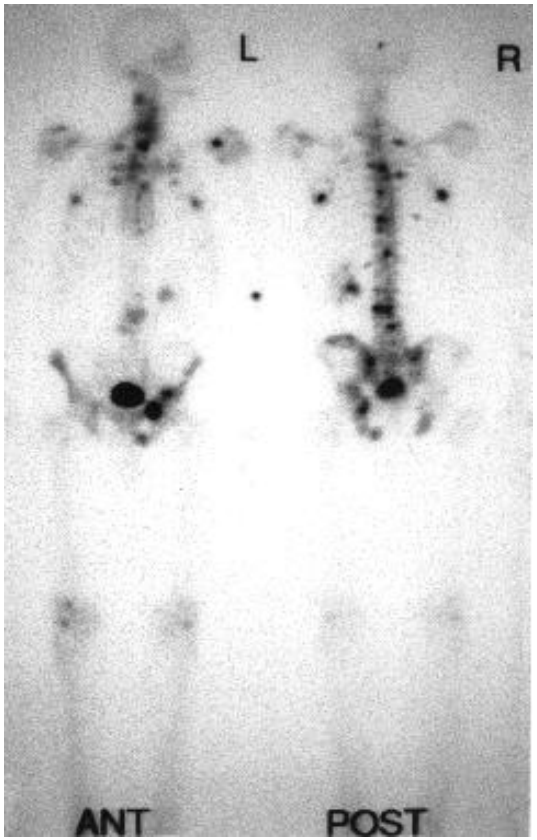
U.S.NRC
UNITED STATES NUCLEAR REGULATORY COMMISSION
Protecting People and the Environment

Medical Isotope Shortage: Update

October 20, 2010

Steve Mattmuller, MS, RPh, BCNP

Need: Patient Care



Fragile Mo-99 Supply

Effect on Patients

JUNE 2009						
S	M	T	W	T	F	S
	1	2	3	4	5	6
7	8	9	10	11	12	13
14	15	16	17	18	19	20
21	22	23	24	25	26	27
28	29	30				

JULY 2009						
S	M	T	W	T	F	S
			1	2	3	4
5	6	7	8	9	10	11
12	13	14	15	16	17	18
19	20	21	22	23	24	25
26	27	28	29	30	31	

AUGUST 2009						
S	M	T	W	T	F	S
						1
2	3	4	5	6	7	8
9	10	11	12	13	14	15
16	17	18	19	20	21	22
23	24	25	26	27	28	29
30	31					

SEPTEMBER 2009						
S	M	T	W	T	F	S
		1	2	3	4	5
6	7	8	9	10	11	12
13	14	15	16	17	18	19
20	21	22	23	24	25	26
27	28	29	30			

OCTOBER 2009						
S	M	T	W	T	F	S
				1	2	3
4	5	6	7	8	9	10
11	12	13	14	15	16	17
18	19	20	21	22	23	24
25	26	27	28	29	30	31

NOVEMBER 2009						
S	M	T	W	T	F	S
1	2	3	4	5	6	7
8	9	10	11	12	13	14
15	16	17	18	19	20	21
22	23	24	25	26	27	28
29	30					

DECEMBER 2009						
S	M	T	W	T	F	S
		1	2	3	4	5
6	7	8	9	10	11	12
13	14	15	16	17	18	19
20	21	22	23	24	25	26
27	28	29	30	31		

JANUARY 2010						
S	M	T	W	T	F	S
					1	2
3	4	5	6	7	8	9
10	11	12	13	14	15	16
17	18	19	20	21	22	23
24	25	26	27	28	29	30
31						

FEBRUARY 2010						
S	M	T	W	T	F	S
	1	2	3	4	5	6
7	8	9	10	11	12	13
14	15	16	17	18	19	20
21	22	23	X	25	X	27
28						

MARCH 2010						
S	M	T	W	T	F	S
	1	2	3	4	5	6
7	8	9	10	11	12	13
14	15	16	17	18	19	20
21	X	23	X	25	X	27
28	29	30	31			

APRIL 2010						
S	M	T	W	T	F	S
				1	X	3
4	5	6	X	!	X	10
11	12	13	14	15	16	17
18	19	20	21	22	23	24
25	26	27	28	29	30	

MAY 2010						
S	M	T	W	T	F	S
						1
X	3	4	X	6	X	8
9	X	11	X	13	14	15
16	X	18	X	!	X	22
23	X	25	26	!	X	29
30	X					

JUNE 2010						
S	M	T	W	T	F	S
		1	X	3	X	5
6	X	8	9	10	11	12
13	14	15	16	17	18	19
20	21	22	23	24	25	26
27	28	29	30			

JULY 2010						
S	M	T	W	T	F	S
				1	2	3
4	X	6	X	8	9	10
11	X	13	X	15	16	17
18	X	20	X	22	X	24
25	X	27	28	29	30	31

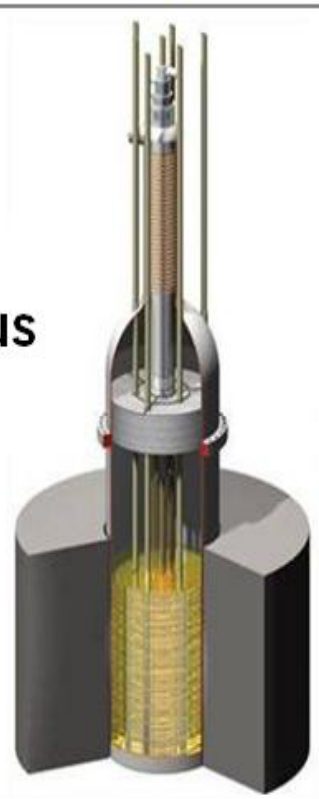
AUGUST 2010						
S	M	T	W	T	F	S
1	2	3	4	5	6	7
8	9	10	11	12	13	14
15	16	17	18	19	20	21
22	X	24	X	26	27	28
29	X	31				

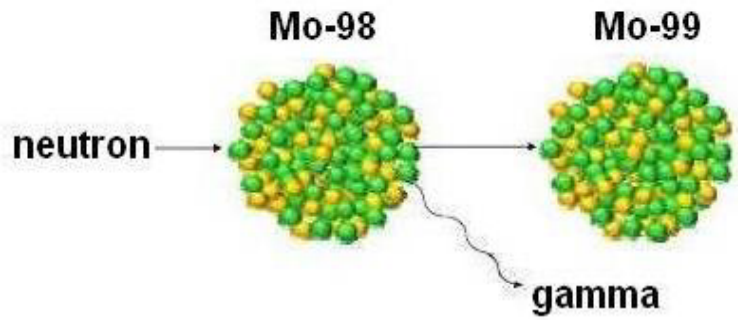
SEPTEMBER 2010						
S	M	T	W	T	F	S
			X	2	X	4
5	X	7	X	9	X	11
12	13	14	15	16	17	18
19	20	21	22	23	24	25
26	27	28	29	30		

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						
15						
22						
29						

Sunday	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday
1	2	3	4	5	6	7
8						
15						
22						
29						

Sunday	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday
1	2	3	4	5	6	7
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29						

Sunday	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday
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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

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**

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**

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**

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**

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 <u>not</u> recommended as sole release criterion by ICRP and IAEA**
- **Inappropriate for NRC regulations**

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

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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

Proposed Background Review Costs

Direct

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

Indirect

$40,000

Proposed cost $100,000

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

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

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.

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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

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

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?**

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**

Nuclear Medicine Byproduct Events

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

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)**

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

Conclusions

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

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

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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**

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.**

Acronyms

HDR – High Dose Rate

NMED – Nuclear Materials Events Database

NRC – Nuclear Regulatory Commission

RCA – Root Cause Analysis