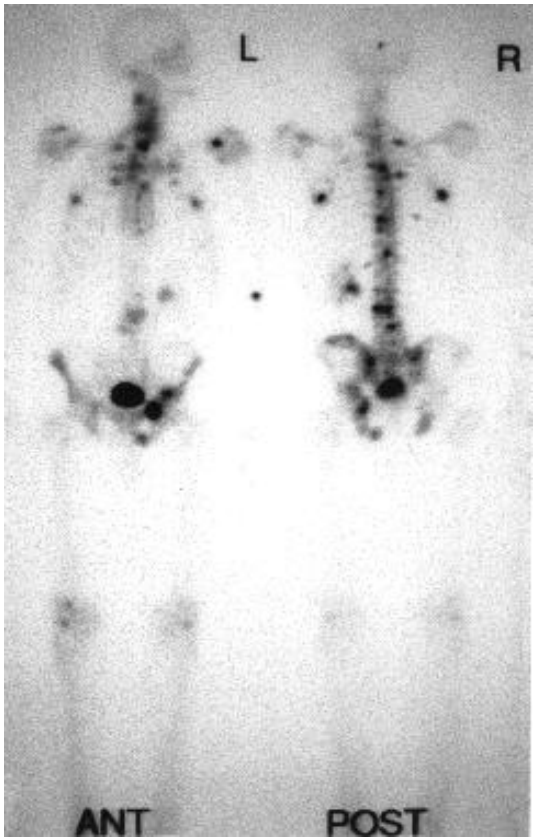
Medical Isotope Shortage: Update

October 20, 2010

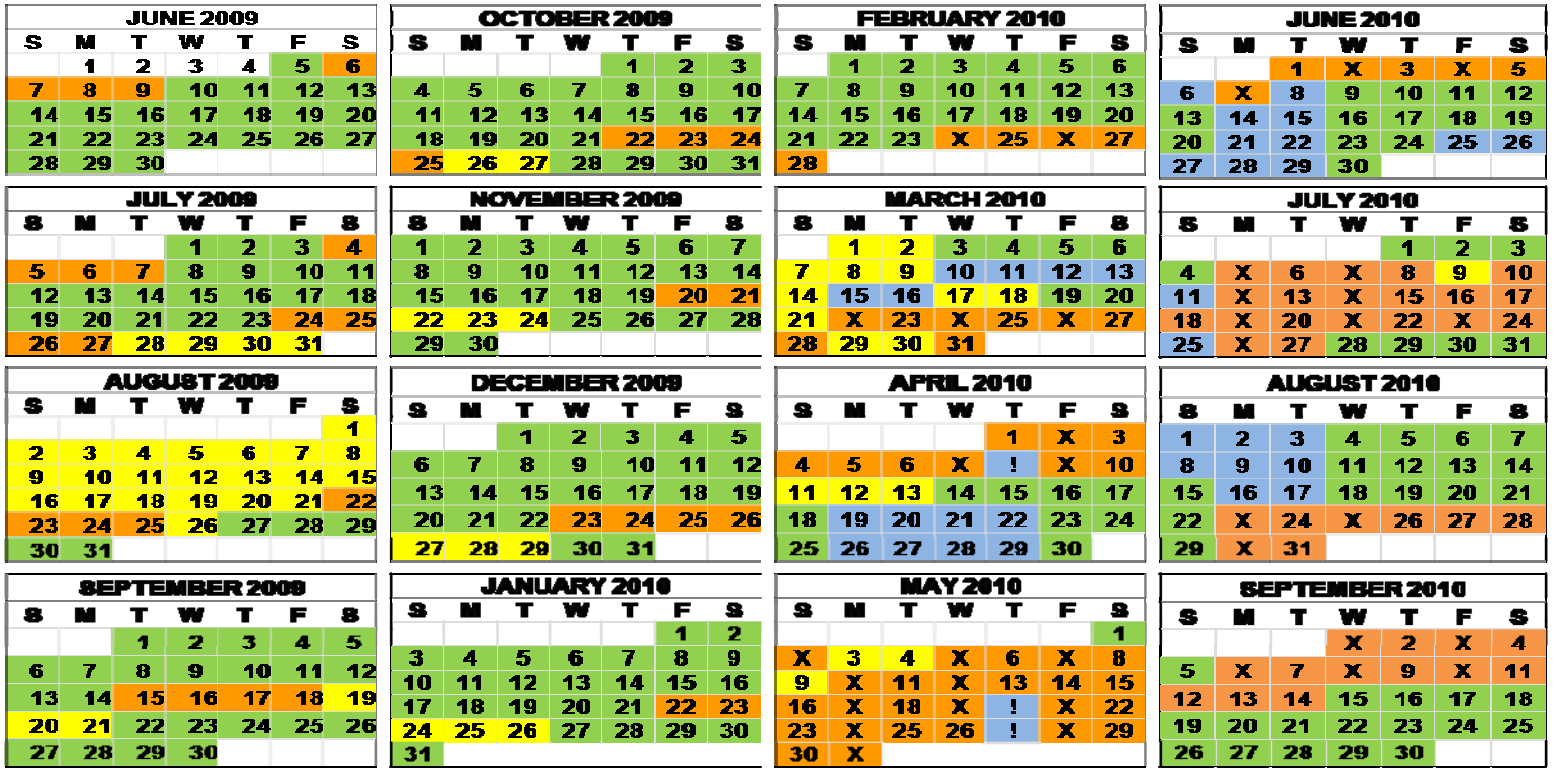
Steve Mattmuller, MS, RPh, BCNP

Need: Patient Care



Fragile Mo-99 Supply

Effect on Patients



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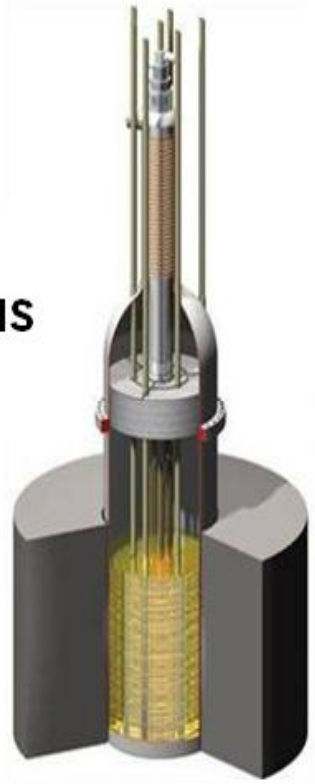
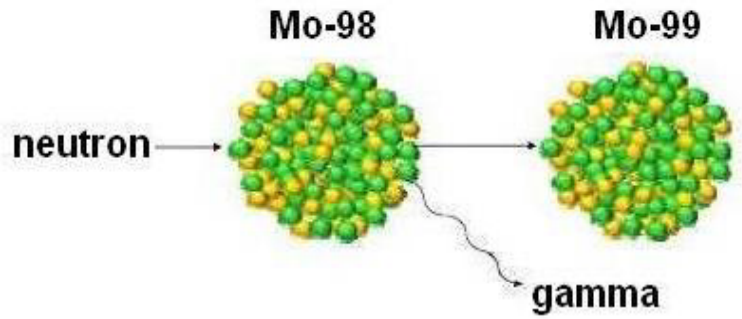
Long Term Solution

Babcock & Wilcox

Aqueous Homogeneous Reactor





General Electric - Hitachi

Neutron activation process

Goal: Optimal Patient Care

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

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

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 b) Accepted	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 though 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 an AU, not the AU, should sign and date both the pre-implantation and post-implantation portions of the WD for all modalities with two part WDs. [Note this allows for one AU to sign the pre-implantation portion of the WD and another AU to sign the post-implantation portion of the WD]	10/28/08	Accepted	Open *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, measureing, & safely preparing patient or human research subject dosages; e) using administratitve controls to prevent a medical event involving the use of byproduct material; f) using procedures to control and to contain spilled byproduct material safely & using proper decontamination procedures; g) follow up and review of each patient's or human research subject's case history; and h) the operation of and quality management for dose calibrators; and 3) board certification in diagnostic radiology with a subspeciality in interventional radiology or 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. Subcommitte 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 subcommitte 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 subcommitte report.	5/25/10	NRC action	Open
7	The ACMUI fully supports Dr. Darrell Fisher as Patients' Rights Advocate. The Committee expressed their appeciation 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 (ROSIS)
- 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
- 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

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

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

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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

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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

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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

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Questions?

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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

MULTIPLE MEDICAL EVENTS INVOLVING PROSTATE BRACHYTHERAPY TREATMENTS AT DEPARMENT 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**

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**

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**

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**

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**

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**

DVA Medical Event Criteria

- **Phase I:** ± 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

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)**

Causes of Medical Events

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

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**

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**

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**

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**

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**

NRC Actions Going Forward

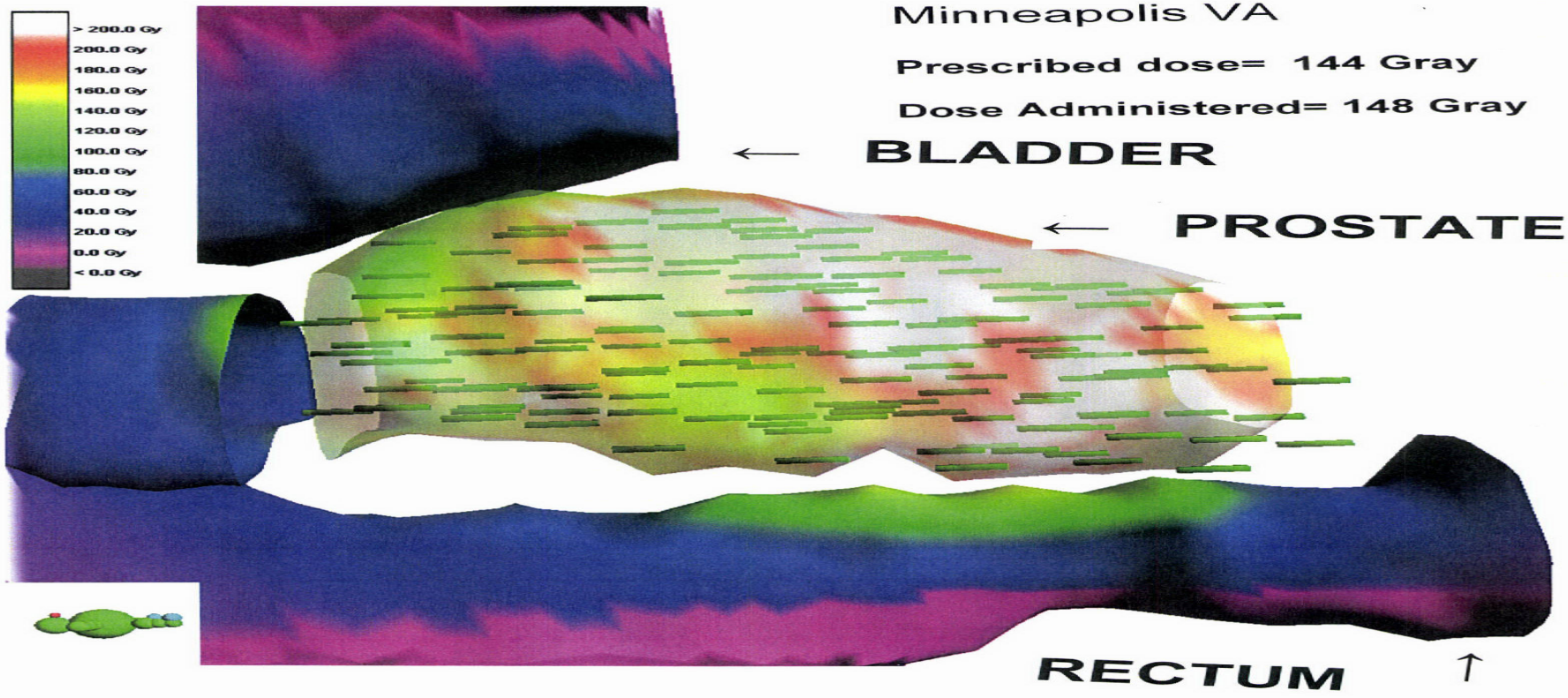
- **Enhanced oversight of the DVA**
  - **Global actions instituted by DVA**
  - **NRC actions to assess performance improvements**

- **Assess NRC's policies, procedures, and practices related to prostate brachytherapy to identify program enhancements**

VariSeed: 3D View Report [Page 1]

VAMC Rad Onc · 1 · 1 · 11/18/2008 10:52:16 AM

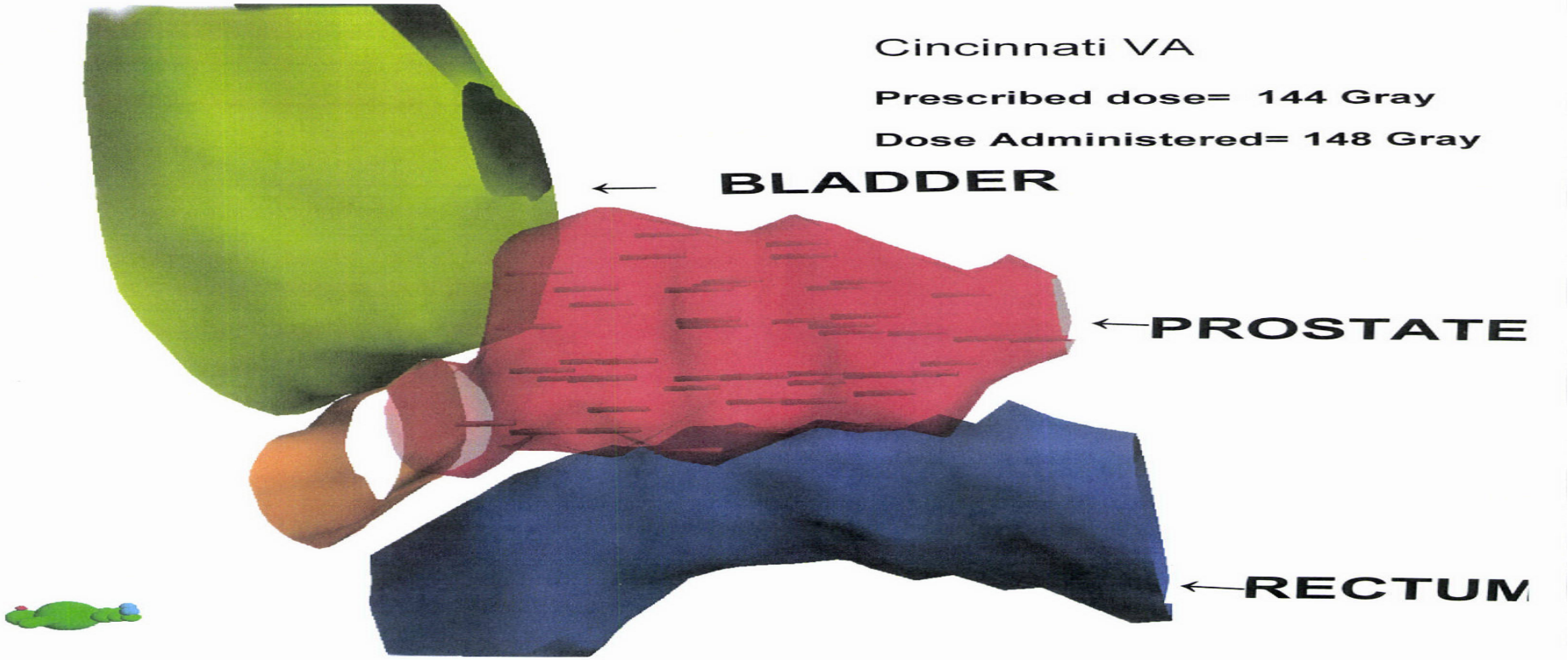
	Study: **POST PLAN** Variation: **Default** Images: **37**	Source: **I-125 (IAI-125A) [NIST 00]** Comment: Sources: **152** Anisotropy: **Function (Line Model)** Source Activity: **0.394 U [0.310 mCi]**
Procedure Date: **7/2/2008**	Prescription Dose: **144.0 Gy**	Total Activity: **59.888 U [47.156 mCi]**



VariSeed: 3D View Report [Page 1]

University Hospital · 10/16/2008 1:56:01 PM

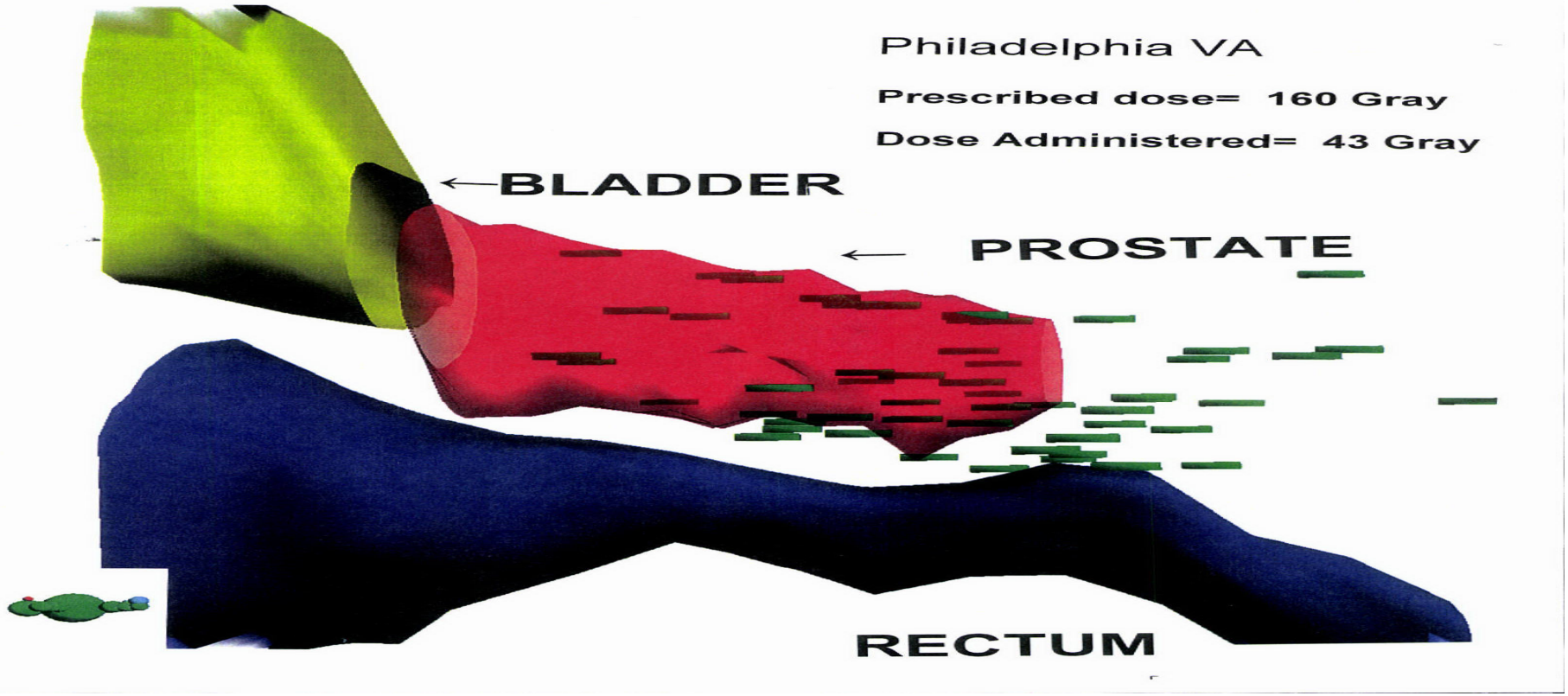
Name: PID: Dept. ID:	Study: **Post Plan Average Act.** Variation: **Default** Images: **57**	Source: **I-125 (6711) [NIST 99]** Comment: Sources: **46** Anisotropy: **Factors (Point Model)** Source Activity: **0.660 U [0.520 mCi]**
Procedure Date: **6/5/2008**	Prescription Dose: **160.0 Gy**	Total Activity: **30.360 U [23.906 mCi]**



VariSeed: 3D View Report [Page 1]

VariSeed 7.0 (Build 1955) · Philadelphia VA Medical Center · · · 9/9/2008 4:47:17 PM

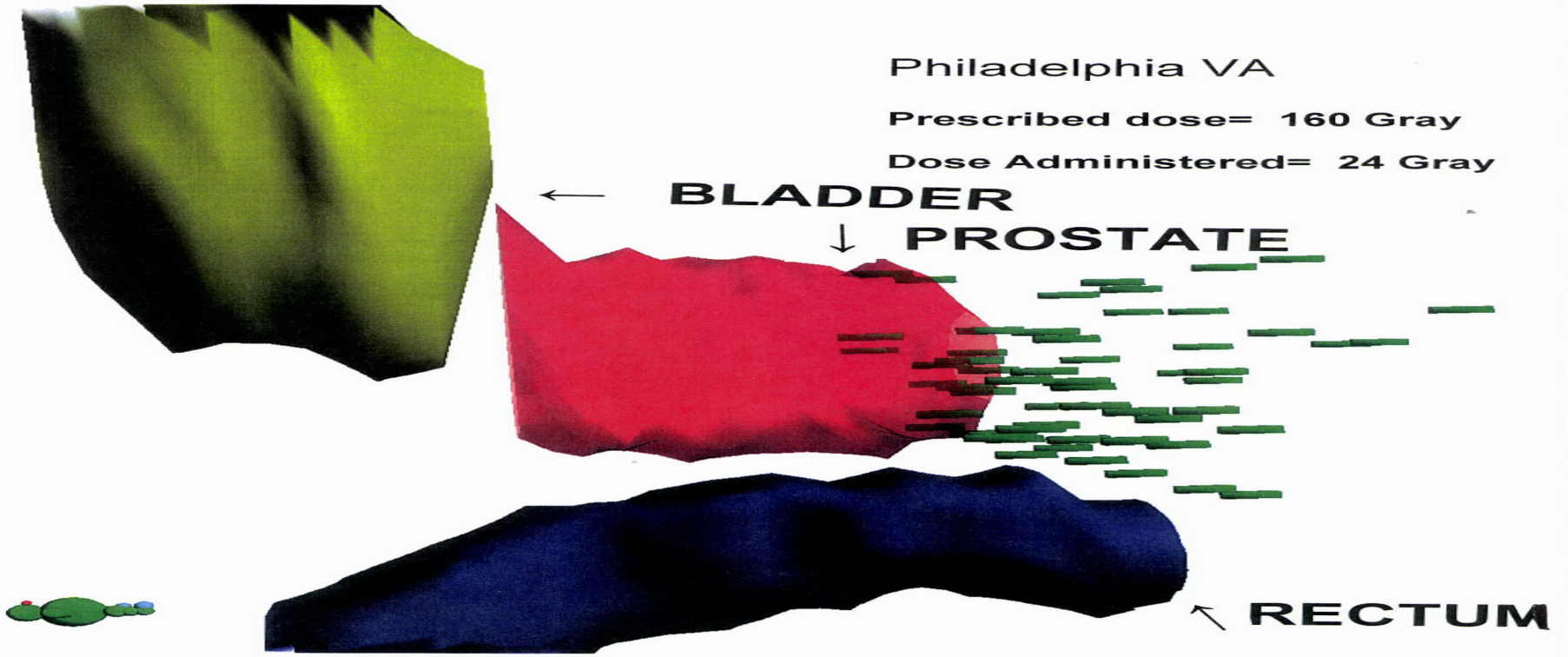
Study: followupEval_061108 Variation: Default # Scans: 29	Isotope: I-125 (2301) [NIST 00] # Seeds: 54 Prescription Dose: 160.000 Anisotropic Correction: 0.982	U/mCi: 1.270 U/Seed: 0.483 mCi/Seed: 0.380



VariSeed: 3D View Report [Page 1]

VariSeed 7.0 (Build 1955) · Philadelphia VA Medical Center · · · 9/9/2008 4:54:55 PM

Study: followupEval_062408 Variation: Default # Scans: 54	Isotope: I-125 (2301) [NIST 00] # Seeds: 58 Prescription Dose: 160.000 Anisotropic Correction: Fac	U/mCi: 1.270 U/Seed: 0.483 mCi/Seed: 0.380



- **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**

Key Points

- **A "medical event" should be <u>of medical significance</u>**
- **The definition should be sensitive enough to potential <u>harm</u> 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**

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**

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**

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.**

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.

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}Mo (^{99m}Tc)) alone per year in the U.S.**
- **There is an acute shortage of fission produced medical radioisotopes in the U.S.**

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**

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**

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: $^{27}Al(\alpha,n)^{30}P$**
- **Enrico Fermi produced a whole range of radioisotopes, including phosphorus-32 (^{32}P)**
- **Soon ^{32}P was used to treat a patient with leukemia**

Brief History of Nuclear Medicine

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

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**

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}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.

Brief History of Nuclear Medicine

- **It was soon discovered that the thyroid accumulated radioiodine (^{131}I)**
- **^{131}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**

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…

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**

Brief History of Nuclear Medicine

- This was all under the secrecy of the Manhattan Project
- To protect this secrecy, the ^{32}P produced by the reactor had to appear as if it had been produced by a cyclotron
- Thus, ^{32}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(!)

Brief History of Nuclear Medicine

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

Means of making isotopes

- **The predominant method of ^{99}Mo production (and the only method used for North American ^{99}Mo) is through fission of uranium-235**
  - **^{235}U(n,f)^{99}Mo**
- **Fission of HEU by thermal neutrons in a reactor**
- **The HEU is generally weapons-grade (about 95% ^{235}U) in the form of a uranium-aluminum (U-Al) alloy**
  - **Roughly 6% of the total fission yield is ^{99}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).**

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}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.

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}Mo shortage due to the expense and political difficulty of building new reactors**

Alternatives to Conventional Methods

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

Alternatives to Conventional Methods

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

Means of Making ^{99}Mo from Non-uranium Targets

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

Means of Making ^{99}Mo from Non-uranium Targets

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

Alternatives to Neutrons

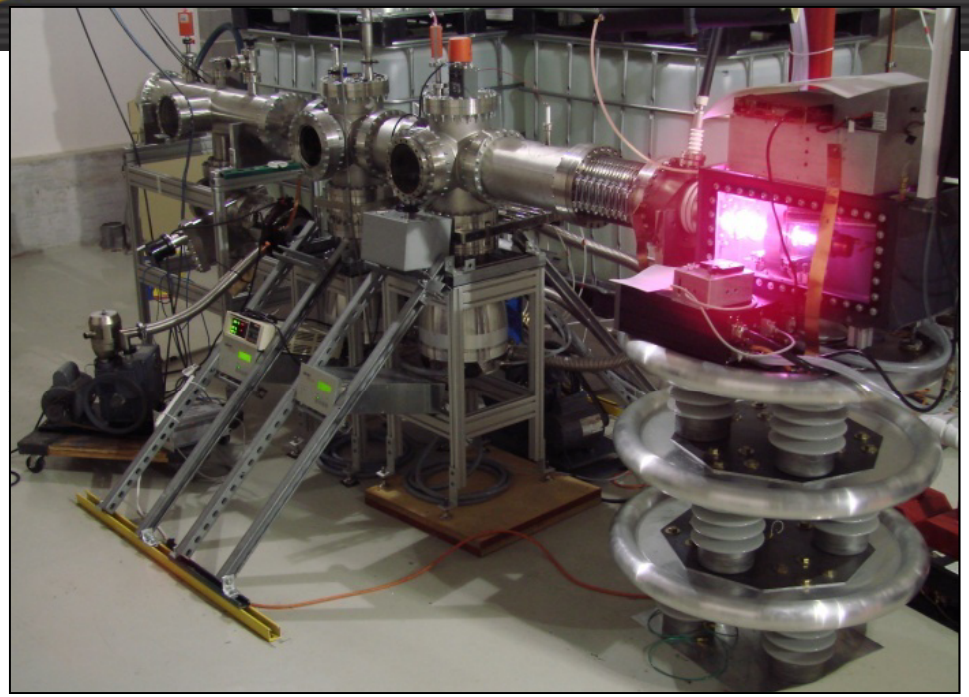
- The $^{100}Mo(p,pn)^{99}Mo$ proton-driven reaction has been investigated by a number of researchers
  - but it (maybe) has a relatively low cross section and
  - would produce a low specific activity product
- The deuteron reaction
  - $^{100}Mo(d,p2n)^{99}Mo$
  - has twice the cross-section of $^{100}Mo(p,pn)^{99}Mo$,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

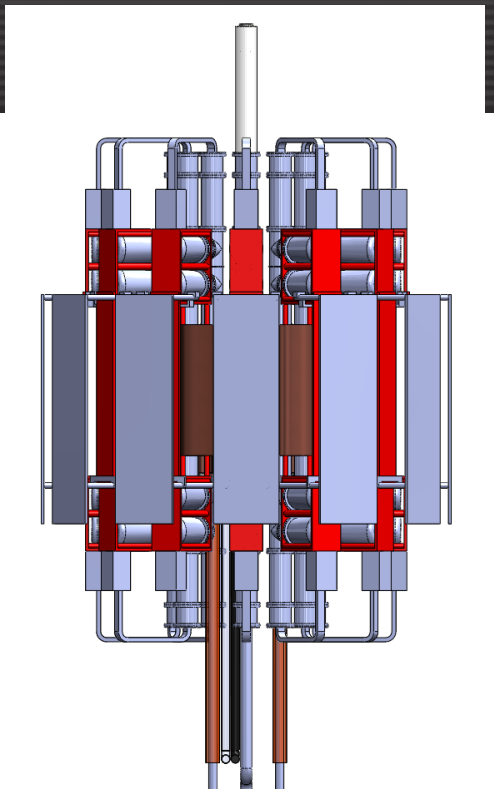
Alternatives to Neutrons

- **Bombarding enriched ^{100}Mo targets with protons from a cyclotron to directly produce ^{99m}Tc**
  - **^{100}Mo(p,2n)^{99m}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}Tc for large metropolitan areas**
- **But of course is not a global or national solution**

PHOENIX NUCLEAR LABS

PROVIDING NUCLEAR TECHNOLOGY FOR THE BETTERMENT OF HUMANITY





Prepared for James Welsh and the NRC ACMUI on September 23rd, 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}Mo and other medical isotopes**

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**

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 (> $2*10^9$ 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}He)

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**

SHINE Driver Specifications

- **Operational**
  - **Deuteron / triton current: 100 mA**
    (50 mA per injector)
  - **Beam energy: 350 keV**
  - **Beam power: 35 kW**
  - **Neutron output: 5*1013 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**

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**

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**

Specifications

- **Key parameters**
  - **Fission power: ~ 250 kW**
  - **^{99}Mo production rate: 2500 6-day kCi/week**
  - **Driver neutron production: $6*10^{14}$ 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^2/s average flux in solution**

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**

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**

Acronyms

DC – direct current

DOE – Department of Energy

HEU – Highly-enriched Uranium

HFR – High Flux Reactor

keV – kiloelectron volt

kW - kilowatt

Acronyms

lbs - pounds

LEU – Low Enriched Uranium

mA - milliamp

MeV – megaelectron volt

NRU – National Research Universal

RF – radio frequency

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Protecting People and the Environment

Physical Protection of Byproduct Material – Proposed Rule

Merri Horn

Senior Project Manager

October 21, 2010

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10 CFR Part 37 - Timeline

- Preliminary language posted for comment
  - complete
- Proposed rule to Commission
  - complete
- Publication for public comment
  - ongoing, extended until January 18, 2011
- Public workshop on guidance
  - complete
- Final rule to Commission
  - Spring 2012

NO HANDOUT

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

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 CRF 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**

Discussion

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

Discussion

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

Discussion

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

Discussion

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

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

Discussion

Comments concerning 30-mCi rule

Discussion

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

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**

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Protecting People and the Environment

Status of Medical Events FY 2010

Donna-Beth Howe, Ph.D.

October 21, 2010

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Medical Events 2010

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

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

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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

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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

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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

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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

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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)

Medical Events 2010

35.600 Medical events 12

- HDR 9
  - Mammosite 2
- Gammaknife 3

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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

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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

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35.600 Medical Events

Gammaknife 3

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

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Medical Events 2010

35.1000 Medical events 7

- Perfexion 2
- Microspheres 4
- Intravascular Brachytherapy 1

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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

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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.

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35.1000 Medical Events

SirSpheres 2

- Leakage around stopper – manufacturer confirmed leakage, but thought physcian put too much pressure to V-vial
- Thought procedure delivered entire dose with out complication, but about 4.4 mCi of intended15.4 mCi left in tubing vial and other contaminated items

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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

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**

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**

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**

Issues

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

Effective Dose

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

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**

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?**

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

Questions?

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.* 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.*

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 20555–0001, or by fax to RADB at (301) 492–3446.

FOR FURTHER INFORMATION CONTACT: Maria E. Schwartz or Catherine Thompson at the U.S. Nuclear Regulatory Commission, Office of Enforcement, Mail Stop O–4 A15A, Washington, DC 20555–0001 or by e-mail or telephone to *Maria.Schwartz@nrc.gov,* (301) 415–1888, or *Catherine.Thompson@nrc.gov,* (301) 415–3409.

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).[1] 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[2] 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 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.

[1] 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.

[2] 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.

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 [3] 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, 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

[3] 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 though 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

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 *oira_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 *oira_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