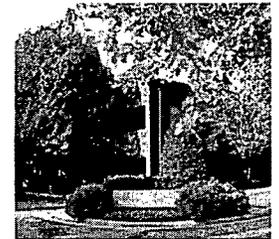
***Richard L. Wahl, MD***

***Society of Nuclear Medicine***



**SNM Overview**

- Founded in 1954
- The largest international scientific organization dedicated to molecular imaging and therapy
- A multi-disciplinary organization
  - over 16,000 physicians, scientists, pharmacists, and technologists
  - industry and other partners interested in the diagnostic, therapeutic, and investigational uses of molecular imaging and therapy agents, instrumentation and techniques





## Richard Wahl, MD, FACR

- Director of Nuclear Medicine/PET  
Vice-Chair of New Technology and Business Development  
Henry N Wagner, Jr Professor of Nuclear Medicine  
Professor of Radiology and Oncology  
Russell H Morgan Department of Radiology and Radiological Sciences  
John Hopkins University
- MD, Washington University, St Louis MO  
Board-Certified: Diagnostic Radiology and Nuclear Medicine
- Pioneered use of FDG-PET imaging in cancer and PET/CT fusion
- Inventor, 12 patents including 2 for FDA-approved radioimmunotherapy drugs for lymphoma.
- Over 320 journal articles, 30 book chapters, 4 books, Over 400 invited lectures



## Medical Isotope Shortage

- With shortage of Tc99m patients had studies cancelled, lower quality studies substituted, some received higher (or lower) radiation dose study, clinical and economic implications.
  - Next shut down may be the last
  - No clear path towards domestic production for the 16 million Tc-99m clinical procedures in the US annually
- 2 non US reactors on which the US depends for the Mo-99 parent of Tc99m have recently re-started but are "ancient" by reactor standards.
- NRC should expedite applications for construction of Mo-99 production reactors.
- NRC should develop a plan for expediting such applications before applications are submitted.
- Infrastructure should be in place to implement the expedited review process.
- An urgent public health issue at the national level.

## Patient Release Criteria

- Current regulations: *Allow* patient release after determination that the patient can comply with safety instructions, restrictions etc given by medical professionals.
- Extensive peer-reviewed data show it quite straightforward to calculate and control the radiation risk to bystanders or that this risk is excessive.
- In addition to undermining public health by basing release on activity rather than dose, the proposed rules drive up health care costs without any evidence-based rationale.
  - Some hospitals cannot accommodate radioactive patients so radioisotope therapy may be made unavailable or may be performed less effectively - as multiple low-activity administrations - simply to avoid hospitalization.
  - Patients without access to isotope therapy will need less effective, higher-risk treatments such as deforming surgery or potentially toxic drugs.
  - Hospitalizing otherwise healthy patients unnecessarily exposes them to hospital-based infections and risks including antibiotic-resistant bacteria.
  - Data, including from EANM 2010, show exposure to public as well as to caregivers from patients is already LOW.

## Radiation Worker Exposure

- Current guidelines: *Allow* radiation workers in medicine to safely and cost-effectively deliver valuable and medically essential procedures to patients with cancer, thyroid disease, heart disease etc
- ALARA for occupational workers universally applied
- Exposure is sometimes unavoidably greater with very ill patients whose procedures take longer than expected
- Reducing occupational exposure potentially jeopardizes care to patients
- Proposed reduction of 50 mSv/year to 20 mSv/year is not based on firm scientific evidence (ie no demonstrated excess cancer risk at 50 mSv/year)
- Every effort should be made to minimize radiation worker exposure, and current regulations accomplish this and appropriately balance patient benefit and provider safety as well as cost
- Recommendation: Keep current safe exposure limit of 50 mSv/year

### Summary:

- Reliable domestic supply of Tc-99m is essential for 16 million patient studies/year in the US. NRC requested to provide prompt yet safe facilitation of new facility licensure.
- Patients must have access to radiopharmaceutical therapies. Current guidelines for patient release are safe and allow the treatments to be given throughout the US. NRC should keep current guidelines for release.
- Radiation exposure of radiation workers is essential for health care delivery. NRC should keep current safe exposure limit of 50 mSv/year.

### For further information

Jessica Lloyd  
Coordinator, Health Policy & Regulatory  
Affairs, SNM  
1850 Samuel Morse Drive  
Reston, VA 20190  
Phone: 703.326.1193  
Email: [JLloyd@snm.org](mailto:JLloyd@snm.org)

## Medical Issues

J. Anthony Seibert, Ph.D., FAAPM, FACR

President-elect

American Association of Physicists in Medicine

October 20, 2010



## AAPM

- Is the the premier organization in medical physics; a broadly-based scientific and professional discipline encompassing physics principles and applications in biology and medicine whose mission is to advance the science, education and professional practice of medical physics.
- Represents over 7,300 medical physicists.



## Event Reporting

- Event reporting in a national system is essential.
- Must be modality independent, easy to use, universal, anonymous, and non-punitive.
- Must be able to collect potential and actual event data completely and efficiently.
- Data on medical errors is essential to conduct a trend analysis, make assessments, inform the community, and make improvements.



## Nuclear Materials Event Database (NMED)

- Not publically accessible
- Only includes radioactive materials
- Doesn't currently allow for trend analysis



## Ritenour Petition PRM-35-20

- Petition was filed on September 10, 2006 by AAPM
- NRC published it in the Federal Register November 1, 2006 (71FR64168)
- Decision published May 14, 2008 (73FR27773)
- Request to the certifying boards for additional information for regulatory basis closed January 15, 2009



## Ritenour Petition PRM-35-20 (continued)

- NRC prepared a regulatory basis document.
- Reviewed by rulemaking staff and found sound.
- Without a regulatory change, this continues to be a problem for listing authorized medical physicists (AMPs) and radiation safety officers, authorized users and authorized nuclear pharmacists
- Impacts negatively on approximately 2,000 AMPs
- Four years later, still don't have final regulatory resolution.



## Isotope Shortage

- A continuous reliable supply of medical radioisotopes is essential.
- AAPM supports *the American Medical Isotope Production Act of 2010*
- Without a reliable US supply of Tc-99, use of alternative radioisotopes can result in increased occupational doses to technologists and may not result in gold standard of care being available for all patients.



## Isotope Shortage

- AAPM acknowledges NRC's efforts in this area and urges NRC to expedite licensing actions for new facilities to produce a US supply of medical isotopes.



Questions?





## **Briefing on Medical Issues**

**R. W. Borchardt**  
**Executive Director for Operations**  
**October 20, 2010**



## **Part 35 Rulemaking Issues**

**J. Piccone, Ph.D**  
**Director, Division of Intergovernmental  
Liaison and Rulemaking**  
**Office of Federal and State Materials and  
Environmental Management Programs**  
**October 20, 2010**

## **AGENDA**

- **Recent Part 35 revisions**
- **Current Rulemaking**
- **High Visibility Issues**
- **Impacts on Current Schedule**

## **Part 35 Revisions**

- **Revised in its entirety in 2002**
- **Training and Experience regulations in 2005**
- **8 additional Part 35 amendments**

## **Current Rulemaking**

- **Items identified through implementation of Part 35, ACMUI recommendations, and a petition for rulemaking**
- **A total of 28 specific items/issues in the expanded Part 35 rulemaking**

5

## **High Visibility Issues in Proposed Rulemaking**

- **Amend preceptor attestations**
- **Ritenour Petition (AAPM) regarding T&E requirements**
- **Frequency of Molybdenum-99m testing**
- **Naming Assistant RSOs on a medical use license**

6

## **Preceptor Attestation Revision**

- **Proposed by the ACMUI**
- **Not required for board-certified individuals prior to 2005**
- **In SRM-SECY-08-0179, the Commission approved the staff recommendations**

## **Preceptor Attestation Revision**

- **Eliminate for all board-certified individuals**
- **Revise the wording on “achievement of competency”**
- **Allow Residency program Directors to provide attestations**

## **Ritenour Petition (PRM-35-20)**

- **Petitioner requested amendment of T&E requirements for experienced AMPs and RSOs**
- **NRC resolved the petition in May 2008 and concluded that 2005 revision may have adversely affected some board-certified professionals, including AUs**

## **Ritenour Petition (cont'd)**

- **NRC staff asked all certifying boards to survey their Diplomates who are or may be affected by the 2005 T&E revision**
- **Responses indicated that about 10,000 individuals may be affected**

## **Frequency of Mo-99 Testing**

- **Current: Mo-99 breakthrough testing on 1<sup>st</sup> elution of Molybdenum-99/Technetium-99m generators**
- **Proposed: Mo-99 testing of each eluate; reporting requirement if the regulatory limit is exceeded**

## **Assistant RSOs on the License**

- **Current policy: Part 35 does not allow more than one permanent RSO on the license**
- **Regulations require licensees to appoint an RSO, who agrees in writing to implement the Radiation Safety program**

### **Assistant RSOs (cont'd)**

- **ACMUI (June 2007 meeting) expressed concern about naming only one person as the RSO**
- **ACMUI believed that it was contributing to a shortage of RSOs**

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### **Assistant RSOs (cont'd)**

- **ACMUI believes that naming more than one individual would**
  - **increase the RSO pool**
  - **duly recognize the qualified individuals**
  - **allow the licensee to quickly appoint an RSO if the named RSO leaves**

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## **Impacts on Schedule**

- **Current**

- Proposed Rule: March 2012**

- Final Rule: September 2013**

- **Incorporation of ACMUI Procedure and expanded comment periods**
- **Development of an Integrated Plan including consideration of high priority medical-related tasks**

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## **Release of Patients and the Nuclear Materials Events Database**

**James G. Luehman**

**Deputy Director, Division of Materials Safety  
and State Agreements**

**Office of Federal and State Materials and  
Environmental Management Programs**

**October 20, 2010**

## **Patient Release Background**

- **May 1997 - NRC revised 10 CFR 35.75 to base each release on dose**
- **September 2005 – NRC received Petition for Rulemaking to return 10 CFR 35.75 to previous activity-based release criteria**

## **Patient Release Background (cont'd)**

- **May 2008 – NRC denied Petition – current rule adequate to protect public health and safety**
- **October 2009 and January 2010 – Congressman Markey sent letters on this issue to NRC**

## **Patient Release Requirements (excluding nursing patients)**

### **Patients can be released if:**

- **Dose to any other individual from exposure to the patient is not likely to exceed 5 mSv (500 mrem)**
- **The patient or parent or guardian is provided written instructions, including recommendations for maintaining doses ALARA, if total dose to other individuals is likely to exceed 1 mSv (100 mrem)**

## **Patient Release Requirements (excluding nursing patients) (cont'd)**

### **Patients can be released if:**

- **The licensee maintains a record of the basis for authorizing the release**

## **Patient Release Criteria for Nursing Patients**

**If TEDE to a nursing infant or child could exceed 1 mSv (100 mrem), the instructions must also include:**

- Guidance on the interruption of breast-feeding; and**
- Consequences, if any, of failure to follow the guidance**

## **National and International Guidance**

- NCRP Report No. 155, "Management of Radionuclide Therapy Patients" (2006)**
- IAEA Safety Report Series # 63 "Release of Patients After Radionuclide Therapy" (2010)**

## **National and International Guidance (cont'd)**

- **ICRP Publication 94, “Release of Patients after Therapy with unsealed Radionuclides” (2005)**

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## **NRC Requirements**

- **NRC's Current Regulations:**
  - **Provide No Distinction Between Exposure Limits for Family Members, General Public, and Children**
  - **Are Silent on the Issue of per Episode vs. per Annum**

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**Table 1: ICRP (2005), NCRP (2006) AND IAEA (2010) RECOMMENDED DOSE LIMITS**

<b>Dose Limits</b>	<b>IAEA &amp; ICRP (2010)</b>	<b>NCRP (2006)</b>	<b>NRC</b>
Pregnant Women & Children	1 mSv/year	1 mSv/year	*5 mSv
Immediate Family	5 mSv/episode	5 mSv/year	*5 mSv **
Public	1 mSv/year	1 mSv/year	*5 mSv

\* ALARA instructions required if dose estimate > 1 mSv.

\*\* NRC regulations make no differentiation between members of the public and the immediate family.

## **Current NRC Guidance**

- **Regulatory Issue Summaries**
  - **Dose Limit for Patient Release Under 10 CFR 35.75 (3/08)**
  - **Precautions to Protect Children Who May Come In Contact with Patients Released After Therapeutic Administration of Iodine -131 (5/08)**
- **NUREG-1556, Vol. 9, App. U.**

## **Path Forward**

- **ACMUI Patient Release Subcommittee Evaluated Adequacy of Existing Regulations and Guidance & Recommended:**
  - **NRC Dose Limit be on a per Episode Basis**
  - **10 CFR 35.75 Not be Changed**

27

## **Path Forward (cont'd)**

- **Staff Will Evaluate All ACMUI Recommendations**
- **Staff Is Developing a RIS for the Release of Iodine-131 Therapy Patients to Locations Other Than Private Residences**

28

## **Nuclear Materials Events Database**

29

## **Why Does NRC Use NMED ?**

- **To Identify:**
  - **Deficiencies in Safe Use of Materials; Precursors in Higher Risk Problems; Generic Issues and Concerns; AO's**
- **Responds to:**
  - **1993 Govt. Performance Results Act**
  - **1993 GAO Report Recommendations**

30

## What Is NMED ?

- **Database Collects Event Info Involving AEA Materials**
  - Medical Events that are Required to be Reported are Captured in NMED
  - Licensees are Identified in NMED
- **Web-based Database at INL**  
(<http://nmed.inl.gov/>)
- **Powerful Search Engine**

31

**NMED Item Number: 100XXX**

**Narrative:**

**10/XX/20XX**

**Last Updated:**

ABC Hospital reported that a gamma knife (Leksell model Perfexion, serial #MV010) gave a fatal error and terminated treatment to a patient on 9/XX/20XX. The gamma knife contained 511.49 TBq (13,824 Ci) of Co-60 sources (model 43047). The error appeared to be a failed computer disc drive. The gamma knife safety system functioned as designed, moving the patient out of the unit and closing the shielding doors. The patient was safely removed from the treatment room. The patient was prescribed a dose of 1,400 cGy (rad) to the brain, but only received 71.5 cGy (rad). The patient was informed of the error on the same day. A service representative was contacted and repairs are in progress. ABC Hospital intends to give the remaining prescribed dose to the patient once the unit is repaired.

**Event Date:    Discovery Date:    Report Date:**

09/27/2010    09/27/2010    09/28/2010

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## **Acronyms**

- **AAPM - American Association of Physicists in Medicine**
- **ACMUI – Advisory Committee on Medical Uses of Isotopes**
- **AEA- Atomic Energy Act**
- **ALARA- As Low As Reasonably Achievable**

## **Acronyms (cont'd)**

- **AMP – authorized medical physicist**
- **AO- Abnormal Occurrence**
- **AS – Agreement States**
- **AU – authorized user**
- **CFR- Code of Federal Regulations**

### **Acronyms (cont'd)**

- **GAO- U.S. Government Accountability Office**
- **IAEA- International Atomic Energy Agency**
- **ICRP- International Commission on Radiological Protection**
- **INL- Idaho National Laboratory**

### **Acronyms (cont'd)**

- **NCRP- National Council on Radiation Protection and Measurements**
- **RIS- Regulatory Issues Summary**
- **RSO – Radiation Safety Officer**
- **SECY- Office of the Secretary**

## **Acronyms (cont'd)**

- **SRM- Staff Requirements Memorandum**
- **T&E – Training and Experience**
- **TEDE- Total Effective Dose Equivalence**

NO HANDOUT

NO HANDOUT

NO HANDOUT

## 2007 ACMUI RECOMMENDATIONS AND ACTION ITEMS

ITEM		DATE	STATUS	
2	NRC staff should remove the attestation requirement for board certified individuals and rewrite the attestation requirement for individuals seeking authorization under the alternate pathway. The rewritten attestation should not include the word "competency" but should instead read "has met the training and experience requirements."	6/12/07	Accepted	Open
3	NRC staff should revise the regulations so that board certified individuals, who were certified prior to the effective date of recognition or were certified by previously recognized boards listed in Subpart J of the previous editions of Part 35, are grandfathered.	6/12/07	Accepted	Open
6	NRC staff should add the words "or equivalent" so it is clear that information included in a letter is the same as that which would have been submitted in NRC Form 313A (35.12(c))	6/13/07	Accepted	Open
7	NRC staff should revise 10 CFR 35.50(c)(2) to include AUs, AMPs, or ANPs identified on any license or permit that authorizes similar types of use of byproduct material. Additionally, the AU, AMP, or ANP must have experience with the radiation safety aspects of similar types of use of byproduct material for which the individual is seeking RSO authorization.	6/13/07	Accepted	Open
8	NRC staff should remove the attestation requirement from 10 CFR 35.50(d) for AUs, AMPs, and ANPs seeking RSO status, if the AU, AMP, or ANP seeking RSO status will have responsibilities for similar types of uses for which the individual is authorized.	6/13/07	Accepted	Open
10	a) NRC staff should allow more than one RSO on a license with a designation of one RSO as the individual in charge. b) NRC should create a Regulatory Issue Summary (RIS) to inform the regulated community of NRC's interpretation. The RIS should be sent to ACMUI and the Agreement States for review and comment.	6/13/07	a) Accepted Accepted	b) a) Open b) Closed
25	NRC staff should revise the current regulations to include Canadian trained individuals who have passed the ABNM certification exam.	8/16/07	Accepted	Open
30	The Elekta Perfexion® should be regulated under 10 CFR 35.1000 until 10 CFR 35.600 is modified to be performance-based, which would allow the Perfexion® to be regulated under 10 CFR 35.600.	10/22/07	Accepted	Open Delayed
31	NRC staff should require experienced RSOs and AMPs to receive additional training, if the individual is seeking authorization or responsibility for new uses.	10/22/07	Accepted	Open
32	NRC staff should not require experienced RSOs to obtain written attestation to become authorized or have responsibility for new uses.	10/22/07	Accepted	Open
34	NRC staff should modify 10 CFR 35.491(b)(2) to specify 'superficial' ophthalmic treatments. Additionally, NRC staff should change the title of 10 CFR 35.491 to specify 'superficial' ophthalmic treatments.	10/22/07	Accepted	Open Delayed
35	NRC staff should not revise 10 CFR 35.491 (intended for ophthalmologists) to include training and experience for the new intraocular device. Instead, NRC staff should regulate the new intraocular device under 10 CFR 35.490.	10/22/07	Partially Accepted	Open Delayed
36	NRC staff should not require medical licensees regulated under 10 CFR 35.400, 500, or 600, as applicable, to only use the sealed sources and devices for the principle use as approved in the SSDR.	10/22/07	Accepted	Open
37	NRC staff should revise 10 CFR 35.290 to allow physicians to receive training and experience in the elution of generators and preparation of kits under the supervision of an ANP.	10/22/07	Accepted	Open

## 2008 ACMUI RECOMMENDATIONS AND ACTION ITEMS

	ITEM	DATE	STATUS	
2	NRC staff should pursue rulemaking to allow more than one RSO on a medical use license with the indication of one RSO as the individual in charge.	4/28/08	Accepted	Open
5	NRC staff should incorporate the subcommittee's recommendations for the Gamma Knife® Elekta Perfexion™ in future rulemaking.	4/28/08	Accepted	Open
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
19	NRC staff should accept the six recommendations of the Permanent Implant Brachytherapy Subcommittee report with one modification. Recommendation six should be modified to read, "When a Written Directive (WD) is required, administrations without a prior WD are to be reported as regulatory violations and may or may not constitute an ME."	10/27/08	Pending	Open Delayed
22	ACMUI encouraged NRC staff to begin the rulemaking process to move the medical use of Y-90 microspheres from 10 CFR 35.1000 to another section of the regulations, so that the training and experience requirements for AUs can be vetted through the public review process instead of residing in guidance space.	10/27/08	Partially 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 Delayed
27	NRC staff should revise 10 CFR 35.40 to clarify that <u>an</u> AU, not <u>the</u> AU, should sign and date both the pre-implantation and post-implantation portions of the WD for all modalities with two part WDs. [Note this allows for one AU to sign the pre-implantation portion of the WD and another AU to sign the post-implantation portion of the WD]	10/28/08	Accepted	Open Delayed
28	NRC staff should revise 10 CFR 35.65 to clarify it does not apply to sources used for medical use; however, NRC should not require licensees to list the transmission sources as a line item on the license. NRC staff should also revise 10 CFR 35.590 to permit the use of transmission sources under 10 CFR 35.500 by AUs meeting the training and experience requirements of 10 CFR 35.590 or 35.290.	10/28/08	Accepted	Open
29	NRC staff should revise 10 CFR 35.204(b) to require a licensee that uses Mo 99/Tc-99m generators for preparing a Tc-99m radiopharmaceutical to measure the Mo-99 concentration of each eluate after receipt of a generator to demonstrate compliance with not administering to humans more than 0.15 microcurie Mo-99 per millicurie Tc-99m.	10/28/08	Accepted	Open
30	NRC staff should require licensees to report to the NRC events in which licensees measure molybdenum breakthrough that exceeds the regulatory limits.	10/28/08	Accepted	Open

2009 ACMUI RECOMMENDATIONS AND ACTION ITEMS

	ITEM	DATE	STATUS	
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, measuring, & safely preparing patient or human research subject dosages; e) using administrative 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 three years supervised clinical experience in diagnostic radiology with one year in interventional radiology	5/7/09	Accepted	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
10	ACMUI recommends NRC staff delete the phrase "at a medical institution" from 10 CFR 35.2, 35.490(b)(1)(ii), 35.491(b)(2) and 35.690(b)(1)(ii).	10/19/09	Accepted	Open

## 2010 ACMUI RECOMMENDATIONS AND ACTION ITEMS

	ITEM	DATE	STATUS	
1	Dr. Thomadsen created a subcommittee to evaluate patient release issues; to objectively review and analyze available data, which may include state regulations and guidance and international recommendations; to provide a statement on the issue; and to provide recommendations for improvements to existing NRC rules and guidance, if necessary, which should include the issue of patient release to hotels. Subcommittee members include: Dr. Darrell Fisher, Ms. Debbie Gilley, Dr. Susan Langhorst (chair), Mr. Steve Mattmuller, Dr. Orhan Suleiman, Dr. Bruce Thomadsen, Dr. James Welsh, Dr. Pat Zanzonico. The subcommittee should report to the full ACMUI at the fall meeting.	5/24/10	No NRC action	Open
2	The Permanent Implant Brachytherapy subcommittee will revise the draft subcommittee report and resubmit it to the full ACMUI for an email vote. The ACMUI will submit a final subcommittee report to the NRC.	5/24/10	No NRC action	Open
3	NRC staff should provide information that describes safety culture problems as contributing factors to violations.	5/25/10	NRC action	Closed 9/29/10
4	NRC staff should revise the Y-90 microsphere brachytherapy guidance to delete "but before the patient or human research subject leaves the post-prodecural recovery area" under item 2 of the written directive section.	5/25/10	Accepted	Open
5	NRC staff should revise the Y-90 microsphere brachytherapy guidance to read (under 1 for written directives) "and, if the procedure was not performed in accorandae with the pre-adminstration written directive", then 2) "after administration and within 48 hours of the procedure, the signature of an AU."	5/25/10	Accepted	Open
6	NRC staff should consider the necessity and evaluate options to collect or obtain data for the denominator for medical events to improve the overall value of the medical events subcommittee report.	5/25/10	NRC action	Open
7	The ACMUI fully supports Dr. Darrell Fisher as Patients' Rights Advocate. The Committee expressed their appreciation and honor to serve with him.	5/25/10	No NRC action	Closed
8	NRC staff should provide optimal staff and support to facilitate the licensing process for new domestic producers of the medical isotope, molybdenum 99.	5/25/10	Acknowledged	Closed



## H-38 Committee on Radiation Medical Events

Jennifer Elee, Chair

Conference of Radiation Control Program Directors (CRCPD)

## Why is CRCPD interested in Medical Events?

- CRCPD represents state and local radiation programs and can host national database of medical events
- State programs already receive and evaluate reports of medical events
- State programs license/approve physicists, therapists, physicians
- State programs track compliance with QA as part of the regulatory inspection

## Committee's charges

- Oversee the development and maintenance of a national database of radiation medical events
- Develop a definition of reportable radiation medical events from radiation producing machines
- Develop a format and mechanism for reporting radiation medical events
- Review submitted reports for completeness and accuracy

## Committee's charges (cont.)

- Establish a mechanism for preparing an annual summary and an article for the CRCPD *Newsbrief*.
- Establish a mechanism for referring information to CRCPD subject matter committees to determine the need for timely notices
- Provide a verbal report at the CRCPD annual meeting

## Committee Members, Advisors and Resources

Chair: Jennifer Elee (LA)

### Members

- Janaki Krishnamoorthy (NY)
- Jim Castle (OH)
- John Winston (PA)
- Jimmy Carson (MS)

### Resource Individuals:

- Ralph Lieto, AAPM
- Per Halvorsen, AAPM
- Tom Payne, ACR
- Albert Blumberg, ACR
- Richard Martin, ASTRO
- Lauren Hefner, FDA
- Sean Boyd, FDA
- Duane White, NRC

## What has CRCPD done?

- Developed Suggested State Regulations which include medical event reporting (for therapy-Part X)
- Created and staffed the committee
- Conducted two surveys of state programs regarding reporting of events and state regulations and requirements

### What has CRCPD done?

- Held a Special Interest Meeting in Rhode Island in April, 2010 in conjunction with the CRCPD Annual Meeting
- Participated in FDA Workshops on CT/Fluoroscopy and Therapy
- Participated in AAPM meeting on CT and on Safety in Therapy
- Participated in FDA/NIH Roundtables

### Initial Survey Results

- Twenty-nine of Forty-eight CRCPD Director members surveyed responded
- 79.3% (23 states) responded that their state had adopted regulations similar to Suggested State Regulations developed by CRCPD for Radiation Safety Requirements for Linear Accelerators (Part I)

### Initial Survey Results

- 70% (20 states) have adopted regulations similar to SSRCR for Medical Therapy (part X)
  - 16 of the 20 required reporting of Therapy Misadministrations
  - One has provisions for the facility to investigate and document deviations, but did not require reporting
  - All of those stating “no” indicated that they are planning to adopt regulations in the near future

### Special Interest Meeting

- Attendees from states, AAPM, ACR, ASTRO, CDC, FDA, EPA, NRC, and others
- Discussion of what states and/or facilities would be willing to report
- Discussion of how a Non-Material Event Database could coincide with NMED for material events and with the FDA database for manufacturer issues-Single Database?

### Special Interest Meeting

- Discussion of state databases (NY and FL) and of European databases (ROSIIS)
- Would we be collecting for regulatory or best practice purposes
- How do we have a database which includes all Non-Material Events-therapy and Diagnostic
- Concerns about Liability

### Follow up Survey

- 36 responses from states, LA county and New York City
- 97% of responders have regulations in place for either RAM or Machine based radiation medical event reporting
- 92% have reporting for RAM based therapy radiation medical event reporting
- 81% have reporting for RAM based diagnostic medical event reporting

### Follow up Survey

- 83% have reporting for machine based therapy radiation event reporting
  - Since Jan, 2009; ~130 events have been reported to the state and/or local programs (26 responses)
- 43% have reporting for machine based diagnostic x-ray radiation event reporting
  - Since Jan, 2009; ~53 events have been reported to the state and/or local programs (12 responses)

### Follow up Survey

- Of the states and local entities responding 30% make the events easily available to the general public
  - Posted on the state website
  - Annual summary report
  - Etc.
- Other states do have methods in place for the records of the events to be requested through FOIA, etc.

### Where are we?

- Developed a definition for a machine based radiation which includes therapy and diagnostic
- Held one face to face meeting and several conference calls
- Participated in many meetings and round tables concerning medical events

### Where are we going?

- The committee is proceeding with the development of a reporting form for all radiation medical events
- The committee has discussed creating/expanding the definition of RAM radiation medical events especially in the diagnostic area
- The committee is looking into the costs and issues that need to be addressed for CRCPD to house a radiation medical events database

### What can we do with the information?

- Identify causes and/or contributing factor
- Identify event by type of error
- Identify event by type of error made
- Prepare summary reports
- Prepare timely notices

### Summary

- Many state and local radiation control programs require reporting
- Several states have experience tracking medical event data, and some have developed databases that allow tracking/trending specific events
- CRCPD would like to provide a single point for all states and facilities to input events into a single database

### Summary

- CRCPD plans to establish a database for housing radiation medical events
- Evaluation of data will be done in consultation with advisors, resource individuals and other experts in the field
- Data will be used to inform interested parties on trends, root causes, and methods for improvement

### CRCPD Contact Information

- [www.crcpd.org](http://www.crcpd.org)
- [Jennifer.elee@la.gov](mailto:Jennifer.elee@la.gov)

### Acronyms

- AAPM – American Association of Physicist in Medicine
- ACR – American College of Radiology
- ASTRO – American Society for Radiation Oncology
- CDC – Centers for Disease Control and Prevention

### Acronyms (cont.)

- CRCPD – Conference of Radiation Control Program Directors
- CT – Computed Tomography
- EPA – Environmental Protection Agency
- FDA – Food and Drug Administration
- FOIA – Freedom of Information Act
- NIH – National Institutes of Health

### Acronyms (cont.)

- NMED – Nuclear Material Events Database
- NRC – Nuclear Regulatory Commission
- QA – quality assurance
- RAM – Radioactive Material
- ROSIS – Radiation Oncology Safety Information System
- SSRCR – Suggested State Regulations for Control of Radiation



## 10 CFR Part 35 Medical Event Reporting Rule and Implementation Plan

Michael Fuller  
Team Leader  
Medical Radiation Safety Team  
October 20, 2010

1



## A Brief History

- July 25, 2008: SRM-SECY-08-0080
- May 18, 2010: SECY-10-0062
- July 8, 2010: Commission Meeting
- August 10, 2010: SRM-SECY-10-0062

2



## SRM-SECY 10-0062

- Commission Disapproved Re-proposed Rule and Directed Staff to:
  - Work Closely with ACMUI and Broader Medical and Stakeholder Community to Develop Medical Event Definitions
  - Hold a Series of Stakeholder Workshops to Discuss Issues Associated with the Medical Event Definition
  - Develop Integrated Plan Denoting Schedule and Agreement State Participation

3



## Integrated Plan

- NRC Has Three Options for Rulemaking:
  - Continue with 10 CFR Part 35 (expanded) Rulemaking Then Begin a New Permanent Implant Brachytherapy Medical Event Rulemaking
  - Begin a New Permanent Implant Brachytherapy Medical Event Rulemaking Then Begin the 10 CFR Part 35 (expanded) Rulemaking
  - Combine the 10 CFR Part 35 (expanded) Rulemaking with a New Permanent Implant Brachytherapy Medical Event Rulemaking

4



## Integrated Plan

- Current Rules Will Be in Effect for At Least Three Years
  - Currently Drafting Enhanced Permanent Implant Brachytherapy and Medical Event Reporting Inspection and Licensing Guidance for Current Rules
  - Will Soon Be Sharing Enhanced Guidance with ACMUI and OAS for Feasibility Review
  - Will Use Draft Guidance as a Starting Point for Series of Public Workshops
  - If Enhanced Guidance is Found to be Effective, a Combined Rulemaking May Be Feasible (with some limited changes to rules for Medical Event reporting)

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## Schedule

- Winter/Spring 2011 - Develop Enhanced Guidance for Permanent Implant Brachytherapy and Medical Event Reporting, with Agreement State Participation
- May Devote Spring 2011 ACMUI Meeting to 10 CFR Part 35 Rulemaking Issues
- Spring/Summer 2011 - Hold Two or Three Public Workshops
  - Scope of Workshops May Be Expanded to Include Discussion of All of the More Controversial 10 CFR Part 35 Rulemaking Topics if a Combined Rule is Undertaken

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## Schedule Continued

- Current Schedule for 10 CFR Part 35 Rulemaking :
  - Proposed Rule March 2012
  - Final Rule September 2013
- If Rulemaking is Expanded:
  - Workshops - Spring/Summer 2011
  - Consolidate - Comments Summer 2011
  - Start Proposed Rule – Fall 2011

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## Schedule Continued

- If Rulemaking is Expanded (continued):
  - Complete Proposed Rule – Winter 2012/2013
  - Publish Proposed Rule – Spring 2013
  - Conduct Three Public Meetings for Comment on Proposed Rule – Spring 2013
  - Final Rule to Commission Fall 2014

8



## Questions?

9



## Acronyms

ACMUI – Advisory Committee on the Medical Uses of Isotopes  
CFR – Code of Federal Regulations  
NRC – Nuclear Regulatory Commission  
OAS – Organization of Agreement States  
SRM – Staff Requirements Memorandum

10



**MULTIPLE MEDICAL EVENTS INVOLVING  
PROSTATE BRACHYTHERAPY  
TREATMENTS AT DEPARTMENT OF  
VETERANS AFFAIRS MEDICAL CENTER  
PHILADELPHIA - UPDATE**

Patricia Pelke, Chief  
Materials Licensing Branch  
Division of Nuclear Materials Safety  
NRC Region III  
ACMUI Meeting October 20, 2010

### **Background**

- Department of Veterans Affairs (DVA) holds a master materials license (MML)
- An MML is a materials license issued to a Federal organization, authorizing the use of material at multiple sites
- DVA National Radiation Safety Committee (NRSC) has responsibility for providing oversight of the DVA's implementation of its MML

2

### **Background**

- NRSC has delegated the authority to manage the DVA radiation safety program to its National Health Physics Program (NHPP)
- NHPP is responsible for issuing permits, conducting inspections and event follow-up, investigating incidents, allegations, and enforcement
- Veterans Affairs Medical Center, Philadelphia (PVAMC) is a permittee issued under the DVA's MML

3

### **Background**

- PVAMC retained the services of consulting radiation oncology physicians and medical physics from Hospitals of the University of Pennsylvania for pre-treatment planning, implant preparations, implant treatments, post treatment planning, etc
- 114 patients treated from February 2002 thru May 2008

4

### **Sequence of Events**

- February 2002: PVAMC initiated prostate brachytherapy program and implanted first patient
- May 2008: NRC notified of a medical event where dose to the prostate was less than 80% of the prescribed dose

5

### **Sequence of Events**

- May 2008: the NHPP conducted inspection at the PVAMC in response to the reported medical event
- June 2008: the PVAMC prostate brachytherapy program suspended
- PVAMC commissioned an external review of the prostate brachytherapy program

6

## Sequence of Events

- **July 2008:** the NRC began independent Special Inspection
- **October 2008:** NRC issued Confirmatory Action Letter
- **As of December 2009,** the licensee identified and reported to the NRC a total of 97 medical events

7

## DVA Medical Event Criteria

- **Phase I:**  $\pm 20\%$  of prescribed dose
- **Phase II:**
  - Rectum** – dose to 1.33cc volume exceeds 150% of pre-treatment plan dose
  - External Tissue** – 5 or more seeds located beyond 1cm exterior, and inferior, to the surface of prostate
  - Bladder** – 3 or more seeds located in bladder wall

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## 97 Medical Events Reported to NRC

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

9

## Causes of Medical Events

- **Incorrect Placement of Seeds**
- **Inadequate Procedures**
- **Poor Management Oversight of Contractors**
- **Inadequate Training of Licensee Staff**

10

## Causes of Medical Events

- **Poor Management Oversight of Brachytherapy Program**
- **No Peer Review**
- **Observed Poor Placement of Seeds and No Corrective Actions Taken**
- **Lack of Safety Culture**

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## PVAMC Patient Care Actions

- **Performed verification CT scans on patients that received prostate implants**
- **Re-evaluated the dose delivered to the treatment area**
- **Re-implanted seeds at a different DVA location for at least four individuals**
- **Removed one individual from performing brachytherapy treatments at PVAMC**

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### NRC Response to Events

- Conducted inspections at PVAMC in July and September 2008; June, August, and October 2009
- Issued a Confirmatory Action Letter to the DVA in October 2008
- Issued two inspection reports in March and November 2009
- Issued Demand for Information to a physician authorized user in May 2009

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### NRC Response To Events

- Conducted a Pre-Decisional Enforcement Conference with the DVA in December 2009
- Substantial civil penalty issued to DVA for violations identified at PVAMC (\$227,500) in March 2010
- Conducted inspections at other DVA facilities performing prostate implants

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### NRC Response To Events

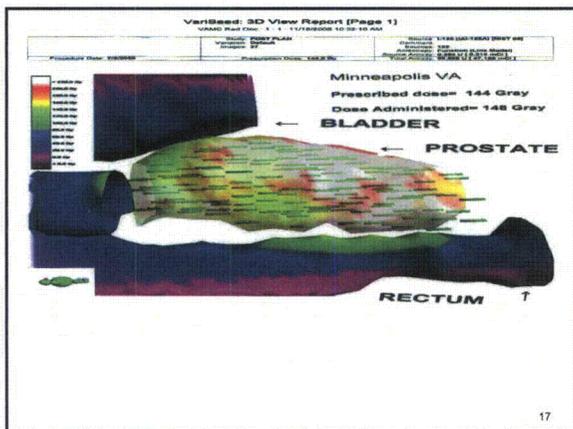
- Conducted inspections at NHPP
- Results of inspections at other DVA facilities performing prostate implants and at NHPP issued May 2010
- Conducted a Pre-Decisional Enforcement Conference with the DVA in June 2010
- Civil penalty (\$39,000) issued to DVA in August 2010 for violations identified at other DVA facilities

15

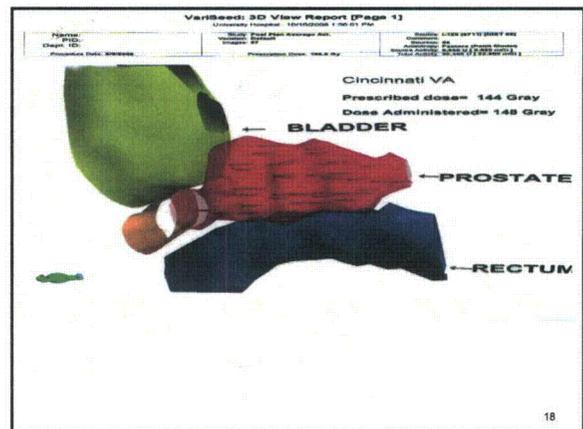
### NRC Actions Going Forward

- Enhanced oversight of the DVA
  - Global actions instituted by DVA
  - NRC actions to assess performance improvements
- Assess NRC's policies, procedures, and practices related to prostate brachytherapy to identify program enhancements

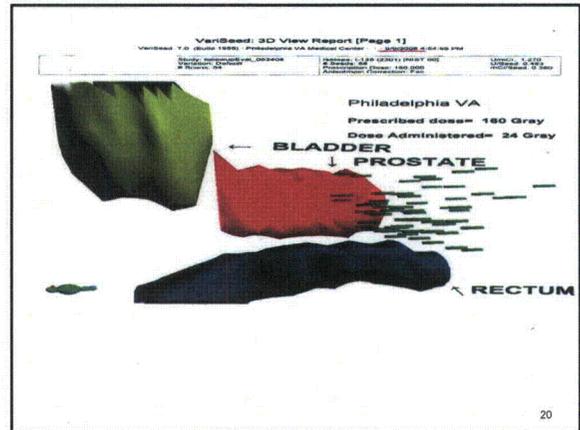
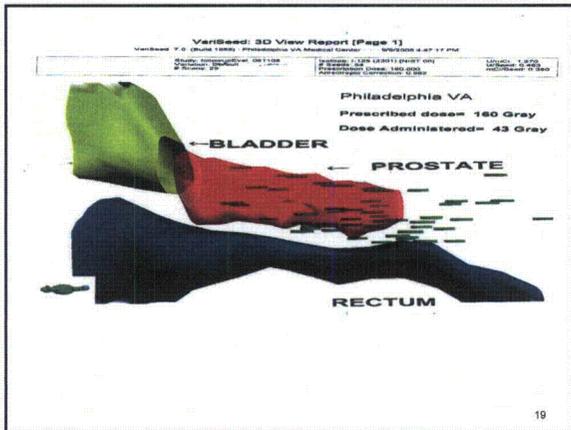
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17



18



**• Questions ?**

Patricia Pelke, Chief  
 Materials Licensing Branch  
 Division of Nuclear Materials Safety  
 NRC Region III  
 ACMUI Meeting October 20, 2010



## Permanent Implant Brachytherapy Subcommittee Report

**James S. Welsh, MS, MD**  
Debbie Gilley      Darrell Fisher  
Susan Langhorst      Bruce Thomadsen

### Key Points

- **The Subcommittee**
  - finds that activity-based metrics for the definition of Medical Events remain preferable to any dose-based metric
    - Dose-based metrics are fraught with difficulties
  - strongly recommends that NRC seek specific help from stakeholders for development of the definition

2

### Key Points

- A “medical event” should be of medical significance
- The definition should be sensitive enough to potential harm to a patient
  - Harm due to overdosing of sensitive normal structures and tissues
  - Harm due to under-dosing the cancer and not curing the patient

3

### Key Points

- **Post-implant dosimetry is important and should be performed**
- **The 60-day timeline is controversial**
  - Patient refusal to return within the defined time-frame should be considered a “patient-related factor” and excluded from classification as Medical Events

4

### Key Points

- **The Subcommittee suggests separation into two categories:**
  - Those which result in significant rearrangement of implant location during completion of the surgical implant procedure
    - such as operative lung implants
  - and those procedures that do not
    - such as prostate implants

5

### 10 CFR Part 35.3045(a)(3)

- “A dose ... that exceeds by 0.5 Sv (50 rem) to an organ or tissue and 50 percent or more of the dose expected ....”
  - 0.5 Sv is a very small amount compared to therapeutic doses prescribed (amounting typically to 0.35%).
  - A 50% overdose could be medically inconsequential if the original expected dose to that normal tissue was very low
  - the units used remain inconsistent and confusing. It is suggested that the final rule use appropriate units in a consistent manner.

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**ACMUI Permanent Implant Brachytherapy Subcommittee Report**  
Revised September 27, 2010

**Permanent Implant Brachytherapy Subcommittee Members**

Debbie Gilley  
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**Introduction**

At the ACMUI meeting on October 27, 2008, the ACMUI and NRC staff discussed the proposed rule on medical use of byproduct material for permanent brachytherapy procedures ("permanent implants"). Several suggestions made at that meeting were incorporated into a formal Subcommittee report. On November 5, 2008 the formal report (*Advisory Committee on the Medical Uses of Isotopes (ACMUI) comments on the Proposed Rule for Medical Use of Byproduct Material—Amendments/Medical Event Definitions (RIN 3150-AI26, NRC-2008-0071)*) of the ACMUI Permanent Implant Brachytherapy Rulemaking Subcommittee was made available. (Report available on NRC's ACMUI web page at: <http://www.nrc.gov/about-nrc/regulatory/advisory/acmui.html> )

Since the time of the November 5, 2008 report, NRC has made extensive review of medical events involving permanent implant brachytherapy at the Department of Veterans Affairs (DVA) hospitals. As a result, NRC decided it was necessary to re-evaluate the proposed rules. This led NRC Staff to issue the following charge to the ACMUI permanent brachytherapy subcommittee:

***Charge: The subcommittee should draft a report to provide recommendations on regulatory changes or improvements to the NRC's processes for permanent implant brachytherapy programs, as an outgrowth of the investigation of the Department of Veterans Affairs medical events.***

In the interim, a re-proposed rule based partly on analysis of the medical events involving the VA was submitted for the Commission to consider. Thus, this Subcommittee Report addresses not only the above charge but also various aspects of the re-proposed rule.

**Subcommittee Recommendations**

The definition of a permanent implant brachytherapy medical event should be based on the following concepts:

- I. A medical event ideally should be **of true medical significance** to a patient.

If this requirement is not fundamental, there is the risk of being overly sensitive and designating as "Medical Events" many cases that are of no potential harm to a patient and thereby inundating the regulatory and health care systems with many unnecessary investigations. The NRC definition of a "medical event" for permanent implant brachytherapy should be based on medical actions that could either cause harm to the patient, result in grossly inadequate treatment or identify patterns or trends that could lead to patient harm or inadequate treatment.

II. This concept should be balanced by the concept that: **The definition should be sensitive enough to detect any implant that is truly of potential harm to a patient.**

Furthermore, "harm" to a patient can be of two forms:

- 1.) Harm due to overdosing of sensitive normal structures and tissues
- 2.) Harm due to under-dosing the cancer and not curing the patient

III. Procedures with expected large changes in the source positions, such as permanent intra-operative lung implants, should be considered separately from more stable procedures, such as prostate implants. An appropriate Medical Event definition must balance the factors discussed above. This is a difficult task and could be even more difficult if an attempt is made at encompassing ALL forms of permanent implant brachytherapy under one set of Medical Event criteria. Therefore, the Subcommittee recommends that unless an activity-based (as opposed to dose-based) Medical Event set of criteria is adopted, consideration be given to separation of permanent brachytherapy procedures into various categories, e.g. permanent implant brachytherapy procedures which result in significant rearrangement of implant location during completion of the surgical implant procedure (such as operative lung implants) and those procedures that do not generally experience this phenomenon (such as prostate implants). The Subcommittee suggests that the former implant procedures be covered under separate categories within 10 CFR 35.400 or perhaps 10 CFR 35.1000 for the present.

IV. The Subcommittee strongly recommends that NRC seek specific help from stakeholders, particularly the medical community with expertise in permanent implant brachytherapy to discuss the definition of Medical Event for permanent implants, due to the complex nature of the issues.

V. The event metric should be source-strength based as opposed to dose based. The Subcommittee has focused on its primary charge above but is also aware of the recently re-proposed rule and has devoted considerable deliberation to this closely related subject. The Subcommittee is aware of certain circumstances in which the original recommendations of ACMUI may be inadequate. Previously, the ACMUI was in favor of abandoning a dose-based metric in favor of an exclusively source-strength-based definition. The Subcommittee remains in favor of not using a dose-based metric for defining medical events. However, the Subcommittee is aware of certain clinical scenarios in which the ACMUI-proposed source-strength-based definition may fall

short. For instance, the extremely unusual and unlikely situation in which all seeds are placed within the prostate but not distributed in the intended fashion. If they are all clumped into one location, this would not be a Medical Event under the source-strength-based proposed definitions. Consideration of this particular situation has caused the Subcommittee to reconsider its initial position on fully endorsing and advocating the previous activity-based definition.

V. If any dose-based criteria are to be applied, these criteria must be able to account for:

- 1.) True anatomic prostate volume or shape changes during and after the implant procedure,
- 2.) Differences in prostate volumes identified on CT vs. ultrasound (or any other modality),
- 3.) Inherent inter- and intra-observer differences in prostate contours (and thus volume estimates, which go into dose calculations), and
- 4.) Volume estimate uncertainties due to artifacts from the seeds and the indistinct prostate boundaries seen on post-implant CT images.

We recommend that if an apparent medical event were found to be due to anatomic prostate volume changes (item 1. above) after the administration, it would not be deemed a Medical Event, and that such cases be addressed in the fashion of other patient-related or patient-specific factors such as a patient removing a temporary implant, migration of properly implanted radioactive seeds, or incompleteness of a Y-90 administration because of stasis.

Additionally, it should be kept in mind that brachytherapy is an art as well as a science and on occasion, skilled, experienced practitioners may intentionally “dose-intensify” certain regions within a target. Conversely, practitioners may elect to “dose de-escalate” in areas such as the urethra in a patient who has had a TURP (transurethral resection of the prostate) for example. Such aspects of the art and science of brachytherapy must be accommodated in any dose-based definitions of Medical Events and further strengthen the argument in favor of exclusively activity-based Medical Event definitions.

### Discussion

In general, the Subcommittee finds that much of the intent of the Permanent Implant Brachytherapy Rulemaking Subcommittee Report of November 5, 2008 remains valid. The 97 medical events in 2008-09 within the Department of Veterans Affairs and the subsequent investigation of those medical events have not changed the general recommendations of the ACMUI Permanent Implant Brachytherapy Rulemaking Subcommittee. Some relevant points include:

- 1.) Part § 35.3045(a)(3) reads, “A dose to the skin or an organ or tissue other than the treatment site that exceeds by 0.5 Sv (50 rem) to an organ or tissue and 50 percent or more of the dose expected from the administration defined in the written directive

(excluding, for permanent implants, seeds that were implanted in the correct site but migrated outside the treatment site.” In otherwise normal cases, this 0.5 Sv is a very small amount compared to therapeutic doses prescribed in most of these permanent brachytherapy cases (amounting typically to 0.35%). Also, a 50% overdose (as described in §35.3045(a)(3) could be medically inconsequential if the original expected dose to that normal tissue was very low (for example, the predicted skin dose in most permanent brachytherapy procedures or the penile bulb dose in prostate brachytherapy). With the very high gradients in the dose distributions and the inverse square law, very small shifts in a.) the source distribution b.) the target organ or c.) the normal tissues in question can cause much larger changes than 0.5 Sv or 50% of the expected dose with no consequences to the patient and constituting a perfectly normal and appropriate implant. A typical prostate implant may give 6 Gy to the skin 5 cm anterior to the prostate. If at the time of CT the prostate falls only 4 cm from the skin, not an uncommon occurrence, the dose to the skin would be twice that expected. Thus, if this criterion is applied strictly, some and perhaps many properly executed, medically acceptable implants could be inappropriately categorized as medical events. This underscores the concept that ideally Medical events should be of potential medical significance (or perhaps should identify trends that could lead to consequences of medical significance if not identified and acted upon). The 0.5 Sv threshold/20% definition of “Medical Event” is problematic when one considers the variability and inherent uncertainty in current medical practice, with dose uncertainties as high as 50% possible and medically acceptable. The inherently high level of uncertainty for many brachytherapy procedures *in absorbed dose estimation* is due to the variability of the tumor border, which is dependent on the imaging modality and imaging technique, normal movement of organs in the body, and significant volumetric changes associated with the surgical procedure itself resulting in inflammation and subsequent biological response.

Implanted amounts of radioactivity are not fully equivalent to absorbed dose and an appreciation that the spatial rearrangement of the same constant amount of activity can result in very different values of radiation dose. In current medical practice, the uncertainty in defining treatment volumes due to different imaging modalities and procedures and temporal variations due to the effects of the invasive procedures (e.g. edema) makes the 20% Medical Event criteria unrealistic.

The Subcommittee suggests defining specific volumes or areas of organs, tissues and skin if §35.3045(a)(3) is to remain. The Subcommittee suggests revision of §35.3045(a)(3) to adjust the nominal 0.5 Sv dose and the 50 percent figure to more appropriate figures and/or to specify an area of maximally irradiated skin and volume of maximally irradiated organ or tissues (e.g. 30 cm<sup>2</sup> of maximally irradiated skin or 5 cm<sup>3</sup> of maximally irradiated organs or tissues, based on Perera F, Chisela F, Stitt L, et al, TLD skin dose measurements and acute and late effects after lumpectomy and high-dose-rate brachytherapy only for early breast cancer. Int J Radiat Oncol Biol Phys. 62,1283-90; 2005 and S. L. Schoepel, M. L. LaVigne, M. K. Martel *et al.*, “Three-dimensional treatment planning of intracavitary gynecologic implants: analysis of ten

cases and implications for dose specification," Int J Radiat Oncol Biol Phys **28** (1), 277-83 (1994).

The Subcommittee maintains that the units in the language above remain inconsistent and confusing in that absorbed dose (Gy or rads) and equivalent dose (Sv or rem) are used almost interchangeably. It is suggested that the final rule use appropriate units in a consistent manner.

2.) In the previous Subcommittee report, the ACMUI recommended that section § 35.3045(a)(2) (ii) be modified to "The total source strength implanted outside the treatment site (including the gross tumor, the clinical target volume plus a variable planning margin as defined by the AU) exceeding 20 percent of the total source strength documented in the written directive". This would take into account source migrations, seeds that become dislodged and seeds suctioned out of position but would still hold accountable cases in which the target organ was grossly misidentified and the wrong area was implanted.

The Subcommittee is aware of the preference for regulatory language that will broadly encompass all organs/situations rather than design regulations for each organ/situation. **However, it would be prudent to devise separate categories for: 1) permanent implant brachytherapy procedures that result in significant rearrangement of implant location during completion of the surgical implant procedure, e.g., mesh lung implants and 2) those procedures that do not generally experience this phenomenon, such as prostate or breast implants.** This would take into account the vast differences in sophistication and technology for pre-implantation treatment planning and post-implant dose distribution assessment between the two categories. Such separate classification could hopefully obviate the unnecessary assignment of the title of medical event to numerous medically acceptable non-prostate implants because of modifications to source geometries with the closing of surgery. The question of where to put such procedures in which implant relocation does occur was the subject of discussion within the Subcommittee with some favoring placement into 10CFR 35.1000 and others suggesting a revision within 10CFR 35.400.

3.) The Subcommittee felt that the old definition of "treatment site" (described in §35.2 as "the anatomical description of the tissue intended to receive a radiation dose, as described in a written directive") could lead to some uncertainty regarding the exact volume to which "treatment site" refers in §35.3045(a)(2)(ii). The Subcommittee recommends refinement of the previously ambiguous term "treatment site" to encompass the more rigorously defined concepts of gross tumor volume (GTV), clinical target volume (CTV) and planning target volume (PTV) (*ICRU Report 62: Prescribing, Recording, and Reporting Photon Beam Therapy. Bethesda, MD: International Commission on Radiation Units and Measurements (ICRU), 1999*). **The Subcommittee recommends that any revised rule and all subsequent matters dealing with this subject adopt the currently accepted nomenclature.** If a source-strength-based criterion is used, the basis for defining a medical event should be of the form of 20% of the source strength fall outside of the *planning target volume*, whereas

a dose-based criterion should relate to the *clinical target volume*, both according to conventional clinical practice.

4.) The Subcommittee is in agreement that post-implant dosimetry is important and should be required. There was some discussion about the proposed requirement of licensees assessing the dose within 60 days from when the patient leaves the post-treatment recovery area. While imposing a timeline for such dosimetric evaluation may be challenging or difficult for some licensees, it is acknowledged that NRC desires some defined timeline for regulatory purposes. The 60-day timeline is acceptable as it is in alignment with recommendations of national organizations and guidelines. Situations in which a patient refuses or doesn't show up within the defined time-frame should be considered patient related factors and excluded from classification as Medical Events.

There was some discussion within the Subcommittee regarding the idea of using this post-implant dosimetry rule for regulatory purposes. Not all were in agreement that this requirement is appropriate for regulatory purposes (i.e. that if a licensee does not perform post-implant dosimetry within 60 days it would be a Medical Event). The decision of when to image and which modality to use for such imaging may be a medical decision. The main point is that after the treatment, there should be some imaging-based assessment with which dose can be re-estimated. Current practice varies enough that an NRC imposed regulatory requirement specifying the imaging modality could impede the development of good practice.

5.) ***Devising a truly acceptable, universally appropriate dose-based criterion for medical events remains challenging.*** One challenge is the potential for difference in the prostate anatomy between the pre-procedure images and those performed afterwards that will affect the *calculated* total dose.

Prostate volume can be affected by:

- 1.) Anatomic changes such as edema or atrophy
- 2.) Contouring differences due to:
  - a. different modalities (e.g CT vs ultrasound)
  - b. inter- and intra-user contouring differences,
  - c. artifacts introduced by the metallic seeds on CT, and
  - d. Organ motion, which can be several centimeters, between the ultrasound and the CT.

Based on factor 1.) above, anatomic changes, depending on exactly when in the edema-resolution time course the post-implant dosimetric analysis is performed, the calculation of total dose can vary, although in general, the variations seem to fall in the range of less than 10% (AAPM recommendations on dose prescription and reporting methods for permanent interstitial brachytherapy for prostate cancer: report of Task Group 137. Nath R, Bice WS, Butler WM, Chen Z, Meigooni AS, Narayana V, Rivard MJ, Yu Y; American Association of Physicists in Medicine. Med Phys. 2009 Nov;36(11):5310-22). Therefore, the Subcommittee continues to feel that dose-based assessments are not be ideal for regulatory purposes.

A dose-based definition must be capable of addressing all of the factors above that can affect prostate volume and calculated absorbed dose. To design a truly appropriate a dose-based criterion, it may be reasonable to introduce the concept of normalization to  $V_{init}$ , the initial pre-implant volume, so that any subsequent calculations of total dose afterwards are related back to this volume that the Authorized User based his/her initial dose prescription on. Thus, if in a prostate brachytherapy procedure, the prostate volume on which planned dose calculations are made is  $V_{init}$  but the post-implant dosimetry is done during the edematous period and the measured volume is 140%  $V_{init}$ , any deviations from the written directive prescribed dose due to this volume-related dose discrepancy should not be considered a Medical Event. The same concept would hold should the prostate shrink considerably following the implant due to the actions of hormonal therapy. In addition to addressing the concern about anatomic volume changes that affect dose calculations, the concept of normalizing back to  $V_{init}$  also addresses the problems posed by the non-anatomic, contouring-related volume estimations. Any dose-based criteria for Medical Events must refer back to  $V_{init}$ , not the volume measured during the post-implant dosimetry procedure if there is a volume change. It is noted that normalization to  $V_{init}$  will eliminate categorization of many perfectly acceptable implants as Medical Events, but would not preclude identification of truly sub-standard implants irrespective of edema, atrophy or contouring discrepancies. In other words, a volume change should not be the basis for a Medical Event, but conversely just because a volume change occurred does not exclude the possibility of a Medical Event.

In general, alterations of a final brachytherapy dose due to "patient factors" such as a patient removing a temporary implant, migration of properly implanted radioactive seeds, or incompleteness of a Y-90 administration because of stasis are not considered Medical Events. It is highly recommended that prostate volume changes due to edema, hematoma, hormone therapy-induced shrinkage, etc. also be considered "patient factors." Thus, item 1.) above, anatomic changes that cause alterations in volume that affect dose calculations should not be cause for the label of Medical Event.

Additionally, brachytherapy dose is not homogenous. Authorized User brachytherapists often intentionally intensify dose (to perhaps 125-150% of the prescribed dose) to the high-risk areas of the prostate (e.g. the peripheral lobe where many tumors are located). In the opinion of many experts, the reason why brachytherapy is so effective is precisely because of this much higher dose to the tumor areas than stated in the prescription dose. This reality creates an intrinsic challenge to the use of dose-based criteria for regulatory purposes. The concept of intentional underdosing to certain areas within the clinical target volume (CTV) also poses a challenge to most dose-based criteria including those previously proposed by NRC.

The Subcommittee has decided to not put forth a proposition explicitly in writing at this time. But if requested the Subcommittee would be pleased to engage in further discussion with NRC staff on this complicated, important and sensitive matter in a highly efficient manner to help develop the regulatory wording.

## **Final Comments**

Medical events are defined by the specific situations that constitute medical events. NRC's Policy Statement on Medical Uses (August 2000) states, "NRC will, when justified by the risk to patients, regulate the radiation safety of patients primarily to assure the use of radionuclides is in accordance with the physician's directions." Therefore, it is important that the situations chosen to define a medical event for permanent implant brachytherapy be justified as having the potential of causing patient harm. In order to determine whether the use of the permanent implant is in accordance with the physician's directions, the requirements need to be understandable and unambiguously measurable for proper implementation and inspection and compatible with good medical practice.

Permanent implant brachytherapy is an effective, safe and convenient medical procedure that addresses a potentially lethal disease, cancer. Compared to other potentially cancer-curing treatment such as surgery and chemotherapy, permanent implant brachytherapy maintains a very safe overall clinical profile. Because of its safety, effectiveness and convenience, permanent implant brachytherapy is often the preferred first choice therapy. NRC should remain aware that compared to other modalities such as surgery and chemotherapy, permanent implant brachytherapy maintains its standing as a low-risk yet highly effective treatment. It would defeat our purpose if through overly restrictive regulations this treatment alternative were to fall out of fashion and become unavailable to those who could benefit. In the estimation of some, strict enforcement of the event rule could lead to many thousands of perfectly acceptable permanent brachytherapy cases (in prostate alone) being considered Medical Events. This would have obvious consequences on the practice and future availability of this proven effective medical option.

The Subcommittee recommends that the Subcommittee and all of ACMUI review any changes made to the rule before the Commission approves it for publication. It is also strongly recommended that NRC seek specific input from the medical community with expertise in permanent implant brachytherapy.

Finally, this Subcommittee has crafted what it believes is an important first step towards an understandable, unambiguously measurable and carefully considered solution for a dose-based criterion. The Subcommittee has decided to not put this proposition explicitly in proposed regulatory language within this report, but if requested, would be pleased to engage in further discussion on this complicated, important and sensitive matter in a highly efficient manner.

## **Addendum**

This subject is presently hotly debated matter not just within the Subcommittee but in the radiation oncology community as a whole. Several points in the above report were not unanimously favored. Examples include:

The point about an exclusively activity-based metric rather than adding or switching to dose-based criteria was controversial. Three members were opposed to any dose-based criteria for the purposes of a medical event definition.

Two members felt strongly that this Subcommittee report should include a specific recommendation with regards to a dose-based metric. Three were opposed to dose-based criteria and did not wish to spell out any dose-based recommendations for fear that these would then be implemented when the preference was to steer clear of dose-based criteria altogether.

One member was opposed to the statement that brachytherapy is an "art" as well as science. Others were not opposed to such labeling. Three members felt that IF a dose-based definition were implemented, it would be more critical to emphasize this point about the art of medicine. Another member mentioned that this IS an art and therefore it will always be challenging for NRC to not encroach upon the practice of medicine in permanent implant brachytherapy. This difficulty in avoiding such encroachment will be compounded by attempts towards dose-based criteria.

One member was opposed to the concept of separating prostate brachytherapy (and other permanent brachytherapy procedures that do not typically experience significant rearrangement of seed location during completion of the procedure) from other permanent implant brachytherapy procedures that do result in significant rearrangement of implant location during completion of the surgical implant procedure, such as mesh lung implants.

One member was opposed to the requirement of post-implant dosimetry as a basis for medical events. Two others were not opposed to the requirement of post-implant dosimetry but were opposed to the idea of placing a 60-day limit for performing this.

Because three members were opposed to any dose-based criteria, (two adamant, the other not adamant), all matters related to dose-based criteria (such as including a specific recommendation) were controversial and one member suggested not including any discussion of the concept at all in this report.



## **Patients' Rights Advocate Responsibilities: Outreach, Feedback, and Plans**

Darrell Fisher  
Advisory Committee on the  
Medical Uses of Isotopes  
Rockville, Maryland  
October 20, 2010

### **Patient concerns**

- **Best possible medical care when faced with illness and disease**
- **Access to latest scientific advances**
- **Protection from poor health care practices**
- **Good information; options for treatment**
- **To be treated with dignity and respect**
- **Long-term consequences of disease, including quality of life and financial impacts**

### **The patients' rights advocate**

- **A liaison between patients and health care providers to help improve or maintain a high quality of health care for patients**
  - **An individual or organization**
  - **Provides educational materials and counseling to help patients make wise choices**
- Usually non-profit, focusing on one aspect of health care or a specific disease.*

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### **Who are the stakeholders?**

- **The uninformed public as patients and caregivers**
- **Hospital-designated (employee) advocates**
- **Patients' rights advocacy organizations**
  - The National Patient Advocate Foundation (Washington, DC)
  - American Association of Kidney Patients (Tampa, FL)
  - National Breast Cancer Coalition (Washington, DC)
  - National Marrow Donor Program, Patient Advocacy Office (Minneapolis, MN)

### **Stakeholders? (continued)**

- Breast Cancer Task Force, American Bar Association (Chicago, IL)
- Patient Action Network, American Medical Association (Chicago, IL)
- National Women's Health Network (Washington, DC)
- National Hospice and Palliative Care Organization (Princeton, NJ)
- American Pain Foundation (Baltimore, MD)
- Coalition for Patients' Rights (Baltimore, MD)
- National Association for Rights Protection and Advocacy (Phoenix, AZ) (mental health)
- Us Too International

### **Stakeholders? (continued)**

- **Fee-based organizations**
  - Houston Patient Advocacy (Bellaire, TX)
  - RN Patient Advocates (Tucson, AZ)
  - AdvoConnections (Baldwinsville, NY)
  - The Karis Group (Austin, TX)
  - The Patient Advocate Foundation (Hampton, VA)
  - Coalition for Patients' Rights (Baltimore, MD)
  - National Association for Rights Protection and Advocacy (Phoenix, AZ) (in mental health)
- **Individuals as patient counselors**

### **Regulation and patient access to health care**

In a regulatory context, factors that impact patients' rights:

- Trade-offs between regulations that restrict availability or patient access to new treatments
- Slow process for new drug or device regulatory approval
- Regulations that restrict hospitals' and physicians' ability to provide most effective treatments

### **Patients' Bill of Rights in Medicare and Medicaid (1997)**

- Pres. Clinton created the Advisory Commission on Consumer Protection and Quality in the Health Care Industry
  - to promote and assure health care quality and value, and to protect consumers and workers in the health care system
- The President asked the Commission to develop a "Patients' Bill of Rights"

### **Patients' Bill of Rights: goals**

- Strengthen consumer confidence that the health care system is fair and responsive to consumer needs
- Reaffirm the importance of a strong relationship between patients and their health care providers
- Reaffirm the critical role consumers play in safeguarding their own health

### **Federal statement on patients' rights**

1. The right to information... to receive accurate, easily understood information needed to make informed decisions about health plans, facilities and professionals.
2. The right to choose... health care providers; access to appropriate high-quality health care, including access for women to qualified obstetrician-gynecologists and for patients with serious medical conditions and chronic illnesses access to specialists.

### **Patients' Rights (continued)**

3. Access to emergency services... the right to emergency services when needed.
4. Being a full partner in health care decisions... the right to participate in all decisions related to their health care.
5. Care without discrimination... the right to considerate, respectful care, without discrimination based on race, ethnicity, national origin, religion, sex, age, mental or physical disability, sexual orientation, genetic information, or source of payment.

### **Patients' Rights (continued)**

6. The right to privacy... to communicate with health-care providers in confidence, with confidentiality of individually-identifiable health care information.
7. The right to speedy complaint resolution... to a fair and efficient process for resolving differences with health plans, health care providers, and institutions that serve them.

### **Patients' responsibilities**

1. **Maintain good health.** In a health care system that affords patients rights and protections, patients must also take greater responsibility for maintaining good health.

**Source:** Health and Safety Code Section 1288.4; 42 CFR 482.13, *Medicare Conditions of Participation* (64 Fed. Reg. 36070-36089, July 2, 1999)

### **Role of the ACMUI Patients' Rights Advocate**

- Provide technical advice that helps the NRC develop useful and practical medical regulations (that are not overly burdensome)
- Provide technical assistance in licensing, inspection, and enforcement cases, if needed

### **Role (continued)**

- Provide consulting services to NRC staff when requested
- Bring key issues to the attention of NRC staff for appropriate action
- Be cognizant of the impacts of NRC actions on patient access to health care, and represent the concerns of patients' rights stakeholders

### **Outreach**

- The ACMUI Patients' Rights Advocate can also be a useful liaison between patients' rights advocacy organizations and the federal regulatory process
  - Limited to the medical use of radioisotopes in diagnostic and therapeutic medicine

### **Organizations contacted**

- Citizens for Medical Isotopes
- The Patient Advocate Foundation
- Us Too International Prostate Cancer Education/Support
- Fighting Children's Cancer Foundation
- Conservatives for Patients' Rights

### **Feedback**

- Most advocacy organizations are not familiar with the nuclear regulatory process and regulations that impact the use of radioisotopes in medicine
- Notable exception: Us Too International, which participated at NRC request in the most recent Commissioner's briefing (July 8, 2010)

## **Feedback**

*"In relation to...requirements for reporting medical events with brachytherapy...it is important for doctors to use their clinical judgment to best treat the patient..."*

*"In closing, I would state that Us TOO would be happy to work through the NRC Advisory Committee Patient Rights' Advocate...relating to issues that our organization has in regards to the use of medical isotopes."*

— Dr. David Houchens, Columbus, Ohio

## **Plans**

- Continue outreach to patients' rights advocacy organizations
- Continue outreach to professional and scientific organizations involved in patient education and counseling
- Help organizations better understand the regulatory issues that affect patient access to best medical care
- Provide a meaningful liaison between these organizations and the NRC

## **Summary and conclusions**

- The most important elements of patient's rights are established in federal law
- The patients' rights advocate is an integral part of this NRC Advisory Committee
- Most patients, care givers, and rights advocacy organizations are not well informed on the medical isotope regulatory process
- The patients' rights advocate can provide a meaningful liaison between the NRC and patient advocacy organizations



## **Emerging Technology Novel Means of Radioisotope Production**

**October, 2010  
James Welsh, MS, MD  
Member, ACMUI**

### **The Problem**

- **Approximately 16 million procedures involving Molybdenum-99 (Technetium-99m) ( $^{99}\text{Mo}$  ( $^{99\text{m}}\text{Tc}$ )) alone per year in the U.S.**
- **There is an acute shortage of fission produced medical radioisotopes in the U.S.**

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### **The Problem (cont.)**

- **The shortage is due to unreliable operation of the two reactors that produce nearly all of the U.S. supply**
  - **NRU reactor in Canada**
  - **HFR reactor in the Netherlands**
- **These reactors are very old and unreliable, and require HEU as feedstock to produce medical isotopes**

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### **Stating the Obvious**

- **Presently the U.S. has no capability to produce these radioisotopes**
- **A domestic solution is desperately needed**
- **Most proposed solutions use either old existing reactors or reactor concepts**
  - **Research reactors are all ~50 years old and not designed for isotope production**
  - **Aqueous reactors must resolve power instabilities demonstrated previously, NRC must determine licensing strategy for liquid core reactors**

4

### **Brief History of Nuclear Medicine**

- **All medical radioisotopes were originally manufactured by other mechanisms**
- **By bombarding an aluminum sheet with particles emitted by polonium the Joliot-Curies created the first artificially produced radioactive element, which they called radio-phosphorus:  $^{27}\text{Al}(\alpha, n)^{30}\text{P}$**
- **Enrico Fermi produced a whole range of radioisotopes, including phosphorus-32 ( $^{32}\text{P}$ )**
- **Soon  $^{32}\text{P}$  was used to treat a patient with leukemia**

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### **Brief History of Nuclear Medicine**

- **In contrast to carbon-11 which has a 20 min half-life,  $^{14}\text{C}$  has a long half-life (5770 y) thereby allowing practical exploration of metabolism with radiolabeled carbon**
- **In 1940, bombardment of carbon-13 with deuterons led to discovery of carbon-14:  
-  $^{13}\text{C}(d, p)^{14}\text{C}$**

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### **Brief History of Nuclear Medicine**

- Ernest O. Lawrence used his cyclotron to bombard molybdenum-98 with deuterons possibly creating element 42 (which at that time was a gap in the Periodic Table)
- 1937 - Emilio Segre (who later won the 1959 Nobel Prize for the discovery of the antiproton) studied a sample of Lawrence's product and confirmed it was a new element not existing in nature
- Because it was the result of man-made nuclear reactions he dubbed it "technetium"
  - Doesn't exist in nature

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### **Brief History of Nuclear Medicine**

- John Lawrence (brother of Ernest O.) developed and administered the therapeutic procedures
- In 1936 he treated a 28-year old leukemia patient using  $^{32}\text{P}$  produced in one of his brother's cyclotrons
- It was the first time a radioisotope was used in the treatment of a disease, marking the birth of nuclear medicine.

8

### **Brief History of Nuclear Medicine**

- It was soon discovered that the thyroid accumulated radioiodine ( $^{131}\text{I}$ )
- $^{131}\text{I}$  could be used to study abnormal thyroid metabolism in patients with goiter and hyperthyroidism
- In patients with thyroid cancer, distant metastases were identified by scanning the whole body with the Geiger counter

9

### **Brief History of Nuclear Medicine**

- The names "radioisotope scanning" and "atomic medicine" were introduced
- All of these radioisotopes are now considered as 'reactor-produced isotopes'
  - But none were reactor-produced at that time...

10

### **Brief History of Nuclear Medicine**

- The first commercial medical cyclotron was installed in 1941 at Washington University, St. Louis
- Soon there wasn't enough cyclotron capacity to meet the rising demand for isotopes
- Civilian use of a military nuclear reactor provided relief
- The Manhattan Project resulted in an unprecedented expansion of radiation research and expertise, as well as its diagnostic and therapeutic application in the new field of nuclear medicine
- Radioisotopes became abundant - most medical radioisotopes began to be produced in nuclear reactors during World War II

11

### **Brief History of Nuclear Medicine**

- This was all under the secrecy of the Manhattan Project
- To protect this secrecy, the  $^{32}\text{P}$  produced by the reactor had to appear as if it had been produced by a cyclotron
- Thus,  $^{32}\text{P}$  was sent from Oak Ridge to the cyclotron group at the University of California at Berkeley, from where it was distributed to the medical centers(!)

12

## Brief History of Nuclear Medicine

- The shortage of radioisotopes ended in 1945, when isotopes became widely available, including reactor-produced  $^{131}\text{I}$  from Oak Ridge
- Globally, particle accelerators produced the vast majority of radioisotopes with medical applications until the 1950s when other countries followed the US by generating isotopes in reactors

13

## Means of making isotopes

- The predominant method of  $^{99}\text{Mo}$  production (and the only method used for North American  $^{99}\text{Mo}$ ) is through fission of uranium-235
  - $^{235}\text{U}(n,f)^{99}\text{Mo}$
- Fission of **HEU** by thermal neutrons in a reactor
- The HEU is generally weapons-grade (about 95%  $^{235}\text{U}$ ) in the form of a uranium-aluminum (U-Al) alloy
  - Roughly 6% of the total fission yield is  $^{99}\text{Mo}$
- Few other Mo isotopes are produced, resulting in a "carrier-free," high specific activity product
  - The specific activity is about 5000 Curies/gram (Ci/g).

14

## Means of Making Isotopes

- It is possible to use LEU in a reactor
- But requires about 5x increased neutron flux to produce the same amount due to the 5x lower abundance of  $^{235}\text{U}$
- It is hoped that this can be partially offset by development of denser U-foil targets
- The proportion of undesirable fission products will increase
  - may require modifications to the present chemical purification process and will require new FDA regulatory approvals.

15

## Means of Making Isotopes

- Babcock & Wilcox and others are investigating novel reactor concepts, such as liquid LEU solutions for both fuel and target
- Some have argued LEU is not a practical solution to the  $^{99}\text{Mo}$  shortage due to the expense and political difficulty of building new reactors

16

## Alternatives to Conventional Methods

- A photofission process can be used with either of two reactions
  - $^{235}\text{U}(\gamma,f)^{99}\text{Mo}$
  - $^{238}\text{U}(\gamma,f)^{99}\text{Mo}$
- About 50% higher yield is obtained with  $^{235}\text{U}$
- For either reaction, roughly 6% of the total photofission yield is  $^{99}\text{Mo}$
- The cross section is relatively low
- A high electron beam power is required to make significant amounts of  $^{99}\text{Mo}$  through these reactions

17

## Alternatives to Conventional Methods

- An accelerator-driven neutron source could be used for
- $^{235}\text{U}(n,f)^{99}\text{Mo}$  or
- $^{98}\text{Mo}(n,\gamma)^{99}\text{Mo}$

18

## Means of Making $^{99}\text{Mo}$ from Non-uranium Targets

- Neutron capture by enriched  $^{98}\text{Mo}$  (natural molybdenum is ~24%  $^{98}\text{Mo}$ ) is the most commonly used alternative to  $^{235}\text{U}$  fission for production of  $^{99}\text{Mo}$ , eliminating the need for uranium targets
  - $^{98}\text{Mo}(n,\gamma)^{99}\text{Mo}$
- Other non-uranium approaches exist:
- A photoneutron ( $\gamma,n$ ) reaction has been proposed targeting  $^{100}\text{Mo}$  with a photon beam from a linac
  - $^{100}\text{Mo}(\gamma,n)^{99}\text{Mo}$

19

## Means of Making $^{99}\text{Mo}$ from Non-uranium Targets

- Another possible neutron reaction is
  - $^{100}\text{Mo}(n,2n)^{99}\text{Mo}$
- Using 14MeV neutrons on an enriched  $^{100}\text{Mo}$  target
- This reaction has an order of magnitude larger cross-section than the  $^{98}\text{Mo}(n,\gamma)^{99}\text{Mo}$  thermal neutron capture reaction, but yields a similar low specific activity product

20

## Alternatives to Neutrons

- The  $^{100}\text{Mo}(p,pn)^{99}\text{Mo}$  proton-driven reaction has been investigated by a number of researchers
  - but it (maybe) has a relatively low cross section and
  - would produce a low specific activity product
- The deuteron reaction
  - $^{100}\text{Mo}(d,p2n)^{99}\text{Mo}$
  - has twice the cross-section of  $^{100}\text{Mo}(p,pn)^{99}\text{Mo}$ , but requires higher energy beams

21

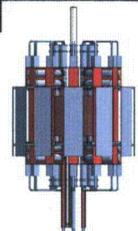
## Alternatives to Neutrons

- Bombarding enriched  $^{100}\text{Mo}$  targets with protons from a cyclotron to directly produce  $^{99m}\text{Tc}$ 
  - $^{100}\text{Mo}(p,2n)^{99m}\text{Tc}$
- This direct production has a relatively large cross section in the region of 20 MeV
- This approach could possibly use regional cyclotrons to provide a local source of  $^{99m}\text{Tc}$  for large metropolitan areas
- But of course is not a global or national solution

22



**PHOENIX NUCLEAR LABS**  
PROVIDING NUCLEAR TECHNOLOGY FOR THE BETTERMENT OF HUMANITY

Prepared for James Welsh and the NRC ACMUI on September 23<sup>rd</sup>, 2010 by Dr. Gregory Piefer

- The Morgridge Institute for Research and Phoenix Nuclear Labs are developing a system to produce reactor grade medical isotopes without a reactor
- Two key aspects:
  - Primary neutrons created by high output deuterium-tritium (D-T) source
  - Neutrons enter aqueous LEU solution where they multiply subcritically and create medical isotopes
- This single device could possibly produce nationally relevant quantities of  $^{99}\text{Mo}$  and other medical isotopes

24

### SHINE Overview

- **SHINE: Subcritical Hybrid Intense Neutron Emitter**
- Based on smaller **FLAME™** (Fusion Linear Accelerator for Medicine) technology
  - Creates up to  $10^{15}$  neutrons/second (n/s) through fusion by colliding deuteron beams with a tritium gas target
  - Neutrons are multiplied and moderated with a combination of beryllium and water
- Neutrons strike uranium targets dissolved in solution
- Uranium targets provide further multiplication of the neutron flux, but system is operated below criticality
- Isotope separation made simpler by aqueous technology

25

### SHINE Overview

- Deuterium gas flows into ion source, is ionized by RF or microwaves
- Simple DC accelerator pushes ions toward target chamber (300 keV)
- Accelerated deuterons strike tritium gas in target chamber, creating neutrons
  - Neutrons are made by reactions between deuterium and tritium atoms
- Proof of high efficiency and yield already demonstrated ( $> 2 \cdot 10^9$  n/s per watt)
- High energy neutrons allow for (n,2n) multiplication on beryllium
- Only reaction products from this process are neutrons and helium-4 ( $^4\text{He}$ )

26

### SHINE Driver Specifications

- **Physical**
  - Consists of two ion injector / accelerator pairs discharging into a common target chamber
  - Structure held together with aluminum frame
  - Integrated beryllium multiplier ~ 1000 lbs
  - Total driver weight ~ 2000 lbs
  - Ion source, pumping power supplies, cooling systems fully integrated
  - High voltage delivered externally

27

### SHINE Driver Specifications

- **Operational**
  - Deuteron / triton current: 100 mA (50 mA per injector)
  - Beam energy: 350 keV
  - Beam power: 35 kW
  - Neutron output:  $5 \cdot 10^{13}$  n/s (14.1 MeV)
  - Tritium inventory: 0.015 grams (< 150 Ci)
  - Tritium consumption (per year): 0.007 grams (~ 60 Ci)
  - Wall power (with pumping): 50 kW

28

### Subcritical Hybrid Intense Neutron Emitter

- **SHINE (Subcritical Hybrid Intense Neutron Emitter)**
  - Consists of an aqueous pool of uranium nitrate or sulfate
- Pool driven by 12 D-T drivers
- Beryllium surrounding pool provides neutron reflection and multiplication
- Isotopes made from fission of uranium in solution
- Uranium concentration controlled to keep pool subcritical
- Solution chamber partitioned so sections may be drained on different days

29

### Specifications

- **Physical**
  - Size: 7 meters long by 3.5 meter diameter
  - Weight: 20 tons
  - Materials: primarily Zircalloy, aluminum, beryllium
- **Safety**
  - Subcritical, criticality monitored by in-core neutron detectors
  - Large negative power coefficient caused by radiolysis
  - Neutron poisons to be added if criticality exceeds operational limits
  - Dump tank if reactivity exceeds safety thresholds with passive and active valves

30

## Specifications

- **Key parameters**
  - Fission power: ~ 250 kW
  - <sup>99</sup>Mo production rate: 2500 6-day kCi/week
  - Driver neutron production:  $6 \times 10^{14}$  n/s @ 14.1 MeV
  - Driver power consumption: 600 kW
  - Multiplication factor from Be: 2-3
  - Maximum Keff : ~ 0.95
  - Neutron flux: ~  $10^{13}$  n/cm<sup>2</sup>/s average flux in solution

31

## Specifications

- **Key Benefits**
  - No criticality
  - No instability as demonstrated with all previous aqueous reactor systems
  - Inherent safety-needs to be driven to operate
  - Greatly reduced nuclear waste (no reactor needed)
  - Utilizes low enriched uranium (19.5%)
  - Aqueous process improves chemical extraction efficiency
  - Simplified regulatory approval process

32

## Present Status (Summer 2010)

- Phoenix Nuclear (and the Morgridge Institutes for Research and University of Wisconsin-Madison) is seeking a DOE grant to assist with construction of SHINE production facility
- Several key partners secured or in negotiation
  - Los Alamos National Laboratory
  - Lawrence Berkeley National Laboratory
  - TechSource
  - MDS-Nordion
  - GE
  - Lantheus Medical Imaging
  - INVAP-Argentina
- Goal is to commercialize SHINE by Jan. 1, 2014

33

## Acronyms

**DC** – direct current  
**DOE** – Department of Energy  
**HEU** – Highly-enriched Uranium  
**HFR** – High Flux Reactor  
**keV** – kiloelectron volt  
**kW** - kilowatt

34

## Acronyms

**lbs** - pounds  
**LEU** – Low Enriched Uranium  
**mA** - milliamp  
**MeV** – megaelectron volt  
**NRU** – National Research Universal  
**RF** – radio frequency

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NO HANDOUT

NO HANDOUT

NO HANDOUT

NO HANDOUT

NO HANDOUT

NO HANDOUT



## **Physical Protection of Byproduct Material – Proposed Rule**

Merri Horn  
Senior Project Manager  
October 21, 2010

1



## **10 CFR Part 37 - Timeline**

- Preliminary language posted for comment
  - complete
- Proposed rule to Commission
  - complete
- Publication for public comment
  - ongoing, extended until January 15, 2011
- Public workshop on guidance
  - complete
- Final rule to Commission
  - Spring 2012

2



**Overview of the  
U.S. Nuclear Regulatory Commission's  
Initiatives on the Use of Cesium-137 Chloride Sources**

**John P. Jankovich, Ph.D.  
U.S. Nuclear Regulatory Commission  
Office of Federal and State Materials and Environmental  
Management Programs**

**Use of CsCl Sources**

- Primary Applications
  - Blood irradiators
  - Research irradiators
  - Calibrators
- Use of Cesium-137 Chloride (CsCl)
  - Ideal energy spectrum (670 keV)
  - long half life (30 years)
  - Readily available
- Materials Properties
  - Currently in compressed powder form
  - Highly soluble
  - Highly dispersible

2

Gammacell 40 irradiator



3

Category I Irradiator - Gammacell 1000 Elite



J.L. Shepherd - Category 1 Irradiator



J.L. Shepherd Calibrator





Hopewell Designs, Inc. irradiator

7

#### History of NRC's CsCI Work

- 2005 The Energy Policy Act of 2005
  - Radiation Source Protection and Security Task Force is to be established
  - NRC is to fund a study by the National Academy of Science
- 2006 Task Force 1<sup>st</sup> Report issued
- 2008 National Academy study completed
- 2008 CsCI Working group report completed
- 2008 Public Workshop on the use of Cs-137
- 2010 Task Force 2<sup>nd</sup> report issued
- 2010 Draft Policy Statement published in Federal Register
- 2010 Nov. 8-9: Public Meeting on Draft Policy

8

#### Task Force Objectives

- Primary vehicle for advancing source security issues across the Government
- Identify gaps, overlaps, inconsistencies or weaknesses in current programs
- Provide recommendations related to security of radiation sources in the U.S. from potential terrorist threats, including acts of sabotage, theft, or use of radiation source in a Radiological Dispersal Device (RDD)

9

#### 2006 Task Force Report

- Conclusions:
  - No significant gaps that are not already being addressed
  - Current framework provides reasonable assurance that risk-significant sources (Category 1 and 2 sources) in use and storage are safe and secure through inspection and enforcement
- 10 Recommendations
- 18 Actions

10

#### 2008 CsCI Working Group Report

- Immediate phase-out would not be feasible
- Step-wise phase-out could be feasible
- Challenges would have to be overcome
- Sufficient time would be necessary for replacement technologies to be established and for disposal pathways
- Sequences and time-frames would be critical
- Interim security measures are important

11

#### 2010 Task Force Report

- Shorter, more concise (accessible as ML102230141)
- Four main topical areas/chapters:
  - Coordination and communication
  - Advances in the security and control of radioactive sources
  - Status of recovery final disposition of radioactive sources
  - Progress in the area of alternative technologies
- 11 recommendations
  - 4 directly related to CsCI sources (#'s 3, 4, 10, 11)
  - 1 indirectly related to CsCI sources (# 9)

12

#### 2010 Task Force Report: Cs-137 Recommendations

- Recommendation 3: discontinue licensing exports (contingent on disposal capacity, alternative technologies, threat)
- Recommendation 4: continue evaluation of disposal options, including handling large number of CsCl sources
- Recommendation 10: investigate options for voluntary use of alternative technologies with initial focus on CsCl sources
- Recommendation 11: review discontinuation of licensing CsCl sources (contingent on alternatives and threat)
- Recommendation 9 (indirectly related): support Research & Development (R&D) for alternative technologies

13

#### 2008 ACMUI Report

- "ACMUI Report on <sup>137</sup>CsCl Irradiators" (ML083030593)
- Purpose: provide input for NRC staff to develop Draft Policy Statement
- Issues addressed:
  - Practicality of alternatives, i.e. x-ray devices for blood irradiation and animal research
  - American Association of Physicist in Medicine (AAPM) survey results
  - Linear accelerators
  - Alternative radionuclides
  - Further considerations for blood irradiation
  - Irradiator security
  - Alternative forms for <sup>137</sup>Cs sources

14

#### 2010 Draft Policy Statement

- Published in the Federal Register (75 FR 37483), June 29, 2010:
  - to solicit public input
  - to announce a public meeting November 8-9, 2010
- 7 major statements
- discussion of specific issues:
  - Security and control of sources
  - Areas use
  - Disposal
  - NRC's perspectives on further security enhancements

15

#### 2010 Public Meeting Issues

1. The safety and security of risk significant sources is an essential part of the NRC's mission. Licensees have the primary responsibility to securely manage and to protect sources in their possession from misuse, theft, and radiological sabotage.
2. Adequate protection of public health and safety is maintained if CsCl sources are managed in accordance with the security requirements of the NRC and the Agreement States. NRC monitors the threat environment and maintains awareness of international and domestic security efforts. If changes in the threat environment necessitate regulatory action, the NRC is ready to issue additional security requirements to apply appropriate limitations for the use of CsCl in its current form.
3. Could hardware improvements be made that would further mitigate or minimize the radiological consequences?

16

#### Public Meeting Issues (cont'd)

4. The development and use of alternative forms of cesium-137, while not required for adequate protection, is prudent and the NRC intends to monitor these developments closely.
5. CsCl enables three specific classes of applications that benefit society: (a) blood irradiation, (b) bio-medical and industrial research, and (c) Calibration of instrumentation and dosimetry.
6. The NRC recognizes that currently there is no disposal capability for such commercial sources. The NRC considers it imperative to develop a pathway for the long term storage and disposal of these sources whether or not there are alternatives developed.

17

#### 2010 Public Meeting Participation

- Date: November 8-9, 2010
- Location: The Universities at Shady Grove Conference Center, 9630 Gudelsky Drive, Rockville, MD 2085
- Attendance:
  - Panelists
  - Participants
- All relevant information continually posted:  
<http://www.nrc.gov/materials/miau/licensing.html#cc>

18

#### 2010 Public Meeting Contacts

- Correspondence:  
[CesiumDraftPolicy@nrc.gov](mailto:CesiumDraftPolicy@nrc.gov)
- Contacts:
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  - Cynthia G. Jones, (301) 415-0298, e-mail  
[cynthia.jones@nrc.gov](mailto:cynthia.jones@nrc.gov)

19

#### CsCl Source Security

- CsCl sources are widely used and safely secured in medical, industrial, and research applications
- Several initiatives have been implemented already to improve security of these sources
- Strengthening domestic/international collaboration is a top priority for further enhancing security of CsCl sources
- Publication of the final Policy Statement on the use and protection of CsCl sources is scheduled for 2011

20



## **Patient Release Subcommittee Report**

**October 21, 2010**

**Susan M. Langhorst, Ph.D.**

**Advisory Committee on the Medical Uses of Isotopes**

**Acknowledgements: D. Fisher, D. Gilley, S.  
Mattmuller, O. Suleiman, B. Thomadsen, J.  
Welsh, P. Zanzonico**

## **Subcommittee Charge**

### **Evaluate patient release issues**

- Objectively review and analyze data, regulations/guidance, and international recommendations
- Provide statement on issues, including –
  - Release to other than private residence
  - Per-release limit vs. annual limit
- Recommend needed changes/improvements

2

## **Statement**

**Dose to other individuals is safely and cost-effectively controlled by –**

- Current 10 CFR 35.75 release criteria
- Scientifically developed, dose-based release calculation methods and physician assessment of patient release suitability
- Patients' and caregivers' understanding of and adherence to release instructions on maintaining dose to others ALARA

3

## **Fundamental principles for use of radioactive materials**

- Justification
- Optimization of Protection (ALARA) – account for economic and societal as well as medical factors
- Application of Dose Limits

4

## **Statements**

**Current release criteria appropriately balance safety, access to treatment and cost**

- Consistent with national and international recommendations in principle/practice
  - 5 mSv/episode for caregivers/relatives
  - 1 mSv/y for child/pregnant woman/public
- Apply to single releases - not annual limit
- Focus on patient precautions to maintain dose to others ALARA

5

## **Statements**

**Concerning a return to previous NRC patient release criteria – “30 mCi rule”**

- Has no identifiable scientific basis
- Excessive for some radionuclides and inadequate for other radionuclides
- Does not account for patient actions
- Specifically not recommended as sole release criterion by ICRP and IAEA
- Inappropriate for NRC regulations

6

## Recommendations

### NRC guidance on patient release dose calculation

- Update with current information and realistic assumptions
- Support development of computer-based calculation tools available to licensees
- Address different patient living and other release situations

7

## Recommendations

### NRC guidance on patient release instructions

- Incorporate new release calculation information, use new communication tools
- Support research efforts to advance understanding and communication of circumstances that impact patient release decisions, instructions and perceptions

8

## Conclusions

- Medical use is important – benefits millions of patient lives each year
- 10 CFR 35.75 should not be changed
- NRC should focus on providing
  - Appropriate/realistic guidance for licensees and patients
  - Research support for understanding and communication of the real-world issues impacting patient care and public safety

9

## Discussion

- Justification (benefits)
- Maintaining doses as low as reasonably achievable
- Applying appropriate limits

10

## Discussion

- Per release vs. annual limit
- I-131 vs. other medical radionuclides
- NCRP, ICRP and IAEA recommendations - consistency in principle and practice

11

## Discussion

- Use of realistic assumptions to assess patient release
- Different release scenarios, e.g., hotels
- Actual data on exposure to other individuals

12

## Discussion

- **Written/oral instructions**
- **When given and at what level**
- **Determining suitability of patient release**
- **Development of communication tools**

13

## Discussion

### Licensee accountability in regard to

- **Released patient waste**
- **Death of released patient**
- **Patient self-discharge (State use of quarantine authority)**
- **Documentation of patient housing arrangements**

14

## Discussion

### Comments concerning 30-mCi rule

15

## Discussion

### Need for scientific data on patient behavior and effectiveness of communication for patient comprehension

16

## Acronyms

- **ALARA - As low as reasonably achievable**
- **CFR - Code of Federal Regulations**
- **IAEA - International Atomic Energy Agency**
- **ICRP - International Council on Radiological Protection**
- **1 mSv - 1 millisievert = 100 mrem**
- **NRC - Nuclear Regulatory Commission**
- **Patient - includes clinical patients and human research subjects**

17

1  
2  
3 **Advisory Committee on the Medical Use of Isotopes (ACMUI)**  
4 **Patient Release Subcommittee Report**  
5  
6  
7

8 **Subcommittee Members:** D. Fisher, Ph.D.; D. Gilley, MPA; S. Langhorst, Ph.D. (Chair); S.  
9 Mattmuller, MS, R.Ph, BCNP; O. Suleiman, Ph.D.; B. Thomadsen, Ph.D.; J. Welsh, M.D.; P.  
10 Zanzonico, Ph.D.  
11

12  
13  
14 **Charge:** To evaluate patient release/human research subject release issues; to objectively review  
15 and analyze data, which may include state regulations and guidance as well as recommendations in  
16 international guidance documents; to provide a statement on the issues, including patient release to  
17 other than private residences and an annual rather than per-release limit on radiation doses to others  
18 from released individuals; and, if appropriate, to provide recommendations for improvements to  
19 existing NRC rules and guidance.  
20

21  
22  
23 **Summary Statements and Recommendations**  
24

- 25 1. The medical use of radioisotopes provides unique and important diagnostic and therapeutic tools  
26 that have well-recognized health benefits<sup>1,2,3,4</sup>. Use of radioisotopes in medicine and patient  
27 access to radioisotope-based medical procedures, with associated public doses at or below  
28 typical environmental background levels, should not be burdened by excessive regulatory  
29 controls. The Subcommittee affirms that doses to other individuals from released patients<sup>5</sup> can  
30 be safely controlled by:  
31 a. the current 10-CFR 35.75 patient release criteria,  
32 b. licensees' use of scientifically developed dose-based release calculation methods, and  
33 patient release instructions based on patient circumstances, and  
34 c. patients' and caregivers' understanding of and adherence to the patient release instructions.  
35

<sup>1</sup> NCRP Commentary No. 11, "Dose Limits for Individuals Who Receive Exposure from Radionuclide Therapy Patients", National Council on Radiation Protection and Measurements, February 1995.

<sup>2</sup> ICRP Publication 94, "Release of Patients after Therapy with Unsealed Radionuclides", International Commission on Radiological Protection, March 2004.

<sup>3</sup> NCRP Report No. 155, "Management of Radionuclide Therapy Patients", National Council on Radiation Protection and Measurements, December 2006.

<sup>4</sup> IAEA Safety Reports Series No. 63, "Release of Patients after Radionuclide Therapy", International Atomic Energy Agency, 2009.

<sup>5</sup> Use of the term "patient" in this report is intended to also include human research subject.

- 36 2. Current 10 CFR 35.75 patient release criteria, along with NRC RIS 2003-04<sup>6</sup>, appropriately  
37 balance public safety with patient access to medical treatment.  
38 a. The current 10 CFR 35.75 patient release criteria apply to single patient releases.  
39 b. National and international scientific recommendations on patient release are consistent, in  
40 principle and practice, with NRC patient release regulations and guidance.  
41 c. The NRC per-release 500-mrem dose limit for any individual is consistent with ICRP and  
42 IAEA recommendations for caregivers and other members of the patient's household.  
43 d. For all other members of the general public, NRC requires the licensee to provide written  
44 instructions to the patient on ways to keep radiation dose as low as reasonably achievable, or  
45 less than 100 mrem. Specifically, these instructions protect children, pregnant women, and  
46 non-caregivers.  
47 e. The NRC patient release criteria should apply to individual patient-release events and should  
48 not be construed as an annual limit on multiple releases of the same patient.  
49
- 50 3. NRC guidance on patient release calculations, originally proposed in 1997<sup>7</sup>, overestimates  
51 caregiver and public doses by use of unrealistically conservative assumptions. The  
52 Subcommittee recommends that:  
53 a. The NRC guidance and assumptions should be updated, with assistance from experts, and  
54 should include current information on actual radiopharmaceutical biokinetics and calculated  
55 patient dose rates.  
56 b. Updated scientific tools should be developed to assist licensees for determining and  
57 documenting compliance with the patient-release criteria.  
58 c. Reasonable assumptions should be employed for calculating dose to people from a released  
59 patient.  
60 d. In addition to private residences, release scenarios should address patient release to other  
61 locations (such as hotels, public transport, public events).  
62
- 63 4. NRC instructions for patient release, originally proposed in 1997<sup>7</sup>, should be updated, in  
64 conjunction with release calculation methods and assumptions, and the NRC should support  
65 research efforts to advance understanding and communication of circumstances that impact  
66 patient release decisions, instructions and perceptions.  
67

## 70 Scientific Evaluation of Patient/Human Research Subject Release Issues

71  
72 Experts in radiation protection<sup>8,9</sup> apply three fundamental principles to the use of radioactive  
73 materials:  
74

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<sup>6</sup> NRC Regulatory Issue Summary 2003-04 "Use of the Effective Dose Equivalent in Place of the Deep Dose Equivalent in Dose Assessments" (February 13, 2003).

<sup>7</sup> NRC Regulatory Guide 8.39, "Release of Patients Administered Radioactive Materials", Nuclear Regulatory Commission, April 1997.

<sup>8</sup> NCRP Report No. 116, "Limitation of Exposure to Ionizing Radiation", National Council on Radiation Protection and Measurements, March 1993.

<sup>9</sup> ICRP Publication 103, "The 2007 Recommendations of the International Commission on Radiation Protection", March 2007.

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

85 The appropriate use of radioactive materials in medicine is accepted as doing more good than  
86 harm. Exposure to the patient is intentional for the direct medical benefit of the patient. Radiation  
87 protection experts oppose dose limits for patients because doing so may compromise the  
88 effectiveness of the patient's diagnosis or treatment, and thus do more harm than good. Instead,  
89 experts emphasize the physician's informed medical justification for a patient's medical procedure  
90 while maintaining the patient's radiation dose as low as reasonably achievable, taking into account  
91 economic and societal as well as medical factors.

92

93

94 Exposure to Other Individuals from Patients Released from Licensee Control

95

96 Patients undergoing therapeutic medical procedures using radioactive materials may expose  
97 other individuals to radiation fields that warrant appropriate precautions for limiting doses to those  
98 individuals. Patients undergoing diagnostic radiopharmaceutical procedures may also expose other  
99 individuals to radiation fields; however, the likely exposure is low, but not necessarily zero<sup>10,11</sup>. In  
100 addition to its diagnostic applications, iodine-131 (I-131) is the most commonly used therapeutic  
101 radionuclide with potential for measureable dose to others. Thus, the Subcommittee focused its  
102 review of exposures to individuals from released I-131 therapy patients.

103

104

105 Scientific Development of Current NRC Patient Release Criteria

106

107 The NRC received three petitions for rule making<sup>12,13,14</sup> in the early 1990s concerning 10 CFR  
108 35.75 patient release criteria, which at that time included an activity-based limit, and 10 CFR  
109 20.1301 public dose limits. In response to these petitions, the NRC evaluated patient release criteria  
110 which appropriately applied the three fundamental principles previously discussed. The NRC  
111 considered three alternatives in its cost-benefit analysis<sup>10</sup> of the controlling criterion for determining  
112 when a patient may be released from the licensee's control:

<sup>10</sup> ICRP Publication 94, "Release of Patients after Therapy with Unsealed Radionuclides", International Commission on Radiological Protection, March 2004.

<sup>11</sup> NRC NUREG-1492, "Regulatory Analysis on Criteria for the Release of Patients Administered Radioactive Materials, Final Report", by Stewart Schneider and Stephen A. McGuire, Nuclear Regulatory Commission, April 1996.

<sup>12</sup> 56 FR 26945: "Carol S. Marcus; Filing of Petition for Rulemaking" (NRC Docket No. PRM-20-20).

<sup>13</sup> 57 FR 8282: "American College of Nuclear Medicine; Receipt of Petition for Rulemaking" (NRC Docket No. PRM-35-10) and 57 FR 21043: "American College of Nuclear Medicine; Receipt of Amended Petition for Rulemaking" (NRC Docket No. PRM-35-10A).

<sup>14</sup> 59 FR 37950: "American Medical Association; Petition for Rulemaking" (NRC Docket No. PRM-35-11).

113  
114 **Alternative 1** – 1 mSv (100 mrem) per year dose limit in 10 CFR 20.1301

115  
116 **Alternative 2** – less than 1,110 MBq (30 mCi) or less than 0.05 mSv/h (5 mrem/h) at 1  
117 meter per the activity-based, 1996 version 10 CFR 35.75<sup>15</sup>

118  
119 **Alternative 3** – 5 mSv (500 mrem) dose limit

120  
121 NRC concluded that **Alternative 3** best served the interest of patients and society<sup>16</sup> based on the  
122 following reasons:

- 123  
124 1. All of the alternatives are compatible with generally accepted radiation protection principles.  
125 2. **Alternative 1** was dismissed due to its excessive economic costs and adverse psychological  
126 impact on patients and their families due to the required patient isolation.  
127 3. **Alternative 3** was preferred over **Alternative 2** because of its more favorable cost-  
128 effectiveness and more positive psychological impact on patients and their families.  
129 4. Basing patient release criteria on the dose to individuals exposed to a patient provided the  
130 consistent, scientific basis of dose for such decisions that treats all radionuclides on a risk-  
131 equivalent basis. The 30-mCi limit (**Alternative 2**), which may be appropriate for iodine-  
132 <sup>131</sup>I under some circumstances, was excessive for some patients and clinical situations using  
133 certain other radionuclides (projected doses would be well below the dose limit), but  
134 inadequate for other situations and radionuclides (projected doses exceed the dose limit).  
135 5. **Alternative 3** would allow physicians flexibility to *not* have to fractionate therapy doses,  
136 leading to improved effectiveness of treatment for the patient while avoiding unnecessary  
137 hospitalization associated with the 30-mCi rule<sup>17</sup>.  
138 6. Reduction of medically unwarranted hospital stays would provide emotional benefits to  
139 patients and their families. Allowing earlier reunion of families could improve the patient's  
140 state of mind, which in itself may improve the outcome of the treatment and lead to the  
141 delivery of more effective health care. At the same time, the opportunity to personally care  
142 for a seriously ill family member is comforting to many individuals.

143  
144 The Subcommittee affirms the thorough analysis found in NUREG-1492 and its rational  
145 development for evaluating the three alternatives. The NRC's final decision to implement  
146 **Alternative 3** as the patient release criteria found in 10 CFR 35.75 appropriately considered the  
147 balance of the three fundamental radiation protection principles for use of radioactive materials in  
148 medicine.

149  
150  

---

<sup>15</sup> Also referred to as the "30-mCi rule"

<sup>16</sup> NRC SECY 96-100: "Final Amendments to 10 CFR Parts 20 and 35 on Criteria for the Release of Individuals Administered Radioactive Material", Nuclear Regulatory Commission, May 8, 1996.

<sup>17</sup> In locations where the 30-mCi rule is in effect, some physicians treat thyroid cancer with multiple administrations of 29.9 mCi of I-131 for no reason other than to avoid hospitalization of patients, thereby treating the patient in a protracted, less therapeutically-effective manner, which can compromise the treatment and, ultimately, the well-being of the patient. When physicians choose to treat thyroid cancer with one administration greater than 30 mCi of I-131, patients can be denied treatment, some for many months, until a private hospital bed is available.

151 National and International Recommendations Regarding Released Patients

152  
153 The most recent National Council on Radiation Protection and Measurements (NCRP)  
154 recommendations specific to release criteria for radionuclide therapy patients were in place at the  
155 time NRC established the current 10 CFR 35.75 release criteria. The NCRP recommends<sup>18</sup> the  
156 following:

<u>Other Individual</u>	<u>NCRP<sup>18</sup> Recommended Dose Limit</u>
Public	1 mSv/y, but 5 mSv/y may be used for infrequent exposures
Patient's Family, Adults	5 mSv/y, 50 mSv/y with special training
Patient's Family, Children and Pregnant Women	1 mSv/y

158  
159 The International Commission on Radiation Protection (ICRP) recently updated its  
160 recommendations on limiting dose to other individuals from the release of patients after therapy  
161 with unsealed radionuclides<sup>19</sup>. The ICRP recommendations incorporate the concept of dose  
162 constraint, rather than a dose limit, as follows:

<u>Other Individual</u>	<u>ICRP<sup>19</sup> Recommendations</u>
Public	1 mSv/y (limit)
Relatives, Visitors, and Caregivers	A few mSv/episode (constraint)
Infants, Young Children, and Casual Visitor	1 mSv/y (limit)

164  
165 The International Atomic Energy Agency (IAEA) also recently published a safety series report  
166 on the release of radionuclide therapy patients<sup>20</sup>. The IAEA endorsed the ICRP recommendations  
167 and further clarified its criteria in a recent position statement<sup>21</sup>.

168  
169 All three of the above authoritative national and international advisory bodies agree that the  
170 decision to hospitalize or release a patient should be determined on an individual basis and should  
171 be based on dose criteria rather than on residual-activity criteria (as with the previous 30-mCi rule).  
172 The physician's decision should also take into account the patient's wishes and medical condition,  
173 his or her physical and mental capacity to understand and follow instructions, occupational and  
174 public exposures, family considerations (including the presence of children and pregnant women in  
175 the household), cost, and environmental factors. These advisory bodies' recommendations  
176 incorporate the concept of keeping the dose to other individuals as low as reasonably achievable,  
177 and recognize the need for flexibility for the regulatory authority's practical application of limits  
178 and constraints so that patient physical and psychological factors, and economic and social factors  
179 are properly considered.

<sup>18</sup> NCRP Commentary No. 11, "Dose Limits for Individuals Who Receive Exposure from Radionuclide Therapy Patients", National Council on Radiation Protection and Measurements, February 1995.

<sup>19</sup> ICRP Publication 94, "Release of Patients after Therapy with Unsealed Radionuclides", International Commission on Radiological Protection, March 2004.

<sup>20</sup> IAEA Safety Reports Series No. 63, "Release of Patients after Radionuclide Therapy", International Atomic Energy Agency, 2009.

<sup>21</sup> IAEA Position Statement, "Release of Patients after Radionuclide Therapy", International Atomic Energy Agency, February 23, 2010.

181 The ICRP noted that determination of the costs associated with various methodologies related to  
 182 release of patients after therapy with unsealed radionuclides had generally not been attempted<sup>18</sup>.

183 The ICRP stated:

184  
 185 “Ideally, ‘costs’ should include psychological and adverse health consequences, as well as  
 186 monetary costs. Cost-benefit analysis for a specific issue may vary substantially from  
 187 country to country, but it does provide a tool that may help the optimization process.”  
 188

189 The ICRP cited the NRC’s NUREG-1492 cost-benefit analysis as a scientifically appropriate  
 190 example.

191  
 192 The Subcommittee considers the current 10 CFR 35.75 release criteria to be consistent with the  
 193 practical application of nationally and internationally recommended dose constraints and limits,  
 194 and, in harmony with current international standards, most compatible with public safety, humane  
 195 patient care, and cost-effective delivery of treatment.  
 196

#### 197 198 Control of Dose to Other Individuals from Released Patients 199

200 In contrast to diagnostic nuclear medicine procedures, doses to the public, patients’ relatives,  
 201 and others may need to be limited after some therapeutic procedures. The preponderance of peer-  
 202 reviewed scientific data demonstrate that the radiation dose from internal contamination of other  
 203 individuals from released patients is less significant than that from external exposure<sup>22,23,24,25</sup>  
 204 Because of its physical properties and the extent of its use, I-131 is the most likely therapeutic  
 205 radionuclide having potential to cause radiation dose to medical staff, the public and family  
 206 members. Therefore, the Subcommittee has focused its review on circumstances associated with I-  
 207 131 therapy patients.  
 208

209 Prior to patient release, the licensee has regulatory responsibilities established by NRC  
 210 regulations and license conditions for controlling dose to other individuals exposed to an I-131  
 211 therapy patient. These controls incorporate well-established and straightforward concepts of  
 212 limiting exposure: minimizing time, maximizing distance from the source (i.e., the patient), and, to  
 213 the extent practical, using shielding. Controls include measures to control radioactive  
 214 contamination; a medical facility’s use of universal precautions<sup>26,27</sup> and infection controls<sup>28,29</sup>

<sup>22</sup> NCRP Commentary No. 11, “Dose Limits for Individuals Who Receive Exposure from Radionuclide Therapy Patients”, National Council on Radiation Protection and Measurements, February 1995.

<sup>23</sup> NRC NUREG-1492, “Regulatory Analysis on Criteria for the Release of Patients Administered Radioactive Materials, Final Report”, by Stewart Schneider and Stephen A. McGuire, Nuclear Regulatory Commission, April 1996.

<sup>24</sup> ICRP Publication 94, “Release of Patients after Therapy with Unsealed Radionuclides”, International Commission on Radiological Protection, March 2004.

<sup>25</sup> IAEA Safety Reports Series No. 63, “Release of Patients after Radionuclide Therapy”, International Atomic Energy Agency, 2009.

<sup>26</sup> OSHA Regulation 29 CFR 1910.1030, “Bloodborne Pathogens”, Occupational Safety & Health Administration, Department of Labor.

<sup>27</sup> CDC Fact Sheet, “Universal Precautions for Prevention of Transmission of HIV and Other Bloodborne Infections”, Centers for Disease and Control Prevention, Department of Health and Human Services, 1996 update.

<sup>28</sup> CDC, “Guidelines for Environmental Infection Control in Health-Care Facilities”, Centers for Disease and Control Prevention, Department of Health and Human Services, 2003.

215 effectively control the spread of radioactive material. The licensee has regulatory responsibility to  
216 evaluate the circumstances of the planned patient release to ensure compliance with 10 CFR 35.75<sup>30</sup>  
217 which permits a licensee to “authorize the release from its control any individual who has been  
218 administered unsealed byproduct material or implants containing byproduct material if the total  
219 effective dose equivalent to any other individual from exposure to the released individual is not  
220 likely to exceed 5 mSv (0.5 rem)”. The licensee is also required to “provide the released individual,  
221 or the individual's parent or guardian, with instructions, including written instructions, on actions  
222 recommended to maintain doses to other individuals as low as is reasonably achievable if the total  
223 effective dose equivalent to any other individual is likely to exceed 1 mSv (0.1 rem)”. It is  
224 noteworthy and appropriate that this regulatory language characterizes the responsibility of the  
225 licensee as ensuring that the dose to an individual from a released patient is not *likely* to exceed the  
226 specified dose limit, rather than certitude that the dose limit will not be exceeded.  
227

228 Once an I-131 therapy patient is released, NRC’s regulatory control, and thus the licensee’s  
229 regulatory responsibilities<sup>31</sup>, is completed. At this point, the patient, or parent/guardian, assumes  
230 responsibility for managing radiation exposure to other individuals. The instructions that a licensee  
231 provides to the patient should be easy to understand and follow so that the patient will understand  
232 how to keep doses to other individuals below 1 mSv and as low as reasonably achievable.  
233 Instructions include maintaining distance from other people, minimizing time in public places,  
234 measures to reduce the spread of radioactive contamination, and the length of time the patient  
235 should follow each such precaution<sup>32</sup>. As part of the implementation of the current 10 CFR 35.75  
236 release criteria, the NRC worked with the Society of Nuclear Medicine (SNM) to prepare a  
237 pamphlet that provides practical information for patients receiving treatment with radioiodine<sup>33</sup>.  
238

239 As licensees review the I-131 therapy patient’s living and traveling circumstances, certain  
240 precautions may be emphasized or lengths of time adjusted for special circumstances, such as those  
241 involving potential exposure of children or pregnant women or the need to use public transportation  
242 to return home or to stay in a non-private residence prior to returning home. As the IAEA notes<sup>34</sup>,  
243 “The success of a patient release program is critically dependent on the quality and specificity of the  
244 information provided to the patient, the skill with which it is communicated, and whether or not the  
245 patient believes the information provided.” The IAEA also advises that the precautions “should be

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<sup>29</sup> CDC, “2007 Guidelines for Isolation Precautions: Preventing Transmission of Infectious Agents in Healthcare Settings”, Centers for Disease and Control Prevention, Department of Health and Human Services, 2007.

<sup>30</sup> NRC Regulation 10 CFR 35.75, “Release of individuals containing unsealed byproduct material or implants containing byproduct material”, Nuclear Regulatory Commission.

<sup>31</sup> The term “regulatory responsibilities” refers only to the control of radioactive material under NRC regulations, and does not include the physician’s continuing responsibilities for medical care of the patient.

<sup>32</sup> NRC NUREG-1556, Volume 9, Revision 2, “Program-Specific Guidance About Medical Use Licenses; Appendix U - Model Procedure for Release of Patients or Human Research Subjects Administered Radioactive Materials”, Nuclear Regulatory Commission, January 2008.

<sup>33</sup> SNM Pamphlet, “Guidelines for Patients Receiving Radioiodine Treatment,” Society of Nuclear Medicine, 1997. This pamphlet may be obtained from the Society of Nuclear Medicine, 1850 Samuel Morse Drive, Reston, VA 20190-5316.

<sup>34</sup> IAEA Safety Reports Series No. 63, “Release of Patients after Radionuclide Therapy”, International Atomic Energy Agency, 2009.

246 based upon realistic models of behavior, including realistic occupancy factors, and should not be  
 247 over-cautious<sup>35</sup>.”

248  
 249 Scientists<sup>36,37</sup> have measured doses to other individuals, primarily family members and other  
 250 caregivers, from released I-131 therapy patients, and the actual doses received by these individuals  
 251 are significantly less than those conservatively projected by the licensee as the basis for the patient  
 252 release.

#### 253 254 255 Use and Misuse of Conservative Assumptions in Estimating Dose to Other Individuals

256  
 257 With implementation of the current 10 CFR 35.75 release criteria, NRC issued guidance<sup>38</sup> to  
 258 assist licensees on determining when a patient could be released, when instructions to patients were  
 259 required, and what records must be generated and maintained. NRC guidance on calculating dose  
 260 to other individuals was primarily based on release of an I-131 therapy patient using what is now  
 261 judged to be overly conservative assumptions<sup>39,40</sup>. As noted, the IAEA advises that these dose  
 262 calculations “should be based upon realistic models of behavior, including realistic occupancy  
 263 factors, and should not be over-cautious”<sup>41</sup>. Although NRC’s 1997 guidance is now considered too  
 264 conservative, the NRC practice of establishing risk-informed and performance-based regulations<sup>42</sup>  
 265 allows licensees the practical flexibility to use more reasonable guidance and realistic calculations  
 266 in determining compliance with the current 10 CFR 35.75 release criteria.

267  
 268 As previously discussed, licensees must evaluate an I-131 therapy patient’s post-release living  
 269 circumstances in order to choose reasonable specific calculation assumptions and to provide  
 270 appropriate instructions specific for that patient. On the other hand, when performing such analyses  
 271 for a generalized patient population, more conservative assumptions may be chosen to account for a  
 272 greater range of living circumstances. And, experts may at times assume activities, distances,  
 273 occupancy factors, and so forth, that far exceed any values likely to be encountered in practice to  
 274 thereby demonstrate that if such highly improbable scenarios are compatible with release criteria,  
 275 then more realistic dose-projections can be expected to be much lower. However, some may misuse  
 276 the end result from such extreme calculations uncritically, that is without consideration of how

<sup>35</sup> IAEA Position Statement, “Release of Patients after Radionuclide Therapy”, International Atomic Energy Agency, February 23, 2010.

<sup>36</sup> Grigsby PW, Siegel BA, Baker S, & Eichling, JO. “Radiation exposure from outpatient radioactive iodine (I-131) therapy for Thyroid Carcinoma”. JAMA. 2000;283:2272–2274.

<sup>37</sup> Rutar FJ, Augustine SC, Colcher D, et al. “Outpatient treatment with 131I-anti-B1 antibody: radiation exposure to family members”. J Nucl Med. 2001;42:907–915.

<sup>38</sup> NRC Regulatory Guide 8.39, “Release of Patients Administered Radioactive Materials”, Nuclear Regulatory Commission, April 1997.

<sup>39</sup> Siegel JA, Marcus CS, Stabin MG, “Licensee Over-Reliance on Conservatism in NRC Guidance Regarding the Release of Patient Treated with I-131”, Health Physics (93:667-677), December 2007.

<sup>40</sup> ICRP Publication 94, “Release of Patients after Therapy with Unsealed Radionuclides”, International Commission on Radiological Protection, March 2004.

<sup>41</sup> IAEA Position Statement, “Release of Patients after Radionuclide Therapy”, International Atomic Energy Agency, February 23, 2010.

<sup>42</sup> NRC “The Risk-Informed and Performance-Based Plan (RPP)”, <http://www.nrc.gov/about-nrc/regulatory/risk-informed/rpp.html>.

277 unlikely or unrealistic the underlying assumptions are, and thus precipitate unnecessary public  
 278 safety concerns and alarm.

279

280 An example of such a calculation is found in the latest ICRP recommendations<sup>43</sup>. The ICRP  
 281 made this calculation to demonstrate the importance of an I-131 therapy patient taking precautions  
 282 to reduce or prevent internal contamination of children and infants. The ICRP's concluding  
 283 statements accompanying this calculation are as follows:

284

285 "Contamination of infants and young children with saliva from a treated patient during the  
 286 first few days after radioiodine therapy could result in significant doses to the child's  
 287 thyroid, and potentially raise the risk of subsequent radiation-induced thyroid cancer".

288

289 "Thyroid cancer as a result of contamination (particularly with saliva) may be a significant  
 290 risk for those under 20 years of age."

291

292 In Paragraphs (68) and (69) of the ICRP report<sup>43</sup>, the following unrealistic assumptions were used:

293

- 294 • the I-131 therapy patient (parent) does not follow the precautions given in their oral and  
 295 written instructions to minimize contact with their own infants and children;
- 296 • the I-131 therapy patient (parent) transfers 1 milliliter (e.g., approximately ¼ teaspoon) of  
 297 saliva (55,500 Bq = 1.5 µCi) by kissing the child in the first day after therapy; and,
- 298 • the thyroid cancer incidence from this child's calculated thyroid dose is estimated based on  
 299 preliminary data of cancer incidence being studied in children who ingested larger amounts  
 300 of radioactive iodine and other radionuclides in milk and vegetables contaminated from the  
 301 Chernobyl accident<sup>44</sup>

302

303 The ICRP report stated that actual measurements from children when parents followed appropriate  
 304 precautions resulted in lower thyroid doses than those indicated by this calculation. In one study<sup>45</sup>,  
 305 iodine activity was detected in only 25 of 89 children; some of these parents did not receive,  
 306 understand, or follow the precautions.

307

308 The Subcommittee agrees that a released I-131 therapy patient should be instructed to take  
 309 special precautions to minimize dose to children and pregnant women. The 1997 SNM pamphlet<sup>46</sup>  
 310 that many licensees provide to their I-131 therapy patients instructs the patient to avoid kissing the  
 311 first few days following treatment, and to avoid prolonged physical contact, especially with children  
 312 and pregnant women, explaining that the thyroid glands of children and fetuses are more sensitive  
 313 to the effects of I-131 than those of adults.

<sup>43</sup> ICRP Publication 94, "Release of Patients after Therapy with Unsealed Radionuclides", International Commission on Radiological Protection, March 2004.

<sup>44</sup> Another study of children administered diagnostic amounts (5 to 15 µCi) of I-131 found no incidence of cancer – Dickman PW, et. al., "Thyroid Cancer Risk After Thyroid Examination with I-131: a Population-Based Cohort Study in Sweden", Int. J. Cancer: 106, 580-587 (2003).

<sup>45</sup> Barrington, S.F., O'Doherty, M.J., Kettle, A.G., et al. "Radiation Exposure of Families of Outpatients Treated with Radioactive Iodine (iodine-131) for Hyperthyroidism", Eur. J. Nucl. Med. 26, 686-692 (1999).

<sup>46</sup> SNM Pamphlet, "Guidelines for Patients Receiving Radioiodine Treatment," Society of Nuclear Medicine, 1997. This pamphlet may be obtained from the Society of Nuclear Medicine, 1850 Samuel Morse Drive, Reston, VA 20190-5316.

314  
315 The NRC issued a Regulatory Issue Summary (RIS)<sup>47</sup> in 2008, which includes the first ICRP  
316 concluding statement listed above, but provides no details regarding the assumptions used. The RIS  
317 also stated:

318  
319 “However, as described in the Background section of this RIS, for some I-131 therapies,  
320 such as oral administration of sodium iodide I-131, the ICRP cautions that the internal dose  
321 to infants and young children who may come in contact with a released patient could be  
322 significant.”

323  
324 “The guidance recommends that licensees consider not releasing patients, administered I-  
325 131, whose living conditions may result in unnecessary exposure of infants and young  
326 children.”

327  
328 The intent of this RIS was to remind licensees of precautions (established in 1997 with the current  
329 10 CFR 35.75 release criteria) that should be discussed with their I-131 therapy patients. The  
330 Subcommittee recommends that the wording used in these RIS statements should not be used, and  
331 that future documents of this type should include a statement for patients that they should consult  
332 their physician.

#### 333 334 335 Release of I-131 Therapy Patients to Locations other than a Private Residence

336  
337 The NRC asked the ACMUI to review a draft RIS being developed to address the release of I-  
338 131 therapy patients to locations other than a private residence. As part of the ACMUI’s analysis,  
339 the Subcommittee calculated the radiation dose to other individuals from release of an I-131 therapy  
340 patient to a hotel. Despite the possibility of misunderstanding or misuse of the resulting calculation  
341 and conclusions, the Subcommittee used conservative assumptions to demonstrate that even highly  
342 unlikely dose projections do not exceed the release criteria and actual doses would be much lower.

343  
344 The calculation and assumptions used in and the results of this analysis are presented in  
345 Appendix 1. The Subcommittee concluded that when a licensee assesses the I-131 therapy patient’s  
346 planned living situation upon release, provides the patient with simple and easily understood written  
347 instructions, and judges that the patient, or the patient’s parent or guardian, understands the  
348 instructions and is capable of complying with the recommended precaution actions, then the dose to  
349 any other individual exposed to the I-131 therapy patient is likely not to exceed 1 mSv even when  
350 released to a location other than a private residence.

351  
352 The ICRP<sup>48</sup> suggests in item (v) of paragraph (106) that a patient could “stay at a nonhospital  
353 living facility, such as a hotel, for several days” when the patient’s home situation would put the  
354 patient in close contact with children due to physical or social constraints, because this “is less

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<sup>47</sup> NRC RIS 2008-11, “NRC Regulatory Issue Summary 2008-11: Precautions to Protect Children Who May Come in Contact with Patients Released After Therapeutic Administration of Iodine-131”, Nuclear Regulatory Commission, May 2008.

<sup>48</sup> ICRP Publication 94, “Release of Patients after Therapy with Unsealed Radionuclides”, International Commission on Radiological Protection, March 2004.

355 expensive than staying in a hospital". Initial research surveys results conducted with voluntary  
 356 respondents from the Thyroid Cancer Survivors' Association indicate most released patients in the  
 357 U.S. go to a private residence (approximately 94%) and only a few (approximately 5%) go to  
 358 hotels<sup>49</sup>. The Subcommittee agrees that an I-131 therapy patient release to a private residence  
 359 should be encouraged, and release to other locations, like a hotel, should be carefully evaluated by  
 360 the licensee and additional radiation safety precautions appropriate for such a location  
 361 communicated to the patient.  
 362  
 363

#### 364 Annual Dose Limits versus Per-Release Dose Limits

365  
 366 The current 10 CFR 35.75 release criteria were developed in accordance with the NRC's stated  
 367 practice of implementing risk-informed performance-based regulations for licensees. The NRC  
 368 appropriately recognized that licensees would only be able to judge "likely" doses to other  
 369 individuals based on knowledge shared by patients of their post-release living situation and on the  
 370 patients' ability to follow instructions in maintaining these doses as low as reasonably achievable.  
 371 Once the patient is released, the licensee no longer controls the patients' actions, and patients are  
 372 not accountable to NRC regulations. The current 10 CFR 35.75 release criteria are thus dose  
 373 constraints applied on a per-patient-release basis.  
 374

375 The ICRP recommended dose constraint of a few mSv/episode "has often been inappropriately  
 376 interpreted as a rigid annual dose limit"<sup>50</sup>. The Subcommittee considered the consequences of  
 377 changing the current 10 CFR 35.75 release criteria, which apply to all diagnostic and therapeutic  
 378 radioactive materials administered to patients and human research subjects, to rigid annual dose  
 379 limits. The primary difficulty identified was the practicality of licensees tracking all doses to other  
 380 individuals on an annual basis, potentially including those from multiple therapy administrations to  
 381 the same patient in a single calendar year. The Subcommittee believes the impact of annualized  
 382 dose limits may severely limit patients' access to appropriate medical care at reasonable costs, and  
 383 the focus should be placed on providing updated licensee guidance to meet the 10 CFR 35.75  
 384 release criteria, and patient instruction to assure dose to individuals is as low as reasonably  
 385 achievable.  
 386

387 Some have asked the NRC to return the 1986 10 CFR 35.75 release criteria<sup>51</sup>, widely known as  
 388 the "30-mCi" rule<sup>52</sup>. The Subcommittee finds no scientific merit in returning to such activity-based  
 389 release criteria, criteria which have no identifiable scientific basis<sup>53</sup>. Dose-based release criteria are  
 390 more scientifically rigorous than activity-based criteria and better protect the public by basing  
 391 patient releasability on the quantity, dose, *directly* related to potential radiation hazard rather than  
 392 on a quantity, activity, *indirectly* related to this potential hazard. In the case of radioiodine  
 393 treatment of thyroid cancer, for example, the administered radioiodine is rapidly excreted (assuming

<sup>49</sup> Vetter R, Van Nostrand D, Khorjekar G, et al, Presentation on "Use of a Patient Survey to Evaluate Compliance with and Quality of Instructions Given to Patients Treated with Radioiodine", Annual Meeting of the Health Physics Society, Salt Lake City, Utah, June 27-July 1, 2010.

<sup>50</sup> ICRP Publication 94, "Release of Patients after Therapy with Unsealed Radionuclides", International Commission on Radiological Protection, March 2004.

<sup>51</sup> 51 FR 36932, "Nuclear Regulatory Commission Medical Use of Radioactive Material-Final Rule", October 16, 1986.

<sup>52</sup> See Appendix 2 of this report for further scientific evaluations by Subcommittee on patient release concerns.

<sup>53</sup> Siegel JA, "Tracking the Origin of the NRC 30-mCi Rule", J Nucl Med. 2000;41:10-16N.

394 a whole-body biological half-time of only about 2 days or less). In treating hyperthyroidism,  
395 however, 25 to 50% or more of the radioiodine localizes in the thyroid, and that activity is cleared  
396 from the gland (and, in turn, the body) much more slowly, with half-times of about 20 days or  
397 longer. Accordingly, the retained activity from the much higher activity (typically greater than 100  
398 mCi) administered to the thyroid cancer patient is rapidly reduced to a lower activity than that  
399 retained by hyperthyroid patients (who typically receive about 10 mCi). Thus, higher dose-rate  
400 irradiation of individuals persists longer for lower-activity treatment of hyperthyroidism than for  
401 higher-activity treatment of thyroid cancer, illustrating the fallacy that activity-based release criteria  
402 (i.e. the "30-mCi" rule) is more protective of public safety<sup>54,55,56</sup>

403  
404 The Subcommittee has concluded that the most effective and practical way to control the dose to  
405 other individuals from the release of patients administered radioactive materials is to support  
406 development of new guidance and other tools to assist: (a) licensees in assessing, carrying out, and  
407 documenting patient release; and (b) patients in taking appropriate precautions for their specific  
408 living situations.

#### 409 410 411 Developing Updated Guidance in Support of Patient Release Dose Controls

412  
413 The NRC guidance to licensees on patient release criteria<sup>57</sup> is based on dose calculation methods  
414 and assumptions that are overly conservative and outdated. The Subcommittee recommends that  
415 the NRC, with assistance from experts, update the patient release guidance using reasonable  
416 assumptions based on an expanded list of radionuclides used in medicine, current  
417 radiopharmaceutical biokinetics information, and reported dose measurements from patients. The  
418 widely varied computer-based modes of communications, data gathering, and data processing  
419 available should be used to develop tools and accrue data for guidance of licensees in assessing  
420 various living situations, including patient release to other locations (such as hotels, public  
421 transport, public events), choosing realistic precautions for patients to take, instructing patients on  
422 these precautions and specific applications, and documenting compliance with the patient release  
423 criteria.

424  
425 During this review, the Subcommittee found many scholarly efforts that advance understanding  
426 and communication of real-world situations that impact patient release decisions and perceptions.  
427 The NRC should support research activities to better identify what aspects of patient release have  
428 realistic impact on doses to other individuals. As examples, the scholarly efforts listed here provide  
429 insights on various aspects of patient release.

54 ICRP Publication 94, "Release of Patients after Therapy with Unsealed Radionuclides", International Commission on Radiological Protection, March 2004.

55 IAEA Safety Reports Series No. 63, "Release of Patients after Radionuclide Therapy", International Atomic Energy Agency, 2009.

56 See additional discussion in Appendix 1.

57 NUREG 1556 Volume 9 Revision 2, "Program-Specific Guidance About Medical Use Licenses, Appendix U: Model Procedure for Release of Patients or Human Research Subjects Administered Radioactive Materials", Nuclear Regulatory Commission, January 2008.

- 431 • Measurements of radiation exposure to household members from released patients<sup>58</sup>
- 432 • Surveys of patients and caregivers to determine understanding of and adherence to patient
- 433 release instructions<sup>59</sup>
- 434 • Communication tools to help convey personalized instructions to patients<sup>60</sup>
- 435 • Credible websites providing objective, scientific information about radiation<sup>61</sup>
- 436 • Medical protocol enhancements for patient release<sup>62</sup>.

#### 440 Subcommittee Conclusions on Patient/Human Research Subject Release Issues

441  
442 The Subcommittee commends the NRC for its leadership role in developing and implementing  
443 practical regulatory control of the use of radioactive materials in patients which appropriately  
444 applies the three fundamental radiation protection principles of justification, optimization and  
445 limits. Benefits from medical use of radioactive materials are many and well-recognized,  
446 improving the health and lives of millions of people in the U.S. These benefits by far exceed the  
447 small theoretical risks associated with exposure from released patients.

448  
449 The Health Physics Society<sup>63</sup> recently updated their position statement regarding radiation  
450 risk<sup>64</sup>, and they state the following:

451  
452 “In accordance with current knowledge of radiation health risks, the Health Physics Society  
453 recommends against quantitative estimation of health risks below an individual dose of 5  
454 rem in one year or a lifetime dose of 10 rem above that received from natural sources. Doses  
455 from natural background radiation in the United States average about 0.3 rem per year. A  
456 dose of 5 rem will be accumulated in the first 17 years of life and about 25 rem in a lifetime  
457 of 80 years. Estimation of health risk associated with radiation doses that are of similar  
458 magnitude as those received from natural sources should be strictly qualitative and

<sup>58</sup> Grigsby PW, Siegel BA, Baker S, & Eichling, JO. “Radiation exposure from outpatient radioactive iodine (I-131) therapy for Thyroid Carcinoma”. JAMA. 2000;283:2272–2274.

<sup>59</sup> Vetter R, Van Nostrand D, Khorjekar G, et al, Presentation on “Use of a Patient Survey to Evaluate Compliance with and Quality of Instructions Given to Patients Treated with Radioiodine”, Annual Meeting of the Health Physics Society, Salt Lake City, Utah, June 27-July 1, 2010.

<sup>60</sup> Freidman MI, Ghiesani M, “Interactive Software Automates Personalized Radiation Safety Plans for Na<sup>131</sup>I Therapy”, Health Physics (83-Supplement 5:S71-S84), November 2002.

<sup>61</sup> “Radiation Answers: Answers to Questions About Radiation and You”, [www.radiationanswers.org](http://www.radiationanswers.org), supported by the Health Physics Society.

<sup>62</sup> Khorjekar G, Van Nostrand D, Vetter R, et al, Poster on “The Relationship of Several Factors and Vomiting After Outpatient I-131 Therapy in Patients with Well-Differentiated Thyroid Cancer”, Society of Nuclear Medicine Annual Meeting, Salt Lake City, Utah, June 5-9, 2010.

<sup>63</sup> The Health Physics Society is a nonprofit scientific professional organization whose mission is excellence in the science and practice of radiation safety. Since its formation in 1956, the Society has grown to approximately 6,000 scientists, physicians, engineers, lawyers, and other professionals representing academia, industry, government, national laboratories, the Department of Defense, and other organizations. Society activities include encouraging research in radiation science, developing standards, and disseminating radiation safety information. Society members are involved in understanding, evaluating, and controlling the potential risks from radiation relative to the benefits.

<sup>64</sup> HPS PS010-2, “Radiation Risk in Perspective”, Position Statement of the Health Physics Society, revised July 2010.

459 encompass a range of hypothetical health outcomes, including the possibility of no adverse  
460 health effects at such low levels.

461  
462 There is substantial and convincing scientific evidence for health risks following high-dose  
463 exposures. However, below 5–10 rem (which includes occupational and environmental  
464 exposures), risks of health effects are either too small to be observed or are nonexistent.”  
465

466 Ongoing research efforts are exploring the effects of low dose radiation exposures<sup>65,66</sup> and  
467 examining whether health impacts exist in populations exposed to low levels of radiation<sup>67,68,69,70</sup>  
468

469 Regulatory decision-making is ultimately a politically-based national policy discussion<sup>71</sup> which  
470 is subject to opinions based on risk perceptions rather than real risk<sup>72</sup>. The NRC remains an  
471 important leader in this national discourse<sup>73</sup>. In light of limited health care resources, it is  
472 increasingly important that regulations serve not only to protect society from real hazards, but that  
473 they also be based on realistic projections of the severity and/or likelihood of such hazards, and  
474 consideration of the actual costs, financial and otherwise, from overly cautious and potentially  
475 intrusive regulations. In the case of radionuclide therapy, which is a safe, effective, and financially  
476 viable treatment for certain cancers and other serious diseases, release criteria and relevant  
477 regulations based on realistic dose protections are both conducive to public safety and promote  
478 access to and affordability of such therapy. The Subcommittee affirms that the current dose-based  
479 release criteria 10 CFR 35.75 meet these essential benchmarks.  
480

481 The Subcommittee therefore concludes that the current 10 CFR 35.75 release criteria  
482 appropriately balance public safety with patient access to medical treatment. The Subcommittee  
483 suggests that the NRC update guidance for the release of patients administered radioactive materials  
484 to include expanded scientific knowledge and recommendations, and to use the widely varied  
485 computer-based modes of communications, data gathering, and data processing available today.

<sup>65</sup> Brooks AL, “Developing a Scientific Basis for Radiation Risk Estimates: Goal of the DOE Low Research Program”, *Health Physics* (85:85-93), July 2003.

<sup>66</sup> Averbeck D, “Does Scientific Evidence Support a Change from the LNT Model for Low-Dose Radiation Risk Extrapolation?”, *Health Physics* (97:493-504), November 2009.

<sup>67</sup> Shore RE, “Low-Dose Radiation Epidemiology Studies: Status and Issues”, *Health Physics* (97:481-486), November 2009.

<sup>68</sup> Dickman PW, et. al., “Thyroid Cancer Risk After Thyroid Examination with I-131: a Population-Based Cohort Study in Sweden”, *Int. J. Cancer*, 106, 580-587 (2003).

<sup>69</sup> Ghiassi-nejad M, et al., “Very High Background Radiation Areas of Ramsar, Iran: Preliminary Biological Studies”, *Health Physics* (82:87-93), January 2002.

<sup>70</sup> Nair RRK, et al., “Background Radiation and Cancer Incidence in Kerala, India-Karunagappally Cohort Study”, *Health Physics* (96:55-66), January 2009.

<sup>71</sup> Locke P, “Incorporating Information from the U.S. Department of Energy Low-Dose Program into Regulatory Decision-Making: Three Policy Integration Challenges”, *Health Physics* (97:510-515), November 2009.

<sup>72</sup> Jenkins-Smith HC, Silva CL, Murray C, “Beliefs about Radiation: Scientists, the Public and Public Policy”, *Health Physics* (97:519-527), November 2009.

<sup>73</sup> Tenforde TS, Brooks AL, “Perspectives of U.S. Government Agencies on the Potential Role of Greater Scientific Understanding of Low-Dose Radiation Effects in Establishing Regulatory Health Protection Guidance”, *Health Physics* (97:516-518), November 2009.

**Appendix 1 – Example dose calculations for I-131 therapy patient release to a hotel**486  
487  
488

489 Three levels of assumptions (unrealistic, highly unlikely and conservative) are used in Table  
490 1 (I-131 cancer therapy patient) and Table 2 (I-131 hyperthyroid patient) to calculate dose  
491 projections to hotel workers and guests from different I-131 therapy patients released to a hotel.  
492 The assumptions used in each case are described in each table.

493

494 There are many choices one may make in deciding what assumptions are unrealistic, highly  
495 unlikely or conservative. The Subcommittee believe even the conservative assumptions used in  
496 these tables are not based upon realistic models of behavior of patients, hotel workers and other  
497 guests, and thereby remain overly-cautious assumptions.

498

499 Despite the use of these overly-cautious levels of assumptions, the highest projected dose to a  
500 hotel housekeeper from a released cancer therapy patient is less than 100 mrem. In the case of a  
501 released hyperthyroid patient treated for immediate release under the 30-mCi rule, the amount of  
502 I-131 administered is 17% of the amount administered to the cancer therapy patient, but the  
503 highest projected dose to a hotel housekeeper is 67% of that from the released cancer therapy  
504 patient.

505

506 Use of patient-specific parameters in conjunction with realistic models of behavior by the  
507 patient, hotel workers and other guests would likely result in doses to others much less than those  
508 projected from the conservative-level assumptions.

DRAFT

**TABLE 1 – Radiation Doses (in mrem) to Hotel Workers and Guests from an I-131 Cancer Therapy Patient**

- 175 mCi <sup>131</sup>I-iodide administered to a post-thyroidectomy thyroid cancer patient
- Doses calculated assuming point source\*: patient self-shielding\*\* (0.13 mR-m<sup>2</sup>/h-mCi); laundry no shielding (0.22 mR-m<sup>2</sup>/h-mCi)
- Total-body effective time-activity function\*:  $0.95 e^{(0.693/0.32 \text{ day}) t} + 0.05 e^{(-0.693/7.3 \text{ day}) t}$
- Mean distance from patient to guest in adjoining room is 2.2 m (based on mid-point of 80 inch long beds + 6 inch wall), assuming no shielding provided by walls between rooms, and assuming head to head exposure equals mid-body to mid-body exposure
- Dose contribution of possible internal radioactive contamination is considered minor and not included

Assumptions and Parameters	<u>Unrealistic</u> <u>Unlikely</u> <u>Conservative</u>								
	Time (in days) Patient Remained in Hotel								
Cohort	1	2	3	1	2	3	1	2	3
Hotel Housekeeper	69	83	91	35	43	47	14	17	18
Hotel Laundry Worker	39	47	52	16	19	21	3.9	4.7	5.2
Non-Housekeeping/Non-Laundry Hotel Worker or Hotel Guest in Non-Adjoining Room	30	36	39	20	24	26	10	12	13
Hotel Guest in Room Adjoining that of Patient	54	65	71	40	48	53	26	32	34
<b>Parameters</b>									
Remaining activity in patient excreted into bed linens at midpoint of each day	50% per day			20% per day			5% per day		
Time hotel housekeeper and laundry worker each hold contaminated linens (0.3 m away)	30 minutes per day			20 minutes per day			10 minutes per day		
Time hotel housekeeper, other workers (except laundry), and other guests are 1 meter from patient	3 hours per day			2 hours per day			1 hour per day		
Additional time patient and other hotel guest in adjoining room are both in their respective beds	12 hours per day			10 hours per day			8 hours per day		

\* Values used are from NRC Regulatory Guide 8.39

\*\* Patient self-shielding value from SPARKS, R.B., SIEGEL, J.A. and WAHL, R.L. (1998). "The need for better methods to determine release criteria for patients administered radioactive material," Health Phys. 75(4), 385–388.

**TABLE 2 – Radiation Doses (in mrem) to Hotel Workers and Guests from an I-131 Hyperthyroid Patient**

- 29.9 mCi <sup>131</sup>I-iodide administered to a hyperthyroid patient
- Doses calculated assuming point source\*: patient self-shielding\*\* (0.13 mR-m<sup>2</sup>/h-mCi); laundry no shielding (0.22 mR-m<sup>2</sup>/h-mCi)
- Total-body effective time-activity function\*:  $0.20 e^{(0.693/0.32 \text{ day}) t} + 0.80 e^{(-0.693/5.2 \text{ day}) t}$
- Mean distance from patient to guest in adjoining room is 2.2 m (based on mid-point of 80 inch long beds + 6 inch wall), assuming no shielding provided by walls between rooms, and assuming head to head exposure equals mid-body to mid-body exposure
- Dose contribution of possible internal radioactive contamination is considered minor and not included

Assumptions and Parameters	<b>Time (in days) Patient Remained in Hotel</b>								
	<u>Unrealistic</u>			<u>Unlikely</u>			<u>Conservative</u>		
Cohort	1	2	3	1	2	3	1	2	3
Hotel Housekeeper	25	44	61	12	22	31	4.7	8.5	12
Hotel Laundry Worker	15	27	37	5.9	11	15	1.5	2.7	3.7
Non-Housekeeping/Non-Laundry Hotel Worker or Hotel Guest in Non-Adjoining Room *	10	17	24	6.4	12	16	3.2	5.8	8.0
Hotel Guest in Room Adjoining that of Patient	18	32	44	13	24	33	8.5	15	21
<b>Parameters</b>									
Remaining activity in patient excreted into bed linens at midpoint of each day	50% per day			20% per day			5% per day		
Time hotel housekeeper and laundry worker each hold contaminated linens (0.3 m away)	30 minutes per day			20 minutes per day			10 minutes per day		
Time hotel housekeeper, other workers (except laundry), and other guests are 1 meter from patient	3 hours per day			2 hours per day			1 hour per day		
Additional time patient and other hotel guest in adjoining room are both in their respective beds	12 hours per day			10 hours per day			8 hours per /day		

\* Values used are from NRC Regulatory Guide 8.39

\*\* Patient self-shielding value from SPARKS, R.B., SIEGEL, J.A. and WAHL, R.L. (1998). "The need for better methods to determine release criteria for patients administered radioactive material," Health Phys. **75**(4), 385–388.

509 **Appendix 2 – Review of March 18, 2010 Report by the Staff of Edward J. Markey (D-MA)**

510

511

512 The political nature of discussing and establishing national regulations is made evident in the  
513 recent report released by Representative Markey's staff concerning the NRC patient release  
514 criteria (Markey Report)<sup>1</sup>. The Subcommittee reviewed this report for scientific merits  
515 supporting the report's conclusion that the current 10 CFR 35.75 release criteria are inadequate.  
516 The Subcommittee found no such merits.

517

518 The Markey Report offers the following recommendations.

519

520

- 521 1) *The NRC should immediately commence a rulemaking to return to its pre-1997, dose*  
522 *based regulations surrounding the treatment of patients with radionuclides, and ensure*  
523 *that its regulations are made to be consistent with the International Commission on*  
524 *Radiological Protection (ICRP). Hospitalization should be mandatory for those patients*  
525 *who are treated with doses of I-131 above internationally accepted threshold limits.*

526

527 **Subcommittee Review** – The Markey Report presents no scientific basis to justify this  
528 recommendation for NRC to return to the pre-1997 patient release criteria, or the 30-mCi rule.  
529 The recommendation incorrectly describes the previous release criteria as “dose based  
530 regulations” rather than the correct description as activity-based criteria. The current NRC  
531 patient release criteria are consistent, in principle and practice, with national and international  
532 scientific recommendations (see the Subcommittee discussion in National and International  
533 Recommendations Regarding Released Patients). Both the International Commission on  
534 Radiation Protection (ICRP) and the International Atomic Energy Agency (IAEA) recommend  
535 that release “should not be linked solely to residual activity in the patient”, but also to many  
536 other factors<sup>2,3</sup> which are considered for the current 10 CFR 35.75 release criteria.

537

538

- 539 2) *Patients should be prohibited from recovering from such treatments in hotels, and*  
540 *specific written and verbal guidance in opposition to hotel release should be provided*  
541 *both to medical licensees and to patients.*

542

543 **Subcommittee Review** – The Subcommittee finds this practice acceptable (see the  
544 Subcommittee discussion in Release of I-131 Therapy Patients to Locations other than a Private  
545 Residence and in Appendix 1- Example dose calculations for I-131 therapy patient release to a  
546 hotel). The Markey Report presents no scientific basis to justify this recommendation to prohibit  
547 release of patients to hotels, but references dose projections, such as kissing a child, without fully

<sup>1</sup> “Radioactive Roulette: How the Nuclear Regulatory Commission’s Cancer Patient Radiation Rules Gamble with Public Health and Safety”, A report by the Staff of Edward J. Markey (D-MA), Chairman, Subcommittee on Energy and Environment, Energy and Commerce Committee, U.S. House of Representatives, March 18, 2010.

<sup>2</sup> ICRP Publication 94, “Release of Patients after Therapy with Unsealed Radionuclides”, International Commission on Radiological Protection, March 2004.

<sup>3</sup> IAEA Safety Reports Series No. 63, “Release of Patients after Radionuclide Therapy”, International Atomic Energy Agency, 2009.

548 disclosing the assumptions used in the calculations (see the Subcommittee discussion in Use and  
549 Misuse of Conservative Assumptions in Estimating Dose to Other Individuals).

- 550  
551  
552 3) *The NRC should immediately commence a rulemaking to determine whether its current*  
553 *regulations for safe radiation exposure levels adequately, and in a manner consistent*  
554 *with international standards, protect the most vulnerable populations – pregnant women*  
555 *and children – and make revisions where necessary.*

556  
557 **Subcommittee Review** – The NRC received a total of 63 comment letters<sup>4</sup> on the proposed rule,  
558 the draft regulatory guide, and the draft regulatory analysis during establishment of the current  
559 10 CFR 35.75 patient release criteria with about three-quarters of the comment letters in support  
560 of the proposed rulemaking<sup>4</sup>. In 2005, a petition for rulemaking was filed with the NRC  
561 requesting revocation of 10 CFR 35.75, insofar as it allows patients to be released from  
562 radioactive isolation with more than the equivalent of 30 millicuries of I-131 in their systems<sup>5</sup>.  
563 The NRC conducted their review of this petition for rulemaking in an open manner<sup>6</sup> and received  
564 overwhelming response from individual health care professionals and nine professional medical  
565 organizations<sup>7</sup> representing thousands of health care professionals in support of the current 10  
566 CFR 35.75 release criteria. The NRC ultimately concluded that the arguments presented in the  
567 2005 petition did not support a rulemaking to change the current 10 CFR 35.75 patient release  
568 criteria<sup>8</sup>. A suit was filed against the NRC seeking review of NRC's denial of this petition for  
569 rulemaking<sup>9,10,11</sup>. The U.S. Court of Appeals dismissed the case<sup>12</sup>. A written statement  
570 concerning patient release<sup>13</sup> was presented at the ACMUI May 24, 2010 meeting. The  
571 Subcommittee has reviewed the content of the documents referenced here, along with the  
572 Markey Report, and we find no new credible, scientifically-based data that support the need for  
573 the NRC to change the current 10 CFR 35.75 patient release criteria. The current 10 CFR 35.75

<sup>4</sup> 62 FR 4121, "Nuclear Regulatory Commission Final Rule: Criteria for the Release of Individuals Administered Radioactive Material", January 29, 1997.

<sup>5</sup> 70 FR 75752, "Peter G. Crane, Receipt for Rulemaking", NRC Docket No. PRM-35-18, December 21, 2005.

<sup>6</sup> All documents submitted in regard to NRC Docket No. PRM-35-18 are available for public view at [www.regulations.gov](http://www.regulations.gov) under Docket ID NRC-2005-0020.

<sup>7</sup> Professional organizations included the American Society of Therapeutic Radiation Oncologists (ASTRO), the American Association of Physicists in Medicine (AAPM), the American Board of Nuclear Physicians (ABNP), the American Thyroid Association, the Endocrine Society, the American College of Radiology (ACR), the Society of Nuclear Medicine (SNM), the National Association of Nuclear Pharmacists, the American Pharmacists Association, and the Council on Radionuclides and Radiopharmaceuticals (CORAR). [73 FR 29445]

<sup>8</sup> 73 FR 29445, "Peter G. Crane, Denial of Petition for Rulemaking", NRC Docket No. PRM-35-18; NRC-2005-0200], May 21, 2008.

<sup>9</sup> No. 08-72973, *Peter G. Crane v. United States Nuclear Regulatory Commission* (U.S. Court of Appeals for the Ninth Circuit), Brief for Petitioner (filed September 22, 2008).

<sup>10</sup> No. 08-72973, *Peter G. Crane v. United States Nuclear Regulatory Commission* (U.S. Court of Appeals for the Ninth Circuit), Brief for Respondents (November 4, 2008).

<sup>11</sup> No. 08-72973, *Peter G. Crane v. United States Nuclear Regulatory Commission* (U.S. Court of Appeals for the Ninth Circuit), Reply Brief for Petitioner (December 5, 2008).

<sup>12</sup> 2009 U.S. App. LEXIS 18674, \*,344 Fed. Appx. 316: PETER G. CRANE, Petitioner, v. UNITED STATES NUCLEAR REGULATORY COMMISSION; UNITED STATES OF AMERICA, Respondents. No. 08-72973.

<sup>13</sup> "Statement of Peter Crane before the ACMUI", May 24, 2010, available on <http://www.nrc.gov/reading-rm/adams/web-based.html> using Accession Number ML101480965, and on Page 16.

574 patient release criteria appropriately balance public safety with patient access to medical  
575 treatment.

576

577

578 4) *The NRC should aggressively enhance its oversight of medical licensees to better*  
579 *identify, track and respond to potential regulatory violations, including its oversight of*  
580 *such activities by Agreement States.*

581

582 **Subcommittee Review** – The IAEA recognized that there is diversity of international practice in  
583 the area of patient release criteria and advocated an approach, in line with ICRP  
584 recommendations, that “provides a practical and humane implementable solution to the problems  
585 of patient release that is consistent with most regulatory systems”<sup>14</sup> (see the Subcommittee  
586 discussion in National and International Recommendations Regarding Released Patients).  
587 Patient release criteria in the United States are as diverse as the international practices observed  
588 by the IAEA. Each regulatory body (federal or agreement state) is responsible for meeting the  
589 needs of their citizens, licensees and medical community to provide a level of regulatory control  
590 that balances these needs with the respective regulations. The Subcommittee hopes this review  
591 of patient release criteria issues is helpful to the NRC and Agreement States in their discussions  
592 of their respective criteria. The NRC responded to questions on its inspection program<sup>15</sup>. The  
593 Markey Report provides no credible data that enhancement of NRC’s medical inspection  
594 program is necessary.

595

596

597 5) *The NRC’s Inspector General should investigate, and NRC should then take all*  
598 *appropriate action, regarding conflicting statements made by its Office of General*  
599 *Counsel (OGC) as to whether NRC regulations permit the release of patients to hotels.*  
600 *These include OGC’s April 2008 concurrence with an NRC document that provided*  
601 *assistance to a regional office, which stated that “release to a hotel was not prohibited by*  
602 *the regulations,” and the conflicting statement made by OGC in a legal brief submitted to*  
603 *the U.S. Court of Appeals for the Ninth Circuit on November 4, 2008, which inaccurately*  
604 *states that “NRC’s rule does not permit or encourage doctors to send treated patients to*  
605 *hotels.”*

606

607 **Subcommittee Review** – In our review of the documents advocating need to change the current  
608 10 CFR 35.75, the Subcommittee finds many arguments rely heavily on the regulatory or legal  
609 process, often through an incomplete interpretation of reported events or outcomes. More  
610 importantly, these kinds of ancillary arguments identify no scientific bases in terms of radiation  
611 dose or risk to persons involved to support of changing the current 10 CFR 35.75 patient release  
612 criteria. Finally, the Markey Report provides no credible information that an investigation by the  
613 OGC is necessary.

614

615

<sup>14</sup> IAEA Safety Reports Series No. 63, “Release of Patients after Radionuclide Therapy”, International Atomic Energy Agency, 2009.

<sup>15</sup> March 5, 2010 letter to the Honorable Edward J. Markey from NRC Chairman Gregory B. Jaczko, available at [www.nrc.gov](http://www.nrc.gov).



**Status of Medical Events FY 2010**

Donna-Beth Howe, Ph.D.  
October 21, 2010



**Medical Events 2010**

- 47 Medical events reported - FY 2009
- 49 Medical events reported - FY 2010

	<u>FY09</u>	<u>FY10</u>
35.200	1	1
35.300	5	4
35.400	17	25
35.600	14	12
35.1000	10	7



**Medical Events 2010**

**Diagnostic Medical Event**

35.200 1

**Communication errors**

- Referring physician intended I-123
- Wrote I-123 prescription and gave to patient
- Physician's office faxed request for I-131
- Hospital gave I-131
- Hospital refused patient's written prescription
- Technologist noted patient had thyroid



**Medical Events 2010**

**35.300 Medical events 4**

- Oral Sodium Iodide I-131 3
  - Wrong Patient
  - Left capsules in vial (2 events - 5 capsules)
- MIBG I-131 1
  - Preparation volume error lead to air in infusion line



**Medical Events 2010**

**35.400 Medical events 25**

- Gynecological 3
- Anus 1
- Prostate 21



**35.400 Medical Events**

**Gynecological Cs-137 3**

- Applicator came out after 20 minutes – may have received 76 rem to thigh
- Applicator dislodged after vigorous coughing after 20 hours (total prescribed 45 hours)
- Failure to place sources in applicator one fell out and fell on buttocks (1,050 rad) other was missing and found in trash

**Anus I-125 1**

- 4 cm superior to intended location – 10 cm mark mistaken for 5 cm mark

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

**35.400 Medical Events**

**Prostate (40 Patients) 21**

- 4 licensees had multiple medical events - licensee not reviewing results against medical event criteria
  - DVA had 11 under one medical event report
  - Mercy St Vincent Medical Center and an associated facility had 9 reported individually
  - Marshfield Clinic had 9 in one report and 1 in another report
  - Jewish Hospital had 2 events in one report
  - Bristol Hospital had 2 events in one report

7

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

**35.400 Medical Events**

**Prostate (Continued)**

- 20 under dose to the prostate, no reason given
- 3 Over dose to prostate, no reason given
- 2 Multiple seeds eliminated from bladder or urethra
- 1 Tumor volume increase due to edema
- 11 Suboptimal dose distribution, poor placement, poor visualization, incorrect identification of prostate
- 3 Over doses to other organs (e.g., urethra)

8

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

**Medical Events 2010**

**35.600 Medical events 12**

- HDR 9
  - Mammosite 2
- Gammaknife 3

9

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

**35.600 Medical Events**

**HDR Only (11 patients) 7**

- 1 Software failure
- 2 Human error
  - hit "auto radiograph" instead of "treatment" button
  - - entered treatment site incorrectly
- 3 Catheter issues-tight bend, catheter movement
- 1 No reason given - 5 patients 30-50% under dosing

10

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

**35.600 Medical Events**

**HDR Mammosite (3 patients) 2**

- 2 source positioning error not discovered until after 10 of 10 fractions for patient 1 and 8 of 10 fractions for patient 2 -
- 1 incorrect distance measurement - used damaged source positioning simulator tool

11

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

**35.600 Medical Events**

**Gammaknife 3**

- removed right anterior pin from frame - left pin slipped 2 cm superiorly
- wrong coordinates put in 1<sup>st</sup> 5 of 10 fractions - used x coordinate value for both x and z
- head immobilization bracket not fully secured - patient pain

12



### Medical Events 2010

**35.1000 Medical events** 7

- Perfexion 2
- Microspheres 4
- Intravascular Brachytherapy 1

13



### 35.1000 Medical Events

**Perfexion** 2

- Wrong site – intended left side gave to right side of brain error discovered at 1.4 minutes into 30 minutes
- Failed computer disk froze treatment screen gave fatal error and terminated treatment intended

14



### 35.1000 Medical Events

**35.1000 TheraSpheres** 2

- Wrong site intended left lobe of liver delivered to right lobe – right lobe was scheduled to get dose on later date prescribed for later date 12,500 rad got 7,600 rad
- Waste container assay indicated 25% of pretreatment activity – iodine contrast media put in catheter, thought this impeded or caused aggregation.

15



### 35.1000 Medical Events

**SirSpheres** 2

- Leakage around stopper – manufacturer confirmed leakage, but thought physician put too much pressure to V-vial
- Thought procedure delivered entire dose with out complication, but about 4.4 mCi of intended 15.4 mCi left in tubing vial and other contaminated items

16



### 35.1000 Medical Events

**Intravascular Brachytherapy**

- Wrong treatment time selected for treatment intended 1,840 rad gave 2300 rad – AU did not sign written directive before administration

17



## **Options to Revise Radiation Protection Regulations and Guidance - Further Considerations**

**Donald A. Cool, PhD**  
**Office of Federal and State Materials and Environmental Management Programs**

## **Background**

- **International Commission on Radiological Protection (ICRP) completed revised recommendations in late 2007**
- **Ongoing stakeholder engagement and technical basis development**

2

## **Future Plans**

- **Facilitated roundtable workshops**
  - **Washington, DC, October 25-27, 2010**
  - **Los Angeles, CA, November 3-4, 2010**
  - **Houston, TX, November 8-9, 2010**
- **Staff recommendations to Commission**
  - **Fall 2011**

3

## **What Have We Heard?**

- **Wide range of views on major topics**
- **General support for increasing alignment with international recommendations**
- **General agreement that scientific information should be updated**

4

## **Issues**

- **Effective Dose and Numerical Values**
- **Occupational Dose Limits**
- **Dose Limits for Special Populations**
- **As Low As Reasonably Achievable (ALARA) planning**

5

## **Effective Dose**

- **Effective Dose**
  - **Supportive of update**
  - **Questions on application of current rule**
  - **Recognition of schedule**

6

### **Occupational Dose Limits**

- **Certain groups of licensees continue to have individuals above 20 millisievert/year (mSv/yr) (2 rem)**
- **Many want limit to stay at 50 mSv/yr (5 rem)**
- **Suggestion to keep higher limit as legal boundary, and increase ALARA requirements with mandatory constraints**

7

### **Limits for Special Populations**

- **Occupational Limits for Embryo/Fetus**
  - Mixed feedback
  - Lack of data
- **Public Exposure**
  - **Should special provisions for doses greater than 100 mrem be discontinued for embryos/fetuses, children, pregnant females, and nursing mothers?**

8

### **ALARA Planning - Constraints**

- **Tool in optimization of protection**
- **Not to be limits**
- **Details critical - Impact to licensees?**
- **Alternative to changing limits?**
  - Numerical value
  - **Approval to go above constraint**

9

**Questions?**

10

Dated at Rockville, Maryland this 13th day of September, 2010. For the Nuclear Regulatory Commission.

**Timothy J. McGinty,**

*Director Division of Policy and Rulemaking,  
Office of Nuclear Reactor Regulation.*

[FR Doc. 2010-23250 Filed 9-16-10; 8:45 am]

BILLING CODE 7590-01-P

## NUCLEAR REGULATORY COMMISSION

[NRC-2010-0282]

### Revised Draft Safety Culture Policy Statement: Request for Comments

**AGENCY:** Nuclear Regulatory  
Commission (NRC).

**ACTION:** Issuance of revised Draft Safety  
Culture Policy Statement and notice of  
opportunity for public comment.

**DATES:** Comments are requested 30 days  
from the date of this *Federal Register*  
Notice. Comments received after this  
date will be considered if it is practical  
to do so, but the NRC is only able to  
assure consideration of comments  
received on or before this date. Please  
refer to the **SUPPLEMENTARY INFORMATION**  
section for additional information  
including specific questions for which  
the NRC is requesting comment.

**ADDRESSES:** You may submit comments  
by any one of the following methods.  
Please include Docket ID NRC-2010-  
0282 in the subject line of your  
comments. Comments submitted in  
writing or in electronic form will be  
posted on the NRC Web site and on the  
Federal rulemaking Web site  
[www.Regulations.gov](http://www.Regulations.gov). Because your  
comments will not be edited to remove  
any identifying or contact information,  
the NRC cautions you against including  
any information in your submission that  
you do not want to be publicly  
disclosed. Additionally, the NRC  
requests that any party soliciting or  
aggregating comments received from  
other persons for submission to the NRC  
inform those persons that the NRC will  
not edit their comments to remove any  
identifying or contact information, and  
therefore, they should not include any  
information in their comments that they  
do not want publicly disclosed.

**Federal Rulemaking Web site:** Go to  
<http://www.regulations.gov> and search  
for documents filed under Docket ID  
NRC-2010-0282. Address questions  
about NRC dockets to Carol Gallagher  
301-492-3668; e-mail

[Carol.Gallagher@nrc.gov](mailto:Carol.Gallagher@nrc.gov).

**Mail comments to:** Cindy K. Blady,  
Chief, Rules, Announcements, and  
Directives Branch (RADB), Division of  
Administrative Services, Office of

Administration, Mail Stop: TWB-05-  
B01M, U.S. Nuclear Regulatory  
Commission, Washington, DC 20555-  
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3446.

**FOR FURTHER INFORMATION CONTACT:**

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[Maria.Schwartz@nrc.gov](mailto:Maria.Schwartz@nrc.gov), (301) 415-  
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**SUMMARY:** On November 6, 2009, the  
NRC published a draft policy  
statement, "Safety Culture Policy  
Statement," in the **Federal Register**  
(FRN) (74 FR 57525; NRC ADAMS  
Accession Number ML093030375).<sup>1</sup> The  
Statement of Policy (SOP) contained in  
the FRN focuses on the interface of  
nuclear safety and security in a positive  
safety culture, and highlights the  
Commission's expectation that all  
licensees and certificate holders<sup>2</sup>  
establish and maintain a positive safety  
culture that protects public health and  
safety and the common defense and  
security when carrying out licensed  
activities. The FRN requested that  
interested persons provide comments  
within 90 days of its publication. On  
January 12, 2010, the comment period  
was extended to March 1, 2010 (75 FR  
1656; ML100050288). As part of its  
outreach activities, the NRC held a  
Safety Culture Workshop in February  
2010 that provided a venue for  
interested parties to provide comments  
on the draft safety culture policy  
statement. The additional goal of the  
workshop was for panelists representing  
a broad range of stakeholders to reach  
alignment on a common definition of  
safety culture and a high-level set of  
traits that describe areas important to a  
positive safety culture. The workshop  
panelists, with the assistance of the  
other workshop participants, developed  
both. Following the February workshop,  
the staff evaluated the public comments  
that were submitted in response to the  
November 2009 FRN. Additionally, the

<sup>1</sup> The Commission may use a policy statement to  
address matters relating to areas that are within  
NRC jurisdiction and are of particular interest to the  
Commission in order to guide staff's activities and  
to express its expectations; however, policy  
statements, unlike regulations/rules are not binding  
upon, or enforceable against, NRC or Agreement  
State licensees and certificate holders.

<sup>2</sup> The reference in the November 2009 FRN to  
"licensee and certificate holder" included licensees,  
certificate holders, permit holders, authorization  
holders, holders of quality assurance program  
approvals, and applicants for a license, certificate,  
permit, authorization, or quality assurance program  
approval.

staff participated on panels and made  
presentations at various industry forums  
in order to provide information to  
stakeholders about the development of  
the safety culture policy statement and/  
or to obtain additional input and to  
ascertain whether the draft definition  
and traits developed at the workshop  
accurately reflect a broad range of  
stakeholders' views.

In its ongoing effort to continue this  
dialogue with stakeholders, the NRC is  
publishing this FRN containing the  
revised draft SOP for a 30-day public  
comment period. The revised draft SOP,  
including the revised definition and  
traits, is based on careful consideration  
of the Commission guidance in the  
October 2009 Staff Requirements  
Memorandum (SRM) for SECY-09-0075  
(ML092920099), the NRC staff's  
evaluation of the public comments  
received on the November 2009 FRN,  
the revised definition and traits  
developed at the February 2010  
workshop, and the outreach efforts the  
NRC staff has engaged in since February  
2010.

The information contained in this  
FRN will be used to focus discussions  
at a public meeting the NRC is holding  
on September 28, 2010, at its Las Vegas,  
Nevada, hearing facility. Both this FRN  
and the September meeting are intended  
to provide additional opportunities for  
stakeholders to provide comments on  
the revised draft SOP, including the  
revised draft definition and traits.

## I. Background

### *Previous Policy Statements*

While the NRC has increased its  
attention on the importance of a positive  
safety culture, the agency has long  
recognized the importance of a work  
environment with a safety-first focus. In  
1989, in response to an incident  
involving operators sleeping in the  
control room, the NRC issued a policy  
statement on the conduct of operations  
which describes the NRC's expectation  
that licensees place appropriate  
emphasis on safety in the operations of  
nuclear power plants. The "Policy  
Statement on the Conduct of Nuclear  
Power Plant Operations" (54 FR 3424;  
January 24, 1989) states the  
Commission's expectations of utility  
management and licensed operators  
with respect to the conduct of  
operations, noting that it applies to all  
individuals engaged in any activity  
which has a bearing on the safety of  
nuclear power plants. The Commission  
issued the policy statement to help  
foster the development and  
maintenance of a positive safety culture  
at these facilities.

In 1996, the Commission published a policy statement, "Freedom of Employees in the Nuclear Industry to Raise Safety Concerns Without Fear of Retaliation" (61 FR 24336; May 14, 1996), to set forth its expectations that licensees and other employers subject to NRC authority establish and maintain safety-conscious work environments in which employees feel free to raise safety concerns, both to their management and to the NRC, without fear of retaliation. This policy statement applies to the regulated activities of all NRC licensees and their contractors and subcontractors. A safety conscious work environment is an important attribute of a positive safety culture and is one of the safety culture characteristics in the initial draft safety culture policy statement. It is also one of the revised traits captured by the February 2010 workshop participants as an "Environment for Raising Concerns."

*Events Underscoring the Importance of a Positive Safety Culture*

The importance of a positive safety culture has been demonstrated by a number of significant, high-visibility events world-wide involving civilian uses of radioactive materials that have occurred in the 20-year period since the Commission published its 1989 policy statement. These events are not confined to a particular type of licensee or certificate holder as they occurred at nuclear power plants and fuel cycle facilities and during medical and industrial activities involving regulated materials. Because of their significance to public health and safety, the Commission has required the regulated entity involved to determine the underlying root causes of the problem and, in some instances, to commit to having a third-party assessment of its safety culture in order to establish appropriate corrective actions. These assessments have revealed that weaknesses in the regulated entities' safety culture were an underlying root cause of the problem or increased the severity of the problem. These root causes included, for example, inadequate management oversight of process changes, perceived production pressures, lack of a questioning attitude, and poor communications.

One such incident indicated the need for additional NRC efforts to evaluate whether it should increase its attention to reactor licensees' safety cultures. During a planned outage, a nuclear power plant licensee discovered a cavity caused by boric acid corrosion in the top of the reactor pressure vessel. In response to this serious deterioration, the NRC required the licensee to

determine the underlying root causes of the problem. The licensee's evaluation identified that the root causes for the failure to take appropriate corrective actions included an inadequate safety culture and an emphasis on production over safety. NRC lessons learned from this incident indicated the need for additional NRC efforts to evaluate nuclear power plant licensees' safety cultures. In SRM-SECY-04-0111 (ML042430661), dated August 30, 2004, the Commission approved the staff's plan to enhance the Reactor Oversight Process (ROP) treatment of cross-cutting issues to more fully address safety culture. As part of this effort, the staff made important changes to the ROP to address Commission direction, including: (1) Enhancements to problem identification and resolution initiatives; (2) inspector training on safety culture; (3) establishment of processes for revising the ROP while involving stakeholders; (4) evaluation of safety culture at plants in the Degraded Cornerstone Column of the ROP Action Matrix; and (5) the treatment of cross-cutting issues to more fully address safety culture. Commission paper SECY-06-0122, dated May 24, 2006, (ML061320282) describes the NRC's safety culture activities at that time and the outcomes of those activities. On July 31, 2006, the agency issued Regulatory Issue Summary 2006-13, "Information on the Changes Made to the Reactor Oversight Process to More Fully Address Safety Culture," (ML061880341) to provide information to nuclear power reactor licensees on the revised ROP.

*Increased Focus on Security Issues*

Following the terrorist attacks of September 11, 2001, the Commission increased its focus on the security of regulated facilities whose operations can have an impact on public health and safety. The Commission issued orders enhancing security at these facilities. During the early years of implementation of these security enhancements, several violations of the Commission's security requirements were identified, in which the licensee failed to cultivate an effective safety culture in its security program. The most visible of these involved a culture of complacency involving security officers sleeping while on shift at a nuclear power plant. Most of these violations involved inadequate management oversight of security, lack of a questioning attitude within the security organization, inability to raise concerns about security issues, and inadequacy of training for security personnel. These issues prompted the

Commission in SECY-09-0075 to direct the staff to evaluate "[w]hether publishing NRC's expectations for safety culture and for security culture is best accomplished in one safety/security culture statement or in two separate statements, one each for safety and security, while still considering the safety and security interfaces." Based on the staff's review and stakeholder feedback, the staff concluded that the Commission's expectations for safety culture should be published in one policy statement entitled, "A Safety Culture Policy Statement," but should emphasize that safety and security be treated in a balanced, commensurate with the significance, manner, within the overarching safety culture. Thus, while the term "security" is not included in the revised draft definition of safety culture, as the preamble to the traits points out, the traits of an effective safety culture should be balanced commensurate with their significance in ensuring that the security program is effectively implemented.

Additionally, one of the insights gained from the increased emphasis on security is the importance of incorporating security considerations into a safety culture and effectively managing the safety and security interface. An effective safety and security interface integrates safety and security activities so as not to diminish or adversely affect either. Capturing both safety and security activities under an overarching safety culture policy statement is important because, while many safety and security activities complement each other, there may be instances in which safety and security interests create competing goals. Mechanisms should be established to identify and resolve these differences.

**II. Development of the Current Statement of Policy**

*Commission Direction*

In February 2008, the Commission issued SRM-COMGBJ-08-0001 (ML080560476) directing the NRC staff to expand the Commission's policy on safety culture to address the unique aspects of security and to ensure the resulting policy is applicable to all licensees and certificate holders. The Commission posed several additional questions for the staff to answer including (1) whether safety culture as applied to reactors needs to be strengthened; (2) how to increase attention to safety culture in the materials area; (3) how stakeholder involvement can most effectively be used to address safety culture for all NRC and Agreement State licensees and

certificate holders, including any unique aspects of security; and (4) whether publishing NRC's expectations for safety culture and for security culture is best accomplished in one safety/security culture statement or in two separate statements while still considering the safety and security interfaces.

To address the Commission's direction, NRC staff reviewed domestic and international safety culture related documents, considered NRC lessons learned, and obtained wide ranging stakeholder input on questions related to the issues in the SRM. In February 2009, the NRC held a public workshop on the "Development of a Policy Statement(s) on Safety and Security Culture" in which a broad range of stakeholders participated, including a representative from the Agreement States (Meeting Summary: ML090930572). The 2009 workshop developed a draft definition and characteristics<sup>3</sup> of a positive safety culture. Additionally, mindful of the increased attention to the important role of security, the staff also sought input from the workshop participants on whether there should be a single safety culture policy statement or two policy statements addressing safety and security independently while considering the interface of both. The staff also sought input on the additional questions the Commission posed to the staff in SRM-COMGBJ-08-0001.

The staff provided its recommendations to the Commission in May 2009 in Commission paper SECY-09-0075, "Safety Culture Policy Statement" (ML091130068). Based on its review and stakeholder feedback, the staff (1) concluded that the NRC's oversight of safety culture as applied to reactors has been strengthened, is effective, and continues to be refined in accordance with the existing reactor oversight process (ROP) self-assessment process; (2) described actions taken and planned for increasing attention to safety culture in the materials area; (3) described actions taken and planned for most effectively utilizing stakeholder involvement to address safety culture, including any unique aspects of security, for all NRC and Agreement State licensees and certificate holders; and (4) developed one draft safety culture policy statement that acknowledges the equal importance of

safety and security within the overarching safety culture.

In SRM-SECY-09-0075 (ML092920099), the Commission directed the staff to: (1) Continue to engage a broad range of stakeholders, including the Agreement States and other organizations with an interest in nuclear safety, to ensure the final policy statement presented to the Commission considers a broad spectrum of views and provides the necessary foundation for safety culture applicable to the entire nuclear industry; (2) make the necessary adjustments to encompass security within the statement; (3) seek opportunities to comport NRC terminology, where possible, with that of existing standards and references maintained by those that the NRC regulates; and (4) consider incorporating suppliers and vendors of safety related components in the safety culture policy statement.

#### *February 2010 Workshop*

The February 2010 workshop was part of the staff's efforts to further engage all NRC-regulated entities as well as the Agreement States, the Indian Tribes, and organizations and individuals interested in nuclear safety. The goals of the February workshop were to (1) provide an additional opportunity for comments on the November 2009 FRN and (2) develop a common definition of safety culture and a high-level set of traits describing areas important to a positive safety culture. The workshop participants represented a wide range of stakeholders regulated by the NRC and/or the Agreement states including medical, industrial, and fuel cycle materials users, and nuclear power reactor licensees, as well as the Nuclear Energy Institute (NEI), the Institute of Nuclear Power Operations (INPO), and members of the public. The workshop panelists reached alignment with input from the other meeting attendees on a common definition of safety culture and a high-level set of traits describing areas important to a positive safety culture.

#### *Additional Outreach Activities*

Following the February workshop, the staff evaluated the public comments that were submitted in response to the initial draft SOP. Additionally, the staff participated on panels and made presentations at various industry forums in order to provide information to stakeholders about the development of the safety culture policy statement and/or to obtain additional input and to ascertain whether the draft definition and traits developed at the workshop accurately reflect a broad range of stakeholders' views. These outreach

activities included, for example, participation in a Special Joint Session on Safety Culture at the Health Physics Society Annual Meeting, and presentations on the development of the Safety Culture Policy Statement at the Annual Fuel Cycle Information Exchange, the Conference of Radiation Control Program Directors' Annual National Conference on Radiation Control, the Institute of Nuclear Materials Management's Annual Meeting, the 2nd NRC Workshop on Vendor Oversight for New Reactors,<sup>4</sup> and the Organization of Agreement States Annual Meeting.

#### **III. Statement of Policy**

The purpose of this Statement of Policy is to set forth the Nuclear Regulatory Commission's expectation that individuals and organizations, performing or overseeing regulated activities involving nuclear materials, establish and maintain a positive safety culture commensurate with the safety and security significance of their activities and the nature and complexity of their organizations and functions. This applies to all licensees, certificate holders, permit holders, authorization holders, holders of quality assurance program approvals, vendors, suppliers of safety related components, and applicants for a license, certificate, permit, authorization, or quality assurance program approval, subject to NRC authority. Additionally, it is the Commission's expectation that the Agreement States and other organizations interested in nuclear safety will support the development and maintenance of a positive safety culture, as articulated in this Statement of Policy, within their regulated communities.

The Commission defines Nuclear Safety Culture as the core values and behaviors resulting from a collective commitment by leaders and individuals to emphasize safety over competing goals to ensure protection of people and the environment. The Commission considers nuclear safety and nuclear security issues to be equally important in a positive safety culture. Thus, as part of this collective commitment, organizations should ensure that personnel in the safety and security sectors have an appreciation for the importance of each, emphasizing the need for integration and balance to achieve optimized protection. Safety and security activities are closely intertwined, and it is critical that consideration of these activities be integrated so as not to diminish or adversely affect either. A safety culture that accomplishes this would include

<sup>3</sup> At the February 2010 workshop, the panelists referred to the characteristics (NRC term) or principles (INPO term) as traits. The term "traits" is used in the revised draft SOP and throughout this FRN and describes areas important to a positive safety culture.

all nuclear safety and security issues associated with NRC-regulated activities.

Individuals and organizations performing or overseeing regulated activities involving nuclear materials bear the primary responsibility for safely handling and securing these materials. The Commission, as the regulatory agency, has an independent oversight role that reviews the performance of those individuals and organizations through its inspection and assessment processes, including their performance as it relates to areas important to safety culture.

Experience has shown that certain personal and organizational traits are present in a positive safety culture. A trait, in this case, is a pattern of thinking, feeling, and behaving that emphasizes safety, particularly in goal conflict situations, *e.g.*, production vs. safety, schedule vs. safety, and cost of the effort vs. safety. It should be noted that although the term "security" is not expressly included in these traits, safety and security are the primary pillars of the NRC's regulatory mission.

Consequently, consideration of both safety and security issues, commensurate with their significance, is an underlying principle of this Statement of Policy. The traits of a positive safety culture include, but are not limited to: (1) Leadership Safety Values and Actions in which leaders demonstrate a commitment to safety in their decisions and behaviors; (2) Problem Identification and Resolution in which issues potentially impacting safety are promptly identified, fully evaluated, and promptly addressed and corrected commensurate with their significance; (3) Personal Accountability in which all individuals take personal responsibility for safety; (4) Work Processes in which the process of planning and controlling work activities is implemented so that safety is maintained; (5) Continuous Learning in which opportunities to learn about ways to ensure safety are sought out and implemented; (6) Environment for Raising Concerns in which a safety conscious work environment is maintained where personnel feel free to raise safety concerns without fear of retaliation, intimidation, harassment or discrimination; (7) Effective Safety Communication in which communications maintain a focus on safety; and (8) a Respectful Work Environment in which trust and respect permeate the organization. It is the Commission's expectation that all individuals and organizations, performing or overseeing regulated activities involving nuclear materials

should take the necessary steps to promote a positive safety culture by fostering these traits as they apply to their organizational environments.

#### **IV. Changes to the Initial Draft Statement of Policy**

Like the initial draft SOP, the revised draft SOP begins by indicating to whom the policy applies as a general matter. In the initial draft SOP, licensees and certificate holders are listed; however, earlier in the FRN, there is a footnote indicating that throughout the document, the phrase "licensees and certificate holders" includes licensees, certificate holders, permit holders, authorization holders, etc. The revised draft SOP refers to "individuals and organizations, performing or overseeing regulated activities involving nuclear materials," which includes vendors and suppliers of safety-related components. Additionally, the revised draft SOP notes the Commission's expectation that the Agreement States and other organizations interested in the safe use of nuclear materials also develop and maintain a positive safety culture within their regulated communities as well.

The definition of safety culture in the initial draft SOP is based on the International Atomic Energy Agency (IAEA) definition of safety culture, modified to broaden its applicability to materials users and to include security. The definition of safety culture has been changed in the revised draft SOP to the definition that was developed during the February 2010 workshop. This definition is broad enough to apply to all individuals and organizations, performing or overseeing regulated activities involving nuclear materials. Additionally, the February 2010 workshop definition does not include the term "security." The revised definition resonated with the workshop panelists. Additionally, it was the preferred definition in the comments received on the initial draft policy statement and the comments received during several industry forums held after the February 2010 workshop. The initial draft SOP, like the revised draft SOP, discusses the importance of providing personnel in both the safety and security sectors with an appreciation for the importance of each. Both SOPs also discuss the importance of recognizing how closely intertwined safety and security activities are and the importance of integrating these activities so as not to diminish or adversely affect either. The initial draft SOP indicates areas that should receive the greatest attention as a matter of priority. The revised draft SOP is silent on this point because each entity should

examine its specific regulated activities to determine the areas that should receive the greatest attention.

Both SOPs stress the fact that those entities that use or provide services related to the use of radioactive materials bear the primary responsibility for safely handling and securing such materials; however, the revised draft SOP, as noted above, expands those entities to include individuals and organizations performing regulated activities to support the ability of the Agreement States to apply this SOP to their licensees. Both SOPs also point out that the NRC, as the regulatory agency, has an independent oversight role of those individuals and organizations through their inspection and assessment processes including their performance as it relates to areas important to safety culture.

Based on responses to a question posed in the FRN containing the initial draft SOP, the revised draft SOP contains the traits (*i.e.*, descriptions of areas important to safety culture). The November 2009 FRN describes the traits in another section of the policy statement rather than in the actual Statement of Policy (SOP) section. The traits that are included in the revised draft SOP, while similar to those proposed by the NRC in the November 2009 FRN, are based on the traits developed by the February workshop panelists. Taking into consideration the public comments on the initial draft safety policy statement, the NRC staff revised the workshop traits to make them clearer but made no substantive changes. Additionally, the revised draft SOP contains a preamble to the traits explaining what is a trait, and a discussion of the use of the term "security" in the traits, noting that although not expressly included in the traits, consideration of both safety and security issues commensurate with their significance is an underlying principle of the SOP.

The initial draft SOP also refers to the scope of the Commission's responsibilities as well as how it carries out these responsibilities. This paragraph was removed from the revised draft SOP to avoid confusing the SOP with a regulation; rather, the SOP provides the Commission's expectations regarding the applicability of this statement to individuals and organizations, performing or overseeing regulated activities involving nuclear materials.

#### **V. Evaluation of Public Comments**

Sixty-six public comments were received on the initial draft policy

statement published in the November 2009 FRN. Several of the comments were statements of agreement on the information and/or draft SOP that was published in the November 2009 FRN. Although the NRC staff used these comments to validate work the staff had already completed, these comments did not require further clarification. Of the remaining public comments, most fell into one of three themes: (1) More guidance is needed on implementation issues; (2) should the term "security" be included in the definition and, if not, should there be a separate security policy statement; and, (3) how will the NRC use a policy statement (which is voluntary) to enforce implementation of safety culture.

#### (1) Implementation Comments

Several of the comments requested clarification on the NRC's plans to implement the SOP. After the Commission has approved the policy statement, the Commission will issue an SRM to provide direction to the staff regarding next steps. The NRC offices that are responsible for overseeing regulated activities will assess their inspection and oversight programs to determine whether (and if so, how) to revise their programs based on the Commission's direction. The Commission is aware that there are many different settings in which the policy statement will be implemented and that implementation will be more complex in some settings than others. For example, as discussed above, the NRC's Reactor Oversight Program (ROP) already addresses safety culture in the inspection of nuclear power reactors. In addition, the power reactor community has ongoing programs and activities in place for assessing safety culture and implementing improvement strategies. This may not be the case with other categories of regulated activities, such as industrial radiography and medical use of isotopes. Variants such as these will be factored into the agency's approach and schedule for implementing the policy statement.

#### (2) Security Comments

As noted above, the panelists at the February workshop aligned on a common definition of safety culture. That definition, however, differs from the draft definition proposed in the November 2009 FRN which defines safety culture as "that assembly of characteristics, attitudes, and behaviors in organizations and individuals which establishes that as an overriding priority, nuclear safety and security issues receive the attention warranted by their significance." The initial draft

definition includes the terms "safety" and "security," underscoring the significance the Commission places on consideration of both within NRC's regulatory framework. In subsequent internal discussions and during the various outreach activities with stakeholders, the February workshop definition, which does not include the term "security," has been well received and thus, has been adopted in the revised draft SOP. The workshop definition is as follows: "Nuclear safety culture is the core values and behaviors resulting from a collective commitment by leaders and individuals to emphasize safety over competing goals to ensure protection of people and the environment." Deletion of the term "security" was deliberate. The panelists believe that leaving it in the definition would cause unnecessary confusion, particularly for smaller regulated entities that do not have to consider the same security issues as a nuclear power plant or fuel processing facility, for example. Their position is that security, like radiation protection, safeguards, material control and accounting, physical protection, and emergency preparedness, falls under an overarching definition of safety and should not be singled out. These views on removing the term "security" from the definition were also expressed by several members of a stakeholder panel during the Safety Culture Commission Briefing on March 30, 2010 (ML100950527).

Likewise, the traits that are included in the revised draft SOP, while similar to those proposed by the NRC, do not include the term "security" wherever the term "safety" is used. In recognition of the importance the agency places on security in a post "9/11" environment, the staff developed a preamble to the traits which points out that while the term "security" is not expressly included in each of the traits, safety and security are the primary pillars of the NRC's regulatory mission.

Finally, unlike the initial draft safety culture policy statement, the revised traits are included in the revised draft SOP itself. The November 2009 FRN specifically asked whether commenters would prefer this approach. There was almost unanimous agreement that the traits should be included to clarify the SOP.

#### (3) Policy Statement vs. Regulation/Rule Comments

Because public comments reflected some misunderstanding regarding the Commission's use of a policy statement rather than a regulation or rule, the following clarification is offered: The

Commission may use a policy statement to address matters relating to activities that are within NRC jurisdiction and are of particular interest and importance to the Commission. Policy statements help to guide the activities of the NRC staff and can express the Commission's expectations. The NRC's Enforcement Policy, for example, describes the policy and procedures the agency intends to follow in initiating and reviewing enforcement actions in response to violations of NRC requirements.

Policy statements are not regulations/rules and are not accorded the status of a regulation/rule within the meaning of the Administrative Procedure Act (Pub. L. 79-404), the primary goal of which is to ensure that agencies observe procedural due process (i.e., fairness), in conducting their regulatory and administrative affairs. For example, Agreement States that are responsible for overseeing materials licensees are not required to implement the elements of a policy statement because such statements, unlike NRC regulations, are not a matter of compatibility. Additionally, policy statements cannot be considered binding upon, or enforceable against, NRC or Agreement State licensees and certificate holders.

While the option to consider rulemaking exists, the NRC believes that, at this time, developing a policy statement is a more effective way to engage stakeholders.

#### *Additional Recommendations Based on Public Comments*

Based on its evaluation of the public comments, the NRC staff made several additional recommendations. These recommendations have been included in the revised draft SOP or are addressed elsewhere in this FRN.

- In SRM-SECY-09-0075, the Commission directed the staff to consider incorporating vendors and suppliers of safety related components in the safety culture policy statement. Although there is strong support for doing so, some stakeholders have raised implementation issues. While implementation issues (particularly in cases where such vendors and suppliers are outside of NRC jurisdiction) may be complicated, most comments indicated that vendors and suppliers of safety-related components should be developing and maintaining a positive safety culture in their organizations for the same reasons that NRC licensees and certificate holders should be doing so. Thus, the revised draft SOP indicates that it is applicable to vendors and suppliers of safety-related components.

- Because of the emphasis that the public comments place on strong

leadership, the NRC staff recommended moving the trait "Leadership Safety Values and Actions" to the top of the traits list to give it visual prominence.

• Several comments indicated that there should be a discussion of complacency in the SOP. Complacency can occur because of long term success and repetition. Although this is already indirectly addressed in the traits (e.g., Effective Safety Communication and Personal Accountability are traits that prevent complacency), the NRC staff recommended further discussion of complacency in the revised draft SOP. The NRC is asking for comments as to whether it is useful to add a discussion on this aspect of safety culture to the SOP.

#### VI. Questions for Which NRC Is Seeking Input

(1) The revised definition of Nuclear Safety Culture is: "Nuclear Safety Culture is the core values and behaviors resulting from a collective commitment by leaders and individuals to emphasize safety over competing goals to ensure protection of people and the environment." Should this be retained, as currently written, or should it be revised?

(2) Does including the safety culture traits in the SOP itself clarify your understanding of what the Commission means by a positive safety culture? If not, what additional guidance do you think is needed?

(3) Does the revised draft SOP provide a clear statement of the NRC's expectations that the regulated community should maintain a safety culture that includes balanced consideration of safety and security? If not, what changes or additions should be made?

(4) Should a discussion regarding complacency be added to the SOP and/or to the traits that describe areas important to safety?

(5) In late August 2010, the Institute of Nuclear Power Operations (INPO) completed a validation study to assess the extent to which the factors that emerged from analyzing responses to a safety culture survey match the traits that were identified during the February 2010 workshop. Only individuals working at nuclear reactors participated in the survey.

The study provides general support for the traits developed at the workshop; however, the study provides a slightly different grouping. Under the validation study, there are nine traits: (1) Management Responsibility/Commitment to Safety; (2) Willingness to Raise Concerns; (3) Decision-making; (4) Supervisor Responsibility for Safety;

(5) Questioning Attitude; (6) Safety Communication; (7) Personal Responsibility for Safety; (8) Prioritizing Safety; and (9) Training Quality. Four of these are consistent with the eight traits developed by the workshop participants, i.e., Management Responsibility is consistent with Leadership Safety Values and Actions; Willingness to Raise Concerns relates to Environment for Raising Concerns; Safety Communication relates to Effective Safety Communication; and Personal Responsibility for Safety is consistent with Personal Accountability. The remaining five traits identified in the study, i.e., Decision-making, Supervisor Responsibility for Safety, Questioning Attitude, Prioritizing Safety, and Training Quality, are not as closely related (although they are not completely dissimilar). This is new information. The NRC is seeking stakeholder comments on this information through the FRN and through the public meeting scheduled for September 28 in Las Vegas.

To ensure efficient consideration of your comments, if you are responding to a specific question, please identify it by number with your comment. When commenting, please exercise caution with regard to site-specific security-related information. Comments will be made available to the public in their entirety. Personal information such as your name, address, telephone number, and e-mail address will not be removed from your submission.

For the Nuclear Regulatory Commission.

Dated at Rockville, Maryland, this 10th day of Sept, 2010.

**Roy P. Zimmerman,**  
Director, Office of Enforcement.

[FR Doc. 2010-23249 Filed 9-16-10; 8:45 am]

BILLING CODE 7590-01-P

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#### OFFICE OF PERSONNEL MANAGEMENT

#### Submission for Review: Federal Cyber Service: Scholarship for Service (SFS) Registration Web Site

**AGENCY:** Office of Personnel Management.

**ACTION:** 30-Day Notice and request for comments.

**SUMMARY:** The Office of Personnel Management (OPM), Human Resources Solutions Division, offers the general public and other Federal agencies the opportunity to comment on an existing information collection request (ICR) 3206-0246, SFS Registration. As required by the Paperwork Reduction

Act of 1995 (Pub. L. 104-13, 44 U.S.C. chapter 35), as amended by the Clinger-Cohen Act (Pub. L. 104-106), OPM is soliciting comments for this collection. The information collection was previously published in the **Federal Register** on April 19, 2010 at 75 FR 20400, allowing for a 60-day public comment period. One comment was received, and OPM provided a response. The purpose of this notice is to allow an additional 30 days for public comments. The Office of Management and Budget is particularly interested in comments that:

1. Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

2. Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

3. Enhance the quality, utility, and clarity of the information to be collected; and

4. Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submissions of responses.

**DATES:** Comments are encouraged and will be accepted until October 18, 2010. This process is conducted in accordance with 5 CFR 1320.1.

**ADDRESS:** Interested persons are invited to submit written comments on the proposed information collection to the Office of Information and Regulatory Affairs, Office of Management and Budget, 725 17th Street, NW., Washington, DC 20503, Attention: Desk Officer for the Office of Personnel Management or sent via electronic mail to [oir\\_submission@omb.eop.gov](mailto:oir_submission@omb.eop.gov) or faxed to (202) 395-6974.

**FOR FURTHER INFORMATION CONTACT:** A copy of this ICR, with applicable supporting documentation, may be obtained by contacting the Office of Information and Regulatory Affairs, Office of Management and Budget, 725 17th Street, NW., Washington, DC 20503, Attention: Desk Officer for the Office of Personnel Management or sent via electronic mail to [oir\\_submission@omb.eop.gov](mailto:oir_submission@omb.eop.gov) or faxed to (202) 395-6974.

**SUPPLEMENTARY INFORMATION:** The SFS Program was established by the National Science Foundation in accordance with

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.

## BYLAWS-ADVISORY COMMITTEE ON THE MEDICAL USES OF ISOTOPES

### 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.

**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 13 members utilize 2.3 FTE (includes approximately 1.6 FTE for NRC staff and 0.7 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, 2012.

10. **Filing date:**

March 16, 2010.

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