

United States Nuclear Regulatory Commission

Advisory Committee on the Medical Uses of Isotopes

May 24-25, 2010

ADAMS

**MEETING AGENDA
ADVISORY COMMITTEE ON THE MEDICAL USES OF ISOTOPES**

**May 24-25, 2010
Two White Flint North Building (T2-B3), Rockville, Maryland**

**Monday, May 24, 2010
CLOSED SESSION**

- 8:00 – 10:00 **1. ACMUI Badging**
ACMUI members will enroll for new NRC badges.

NOTE: The above session may be closed pursuant to 5 U.S.C. 552(b) to discuss organizational and personnel matters that relate solely to internal personnel rules and practices of the ACMUI; information the release of which would constitute a clearly unwarranted invasion of personal privacy; information the premature disclosure of which would be likely to significantly frustrate implementation of a proposed agency action; and disclosure of information which would risk circumvention of an agency regulation or statute.

OPEN SESSION

- 10:00 – 10:15 **2. Opening Statements** **R. Lewis, NRC**
Mr. Lewis will formally open the meeting.
- 10:15 – 10:45 **3. Old Business** **A. Cockerham, NRC**
Ms. Cockerham will review past ACMUI recommendations and provide NRC responses.
- 10:45 – 11:15 **4. Status of Current and Future Rulemaking** **E. Lohr & N. Bhalla, NRC**
NRC staff will provide updates on 10 CFR Parts 35 and 37 rulemakings.
- 11:15 – 12:00 **5. Patient Release** **DB. Howe, NRC**
Dr. Howe will provide an update on the issue of patient release following administration of iodine 131.
- 12:00 – 1:00 **LUNCH**
- 1:00 – 1:30 **6. Update on Medical Isotope Shortage** **S. Mattmuller, ACMUI**
Mr. Mattmuller will provide updated information on the impact of the medical isotope shortage.
- 1:30 – 2:00 **7. Domestic Production of Molybdenum 99** **MJ. Ross-Lee, NRC**
Ms. Ross-Lee will provide the latest information on the domestic production on the medical isotope, molybdenum 99.
- 2:00 – 2:30 **BREAK**
- 2:30 – 3:00 **8. Update on Permanent Prostate Brachytherapy Medical Events** **P. Pelke, NRC**
Ms. Pelke will provide an update on the medical events that occurred at the Veteran's Affairs Medical Centers.
- 3:00 – 5:00 **9. Permanent Implant Brachytherapy Subcommittee** **J. Welsh, ACMUI**
Dr. Welsh will discuss the ACMUI subcommittee report on permanent implant brachytherapy.

**Tuesday, May 25, 2010
OPEN SESSION**

- 8:00 – 8:45 **10. Safety Culture** **D. Gilley, ACMUI**
Ms. Gilley will open a discussion on safety culture in medical practices.
- 8:45 – 9:30 **11. Update on Grandfathering Certified Medical Physicists** **R. Zelac, NRC**
Dr. Zelac will provide an update on the status of the technical basis to support Part 35 rulemaking addressing the issues raised in the 2006 Ritenour petition (PRM-35-20), resolved in 2008 (73 FR 27773, May 14, 2008).
- 9:30 – 10:00 **12. Revisions to the NRC Radiation Protection Requirements: Potential Impacts to the Medical Community** **B. Thomadsen, ACMUI**
Dr. Thomadsen will provide information on the International Atomic Energy Agency's revision to Draft Safety Requirements DS379.
- 10:00 – 10:30 **B R E A K**
- 10:30 – 11:15 **13. Post-Implant Written Directives for Yttrium 90 Microspheres Procedures** **B. Thomadsen, ACMUI**
Dr. Thomadsen will discuss an issue regarding signatures for post-implant written directives for yttrium 90 microspheres procedures.
- 11:15 – 12:00 **14. Subcommittee Report on Byproduct Material Events** **J. Welsh, ACMUI**
Dr. Welsh will present the subcommittee's analysis on byproduct material events for fiscal year 2010.
- 12:00 - 12:30 **15. Administrative Closing** **A. Cockerham, NRC**
Ms. Cockerham will provide a meeting summary and propose dates for the next meeting.

12:30

A D J O U R N

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

NRC

1. Rob Lewis – Director, Division of Materials Safety & State Agreements
2. Jim Luehman – Deputy Director, Division of Materials Safety & State Agreements
3. Chris Einberg – Branch Chief, Radioactive Materials Safety Branch
4. Mike Fuller – Team Leader, Medical Radiation Safety Team
5. Ashley Cockerham – NRC staff
6. Ron Zelac, Ph.D. – NRC staff
7. Donna-Beth Howe, Ph.D. – NRC staff
8. Sandy Gabriel, Ph.D. – NRC staff
9. Gretchen Rivera-Capella – NRC staff
10. Glenda Villamar – NRC staff
11. Said Daibes, Ph.D. – NRC staff
12. Sophie Le – NRC staff
13. Meg Audrain – NRC staff

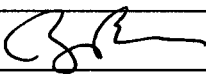
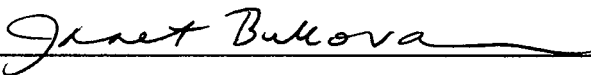
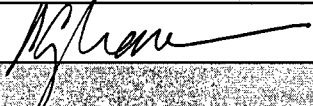
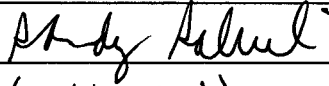
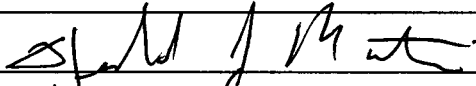

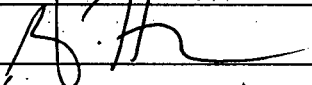
ACMUI

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

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ACMUI VISITOR LIST

MAY 24, 2010

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

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ACMUI VISITOR LIST

MAY 24, 2010

NAME	ORGANIZATION	SIGNATURE
Sutlief, Steven G.	VA	
Weber, Mike	NRC/OEDO	
Wilkes, Jenna M.	ASNC	Jenna Wilkes
Williams, Gary E.	VA NHPP	G E Williams
Wolff, Sandy J.	Sentara	
Langley, Karen	Univ. of UT	
Allen, Melissa	GE Hitachi Nuclear Energy	
Fuller, Michael	NRC/FSME	
Armanda Potter	AAPM	Armanda Potter
Ferdos, Marc	NRC/Region I	Marc Ferdos
Day, Kerstun	NRC/OE	
Cindy Tomlinson	SNM	Cindy Tomlinson
Mark Banks	NRC/OIG	Mark Banks
Leela Sreenivas	OE	Leela Sreenivas
Janet Schlueter	N&I	Janet Schlueter
Kathryn Brock	OEDO	Kathryn Brock
McIntosh, Angela	FSME	Angela R. McIntosh
Alicia Felke	NRC-KIII	Alicia Felke
Doug Heiffer	AAPM	Doug Heiffer
Jenny Weil	NRC/OCA	Jenny Weil
James Firth	NRC/FSME	James Firth
Chris Anderson	MEF Associates	Chris Anderson
Cathy Colletti	NRC/OIG	Cathy Colletti
Cindy Flannery	NRC/FSME/SAR	Cindy Flannery
Kevin Nigman	NRC/OIG	Kevin Nigman
Varughese Kurian	NRC/FSME	Varughese Kurian

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ACMUI VISITOR LIST

MAY 25, 2010

NAME	ORGANIZATION	SIGNATURE
Browder, Rachel	NRC RIV	
Brown, Roy	CORAR	<i>[Signature]</i>
Bukovcan, Janet	MDS Nordion	<i>Janet Bukovcan</i>
Chidakel, Susan	NRC/OGC	
Choi, Simon	FDA	
Crane, Peter		
Dansereau, Robert	NY	
Davidson, Will	University of Pennsylvania	
Flannery, Cindy	NRC/FSME	
Florian, Carol	Symetosphere	<i>Carol Florian</i>
Gabriel, Sandy	NRC RI	<i>Sandra Gabriel</i>
Katanic, Janine	NRC RIV	
Langley, Karen	Univ of UT	
Martin, Richard J.	ASTRO	
Nance, Jim	Symetosphere	<i>[Signature]</i>
Peters, Michael	ACR	<i>[Signature]</i>
Potters, Louis	NSUH and LIJ Medical Center	
Sutlief, Steven G.	VA	
Weber, Mike	NRC/OEDO	
Wilkes, Jenna M.	ASNC	
Williams, Gary E.	VA NHPP	<i>GT Wilkes</i>
Wolff, Sandy J.	Sentara	
HOLAHAN, Vince	NRC/FSME	<i>[Signature]</i>
COOL, DONALD	NRC/FSME	<i>[Signature]</i>
Firth, James	NRC/FSME	<i>James P. Firth</i>
FLUKE, Patrick	NRC/RTI	<i>Patrick Fluke</i>
Ferdas, Marc	NRC/RTI	<i>Marc Ferdas</i>
Heiffer, Douglas	AAPM	<i>Douglas Heiffer</i>
Butler, Kungwa Morgan	NRC/FSME	<i>Kungwa Morgan Butler</i>
Fuller, Michael	NRC/FSME	<i>[Signature]</i>
CARPENTER, CINDI	FSME	<i>Cynthia Carpenter</i>
Glenda Villamar	FSME	<i>Glenda Villamar</i>

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

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
22	ACMUI encouraged NRC staff to begin the rulemaking process to move the medical use of Y-90 microspheres from 10 CFR 35.1000 to another section of the regulations, so that the training and experience requirements for AUs can be vetted through the public review process instead of residing in guidance space.	10/27/08	Partially accepted	Open
25	NRC staff should revise 10 CFR 30.35(b) to allow licensees to exceed the limits short term (e.g. 60 days) during source exchange.	10/28/08	Accepted	Open
26	NRC staff should revise 10 CFR 35.40 to clarify that the AU should sign and date both the pre-implantation and post-implantation portions of the WD for all modalities with two part WDs.	10/28/08	Accepted	Open
27	NRC staff should revise 10 CFR 35.40 to clarify that <u>an</u> AU, not <u>the</u> AU, should sign and date both the pre-implantation and post-implantation portions of the WD for all modalities with two part WDs. [Note this allows for one AU to sign the pre-implantation portion of the WD and another AU to sign the post-implantation portion of the WD]	10/28/08	Accepted	Open
28	NRC staff should revise 10 CFR 35.65 to clarify it does not apply to sources used for medical use; however, NRC should not require licensees to list the transmission sources as a line item on the license. NRC staff should also revise 10 CFR 35.590 to permit the use of transmission sources under 10 CFR 35.500 by AUs meeting the training and experience requirements of 10 CFR 35.590 or 35.290.	10/28/08	Pending	Open
29	NRC staff should revise 10 CFR 35.204(b) to require a licensee that uses Mo 99/Tc-99m generators for preparing a Tc-99m radiopharmaceutical to measure the Mo-99 concentration of each eluate after receipt of a generator to demonstrate compliance with not administering to humans more than 0.15 microcurie Mo-99 per millicurie Tc-99m.	10/28/08	Accepted	Open
30	NRC staff should require licensees to report to the NRC events in which licensees measure molybdenum breakthrough that exceeds the regulatory limits.	10/28/08	Accepted	Open

2009 ACMUI RECOMMENDATIONS AND ACTION ITEMS


	ITEM	DATE	STATUS	
1	NRC staff should allow IRs to become AUs for Y-90 microspheres with: 1) 80 hours training in: a) radiation physics & instrumentation; b) radiation protection; c) mathematics pertaining to the use and measurement of radioactivity; d) chemistry of byproduct material for medical use; and e) radiation biology; and 2) work experience under the supervision of an Authorized User involving: a) ordering, receiving, & unpacking radioactive materials safely & performing the related radiation surveys; b) checking survey meters for proper operation; c) examination of each individual; d) calculating, measuring, & safely preparing patient or human research subject dosages; e) using administrative controls to prevent a medical event involving the use of byproduct material; f) using procedures to control and to contain spilled byproduct material safely & using proper decontamination procedures; g) follow up and review of each patient's or human research subject's case history; and h) the operation of and quality management for dose calibrators; and 3) board certification in diagnostic radiology with a subspecialty 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
3	NRC staff should revise 10 CFR 35.490 & 690 as proposed with one exception. Delete "private practice." The regulation should read "500 hours of work experience, under the supervision of an Authorized User who meets the requirements in [35.490 or 35.690] or equivalent Agreement State requirements at a medical institution or clinic..."	5/7/09	Superseded by item 10	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



Status of 10 CFR Part 35 Rulemakings

Ed Lohr / Neelam Bhalla
 Rulemaking Branch B
 Division of Intergovernmental Liaison and Rulemaking


May 24, 2010
 Advisory Committee on the Medical Uses of Isotopes



Part 35 Ongoing Rulemakings


Medical Event (ME) Definitions Proposed Rule

Next Proposed Rulemaking




Part 35 - Medical Event Definitions Proposed Rule

- Changes most ME criteria from dose-based to activity-based for permanent implants.
- Clarifies Written Directive (WD) requirements for permanent implants.
- Adds an ME criterion for failure to prepare a WD for all procedures that require a WD.



Part 35 - Medical Event Definitions Proposed Rule

- Proposed Rule published in the *Federal Register* August 6, 2008.
- Public comment period ended November 7, 2008.
- Large number of ME's reported in Summer-Fall 2008 caused reevaluation of the proposed rule.
- Based on public comments and the circumstances involving a large number of ME's, the proposed rule has been revised significantly.
- Reproposed rule due to the Commission by June.



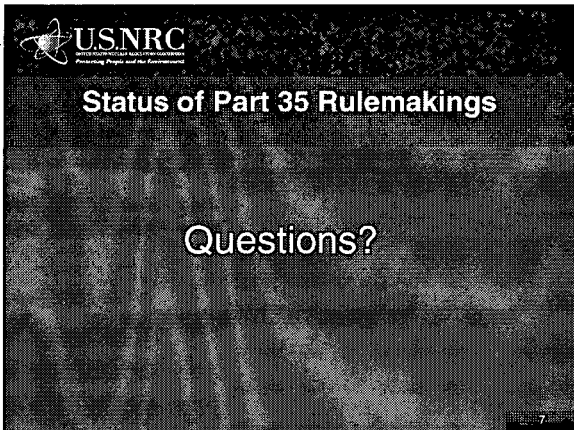
Next Part 35 Rulemaking


- Based on the implementation experience of the 2002 revision of Part 35, staff has proposed numerous changes to the current regulations.
- The potential changes have been presented at the ACMUI meetings (November 2008-October 2009).
- Plan to include consideration of Ritenour Petition for Rulemaking (PRM-35-20) and preceptor attestation requirements (Staff Requirements Memorandum to SECY-08-0179).



Next Part 35 Rulemaking Time Lines

- Scheduled to begin Summer 2010.
- Proposed Rule – Tentative March 2012
- Final Rule – Tentative September 2013






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UNITED STATES NUCLEAR REGULATORY COMMISSION
Protecting People and the Environment

Patient Release Following Therapeutic Administration of Iodine 131

Donna Beth Howe, PhD


May 24, 2010
Advisory Committee on the Medical Uses of Isotopes



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UNITED STATES NUCLEAR REGULATORY COMMISSION
Protecting People and the Environment

Background


- May 1997 - NRC revised the patient release regulation (10 CFR 35.75) to base each release on dose to the maximally exposed individual. This allowed outpatient I-131 cancer therapy.
- September 2005 - NRC received Petition for Rulemaking (PRM 35-18, Crane petition) to return 10 CFR 35.75 to previous activity-based release criteria. PRM 35-18 also raised issues of dose to children and pregnant women.
- May 2008 - NRC denied PRM 35-18 (73 FR 29445) - current rule adequate to protect public health and safety. NRC developed guidance for calculating doses to children and pregnant women.
- October 2009 and January 2010 - Congressman Markey letters to NRC - focus on dose calculations for individual patients and doses to individuals at hotels especially to children and pregnant women.



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Protecting People and the Environment

Patient Release Requirements (excluding nursing patients)


- Patients can be released if:
- The dose to any other individual from exposure to the released patient is not likely to exceed 5 mSv (0.5 rem).
- The patient or patient's parent or guardian is provided with instructions, including written instructions, on actions recommended to maintain doses to other individuals as low as is reasonably achievable, if the total dose to any other individual is likely to exceed 1 mSv (0.1 rem).
- The licensee maintains a record of the basis for authorizing the release.



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Protecting People and the Environment

National and International Documents

- National Council on Radiation Protection & Measurements (NCRP) Report No. 155, "Management of Radionuclide Therapy Patients" (2006).
- International Atomic Energy Agency (IAEA) Safety Report Series # 63 "Release of Patients After Radionuclide Therapy" with contributions from the International Commission on Radiological Protection (ICRP) (2010).
- ICRP Publication 94: "Release of Patients after Therapy with unsealed Radionuclides" (2005).



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Protecting People and the Environment

Path Forward

Based on earlier commitments, NRC is reviewing the need for guidance relating to the release of an I-131 therapy patient to a place other than the patient's residence.

Statement of Peter Crane
Counsel for Special Projects, Office of General Counsel, U.S.N.R.C. (Retired)
before the
Advisory Committee on the Medical Uses of Isotopes (ACMUI)
Rockville, Maryland
May 24, 2010

I very much appreciate the opportunity to address this Committee. I have read a great many transcripts of the Committee's meetings, and I see that directness and candor are the norm. I will follow that example today. The issue before us involves safeguarding American children from the risk of radiation-caused cancer, and if any subject calls for plain speaking, that is it.

First I should introduce myself. I joined the NRC just ten weeks after it came into existence in 1975, as an assistant to then Commissioner, later Chairman, Marc Rowden. I moved to the Office of General Counsel in 1977. I was named Counsel for Special Projects in 1985 or 1986 and remained in that position until I retired in 1999. My service was continuous except for a year spent as an administrative judge with the Nuclear Claims Tribunal of the Republic of the Marshall Islands. I have thus had 35 years in which to view the ebb and flow of NRC regulation in the medical area. I was an invited speaker at a United Nations conference in Moscow in 1997, and presented a paper at a conference, sponsored by the European Commission, National Cancer Institute, and Cambridge University, at Cambridge, England, in 1998. (That talk can be found in *Radiation and Thyroid Cancer*, a book published by the European Commission in 1999.) Several years after that, I was an invited speaker at an American Thyroid Association symposium in Washington.

I have also been a thyroid cancer patient for 37 years.¹

During that time I have had seven treatments with iodine 131: two as an outpatient, 25

¹I did not join the NRC thinking that my medical past would ever be relevant at work. But when you go to a briefing, as I did in 1983, and a senior official declares – in explaining why the NRC staff is reversing its commitment to stockpile potassium iodide – that thyroid cancer is “easily diagnosed, easily cured, no fatalities,” and you happen to know that the disease kills 1200 Americans each year, you can't help but speak up.

years ago, to ablate what was left of my thyroid, and five as an inpatient, during a recurrence of cancer that began about 20 years ago. No one in this room, therefore, has more reason than I to appreciate the value of I-131, and how imperative it is that we ensure an ample and uninterrupted supply of it. But having children who were two and four when my recurrence was diagnosed, I also have reason to appreciate the special risks that go with its use.

Second, I wish to say that the NRC has always had many fine, capable, and dedicated employees. I was proud to have such people as colleagues, and many are my friends today.² Often it is said of an organization that it is greater than the sum of its parts; in the case of the NRC, I would say that it is sometimes *less* than the sum of its parts. I have seen very good people doing their very best, but sometimes getting overruled, or outvoted, or even misinformed or misled, and the result can be a very bad outcome. In short, the fact that I have critical things to say about the actions of the Commission, the NRC staff, and this Committee is far from being a criticism of everyone belonging to those organizations.

To summarize my views briefly, I believe that the NRC's deregulation of I-131 treatments in 1997 will someday be seen as perhaps the most radical and irresponsible of all deregulations ever made in the health and safety area. It violated the International Basic Safety Standards established by the International Atomic Energy Agency and other international groups – not that this fact was even mentioned to the Commissioners in the staff memorandum proposing the change. The NRC disregarded warnings from New York and several other states that I-131 was a special case, because of its extreme radiotoxicity. The NRC also reversed fields on the danger of I-131 contamination, and the resultant internal dose. Whereas only a decade earlier, the NRC had correctly explained that I-131 patients could cause members of the public to receive both an external dose, from proximity, and an internal dose, from contamination, the 1997 rule declared internal dose to be negligible. (The NRC would rediscover the danger of internal dose in 2008, more than four years after a report from the International

²I served in the trenches with some who are here today. Dr. Donna Beth Howe will remember when Dr. Carol Marcus was denouncing both of us in letters to the Commission that were notable for the colorful adjectives employed. She wanted me fired – I can't remember about Donna Beth – but the prize went to Jim Lieberman, a senior lawyer. When Dr. Marcus wrote to the Commission demanding that he be sent to an insane asylum, he gleefully taped the letter to his office door.

Commission on Radiation Protection highlighted the risk to children of internal exposure from patients' radioactive saliva.)

The rule change had several effects that the NRC had not foreseen. One was that insurance companies would refuse to pay for inpatient treatment, even when the patient's family situation required it. The definitive source on that is the transcript of this Committee's meeting in October 2007, in which Dr. Malmud and Dr. Egli describe the difficulty or impossibility of getting inpatient treatment for patients. A second was that this would require the NRC to make a choice: either enforce the rule, and compel providers to give inpatient treatments for which they might not be compensated by insurance, or quietly allow many providers to ignore the rule. What is the result? People are often told, flatly, that outpatient treatment is their only option. Jim Luehmann of the NRC staff was present last October at the conference of the Thyroid Cancer Survivors' Association, held in Danvers, Massachusetts, at which a young woman from Arizona said that she had been sent home after receiving her dose (125 millicuries), although she had a six-month-old and a three-year-old. It is hard, she said, to keep your distance from children of that age.

I hope I'm not damaging Jim Luehmann's career when I say that the patients there very much appreciated that he was listening to what they had to say, and that since then, he has been helpful to patients having difficulty with insurance companies in securing inpatient coverage. Jim was also forthright in saying that the NRC's rules require an individualized calculation of the likely dose received by family members, and that if the dose exceeds 500 millirem, the patient must be hospitalized – no two ways about it.

But the NRC has passed up multiple opportunities to make that clear to the licensee community, and the rule is being widely ignored. Jean St. Germain of Sloan-Kettering told me that her institution is punctilious in performing these case-specific calculations, and if the criterion isn't met, the patient is hospitalized. "Is that the norm?" I asked. She replied with a firm "No." "What is the norm?" I asked. "Oh, they give them some piece of paper."

Another young woman who came up to the speaker's lectern after Jim Luehmann's presentation in Danvers volunteered that her hospital had advised her to go to a hotel after

receiving her outpatient dose, and to have her husband pick her up there the following day.

In the last couple of years, as you may know, New York City, Minnesota, and Washington State have all warned licensees not to send radioactive patients to hotels. New York City pointed to the not implausible worst case scenario: that a pregnant hotel housekeeper gets a radiation dose to her baby's thyroid from contamination left in the room.

While the NRC was considering my petition for rulemaking, I and a number of other commenters mentioned the issue of patients going to hotels while radioactive. I had described this as "a medical and moral issue that the NRC cannot in conscience ignore." I actually mentioned the issue in three separate filings. Why this stress? Because I was keenly aware of an NRC operating principle that you won't find among the NRC's "Principles of Good Regulation," but which will be familiar to anyone who knows how the NRC staff operates. And that is: if you don't have a good answer, pretend you didn't hear the question. I wanted to make sure that no one later claimed not to have noticed the issue.

Do we want radioactive patients going to hotels and contaminating bathrooms and bedsheets? When Minnesota issued its warning on the subject, I called a regulator there, who told me that the state was responding to an event in Illinois in which a hotel room had to be taken out of service for an extended period – several months, he thought – until the state could certify that it was acceptable for occupancy. The bathroom, the bed, and the telephone had all been contaminated.

Of course, patients could come to the hotel equipped with cleaning implements and clean up after themselves, just as they would at home. But it's a truism that nobody ever took a rental car to a car wash. By the same token, it is not reasonable to expect that patients who have just had I-131 treatment will be as scrupulous in cleaning a hotel toilet before they check out as they would be with a toilet that their children or spouse will be using. Add to that the fact that thyroid cancer patients who have been off their medications in preparation for treatment are likely to be feeling exhausted and depleted, and not necessarily in shape for scrubbing out toilets and bathtubs.

But when the NRC denied my petition, it didn't say one word about radioactive patients in hotels, despite my efforts to make sure that the issue was not evaded. And it is basic administrative law that agencies are supposed to deal with significant issues raised in a rulemaking petition.

When I took the agency to the U.S. Court of Appeals for the Ninth Circuit, my strongest argument, therefore, was that the NRC had failed to address the hotel issue, and that the case should therefore be remanded to the NRC with instructions to deal with it. The NRC's lawyers had a couple of answers for that. One was that the agency had thought that I had "recanted" and dropped the issue, which was patent nonsense. (What I had done was to file what I titled a "minor correction," because, writing from memory while out of the country, I had given an incorrect source for one patient's comment about a hospital that sent all its patients to the same hotel.) But their weightier argument was, and I quote from p. 39 of the brief, "the NRC's rule does not permit or encourage doctors to send treated patients to hotels."

If that statement was true, then it follows logically that the idea that radioactive patients were going to hotels was my invention.

The court did not reach the merits of the case. It bought the NRC's argument that because I was not currently in treatment with I-131, or, on the evidence, likely to be in the foreseeable future, I lacked standing to be in court at all. At oral argument, one of the judges suggested that if a case were to be brought by a group, the standing problem would go away. (That remains an option.) Did the court avoid the merits because it was made uneasy by the Government's assurance that the problem of radioactive patients in hotels was my invention? We'll never know.

We now know, thanks to documents obtained from the NRC by Congressman Ed Markey and his staff, that only a few months before that brief was filed, the NRC's Office of General Counsel approved an internal memorandum, replying to a request for advice from NRC Region 1, that said that the NRC's rules did *not* prohibit doctors from sending treated patients to hotels; that this was a not uncommon practice, and that the agency would be issuing appropriate guidance on this subject. Congressman Markey has asked

the NRC's Inspector General to investigate.

There is a listserv on Yahoo on which thousands of thyroid cancer patients ask questions pertaining to their care. Typically, these are new patients, looking for advice, and the oldtimers supply the answers. Scores of questions come in every day, and no one who posts a question on this listserv has the slightest motivation to lie. Time and again, you read postings from patients with small children who have been told by their doctors to go to a hotel for the first couple of days. Sometimes patients will volunteer that they have decided on their own to go to a hotel, because they are concerned about exposing their children. The oldtimers invariably tell them not to – they shouldn't be using a room that others will be occupying, or cleaning, with no knowledge that it is contaminated.

What does it say about the NRC that patients are having to get this advice from other patients, because the NRC itself has been resolutely silent on the issue to this day?

Is there anyone in this room who wouldn't have qualms about the idea of their young child or grandchild staying in a hotel room vacated a few hours earlier by a patient who had just spent several days there after swallowing 200 or 300 or 400 millicuries of iodine 131? My daughter, as a college student, changed beds and cleaned toilets in a Seattle youth hostel. Is there anyone here who would feel comfortable about having their college-age daughter, quite unknowingly, cleaning the toilet that had been used for several days by the patient I just described? If you wouldn't wish this on your own child, you shouldn't wish it on anyone else's either.

Does the Commission have a clue about what is going on in this area? The sad fact is that the Commissioners have done their best to keep themselves well insulated from knowledge of what is happening.³

³ Willful ignorance can sometimes be handy. Take the Philadelphia VA overexposures. In 2008, when the story broke, both the NRC and the VA rushed out statements, the gist of which was that both agencies had acted swiftly and decisively to address the problem as soon as they learned of it. It made for nice press releases, but the reality was that the two agencies first learned of the doctor's bungling of a prostate implant in 2003. Then he did the same thing in 2005. Wouldn't you think that this would have been an alarm bell, causing both agencies to ask themselves whether there was an incompetent at work, possibly harming many more patients? But it didn't work that way.

You might think that it was obvious and beyond debate that if the prescription calls for the implantation of 90 seeds in the prostate, and the doctor succeeds in getting only half of them into the prostate, while the rest have to be extracted from the bladder, or rectum, or wherever they have wound up, a "medical event" has taken place.

Efforts had been made to enlighten the NRC. The State of Illinois had written in 2001 that just because the NRC didn't receive reports of such overexposures didn't mean they weren't happening. What Illinois didn't understand was that the Commission, in order to buy peace with the licensee community, had essentially washed its hands of medical regulation, and it did not want to be confronted with the evidence of how unwise and irresponsible it had been to do so.

One need only look at the vote sheets on a 2002 SECY paper by which the Commission rejected, on a three to two vote, the proposal to require a report to the NRC whenever a released patient caused a family member or other member of the public to receive a radiation dose ten times in excess of allowable limits. They are highly illuminating. Chairman Meserve, writing in dissent, made two irrefutable points. First, the Commission was acting without hearing from the public – it had heard only one side of the debate, the licensees'. Second, without a mechanism for reporting overexposures, the Commission was depriving itself of the means of knowing whether its regulations were doing the job.

Look at the three votes on the other side. One Commissioner says that to adopt this proposal would reverse the recent improvement in the NRC's relations with the medical licensee community. (An agency that is afraid of offending the entities it is supposed to regulate is an agency in trouble.) Another says that since the NRC wouldn't do anything with information about an overexposure if it received it, there is no point in

("Medical events" used to be called "misadministrations," until the Commission, in an effort to appease the licensee community, changed the name.) But in 2003, the ingenuity of the NRC staff, at the service of a licensee that did not want a reportable "medical event" to deal with, came to the rescue. The NRC found that if the prescription was changed in the operating room – cross out 90 seeds, write in 45 seeds – then the seeming mistake becomes a non-mistake, and does not have to be reported to the patient. Does it matter that the patient has been underdosed by fifty percent, and that his risk of a recurrence is therefore increased? Apparently not.

Then in 2005, when the same thing happened to another of this doctor's patients, the VA was in a position to say to the NRC, "You remember 2003? Well, this is the same thing, so as in 2003, it's not a medical event." And the NRC obliged.

The NRC staff, to its credit, did understand that there was a glitch in its reporting requirements that needed to be fixed. And it came to this Committee to propose a very minor tightening of the rules. What was this Committee's response? It was, as the transcripts show, to protest that any change in the reporting requirements should be in the direction of weakening them. There is an illuminating discussion in which one member proposes adoption of a statement saying that the NRC's primary role in regulating medicine should be to reduce licensees' liability. Then another member suggests that this could be seen as self-serving, so the language is tweaked, without altering the meaning. The result of all this is that the fix that the NRC staff began discussing six or seven years ago has yet to be made.

receiving it in the first place.

That second Commissioner's point was that the NRC had already made clear that it wouldn't penalize a licensee because a released patient overexposed a member of the public. But as Chairman Meserve's comments implied, what the Commission *might* have to do, if it learned that many members of the public were being overexposed, was reconsider the regulations. And since that was something the Commission majority was utterly unwilling to consider, it needed to ensure it never received such reports.

So who is there, except for the outvoted Dick Meserve, to make the point that protecting the public from harm is supposed to be among the NRC's priorities? Is it, perhaps, the Patient's Rights Advocate on this Committee?

That position was created in the early 1990's because the Commission was concerned that the ACMUI was weighted heavily to the licensee side, and there was no one to function as a kind of ombudsman for patients. The first to hold the post was a nurse, Judith Brown, and she did a fine and conscientious job – for some, too good a job. When the staff was first presenting its plan of deregulating I-131, and making high-dose outpatient treatment possible, Don Cool was explaining the psychological benefits this would have for patients, by allowing a speedy return to their families. Ms. Brown asked, as a point of information, how patients felt *physically* after such a treatment. Mr. Cool couldn't answer the question – thus illuminating the fact that the staff was purporting to pass judgment on the psychological condition of thyroid cancer patients when it had not troubled to inform itself as to their physical condition. Ms. Brown also made the sensible point that the proposal meant relying on the altruism of patients.⁴

When Ms. Brown's term ended in 1997, she was replaced as Patient's Rights Advocate by Nekita Hobson, a longtime public relations officer for General Atomics who was now Executive Director of the National Association of Cancer Patients. The NACP, despite

⁴ Her point was well taken. Back when the proposal was first floated, NIH warned that although they always advised their released patients to avoid close contact with others for the first few days, they knew that many of their foreign patients went directly to the airport on release to board long transoceanic flights. In those days, of course, the maximum amount of I-131 that a released patient's system could contain was 30 millicuries. Today, patients may be boarding airplanes with several times that amount of I-131 in their system. I doubt that anyone in this room would be comfortable with the idea that a child or grandchild of theirs was spending six or seven hours elbow to elbow with a patient newly released after a dose of 200 millicuries or more of I-131. Again, if it's not acceptable for your child or grandchild, then it shouldn't be acceptable for anyone else's.

its name, was in fact a 501(c)(4) lobbying group, created in part to lobby for the proposed Ward Valley radioactive waste dump in the Mojave Desert. Two weeks before the mid-term elections of 1998, in which Senator Barbara Boxer was running for re-election, the NACP issued a statement accusing Senator Boxer of having delayed for “many years, perhaps decades,” the search for a cure for cancer, because of her opposition to Ward Valley. The NACP newsletter also boasted of having contacted over 1000 Clinton-Gore donors to make similar claims about what the Administration had done to harm the interests of cancer patients. When Ms. Hobson’s term was up, she was replaced by another NACP Executive Director, Robert Schenter, and when he left to join a company selling radioactive isotopes, he was replaced by his former assistant at the NACP, Darrell Fisher, the current holder of the Patient’s Rights Advocate position.⁵

I have nothing personal against Dr. Fisher. I am assured by Dr. Carl Paperiello, whose opinion I trust implicitly, that Dr. Fisher knows his isotopes, after a lifetime in the field, and I do not doubt for a moment that he is a valuable asset to this Committee. My objection is solely that the position in which he serves on this Committee should not be that of Patient’s Rights Advocate. That position, which for 13 years has been monopolized by people from the isotope producing community, should properly be held by someone from the patient community.⁶

⁵ Several years ago, the NRC staff asked the Commission for authority to name ACMUI members on its own. The Commission refused: it would make the decision. The next vacancy to come up was that of the Patient’s Rights Advocate. The staff sent only a single name to the Commission, Dr. Fisher’s, in a paper that failed to mention that he was Scientific Director of the Department of Energy’s isotope program, failed to say who had nominated him, and failed to say who else had been nominated. (One cannot help wondering whether the staff intended, as a private joke at the Commissioners’ expense, to demonstrate just how little attention they really paid to appointments to the Committee.) Not a single Commissioner’s office said, “Wait a minute, don’t I need a little more information?” The staff wrote to me that it would not tell me who the other candidates were, nor who nominated Dr. Fisher, and that it would not tell me, even if I filed a Freedom of Information Act request. (It made good on this promise.) From an agency that purports to be committed to “openness” as one of its “Principles of Good Regulation,” this is remarkable. So how *does* the staff go about choosing its Patient’s Rights Advocate? The NRC, in answers to Congressman Markey, indicated that it seeks nominations from the professional organizations with which it deals. (Perhaps in time Congress and the public will learn which ones.) It did not claim to seek nominations from patients’ groups.

⁶ I must have hit a nerve in describing the NACP’s history and purposes to the Commission, for sometime in 2008, after I wrote to the Commission about the Patient’s Rights Advocate and its monopolization by persons from the NACP, the NACP’s website was altered, although the organization itself had apparently been defunct for some years. What is more, major deletions were made in an article from a 1998 issue of *Lifelines*, the NACP newsletter, some ten years after its publication. I had foreseen some such fiddle, however, and had taken the precaution of printing out the article in its original form at the time I wrote to the Commission. The before and after versions of the article make amusing reading.

So who today speaks for the patients, the tens of thousands of patients treated with radiopharmaceuticals every year?

There was an illuminating section of ACMUI transcript, not long ago, when the staff briefed this Committee on the events at the Philadelphia VA hospital, and the members for the first time realized the magnitude of the disaster. Chairman Malmud, to his credit, was plainly anguished about the fate of the patients, and he made the point that the Committee members were, after all, human beings, and knowing what they now knew, could not ignore the patients. (Spoken like a *mensch*, Dr. Malmud.) To this, one of his colleagues countered that this was "getting down in the weeds." His point was that it was important that the public not be frightened away from a beneficial technology.

It's an old, old story that people think this way when mistakes occur that harm individuals but reflect badly on institutions, organizations, or professions. If you are the Army, and a football hero is killed by so-called friendly fire in Afghanistan, it is easy to rationalize: "It was a mistake, nothing will bring him back, and if we tell the truth about what happened, it could cause people to lose confidence in the Army, which would be bad both for the Army and for the country." Likewise if you are a religious institution, and discover that someone in your employ has molested a minor, you can come up with a similar rationale for not calling the police.

When you decide that other interests take precedence over the human beings who are the victims of mistakes or misdeeds, it all too often winds up backfiring, because then the whole organization is seen as corrupt, rather than the individuals originally responsible. Once trust is forfeited in this way, it may be very difficult to regain it. If the American public decides that it cannot depend on the NRC to protect its veterans from hideous medical mistakes, or its children from exposure to carcinogenic radioisotopes, will it have confidence in the agency's competence and integrity in the licensing and regulation of new nuclear power plants?

One need only look at the Securities and Exchange Commission to see how a once respected federal agency can do incalculable and perhaps irrevocable damage to its reputation, thereby inviting Congress to step in with new and more stringent controls. Or

look at the agency which is supposed to regulate offshore drilling. Already the Administration has announced plans to break it up.

In short, I would suggest that if the NRC, or this Committee, thinks too much about fulfilling the wishes of the professional organizations of the nuclear medicine practitioners, and too little about what is good for patients, it could well backfire.

I realize that there is scientific support for the NRC's patient release rule, to the extent that Dr. Grigsby's study of 22 patients and their families, published in the Journal of the American Medical Association in 2000, scientific support. Twenty-two patients is hardly enough, I would submit, to support a deregulation of massive proportions, that flies in the face of the consensus of the international community. I might add that Dr. Grigsby has also told the NRC that he has treated over a thousand patients with I-131 and never had a case of a patient vomiting. Jim Luehmann will confirm that when I reported this to a roomful of thyroid cancer patients last fall, they erupted in laughter.

The NRC has issued regulatory guidance that is supposed to help licensees determine who can and cannot be released. Dr. Marcus has announced that this guidance is not binding, far too conservative, and should be ignored. If the NRC has yet dared to contradict her, I am unaware of it. In 1992, incidentally, Dr. Marcus was writing to the Commission that the idea of giving 400 millicuries of I-131 on an outpatient basis was "ludicrous," unless the patient was a hermit, living in the wilds. I gather she thinks otherwise today.⁷ Anyone who reads the thyroid cancer patients' listserv, as I do, knows that the safety guidance that patients receive – if they receive it at all – is all over the map. What has the NRC done, in the 13 years that this rule has been in effect, to ensure that patients get appropriate and consistent instructions about the precautions they should take to protect their families and others? Precious little. It has pointed to guidance jointly prepared by the NRC and the Society for Nuclear Medicine in 1987. To be sure, it said, that guidance was prepared in the days of the 30 millicurie maximum for released patients, but that was

⁷ In the same year, Dr. Marcus jeered at me for suggesting that in view of the reports from Belarus of an upsurge of thyroid cancer in children exposed to radiation from the 1986 Chernobyl accident, it behooved the NRC not to make changes in its regulations which would have the effect of increasing American children's exposure to I-131. Today, of course, it is the data on childhood thyroid cancer in children affected by Chernobyl that has caused the international community to advocate sharp reductions in allowable radiation exposure to children. (See ICRP 94.) The NRC has rejected that recommendation.

all right – just fill in the blanks appropriately.

That kind of advice is worthless. It's like the old joke about how to sculpt an elephant: take a block of stone and remove everything that doesn't look like an elephant. It tells the doctor and the patient nothing. Why, in 13 years, couldn't the NRC come up with meaningful guidance, something appropriate, for example, for the woman sent home to her seven-year-old with more than 400 millicuries of I-131 in her system? Is it because truly appropriate guidance would include precautions so extensive that people would realize that outpatient treatment might not be a good idea under these circumstances? I do not know.

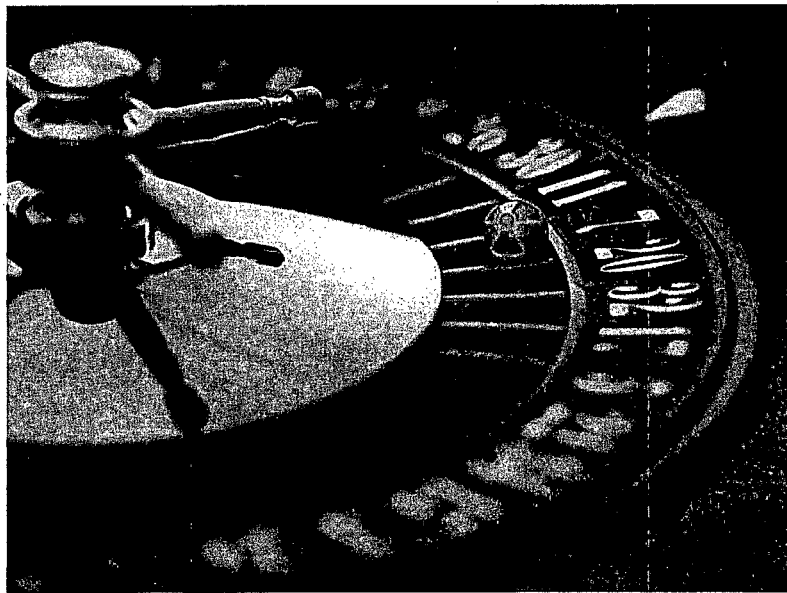
So what should be done now? I myself have never claimed to have all the answers. A return to the blanket 30 millicurie standard in every case might be overregulation; it might also at this point be underregulation, given that Europe has already moved to more stringent standards, based on the data from Chernobyl on children's susceptibility to radioiodine-induced cancer.

What we need at this point is a thorough reexamination of the patient release issue, fair and dispassionate, without a preordained outcome. Though I have not seen his letter to Congressman Markey, I understand that Aubrey Godwin, a wise and deeply experienced regulator who heads Arizona's program, has said that such a reexamination would be timely. But whether the NRC itself is capable of conducting this effort is doubtful, given the record of the past 15 or 20 years. It is not only that this would mean confronting the agency's grave mishandling of the patient release issue; it is also that the analysis might lead to the conclusion that the NRC has failed irretrievably in the medical area, and that legislation is needed to transfer these responsibilities to an agency better capable of discharging them. But the latter question is beyond the scope of our discussion today.

Once again, I wish to thank Chairman Malmud and the Committee for the opportunity to speak here today.

RADIOACTIVE ROULETTE:

How the Nuclear Regulatory Commission's Cancer Patient Radiation Rules Gamble with Public Health and Safety



**A report by the Staff of Edward J. Markey (D-MA)
Chairman, Subcommittee on Energy and Environment
Energy and Commerce Committee
U.S. House of Representatives
March 18, 2010**



**EMBARGOED UNTIL THURSDAY MARCH 18, 2010
12:01 AM**

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EXECUTIVE SUMMARY

In 1997, the Nuclear Regulatory Commission (NRC), in response to a proposal initiated by its own staff, weakened its rules surrounding the release of patients treated with radioactive iodine. The rules were changed away from a system used in Europe and other countries that requires the hospitalization of patients emitting high levels of radiation in order to protect children and other members of the public from being irradiated to one that allows most treatments to be performed on a less expensive outpatient basis.

NRC's weaker, current regulations depend on the ability of medical professionals to assess the living conditions of patients and use the results of this assessment to calculate the likely radiation dose to those people the patient might come into contact with. It is unclear whether such a calculation could be accurately performed for a patient choosing to recover from treatment with radioactive iodine in a hotel, since it would be impossible to characterize every hotel's layout, or know whether the hotel staff or other hotel guests included vulnerable populations such as pregnant women or children.

Despite reports from individuals and State regulatory authorities that patients are choosing to recover from treatment with radioactive iodine in hotels – thus unwittingly exposing members of the public to radiation –the NRC has consistently refused to ban or limit this practice, and indeed, has never even issued guidance in this area to its licensees. Instead, the NRC actually twice voted to reject NRC staff proposals that would have required reports of dangerous radiation doses delivered to members of the public, through exposure to released patients, to be submitted. One such vote would have only required notification of exposures that are ten times as high as NRC's own regulatory dose limits for released patients. Rather than addressing or remedying the problem, the NRC instead chose to actively ignore it.

Of the 3,700 facilities licensed to perform treatments using radioactive iodine, the NRC directly oversees only 500 of them, with the remainder overseen by State regulators. The NRC collects no information regarding the adequacy or enforcement of its regulations in the 3,200 facilities overseen by the States. Nor does it require the States to report back instances of severe violations. Even for the remaining 500 licensees, the NRC doesn't keep sufficient records to enable it to determine whether patients chose to recover in hotels – in fact, it doesn't even track how frequently its own inspectors request additional documentation regarding regulatory compliance from licensees.

While internal NRC documents indicate a clear awareness by the NRC that some patients treated with radioactive iodine do choose to recover in hotels, and that its regulations allow for this practice to be continued, the NRC Office of General Counsel, in a brief submitted to a federal court in opposition to a citizen petition urging strengthening of the NRC regulations in this area, stated that "NRC's rule does not permit or encourage doctors to send treated patients to hotels."

In summary, rather than protect public health and safety, NRC has turned a blind eye to the radiation standards used in many other parts of the world, a deaf ear to reports of problems with its own less stringent regulations, and has consistently opposed attempts to strengthen its standards –

to the point of submitting inaccurate or misleading statements to a Federal Court. Simply put, the NRC has gambled with public health and safety.

RECOMMENDATIONS

- 1) The NRC should immediately commence a rulemaking to return to its pre-1997, dose based regulations surrounding the treatment of patients with radionuclides, and ensure that its regulations are made to be consistent with the International Commission on Radiological Protection (ICRP). Hospitalization should be mandatory for those patients who are treated with doses of I-131 above internationally accepted threshold limits.
- 2) Patients should be prohibited from recovering from such treatments in hotels, and specific written and verbal guidance in opposition to hotel release should be provided both to medical licensees and to patients.
- 3) The NRC should immediately commence a rulemaking to determine whether its current regulations for safe radiation exposure levels adequately, and in a manner consistent with international standards, protect the most vulnerable populations – pregnant women and children – and make revisions where necessary.
- 4) The NRC should aggressively enhance its oversight of medical licensees to better identify, track and respond to potential regulatory violations, including its oversight of such activities by Agreement States.
- 5) The NRC's Inspector General should investigate, and NRC should then take all appropriate action, regarding conflicting statements made by its Office of General Counsel (OGC) as to whether NRC regulations permit the release of patients to hotels. These include OGC's April 2008 concurrence with an NRC document that provided assistance to a regional office, which stated that "release to a hotel was not prohibited by the regulations," and the conflicting statement made by OGC in a legal brief submitted to the U.S. Court of Appeals for the Ninth Circuit on November 4, 2008, which inaccurately states that "NRC's rule does not permit or encourage doctors to send treated patients to hotels."

BACKGROUND AND EARLY HISTORY

Medical Practices Involving Radioactive Materials

Millions of patients are treated each year with radioactive compounds (called radionuclides) for diagnosis or treatment of diseases such as cancer. These patients can expose others around them to radiation until the radioactive material administered to them has been eliminated from their bodies or the radioactivity has decayed. The field of nuclear medicine was developed in the 1950s initially using radioactive iodine (I-131) to diagnose and then treat thyroid disease. Iodine-131 is among the most widely used radionuclides in the medical field, because of its short half-life and medical effectiveness.

Iodine is essential for proper function of the thyroid gland, which uses it to make the thyroid hormones. The thyroid is equipped with an active system or "pump" for moving iodine into its cells. Because of this property doctors are able to use I-131 treatment to successfully destroy thyroid cancer cells as well as treat an overactive thyroid, a condition called hyperthyroidism.

The thyroid cannot tell the difference between radioactive and non-radioactive iodine. It will take up radioactive iodine in whatever proportion it is available. When normal healthy cells are exposed to this radiation it can lead to cancer formation, because the same toxicity that makes I-131 capable of destroying cancer cells also makes it capable of damaging healthy thyroid cells -- damaging them to the point where it causes thyroid cancer to develop years later. Small children and babies in the womb are particularly sensitive to radiation-induced cancer as a result exposure to I-131. A stark illustration of this took place after the accident at the Chernobyl nuclear reactor, which caused numerous thyroid cancers and other thyroid disorders in Belarusian children (as well as children in other countries) due to exposure to radioactive iodine. However, exposed individuals in Poland did not experience such an increase because they ensured that prophylactic non-radioactive iodine was provided to its citizens¹.

In fact, the authoritative International Commission on Radiation Protection (ICRP), which offers recommendations for regulatory and advisory agencies to help in the management of radiological risks, warned that just one kiss from a thyroid patient treated with the radioisotope I-131 can double a child's risk of thyroid cancer.² Additionally, in 1986, the Nuclear Regulatory Commission (NRC), which has jurisdiction over the medical uses of radioisotopes, called I-131 "The most radiotoxic byproduct material used for medical use," and indicated that there were two ways that an I-131 patient can be dangerous to others: (1) external radiation dose, simply from being near someone emitting radiation, and (2) internal dose, from contamination, when I-131 is ingested, or inhaled, or absorbed through the skin.³

¹http://www.birdflumanual.com/resources/Self_Defense/files/Guidance%20for%20use%20of%20KI%20for%20nuclear%20emergency%20USG.pdf

² ICRP Publication 94: Release of Patients after Therapy with Unsealed Radionuclides (March, 2004)

³ 50 F.R. 30616 and 51 F.R. 36932

The Nuclear Regulatory Commission's Early Steps to Protect the Public from Radiation

There are two ways in which radiation levels can be measured. A measure of how much radioactivity is in the material administered to the patient is described in "curies (or millicuries, where one millicurie is one thousandth of a curie)," while the radiation dose that a person, such as a family member, receives from an irradiated patient is expressed in "rem's".⁴ Converting from an amount emitted to a dose received depends on several factors including the proximity of the person receiving the dose to the patient emitting it. Thus, while it is possible to assess how much radiation is emitted by a patient if one knows how much radioactive iodine he or she received, the only way one could calculate the dose received by a member of the public, as a result of exposure to the patient, is if one also knows specific information such as how far away the member of the public was from the patient, for how long, whether the member of the public came into direct physical contact with the patient, and other factors..

To reduce the risk of exposure to others from radiation emitted from the patient, NRC maintains regulations governing the release of patients from medical care after they are given radiopharmaceuticals. Until 1997, the NRC controlled this risk by requiring patients given large doses of I-131 to remain hospitalized in radiological isolation until the level of radioactivity in their bodies dropped below 30 millicuries, consistent with international standards.⁵ Hospitalization protected members of the public from both internal radiation, caused by contamination by patients' saliva, sweat, and other bodily fluids, and external radiation, caused simply by proximity to the patient.

NRC documentation relating to this 30-millicurie release rule, the NRC stated that this "limit provides an adequate measure of public health and safety" and that the "validity of the assumptions" necessary to calculate approximate dose rates emanating from the patient to a member of the public "are tenuous." According to NRC, in order to determine the approximate dose a person would receive from a treated patient requires making assumptions and approximations of the biological half-life of the radioactive material in the specific patient, duration of time spent near other individuals, and exact distance of household members.⁶

⁴ Note: in the International System of units, the becquerel (Bq) is the unit of radioactivity, while the dose received is expressed in sieverts (Sv)

⁵ 51 F.R. 36932

⁶ 51 FR 36945

THE 1990S: THE NRC BEGINS TO YIELD TO PRESSURE TO RELAX PROTECTIONS

Regulatory Confusion: Protection from Radiation Exposures from Patients Falls Through the Cracks

In 1987, President Reagan, in recognition of increased awareness of the hazards of radiation, especially to unborn children, approved new guidance directing federal agencies to implement the current International Commission on Radiation Protection (ICRP) recommendations, which substantially lowered acceptable radiation levels for occupational radiation protection.⁷ The President's guidance noted that the ICRP's recommendations were "now in use, in whole or substantial part, in most other countries." The Presidential guidance went further, stating that the unborn child of a radiation worker should receive a maximum of 0.5 rem during the entire period of gestation.

In 1991, the NRC, as part of new rules amending general radiation standards to incorporate these new occupational limits recommended by the President, also set dose limits for protecting members of the public from radiation of 0.1 rem and required notification of the NRC and the individual if the dose received exceeded this threshold.⁸ However, this rule did not clarify whether these new general limits on public exposure to radiation were also meant to apply to public exposures created by the release of patients treated with radioisotopes.

When the 1991 rule was promulgated, there was no discussion of whether the dose limits for the individual members of the public were intended to apply to the release of patients treated with radioisotopes.⁹ If this new 0.1 rem rule *did* apply, then patients treated with I-131 would have to remain hospitalized longer, until their radioactivity was reduced to an appropriate level. This could have caused regulatory confusion for the medical community because a patient with 30 millicuries of radioactive material in their body that was deemed releasable from the hospital under NRC regulations was likely to emit radiation at levels that would create exposure to family and others exceeding the new 0.1 rem safe limit.

Pressure to Relax the Regulations from the Medical Community Begins

Beginning in 1990, the NRC received a series of three petitions for rulemaking submitted by Dr. Carol S. Marcus (a nuclear medicine practitioner), by the American College of Nuclear Medicine (ACNM), and by the American Medical Association (AMA), requesting that the patient release rule be amended to ensure that radiation emitted by patients treated with radionuclides would not be treated the same way as radiation emitted by other sources.

These petitions went beyond a request to clarify whether the new more stringent radiation protection regulations applied to patients treated with radionuclides. The first of these petitions which was submitted by Dr. Marcus in 1991 (and then amended in 1992) requested that NRC raise the radiation dose limits to members of the public from 0.1 rem to 0.5 rem, if the exposure was

⁷ 52 F.R. 2822 (January 27, 1987). The President's Guidance noted ICRP Publications 26 and 30 which were published in 1977 and 1978.

⁸ 10 C.F.R. § 20.1301.

⁹ SECY-96-100

due to patients treated with radioactive materials.¹⁰ These petitions also asserted that if the 0.1 rem exposure dose limit promulgated by the NRC in 1991 also applied to doses received as a result of patient exposure it “would be extremely expensive”¹¹ since it would require longer hospitalization of patients who could have at the time been released under NRC’s patient release rules because their systems contained under 30 millicuries.

In the original petition submitted by Dr. Marcus, she requested the elimination of the 30 millicurie rule for all radionuclides other than I-131, clearly making a distinction because of the toxicity of this isotope. However, after “discussing the issues at leisure” with “members of the NRC, Society for Nuclear Medicine”¹² and other nuclear-medicine related stakeholders, Dr. Marcus wrote an addendum to the petition that proposed to eliminate the 30 millicurie rule for I-131 as well, thereby allowing for most I-131 patients to be treated as outpatients. This new proposed change in regulations would allow for doctors to treat almost all thyroid cancer patients at their private practices as outpatients, rather than following the practices used for decades which involved the referral of these patients to hospital facilities for treatment and subsequent radiological isolation in order to protect the patients’ families and the public from radiation exposure.

Oddly, the original petition submitted by Dr. Marcus was reportedly requested by NRC staff. The NRC petition process is intended to enable members of the public to propose regulatory actions for consideration by the Commission. However, in this case, the petition process was apparently used by the NRC staff to solicit a petition that resulted in a request to weaken the Commission’s own regulations for members of the public exposed to patients treated with radiation – at the same time that the Commission was strengthening its regulations for members of the public exposed to radiation from any other source. In letters relating to the petition, Dr. Marcus explains that this was the second time in two years that the NRC staff had used a rulemaking petition from her to weaken an earlier NRC decision, describing the resulting rulemaking as an “inside job from the start.”¹³

Dr. Marcus’s petition (in both the original and amended form) also proposed to replace the 30 millicurie release limit with the very same sorts of estimated dose calculations that rely on assumptions regarding the patient’s distance from members of the public they might expose to radiation that the NRC previously deemed to be “tenuous” when it promulgated its original regulations.

1997:- NRC Gives In

In 1994, the NRC published a proposal that essentially adopted the Marcus petition to change the patient release limit from an activity-based standard of 30 millicuries (measuring the patient’s radioactivity) to a dose-based standard of 0.5 rem (calculating, based on assumptions, the predicted exposure of family or others in proximity to the patient).¹⁴ This dose-based standard also failed to take into account direct contact with the exposed individual, as would occur with a kiss or with a breastfeeding infant. This was codified on January 29, 1997, when the NRC finalized its new rule that abolished the 30

¹⁰ PRM-20-20 from Dr. Marcus was published in the FR on June 12, 1991 (56 FR 26945)

¹¹ No. 08-72973, *Peter G. Crane v. United States Nuclear Regulatory Commission* (U.S. Court of Appeals for the Ninth Circuit), Brief for Respondents (November 4, 2008),

¹² Appendix B, page 1

¹³ Appendix B, page 4

¹⁴ See 59 Fed. Reg. 30724 (June 15, 1994).

millicurie maximum limit for outpatient treatment.

The Commission's decision flew in the face of international basic safety standards, adopted just the year before by the International Atomic Energy Agency (IAEA). These standards declared that to be considered adequate, national radiation safety programs must provide for hospitalizing patients given 30 millicuries or more of I-131.¹⁵ These regulations have been adopted by most Member States of the European Union and are still the baseline approach taken by the international community, although many countries now think that 30 millicuries is too lax a standard. In the European Union, the requirement to hospitalize is usually for those receiving doses of greater than 11 to 16 millicuries, in Germany, the limit is 7 millicuries and in Japan the limit is 14 millicuries.¹⁶

In place of radiological isolation in a hospital, the new NRC rule required two things (1) that physicians perform an individualized analysis of the patient's living situation to determine how much radiation others would receive, and only release patients "not likely" to expose other individuals. (2) that medical licensees (*e.g.*, hospitals) would provide written instructions to patients on how to keep doses to others "as low as is reasonably achievable."¹⁷ This assumed the ability and willingness of newly released thyroid cancer patients – highly radioactive, ill, and under stress both from the disease and its treatment – to maintain sufficient distance from others to ensure that no other person received an external radiation dose exceeding 0.5 rem. It also assumed that physicians would have the ability to perform such a calculation about a wide variety of typical living situations expected to be utilized by their patients. However, nothing in the NRC rulemaking documents suggests that NRC considered the possibility that patients would choose to recover in hotels, with layouts and occupancies that are unknown to a physician.

In short, the Commission adopted a rule that not only assumed a significantly less stringent "safe" dose of radiation exposure than most of the rest of the world, but it additionally adopted a protocol for implementing the regulation that required physicians to make imprecise calculations related to the likely living circumstances and behaviors of patients, rather than simply setting a dose above which patients could not be released from the hospital.

¹⁵ International Basic Safety Standards (Vienna, 1996).

See http://www.pub.iaea.org/MTCD/publications/PDF/Pub1117_scr.pdf

Note: in the international System of units, the becquerel (Bq) is the unit of radioactivity. The BSS states that hospitalization should occur at 1100 MBq (Megabecquerels), which is approximately equal to 30 millicuries.

¹⁶ International Commission on Radiation Protection, ICRP Publication 94: "Release of patients after therapy with unsealed radionuclides," *Annals of the ICRP* Vol. 34(2) (March 2004), p 53.

¹⁷ <http://www.nrc.gov/reading-rm/doc-collections/cfr/part035/part035-0075.html>

SEE NO EVIL, HEAR NO EVIL

The NRC Stamps Radiation Exposure Reports “Return to Sender” – Twice

Shortly after the NRC weakened its regulations allowing patients emitting radiation to leave the hospital, the NRC staff realized there was an inconsistency in the Commission's rules. Under another 1991 rule, in most scenarios, exposure that occurs in excess of general threshold limits must be reported to the NRC and to the individual who was exposed.¹⁸ This 1991 rule didn't explicitly refer to exposures that came about as a result of contact with or proximity to a patient treated with radioactive iodine.

On August 3, 1999 the NRC altered its guidelines that require reporting of radiation exposures to specifically exclude exposures that occurred as a result of contact with or proximity to patients treated with radioactive materials released from the hospital, – claiming that rules related to the release of patients treated with radionuclides should all reside in the same section of NRC's regulations.¹⁹ The NRC staff then put together a recommendation to revise the regulations that relate to the medical use of isotopes, proposing to add a requirement for a licensee to report events in which an individual receives a dose in excess of 0.5 rem (the limit for which a patient can be released) as a result of being exposed to a treated patient. In October 2000, the NRC Commissioners unanimously rejected this recommendation and instead told the NRC staff to develop an alternative proposal – one that would only require such notification to take place if the dose received to the individual exceeded 5 rem, or ten times NRC's patient release dose limit and 50 times NRC's more general 0.1 rem safe dose limit for members of the public.²⁰

As the NRC staff began to develop its new proposal and it engaged with stakeholders and solicited comments from Agreement States, it became clear that some States had already experienced problems related to NRC's patient release regulations.

On July 24, 2001, Joseph Klinger of the Illinois Department of Nuclear Safety wrote the NRC²¹ providing comments on the need for a reporting requirement. In Mr. Klinger's letter he responded to a comment by NRC's Advisory Committee on the Medical uses of Isotopes (ACMUI) which claimed that the “low frequency of known events and problems with rule enforcement and implementation do not justify NRC resource expenditures.”²²

“The (Illinois Nuclear Safety) Department would question the basis, including supporting data, for NRC's statements regarding the low frequency of known events associated with patient release. Simply because NRC does not keep records on such events, does not mean that such events are not occurring. Such events have occurred in Agreement States and means of addressing them have been problematic because hospitals will accept no responsibility for them....”

Mr. Klinger goes on to state that Illinois has had issues with NRC licensees who have disregarded aspects of the patient release criteria, and subsequently “rebuffed the State's inquiries

¹⁸ 10 C.F.R. § 20.2203

¹⁹ SECY-99-201

²⁰ <http://www.nrc.gov/reading-rm/doc-collections/commission/secys/2002/secy2002-0111/attachment1.pdf>

²¹ <http://www.nrc.gov/reading-rm/doc-collections/commission/secys/2002/secy2002-0111/attachment2.pdf>

²² <http://www.nrc.gov/reading-rm/doc-collections/commission/secys/2002/secy2002-0111/2002-0111scy.html>

about doses to the public.”

In discussing NRC’s claim that reporting requirements would be too onerous for the licensees and physicians, the New Jersey State Department of Environmental Protection wrote²³:

“NRC's concerns for their rules to be less intrusive into the practice of nuclear medicine may result in them being more intrusive on the general public as a result of increased patient excreta contaminating trash which sets off radiation monitors at landfills and incinerators.”

The Washington State Department of Health also wrote to the NRC in 2001²⁴, expressing its view that the issue was not reporting of radiation exposures, but rather that the root of the problem was the 1997 rule itself. In referring to the part of the rule that requires physicians to perform an individualized calculation, the State felt that the rule allowed the physician to “adjust the assumptions made” for occupancy and other factors so that patients can be released with incredibly high levels of residual activity – even making the point that the regulation allows licenses to retroactively tweak the numbers used in the calculations to ‘prove’ that the threshold limit was not exceeded, therefore keeping the licensees in compliance with NRC regulations. This comment highlighted similar problems with the calculations that NRC itself deemed to be “tenuous” when it first codified the 30-millicurie patient release regulation.²⁵

A representative from the Alabama Department of Public Health found issue with the fact that NRC’s proposed reporting requirements (5 rem) were not equivalent with its patient release requirements (0.5 rem). Stating “this change seems to muddy the waters even further...by saying that if you exceed the specified (release) limits you don’t need to report it to the NRC. It appears to trivialize your own limits and says they are of no consequence”.²⁶

In June 2002, after considering these and other reports, the NRC staff submitted a proposed rule that would have required medical licensees, whenever they learned that a released patient had caused someone to receive a radiation dose in excess of 5 rem, or ten times NRC’s patient release dose limit and 50 times NRC’s more general 0.1 rem safe dose limit for members of the public, to report the event to NRC and the overexposed person. Even this proposal was rejected by the NRC Commissioners (by a vote of 3 to 2).

In the minority, then-NRC Chairman Richard Meserve²⁷ observed that “members of the public who may have received involuntary doses from the release of patients will never be informed of their exposure.” He goes on to state “We have thus ignored the very individuals who have the greatest stake in assuring that there is a reporting and notification process.”

Chairman Meserve also noted “As a result of not moving forward with this proposed regulation, the NRC will lose the insight into compliance with our regulations that the reporting

²³ <http://www.nrc.gov/reading-rm/doc-collections/commission/secys/2002/secy2002-0111/attachment2.pdf>

²⁴ <http://www.nrc.gov/reading-rm/doc-collections/commission/secys/2002/secy2002-0111/attachment2.pdf>

²⁵ 51 FR 36945

²⁶ <http://www.nrc.gov/reading-rm/doc-collections/commission/secys/2002/secy2002-0111/attachment2.pdf>

²⁷ <http://www.nrc.gov/reading-rm/doc-collections/commission/cvr/2002/2002-0111vtr.pdf>

requirements provide. We will thus not have this tool as a means to assess the effectiveness of our regulatory program.”

The Crane Petition to Strengthen Regulations

In 2005, Mr. Peter Crane, a former NRC attorney who, as a thyroid cancer patient had received multiple I-131 treatments in the 1980's and 1990's, filed a petition for the NRC to begin a rulemaking to partially revoke its 1997 rule.²⁸ He particularly objected to the part of the rule that allows patients to be released with more than the equivalent of 30 millicuries of I-131 in their systems, stating that the 1997 rule change:

“has had precisely the adverse effects on health and safety that were predicted at the time by States and other commenters, and that were brushed aside by the NRC. Patients treated for thyroid cancer with radioactive I-131 are now being sent home to their families under conditions that guarantee that family members would receive larger and potentially harmful doses of radiation, under uncontrolled conditions.”

In January 2006, Mr. Crane submitted further comments to the public docket for his petition.²⁹ In these comments he discussed situations in which patients treated with I-131 on an outpatient basis, take public transportation home, potentially exposing other passengers; patients who vomit after returning home or while returning home on public transportation; and patients who are advised to go to hotels, where they present a radiation hazard to other guests, the housekeepers who clean their rooms, and subsequent occupants of their rooms. This petition put particular emphasis on the hotel issue, writing:

“And what about the next hotel guest, who arrives, possibly pregnant or with small children, in a room just vacated by a radioactive patient?” Transferring the radiation burden to unsuspecting third parties represented, he wrote, “a public health issue and a moral issue that NRC cannot in conscience ignore.”

One year later, NRC's patient release rule was discussed at a meeting of the Advisory Committee on the Medical Uses of Isotopes (ACMUI).³⁰ During this meeting Dr. Douglas Eggl, a nuclear medicine physician, complained that ever since the release rule went into effect “the chances that I can get an insurance authorization for a hospitalization to isolate them, even when I have family situations that require it, it's fighting tooth and nail with the insurance companies.”

The Chairman of the Committee Dr. Leon Malmud put it even more strongly:³¹

“... all patients are discharged upon treatment. We whisk them out the doors as fast as possible.”

²⁸ 70 FR 75752

²⁹ Docket ID: NRC-2005-0020 Comment (11) submitted by Peter G. Crane on Petition for Rulemaking PRM-35-18, Regarding Partial Revocation of the Patient Release Criteria Rule

³⁰ Transcript of the U.S. NRC Advisory Committee on the Medical Uses of Isotopes, Monday October 22, 2007

³¹ Transcript of the U.S. NRC Advisory Committee on the Medical Uses of Isotopes, Monday October 22, 2007

“There’s also an impossibility of keeping the patient in the hospital since the insurer will not cover it. The insurer will not cover it, will not cover the inpatient stay. It will cover the treatment, but not the inpatient stay.”

In 2008, NRC denied the Crane petition claiming that the patient release rule did not warrant re-examination.³² In the docket for the Crane petition, NRC stressed that those opposing the petition “doctors, medical physicists, and radiation safety officers, as well as several medical professional organizations” – “stated that reverting from the current release criteria back to the 30 millicurie (pre-1997) rule would result in additional and unnecessary healthcare costs.” NRC’s denial made no mention of the concerns related to patients being released to hotels.

Concurrent with its denial of the petition, NRC issued a non-binding “Regulatory Issue Summary (RIS)”³³ that advised its medical licensees of the International Commission on Radiation Protection (ICRP) 2004 findings³⁴, which stated that “contamination of infants and young children with saliva from a treated patient during the first few days after radioiodine therapy could result in significant doses to the child’s thyroid, and potentially raise the risk of subsequent radiation-induced thyroid cancer.” This informational summary explained that the current regulatory standards had been based on the assumption that the risks of internal doses to individuals exposed to released patients were small compared to the external exposures. However, NRC said, ICRP cautioned that the opposite was true, and that saliva from released patients “could result in significant doses to the child’s thyroid, and potentially raise the risk of subsequent radiation-induced thyroid cancer.” NRC therefore advised licensees that in implementing the current rule, they should “take into account whether the released patient may come in contact with infants or young children,” and if so, provide additional instructions. Finally, NRC said, “Licensees should also consider not releasing patients, administered I-131, whose living conditions may result in the contamination of infants and young children.”

NRC did not explain why it had waited from April 2004, when ICRP Publication 94 appeared, until May 2008, when the RIS was issued, to communicate this warning from an authoritative international safety body. NRC also did not address the question of whether infants and young children could be exposed to radiation if a patient was released to a hotel.

³² 73 F.R. 29445

³³ http://www.kdheks.gov/radiation/download/RIS_2008-11.pdf

³⁴ International Commission on Radiation Protection, ICRP Publication 94: “Release of patients after therapy with unsealed radionuclides,” Annals of the ICRP Vol. 34(2) (March 2004)

WARNINGS CONTINUE TO MOUNT, AND CONTINUE TO BE IGNORED

NRC conducts weak oversight, but even limited inspections reveal regulatory violations and policy confusion

In a response to a request for information by Congressman Edward J. Markey³⁵, the NRC indicated that of the 3,700 facilities licensed to perform treatments using radioactive iodine, the NRC directly oversees only 500 of them, with the remainder overseen by State regulators. The NRC collects no information regarding the adequacy or enforcement of its regulations in the 3,200 facilities overseen by the States. In fact, according to NRC "Agreement States do not send their inspection reports to the agency nor do they let the agency know about any violations they may cite. Violations related to patient release are not normally reported to the NRC."

Even for the remaining 500 licensees that are under NRC 's direct authority, the NRC doesn't request or retain records that would enable it to determine whether patients choose to recover in hotels. In a letter to Chairman Markey on March 5, 2010, NRC states that it "does not keep a record of how many times inspectors have requested records" as a result of observing potential deficiencies in meeting patient release criteria. NRC additionally notes that when such records are requested, they are "reviewed at the licensee's site during the inspection." Consequently, NRC has no way of tracking how frequently these types of violations in patient release criteria may be occurring in medical facilities across the country.

However, during the limited routine inspections NRC conducted between 2001 and 2008, it noted four licensees who violated the patient release rule. In all of these cases the licensees failed to perform the individualized analysis that is required by NRC regulations to ensure that individuals who come into contact with the patient do not receive a radiation dose above the default limit (0.5 rem). In two release cases that occurred at the Forbes Regional Hospital in Pennsylvania, the NRC inspector noted that the patients received doses that were 5 times higher than the pre-1997 threshold dosage, which would have required default hospitalization at 30 millicuries.³⁶

In response to these incidents, NRC issued a "Notice of Violation"³⁷ that required the licensees to take corrective actions to prevent recurrence of this patient release error. Since these facilities either claimed that they were unaware of the requirement for calculations or did not keep records for these calculations, the corrective actions were comprised of staff training sessions and education on NRC requirements as well as a commitment to keep records relating to the individualized analysis going forward.

There was no mention of whether the patients that were released by these licensees went to a hotel after their treatment, but inspectors are unlikely to request this information since NRC does

³⁵ See: U.S. NRC response to Congressman Edward Markey, March 5, 2010

³⁶ See: U.S. NRC letter to Congressman Edward Markey, March 5, 2010; Attachment 2: 10CFR 35.75 Severity Level IV Violations for I-131 therapy.

³⁷ See: U.S. NRC letter to Congressman Edward Markey, March 5, 2010; Attachment 2: 10CFR 35.75 Severity Level IV Violations for I-131 therapy.

not maintain or require licensees to maintain records regarding the destinations of released patients.

Release of Patients to Hotels: NRC Admits that It Isn't Prohibited and Realizes it Occurs

In its response to Chairman Markey's inquiry³⁸, the NRC did disclose and identify four cases involving two medical licensees in which patients were released to hotels immediately after I-131 treatment. In both cases, the patients provided written notification of their plans to stay in a hotel, and NRC inspectors only discovered the information because they had made a broader request for records from the licensees. During a 2007 inspection of MedStar Georgetown Medical Center in Washington, DC, the inspector noted that the facility had released two patients to area hotels to recover in 2006. For one of these patients the licensee justified the release to a hotel, by showing in a retroactive calculation that the likelihood of the patient exposing members of the public with doses over the threshold limit would have been low.

A similar situation occurred at the University of Virginia, where the NRC discovered during a 2008 inspection that the licensee was incorrectly performing dose calculations and as a result was releasing patients who exceeded the patient release limit. After the NRC instructed the licensee of the correct dose calculation methodology, the licensee retroactively performed the patient specific analysis and determined that it would not have been in violation of the NRC release rule since the calculated dose fell below the 0.5 rem limit (though in one case, the retroactive calculation indicated a 0.498 rem dose would have been received, barely below the regulatory limit). At this same facility, the NRC discovered that in 2007, the facility had released two I-131 patients to recover in nearby hotels. These patients, who were also sisters, shared one room in the hotel and would have contributed a combined dosage of over 0.5 rem to any guests or hotel staff.

As a result of these two inspections that occurred within a year of each other, the NRC Region 1 Division of Nuclear Materials Safety wrote to NRC headquarters³⁹ to gain clarification on whether releases to hotels were allowed under NRC regulations, and specifically whether the standard calculations that are performed as a part of the patient release process are also valid when patients are released to a hotel. The technical assistance also requested that NRC provide additional guidance for patients who go to a hotel, noting that "these types of releases are not uncommon." In fact, the technical assistance referenced a *USA Today* article that performed a survey of thyroid patients and found that 4% of the patients checked into hotels or other accommodations instead of going home and 2% of patients used public transportation after being released from the hospital. The survey also noted that only 86% of the outpatients went directly home after being treated, meaning there is plenty of opportunity for these patients to expose members of the public to radiation unwittingly.⁴⁰

³⁸ See: U.S. NRC letter to Congressman Edward Markey, March 5, 2010

³⁹ Region 1 Technical Assistance Request. November, 28, 2007. See: U.S. NRC letter to Congressman Edward Markey, March 5, 2010; Attachment 5

⁴⁰ It kills thyroid cancer, but is radiation safe? Steve Sternberg and Anthony DeBarros, *USA Today*, November 18, 2007.

On June 12, 2008, in response to this technical assistance request, the NRC informed Region 1⁴¹ that the “licensees acted in accordance with existing NRC regulations and that these regulations “do not prohibit the release of a patient to a hotel.” The NRC Office of General Counsel (OGC) reviewed and concurred with this assessment of current regulations in April, 2008.

NRC also stated in the June 12 document that it would develop additional instructions to be provided to patients released to a hotel. This guidance has yet to be developed. NRC notes in its response to Mr. Markey on March 5, 2010 that NRC staff plans to “review the guidance relating to the release of I-131 therapy patients to hotels.” However, the guidance that the NRC says it plans to review⁴² doesn’t include any mention of patient release to hotels whatsoever, making it unclear what such a review will entail.

States take matters into their own hands

Since the NRC regulations do not prohibit releases to hotels and to date the NRC has not given States or licensees any guidance in this area, some States have begun to develop and implement their own guidance, which they largely attribute to the 2004 ICRP Publication 94 that advises licenses to especially take into consideration the potential for released patients to expose infants and children to radiation. In a 2008 Minnesota Department of Health (MDH) notice to licensees, MDH warned against sending patients to hotels stating that it should not be considered an alternate means of separation from children and that the “practice has proven to cause significant exposure concerns to hotel property, housekeeping staff, and guests.”⁴³

In 2009, both the Washington State Department of Health and the New York City Office of Radiological Health sent similar letters⁴⁴ to their licensees emphasizing that the patients should not be advised to go to a hotel immediately after release. New York City explained that

“a hotel presents substantial probability of close contact with infants, young children, pregnant women, and of course the general public. In a serious and not at all implausible case, a patient could have their room or dining area cleaned by a pregnant woman who could come into very close contact with radioiodine-containing-bodily fluids.”

NRC’s Office of General Counsel Inaccurately Tells a Federal Court that Patient Release to Hotels isn’t Permitted

On July 9, 2008, Mr. Crane filed a petition for review in the U.S. Court of Appeals for the Ninth Circuit regarding the denial of his NRC petition for rulemaking. Mr. Crane argued in his brief to the court that the NRC failed to adequately address the significant safety issue of releasing treated I-131 patients from the hospital to hotels.

⁴¹ NRC June 12, 2008 Memorandum to Region 1. See U.S. NRC letter to Congressman Edward Markey, March 5, 2010; Attachment 5

⁴² http://www.kdheks.gov/radiation/download/RIS_2008-11.pdf and NUREG-1556, Volume 9 Revision 2

⁴³ MDH Information Notice 2008-04, www.health.state.mn.us/divs/eh/radiation/radioactive/infonot0408.pdf

⁴⁴ NYC Information Notice ORH 2009-01, <http://www.ci.nyc.ny.us/html/doh////downloads/pdf/radioh/radioh-Info-noticeorh.pdf> and State of Washington Information Notice, March 26, 2009; See Appendix C

In NRC's November 2008 brief to the court, the Office of General Counsel (OGC) called Mr. Crane's description of patients sent to hotels "unverifiable and unscientific." In spite of this very same office's April 2008 concurrence with NRC's opinion that release to a hotel was "not an uncommon practice" and was not prohibited by NRC regulations, this OGC filing declared to the court that: "NRC's rule does not permit or encourage doctors to send treated patients to hotels."⁴⁵

It was decided on August 19, 2009 that Mr. Crane, a thyroid cancer patient and survivor, lacked standing to bring the case because he was not currently undergoing or about to undergo treatment with radioactive iodine, and was therefore unaffected by the NRC rule. The court did not decide on the merits of the case, including Mr. Crane's claim that some radioactive patients were going to hotels and creating a hazard to other guests and hotel staff.

⁴⁵ No. 08-72973, *Peter G. Crane v. United States Nuclear Regulatory Commission* (U.S. Court of Appeals for the Ninth Circuit), Brief for Respondents (November 4, 2008), p. 39.

Appendix A – Detailed Chronology

1986- NRC issued regulations that required the hospitalization of patients with the equivalent of 30 millicuries or more of radioactive iodine 131 (I-131) in their systems. (This was consistent with the International Basic Safety Standards on radiation protection) NRC called I-131 “the most radiotoxic byproduct material used for medical use,” and indicated that there were two ways that an I-131 patient can be dangerous to others: (1) external radiation dose, simply from being near someone emitting radiation, and (2) internal dose, from contamination, when I-131 is ingested, or inhaled, or absorbed through the skin.

1987- President Reagan, in recognition of increased awareness of the hazards of radiation, especially the potential dangers to unborn children, approved new guidance directing federal agencies to implement the current International Commission on Radiation Protection (ICRP) recommendations, which stated basic principles for occupational radiation protection and recommended a safe dose of 0.5 rem for pregnant women that were occupationally exposed.¹ The President’s guidance noted that the ICRP’s recommendations were “now in use, in whole or substantial part, in most other countries.”

1991 - The NRC issued new rules amending general radiation standards and set dose limits for protecting members of the public from radiation of 0.1 rem, and required notification of the NRC and the individual if the dose received exceeded this threshold.² The rule did not explicitly specify whether these rules applied to doses given to members of the public due to exposures from patients treated with radionuclides.

1992- NRC gave public notice of the receipt of an original and amended petition submitted by Dr. Carol Marcus. The original petition requested that the 30-millicurie limit for the release of patients be eliminated for all radiopharmaceuticals except I-131, and was reportedly initiated by NRC staff. The amended petition requested elimination of the 30-millicurie limit for all radiopharmaceuticals, and recommended that patients treated with radioactive iodine be released from the hospital if a calculation performed by a physician could demonstrate that radiation received by family members or a member of the public was unlikely to exceed 0.5 rem, five times NRC’s safe radiation limit for members of the public.

March 1996- The International Atomic Energy Agency (IAEA) issued its Basic Safety Standards (BSS) entitled “Radiological Protection for Medical Exposure to Ionizing Radiation.”³ This safety guide is one part of a series of international standards based on worldwide consensus, knowledge of biological effects of radiation and principles for protection from undesirable effects. The BSS declared that to be considered adequate, national radiation safety programs must provide for hospitalizing patients given 30 millicuries or more of I-131 and that in some

¹ 52 F.R. 2822 (January 27, 1987). The President’s Guidance noted ICRP Publications 26 and 30 which were published in 1977 and 1978.

² 10 C.F.R. § 20.1301

³ International Basic Safety Standards (Vienna, 1996).

See http://www-pub.iaea.org/MTCD/publications/PDF/Pub1117_scr.pdf

countries a level of 10 millicuries is used as an example of good practice.⁴ I-131 is the only nucleotide that IAEA recommended specific standard for.

January 29, 1997- NRC adopted the amended 1992 petition and published revisions to its regulations, which authorized the immediate release of most patients treated with I-131 (or any other radioactive material) as long as the likely exposure to others would not exceed 0.5 rem, or five times NRC's own safe level for members of the public. This rule stated that for patients with more than 30 millicuries of radioactive content in their bodies, an individualized analysis of the patient's living situation was necessary to determine the likely dose to others, and as long as that dose wasn't expected to exceed 0.5 rem, the patient could be released from the hospital. The rule presented two scenarios – hospitalization, and release to one's home. It did not, however, discuss the possibility that a patient might wish to recover in a hotel, whether release to a hotel was permissible, and how such an individualized analysis might be performed for a hotel.

1998- A European Commission document entitled "Radiation Protection Following Iodine-131 therapy (exposures due to out-patients or discharged in-patients⁵)" stated that "sending patients home immediately after the administration of the radionuclide cannot be justified in most situations because both excretion and external radiation (the patient is a source) will give rise to high doses to other individuals in contact with the patient for a few days." This risk is particularly high for infants and children who may come in contact with bodily fluids, such as saliva and sweat, as well as a treated patient's breath, all sources of I-131 radiation. "As a general rule, treatment of thyroid cancer patients using radioactive iodine will only be performed in conjunction with hospitalization of the patient."

August 3, 1999- NRC adopted a revision to its regulations that ensured that the safe radiation levels for the public would exclude from consideration doses given to members of the public as a result of exposure to a patient treated with radionuclides, citing the 1997 regulations that governed patient release.⁶ This clarification meant that if a member of the public was exposed to more than 0.5 rem from a patient treated with radioisotopes, that exposure would not need to be reported to the NRC.⁷

October 23, 2000: The NRC unanimously rejected a staff proposal to require reporting of radiation doses of greater than 0.5 rem to members of the public as a result of exposure to a patient treated with radioisotopes⁸, even though this level was NRC's own regulatory dose limit for patients treated with radioisotopes. Instead, staff was directed to develop a proposal that would only require notification of radiation doses to members of the public of greater than 5 rem – ten times NRC's own regulatory dose limit and fifty times its safe dose level for members of the public.

⁴ Note: in the international System of units, the becquerel (Bq) is the unit of radioactivity. The BSS states that hospitalization should occur at 1100 MBq (Megabecquerels), which is approximately equal to 30 millicuries.

⁵ See http://ec.europa.eu/energy/nuclear/radioprotection/publication/doc/097_en.pdf

⁶ 10 CFR 20.1301 and SECY-99-201

⁷ <http://www.nrc.gov/reading-rm/doc-collections/commission/secys/2000/secy2000-0118/2000-0118scy.html>

⁸ See <http://www.nrc.gov/reading-rm/doc-collections/commission/secys/2002/secy2002-0111/attachment1.pdf>

2001- Illinois's Department of Nuclear Safety wrote to the NRC stating that Illinois has experienced issues with patients being released under circumstances that may cause exposure to the general public. Illinois stated that "Simply because NRC does not keep records on such events does not mean that such events are not occurring." The difficulty with these events, Illinois said, is that "hospitals will accept no responsibility for them."⁹

June 21, 2002 – In response to the October 23, 2000 direction from then-NRC Chairman Richard Meserve, NRC staff proposed an amendment to NRC's patient release regulations that would require medical licensees to notify the NRC if the licensee became aware that an individual received or is estimated to have received a dose of 5 rem -which was ten times higher than NRC's own patient release regulations dose thresholds-¹⁰ as a result of being exposed to a radioactive patient and fifty times its safe dose level for members of the public.

August 27, 2002- NRC Commissioners rejected (by a vote of 3 to 2) the staff proposal requiring that it be notified if a released patient causes a family member or member of the public to receive a dose of 5 rem - ten times higher than NRC's own patient release regulations dose thresholds and fifty times its safe dose level for members of the public.¹¹

March 2004- The International Commission on Radiation Protection (ICRP) issued Publication 94: Release of Patients after Therapy with Unsealed Radionuclides¹², which states that "contamination of infants and young children with saliva from a treated patient during the first few days after radioiodine therapy could result in significant doses to the child's thyroid, and potentially raise the risk of subsequent radiation-induced thyroid cancer." This statement was repeated in the new comprehensive radiation safety recommendations in ICRP Publication 103, The 2007 Recommendations of the International Commission on Radiological Protection,¹³ which specifically states that particular care should be taken to avoid the contamination of infants and children from patients treated with radioiodine. The ICRP recommended that the threshold for permissible radiation exposure of pregnant women and children be lowered to 0.1 rem, one fifth of what the NRC permits for patients released from the hospital. The NRC did not pass along the ICRP's warnings to its medical licensees until May 2008.

September 2, 2005- Peter Crane, a former NRC attorney and thyroid cancer patient who received multiple I-131 treatments in the 1980's and 1990's, filed a petition for rulemaking calling for partial revocation of the patient release criteria rule.¹⁴ He objected to the part of the rule that allows release of I-131 patients with 30 millicuries or more in their systems asserting that the 1997 issued rule was defective on legal and policy grounds. Mr. Crane objected to the current patient release criteria stating that it "creates unwarranted hazards as patients are sent out the door," where they may come into close contact with family members and members of the public."

⁹ See Appendix 2

¹⁰ <http://www.nrc.gov/reading-rm/doc-collections/commission/secvs/2002/secv2002-0111/attachment1.pdf>

¹¹ <http://www.nrc.gov/reading-rm/doc-collections/commission/cvr/2002/2002-0111vtr.pdf>

¹² International Commission on Radiation Protection, ICRP Publication 94: "Release of patients after therapy with unsealed radionuclides," Annals of the ICRP Vol. 34(2) (March 2004)

¹³ International Commission on Radiation Protection, ICRP Publication 103: "Recommendations of the ICRP," Annals of the ICRP Vol. 37/2-4 (2007)

¹⁴ 70 FR 75752

January 30, 2006-Peter Crane submitted comments to the public docket for his petition citing concern about patients being released to hotels and unsuspecting hotel cleaning staff coming into contact with radiologically contaminated bathroom surfaces, linens, etc. The comments also note the problem of patients vomiting (in public or private spaces) after treatment and members of the public coming into contact with the radioactive vomitus.¹⁵

October 22, 2007 - The NRC's patient release rule was discussed at a meeting of the NRC's Advisory Committee on the Medical Uses of Isotopes. Dr. Douglas Eggli, a nuclear medicine physician, complained that it had become impossible to get insurance companies to pay for inpatient treatment, "even when I have family situations that require it." The committee's chairman, Dr. Leon Malmud, agreed stating: "Their wonderful insurance stops because it is no longer necessary for them to be an inpatient." As a result, he said: "All patients are discharged upon treatment. We whisk them out the doors as fast as possible."¹⁶

November 28, 2007-After an inspection revealed that patients with high doses of I-131 were knowingly discharged to a hotel, NRC's Region 1 Office made a request to NRC headquarters for technical assistance to determine whether release to a hotel was permissible under the NRC patient release rule. Referring to hotels, the technical assistance request noted that "these types of releases are not uncommon," cited some press reports on the topic, and questioned whether the required dose calculation analysis for patient release that takes into account occupancy can be performed in a valid manner for releases of patients to hotels. The Region also requested information on additional instructions to be provided to patients if they are released to hotels.¹⁷

April 23, 2008- The NRC Office of General Counsel (OGC) reviewed and approved the NRC headquarters response to the technical assistance request for NRC's Region 1 Office, which stated that "release to a hotel was not prohibited by the regulations."¹⁸

May 12, 2008- NRC issued a non-binding "Regulatory Issue Summary (RIS)" to its medical licensees, alerting them to the ICRP Publication 94 published in March 2004.¹⁹ The RIS states that "Licensees should also consider not releasing patients, administered I-131, whose living conditions may result in the contamination of infants and young children." But the report did not address the release of patients to hotels, nor did it mention anything about the mandatory requirement to calculate individualized doses to household members prior to releasing patients.

May 21, 2008- The NRC published in the Federal Register its denial of Mr. Crane's petition for rulemaking, saying that the NRC's patient release rule needed no reexamination, and citing/publishing its May 12, 2008 RIS as a means of addressing risks to infants and young

¹⁵ Docket ID: NRC-2005-0020 Comment (11) submitted by Peter G. Crane on Petition for Rulemaking PRM-35-18, Regarding Partial Revocation of the Patient Release Criteria Rule

¹⁶ Transcript of the U.S. NRC Advisory Committee on the Medical Uses of Isotopes, Monday October 22, 2007

¹⁷ Region 1 Technical Assistance Request. November, 28, 2007. See: U.S. NRC letter to Congressman Edward Markey, March 5, 2010; Attachment 5

¹⁸ NRC Safety Inspection Report Number 2007-002. Licensee: University of Virginia. See U.S. NRC letter to Congressman Edward Markey, March 5, 2010; Attachment 4

¹⁹ http://www.kdheks.gov/radiation/download/RIS_2008-11.pdf

children.²⁰ The NRC discussed and rejected the lower dose threshold for pregnant women and children urged by the ICRP.

May 28, 2008- The Minnesota Department of Health (MDH) issued a notice which advised its medical licensees of NRC's RIS and added its own warning: "MDH would discourage physicians from suggesting that patients use hotels as an alternative means of separation from infants or young children. That practice has proven to cause significant exposure concerns to hotel property, housekeeping staff, and guests."²¹

June 12, 2008 – In its response to NRC's Region 1 Office's request for technical assistance, the NRC stated that "releasing patients from a hospital to go to a hotel or other temporary accommodation is not an uncommon practice" and that current regulations do not "limit the location to which the (treated) individual must be released," and "do not prohibit the release of a patient to a hotel" To address this issue the NRC stated that "guidance for release of radiotherapy patients to hotels" and "additional instructions" to be provided to patients released to hotels "will be developed".²² This promised guidance and instructions were never developed.

July 9, 2008 – Mr. Crane filed a petition in the U.S. Court of Appeals for the Ninth Circuit to review the NRC's denial of his petition for rulemaking. Briefs were filed in the fall of 2008, in which Mr. Crane argued that the NRC failed to adequately address the significant safety issue of releasing treated I-131 patients from the hospital. The petition also addressed the inconsistencies between NRC's regulations and international safety standards.²³

November 4, 2008 – In its brief to the U.S. Court of Appeals for the Ninth Circuit in opposition to Peter Crane's petition for review of the NRC's denial of his original petition, NRC's Office of General Counsel (OGC) called Mr. Crane's description of patients sent to hotels "unverifiable and unscientific." In spite of this very same office's concurrence with the June 2008 NRC headquarters opinion that release to a hotel was not prohibited by NRC regulations, and the clear awareness on the part of the NRC that release of radioactive patients to hotels was not an uncommon practice, OGC declared to the court that: "NRC's rule does not permit or encourage doctors to send treated patients to hotels."²⁴

March 26, 2009- A notice from the State of Washington Department of Health advised its licensees to "actively discourage patient use of hotels immediately after release"²⁵

June 29, 2009 - The New York City Department of Health issued guidance to all medical licensees that specifically warned against sending patients to hotels.²⁶ It stated that "a hotel

²⁰ 73 F.R. 29445

²¹ MDH Information Notice 2008-04, www.health.state.mn.us/divs/eh/radiation/radioactive/infonot0408.pdf

²² NRC June 12, 2008 Memorandum to Region 1. See U.S. NRC letter to Congressman Edward Markey, March 5, 2010; Attachment 5

²³ No. 08-72973, *Peter G. Crane v. United States Nuclear Regulatory Commission* (U.S. Court of Appeals for the Ninth Circuit), Brief for Petitioner Peter G. Crane.

²⁴ No. 08-72973, *Peter G. Crane v. United States Nuclear Regulatory Commission* (U.S. Court of Appeals for the Ninth Circuit), Brief for Respondents (November 4, 2008), p. 39.

²⁵ See Appendix C

²⁶ <http://www.nyc.gov/html/doh/downloads/pdf/radioh/radioh-Info-noticeorh.pdf>

presents substantial probability of close contact with infants, young children, pregnant women, and of course the general public. In a serious and not at all implausible case, a patient could have their room or dining area cleaned by a pregnant woman who could come into very close contact with radioiodine-containing-bodily fluids.”

August 19, 2009 – A decision was issued in the U.S. Court of Appeals for the Ninth Circuit for Mr. Crane’s petition for review.²⁷ The court accepted the NRC’s argument that Mr. Crane, a thyroid cancer patient, lacked standing to bring the case because he was not currently undergoing or about to undergo treatment with radioactive iodine, and was therefore unaffected by the NRC rule. The court did not reach a conclusion regarding the merits of the case, including Mr. Crane’s claim that some radioactive patients were going to hotels and creating a hazard to other guests and hotel staff.

October 13, 2009- Chairman Edward J. Markey sent a letter to NRC Chairman Greg Jaczko highlighting issues with patients being released to public hotels and questioning NRC’s enforcement of patient release criteria. Mr. Markey stated: “I am concerned that current NRC regulations....may result in some unnecessary, unwitting and inappropriate exposures of individuals to dangerous levels of radiation.”²⁸

November 17, 2009- Chairman Greg Jaczko replied to Mr. Markey’s letter stating “the NRC believes the current regulation (10 CFR 35.75) provides adequate protection to members of the public, provided that adequate instructions are provided at discharge to the patient and the family members.” The letter also stated that the regulation “does not limit the location to which the individual may be released nor does it specifically address the release of patients to hotels.” The response indicated that the need to perform an individualized analysis of a patient’s living situation would also apply to those patients who go to hotels after their release from the hospital. In response to a question on protecting vulnerable populations the NRC states “there is no distinction between the dose limits that apply to other members of the public and those that apply to pregnant women and young children”.²⁹

January 14, 2010- Mr. Markey wrote another letter to NRC Chairman Jaczko, stating that he “remains extremely concerned that the Commission is abdicating its responsibility to protect the health and safety of the American people.” In discussing particular concern for patients released to hotels, where they could expose pregnant hotel workers or children of guests, he states for “hotels it would be difficult, if not impossible, to come up with credible assumptions with which to estimate the dose received by an unknown person at an unknown distance when performing the sort of individualized analysis referenced in the 1997 guidance...” Mr. Markey specifically requested an investigation into NRC’s inspection records of facilities licensed to use I-131 in medical treatments.³⁰

²⁷ <http://www.ca9.uscourts.gov/datastore/memoranda/2009/08/19/08-72973.pdf>

²⁸ http://markey.house.gov/docs/signed_isotope_nrc_letter.pdf

²⁹ http://markey.house.gov/docs/nrc_tomarkeyisotopes.pdf

³⁰ <http://markey.house.gov/docs/11410nrc.pdf>

March 5, 2010-Chairman Jaczko responded to Mr. Markey's inquiry.³¹

Notable Points:

- NRC may have recognized that pregnant women and children are different than grown men in their sensitivity to radiation and is considering possible revisions to the regulations that set dose limits for pregnant women and children. However, no timeline or process is provided for this revision.
- NRC has 3,700 I-131 licensee and Agreement State medical use facilities, but only inspects 500 of these facilities for compliance with patient release criteria, with the remaining not subject to NRC oversight. Although the remainder of these facilities are subject to State regulation and enforcement, NRC neither requests nor receive reports of any kind related to State inspections.
- The NRC noted a few examples in which enforcement actions were taken as a result of violations in patient release. These violations included the failure to perform individualized analysis before release and failure to provide written instructions to the patient on how to reduce exposures to others. This included cases in which patients were discharged to hotels.
- The NRC response declared that regulations do not prohibit doctors from sending patients to hotels and believes that physicians can reasonably calculate dose estimates for patients who go to a hotel, by using assumptions on building geometry and other factors.
- The Commission will not reconsider its decision to not be notified if harm has occurred as a result of patient exposure to the public, because the NRC is "not aware of any scenario in which a member of the public received a 0.5 rem exposure from a released patient." Since the NRC twice voted not to be told if such events occur, it is unclear how it would have become aware of such a scenario in the first place.

³¹ See: U.S. NRC letter to Congressman Edward Markey, March 5, 2010

Appendix B

UNIVERSITY OF CALIFORNIA, LOS ANGELES

DOCKET NUMBER
PETITION RULE PRM 3-5-10A
(57 FR 21043)

UCLA

BERKELEY · DAVIS · IRVINE · LOS ANGELES · RIVERSIDE · SAN DIEGO · SAN FRANCISCO

SANTA BARBARA · SANTA CRUZ



'92 NOV 17 AS 53

November 9, 1992

UCLA SCHOOL OF MEDICINE
HARBOR - UCLA MEDICAL CENTER
DEPARTMENT OF RADIOLOGY
1000 CARSON STREET
TORRANCE, CALIFORNIA 90509

Samuel Chilk, Secretary of the Commission
U.S. Nuclear Regulatory Commission
Docketing and Service Branch
Washington, DC 20555

Subject: Letter of Peter Crane dated 10/31/92 regarding PRM-20-20, PRM-35-10, PRM-35-10A, and the 23 October 92 meeting of the ACMUI

Dear Mr. Chilk:

I am writing to correct the scientific mistakes and misunderstandings contained in Mr. Crane's letter of 31 Oct. 92, and to point out that certain opinions ascribed to me by Mr. Crane are grossly inaccurate. Fortunately my opinions are amply documented, in writing, in your office, so this should be quite straightforward. I recommend that Mr. Crane review my Petition dated 12/26/90, my important Addendum of 6/12/92, and my comments of 3/14/92 concerning the ACNM Petition.

My Petition was written at the request of Hal Peterson, who was embarrassed at the uncorrected errors in 10 CFR Part 20, and who urged me to "write a Petition YESTERDAY". At the time, the new Part 20 was supposed to go into effect 1 Jan 92, and we did not have many months to waste. I argued at the time that I did not want to write another petition (I wonder why?), but he insisted it was the only option open, and that is how I spent Christmas Eve, 1990. It was hastily done, and recommended honoring the methodology of NCRP no. 37, getting rid of the "30 mCi rule" for all radionuclides other than I-131, and retaining the 5 mSv maximum for members of the public from patient sources; this is in keeping with the most recent recommendations of NCRP, ICRP, and the IAEA. I recommend that Mr. Crane review this literature as well, as NRC asserts frequently that it uses such sources for its standards.

Much later, after discussing the issues at leisure in much more detail with members of NCRP, ACNP, SNM, and NRC, I wrote an Addendum covering the "30 mCi" issue. Due to the fact that the "30 mCi" value was embarrassingly based on a naive mistake by the AEC in the early 1950's and never fixed thereafter, and due also to the fact it is not mentioned anywhere in NCRP no. 37 (nor should it have been), I made a scientifically valid case for a "default" value of I-131 patient discharge which came out to 33

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mCi. However, there is excellent reason to raise that number, especially for athyretic carcinoma patients with normal renal function. NCRP no. 37 lists limits of 50 mCi for certain home situations and 80 mCi for even more restrictive home situations. Mr. Crane should familiarize himself with these qualifiers, because he is obviously unfamiliar with these long-accepted concepts. NCRP no. 37 is the law in California; the "30 mCi rule" does not exist here. We in California try to base our policies on scientifically valid health physics.

When the ACNM Petition was submitted, I used my comment opportunity to remind NRC that my Petition was drowning at the bottom of Mr. Roecklein's "in" pile, and that it needed resolution. The concept of sending patients home with 400 mCi of NaI-131 was ludicrous. Although I could theoretically concoct a situation where it could possibly be justified, there are not too many patients who would qualify as hermits in isolated areas. In any case, I stated:

"The one aspect of the petition that causes me some concern is the claim of safety of an outpatient dose of 400 mCi. I have not reviewed data supporting this argument and would appreciate the opportunity to do so. Although I'm sure that safety could be satisfied, it would appear to require some very specific circumstances".

As there are no data that could possibly support this except in highly unusual situations, the point is moot. Mr. Crane should also know that I requested that ACNP (absolutely not related in any way whatsoever to ACNM), SNM, the American College of Radiology, and Jack Goodrich, M.D., past ACMUI member, make similar points in their comment letters. I explained to the American Hospital Association that this was NOT a good way to save money, and made a presentation against the ACNM Petition at last Spring's CRCPD meeting at the request of Terry Frazee of the State of Washington.

I hope that NRC clearly understands that I am not now, nor have I ever been, a member of the ACNM nor an espouser of 400 mCi I-131 doses dispensed to patients in an uncontrolled manner. However, NRC's "30 mCi" rule is scientifically unfounded and constitutes bad physics, just as ACNM's claims are unsupported by scientific data.

All I am trying to do is challenge NRC to make an intellectually defensible, scientifically valid regulation based on best available scientific data and scientific judgment. I urge NRC to entertain only scientific discussion, and eschew scientifically

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for data on childhood thyroid cancer near Chernobyl. I recommend that Mr. Crane read Hull AP: Post Chernobyl childhood cancers reported. The Health Physics Newsletter, vol. 20, Nov. 1992, (cover story). There are some interesting problems with Russian "data" at this point.

Mr. Crane's naivete' concerning the first Petition I wrote in June, 1989, with Mr. McElroy's help, is surprising. Mr. Cunningham instructed Mr. McElroy to help me write the Petition. I didn't know how to write regulatory language, and it was Mr. McElroy's job to help me do that. NRC had written some very poor quality and dangerous regulations in 1987, and Mr. Cunningham realized that the language had to be fixed, and asked us to do it together. It was an "inside" job from the start. Mr. Cunningham gave us some very tough boundary conditions, but we did the best we could. This was before NRC rammed through the petitioner's "Gag Rule" without opportunity for public comment. If I were to write my own petition to change Part 35 today, with none of Mr. Cunningham's constraints, I would get rid of nearly everything in it, and upgrade education and experience criteria for nuclear medicine physicians so that NRC stopped licensing incompetent physicians who don't even know what Part 20 is, let alone the basic science necessary to comply with it. Nuclear Medicine would be subject to performance standards only. The only reason we have completely prescriptive regulation is that performance standards require thorough understanding and judgment, and NRC itself cannot seem to rise to that level. So yes, Mr. Crane, the staff "is passing judgment on a petition that the staff itself helped to write", and I did not "misspeak".

Mr. Crane is a lawyer. It is not surprising that he is thoroughly unfamiliar with the areas of nuclear medicine, nuclear pharmacy, and basic nuclear sciences, because he has never had any education, training, or experience in these fields. However, one may expect certain professional behavior from a lawyer. For openers, one would expect him to read the obvious background material on a case, so that he would be aware of the facts. It is well known that I do not deprive the NRC of my opinions on subjects involving my expertise, and a short search on Mr. Crane's part would surely have yielded the facts he so desperately lacked. Although he would not have understood my calculations, he could have asked an expert for some help. He could even have called me! He would, however, have been expected to understand the English. It is not acceptable professional behavior for an NRC lawyer to attempt to deceive NRC about the opinions of an NRC advisor and consultant, refuse to even bother with the facts, and expect NRC licensees to continue to support him with User Fees. I object to his continued employment at NRC.

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uninformed nuclear hysteria from any source. NRC's independent status insures it does not have to honor outside opinion flawed by ignorance. One would hope NRC would not have to honor inside opinion flawed by ignorance, either.

Mr. Crane asks NRC to regard him somehow as a knowledgeable professional on the subject of I-131 for thyroid cancer, based on his personal experience with the disease. Having read Mr. Crane's present missive, and a previous related document at the time the Commission signed the scientifically insupportable "Quality Management" thing, let me assure you, as a knowledgeable professional on the subject of I-131 for thyroid cancer, that Mr. Crane is well-qualified to be a patient, and nothing more. For example, if Mr. Crane really had a partial thyroidectomy in 1973 and then 2 doses of 29.9 mCi each 10 and 11 years later to ablate the remnant, it is no wonder he had recurrences, and it is surprising he isn't in malpractice court. Knowing the excellence of NIH, however, I would tend to doubt the validity of his account.

As far as his story about his confinements, let me explain that one does not need "thick paper" on the floor, only absorbent material with a plastic backing. As far as "smelling strongly of seaweed", this is pure confabulation. In the first place we do not give iodine, we give iodide. Iodide does not smell like seaweed. Second, the mass of 150 mCi of I-131 is $(150)(131)(8)(24)(60)(60)(8.87 \times 10^{-17}) = 1.2$ micrograms. Normal stool contains 10-50 micrograms per day. The average person contains 30,000 micrograms of the element iodine, and another microgram or so, even if converted to a volatile form, should not make his deodorant fail. Mr. Crane's story about his contaminated computer case is indeed a physics first.

"....radiation from stray drops of urine had probably penetrated the thick concrete walls of the bathroom and reached the case. A month later, the case had cooled down to the point that I could collect it from Radiation Safety." Quick, Mr. Bernero! We need at least three contracts to starving DOE labs to understand this new phenomenon. "Beta creep"? Good God! Have all our shielding calculations been for nought all these years? My Uncle Joe Fertik, who designed the 14 foot concrete vault around the very first Oak Ridge reactor after W.W. II, died last year at 94, and never knew. If a gamma ray sneaked through and hit the case it should last no more than about a picosecond at most. A month? Wow!

Mr. Crane makes some other interesting statements, quoting such incontrovertibly superb scientific sources as the New York Times

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In addition to being of no value as a nuclear expert, he is, in my opinion, behaving in an unacceptable manner for a lawyer.

Thank you for the opportunity to comment on this most informative comment letter.

Sincerely,



Carol S. Marcus, Ph.D., M.D.
Director, Nuclear Med. Outpt. Clinic
and
Assoc. Prof. of Radiological Sciences
UCLA

cc: Peter Crane
Commissioner Ivan Selin
Commissioner Gail de Planque
Commissioner Forrest Remick
Commissioner Kenneth Rogers
Commissioner James Curtiss
Hugh Thompson, Deputy EDO
Robert Bernero
Richard Cunningham
John Glenn, Ph.D.
William Parler, Chief Counsel
Joan McKeown
Peter Almond, Ph.D.
Ted Webster, Ph.D.
Gerald Pohost, M.D.
Judy Brown
Curtis Scribner, M.D.
Steve Collins
Barry Siegel, M.D.
Mel Griem, M.D.
Dan Flynn, M.D.
Capt. Wm. Briner
Mark Rotman
Myron Pollycove, M.D.

CSM:sfd

Appendix C




STATE OF WASHINGTON
DEPARTMENT OF HEALTH
OFFICE OF RADIATION PROTECTION
111 Israel Road SE • PO Box 47827 • Olympia, Washington 98504-7827
TDD Relay Services: 1-800-833-6388

INFORMATION NOTICE

March 26, 2009

TO: All Medical Licensees Authorized Therapeutic Use of Iodine-131

FROM: C. DeMaris 
Medical Licensing

SUBJECT: Release of Therapy Patients Administered Iodine-131

[Please discourage the use of hotels following treatment. It has recently been brought to our attention that Regulatory Guide 8.39 does not specifically reference where a patient should reside when released after a therapeutic dose of Iodine-131. It is presumed that most, if not all, patients go home although there is nothing in the Guide preventing a patient from using a hotel.

A specific public complaint has been raised that a patient using a hotel immediately following release could, under certain circumstances, present an unnecessary risk of exposure to others, especially infants and children. We believe the concern is consistent with the International Commission on Radiological Protection's Publication 94, *Release of Patients after Therapy with Unsealed Radionuclides*. This publication cautions that particular care should be taken to avoid the contamination of infants and children from patients treated with radioiodine.

At present, it is our understanding that you neither advise nor encourage the use of a hotel. Nevertheless, we believe it is prudent to eliminate this potential.

We recommend that you actively discourage patient use of hotels immediately after release.

This notice requires no specific response from you. If you have any questions, I can be reached at 360-236-3223.

Thank you for your time and cooperation.

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

Medical Isotope Shortage: the Molybdenum (Mo-99) Crisis

Advisory Committee for the Medical Use of
 Isotopes: May 24-25, 2010
 Steve Mattmuller, MS, RPh, BCNP

U.S.NRC **Need: Patient Care**
 UNITED STATES NUCLEAR REGULATORY COMMISSION
Protecting People and the Environment

U.S.NRC **Fragile Mo-99 Supply**
 UNITED STATES NUCLEAR REGULATORY COMMISSION
Protecting People and the Environment

U.S.NRC **Effect on Patients**
 UNITED STATES NUCLEAR REGULATORY COMMISSION
Protecting People and the Environment

March 29, 2010 **COVIDIEN**

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

- Generator standing orders met with some extra, minimal Tc 99m LD impact
- Majority of generator standing orders met but no extra, some Tc 99m LD impact
- Generator standing order shortage resulting in size reductions, Tc 99m shortages and LD impact
- Significant shortage in generator standing orders, severe Tc 99m shortage and LD impact
- No Mo-99 supply expected. Generator production canceled.
- Special procedures in place due to timing of Mo-99 supply.

U.S.NRC **Effect on Patients**
 UNITED STATES NUCLEAR REGULATORY COMMISSION
Protecting People and the Environment

U.S.NRC **Effect on Patients**
 UNITED STATES NUCLEAR REGULATORY COMMISSION
Protecting People and the Environment

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15	16	17	18	19	20	21	22	23	24	25	26	27	28
29	30						31						

- Standing orders met with some extra, minimal Tc 99m LD impact
- Generator standing orders met but no extra, some Tc 99m LD impact
- Significant shortage in generator standing orders, severe Tc 99m shortage and LD impact
- Significant shortage in generator standing orders, severe Tc 99m shortage and LD impact
- No Mo-99 supply expected. Generator production canceled.
- Special procedures in place due to timing of Mo-99 supply.

Additional lost days due to the volcano in Iceland

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Effect on Patients

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

- inferior in accuracy
- may be more expensive
- may have a higher radiation dose

7

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Minimize Effect on Patients

Coordinate with the generator provider or the central radiopharmacy to align scheduled patients with Technetium-Tc99m (Tc-99m) availability.

- Perform imaging studies throughout the entire week. Generators produce Tc-99m over weekends

8

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Minimize Effect on Patients

9

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Minimize Effect on Patients

Coordinate with the generator provider or the central radiopharmacy to align scheduled patients with Technetium-Tc99m (Tc-99m) availability.

- Perform imaging studies throughout the entire week. Generators produce Tc-99m over weekends.
- Lower the administered dose and extend the time of imaging in order to continue to collect images with the same statistical robustness.

10

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Minimize Effect on Patients

Where possible, use an alternative procedure or radiopharmaceutical for imaging studies, including

- Myocardial perfusion imaging with:
 - Tc-99m Single photon emission computed tomography (SPECT) stress-only imaging when appropriate
 - Rubidium-82 (Rb-82) Positron Emission Tomography (PET)
 - Coronary Angiography (CA)
 - Stress echocardiography

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Minimize Effect on Patients

Where possible, use alternative radiopharmaceuticals for imaging studies, including

- Myocardial perfusion imaging with:
 - Thallium-201 (Tl-201) Single photon emission tomography (SPECT)
- Challenges of Tl-201 SPECT
 - Similar sensitivity, but worse specificity
 - Radiation dosimetry limits amount administered

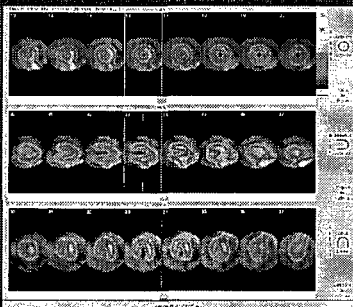
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Minimize Effect on Patients

Challenges of Tl-201 SPECT:

- Unable to perform wall motion and ejection fraction component of the study



SNM

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 Promoting People and the Environment

Minimize Effect on Patients

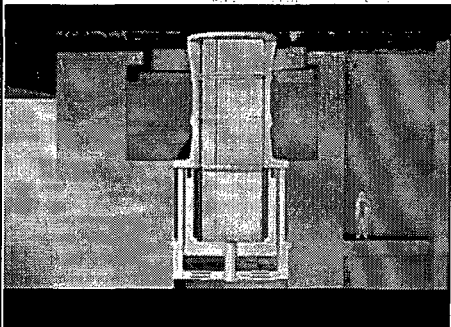
Where possible, use alternative radiopharmaceuticals for imaging studies, including

- Thyroid scintigraphy with Iodine-123 (I-123)
- Bone imaging with Fluorine-18 (F-18) Sodium Fluoride

SNM

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Reactor Repair 101: National Research Universal (NRU)



SNM

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Reactor Repair 101: NRU

New Video Update from David Cox: Summary of weld rep...



SNM

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Reactor Repair 101: NRU

New Video Update from David Cox: Summary of weld rep...



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Reactor Repair 101: NRU

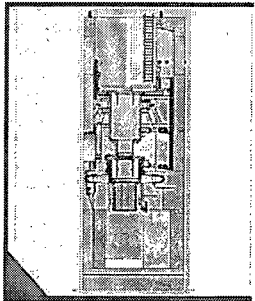
New Video Update from David Cox, NRU Return to Service Project D.



SNM

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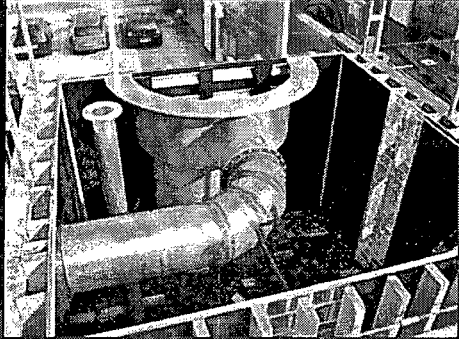
**Reactor Repair 101:
High Flux Reactor (HFR)**



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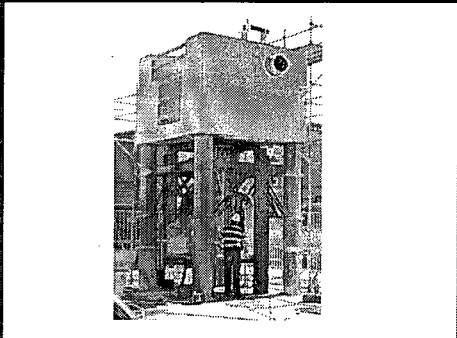
Reactor Repair 101: HFR



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Reactor Repair 101: HFR



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Reactor Repair 101: HFR



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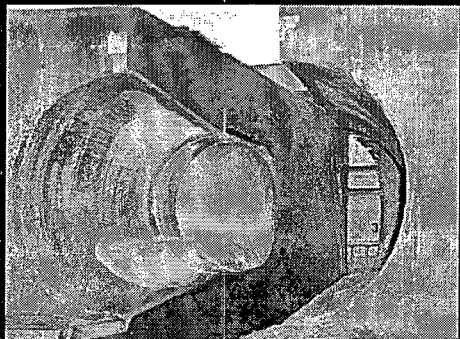
Reactor Repair 101: HFR



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Reactor Repair 101: HFR



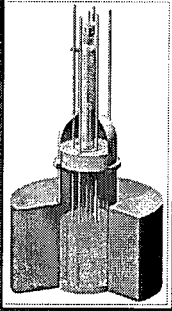
24

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Long Term Solution

Babcock & Wilcox (B&W) Covidien Aqueous Homogeneous Reactor

- Low enriched uranium (LEU) uranyl nitrate solution
- 200 kW reactor, modular
- Large negative coefficient of reactivity
- Received \$9.1 million (matching) grant from Department of Energy (DOE)

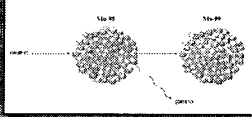


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Long Term Solution

General Electric (GE) Hitachi



- LEU, neutron activation process
- Molybdenum-98 (Mo-98); irradiation could be done in research or commercial reactor
- Mo-99 column will be in gel state
- GE-Hitachi/Excelon Cobalt-60 (Co-60) Pilot Project

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Long Term Solution

House of Representatives (H.R.) 3276: American Medical Isotopes Production Act of 2009

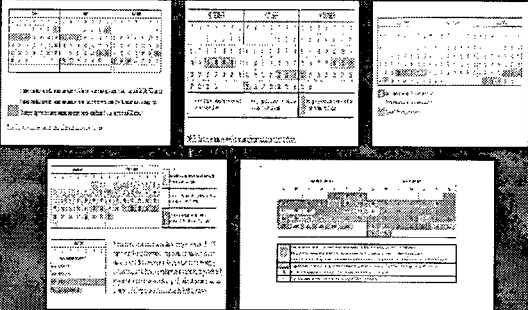
- Convert reactors to LEU for Mo-99 production
- Provide \$163 million for domestic isotope production capability
- **LEU and radioactive waste take-back provision**

MURR Missouri University Research Reactor

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Mo-99 Crisis: A year in review and future...



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Domestic Production of Molybdenum-99

Mary Jane Ross-Lee

May 24, 2010
Advisory Committee on the Medical Uses of Isotopes


NRC Mission

- To license and regulate the Nation's civilian use of byproduct, source, and special nuclear materials in order to protect to public health and safety, promote the common defense and security, and to protect the environment.




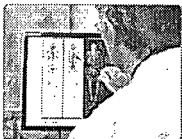


NRC's regulatory mission covers three main areas

- Reactors – Commercial and Research and Test reactors
- Materials - Uses of nuclear materials in medical, industrial and academic
- Waste --Transportation, storage, and disposal of materials and waste




Molybdenum-99/Technicium-99m

<http://nrc.nrc.gov/ohrtoc/10/09/09moly99and99m.pdf>

Picture Today

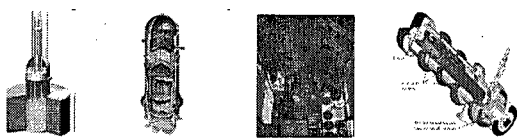
- Canada (53yrs): ~40%; Shutdown May 2009
- Petten (49 yrs): ~30%; Shutdown Feb. 2010
- South Africa, Belgium, France: ~30%
- No Domestic Producers
- Poland: Feb. 2010 agreement to irradiate Petten targets



Canada / Netherlands
 Belgium, France, So. Africa

NNSA Proposed Technologies

- Liquid Solution Reactor [Aqueous Homogeneous Reactor (AHR)]
- Neutron Capture (Natural Moly Irradiation)
- Low Enriched Uranium (LEU) Conventional Targets [Research & Test Reactor (RTR)]
- Accelerator Driven Fission



NRC – where we stand

- Internal Working Group
 - Meet regularly, represent multiple offices
- Interagency Working Group (Office of Science and Technology and Policy)
 - DOE, FDA, HHS, State, etc
 - Public Workshop - March 10, 2010



Letters of Intent

- B&W [Liquid Solution Reactors (AHR)]
- GE Hitachi (Neutron Capture)
- Coqui Radio Pharmaceuticals (RTR)
- Missouri University Research Reactor (MURR) (RTR)
- Advanced Medical Isotope Corporation (AMIC) (Accelerator)
 - Has not submitted a Letter of Intent (LOI), but has requested regulatory feedback on a potential application.

B&W – Medical Isotope Production System (MIPS)

- Signed Cost-Sharing Cooperative Agreement with DOE/NNSA
- Los Alamos National Lab lead support
- INVAP Separation and Purification R&D
- 2-Step Process for Single Part 50 License
- 4 Aqueous Homogeneous Reactors operating at 220kW each

B&W's Aggressive Schedule

- April 2010 – Submit Quality Assurance Program
- June 2010 – Submit Environmental Report
- Dec. 2010 – Submit Construction Application [Preliminary Safety Analysis Report (SAR)]
- Dec. 2011 – Expected Construction Permit
- March 2012 – Submit Operating License Application (Final SAR)
- Sept. 2013 – Expected Operating License
- Dec. 2013 – Begin Production

GE Hitachi Neutron Capture

- Signed Cost-Sharing Cooperative Agreement with DOE/NNSA
- Natural Molybdenum Irradiation
 - In existing reactors
- Shipping Package Application
 - Additional cask shipment request received
- Production Facility License Application
 - GE will support a company to construct the facility

GE-Hitachi Potential Schedule

- 2nd Quarter of 2010 – Shipping Package application submitted
- 2nd Half of 2010 – Processing Facility License Application
- FY 2011 – Reactor License Amendment

Coquí (Puerto Rico)

- Medical Molybdenum 99 Production Complex (MMPC)
- 2 non-power, pool type RTR's irradiating Low Enriched Uranium targets
- Single Processing Facility
- Schedule
 - As Early As Dec. 2010 – Construction and Operating License Application

MURR and AMIC

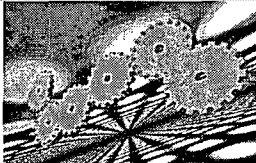
- MURR – existing RTR
 - LEU conventional target technology
 - Schedule unknown at this time
- AMIC – accelerator driven fission
 - Has submitted 2 letters concerning a potential application under Part 70
 - No schedule proposed

Regulatory Framework

- Part 50: Power and non-Power reactors, Production and Utilization Facilities
- Part 70: Special Nuclear Material (SNM)
- Part 30: Byproduct Material – NRC or Agreement States

NRC Path Forward

- Regulatory Framework
 - Existing one sufficient for licensing
- Experienced Staff
 - Agencywide Working group
- Supportive Management



Thank You




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U.S. Nuclear Regulatory Commission
Protecting People and the Environment




Multiple Medical Events Involving Prostate Brachytherapy Treatments at Department of Veterans Affairs Medical Center - Philadelphia

Patricia Pelke, Chief
Materials Licensing Branch
Division of Nuclear Materials Safety
NRC Region III
Advisory Committee on the Medical Uses of Isotopes
Meeting May 24, 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.

7



DVA Medical Event Criteria

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

8



97 Medical Events Reported to NRC

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

9



Causes of Medical Events

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

10



Causes of Medical Events

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

11



PVAMC Patient Care Actions

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

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NRC Response to Events

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

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NRC Response To Events

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

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NRC Response To Events

- Conducted inspections at other DVA facilities performing prostate implants
- Conducted inspections at NHPP
- Results of inspections at other DVA facilities performing prostate implants and at NHPP will be issued in one report due late May 2010

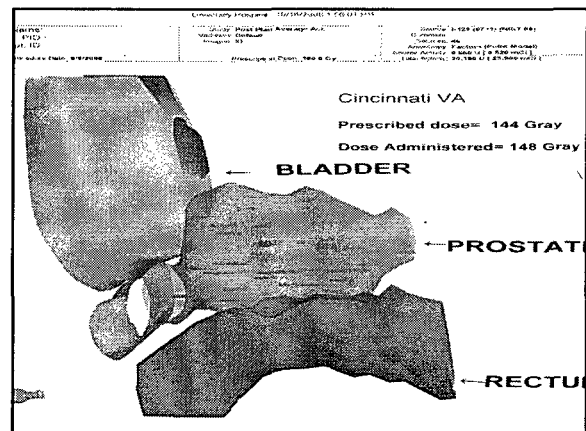
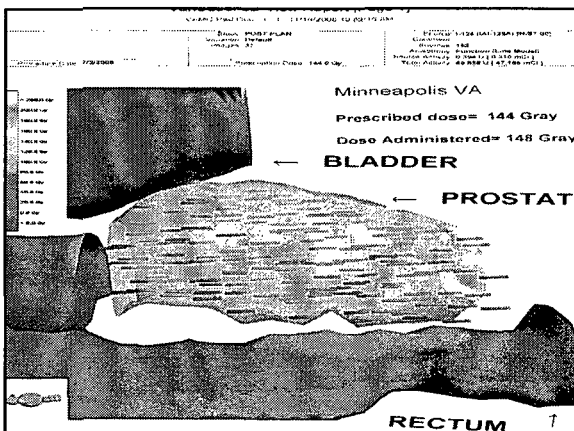
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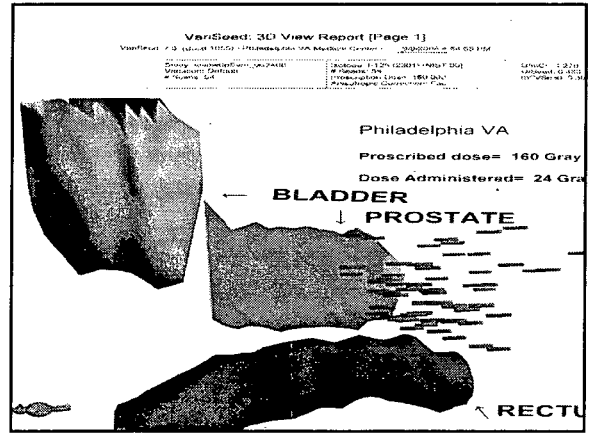
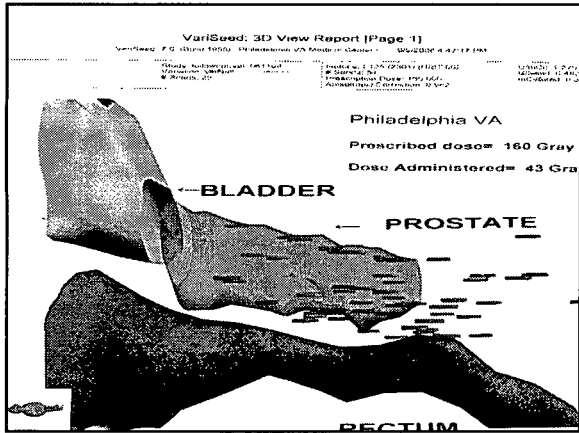
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NRC Actions Going Forward

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

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ACMUI Permanent Implant Brachytherapy Subcommittee May 2010

James Welsh
Debbie Gilley, Susan Langhorst,
Bruce Thomadsen, Darrell Fisher



Charge

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



Subcommittee Findings:

- The 2008 report of the ACMUI Permanent Implant Brachytherapy Rulemaking Subcommittee remains generally valid
- The Medical Events within the Department of Veterans Affairs involving permanent prostate brachytherapy do not alter the previous Subcommittee recommendations significantly
 - In fact, they appear to confirm the validity of that report



10 CFR 35.3045(a)(2)(ii)

- It is suggested that the modern concepts of Gross Target Volume (GTV), Clinical Target Volume (CTV) and Planning Target Volume (PTV) be incorporated into the definition of "treatment site" in § 35.3045(a)(2)(ii) and any new rules as described in the 2008 Subcommittee report
 - Failure to do so can lead to an excess of medically acceptable implants being labeled as medical events



Subcommittee Findings:

- Sections that were reviewed with greater scrutiny:
 - 10 CFR 35.3045(a)(1)
 - § 35.3045(a)(2)(v)
 - § 35.3045(a)(2)(iv)



10 CFR 35.3045(a)(1)

- "A dose that differs from the prescribed dose or dose that would have resulted from the prescribed dosage by more than 0.05 Sv (5 rem) effective dose equivalent, 0.5 Sv (50 rem) to an organ or tissue, or 0.5 Sv (50 rem) shallow dose equivalent to the skin; **and**
 - (A) The total dose delivered differs from the prescribed dose by 20 percent or more;
 - (B) The total dosage delivered differs from the prescribed dosage by 20 percent or more or falls outside the prescribed dosage range; or
 - (C) The fractionated dose delivered differs from the prescribed dose, for a single fraction, by 50 percent or more."

10 CFR 35.3045(a)(1)

- This section does not include permanent implant brachytherapy
- It includes a Boolean “and” with the subsequent (A), (B) and (C) being appropriate
- No changes suggested

7

10 CFR 35.3045(a)(2)(v)

- For cases in which a dose exceeds 0.05 Sv (5 rem) effective dose equivalent, 0.5 Sv (50 rem) to an organ or tissue, or 0.5 Sv (50 rem) shallow dose equivalent to the skin as a result of:
 - administration of the wrong isotope
 - the wrong route of administration or mode of treatment
 - a leaking source or
 - administration to the wrong patient
- The Subcommittee feels that classification as a medical event remains perfectly valid in these cases (i.e. the proposed § 35.3045(a)(2)(v) remains appropriate)

8

10 CFR 35.3045(a)(2)(iv)

- This does deal with permanent implants and reads:
 - “A dose to the skin or an organ or tissue other than the treatment site exceeding by 0.5 Sv (50 rem) and by 50 percent or more the dose expected to that site if the administration had been carried out as specified in the preimplantation written directive.”

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10CFR 35.3045(a)(2)(iv)

- The subcommittee would like to reconsider the 0.5 Sv and 50% dose differences here
- These minor discrepancies may be quite possible *when one is considering organs that are expected to get very low doses*
 - Yet are medically inconsequential
- Also there is no volume or area specified here, which can lead to further confusion
- It may be best to drop this part of the medical event definition

10

Will one rule fit all?

- Some of the newer permanent brachytherapy procedures could be medically acceptable
 - (i.e. effective cancer treatments and with minimal adverse effects)
- But because of the wording in § 35.3045(a)(2)(ii) might still wind up as Medical Events.

11

Will one rule fit all?

- 10CFR 35.3045(a)(2)(ii) suggested changes made in 2008:
- “The total source strength implanted outside the treatment site (including the gross tumor, the clinical target volume plus a variable planning margin as defined by the Authorized User) exceeding 20 percent of the total source strength documented in the written directive”

12



Will one rule fit all?

- 10CFR 35.3045(a)(2)(ii)
- Change dose or activity to "source strength"
- This *might* overcome some of the issues that could arise with newer brachytherapy procedures such as lung permanent implants via sewn in meshes.

13



Will one rule fit all?

- It may be that despite such wording changes some medically acceptable permanent brachytherapy procedures being inappropriately classified as Medical Events
- Thus, there was discussion about the possibility about creating a separation of
 - Prostate permanent implant brachytherapy
 - Others (i.e. non-prostate)

14



NRC Efforts to Develop a Safety Culture Policy

Debbie Bray Gilley
 Agreement State Representative to the
 Advisory Committee on the Medical Uses of
 Isotopes
 May 25, 2010



Commission Guidance

- The safety culture policy statement should:
 - Expand the NRC's policy of safety culture to address the unique aspects of security, and
 - Ensure the resulting policy is applicable to all licensees and certificate holders



Activities

- Published draft policy statement in *Federal Register* for public comment (November 6, 2009)
 - Comment period closed March 1, 2010
- Safety culture workshop (February 2-4, 2010)
 - Develop common terminology
 - Safety culture definition and safety culture traits
 - Comments on the draft policy statement



Draft Safety Culture Policy Statement

Safety Culture is 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.



Workshop Results

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.



ACMUI Guidance in the Process

- Provide comments to the NRC concerning efforts to increase the attention given to safety culture by medical licensees
- Provide guidance on what activities could NRC or agreement states support that could improve or enhance the safety culture concept at medical facilities?
- Identify if the board accreditation process should include safety culture training?
- Identify other activities that could enhance safety culture in medical facilities such as:
 - Work Practices
 - Work Planning and Control
 - Continuous Learning Environment
 - Effective Safety Communication
 - Others?

Thanks to James Firth of NRC for assistance in preparing this information.

Closed—10:30 a.m.–12 p.m. Management topics and status of data; analysis;
 Open—1 p.m.–2:30 p.m. Tour and facilities maintenance;
 Closed—2:30 p.m.–6:30 p.m. Cybersecurity, EPO, LSC status and Executive Session.

Wednesday, December 2, 2009

Closed—8:30 a.m.–12 p.m. Project overview and Project Management status;
 Closed—1:30 p.m.–6 p.m. Technical Progress, Development, R&D support.

Executive Session

Thursday, December 3, 2009

Closed—8:30 a.m.–12 p.m. Executive Session, report writing, Close Out report.

Reason for Closing: The proposal contains proprietary or confidential material including technical information; financial data, such as salaries; and personal information concerning individuals associated with the proposals. These matters are exempt under 5 U.S.C. 552b(c) and (6) of the Government in the Sunshine Act.

Dated: November 3, 2009.

Susanne Bolton,

Committee Management Officer.

[FR Doc. E9-26784 Filed 11-5-09; 8:45 am]

BILLING CODE 7555-01-P

NUCLEAR REGULATORY COMMISSION

[NRC-2009-0485]

Draft Safety Culture Policy Statement: Request for Public Comments

AGENCY: Nuclear Regulatory Commission (NRC).

ACTION: Issuance of draft safety culture policy statement and notice of opportunity for public comment.

DATES: Comments are requested 90 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 able to assure consideration only for comments received on or before this date. Please refer to the **SUPPLEMENTARY INFORMATION** section for additional information including 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-2009-0485 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 website 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.

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-2009-0485. Address questions about NRC dockets to Carol Gallagher 301-492-3668; e-mail Carol.Gallagher@nrc.gov.

Mail comments to: Michael T. Lesar, Chief, Rulemaking and Directives Branch (RDB), 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 RDB at (301) 492-3446.

FOR FURTHER INFORMATION CONTACT:

Alexander Sapountzis, Office of Enforcement, Mail Stop O-4 A15A, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, or by e-mail to Alexander.Sapountzis@nrc.gov.

SUMMARY: The NRC is issuing a draft policy statement that sets forth the Commission's expectation that all licensees and certificate holders¹ 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 Commission 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 issues² receive the attention warranted by their significance. The Commission also considers nuclear safety and security issues to be equally important in a positive safety culture. The importance of treating safety and security in an equal manner within

¹ Throughout this document, the phrase "licensee and certificate holders" includes 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.

² Throughout this document, the terms "safety" or "nuclear safety," "security" or "nuclear security," and "safety culture" are used. These terms refer to matters that are related to NRC-regulated activities, including radiation protection, safeguards, material control and accounting, physical protection, and emergency preparedness.

NRC's regulatory framework is clearly evident in our mission and strategic goals. Experience has shown that certain organizational characteristics and personnel attitudes and behaviors are present in a positive safety culture. These include, but are not limited to, individuals demonstrating ownership and personal responsibility for maintaining safety and security in their day-to-day work activities; the implementation of processes for planning and controlling work activities such that safety and security are maintained; a work environment in which personnel feel free to raise safety and security concerns without fear of retaliation; prompt and thorough identification, evaluation, and resolution of nuclear safety and security issues commensurate with their significance; the availability of the resources needed to ensure that safety and security are maintained; decision-making processes that protect safety and security; clearly defined roles and responsibilities for maintaining safety and security; and the seeking out and implementation of opportunities to improve safety and security. The NRC expects its licensees and certificate holders to foster these characteristics, attitudes, and behaviors in their organizations and among individuals who are overseeing or performing regulated activities commensurate with the safety and security significance of their activities and the nature and complexity of their organization and functions.

The NRC is requesting comments on the draft safety culture policy statement and associated questions.

SUPPLEMENTARY INFORMATION:

(1) Background

The Commission has long expressed its expectations for safety culture in previous policy statements. In 1989, the Commission published its "Policy Statement on the Conduct of Nuclear Power Plant Operations" (54 FR 3424; January 24, 1989) to make clear the Commission's expectations of utility management and licensed operators with respect to the conduct of operations. The policy statement stated, "the phrase safety culture refers to a very general matter, the personal dedication and accountability of all individuals engaged in any activity which has a bearing on the safety of nuclear power plants." The policy statement further stated that the Commission issued the policy statement to help foster the development and maintenance of a safety culture at every facility licensed by the NRC.

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 will establish and maintain safety-conscious 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 applied to NRC-regulated activities of all licensees and their contractors and subcontractors. A safety conscious work environment is an important attribute of safety culture and is one of the safety culture characteristics in the draft safety culture policy statement.

The importance of a positive safety culture for activities involving civilian uses of radioactive materials and other potential hazards has been demonstrated by a number of significant, high-visibility events worldwide that have occurred in the 20-year period since the Commission published its 1989 policy statement addressing safety culture in nuclear power plants. The events occurred across multiple industries including at nuclear power plants, fuel cycle facilities, and in other industries such as chemical processing plants and aerospace. Examples of nuclear industry events include those that occurred at the Davis-Besse Nuclear Power Station and the Peach Bottom Atomic Power Station. Workers at the Davis-Besse Nuclear Power Station discovered a cavity in the reactor pressure vessel head caused by boric acid corrosion. The corrosion developed over a period of several years but was not discovered before the cavity developed. The licensee's analysis of the event identified weaknesses in the station's safety culture as the root cause of the event. It particularly noted that management prioritized "production over safety." At the Peach Bottom Atomic Power Station, personnel behaviors adverse to the security of the plant were identified, specifically, inattentiveness by security officers.

Other licensees have had recurring problems resulting in violations of NRC regulations. Through a Commission confirmatory order, a fuel cycle facility licensee committed to having a third-party assessment of its safety culture to determine the causes of its continuing problems in order to establish appropriate corrective actions. The third-party assessment identified weaknesses in areas important to safety culture. In addition, weaknesses in the safety culture of licensees and certificate holders have contributed to

unscheduled events or incidents that the Commission has determined to be significant from the standpoint of public health and safety. Examples linked to characteristics and attitudes in organizations and individuals associated with weak safety cultures include inadequate procedures; procedures not being followed; inadequate supervision; decision-making that does not ensure that safety and security are maintained; and ineffective problem identification, evaluation, and resolution. They have included medical misadministrations (such as giving iodine-131 to lactating females that resulted in the uptake by their infants and multiple events associated with prostate brachytherapy treatment) and overexposures arising from the loss of control of radiography or well logging sources.

(2) Statement of Policy

It is the Commission's policy that a strong safety culture is an essential element for individuals, both internal to the NRC and external, performing or overseeing regulated activities. As such, the NRC will include appropriate means to monitor safety culture in its oversight programs and internal management processes. The NRC 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. Further, it is important for all organizations to provide personnel in the safety and security sectors with 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 safety or security. A safety culture that accomplishes this would include all nuclear safety and security issues associated with NRC-regulated activities including radiation protection, safeguards, material control and accounting, physical protection, and emergency preparedness issues among the issues that receive attention as a matter of priority.

The Commission's regulations are designed to protect both the public and workers against radiation hazards from the use of radioactive materials. The Commission's scope of responsibility includes regulation of commercial nuclear power plants; research, test, and training reactors; nuclear fuel cycle facilities; medical, academic, and

industrial uses of radioactive materials; and the transport, storage, and disposal of radioactive materials and wastes. The Commission carries out these responsibilities in numerous ways including through such regulatory activities as inspecting licensed and certified facilities and activities; collecting, analyzing, and disseminating information about operational safety and security; investigating nuclear incidents; and developing policy and providing direction on safety and security issues.

The Commission believes that, because licensees and certificate holders use or provide services related to the use of radioactive material, they bear the primary responsibility for safely handling and securing these materials. It is, therefore, each licensee's and certificate holder's responsibility to develop and maintain a positive safety culture which establishes that nuclear safety issues and nuclear security issues, as an overriding priority, receive the attention warranted by their significance. Therefore, licensees and certificate holders should foster a positive safety culture in their organizations and among individuals who are overseeing or performing regulated activities. However, as the regulatory agency, the Commission has an independent oversight role (through inspection and assessment processes) including addressing licensees' and certificate holders' performance related to areas important to safety culture.

(3) Safety Culture Concept

In 1991, as a result of the 1986 Chernobyl accident, the International Nuclear Safety Group (INSAG) emphasized the concept of safety culture for the nuclear industry in its report, INSAG-4, "Safety Culture." INSAG is an advisory group to the International Atomic Energy Agency (IAEA). The INSAG-4 definition of safety culture is, "that assembly of characteristics and attitudes in organizations and individuals which establishes that, as an overriding priority, nuclear plant safety issues receive the attention warranted by their significance."

Implied in the INSAG definition of safety culture is the recognition that every organization is continually faced with resolving conflicts among its goals for cost, schedule, and quality (or safety). The organization's members (groups and individuals) also face conflicts among different goals in performing their jobs. Management establishes the framework (management systems, programs, processes) and communicates its priorities for resolving

conflicts among different goals. Members of the organization work within that framework and are influenced by management's priorities, but they have their own beliefs and attitudes about what is important and make individual choices on how to proceed when faced with multiple competing goals. The INSAG definition emphasizes that in a positive safety culture, the goal of maintaining nuclear safety receives the highest priority in the organization's and individuals' decision-making and actions when faced with a conflict with other organizational or individual goals.

The Commission modified the INSAG definition of safety culture which refers to "nuclear plant safety." The Commission is strongly committed to promoting positive safety cultures among its nuclear reactor licensees; however, the Commission regulates many other organizations and processes involving civilian uses of radioactive materials. These regulated activities include industrial radiography services; hospitals, clinics and individual practitioners involved in medical uses of radioactive materials; research and test reactors; large-scale fuel fabrication facilities; as well as nuclear power plants. The Commission also regulates the construction of new facilities where operations will involve radioactive materials with the potential to affect public health and safety and the common defense and security. Therefore, by revising the INSAG definition of safety culture to replace "nuclear plant safety" with "nuclear safety," the Commission is emphasizing that it expects all of its licensees and certificate holders to place the highest priority on nuclear safety commensurate with the risks inherent in the regulated activities.

The Commission also modified the INSAG definition to adequately capture or communicate the equal importance of nuclear security and nuclear safety in a positive safety culture. Following the terrorist attacks of September 11, 2001, the Commission increased its attention to the important role of security in regulated facilities whose operations can have an impact on public health and safety. The Commission issued orders enhancing security at its NRC-regulated facilities to further ensure public health and safety and the common defense and security. One of the insights gained from the greater emphasis on security is the importance of incorporating security considerations into a safety culture and effectively managing the safety and security interface. In general, the safety and security interface refers to the

organizational and individual awareness that the functions and goals of safety and security must be considered together so that actions to achieve either set of functions and goals do not inadvertently compromise the other. Therefore, to emphasize the equal importance of nuclear security and nuclear safety in a positive safety culture, the Commission has added "nuclear security" to the safety culture definition. The NRC's modified INSAG definition is provided in the Statement of Policy section above.

(4) Stakeholder Outreach

The Commission's February 28, 2009, Staff Requirements Memorandum (SRM)-COMGBJ-08-0001, "A Commission Policy Statement on Safety Culture," (ML080560476) stated in part that the staff should, as part of its public stakeholder outreach, reach out to all types of licensees and certificate holders. In the development of the draft policy statement, the NRC staff sought insights and feedback from stakeholders. This was accomplished by providing information in a variety of forums such as stakeholder organization meetings, newsletters, and teleconferences and by publishing questions in **Federal Register** Notices entitled "Safety Culture Policy Statement: Public Meeting and Request for Public Comments" (ML090260709) that were related to the Commission's SRM. In addition, a significant stakeholder outreach activity was accomplished by a public workshop held on February 3, 2009, at NRC Headquarters in Rockville, Maryland. The staff reviewed and considered the stakeholder feedback derived from these different forums and incorporated it into the development of the draft policy statement and recommendations.

(5) Safety and Security Culture

In SRM-COMGJB-08-0001, the Commission also considered whether publishing the NRC's expectations for safety and 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 interface.

Based on a variety of sources including document reviews and stakeholder feedback, the Commission concluded there is no one definitive view of this issue, but the results weighed heavily toward a single policy statement to be titled a "Safety Culture Policy Statement." Document reviews and stakeholder feedback suggested that a single policy statement (1) builds on the fact that safety and security have the

same ultimate purpose of protecting people and the environment from unintended radiation exposure and (2) encourages attention to the ways safety and security interface. For these reasons, the Commission determined that the term "safety culture" should include both safety and security.

Safety and security have been the primary pillars of NRC's regulatory programs. However, in the current heightened threat environment, there has been a renewed focus on security, and the staff has implemented a number of efforts to enhance security and strengthen the safety and security interface. It is important to understand that both safety and security share a common purpose of protecting public health and safety. In today's environment, safety and security activities are closely intertwined, and it is critical that consideration of these activities be integrated so as to complement each other and not diminish or adversely impact either safety or security. Further, it is important for licensees and certificate holders to provide personnel in the safety and security sectors with an appreciation for the importance of each, emphasizing the need for integration and balance to achieve optimized protection. The importance of both safety and security in an equal and balanced manner within NRC's regulatory framework is clearly evident in the Commission's mission and strategic goals.

While many safety and security activities complement each other or are synergistic, there remain areas where potential conflicts may arise. It is then imperative that mechanisms be established to resolve these potential conflicts to assure the adequate protection of public health and safety and promote the common defense and security. Hence, safety and security have implications for each other in connection with all aspects of nuclear activities.

One potential challenge is the way in which individuals involved in safety and security activities approach the goal of risk mitigation and protection of public health and safety. The safety staff is typically focused on preventing errors that would result in an inadvertent accident while the security staff is focused on preventing deliberate attacks or diversion of certain materials that could cause harm. Another challenge is that the organization/facility must ensure that the existence of motivated and capable persons with ill intent is recognized and that the importance of nuclear security to prevent such persons from unauthorized access is understood.

To manage these potential conflicts of challenges, the Agency has recently issued regulations on the safety/security interface. An overarching safety culture policy statement which encompasses security supports and further enhances those regulations.

Based on the above considerations, the Commission concluded that a single policy statement would accomplish its goal that, as an overriding priority, safety issues and security issues receive the attention warranted by their significance. Although, in some cases, issues relating to security might be handled differently than issues related to safety. A single policy statement recognizes there is one overarching culture in an organization; however, safety and security functions and goals must be treated equally within that overarching safety culture.

(6) Characteristics of a Positive Safety Culture

Experience has shown that certain organizational attributes and personnel attitudes and behaviors are present in a positive safety culture. Therefore, in 2006, when the NRC implemented an enhanced reactor oversight process (ROP) that more fully addressed safety culture, it identified and incorporated safety culture components that are overarching characteristics of a positive safety culture. The NRC based its development of the safety culture components on a review of a variety of sources of information including the Institute of Nuclear Power Operations; the IAEA; the Nuclear Energy Agency; the regulatory approaches of other domestic and international organizations; and the organizational behavior, safety culture, and safety climate research literature. The Commission presented drafts of the safety culture components and aspects in frequent public meetings and modified them in response to stakeholder feedback.

For the purpose of this policy statement, the NRC modified the ROP safety culture components (termed "safety culture characteristics") to explicitly address security in the safety culture characteristics descriptions, create a more generic description for each safety culture characteristic that would apply to the range of NRC licensees and certificate holders, and maintain all the safety culture concepts in the safety culture components. The staff presented the draft safety culture characteristics for stakeholder comment in a February 3, 2009, public workshop and on the NRC's public safety culture Web site (<http://www.nrc.gov/about-nrc/>

[regulatory/enforcement/safety-culture.html](#)).

Although the safety culture characteristics themselves are applicable to all licensees and certificate holders, there may be other examples that more specifically address the unique characteristics of a licensee's or certificate holder's environment (i.e., unique for medical and industrial applications, operating reactors, research and test reactors, fuel cycle facilities, and new reactor construction environments). Hence, the Commission recognizes that these safety culture characteristics are not all inclusive; other characteristics and attitudes in organizations and individuals may be indicative of a positive safety culture. However, the Commission expects its licensees and certificate holders to consider the extent to which these characteristics and attitudes are present in their organizations and among individuals who are overseeing or performing regulated activities and to take steps, if necessary, to foster a positive safety culture commensurate with the safety and security significance of activities and the nature and complexity of the licensee's or certificate holder's organization and functions.

The following characteristics that are indicative of a positive safety culture, are relevant across the broad range of activities carried out by the nuclear industry, the Agreement States and the NRC, and address the importance of nuclear safety and security:

- Personnel demonstrate ownership for nuclear safety and security in their day-to-day work activities by, for example, ensuring that their day-to-day work activities and products meet professional standards commensurate with the potential impacts of their work on safety and security. They proceed with caution when making safety- or security-related decisions and question their assumptions, especially when faced with uncertain or unexpected conditions, to ensure that safety and security are maintained.
- Processes for planning and controlling work ensure that individual contributors, supervisors, and work groups communicate, coordinate, and execute their work activities in a manner that supports safety and security. For example, individuals and work groups communicate and cooperate during work projects and activities to ensure their actions do not interact with those of others to adversely affect safety or security. In addition, managers and supervisors are accessible to oversee work activities, including those of contractors or

vendors, and they challenge work activities and work products that do not meet their standards.

- The organization maintains a safety conscious work environment in which personnel feel free to raise safety and security concerns without fear of retaliation. For example, claims of harassment, intimidation, retaliation, and discrimination are investigated consistent with the regulations regarding employee protection. If an instance of harassment, intimidation, retaliation, or discrimination for raising a safety or security concern is identified, corrective actions are taken in a timely manner.

- The organization ensures that issues potentially impacting safety or security are promptly identified, fully evaluated, and promptly addressed and corrected, commensurate with their significance.

- The organization ensures that the personnel, equipment, tools, procedures, and other resources needed to assure safety and security are available. For example, training is developed and implemented or accessed to ensure personnel competence. Procedures, work instructions, design documentation, drawings, databases, and other job aids and reference materials are complete, accurate, and up-to-date.

- The organization's decisions ensure that safety and security are maintained. For example, production, cost, and schedule goals are developed, communicated, and implemented in a manner which demonstrates that safety and security are overriding priorities.

- Roles, responsibilities, and authorities for safety and security are clearly defined and reinforced. For example, personnel understand their roles and responsibilities in maintaining safety and security. Programs, processes, procedures, and organizational interfaces are clearly defined and implemented as designed. Leaders at all levels of the organization consistently demonstrate that safety and security are overriding priorities.

- The organization maintains a continuous learning environment in which opportunities to improve safety and security are sought out and implemented. For example, individuals are encouraged to develop and maintain current their professional and technical knowledge, skills, and abilities and to remain knowledgeable of industry standards and innovative practices. Personnel seek out and implement opportunities to improve safety and security performance.

(7) Implementation of Policy

This policy statement describes areas important to safety culture, but it does not address how the nuclear industry, the Agreement States, and the NRC should establish and maintain a positive safety culture in their organizations. The nuclear industry, the Agreement States, and the NRC differ in their size and complexity, infrastructure, and organizational frameworks. Therefore, a single approach for establishing and maintaining a positive safety culture is not possible. Nevertheless, the Commission expects that nuclear safety and security issues receive the attention warranted by their significance, and all organizations consider and foster the safety culture characteristics (commensurate with the safety and security significance of activities and the nature and complexity of their organization and functions) in carrying out their day-to-day work activities and decisions.

Questions for Which NRC Is Seeking Input

(1) The draft policy statement provides a description of areas important to safety culture, (i.e., safety culture characteristics). Are there any characteristics relevant to a particular type of licensee or certificate holder (if so, please specify which type) that do not appear to be addressed?

(2) Are there safety culture characteristics as described in the draft policy statement that you believe do not contribute to safety culture and, therefore, should not be included?

(3) Regarding the understanding of what the Commission means by a "positive safety culture," would it help to include the safety culture characteristics in the Statement of Policy section in the policy statement?

(4) The draft policy statement includes the following definition of safety culture: "Safety culture is 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." Does this definition need further clarification to be useful?

(5) The draft policy statement states, "All licensees and certificate holders should consider and foster the safety culture characteristics (commensurate with the safety and security significance of activities and the nature and complexity of their organization and functions) in carrying out their day-to-day work activities and decisions." Given the diversity among the licensees

and certificate holders regulated by the NRC and the Agreement States, does this statement need further clarification?

(6) How well does the draft safety culture policy statement enhance licensees' and certificate holders' understanding of the NRC's expectations that they maintain a safety culture that includes issues related to security?

(7) In addition to issuing a safety culture policy statement, what might the NRC consider doing, or doing differently, to increase licensees' and certificate holders' attention to safety culture in the materials area?

(8) How can the NRC better involve stakeholders to address safety culture, including security, for all NRC and Agreement State licensees and certificate holders?

To ensure efficient consideration of your comments, please identify the specific question numbers with your comments when applicable. 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.

Dated at Rockville, Maryland, this 30th day of October 2009.

For the Nuclear Regulatory Commission.
Cynthia A. Carpenter,
Director, Office of Enforcement.
[FR Doc. E9-26816 Filed 11-5-09; 8:45 am]
BILLING CODE 7590-01-P

NUCLEAR REGULATORY COMMISSION

[NRC-2009-0192; Docket No. 50-244;
Renewed License No. DPR-18]

**In the Matter of EDF Development, Inc.;
Constellation Energy Nuclear Group,
LLC; R.E. Ginna Nuclear Power Plant,
LLC (R.E. Ginna Nuclear Power Plant);
Order Superseding Order of October 9,
2009, Approving Application
Regarding Proposed Corporate
Restructuring**

I

R.E. Ginna Nuclear Power Plant, LLC (Ginna, LLC or the licensee) is the holder of Renewed Facility Operating License No. DPR-18 which authorizes the possession, use, and operation of the R.E. Ginna Nuclear Power Plant (Ginna). The facility is located at the licensee's site in Ontario, New York. The operating license authorizes the licensee to possess, use, and operate Ginna.

II

By letter dated January 22, 2009, as supplemented on February 26, April 8, June 25, July 27, October 15, October 19, October 25 (two letters), October 26, and October 28, 2009 (together, the Application), Constellation Energy Nuclear Group, LLC (CENG), on behalf of the licensee and EDF Development, Inc. (EDF Development) (together, the applicants), requested that the Nuclear Regulatory Commission (NRC, the Commission), pursuant to Title 10 of the Code of Federal Regulations (10 CFR) 50.80, consent to the indirect license transfers that would be effected by the indirect transfer of control of CENG's ownership and operating interests in Ginna. The actions being sought are a result of certain proposed corporate restructuring actions in connection with a planned investment by EDF Development whereby it would acquire a 49.99% ownership interest in CENG from Constellation Energy Group, Inc. (CEG), the current 100% owner of CENG. EDF Development is a U.S. corporation organized under the laws of the State of Delaware and a wholly-owned subsidiary of E.D.F. International S.A., a public limited company organized under the laws of France, which is in turn a wholly-owned subsidiary of Electricité de France S.A., a French limited company.

Following the closing of the transfer of ownership interests in CENG to EDF Development, EDF Development will hold a 49.99% ownership interest in CENG; CEG will hold a 50.01% ownership interest in CENG through two new intermediate parent companies, Constellation Nuclear, LLC and CE Nuclear, LLC, formed for non-operational purposes. In addition, Constellation Nuclear Power Plants, Inc., which is currently an intermediate holding company between CENG and Ginna, LLC and Nine Mile Point Nuclear Station, LLC, will convert to a Delaware limited liability company by operation of law and become Constellation Nuclear Power Plants, LLC, and will exist as an intermediate holding company between CENG and Ginna, LLC, Nine Mile Point Nuclear Station, LLC, and Calvert Cliffs Nuclear Power Plant, LLC by merger. No physical changes to the facilities or operational changes are being proposed in the application.

Approval of the transfer of the license is requested by the applicants pursuant to 10 CFR 50.80. Notice of the request for approval and opportunity for a hearing was published in the **Federal Register** on May 6, 2009 (74 FR 21013). No hearing requests or petitions to

March 12, 2010

MEMORANDUM TO: Roy P. Zimmerman, Director
Office of Enforcement

FROM: David Solorio, Chief /RA/
Concerns Resolution Branch
Office of Enforcement

SUBJECT: SUMMARY OF THE FEBRUARY 2-4, 2010, PUBLIC
MEETING BETWEEN THE U.S. NUCLEAR REGULATORY
COMMISSION AND STAKEHOLDERS REGARDING SAFETY
CULTURE POLICY STATEMENT, DEFINITION, AND
DESCRIPTION/TRAITS (ADAMS ACCESSION NUMBER
ML100700065)

On February 2-4, 2010, the United States Nuclear Regulatory Commission (NRC) hosted a public workshop. The purpose of this meeting was to meet with stakeholders to develop more common terminology for safety culture (SC) as outlined in the agenda (Attachment 1) for NRC regulated entities and included: (1) obtaining input regarding a high-level SC definition that could apply to all licensees/certificate holders; (2) obtaining input regarding description/traits of SC that could apply to all licensees/certificate holders; and (3) receiving comments on the draft SC policy statement that was published in the *Federal Register* Notice (FRN) for public comment until March 1, 2010 (75 FR 1656; 74 FR 57525). The SC definition and description and traits developed from the workshop will be used to inform the development of a final SC policy statement. The final SC policy statement will set forth the agency's expectations for fostering a strong SC for NRC regulated activities. The NRC will continue to work with Agreement States to reach alignment on common terminology and the consistent implementation of the SC policy.

Prior to the workshop, the staff reached out to a large number of NRC-regulated entities. The staff encouraged their participation in this workshop in order to benefit from consideration of a spectrum of views in the development of the SC definition, description and traits, as well as encourage these entities to comment on the SC policy statement. The staff's outreach activities included: (1) issuing a FRN (74 FR 66387) announcing the NRC plans for this workshop and soliciting nominations for panel members to participate in discussions to develop a SC definition and traits; and (2) contacting reactors, materials-industrial, materials-medical, material-fuel cycle, new reactor construction, vendors and suppliers and interested members of the public to encourage their participation in the workshop. In addition, the NRC solicited input from an external workshop planning committee, made up of various stakeholders (external to the NRC) that provided feedback to the NRC for conducting this workshop.

CONTACT: Alex Sapountzis, OE
301-415-7822

The structure of this workshop was fairly unique in that the NRC requested external stakeholders represent interest from a large spectrum of licensees/certificate holders regulated by the NRC. The NRC selected sixteen stakeholders (Attachment 3) from nominations it solicited through the FRN (74 FR 66387) to serve as panel members at the SC February 2-4, 2010, workshop. The workshop was structured so that it included several plenary and breakout sessions, where NRC regulated entities were organized into groups by affiliation and interest (Attachment 3). Panel members in the breakout and plenary sessions were given samples to consider when crafting a new SC definitions and traits. The panel members in the breakout and plenary sessions reviewed the samples and proposed new or revised definitions and traits, with frequent input provided by the attendees (i.e., individuals present in the audience, participating by teleconference, Webinar or web stream/teleconference). The breakout sessions reconvened into a plenary group to discuss the results from the breakout sessions and using various methods, the panel members first aligned on a single draft SC definition and then proceeded to discuss and align on SC traits (Attachment 5). In this workshop, the NRC used a technique generally referred to as the "Affinity Diagram" approach to collect and organize the large amounts of information submitted from panelist and attendees at the workshop related to the SC definition and traits through brainstorming. After performing this exercise, in which information is grouped by finding relationships in the content, solutions emerge, or in this case, a decision was reached by the group on a common definition of SC and traits that describe a positive safety focus.

The workshop participants collaborated and defined SC as the following:

"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."

The major points that were raised during the workshop regarding the development of the SC definition and traits were:

1. The NRC stated that the goal of this workshop was to develop a SC definition and traits by engaging a broad range of stakeholders which would be used along with comments received on the SC policy statement to develop a final draft policy statement to be sent to the Commission in March 2011. If the Commission approves this policy statement, the individual NRC program offices will review their SC programs to determine if they need to be updated based on the policy statement. Finally, the NRC mentioned that there is a Commission meeting scheduled March 30, 2010, at NRC headquarters that will include discussions on SC.
2. Some panelists stated in their opening remarks acknowledged that they all strive to consider safety in their programs, but that it is difficult to create or change organizational cultures and it requires large amount of resources and time.
3. Other panelists noted in their opening remarks that leadership should be a key element in the definition of SC (e.g., professional leadership attitudes, leadership sets the tone for accountability and organizations are driven by their leadership's behaviors and actions).
4. During the discussions in the breakout and plenary sessions on the SC definition, the sample definitions (Attachment 4) were used to generate thoughts and ideas of what constitutes SC, leading to a new draft SC definition (Attachment 5). Some panelists had commented that two criteria necessary in a new SC definition should be that: (1) safety

is a priority; and (2) a strong safety culture should ensure the protection of people and the environment. Others indicated that transparency, trust, attitudes, behaviors, leaders and actions should be part of a SC definition. Additionally, it was decided by the plenary panel that the term security, and other aspects such as emergency preparedness, quality assurance and radiation protection, need not be included in the definition of SC because these aspects were understood to be necessary for the protection of people and the environment.

5. During the discussions in the breakout and plenary sessions on traits, the sample traits (Attachment 4) and the new draft SC definition (Attachment 5) were utilized to generate a list of behaviors needed to support a strong safety culture. The behaviors were grouped into categories and a higher level over-arching trait was developed that summarized the lower level behaviors that were developed (Attachment 5). Additionally, the panel came up with a few words to describe the over-arching new trait (Attachment 5).
6. A panelist indicated at the end of the workshop that adding security to the new draft SC definition (Attachment 5) would not resonate with the medical community because security is inherent in its safety culture.
7. Two workshop attendees offered other definitions of SC, for consideration by the panel, however the panel decided to keep the new draft SC definition developed in Attachment 5.
8. A few other workshop attendees expressed the view that the term "over competing goals" in the SC definition (Attachment 5) was not appropriate because it could cause organizations to implement small improvements to safety (e.g., adding the improvement would only increase safety by a factor of 10^{-19}), regardless of the cost and without any tangible benefit. Another workshop attendee indicated the public views nuclear power plants as regularly facing decisions where competing goals like safety versus the cost to implement the safety feature must be addressed. This same individual stated that having a strong SC reduces plant operational costs since problems are generally identified early and resolved before they can develop into a large more serious and costly problem to resolve. Thus, safety and cost are not competing goals. The panel voted to keep the new draft SC definition (Attachment 5) developed in the workshop rather than modify it.
9. Another panelist at the end of the workshop indicated that the NRC may want to consider honoring the products developed from the workshop. Additionally, the panelist made an observation that the definition developed at the workshop places more emphasis on the individual versus management or leadership found in other SC definitions.
10. An attendee commented that if you work at a nuclear power plant that lacks a strong SC, it is nice to have SC policy statement, with some authority from the NRC that can be used as a reference to help promote change. The attendee further stated that the workshop attendees and panelists did a good job in producing a SC definition and traits (Attachment 5), applicable to various NRC-regulated entities, with the goal of promoting a strong SC.

The major comments that were raised during the workshop regarding the SC policy statement (75 FR 1656; 74 FR 57525) were:

1. An attendee from Exelon Corporation requested that the NRC consider the products developed at the workshop (i.e., safety culture definition and traits; Attachment 5), when the NRC presents to the Commission the draft final SC definition and traits.
2. An attendee from the Nuclear Energy Institute (NEI) stated the importance of developing a common SC language (i.e., definition and traits), and this workshop provided a great start on developing a common SC language. The common SC language will allow licensees and regulators to understand/communicate with each other and adhere to a common policy statement. Furthermore, the nuclear power industry is eager and committed to moving forward with this initiative.
3. Another attendee from Strategic Team and Resource Sharing (STARS) (i.e., several nuclear power reactor sites that share resources consolidate selected support functions and purchases) stated that after polling a number of individuals across nuclear power plants, security is not accepted as part of the definition to SC, because it is an inherent element of safety. Additionally, this individual expressed that he likes the traits developed in this workshop since they take into account the individual attributes and behaviors in a few areas. One area that is important to this individual is the corrective action program (CAP). One of the areas that STARS struggles with regarding the reactor oversight process (ROP) implementation is whether something is a program issue, process issue, or is it an individual issue.
4. An attendee from Kettering Medical Center commented that he liked the NRC draft SC definition in the policy statement versus the one developed in the SC workshop, because it references the significance of the issue which builds needed flexibility into the definition.

Feedback was received which generally indicated success in achieving the goals of the workshop. Additionally, lessons learned on technology shortcomings will be factored into any additional workshops and/or meetings, as necessary.

The NRC is assessing the need for additional workshops and/or public meetings based upon the input from the panelist in the safety culture workshop and the safety culture workshop planning committee members.

- Attachments:
1. February 2-4, 2010, Safety Culture Workshop Agenda
 2. Attendance List
 3. February 2-4, 2010, Safety Culture Workshop Panel List and Affiliation
 4. Sample Safety Culture Definitions and Traits
 5. Safety Culture Definition/Traits Developed from the February 2-4, 2010, NRC Workshop

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Electronic DISTRIBUTION:

R. Albert	J. Adams	V. Barnes	J. Braisted	J. Cai	C. Carpenter	G. Carpenter
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NAME	A. Sapountzis	D. Solorio	R. Zimmerman
DATE	3/ 2 /10	3/12/10	3/12/10

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February 2-4, 2010, Safety Culture Workshop Agenda

Day 1 (8:30 AM – 5:30 PM)

- 8:30 A.M. Opening Remarks (NRC/Roy Zimmerman) (10 min)
- 8:40 A.M. Workshop Details (NRC/Lance Rakovan and David Solorio) (65 min)
- a. Purpose of Workshop/What is success for this workshop? (25 min)
 - o Develop definition of safety culture (SC) and determine description/traits
 - o Discuss relationship between definition and description/traits to SC Policy Statement
 - o Receive comments on SC Policy Statement
 - b. What will be next steps following workshop (including what is plan for implementation down the road)? (5 min)
 - c. Agenda – How meeting is structured (worked with external stakeholders to frame meeting structure) (10 min)
 - d. Workshop ground rules (10 min)
 - e. Introductions – Name/Organization/Affiliation of Panelist/Why Participating? (15 min)
- 9:45 A.M. NRC activities related to SC up to SC Policy Statement (NRC/Jose Ibarra and Molly Keefe) (30 min)
- 10:15 A.M. "What is Safety Culture" & how it affects big and small licensees (NRC/Dr. Valerie Barnes) (30 min)
- 10:45 A.M. Break (15 min)
- 11:00 A.M. Workshop Panelist Remarks – What does Safety Culture mean in their environment? (60 min) (Time will be determined based on number of speakers)
- 12:00 P.M. Lunch – (reflect on morning) (75 min)
- 1:15 P.M. Safety Culture Work So Far – INPO, NRC and Member of the Public safety culture definition (What works for your environment? – Explain what does not) (NRC/Dr. Valerie Barnes, INPO/Dr. Ken Koves, Public/Dave Collins) (30 min)
- 1:45 P.M. Discuss Objective of Breakout Sessions – What is success? (NRC/Maria Schwartz) (15 min)
- 2:00 P.M. Develop the SC common definition (3 Breakout Sessions: New Construction-Reactors and Power Reactors (Plaza Ballroom #3), Materials-Industrial and Fuel Cycle (Roosevelt Room), Materials-Medical (Plaza Ballroom #1 and #2)) (75 min)
- a. Each breakout group will begin discussions from a SC definition that will be provided only as a starting point

- b. Panel members will be asked to add and/or subtract words to definition (using projected Microsoft Word document) and explain and discuss their suggestions
- c. Goal is for NRC and panel members to arrive at a definition of SC they believe is common enough that they can in turn recommend be adopted by the panel as a whole
- d. Facilitator presents to breakout audience for comment

3:15 P.M. Break (15 min)

3:30 P.M. Breakout sessions regroup/come back together and determine SC common definition (Plaza Ballroom #1 and #2) (60 min)

- a. Review definitions produced from breakout sessions
- b. Panel members will be asked to add and/or subtract words to definition (using projected Microsoft Word document) and explain and discuss their suggestions
- c. Goal is for panel members to arrive at a single definition of SC they believe is common enough that they can in turn recommend be adopted by the panel as a whole

4:30 P.M. Opportunity for comment by audience (panel seeks to understand comments) (45 min)

5:15 P.M. Closing Remarks/Summary/Agenda for day 2 (NRC/Roy Zimmerman) (15 min)

5:30 P.M. End of Day 1

Day 2 (8:30 AM – 5:30 PM)

8:30 A.M. Introduction/Ground Rules (NRC/Lance Rakovan) (10 min)

8:40 A.M. Recap of Day 1 (NRC/David Solorio) (10 min)

8:50 A.M. Opportunity for comment by audience (30 min)

9:20 A.M. Resume If Necessary – Continue with development of the SC common definition (3 Breakout Sessions: New Construction-Reactors and Power Reactors (Plaza Ballroom #3), Materials-Industrial and Fuel Cycle (Roosevelt Room), Materials-Medical (Plaza Ballroom #1 and #2)) (70 min)

- a. Review definitions against audience comments
- b. Panel members will be asked to add and/or subtract words to definition (using projected Microsoft Word document) and explain and discuss their suggestions
- c. Goal is for panel members to arrive at a single definition of SC they believe is common enough that they can in turn recommend be adopted by the panel as a whole
- d. Facilitator presents to breakout audience for comment

10:30 A.M. Break (15 min)

- 10:45 A.M. Breakout sessions regroup/come back together and determine SC common definition (Plaza Ballroom #1 and #2) (60 min)
- Review definitions produced from breakout sessions
 - Panel members will be asked to add and/or subtract words to definition (using projected Microsoft Word document) and explain and discuss their suggestions
 - Goal is for panel members to arrive at a single definition of SC they believe is common enough that they can in turn recommend be adopted by the panel as a whole
 - Facilitator presents to audience for comment
- 11:45 P.M. Lunch – (reflect on morning) (75 min)
- 1:00 P.M. NRC Remarks and Questions (NRC/DEDMRT Marty Virgilio) (30 min)
- 1:30 P.M. Opportunity for comment by audience (60 min)
- 2:30 P.M. Break (15 min)
- 2:45 P.M. Breakout sessions to determine SC description/traits (3 Breakout Sessions: New Construction-Reactors and Power Reactors (Plaza Ballroom #3), Materials-Industrial and Fuel Cycle (Roosevelt Room), Materials-Medical (Plaza Ballroom #1 and #2)) (150 minutes)
- Panel members will be asked to write down what they see as primary traits of SC on individual post-it notes
 - Facilitator will collect post-it notes and request panel members provide their reasoning behind a sample of the suggestions
 - Facilitator will aid panel members in organizing the input into broad categories
 - Goal is for panel members to arrive at a list of SC traits they believe should be considered by the panel as a whole
 - Facilitator presents to breakout audience for comments
- 5:15 P.M. Closing Remarks/Summary/Takeaways/Next Steps (NRC/Roy Zimmerman) (15 min)
- 5:30 P.M. End of Day 2

Day 3 (8:30 AM – 5:30 PM)

- 8:30 A.M. Introduction/Ground Rules (NRC/Lance Rakovan) (10 min)
- 8:40 A.M. Recap of Day 2 (NRC/David Solorio) (10 min)
- 8:50 A.M. If Necessary – Come Back Together and Determine the Description/Traits (Plaza Ballroom #1 and #2) (100 min)
- Review description/traits produced from breakout sessions
 - May massage/revise the description/traits into a smaller number of more consistent format
 - Consensus or present prepared definition
 - Adding and subtracting words maybe both using yellow post it notes and Microsoft Word document to broadcast to audience (if time permits)

- 10:30 A.M. Break (15 min)
- 10:45 A.M. Opportunity for comment by audience (60 min)
- 11:45 A.M. Lunch – (reflect on morning) (75 min)
- 1:00 P.M. Continue as a group to determine the description/traits (Plaza Ballroom #1 and #2) (120 min)
- a. Review description/traits produced
 - b. May massage/revise the description/traits into a smaller number of more consistent format
 - c. Consensus or present prepared language
 - d. Adding and subtracting words maybe both using yellow post it notes and Microsoft Word document to broadcast to audience
- 3:00 P.M. Comments on Policy Statement (Address questions in FRN) (Plaza Ballroom #1 and #2) (NRC/Alex Sapountzis and Maria Schwartz) (120 min)
- 5:00 P.M. Closing Remarks/Summary/Takeaways/Next Steps (NRC/Roy Zimmerman) (30 min)
- 5:30 P.M. Workshop Conclusion Day 3

Attendance List

On February 2-4, 2010, the NRC met with stakeholders to obtain input regarding a high-level safety culture (SC) definition, description/traits, in order to develop a more common terminology for SC across NRC-regulated entities. In addition, the NRC received comments on the draft SC policy statement.

Name	Organization
John Adams	Nuclear Regulatory Commission/Nuclear Reactor Regulations
Ron Albert	Nuclear Regulatory Commission/Nuclear Security and Incident Response
Steve Amer	Epsilon Systems Solutions, Inc.
Valerie Barnes	Nuclear Regulatory Commission/Research
Shannon Barton	
Cheryl Ann Beegle	Department of Health and Human Services/CC-National Institute of Health
Charles Bowman	STPNOC
Johnathan Braisted	Nuclear Regulatory Commission/ Enforcement
Kevin Buckley	American Association of Physicists in Medicine
David Burton	Walter Reed AMC
James Cameron	Nuclear Regulatory Commission/R III
Patricia Campbell	General Electric Hitachi
W. Earl Carnes	Department of Energy
Patrick Card	Golden Brook Solutions, LLC
Cynthia Carpenter	Nuclear Regulatory Commission/ Federal and State Materials and Environmental Management Programs
Gene Carpenter	Nuclear Regulatory Commission/Research
John Carter	Virginia Commonwealth University
Gerard Castro	Joint Commission
Paul Chiasson	
Anisuzzaman Chowdhury	George Washington University Hospital
Larry Chung	Washington, D.C. Department of Transportation
Carlos Coffman	Department of Energy
Nicole Coleman	Nuclear Regulatory Commission/Enforcement
Dave Collins	Member of the Public
Lawrence Criscione	Nuclear Regulatory Commission/Research
Mike Crowthers	Susquehanna PPL
Kerstun Day	Nuclear Regulatory Commission/Enforcement
Elizabeth Dean	Virginia Commonwealth University
Curt Demaris	Department of Health for State of Washington
Tony DiPalo	Member of the Public
Dan Doorman	Nuclear Regulatory Commission/Nuclear Material Safety and Safeguards
Lynne Fairobent	American Association of Physicists in Medicine
Carolyn Faria-Ocasio	Nuclear Regulatory Commission/Enforcement
Nilda Feliciano-Rivera	Nuclear Regulatory Commission/New Reactors
James Firth	Nuclear Regulatory Commission/ Federal and State Materials and Environmental Management Programs
John Flack	Member of the Public

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Name	Organization
Roland Fletcher	MD-Radiation Health Program
Carol Florian	Symetosphere, LLC
Wayne Frazier	National Aeronautics and Space Administration
Billie Garde	Attorney, Clifford and Garde, LLP
David Garchow	Institute of Nuclear Power Operations
Roy Garris	Symetosphere, LLC
Ron Gaston	Exelon
Ronnie Gardner	AREVA
Laura Gerke	Nuclear Regulatory Commission/ Enforcement
Ian Gifford	AFRRI
Mark Giles	Entergy
Fred Gigliotti	Westinghouse
Ronald Guye	Virginia Commonwealth University
Sonja Harber	Consultant- Human Performance Analysis Corporation
Nasreen Hasan	Nuclear Regulatory Commission/ Enforcement
Elizabeth Hearne	Frederick Memorial Health Care System
Pete Hernandez	Nuclear Regulatory Commission/ Enforcement
Dan Hibbing	George Washington University
Tomas Houghton	Nuclear Energy Institute
Dan Hudson	Nuclear Regulatory Commission/Research
Earl Hughes	Department of Energy
Jose Ibarra	Nuclear Regulatory Commission/ Enforcement
Alan Jacobson	MD Radiation Health Program
Rich Janati	Department of Environmental Protection-PA
Gary Janosko	PSEG
John Jensen	Department of Agriculture
Jose Jimenez	Nuclear Regulatory Commission/New Reactors
Jeffrey Joe	Idaho National Labs/Dept. of Energy
Mike Junge	Nuclear Regulatory Commission/ New Reactors
Martin Kamishan	Nuclear Regulatory Commission/Nuclear Reactor Regulations
Ernest Kapopulos	Progress Energy
Molly Keefe	Nuclear Regulatory Commission/Enforcement
Felix Kellar	Nuclear Energy Institute
Ken Koves	Institute of Nuclear Power Operations
Craig Lawrence	
Mauri Lemoncelli	Nuclear Regulatory Commission/General Counsel
Bob Link	AREVA
Lily Lodhi	Temple University
Lucy Lopez	Nuclear Regulatory Commission/ Enforcement

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Name	Organization
Phil Lorette	Nuclear Regulatory Commission/Research
George Marshall	American Portable Nuclear Gauge Association
Dr. Charles Martin	Defense Nuclear Facilities Safety Board
Jack Martin	Backpacker
Richard Martin	ASTRO
Steve Mattmuller	Kettering Medical Center
Miles McCord	Howard University
Brett McCreary	Tennessee Valley Authority
Dr. Marlene McKetty	Howard university Hospital
Dave Midlik	Southern Nuclear Operating Company
Marie Miller	Nuclear Regulatory Commission/Region I
Steve Miller	Armed Forces Radiobiology Research Institute
Peter Miner	United States Enrichment Corporation
Bruce Montgomery	Constellation Energy Nuclear Group, LLC
Raul Munoz	UNESA
Chris Mudrick	Excelon
Tony Muschara	Error Management Consulting
Gwen Nalls	Shaw AREVA MOX Services, LLC
Jim Nance	Symetosphere
Paul Narbut	Paul Narbut and Associates
Christine Neely	PSEG
Joe Nick	Nuclear Regulatory Commission/Region I
Patty Nibert	Nuclear Regulatory Commission/Enforcement
Johnathan Ortega-Luciano	Nuclear Regulatory Commission/New Reactors
Mike Palmer	Susquehanna, PPL
Larry Parscale	Honeywell Specialty Materials
Terry Paterson	Constellation Energy Nuclear Group, LLC
Opha Peden	Virginia Commonwealth University
Julius Persensky	Idaho National Labs
Josie Piccone	Nuclear Regulatory Commission/ Federal and State Materials and Environmental Management Programs
Amanda Potter	American Association of Physicists in Medicine
Lance Rakovan	Nuclear Regulatory Commission/Executive Director for Operations
Deann Raleigh	SCIENTECH
Ann Ramey-Smith	Nuclear Regulatory Commission/Nuclear Reactor Regulations
Kevin Ramsey	Nuclear Regulatory Commission/Nuclear Material Safety and Safeguards
Mark Rasmussen	Professional Reactor Operator Society
Rick Rasmussen	Nuclear Regulatory Commission/ New Reactors
Dustin Reinert	Nuclear Regulatory Commission/ Enforcement

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Name	Organization
Wayne Rice	Building and Construction Trades Department, AFL-CIO
Donald Richard	STARS Licensing Specialist, Callaway Plant
Robin Ritzman	First Energy
Joe Rizzi	Westinghouse Nuclear Corporation
Rafael Rodriguez	Nuclear Regulatory Commission/Nuclear Material Safety and Safeguards
Kate Roughan	QSA Global
Gabe Salamon	Xcel Energy
Alex Sapountzis	Nuclear Regulatory Commission/Enforcement
Maria Schwartz	Nuclear Regulatory Commission/Enforcement
Janet Schlueter	Nuclear Energy Institute
Cheryl Schultz	William Beaumont Hospital
Craig Seaman	NAC International
Shawn Seeley	Organization of Agreement States-Maine
Mark Shaffer	Nuclear Regulatory Commission/Federal and State Materials and Environmental Management Programs
Vernon Shanks	United States Enrichment Corporation
Karen Sheehan	Fox Chase Cancer Center
Diane Sieracki	Dominion Resources
Anthony Silakoski	Florida Power & Light Nuclear Fleet Security
Timothy Slede	American UE/Utilities Service Alliance
Kevin Smith	Savannah River Site Contractor
Undine Shoop	Nuclear Regulatory Commission/Nuclear Reactor Regulations
David Solorio	Nuclear Regulatory Commission/Enforcement
Belkys Sosa	Nuclear Regulatory Commission/Enforcement
Gayle Staton	Non-Destructive Testing Management Association
Mike Streitz	LLNL
Leonard Sueper	Xcel Nuclear
Mary Taormina	Virginia Commonwealth University
AJ Teahout	Armed Forces Radiobiology Research Institute
Duann Vanderslice Thistlewaite	Society of Nuclear Medicine
Richard Todaro	Washington CORE
Cindy Tomlinson	Society of Nuclear Medicine
Dr. Richard Toohey	Health Physics Society
Rich Turtill	Nuclear Regulatory Commission/Federal and State Materials and Environmental Management Programs
Marty Virgilio	Nuclear Regulatory Commission/Materials, Waste, Research, State, Tribal and Compliance Programs
Rosetta Virgilio	Nuclear Regulatory Commission/Federal and State Materials and Environmental Management Programs
Cindy Wagner	General Electric Hitachi Nuclear

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Name	Organization
Joe Wang	NdSigma, LLC
Sandra Wastler	Nuclear Regulatory Commission/Nuclear Security and Incident Response
Doug Weaver	Nuclear Regulatory Commission/Nuclear Material Safety and Safeguards
Bruce Williams	Shaw Power Group
Claude Williams	Howard University
Victoria Winfrey	Prairie Island tribal Council
Kevin Witt	Nuclear Regulatory Commission/Nuclear Material Safety and Safeguards
Charles Workman	G4S Regulated Security Solutions
Roosevelt Word	SCE&G SCANA
Roy Zimmerman	Nuclear Regulatory Commission/Enforcement

February 2-4, 2010, Safety Culture Workshop Panel List and Affiliation

Panelist List and Affiliation

1. Kevin Buckley (American Association of Physicists in Medicine)
2. Gerard Castro (Joint Commission)
3. David Collins (Member of the Public)
4. David Garchow (Institute of Nuclear Power Operations)
5. Billie Garde (Attorney, Clifford and Garde, LLP)
6. Tom Houghton (Nuclear Energy Institute)
7. Bob Link (AREVA)
8. George Marshall (American Portable Nuclear Gauge Association)
9. Wayne Rice (Building and Construction Trades Department, AFL-CIO)
10. Diane Sieracki (Dominion Resources)
11. Gayle Staton (Non-Destructive Testing Management Association)
12. Duann Vanderslice Thistlewaite (Society of Nuclear Medicine)
13. Dr. Richard Toohey (Health Physics Society)
14. Victoria Winfrey (Prairie Island Indian Community Tribal Council)
15. Bruce Williams (Shaw Power Group)
16. Chuck Workman (G4S Regulated Security Solutions)

Breakout Session 1: New Construction-Reactors and Power Reactors

1. David Garchow (Institute of Nuclear Power Operations)
2. Victoria Winfrey (Prairie Island Indian Community Tribal Council)
3. Tom Houghton (Nuclear Energy Institute)
4. Wayne Rice (Building and Construction Trades Department, AFL-CIO)
5. Diane Sieracki (Dominion Resources)
6. Bruce Williams (Shaw Power Group)
7. Chuck Workman (G4S Regulated Security Solutions)
8. Billie Garde (Attorney, Clifford and Garde, LLP)
9. David Collins (Member of the Public)

Breakout Session 2: Materials-Industrial and Fuel Cycle

1. George Marshall (American Portable Nuclear Gauge Association)
2. Gayle Staton (Non-Destructive Testing Management Association)
3. Dr. Richard Toohey (Health Physics Society)
4. Bob Link (AREVA)

Breakout Session 3: Materials-Medical

1. Kevin Buckley (American Association of Physicists in Medicine)
2. Gerard Castro (Joint Commission)
3. Duann Vanderslice Thistlewaite (Society of Nuclear Medicine)

Sample Safety Culture Definitions and Traits

Sample Safety Culture Definitions								
European Strategic Safety Initiative	UK Health and Safety Executive (1993)	U.S. Nuclear Regulatory Commission (NRC) (Draft-2009)	Institute of Nuclear Power Operations (INPO)	International Atomic Energy Agency (IAEA)/International Nuclear Safety Group (INSAG-4; 1991)	Member of the Public Mr. David Collins	Guldenmund (2000)	Mearns, et al (2003)	Von Thaden and Gibbons (2008)
Safety Culture is the set of enduring values and attitudes regarding safety issues, shared by every member of every level of an organization. Safety Culture refers to the extent to which every individual and every group of the organization is aware of the risks and unknown hazards induced by its activities; is continuously behaving so as to preserve and enhance safety; is willing and able to adapt itself when facing safety issues; is willing to communicate safety issues; and consistently evaluates safety related behavior.	The product of individual and group values, attitudes, perceptions, competencies, and patterns of behavior that determine the commitment to, and the style and proficiency of, an organization's health and safety management.	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.	An organization's values and behaviors—modeled by its leaders and internalized by its members—that serve to make nuclear safety the overriding priority.	That assembly of characteristics and attitudes in organizations and individuals which establishes that as an overriding priority, nuclear plant safety issues receive the attention warranted by their significance.	Professional leadership attitudes in a High Reliability Organization that ensure potentially hazardous activities are managed to maintain risk to people and the environment as low as reasonably achievable thereby maintaining stakeholder trust.	Those aspects of the organizational culture which will impact on attitudes and behavior related to increasing or decreasing risk.	Safety Culture ... forms the environment within which individual safety attitudes develop and persist and safety behaviors are promoted.	The enduring value and prioritization of worker and public safety by each member of each group and in every level of an organization.

Sample Safety Culture Traits

European Strategic Safety Initiative	NRC (Draft)	INPO	IAEA/INSAG-4	Member of the Public Mr. Dave Collins	Christian, et al
Commitment	Personnel demonstrate ownership for nuclear safety and security in their day-to-day activities.	Everyone is personally responsible for nuclear safety.	Safety is a clearly recognized value.	Excellence Behaviors:(1) Communicates and models values; (2) Clearly communicates expectations; (3) Focus is on value not cost; (4) Ensures training, resources; (5) Good problem-solver and coach; and (6) Promotes open, deep organization learning.	Management commitment to safety.
Behavior	Process for planning and controlling work activities are implemented such that safety and security are maintained.	Leaders demonstrate commitment to safety.	Leadership for safety is clear.	Integrity Behaviors:(1) Does the right thing (behaves ethically); (2) Communicates openly and honestly; (3) Makes conservative decisions; (4) Addresses issues promptly, properly; (5) Uses failures to learn, not punish; and (6) Ensures appropriate accountability.	Human resources practices.
Awareness	The organization maintains a safety conscious work environment in which personnel feel free to raise safety and security concerns without fear of retaliation.	Trust permeates the organization.	Accountability for safety is clear.	Relationship Behaviors: (1) Listens carefully to suggestions; (2) Welcoming and respectful; (3) Promotes diversity, development; (4) Compliments more than criticizes; and (5) Promotes work/life balance.	Quality of safety systems.
Adaptability	The organization ensures that issues potentially impacting safety or security are promptly identified, fully evaluated, and promptly addressed and corrected commensurate with their significance.	Decision-making reflects safety first.	Safety is integrated into all activities.		Supervisor support for safety.
Information	The organization ensures that the personnel, equipment, tools, procedures, and other resources needed to ensure safety and security are available.	Nuclear technology is recognized as special and unique.	Safety is learning driven.		Internal group processes.
Justness	The organization's decisions ensure that safety and security are maintained.	A questioning attitude is cultivated.			Group boundary management
	Roles, responsibilities, and authorities for safety and security are clearly defined and reinforced.	Organizational learning is embraced.			Risk associated with activities/environment
	The organization maintains a continuous learning environment in which opportunities to improve safety and security are sought out and implemented.	Nuclear safety undergoes constant examination.			Work pressure
					Leadership

Safety Culture Definition/Traits Developed from the February 2-4, 2010, NRC Workshop

Safety Culture Definition

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.

Trait #1: Problem Resolution and Metrics

The organization ensures that issues potentially impacting safety or security are promptly identified, fully evaluated, and promptly addressed and corrected commensurate with their significance.

Trait #2: Personal Responsibilities and Attitudes

Everyone is personally responsible for nuclear safety.

Trait #3: Processes and Procedures

Processes for planning and controlling work activities are implemented such that safety is maintained.

Trait #4: Continuous Learning

Organizational learning is embraced.

Trait #5: Leadership Safety Behaviors

Leaders demonstrate commitment to safety.

Trait #6: Effective Safety Communication


Effective communication is essential to maintain focus on safety.

Trait #7: Encouraging Report of Problems

The organization maintains a safety conscious work environment in which personnel feel free to raise concerns without fear of retaliation.

Trait #8: Respectful Work Environment


Trust and respect permeate the organization.



**Update on Grandfathering
Certified Medical Physicists**


Ronald E. Zelac, Ph.D.
Radioactive Materials Safety Branch
U.S. Nuclear Regulatory Commission

May 25, 2010
Advisory Committee on the Medical Uses
of Isotopes




Background

- October 2002 – Part 35 general revision
- April 2005 – Part 35 training & experience revision
- September 2006 – American Association of Physicist in Medicine (AAPM) petition for rulemaking (PRM-35-20)
- May 2008 – PRM-35-20 resolved




**Petition Resolution Follow Up –
Information Gathering through Letter Inquiry**

- To recognized medical certifying boards, past & present
- Nine boards contacted, October 2008
- Boards asked for number and percentage of select currently active diplomates not grandfathered and who were seeking or might seek authorized status



**Petition Resolution Follow Up –
Results From Information Gathering**

- Five boards responded; four conducted member surveys
- Survey return rates averaged 52% (range 36% to 90%)
- Negatively affected diplomates: Average percentage is 33 (range 14% to 66%); Number is 10,298 (range 77 to 7,900)



**Petition Resolution Follow Up –
Conclusion From Info. Gathering Results**

- MSSA: Pursuing corrective rulemaking is warranted & justified; the required technical basis document has been prepared.
- DILR: The technical basis appears to be sufficiently robust and sound; document acceptance soon is anticipated.



Next Step

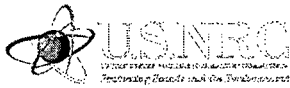
- Inclusion of appropriate grandfathering provision modifications in the next Part 35 rulemaking, which should begin later this year, or
- No further action or consideration by NRC



Update on Grandfathering Certified Medical Physicists

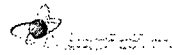
Questions?

Contact: ronald.zelac@nrc.gov
301/415-7635



International Atomic Energy Agency Safety Standard for Protection against Ionizing Radiation

Bruce Thomadsen, Ph.D.
Advisory Committee on the Medical Uses of Isotopes



Background

Based on a meeting February 26, 2010 to receive input on the U.S. Nuclear Regulatory Commission (NRC) response to the International Atomic Energy Agency (IAEA) on the proposed standard



General Reflections on the Standards

For the most part, almost nothing would be objectionable, except:

1. The concept of potential exposure,
2. The use of the term, "optimized" regarding the exposure received for some function,
3. Medical Reference levels (how they are used),
4. Requirement to measure radon in public places.



Note

The American Association of Physicists in Medicine (AAPM) submitted comments on an earlier draft and all the recommendations were incorporated into this draft.



Microsphere Postscripts: Unintended Consequences

Bruce Thomadsen, Ph.D.

May 25, 2010
Advisory Committee on the Medical Uses of Isotopes



Permanent Implant Postscripts

10 Code of Federal Regulations (CFR) 35.40

(6) For all other brachytherapy, including low, medium, and pulsed dose rate remote afterloaders:

- (i) Before implantation: treatment site, the radionuclide, and dose; and
- (ii) After implantation but before completion of the procedure: the radionuclide, treatment site, number of sources, and total source strength and exposure time (or the total dose).



Microspheres Written Directive

From "Microsphere Brachytherapy
Sources and Devices

REVISED SEPTEMBER 2008"



Microspheres Written Directive

Pre-administration:

- The date;
- The signature of the Authorized User (AU);
- The treatment site;
- The radionuclide and physical;
- The prescribed dose/activity;
- Type of microsphere used; and
- Statement "or dose/activity delivered at stasis"



Microspheres Written Directive: Postscript

After administration but before the patient leaves the post-procedural recovery area:

- The date;
- The signature of the AU;
- The total dose/activity delivered to the treatment site.



Microspheres Written Directive: Postscript

If the administration was terminated because of stasis, then the total dose/activity to the treatment site is the value of the total dose/activity administered when stasis occurred and the administration was terminated.

Microspheres Written Directive: Postscript

"Note: The post-administration entries into the written directive are not an amendment to the written directive; rather, these entries complete the written directive."

7

The Issue

At least in our facility, all procedures go to completion.

- We had one problem with a stopcock very early.
- We have had, maybe, three stop because of stasis (two of these were with proctors using their "recommended" techniques.)

8

The Issue

- If the postscript is to "complete" the written directive, it makes no sense if the treatment fully completes the written directive.
- If the written directive is a directive, what need is there for one afterwards if all goes as directed?

9

The Issue

- This causes problems for facilities where the authorized user is not present at the procedure, and may be in lengthy procedures themselves.
- This places an onerous burden on the medical physicist, or someone else, to hunt down the AU to get an unnecessary completion before the patient leaves.

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Comparison with Prostate Implants


- In a prostate implant the total source strength that should be implanted is not known until after the procedure.
- In a microspheres, the desired activity is known at the time the source material is ordered.
- Compromises in the delivery may prevent total use but it is not because of changes in the desired activity.

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Proposal


- A postscript should only be necessary for microspheres if there is a clinical need for premature termination of the delivery.

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**Byproduct Material Events
Subcommittee Report
May 2010**

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




Background

- The subcommittee has reviewed the Nuclear Materials Events Database (NMED) and tabulated the medical events
- The Subcommittee understands the desired aims of:
 - Identifying trends and causes
 - Coming up with possible solutions




Subcommittee Findings:

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




Subcommittee Findings:

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



Subcommittee Findings:

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



Subcommittee Findings:

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



Subcommittee Findings:

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

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Subcommittee Findings:

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

8



Subcommittee Findings:

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

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

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

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

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

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35.600

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

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35.400

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

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35.400 Comments

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

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35.400 Comments

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

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Conclusions

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

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Notes Page

ACMUI
OCTOBER 24, 2006

U.S. NUCLEAR REGULATORY COMMISSION
OFFICE OF FEDERAL AND STATE MATERIALS AND ENVIRONMENTAL MANAGEMENT
PROGRAMS
ADVISORY COMMITTEE ON MEDICAL USES OF ISOTOPES
BYLAWS

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PREAMBLE

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

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

BYLAWS-ADVISORY COMMITTEE ON THE MEDICAL USES OF ISOTOPES

1. Scheduling and Conduct of Meetings

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

1.1 Scheduling of Meetings:

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

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

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

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

1.2 Meeting Agenda:

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

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

1.3 Conduct of the Meeting:

- 1.3.1 All meetings will be held in full compliance with the Federal Advisory Committee Act. Questions concerning compliance will be directed to the NRC Office of the General Counsel.
- 1.3.2 The Chair will preside over the meeting. The Vice Chair will preside if the Chair is absent or if the Chair is recused from participating in the discussion of a particular agenda item. The Designated Federal Officer will preside when both the Chair and the Vice Chair are absent and/or recused from the discussion, or when directed to do so by the Commission.
- 1.3.3 A majority of the current membership of the ACMUI will be required to constitute a quorum for the conduct of business at an ACMUI meeting.
- 1.3.4 The Chair has both the authority and the responsibility to maintain order and decorum, and may, at his or her option, recess the meeting if these are threatened. The Designated Federal Officer will adjourn a meeting when adjournment is in the public interest.
- 1.3.5 The Chair may take part in the discussion of any subject before the ACMUI, and may vote. The Chair should not use the power of the Chair to bias the discussion. Any dispute over the Chair's level of advocacy shall be resolved by a vote on the Chair's continued participation in the discussion of the subject. The decision shall be by a majority vote of those members present and voting, with a tie permitting continued participation of the Chair in the discussion.
- 1.3.6 When a consensus appears to have developed on a matter under consideration, the Chair will summarize the results for the record. Any members who disagree with the consensus shall be asked to state their dissenting views for the record. Any ACMUI member may request that any consensus statement be put before the ACMUI as a formal motion subject to affirmation by a formal vote. No ACMUI position will be final until it has been formally adopted by consensus or formal vote, and the minutes/transcript written and certified.

2. MINUTES/TRANSCRIPTS

- 2.1 Minutes/transcripts of each meeting will be prepared by the ACMUI Chair, with assistance from the FSME staff, in accordance with the requirements in 10 CFR Part 7. The Commission staff will prepare minutes/transcripts of ACMUI meetings with the Commission.
- 2.2 The ACMUI Chair will certify the minutes/transcripts in accordance with 10 CFR Part 7.
- 2.3 In accordance with the requirements of the NRC's Operating Plan, FSME staff will prepare a meeting summary. The FSME staff will e-mail the meeting summary document or web link to the ACMUI members.
- 2.4 Copies of the certified minutes/transcripts will be made available to the ACMUI members, and to the public, not later than 90 days after the meeting.

3. APPOINTMENT OF MEMBERS

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

4. CONDUCT OF MEMBERS

- 4.1 If a member believes that he or she may have a conflict of interest with regard to an agenda item to be addressed by the ACMUI, this member should divulge it to the Chair and the Designated Federal Officer as soon as possible, but in any case before the ACMUI discusses it as an agenda item. ACMUI members must recuse themselves from discussion of any agenda item with respect to which they have a conflict of interest.
- 4.2 Upon completing their tenure on the ACMUI, members will return any privileged documents and accountable equipment (as so designated by the NRC) provided for their use in connection with ACMUI activities, unless directed to dispose of these documents or equipment.
- 4.3 Members of the ACMUI are expected to conform to all applicable NRC rules and regulations, and are expected to attend meetings regularly and perform all assigned duties.

5. ADOPTION AND AMENDMENTS

- 5.1 Adoption or approval of an amendment of these bylaws shall require an affirmative vote of two-thirds of the current ACMUI membership and the concurrence of the Director of the Office of Federal and State Materials and Environmental Management Programs.
- 5.2 Any member of the ACMUI or FSME staff may propose an amendment to these bylaws. The proposed amendment will be distributed to the members by the Chair and scheduled for discussion at the next regular ACMUI meeting.
- 5.3 The proposed amendment may be voted on as early as the next ACMUI meeting after distribution to the members.
- 5.4 The ACMUI shall consult with the Office of the General Counsel regarding conflicts that arise from the interpretation of the bylaws. After consultation, the ACMUI shall resolve interpretation issues by a majority vote of the current membership of the ACMUI.

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

1. Committee's Official Designation:

Advisory Committee on the Medical Uses of Isotopes

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

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

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

3. Time period (duration of this Committee):

Continuing Committee.

4. Official to whom this Committee reports:

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

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

U.S. Nuclear Regulatory Commission.

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

7. Estimated annual direct cost of this Committee:

Members are appointed by the Director, Office of Federal and State Materials and Environmental Management Programs as Special Government Employees (SGEs). Approximately 13 members utilize 2.3 FTE (includes approximately 1.6 FTE for NRC staff and 0.7 FTE for ACMUI member compensation and travel).

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

Five meetings per year, three of which are teleconferences.

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

Continuing Committee subject to Charter renewal on March 17, 2012.

10. **Filing date:**

March 16, 2010.

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