



# **Medical Isotope Shortage: Update**

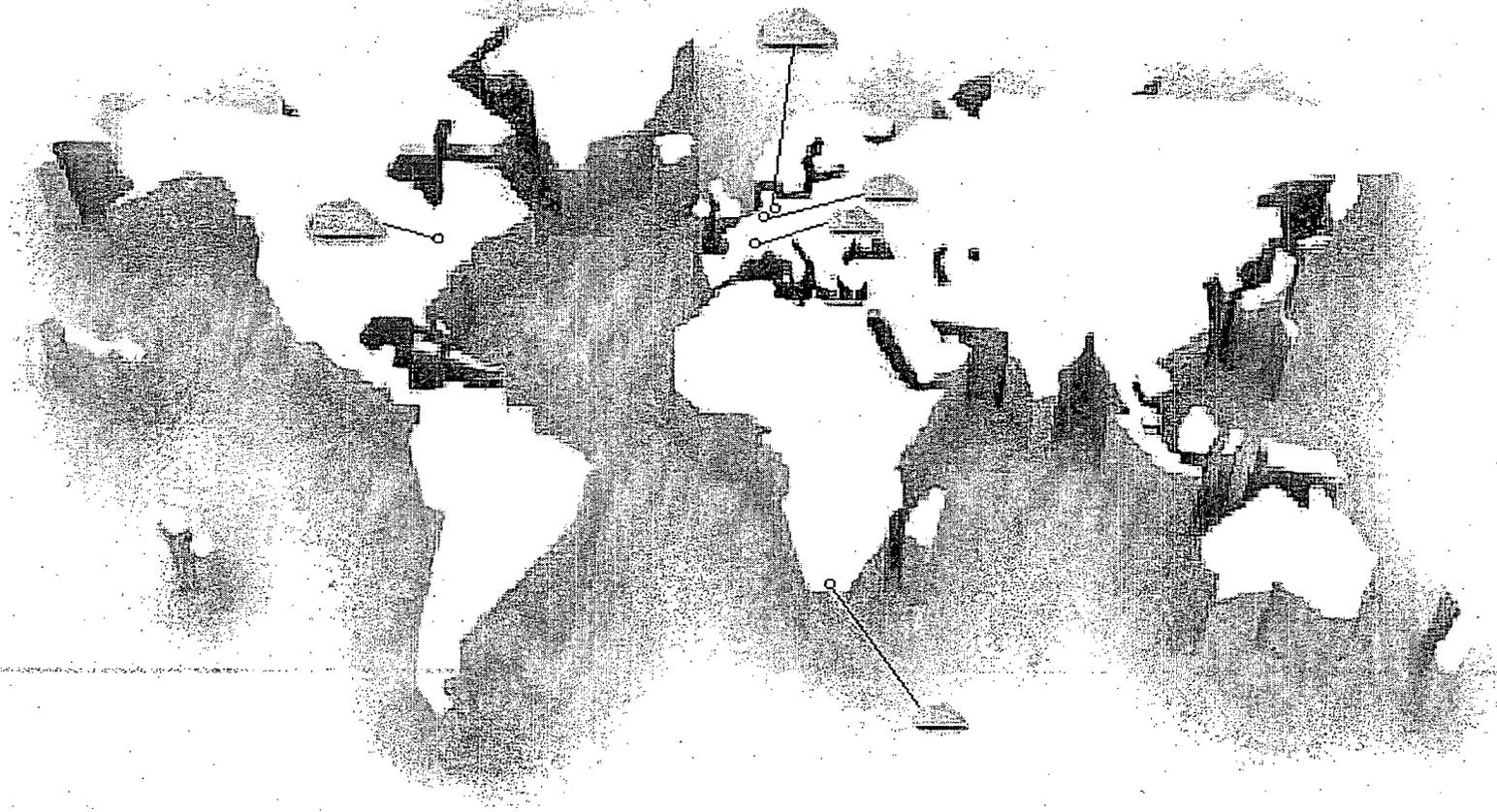
**October 20, 2010**

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

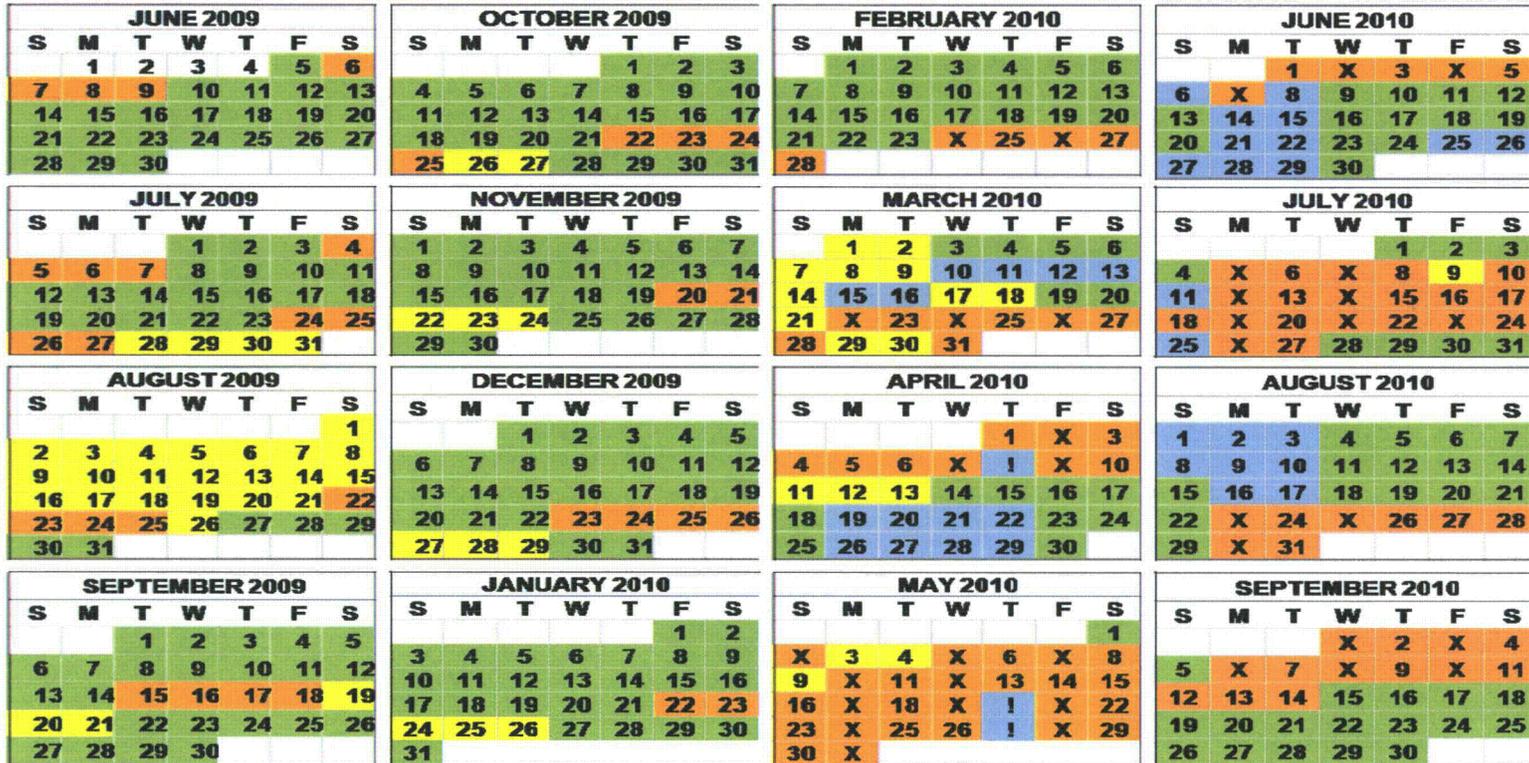
# Need: Patient Care



# Fragile Mo-99 Supply



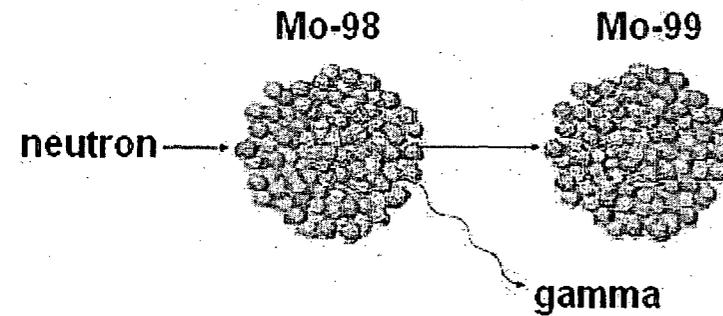
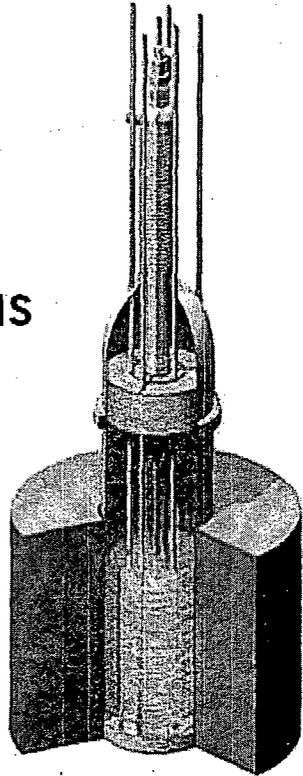
# Effect on Patients



# 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**

# **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 not 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**

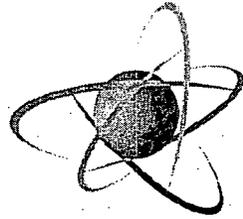
# Conclusions

- **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**
- **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. Welch, P. Zanzonico**



**U.S.NRC**

UNITED STATES NUCLEAR REGULATORY COMMISSION

*Protecting People and the Environment*

# **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.**



# **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**

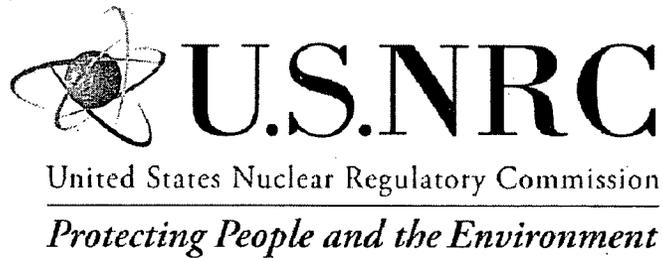
**ME – Medical Event**

**NMED – Nuclear Materials Events  
Database**

**NRC – Nuclear Regulatory Commission**

**WD – Written Directive**

**Y-90 – yttrium 90**



# **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**



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

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

# ***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***

# ***What have we done?***

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

# ***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)***

# ***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?***

# ***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***

## ***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***

# ***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***

# ***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.***

## ***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?***

- ***Development of a reporting form for all radiation medical events***
- ***Creating and 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***

# ***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***

# **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***

# CRCPD Working Group Fact Sheet

H-38 Committee on Radiation Medical Events

August 2010

**Chairperson:** Jennifer Elee (LA) 02/10  
 Email: [jennifer.elee@la.gov](mailto:jennifer.elee@la.gov)

Task Force with a finite life (Exempt from rotation)

Members		Advisors	
Janaki Krishnamoorthy (NY) 2/10 Jim Castle (OH) 02/10 John Winston (PA) 03/10 Jimmy Carson (MS) 03/10		Debbie Gilley (FL) 03/10 Julie Miller (CA) 3/10 Lynne Fairobent (Affil.-MD) 05/10 A. Kyle Jones (Affil.-TX) 05/10 Melissa Martin (Affil.-CA) 05/10 Adela Salame-Alfie (NY) 06/10 Claire Skowronski (Affil.-FL) 06/10 <b>Albert Wiley (Affil. - TN) 08/10*</b>	
Resource Individuals			
CDRH	Lauren Hefner	Sean Boyd	
NRC	Duane White		
ACR	Tom Payne	Albert Blumberg, M.D. (Rad. Oncologist)	
AAPM	Ralph Lieto (Diagnostic)	Per Halvorsen (Therapy)	
ASTRO	Richard Martin		
Notes and Comments			
<i>(Bolded text in a Fact Sheet (other than headings) indicates the most recent change.)</i>			
<b>* Albert Wiley (Affiliate) added as an advisor per his request.</b>			
<b>NOTE:</b> If difficulty in getting resource persons, contact the following Federal Liaisons to the Board of Directors for assistance.			
CDRH	Tom Ohlhaber	(301) 796-5712	
EPA	Mary Clark	(202) 343-9348	
ORA	Mei-Ying Li	(301) 827-2913	
NRC	Robert Lewis	(301) 415-3340	
FEMA	Vanessa Quinn	(703) 605-1535	

08/10/10 - ss

## **CRCPD Working Group Fact Sheet**

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

**August 2010**

### **Charges:\***

- 1. Oversee the development and maintenance of a national database of radiation medical events.**
- 2. Develop a definition of reportable radiation medical events from radiation producing machines.**
- 3. Develop a format and mechanism for reporting radiation medical events.**
- 4. Review submitted reports for completeness and accuracy.**
- 5. Establish a mechanism for preparing an annual summary and an article for the *Newsbrief*.**
- 6. Establish a mechanism for referring information to CRCPD subject matter committees' information to determine the need for timely notices.**
- 7. Provide a verbal report at the CRCPD Annual Meeting.**

Note: When a Letter/Number combination appear in brackets after a charge, it denotes how the charge links to CRCPD's Goals and Objectives, as listed in [CRCPD's Strategic Plan](#).

If interested in serving on this working group, contact the Chairperson at [Jennifer.elee@la.gov](mailto:Jennifer.elee@la.gov)

## Radiation Medical Events

For the purposes of this reporting system, the Conference of Radiation Program Directors (CRCPD) has defined the following reporting criteria for a Radiation Medical Event. A medical event indicates that a facility had technical or quality assurance problems in administering the physician's orders. There is no scientific basis to conclude that such a medical event necessarily results in harm to the patient. These events indicate a potential problem in a medical facility's use of radiation. Radiation Medical Events are separated into two sources: Therapy and Diagnostic.

In therapy the reporting criteria are:

- Other than an event that results from intervention by a patient or human research subject, a registrant shall report any event in which the administration of a therapeutic radiation machine therapy dose:
  - Involves the wrong patient, wrong treatment modality, or wrong treatment site; or
  - For which, the calculated weekly administered dose differs from the weekly prescribed dose by more than thirty percent (30%); or
  - For which, the calculated total administered dose differs from the total prescribed dose by more than twenty percent (20%) of the total prescribed dose; or
  - For which, the dose differs by fifty percent (50%) or greater for any single fraction of a multi-fraction treatment; or
  - Any equipment failure, personnel error, accident, mishap or other unusual occurrence that causes or is likely to cause significant physical harm to the patient

In diagnostic the reporting criteria are:

- Other than events that result from intervention by a patient or human research subject, a registrant shall report any event in which the administration of ionizing radiation from a diagnostic radiation machine:
  - Results in an unintended dose to the skin greater than 2 Gy (200 rads) to the same area for a procedure or series; or
  - Results in a dose greater than 5 times the facility's established protocol for a procedure or series; or
  - Involves the wrong patient or wrong site for the entire diagnostic exam (procedure/service) and results in a total effective dose of greater than 5 rads\* for the procedure or series; or
  - Where any equipment failure, personnel error, accident, mishap or other unusual occurrence involving the administration of ionizing radiation.

\* Any wrong patient or wrong site imaged regardless of dose received should be reported, documented, and addressed internally within the facility.

***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.

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?

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.

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

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.

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).

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.

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

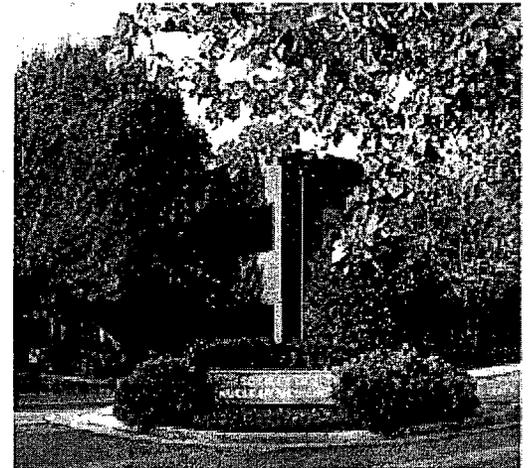
***October 20, 2010***

***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

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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.



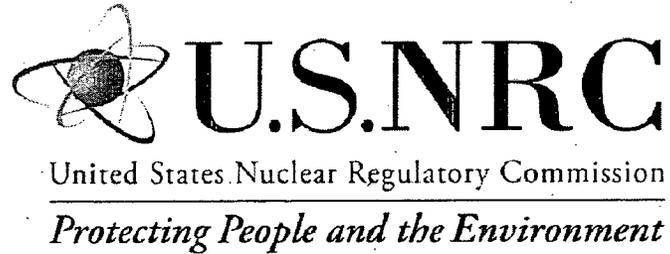
# Isotope Shortage

- 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?



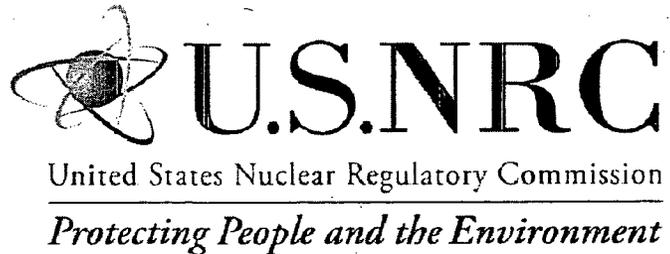


# **Briefing on Medical Issues**

**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**

# **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**

# **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)**

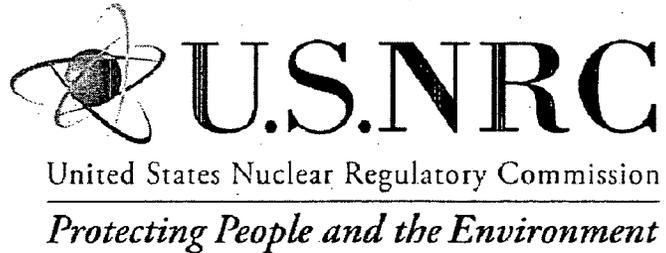
- **ACMUI (June 2007 meeting) expressed concern about naming only one person as the RSO**
- **ACMUI believed that it was contributing to a shortage of RSOs**

## **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**

# **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**



# **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)**

# **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**

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

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

## **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**

# **Nuclear Materials Events Database**

# **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**

# 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**

**NMED Item Number: 100XXX**

**Narrative:**

**Last Updated:**

**10/XX/20XX**

**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**

# 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**