

United States Nuclear Regulatory Commission

Advisory Committee on the Medical Uses of Isotopes

May 7-8, 2009

ADAMS

PLEASE DO NOT REMOVE FROM AUDITORIUM

ACMUI VISITOR LIST

May 7, 2009

NAME	ORGANIZATION	SIGNATURE
Becker, Gary	ABR	phone
Bikowski, Hilary	SIR	
Crowley, Kevin	NAS	(in attendance)
Cacia, Melissa	AACE	phone
Dansereau, Robert	NY	phone
Davidson, William	U of Penn	phone
Eaton, Richard	MITA	Richard Eaton
Fairobent, Lynne	AAPM	Lynne Fairobent
Gardner, Emily	ASNC	
Hamilton, Bonnie	MDS Nordion	(in attendance)
Langley, Karen	Utah	phone
Mauro, Matthew	SIR	
Miller, Katrina	AACE	phonr
Pfeiffer, Doug	AAPM	Doug Pfeiffer
Romanelli, Gloria	ACR	Gloria Romanelli
Rodgers, Joe	Theragenics	phone
Salem, Riad	SIR	(in attendance)
Selwyn, Reed	Unif. Svcs Univ. of Hlth. Sci.	(in attendance)
Stainken, Brian	SIR	(in attendance)
Thomas, Stephen		phone
Thurson, Ken	Sirtex	(in attendance)
Tomlinson, Cindy	SNM	phone
Warbick Cerone, Ann	MDS Nordion	(in attendance)
Williams, Gary	VA NHPP	
Wilson, Emily	ASTRO	(in attendance)
Young, Jennifer	AACE	phone

Baggett, Steven NRC
 Sandy Gabriel NRC RI
 Mila Polace ACR

Patricia Peck NRC R3
 Cassandra Frazier NRC R3
 Tappol (A) ISN MAU NRC R3



PLEASE DO NOT REMOVE FROM AUDITORIUM

ACMUI VISITOR LIST

May 8, 2009

NAME	ORGANIZATION	SIGNATURE
Becker, Gary	ABR	phone
Bikowski, Hilary	SIR	
Crowley, Kevin	NAS	
Cacia, Melissa	AACE	phone
Dansereau, Robert	NY	phone
Davidson, William	U of Penn	phone
Eaton, Richard	MITA	<i>Richard Eaton</i>
Fairobent, Lynne	AAPM	<i>Lynne Fairobent</i>
Gardner, Emily	ASNC	<i>Emily Gardner</i>
Hamilton, Bonnie	MDS Nordion	
Langley, Karen	Utah	phone
Mauro, Matthew	SIR	
Miller, Katrina	AACE	phonr
Pfeiffer, Doug	AAPM	<i>Doug Pfeiffer</i>
Romanelli, Gloria	ACR	<i>Gloria Romanelli</i>
Rodgers, Joe	Theragenics	phone
Salem, Riad	SIR	
Selwyn, Reed	Unif. Svcs Univ. of Hlth. Sci.	
Stainken, Brian	SIR	
Thomas, Stephen		phone
Thurson, Ken	Sirtex	
Tomlinson, Cindy	SNM	phone
Warbick Cerone, Ann	MDS Nordion	<i>Ann Warbick Cerone</i>
Williams, Gary	VA NHPP	
Wilson, Emily	ASTRO	<i>Emily Wilson</i>
Young, Jennifer	AACE	phone

Mike Peters ACR
Patricia Peck NRC RIII
CASSANDRA FERRICE NRC RIII

Sandra Gabriel, NRC RI

Friday, May 8, 2009
OPEN SESSION

8:00 – 8:45 **10. Next Steps to Interact with the Medical Communities on Possible Revisions to Radiation Protection Regulations and Guidance** **D. Cool, NRC**
Dr. Cool will discuss the next steps for potential changes to 10 CFR Parts 20 and 50.

8:45 – 9:45 **11. National Council on Radiation Protection and Measurements (NCRP) Report 160 "Ionizing Radiation Exposure of the Population of the United States" and Its Implications for NRC Programs** **ACMUI**
ACMUI members will discuss the NCRP report and provide feedback to NRC staff.

9:45 – 10:00 **B R E A K**

10:00 – 11:00 **12. T&E Subcommittee Report on American Board of Radiology (ABR) Certification** **D. Egli, ACMUI**
Dr. Egli will present the subcommittee's recommendations for allowing ABR diplomates who have a gap between completion of T&E and the receipt of their board certificate to follow a board certification pathway.

11:00 – 1:00 **L U N C H**

1:00 – 1:45 **13. Subcommittee Report on Byproduct Material Events** **R. Lieto, ACMUI**
Mr. Lieto will present the subcommittee's analysis on byproduct material events for fiscal year 2008.

1:45 – 2:15 **14. Infiltrations of Therapeutic Radiopharmaceuticals as Medical Events** **C. Flannery, NRC**
Ms. Flannery will provide information on a recent infiltration and seek input from the Committee on the applicability of the medical event reporting requirements.

2:15 – 2:45 **15. Summary of the Enforcement Process and Enforcement Actions Against Medical Licensees** **S. Woods, NRC**
Ms. Woods will provide an overview of the enforcement process and give statistics of enforcement actions involving medical licensees.

2:45 – 3:00 **B R E A K**

3:00 – 3:30 **16. Regulatory Responsibilities of the US Food and Drug Administration (FDA)** **O. Suleiman, ACMUI**
Dr. Suleiman will provide a brief overview of the role of the FDA.

3:30 – 4:30 **17. Outgoing Member Presentations** **R. Lieto, S. Nag, R. Vetter**
Drs. Nag and Vetter and Mr. Lieto will provide final words on their experiences on the ACMUI.

4:30 – 5:00 **18. Administrative Closing** **A. Cockerham**
Ms. Cockerham will provide a meeting summary and propose dates for the next meeting.

NO HANDOUT

April 23, 2009

MEMORANDUM TO: Leon S. Malmud, M.D., Chairman
Advisory Committee on the
Medical Uses of Isotopes

FROM: Christian E. Einberg, Designated Federal Officer
Advisory Committee on the
Medical Uses of Isotopes

SUBJECT: RESPONSE TO RECOMMENDATIONS FROM THE OCTOBER 27-
28, 2008 MEETINGS OF THE ADVISORY COMMITTEE ON THE
MEDICAL USES OF ISOTOPES

Below are recommendations and action items from the October 2008 meeting of the Advisory Committee on the Medical Uses of Isotopes (ACMUI). Following each recommendation or action is the U.S. Nuclear Regulatory Commission (NRC) staff response and/or position.

ITEM (1): NRC staff agreed to consider incorporating the subcommittee's recommendations from the August 1, 2008 Fingerprinting Subcommittee Report in NRC's *Questions and Answers with Regards to Fingerprinting and Criminal History Records Checks* or use another appropriate method of communication to transmit the information to licensees.

NRC staff is considering the action item to incorporate the subcommittee's recommendations in NRC's *Questions and Answers with Regards to Fingerprinting and Criminal History Records Checks* or use another appropriate method of communication to transmit the information to licensees.

ITEM (2): 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."

NRC staff is considering the six recommendations of the Permanent Implant Brachytherapy Subcommittee report as comments for the current rulemaking. NRC staff will review the comments received and expects to notify ACMUI in 2009 of the resolution of those comments.

ITEM (3): The ACMUI endorsed the permanent implant brachytherapy subcommittee report.

No NRC staff action is required.

ITEM (4): The ACMUI formed a subcommittee to draft a set of proposed qualifications that interventional radiologists must satisfy to become Authorized Users (AUs) for Y-

90 microspheres. The subcommittee includes: Dr. Bruce Thomadsen (chair), Dr. Douglas Eggli, Dr. Subir Nag, Dr. James Welsh, and Mr. Steve Mattmuller.

No NRC staff action is required. The subcommittee expects to provide final recommendations for a vote at the May 2009 ACMUI meeting.

ITEM (5): 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.

NRC staff partially accepts the recommendation to move the medical use of Y-90 microspheres from 10 CFR 35.1000 to another section of the regulations. Since NRC staff does not believe the guidance is fully developed at this time to include in the rulemaking expected to begin in 2009, NRC staff intends to include the medical use of Y-90 microspheres in the next rulemaking. The guidance was revised in September 2007, December 2007, August 2008, and September 2008, and NRC staff believes the guidance is still evolving.

ITEM (6): The ACMUI strongly encourages NRC to: (a) continue supporting the exportation of Highly-Enriched Uranium (HEU) material for Mo-99 targets used by international producers; (b) provide all possible help towards the development of US producers of Mo-99.

NRC's role in the exporting of HEU for the production of medical isotopes is to issue export licenses to the U.S. Department of Energy (DOE). In 2008, NRC's Office of International Programs issued DOE a license to export HEU target materials to Atomic Energy of Canada for medical isotope production in 2009.

NRC does not have a role in promoting a domestic supply of Mo-99; NRC's role is to provide a stable regulatory basis for evaluating any application and regulating any domestic supplier. In Fiscal Year (FY) 2009, NRC received two letters of intent (from Babcock and Wilcox and the University of Missouri) to develop domestic Mo-99 production facilities in the U.S. The Office of Federal and State Materials and Environmental Management Programs' staff will work with NRC's Office of Reactor Regulation to review and resolve policy issues associated with any licensing request.

ITEM (7): ACMUI formed a subcommittee to develop a solution that satisfies both the training needs of the residency program and the NRC requirements for achieving AU status using the board certification pathway. The subcommittee should create a recommendation to be discussed at a future teleconference prior to the spring 2008 ACMUI meeting. The subcommittee includes: Dr. Douglas Eggli (chair), Dr. Subir Nag, Dr. William Van Decker, and Dr. Mickey Guiberteau (technical assistance).

NRC staff scheduled a teleconference on Thursday, January 22, 2009, to discuss the subcommittee's recommendation for a solution that satisfies both the training needs of the residency program and the NRC requirements for achieving AU status using the board certification pathway.

ITEM (8): 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.

NRC staff accepts the ACMUI recommendation and will add the item to its User Need memorandum requesting changes to Part 35 through rulemaking.

ITEM (9): 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.

NRC staff accepts the ACMUI recommendation and will add the item to its User Need memorandum requesting changes to Part 35 through rulemaking.

ITEM (10): NRC staff should revise 10 CFR 35.40 to clarify that an AU, not the AU, should sign and date both the pre-implantation and post-implantation portions of the WD for all modalities with two part WDs. [Note this allows for one AU to sign the pre-implantation portion of the WD and another AU to sign the post-implantation portion of the WD]

NRC staff accepts the ACMUI recommendation and will add the item to its User Need memorandum requesting changes to Part 35 through rulemaking.

ITEM (11): 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.

NRC staff accepts the ACMUI recommendations and will add these items to its User Need memorandum requesting changes to Part 35 through rulemaking.

ITEM (12): 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.

NRC staff accepts the ACMUI recommendation and will add the item to its User Need memorandum requesting changes to Part 35 through rulemaking.

ITEM (13): NRC staff should require licensees to report to the NRC events in which licensees measure molybdenum breakthrough that exceeds the regulatory limits.

NRC staff accepts the ACMUI recommendation and will add the item to its User Need memorandum requesting changes to Part 35 through rulemaking.

ITEM (14): NRC staff should pursue a change to allow "grandfathered" AUs to be supervisors and preceptors.

NRC staff accepts the ACMUI recommendation and is pursuing expedited rulemaking with the Office of General Counsel and the Division of Intergovernmental Liaison and Rulemaking.

ITEM (15): NRC staff should notify ACMUI when the NRC Office of General Counsel (OGC) makes a determination on the regulations regarding "grandfathered" AUs as supervisors and preceptors for the purposes of training and experience.

NRC staff accepts the recommendation and provided a response to this recommendation separately via email on January 9, 2009.

ITEM (16): The standing ACMUI medical nuclear materials events subcommittee should review events and provide an analysis to the full committee annually in the spring instead of the fall.

NRC staff will add this item to all spring agendas instead of the fall.

ITEM (17): ACMUI believes that 10 CFR 35.491 provides adequate training and experience for the use of NeoVista's EpiRad 90™ device, if the training under 10 CFR 35.491 is accompanied by appropriate device specific training.

NRC staff accepts the ACMUI recommendation to allow physicians who meet the training and experience requirements in 10 CFR 35.491 with device specific training to become Authorized Users for the NeoVista EpiRad 90™ device. The licensing guidance is currently being revised to incorporate ACMUI recommendation.

ITEM (18): NRC should add a training requirement that the individual using the EpiRad 90™ device should be a retinal surgeon.

The motion did not pass; therefore, no NRC staff action is required.

Proposal to Include Medical Events in the International Atomic Energy Agency's (IAEA's) International Nuclear Event Scale (INES)

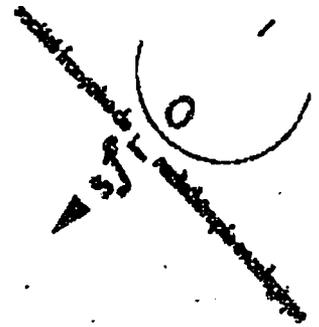
INES is a worldwide tool that the IAEA maintains for communicating to the public in a consistent way the safety significance of nuclear and radiological events. Events in INES are classified on a seven level scale: Levels 1-3 are called "incidents" and Levels 4-7 "accidents." The scale is designed so that the severity of an event is about 10 times greater for each increase in level on the scale (see attached INES leaflet).

NRC is participating in an IAEA Working Group to evaluate a proposal to include Medical Events in IAEA's INES. The Working Group is a subgroup to the INES Advisory Committee, and the function of the Working Group is to evaluate the proposal and to provide a recommendation and a report to the Committee as to whether or not to initiate a pilot on the subject, and if initiating a pilot is advised, to provide the outline for the criteria proposed for use in the pilot. Pilots typically are conducted for a period of 2-3 years, and then evaluated again before a decision is made by the INES Advisory Committee whether to make a permanent inclusion in the INES Manual.

IAEA has conducted two Working Group meetings with IAEA member countries to consider and evaluate the proposal. There is a third meeting proposed for November 2009.

The purpose of this discussion is to make ACMUI aware of this proposal, and to seek feedback and advice, to assist in the preparation for the third Working Group meeting. Items that NRC is seeking feedback on in particular are:

- position/reaction/thoughts/issues on the concept of including the medical events (pros and cons of doing so, and how the cons might be resolved)
- whether medical industry input should be sought, and if yes, what ACMUI recommends regarding the timing and scope for that, and how best to approach industry.



**ASN-SFRO experimental scale
for the rating of radiation protection events affecting patients
undergoing a medical radiotherapy procedure**

(5 July 2007)

**ASN-SFRO experimental scale
for the rating of radiation protection events affecting patients
undergoing a medical radiotherapy procedure**

1. INTRODUCTION

The ASN-SFRO experimental scale is designed to provide the public with comprehensible and explicit information about radiation protection events affecting patients undergoing a medical procedure.

In the 1990s, the Nuclear Safety Authority (ASN) played an essential role in the development of the international nuclear event scale INES, published by IAEA. This scale was initially applied to events likely to affect the safety of basic nuclear installations and subsequently to events related to the transport of radioactive materials and sources.

In 2002, ASN proposed a new scale, compatible with the INES scale, to deal with all events related to radiation protection, particularly radiation protection of workers, regardless of where the incident occurs, so that the public can be given consistent information. These changes led to the publication of a new INES scale by IAEA, applied experimentally since 2006 in several countries, including France.

However, at present this scale does not cover events concerning persons exposed intentionally in the context of medical procedures (radiotherapy). The need for a scale for unplanned exposures occurring during such procedures is recognised by IAEA and since June 2007 has been the subject of work, to which ASN has already contributed.

With this in mind, ASN, together with SFRO, is proposing a scale compatible with the INES scale now used, but also incorporating rating tables already used by practitioners (CTCAE¹).

The ASN-SFRO experimental scale will be tested for 12 months and the results jointly assessed by ASN and SFRO.

2. PRESENTATION OF THE ASN-SFRO EXPERIMENTAL SCALE

The ASN-SFRO scale is appended.

The events are rated on an 8-level severity scale: the upper levels (4 to 7) correspond to events categorised as accidents and the lower levels (1 to 3) to events categorised as incidents.

¹ Cancer Therapy Evaluation Program, August 2006, <http://ctep.cancer.gov>

The severity of the effects is assessed with reference to the international clinical classification (CTCAE) already used by practitioners:

- Grade 1: mild effects
- Grade 2: moderate effects
- Grade 3: severe effects
- Grade 4: serious or life-threatening effects
- Grade 5: death

The effects considered in the declaration submitted to ASN are the unexpected or unforeseeable effects due to inappropriate doses or irradiated volumes. Not included however, are any side-effects, whatever their grade, that may for example result from a strategy agreed by the practitioner and patient, with no error in the irradiated volume or delivered dose (accepted risk).

For patients affected by a radiotherapy event, the effects or complications may not be immediate. A provisional rating followed by a final rating several months later may therefore be necessary.

For confirmed effects, over-rating will be used to take account of the number of patients concerned (see 3.3).

Unlike the INES scale, the defence in depth criterion (assessment of the level of safety of the installation) is not incorporated into this rating system, in order to prevent any confusion between the seriousness of a medical condition and a failure of the installation or breakdown in the organisation of a department.

3. RATING CRITERIA

In the same way as the INES scale, the ASN-SFRO scale was designed so that the rating criteria for an event concern not only its confirmed consequences, but also its potential effects. The number of patients exposed is also taken into account.

3.1 Criteria concerning confirmed consequences (SFRO base)

When the effects are confirmed, the rating refers to the various clinical classification grades, as follows:

- level 5, corresponding to grade 5 of the clinical classification, refers to death,
- level 4, corresponding to grade 4 concerns acute or late serious effects such as post-radiation myelitis, life-threatening extensive unmanageable tissue necrosis, with serious or major disablement (serious colitis, serious cystitis, etc.),
- level 3, corresponding to grade 3, concerns acute or late severe effects such as non-life-threatening manageable tissue necrosis, with moderate disablement (severe colitis, severe cystitis, etc.),
- level 2, corresponding to grade 2, concerns the acute or late moderate effects such as moderate post-radiation stenosis, relatively unproblematic tissue impairment (cutaneous fibrosis), or minimal or no disablement,
- level 1, corresponding to grade 1, concerns mild effects but also events for which no effect is expected,
- level 0 is used to rate events with no dosimetric consequences.

3.2 Dosimetric criteria and potential effects

When the effects are not yet confirmed, dose or irradiated volume criteria are chosen for a provisional rating. The difference between the received dose and the intended dose is evaluated on the basis of accepted or tolerated deviations, in the light of existing practices or available references.

Similarly, the difference between the volume actually irradiated and the volume that should have been treated is analysed, taking account of the presence or otherwise of any organs particularly sensitive to radiation.

For any significant or extremely significant discrepancies, the event will be rated level 2 or 3, or possibly 4.

If there is a high level of uncertainty over whether or not possible effects may have occurred, the event is rated level 1 or 2 (depending on the conditions of the event).

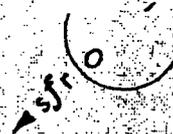
3.3 Criteria concerning the number of patients exposed

For confirmed effects of a level of 5 or more; the minimum rating level defined is increased by:

- 1 if the number of patients concerned is greater than 1
- 2 if the number of patients concerned is greater than 10

For confirmed effects of level 2, 3 or 4, the rating level is given the + sign when the number of patients concerned is greater than 1.

In order to prevent any confusion concerning the severity of the effects, the over-rating criterion concerning the number of cases is not applied to potential effects, except when the information concerning the delivered dose and/or irradiated volumes already allows a prognosis to be made in terms of death, serious or severe effects. The event will eventually be re-rated if there are any confirmed effects that may be linked to the over-exposure or exposure error.



ASN-SFRO SCALE FOR DEALING WITH RADIATION PROTECTION EVENTS AFFECTING PATIENTS UNDERGOING A RADIOTHERAPY PROCEDURE

1 - PURPOSE OF THE ASN-SFRO SCALE

The purpose of the ASN-SFRO scale is to inform the public about radiation protection events affecting patients undergoing a radiotherapy procedure. It was published in July 2007 and has been tested for a 12-month trial period. The scale has been jointly evaluated by ASN, SFPM (French society of medical physicists) and SFRO. The definitive scale has been published on ASN website in July 2008.

2 - PRESENTATION OF THE ASN-SFRO SCALE

The events are rated on eight levels on the ASN/SFRO scale:

- level 0 and 1 are used to rate events with no clinical consequence;
- levels 2 to 3 correspond to events categorised as "incidents";
- levels 4 to 7 correspond to events categorised as "accidents".

The severity of the effects is assessed with reference to the international clinical classification (CTCAE¹ grades) already used by practitioners.

The effects considered in the declaration submitted to ASN are the unexpected or unforeseeable effects due to inappropriate doses or irradiated volumes. Not included however, are any side-effects, whatever their grade, that may for example result from a strategy agreed by the practitioner and patient, with no error in the irradiated volume or delivered dose (accepted risk).

For patients affected by a radiotherapy event, the effects or complications may not be immediate. A provisional rating followed by a final rating several months later may therefore be necessary.

For confirmed effects, over-rating will be used to take account of the number of patients concerned.

Unlike the INES scale, the defence in depth criterion (assessment of the level of safety of the installation) is not incorporated into this rating system, in order to prevent any confusion between the seriousness of a medical condition and a failure of the installation or breakdown in the organisation of a department.

¹ Cancer Therapy Evaluation Program, August 2006, <http://ctep.cancer.gov>

ASN-SFRO SCALE

5 to 7	EVENTS (UNFORESEEN, UNEXPECTED)	CAUSES	CONSEQUENCES (CTCAE V3.0 GRADE)
5 to 7	Death	Dose (or irradiated volume) far higher than normal leading to fatal complications or sequelae	Fatal
4 ²	Severe life-threatening event, disabling complications or sequelae	Dose or irradiated volume far higher than tolerable doses or volumes	Grade 4 or 5, serious effect, other unexpected or unforeseeable, grade 4
3 ³	Event leading to a severe impairment of one or more organs or functions	Dose or irradiated volume higher than tolerable doses or volumes	Grade 3 or 4, serious effect, other unexpected or unforeseeable, grade 3
2	Event leading to or likely to lead to a moderate impairment of an organ or function	Dose higher than recommended doses or irradiation of a volume liable to lead to unexpected but moderate complications	Grade 2 or 3 moderate, unexpected or unforeseeable effect, grade 2 or 3 or 4
1	Event with moderate consequence but no expected clinical consequence	Dose or irradiated area (or accuracy, error of dose or target non-compliance or all of the treatment)	No expected consequence
0	Event without consequence for the patient	Error of dose (irradiated unit, wrong time) comparable on all of the patients. Error of identification of a patient treated for the same pathology (comparable)	No expected consequence

(1) In the event of death of several patients:

- the minimum level 5 is raised to 6 if the number of patients is higher than 1 but no more than 10,
- the minimum level 5 is raised to 7 if the number of patients is higher than 10.

(2) If the number of patients is higher than 1, the minimum level 5 is raised to 6.

3 - RATING CRITERIA

In the same way as the INES scale, the ASN-SFRO scale was designed so that the rating criteria for an event concern not only its confirmed consequences, but also its potential effects.

The number of patients exposed is also taken into account.

Criteria concerning confirmed consequences

When the effects are confirmed, the rating refers to the various clinical classification grades, as follows:

- level 1, corresponding to grade 1, concerns mild effects but also events for which no effect is expected;
- level 2, corresponding to grade 2, concerns the acute or late moderate effects such as moderate post-radiation stenosis, relatively unproblematic tissue impairment (cutaneous fibrosis), or minimal or no disablement;
- level 3, corresponding to grade 3, concerns acute or late severe effects such as non-life-threatening manageable tissue necrosis, with moderate disablement (severe colitis, severe cystitis, etc.);
- level 4, corresponding to grade 4 concerns acute or late serious effects such as post-radiation myelitis, life-threatening extensive unmanageable tissue necrosis, with serious or major disablement (serious colitis, serious cystitis, etc.);
- levels 5, 6 and 7, corresponding to grade 5 of the clinical classification, refers to one or more deaths.

Dosimetric criteria and potential effects

When the effects are not yet confirmed, dose or irradiated volume criteria are chosen for a provisional rating. The difference between the received dose and the intended dose is evaluated on the basis of accepted or tolerated deviations, in the light of existing practices or available references.

Similarly, the difference between the volume actually irradiated and the volume that should have been treated is analysed, taking account of the presence or otherwise of any organs particularly sensitive to radiation.

For any significant or extremely significant discrepancies, the event will be rated level 2 or 3, or possibly 4.

If there is a high level of uncertainty over whether or not possible effects may have occurred, the event is rated level 1 or 2 (depending on the conditions of the event).

Criteria concerning the number of patients exposed

For confirmed effects of a level of 5 or more, the minimum rating level defined is increased by:

- + 1 if the number of patients concerned is greater than 1 and less than 10;
 - + 2 if the number of patients concerned is 10 or more.
- For confirmed effects of level 2, 3 or 4, the rating level is given the + sign when the number of patients concerned is greater than 1.

In order to prevent any confusion concerning the severity of the effects, the over-rating criterion concerning the number of cases is not applied to potential effects, except when the information concerning the delivered dose and/or irradiated volumes already allows a prognosis to be made in terms of death, serious or severe effects.

The event will eventually be re-rated if there are any confirmed effects that may be linked to the over-exposure or exposure error.

4 - SUMMARY OF EVENTS FROM JULY 2007 TO JULY 2008

ASN was notified of 181 events during the period where the experimental scale has been used (July 2007-July 2008):

- 175 were rated level 0 or 1;
- 6 were rated level 2.



6, place du Colonel Bourgoin
75012 Paris - France
Tel.: +33 1 40 19 86 00
Fax: +33 1 40 19 86 69

Société Française de Radiothérapie Oncologique
Centre Antoine Béclère
45 rue des Saints-Pères • 75006 Paris • France
Tel. / Fax +33 1 40 15 92 05

APPENDIX
ASN-SFRO experimental scale
for the rating of radiation protection events affecting patients
undergoing a medical radiotherapy procedure

Event (unforeseen, unexpected)	Cause	Consequences (CTCAE v3.0 grade)	Level	Examples
Death	Dose (or exposed volume) far higher than normal leading to fatal complications or sequela	Death	5 to 7 ⁽¹⁾	Epinal 5+1 = 6 Lyon 5
Serious life-threatening event, disabling complication or sequela	Dose or exposed volume far higher than tolerable doses or volumes	Acute or late serious effect, either unexpected or unforeseeable, grade 4	4 ⁽²⁾	Tours
Event leading to a severe impairment of one or more organs or functions	Dose or exposed volume higher than tolerable doses or volumes	Acute or late severe effect, either unexpected or unforeseeable, grade 3	3 ⁽²⁾	
Event leading to or liable to lead to a moderate impairment of an organ or function	Dose higher than recommended doses, or irradiation of a volume liable to lead to unexpected but moderate complications	Acute or late moderate, unexpected or unforeseeable effect, grade 2, minimal or no disablement	2 ⁽²⁾	Toulouse
Event with no expected consequences or liable to lead to mild consequences	Dose or volume error with no expected consequences (for example, non-compensatable target error during a session)		1	Stereotaxic equipment
Event with no dosimetric consequences for the patient	Error in identification of a patient treated for the same pathology. Anomaly detected in time before treatment started		0	Angers

⁽¹⁾ In the event of death of several patients:

- the minimum level 5 is raised to 6 if the number of patients is higher than 1 but no more than 10
- the minimum level 5 is raised to 7 if the number of patients is higher than 10

⁽²⁾ If the number of patients is higher than 1, a + sign is added to the chosen level (for example: 3 becomes 3+).

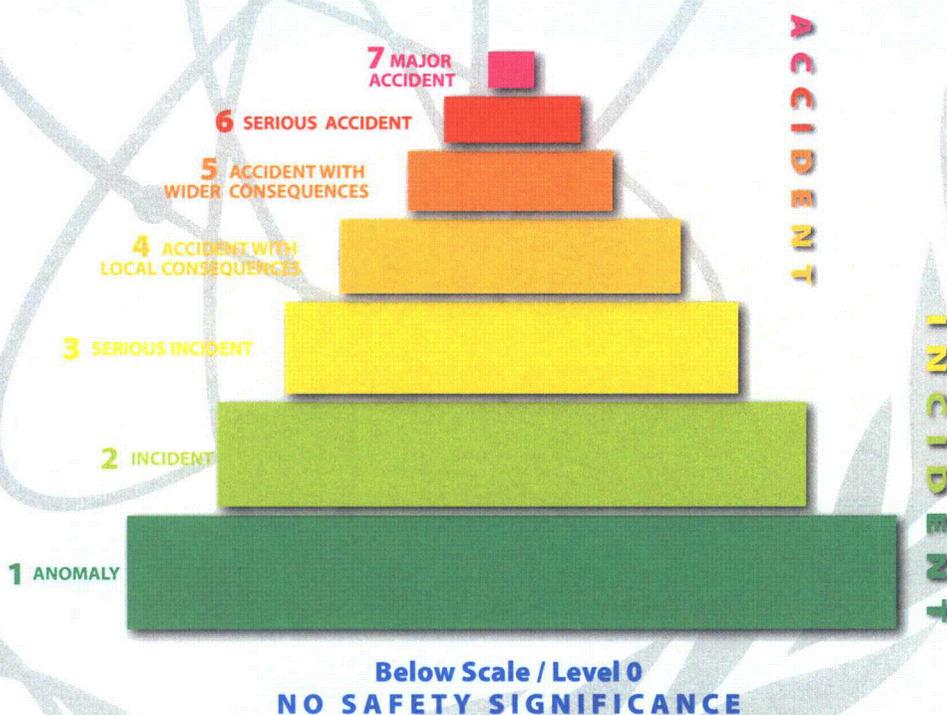
INES

THE INTERNATIONAL NUCLEAR AND RADIOLOGICAL EVENT SCALE

The INES Scale is a worldwide tool for communicating to the public in a consistent way the safety significance of nuclear and radiological events.

Just like information on earthquakes or temperature would be difficult to understand without the Richter or Celsius scales, the INES Scale explains the significance of events from a range of activities, including industrial and medical use of radiation sources, operations at nuclear facilities and transport of radioactive material.

Events are classified on the scale at seven levels: Levels 1–3 are called "incidents" and Levels 4–7 "accidents". The scale is designed so that the severity of an event is about ten times greater for each increase in level on the scale. Events without safety significance are called "deviations" and are classified Below Scale / Level 0.



IAEA
International Atomic Energy Agency
Atoms For Peace



OECD
Nuclear Energy Agency

For more information: www-news.iaea.org

Major Accident Level 7
Serious Accident Level 6
Accident with Wider Consequences Level 5
Accident with Local Consequences Level 4
Serious Incident Level 3
Incident Level 2
Anomaly Level 1
NO SAFETY SIGNIFICANCE (Below Scale/ Level 0)

INES classifies nuclear and radiological accidents and incidents by considering three areas of impact:

People and the Environment considers the radiation doses to people close to the location of the event and the widespread, unplanned release of radioactive material from an installation.

Radiological Barriers and Control covers events without any direct impact on people or the environment and only applies inside major facilities. It covers unplanned high radiation levels and spread of significant quantities of radioactive materials confined within the installation.

Defence-in-Depth also covers events without any direct impact on people or the environment, but for which the range of measures put in place to prevent accidents did not function as intended.

Communicating Events

Nuclear and radiological events are promptly communicated by the INES Member States, otherwise a confused understanding of the

event may occur from media or from public speculation. In some situations, where not all the details of the event are known early on, a provisional rating may be issued. Later, a final rating is determined and any differences explained.

To facilitate international communications for events attracting wider interest, the IAEA maintains a web-based communications network that allows details of the event to immediately be made publicly available.

The two tables that follow show selected examples of historic events rated using the INES scale, ranging from a Level 1 anomaly to a Level 7 major accident; a much wider range of examples showing the rating methodology is provided in the INES Manual.

Scope of the Scale

INES applies to any event associated with the transport, storage and use of radioactive material and radiation sources, whether or not the event occurs at a facility. It covers a wide spectrum of practices, including industrial use

EXAMPLES OF EVENTS AT NUCLEAR FACILITIES

	People and Environment	Radiological Barriers and Control	Defence-in-Depth
7	<i>Chernobyl, 1986</i> — Widespread health and environmental effects. External release of a significant fraction of reactor core inventory.		
6	<i>Kyshtym, Russia, 1957</i> — Significant release of radioactive material to the environment from explosion of a high activity waste tank.		
5	<i>Windscale Pile, UK, 1957</i> — Release of radioactive material to the environment following a fire in a reactor core.	<i>Three Mile Island, USA, 1979</i> — Severe damage to the reactor core.	
4	<i>Tokaimura, Japan, 1999</i> — Fatal overexposures of workers following a criticality event at a nuclear facility.	<i>Saint Laurent des Eaux, France, 1980</i> — Melting of one channel of fuel in the reactor with no release outside the site.	
3	No example available	<i>Sellafield, UK, 2005</i> — Release of large quantity of radioactive material, contained within the installation.	<i>Vandellios, Spain, 1989</i> — Near accident caused by fire resulting in loss of safety systems at the nuclear power station.
2	<i>Atucha, Argentina, 2005</i> — Overexposure of a worker at a power reactor exceeding the annual limit.	<i>Cadarache, France, 1993</i> — Spread of contamination to an area not expected by design.	<i>Forsmark, Sweden, 2006</i> — Degraded safety functions for common cause failure in the emergency power supply system at nuclear power plant.
1			Breach of operating limits at a nuclear facility.

EXAMPLES OF EVENTS INVOLVING RADIATION SOURCE AND TRANSPORT

	People and Environment	Defence-in-Depth
7		
6		
5	<i>Goiânia, Brazil, 1987</i> — Four people died and six received doses of a few Gy from an abandoned and ruptured highly radioactive Cs-137 source.	
4	<i>Fleurus, Belgium, 2006</i> — Severe health effects for a worker at a commercial irradiation facility as a result of high doses of radiation.	
3	<i>Yanango, Peru, 1999</i> — Incident with radiography source resulting in severe radiation burns.	<i>Ikitelli, Turkey, 1999</i> — Loss of a highly radioactive Co-60 source.
2	<i>USA, 2005</i> — Overexposure of a radiographer exceeding the annual limit for radiation workers.	<i>France, 1995</i> — Failure of access controls systems at accelerator facility.
1		Theft of a moisture-density gauge.

such as radiography, use of radiation sources in hospitals, activity at nuclear facilities, and transport of radioactive material.

It also includes the loss or theft of radioactive sources or packages and the discovery of orphan sources, such as sources inadvertently transferred into the scrap metal trade.

When a device is used for medical purposes (e.g., radiodiagnosis or radiotherapy), INES is used for the rating of events resulting in actual exposure of workers and the public, or involving degradation of the device or deficiencies in the safety provisions. Currently, the scale does not cover the actual or potential consequences for patients exposed as part of a medical procedure.

The scale is only intended for use in civil (non-military) applications and only relates to the safety aspects of an event. INES is not intended for use in rating security-related events or malicious acts to deliberately expose people to radiation.

What the Scale is Not For

It is not appropriate to use INES to compare safety performance between facilities,

organizations or countries. The statistically small numbers of events at Level 2 and above and the differences between countries for reporting more minor events to the public make it inappropriate to draw international comparisons.

History

Since 1990 the scale has been applied to classify events at nuclear power plants, then extended to enable it to be applied to all installations associated with the civil nuclear industry. By 2006, it had been adapted to meet the growing need for communication of the significance of all events associated with the transport, storage and use of radioactive material and radiation sources.

The IAEA has coordinated its development in cooperation with the OECD/NEA and with the support of more than 60 Member States through their officially designated INES National Officers.

The current version of the INES manual was adopted 1 July 2008. With this new edition, it is anticipated that INES will be widely used by the Members States and become the worldwide scale for putting into the proper perspective the safety significance of nuclear and radiation events.

INES

THE INTERNATIONAL NUCLEAR AND RADIOLOGICAL EVENT SCALE

INES

THE INTERNATIONAL NUCLEAR AND RADIOLOGICAL EVENT SCALE

GENERAL DESCRIPTION OF INES LEVELS

INES Level	People and Environment	Radiological Barriers and Control	Defence-in-Depth
Major Accident Level 7	<ul style="list-style-type: none"> Major release of radioactive material with widespread health and environmental effects requiring implementation of planned and extended countermeasures. 		
Serious Accident Level 6	<ul style="list-style-type: none"> Significant release of radioactive material likely to require implementation of planned countermeasures. 		
Accident with Wider Consequences Level 5	<ul style="list-style-type: none"> Limited release of radioactive material likely to require implementation of some planned countermeasures. Several deaths from radiation. 	<ul style="list-style-type: none"> Severe damage to reactor core. Release of large quantities of radioactive material within an installation with a high probability of significant public exposure. This could arise from a major criticality accident or fire. 	
Accident with Local Consequences Level 4	<ul style="list-style-type: none"> Minor release of radioactive material unlikely to result in implementation of planned countermeasures other than local food controls. At least one death from radiation. 	<ul style="list-style-type: none"> Fuel melt or damage to fuel resulting in more than 0.1% release of core inventory. Release of significant quantities of radioactive material within an installation with a high probability of significant public exposure. 	
Serious Incident Level 3	<ul style="list-style-type: none"> Exposure in excess of ten times the statutory annual limit for workers. Non-lethal deterministic health effect (e.g., burns) from radiation. 	<ul style="list-style-type: none"> Exposure rates of more than 1 Sv/hr in an operating area. Severe contamination in an area not expected by design, with a low probability of significant public exposure. 	<ul style="list-style-type: none"> Near accident at a nuclear power plant with no safety provisions remaining. Lost or stolen highly radioactive sealed source. Misdelivered highly radioactive sealed source without adequate procedures in place to handle it.
Incident Level 2	<ul style="list-style-type: none"> Exposure of a member of the public in excess of 10 mSv. Exposure of a worker in excess of the statutory annual limits. 	<ul style="list-style-type: none"> Radiation levels in an operating area of more than 50 mSv/hr. Significant contamination within the facility into an area not expected by design. 	<ul style="list-style-type: none"> Significant failures in safety provisions but with no actual consequences. Found highly radioactive sealed orphan source, device or transport package with safety provisions intact. Inadequate packaging of a highly radioactive sealed source.
Anomaly Level 1			<ul style="list-style-type: none"> Overexposure of a member of the public in excess of statutory annual limits. Minor problems with safety components with significant defence-in-depth remaining. Low activity lost or stolen radioactive source, device or transport package.

NO SAFETY SIGNIFICANCE (*Below Scale/Level 0*)

Photo Credits: Chilean Nuclear Energy Commission,
Genkai Nuclear Power Plant, Genkai, Japan/Kyushu Electric Power Co.,
J. Mairs/IAEA

International Atomic Energy Agency
Information Series / Division of Public Information
08-00000 / E

Subject

Consultancy Meeting to discuss the applicability of International Nuclear Event Scale (INES) to events involving unplanned exposure of patients (medical events)

Dates of Travel and Countries/Organizations Visited

February 4-6, 2009, International Atomic Energy Agency (IAEA)/Autorite de Surete Nucleaire (ASN), Paris, France

Author, Title, and Agency Affiliation

Michele L. Burgess, Regional Program Coordinator, Division of Materials Safety and State Agreements, FSME

Background/Purpose

To participate in a consultancy meeting to discuss a proposal by France to include medical events in INES, using a scale adopted by France for rating events related to unplanned exposures of medical patients (medical events) to enable communication with the public, in accessible and explicit terms, regarding medical events. The final objective of the consultancy would be a recommendation to the INES Advisory Committee whether to include medical events in INES. NRC also participated in the initial Consultancy Meeting on this topic in 2006. In both meetings, NRC was a primary participant, given that NRC has an established national reporting system for medical events.

Staff's purpose in participating in the consideration of this proposal is to ensure that the proposed path forward is compatible with NRC goals and mission, given NRC's current commitment to participation in INES. If the proposed path forward is to include medical events in INES; staff's purpose is to ensure that the criteria and reporting timeframes are consistent with significance of the events and other INES events ratings, to ensure an opportunity to assess impact on the medical community before implementation, and to ensure understanding of how IAEA will assess and trend on these events.

Abstract: Summary of Pertinent Points/Issues

The attendees presented summaries of the requirements and systems for reporting and collecting medical events within their countries, discussed sample event ratings for actual events within their countries as rated against the proposed criteria, and discussed issues and concerns raised by the sample ratings.

The group agreed that there is a need to share medical events with the public to bring more transparency and build trust, and recognized that if information regarding medical events is to be shared with the public, there needs to be a common rating scale in order to ensure a consistent communication of the significance of the events relative to other medical events, and relative to other types of events:

The group recognized that there is wide variance in the level of medical event reporting criteria and systems from country to country, ranging from well-developed to non-existent. The group

recommended that the IAEA should consider convening a meeting to share operational experience in the development of national reporting criteria and operating experience feedback systems.

The group agreed that there is a need to continue the discussions on the subject, and recommended that the IAEA prepare a position paper for the INES Advisory Committee to communicate that need, and to recommend the development of a technical document to further explore the issue and propose recommended action.

NRC participation in this effort is beneficial given NRC's commitment to participate in INES. It is important that NRC be involved in any major shifts in the INES content or criteria, such as this proposal to expand the content to include medical events. In addition, if it is agreed to expand the content, it is also important to ensure that criteria for the expanded content is such that the NRC can continue to support its commitment to full INES participation.

Discussion

The meeting was prompted by a proposal from France to include medical events in INES. There was an initial consultancy meeting in 2006, which NRC also attended. The result of the initial consultancy meeting was an agreement to conduct sample ratings on actual events from 2002-2007 and to re-convene to discuss the results, identify any issues raised, and make a recommendation to the INES Advisory Committee whether additional consideration should be given to the proposal. This second consultancy meeting proceeded as outlined in the meeting agenda (attached). The meeting consisted of nine participants, representing IAEA, France, Hungary, Finland, Japan and the US. Additional participants presented background information for the consultancy group, including participants from the Societe Francaise de Radiotherapie Oncologique (SFRO) and additional participants from France.

In summary:

- (1) The attendees presented summaries of the requirements and systems for reporting and collecting medical events within their countries, discussed sample event ratings for actual events within their countries as rated against the proposed criteria, and discussed any issues or concerns raised by the sample ratings.
- (2) The group made the following conclusions and recommendations:
 - a. The group agreed that there is a need to share medical events with the public to bring more transparency and build trust.
 - b. The group expressed appreciation of the efforts done in the development of the ASN/SFRO scale for radiotherapy events (the proposed criteria that was used for the sample ratings).
 - c. The group recognized that if information regarding medical events is to be shared with the public, there needs to be a common rating scale, and that the scale needs to include nuclear medicine and radiology (diagnostic and interventional), in addition to radiotherapy.
 - d. The group recognized that there is wide variance in the level of medical event reporting criteria and systems from country to country, ranging from well-developed to non-existent. The group recommended that the IAEA should consider convening a meeting to share operational experience in the development of national reporting criteria and operating experience feedback systems.

- e. The group recommended that the IAEA prepare a position paper for the INES Advisory Committee, including the following items:
 - i. That it should be possible to develop guidance acceptable to the medical community, although it may not be identical to the SFRO scale (which was developed by the French medical community),
 - ii. That there is a need to continue the discussions on the subject, and to prepare a technical document to discuss in-depth and resolve the differences identified in this meeting in relative event significance between the current INES scale for all events and the ASN/SFRO scale for medical events; in order to determine the appropriate scale for medical events, if they were to be included in INES,
 - iii. That further discussion and development of a scale should involve, where appropriate, the medical community, other medical regulators, and INES experts. This would include World Health Organization (WHO) and Nuclear Energy Agency (NEA), and
 - iv. That the position paper would include a list of the issues identified in the initial sample ratings using the ASN-SFRO scale, and a list of differences between the INES and the ASN/SFRO scales.
- f. The group recommended that IAEA prepare a technical document in consultation with the current group of experts to:
 - i. Discuss the issues and differences identified in the position paper and propose solutions,
 - ii. Develop an international scale with associated guidance that would cover the range of medical events (radiotherapy, nuclear medicine, and radiology). Development would be based on consideration of both the current INES scale/guidance, and the ASN/SFRO scale/guidance,
 - iii. Provide examples of rated events in the guidance, and
 - iv. Propose a path forward and timeframes to evaluate the proposed international scale before implementation.

NRC participation in this effort is beneficial given NRC's commitment to participate in INES. It is important to be involved in any major shifts in the INES content or criteria, such as this proposal to expand the content to include medical events. In addition, if it is agreed to expand the content, it is also important to ensure that criteria for the expanded content is such that the NRC can continue to support its commitment to full INES participation.

Pending Actions/Planned Next Steps for NRC

The proposed next actions were:

- IAEA will prepare a draft position paper and circulate to the members of this group by March 15, 2009, asking for comments by the end of March.
- IAEA will submit the paper to the INES Advisory Committee, requesting Advisory Committee consideration of the position paper at the April 21-24, 2009 Advisory Committee meeting.
- If approved by the Advisory Committee, IAEA will prepare a zero draft of the proposed technical document and circulate in preparation for a third consultants meeting. Proposed dates for the third consultants meeting are November 16-20 or December 7-12, 2009.

Points for Commission Consideration/Items of Interest

No current items for Commission consideration. The Commission has already approved NRC participation in INES. If the proposal is to include medical events in INES, staff intends to inform the Commission due to the interest the Commission has expressed in medical issues and their interactions with the NRC's Advisory Committee on the Medical Use of Isotopes (ACMUI); and to inform the Agreement States.

Attachment

1. Copy of the meeting agenda
2. ASN/SFRO scale

"On the Margins"

None

Training and Experience for Interventional Radiologists to be Authorized Users for radiolabeled Microspheres

Normal T&E Requirements

- Training in basic radiological science
- Training specific to the modality
- Experience under supervision

Basic Radiological Science

Needed topics and duration.
The topics were fairly standard.

Duration options:

- Somewhere between 24 and 80 hours as ophthalmic applications.
- 80 hours as for I-131 treatments, requiring a written directive or not, or parenteral administrations of unsealed sources, and for imaging studies.
- Somewhere between 80 and 200 hours.
- 200 hours as for manual brachytherapy, remote afterloaders, teletherapy, gamma stereotactic.

Basic Radiological Science

The ACMUI approved 80 h:

- (i) Radiation physics and instrumentation;
- (ii) Radiation protection;
- (iii) Mathematics pertaining to the use and measurement of radioactivity;
- (iv) Chemistry of byproduct material for medical use; and
- (v) Radiation biology.

Specific Modality Training

I-131 > 33 mCi

- (2) Has work experience, under the supervision of an authorized user who meets the requirements in §§ 35.390, 35.394, or equivalent Agreement State requirements. A supervising authorized user, who meets the requirements in § 35.390(b), must also have experience in administering dosages as specified in § 35.390(b)(1)(ii)(G)(2). The work experience must involve--
- (i) Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;
 - (ii) Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters;
 - (iii) Calculating, measuring, and safely preparing patient or human research subject dosages;
 - (iv) Using administrative controls to prevent a medical event involving the use of byproduct material;
 - (v) Using procedures to contain spilled byproduct material safely and using proper decontamination procedures; and
 - (vi) Administering dosages to patients or human research subjects, that includes at least 3 cases involving the oral administration of greater than 1.22 gigabecquerels (33 millicuries) of sodium iodide I-131.

Specific Modality Training

Manual Brachytherapy

- (ii) 500 hours of work experience, under the supervision of an authorized user who meets the requirements in § 35.490 or equivalent Agreement State requirements at a medical institution, involving--
 - (A) Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;
 - (B) Checking survey meters for proper operation;
 - (C) Preparing, implanting, and removing brachytherapy sources;
 - (D) Maintaining running inventories of material on hand;
 - (E) Using administrative controls to prevent a medical event involving the use of byproduct material;
 - (F) Using emergency procedures to control byproduct material.

Specific Modality Training

Manual Brachytherapy

And

- (2) Has completed 3 years of supervised clinical experience in radiation oncology

Specific Modality Training

Ophthalmic applicator

- (2) Supervised clinical training in ophthalmic radiotherapy under the supervision of an authorized user at a medical institution, clinic, or private practice that includes the use of strontium-90 for the ophthalmic treatment of five individuals. This supervised clinical training must involve—
 - (i) Examination of each individual to be treated;
 - (ii) Calculation of the dose to be administered;
 - (iii) Administration of the dose; and
 - (iv) Follow up and review of each individual's case history

Specific Modality Training

HDR Brachytherapy

- (ii) 500 hours of work experience, under the supervision of an authorized user who meets the requirements in § 35.690 or, equivalent Agreement State requirements at a medical institution, involving—
 - (A) Reviewing full calibration measurements and periodic spot-checks;
 - (B) Preparing treatment plans and calculating treatment doses and times;
 - (C) Using administrative controls to prevent a medical event involving the use of byproduct material;
 - (D) Implementing emergency procedures to be followed in the event of the abnormal operation of the medical unit or console;
 - (E) Checking and using survey meters; and
 - (F) Selecting the proper dose and how it is to be administered.

Specific Modality Training

HDR Brachytherapy

And

- (2) Has completed 3 years of supervised clinical experience in radiation therapy

Proposed Specific Modality Training

Radiolabeled Microspheres

- (i) Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;
- (ii) Checking survey meters for proper operation;
- (iii) Examination of each individual to be treated;
- (iv) Calculating, measuring, and safely preparing patient or human research subject dosages;
- (v) Administering dosages to patients or human research subjects
- (vi) Using administrative controls to prevent a medical event involving the use of byproduct material;
- (vii) Using procedures to control, and to contain spilled, byproduct material safely and using proper decontamination procedures; and
- (viii) Follow up and review of each individual's case history;

Proposed Specific Modality Training

Radiolabeled Microspheres

- (i) Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;
- (ii) Performing quality control procedures on instruments used to determine the activity of dosages and Checking survey meters for proper operation;
- (iii) [Vague; practice of medicine]
- (iv) Calculating, measuring, and safely preparing patient or human research subject dosages;
- (v) Administering dosages to patients or human research subjects
- (vi) Using administrative controls to prevent a medical event involving the use of byproduct material;
- (vii) Using proper procedures to safely control and decontaminate spills of byproduct material ; and
- (viii) Follow up and review of each individual's case treatment

Proposed Specific Modality Training

Radiolabeled Microspheres

- (i) Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;
- (ii) Checking survey meters for proper operation;
- (iii) Examination of each individual to be treated;
- (iv) Calculating radiation doses, measuring dosages, and preparing microspheres for safe human use;
- (v) Administering microspheres to patients
- (vi) Using administrative controls to prevent a medical event involving the use of byproduct material;
- (vii) Controlling and containing byproduct material, and decontaminating after an inadvertent spill;
- (viii) Follow up and review of each individual's case history

Proposed Specific Modality Training

Radiolabeled Microspheres

- (i) Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;
- (ii) Checking survey meters for proper operation;
- (iii) Examination of each individual to be treated;
- (iv) Calculating, measuring, and safely preparing patient or human research subject dosages;
- (v) Administering dosages to patients or human research subjects
- (vi) Using administrative controls to prevent a medical event involving the use of byproduct material;
- (vii) Using procedures to control, and to contain spilled, byproduct material safely and using proper decontamination procedures; and
- (viii) Follow up and review of each individual's case history;

Day 1

8:00-9:30

- I. Introduction
- II. Basic Principles of Radiation Physics including radiation safety for beta particles
 - A. Describe difference between photon (x-Rays, gamma rays, and Bremsstrahlung radiation) and particulate radiation (beta particles)
 - B. Interaction of Photons and Particles with matter (tissue, lead, acrylic, and air)
 - C. Physical properties of ^{90}Y
 - i. Production Method
 - ii. Radioactive Decay
 - iii. Tissue penetration range vs effective dose range
 - D. Radiation detection and measurement devices used with ^{90}Y
 - i. GM,
 - ii. ion chambers,
 - 1. dose calibrators,
 - 2. personal dosimeters,
 - 3. portable dose measurement instruments (QTpi)
 - iii. Scintillators.
 - E. Radiation SI Units
 - i. Concepts and units of activity, exposure, dose, and dosage
 - F. Basic Radiation Safety and ALARA using ^{90}Y microspheres

9:30 – 9:45

III. Break

9:45 – 10:45

IV. General Radiation Biology

- A. Energy Deposition and Microdosimetry Basic concepts
- B. Physical Factors affecting response
 - i. Energy of radiation and the type of radiation,
 - ii. Radiation dose rate,
 - iii. radiation range or penetration,
 - iv. delivery time for sustained radiation dose
- C. Radiation Chemistry and Chemical Effects
- D. Mechanisms of Cell death and cell death modeling
- E. DNA/Chromosome Damage and Repair mechanisms

10:45 – 12:00

V. Y-90 Radiation Biology for Hepatic Tumors

- A. Hepatic Tumor vascular dependence and hepatic structure
- B. Tumor Cell Killing In vivo
- C. Hepatic Tumor Biology and histology factors
- D. Tumor Hypoxia
- E. Dose Fractionation
- F. Radiation induced liver disease
- G. Radiation induced lung pneumonitis

Day 1

12:00 – 13:00

VI. Lunch - Question and Answers

- 2 8:00 – 9:30 XII. Basic Concepts in Y-90 Radioembolization - Dosimetry Lecture II
A. participants would calculate and review with the instructor dosimetry problems based on real cases
- 9:30 – 10:00 XIII. Basic Concepts in Y-90 Radioembolization - Angiography Lecture II
- 10:00 – 10:15 XIV. Break
- 10:15 – 12:00 XV. Advanced Concepts in Y-90 Radioembolization - Segmentectomy, Retreatment, etc.
- 12:00 – 13:00 XVI. Lunch - Question and Answers
- 13:00 – 14:00 XVII. Advanced Concepts in Y-90 Radioembolization - Chemotherapy, radiosensitizers, etc.
- 14:00 – 15:00 XVIII. Comprehensive Literature Review of Treatment Outcomes.
- 15:00 – 15:15 XIX. Break
- 15:15 – 17:00 XX. Quality Assurance Requirements for Y-90 Radioembolization Program
- A. Radioactive Material Licensing considerations for a new program
 - i. NRC regulations
 - ii. Agreement state issues
 - iii. Written directive
 - 1. TheraSphere model
 - 2. SIR-Sphere BSA model
 - iv. Instrumentation Requirements
 - 1. Dose Calibrator
 - 2. Survey Instrument
 - 3. Portable Dose Measurement Instrument
 - v. Radioactive material storage
 - vi. Surveys
 - 1. Post procedural survey instrumentation
 - 2. Survey Procedure
 - 3. Contamination Containment Procedures
 - vii. Patient release requirements
 - viii. Medical Event reporting requirements
 - B. Microsphere specific quality assurance
 - i. Package receipt & acceptance
 - ii. Patient activity preparation procedures
 - iii. Angiography procedure
 - iv. Delivery procedures
 - v. Dose calibrator accuracy, consistency and linearity
 - vi. Documentation requirements
 - vii. Possible patient adverse events
 - viii. Coordination of the medical team
 - ix. Patient care issues



Potential Changes to 10 CFR Part 35

ACMUI Meeting

May 7, 2009

Donna-Beth Howe, Ph.D.



10 CFR 35.390(b)(1)(ii)(G)

Problem: In 10 CFR 35.390(b)(1)(ii)(G) has 4 categories of radioactive drug administrations needing a written directive.

Category 3 includes parenteral administrations of any beta emitter, or a photon-emitting radionuclide with a photon energy less than 150 keV, for which a written directive is required, regardless of whether the beta or low energy photon is the primary emission used for the medical application.

Category 4 includes parenteral administrations of any other radionuclide, for which a written directive is required.

There are no parenterally administered radionuclides that fall into category 4 since there are no pure alpha emitters.

Now that byproduct material includes accelerator-produced radionuclides, there are more NRC regulated radionuclides that are expected to be used primarily for their alpha emissions. Since the dosimetry for these radionuclides can be much more complicated there is a need to segregate them into their own category and ensure physicians using them have specific training and experience with them.



10 CFR 35.390(b)(1)(ii)(G)

Recommend:

Revise 10 CFR 35.390(b)(1)(ii)(G)(3) and (4) to read:

(3) Parenteral administration requiring a written directive for any radionuclide that is being used because of its beta emission, or low photon- emission; and/or

(4) Parenteral administration requiring a written directive for any radionuclide that is being used because of its alpha particle emission.



10 CFR 35.490(b)(1)(ii) and 35.690(b)(1)(ii)

Problem: Both 10 CFR 35.490(b)(1)(ii) and 35.690(b)(1)(ii) require 500 hours of work experience, under the supervision of an appropriate authorized user at a medical institution.

Medical practice has changed. Now medical practices outside of medical institutions (e.g., in clinics, private practices) treat patients with manual brachytherapy, photon emitting remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units.

The individual seeking authorized user status is still required to complete three years of radiation oncology residency training that will provide training and experience with diverse brachytherapy procedures and therapy devices.

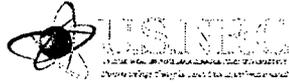


10 CFR 35.490(b)(1)(ii) and 35.690(b)(1)(ii)

Questions: Is a stand alone clinic (that only conducts one NRC-regulated activity) an appropriate place to receive training? Does training obtained at a stand alone clinic have the oversight and validation that it could receive from an institution with programs and support staff in place? If deemed adequate, then 35.490(b)(1)(ii) and 35.690(b)(1)(ii) could be revised to clarify the supervised work experience does not limit experience to be obtained in only a medical institution.

Example

(ii) 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, clinic, or private practice, involving—



Status of Part 35 Rulemakings

Ed Lohr / Neelam Bhalla
Rulemaking Branch B
DILR/FSME



Part 35 Ongoing Rulemakings

Medical Event (ME) Definitions Proposed Rule

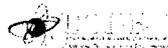
Direct Final Rule – Clarifies 35.57 grandfathered individuals can provide work experience supervision and attestations

Next 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 when required for all procedures.



Part 35 - Medical Event Definitions Proposed Rule

- Proposed Rule published in FR Aug 6, 2008.
- Public comment period ended Nov 7, 2008.
- Staff currently working to resolve public comments.
- Final rule scheduled for publication in August – may be delayed pending outcome of VA MEs



Direct Final Rule – Clarifies 35.57 grandfathered individuals can provide work experience supervision and attestations

- Current regulations do not specifically state that 35.57 grandfathered individuals may serve as work experience supervisors and attestations.
- Technical basis for rulemaking was accepted Jan 15, 2009.
- The request for rulemaking was given top priority because of the potential for disrupting the licensed community.
- Staff is currently developing language to amend Part 3



Direct Final Rule

- DFR is used when the rulemaking is minor and non-controversial.
- By publishing DFR and proposed rule together it can reduce the time by up to 1 year.
- DFR and proposed rule should be published by Aug 2009.
- If no significant adverse public comments received, rule effective 75 days after published (Nov 2009).
- If adverse comment received, comments are resolved and final rule published about 1 year later (Aug 2010).



Next Part 35 Rulemaking

- Will include numerous proposed changes identified by the NRC staff.
- The proposed changes have been or will be reviewed by ACMUI.
- Should include consideration of Ritenour Petition; and preceptor attestation requirements (SRM to SECY-08-0179).



Next Part 35 Rulemaking Time Lines

- Scheduled to begin Summer, 2009 – may be delayed pending completion of the Part 35 ME rulemaking.
- Proposed Rule – Tentative Fall 2010
- Final Rule – Tentative Fall 2011



Status of Part 35 Rulemakings

Questions?

Medical Isotope Production Without Highly Enriched Uranium (HEU)

Dr. Kevin D. Crowley
 Director
 Nuclear and Radiation Studies Board
 The National Academies
 Washington, DC, USA

THE NATIONAL ACADEMIES
 Advisors to the Nation on Science, Engineering, and Medicine

ACMUI Meeting, May 7, 2009

1

Outline of Presentation

- Organization information
- Background
- Study charge
- Study plan
- Selected results
- Report Information

ACMUI Meeting, May 7, 2009

2

Organization Information

The National Academies

- National Academy of Sciences (NAS)
- National Academy of Engineering (NAE)
- Institute of Medicine (IOM)
- National Research Council (NRC)

Congressionally chartered (1863)

Private & nonprofit

"Advisors to the Nation on Science, Engineering, and Medicine"

ACMUI Meeting, May 7, 2009

3

Background

- Study on medical isotope production requested by U.S. Congress (Energy Policy Act of 2005)
- Sponsored by the Department of Energy, National Nuclear Security Administration
- Study request reflects an attempt to strike a balance between two important national interests:
 - Availability of reasonably priced medical isotopes in the United States: No domestic production since 1988
 - Proliferation prevention: Highly enriched uranium (i.e., uranium enriched in U-235 to ≥ 20 percent) can be used to make improvised nuclear devices

ACMUI Meeting, May 7, 2009

4

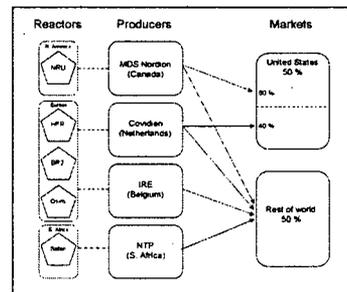
Background (2)

- Isotopes of primary concern are Mo-99/Tc-99m
- Short half lives (66 hours/6 hours) require an efficient production and supply chain
- Primary method of production is irradiation of HEU targets in research and test reactors
- Annual HEU use: ~40-50 kg; mostly U.S. origin
- Liquid waste from Mo-99 production is HEU
 - Loses "self protection" in 1-2 years
 - Hundreds of kilograms of HEU in storage (liquids and solids)
- > 95% of global Mo-99 supply is produced in just four countries: Belgium, Canada, South Africa, and the Netherlands (next slide)

ACMUI Meeting, May 7, 2009

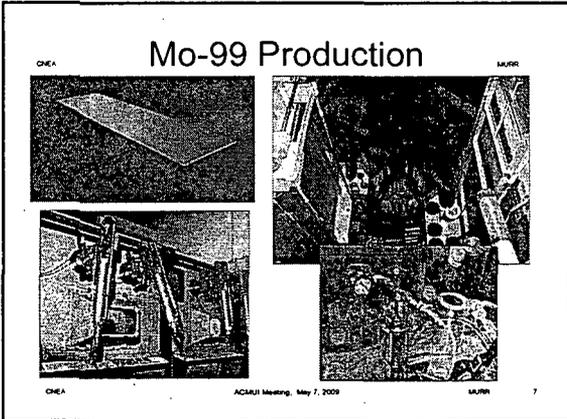
5

"Large-Scale" Mo-99 Producers



ACMUI Meeting, May 7, 2009

6



Study Charge (5 parts)

1. Feasibility of procuring supplies of medical isotopes from commercial sources that do not use HEU
 - Three-part test for feasibility:
 - LEU targets have been developed and demonstrated for use in reactors and target processing facilities that produce medical isotopes to serve U.S. needs
 - Sufficient quantities of medical isotopes are available from LEU targets and fuel to meet U.S. needs
 - Average anticipated total cost increase from production of medical isotopes without HEU is less than 10 percent
 - Not specified: Point in supply chain or time scale for feasibility determination

ACSMU Meeting, May 7, 2009

Study Charge (2)

2. Current and projected demand and availability of medical isotopes in regular current domestic use
3. Progress being made by DOE and others to eliminate all use of HEU in reactor fuel, reactor targets, and medical isotope production facilities
4. Potential cost differential in medical isotope production in reactors and target processing facilities if the products were derived from production systems that do not involve fuels and targets with HEU

ACSMU Meeting, May 7, 2009

Study Charge (3)

5. The National Academies should ... identify additional steps that could be taken by DOE and medical isotope producers to improve the feasibility of such conversions ...and identify any reliability of supply issues that could arise as a result of such conversions

ACSMU Meeting, May 7, 2009

Study Plan

- Committee of 14 experts appointed by the NAS president to carry out study
 - Included 2 nuclear medicine physicians
- Extensive fact finding and facility visits
 - Briefings from medical isotope producers, potential producers, regulators, target manufacturers
 - Visits to medical isotope production facilities in US, Canada, Europe, Australia, and Argentina
- Report received extensive peer review before release

ACSMU Meeting, May 7, 2009

Committee Membership

<p>Chris Whipple, ENVIRON International Corporation (CHAIR)</p> <p>Steven M. Larson, Memorial Sloan-Kettering Cancer Center (VICE CHAIR)</p> <p>Cynthia Atkins-Duffin, Lawrence Livermore National Laboratory</p> <p>Anthony E. Boardman, University of British Columbia Sauder School of Business</p> <p>D. Jeffrey Bostock, Lockheed Martin Energy Systems (retired)</p> <p>G. Brian Estes, U.S. Navy (retired)</p> <p>Milton Levenson, Bechtel International (retired)</p>	<p>Irvin W. Osborne-Lee, Prairie View A&M University</p> <p>Eugene J. Peterson, Los Alamos National Laboratory</p> <p>Richard C. Reba, MedStar Georgetown University Hospital</p> <p>Iain G. Ritchie, International Atomic Energy Agency (retired)</p> <p>Thomas J. Ruth, TRIUMF Meson Facility (TRIUMF)</p> <p>Jasmina Vujic, University of California, Berkeley</p> <p>Raymond G. Wymer, Oak Ridge National Laboratory (retired)</p>
--	---

ACSMU Meeting, May 7, 2009

Selected Results

ACMUI Meeting, May 7, 2006

13

Mo-99/Tc-99m Supply

- Global Mo-99 supply (2006): ~12,000 6-day curies per week (6-day curie = number of curies available 6 days after shipment leaves a producer's facility)
- Mo-99 supply to the US market (2006): ~5,000-7,000 6-day curies per week
- Not much change in supply since 2006
- 95%-98% of global/US supply produced with HEU targets

ACMUI Meeting, May 7, 2006

14

Mo-99/Tc-99m Demand

- Estimates of future demand growth evaluated by the committee ranged from 3%-10%
- Committee judged that demand growth in US will range from 0%-5% over next five years with the likely growth rate in the 3%-5% range
- Demand growth will continue to rise over the long term as the US population ages
- Current practices favoring the clinical use of Tc-99m radiopharmaceuticals will continue for the foreseeable future

ACMUI Meeting, May 7, 2006

15

Feasibility of Conversion to LEU

- Conversion feasibility was assessed at three points in Mo-99/Tc-99m supply chain
 - Costs to produce Mo-99
 - Costs for technetium generators
 - Costs for Tc-99m doses
- Potential impediments to conversion were assessed
 - Technical
 - Regulatory
 - Timing
 - Impacts on supply reliability
- Examined "large-scale" and "regional" producer experiences and capabilities

ACMUI Meeting, May 7, 2006

16

Feasibility (2)

- **Test 1:** Have LEU targets been developed and demonstrated for use in target and processing facilities that produce medical isotopes to serve U.S. needs?
 - No—neither MDS Nordion nor Mallinckrodt are producing Mo-99 with LEU targets
 - LEU targets have been developed and demonstrated
 - There are no technical barriers to their use by producers that currently supply the U.S. market
 - These producers can probably convert to LEU-based production within current facilities, although some modifications of process equipment would be necessary, and conversion could take time

ACMUI Meeting, May 7, 2006

17

Feasibility (3)

- **Test 2:** Are sufficient quantities of medical isotopes available from LEU targets and fuel to meet U.S. needs?
 - Not at present
 - No technical reasons that adequate quantities cannot be produced with LEU
 - Committee saw no demonstrated evidence that current large-scale producers were taking the necessary steps to convert

ACMUI Meeting, May 7, 2006

18

Feasibility (4)

- **Test 3:** Is the average anticipated total cost increase from production of medical isotopes without HEU less than 10 percent?
 - Conversion is feasible with a 10 percent cost increase if conversion is carried out within producers' existing facilities
 - Conversion might also be feasible even if extensive facility modification or new construction is required
 - A 10 percent increase in Mo-99 production costs would have a negligible ($\leq 0.1\%$) impact on the costs of typical U.S. medical isotope procedures
 - Current variations in costs at the 3 points in the Mo-99 supply chain are $\gg 10$ percent

ACMUI Meeting, May 7, 2008

19

Steps to Improve Feasibility

Mo-99 Producers

- Announce a commitment to and best-effort schedule for conversion
- Identify needs for technical assistance, if any, to enable conversion
- Industry organizations (CORAR, AIPES), working with scientific and medical societies, can play key roles in marshaling, coordinating, and supporting conversion

ACMUI Meeting, May 7, 2008

20

Steps (2)

Department of Energy

- Make the considerable technical expertise of the U.S. national laboratory system available to assist producers with conversion-related research and development (R&D)
- Examine options to share R&D costs with producers
- Work with organizations in other countries (e.g., IAEA, CNEA/INVAP) to assist producers with conversion
- Maintain consistent pricing for LEU vs. HEU on a common U-235 mass basis

ACMUI Meeting, May 7, 2008

21

Steps (3)

U.S. Congress

- Fund government cost sharing for conversion-related R&D
- Condition the supply of U.S.-origin HEU for medical isotope production
 - Reinstate the Schumer Amendment with a 7-10 year phase-out date for HEU exports
 - Prohibit export of HEU for medical isotope production in new reactors

ACMUI Meeting, May 7, 2008

22

Steps (4)

U.S. Congress, continued

- Provide temporary financial incentives for production or purchase of LEU-based Mo-99 used in the U.S.

Food and Drug Administration

- Work with industry and DOE's technical experts to ensure that there is a common understanding of LEU-based processes from a regulatory perspective and a good understanding of FDA requirements

ACMUI Meeting, May 7, 2008

23

Reliability of Mo-99 Supply

- Mo-99 supply to the U.S. is fragile
- Primarily the result of reliance on aging reactors
- Supply reliability is likely to become a serious problem for the U.S. in the early part of the next decade without new or refurbished reactors
- It will take time (5-10 years +) for substantial supplies of Mo-99 to become available to the U.S. from other foreign and domestic producers
- AECL's May 2008 decision to discontinue work on the Maple Reactors is a blow to worldwide supply reliability

ACMUI Meeting, May 7, 2008

24

Reliability (2)

- Conversion to LEU-based production would not address current and projected future supply reliability problems
- Conversion would improve supply reliability by removing uncertainties associated with the continued availability of HEU
- Conversion could cause reliability problems if not carried out in a technically sound manner
- Government assistance is likely to be required to improve supply reliability

Report Information

- Final report released in prepublication form on January 15, 2009
- Available for free downloading at http://www.nap.edu/catalog.php?record_id=12569
- Report will be issued in final form before the end of May 2009



**DEPARTMENT OF VETERANS AFFAIRS
MEDICAL CENTER – PHILADELPHIA
MULTIPLE MEDICAL EVENTS INVOLVING
PROSTATE BRACHY THERAPY TREATMENTS**

Patricia Pelke, Chief, Materials Licensing Branch, Region III
Darrel Wiedeman, Senior Health Physicist, Region III
Cassandra Frazier, Senior Health Physicist, Region III



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.
- The DVA National Radiation Safety Committee (NRSC) has responsibility for providing oversight of the DVA's implementation of its MML .



Background

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



Background

- The PVAMC retained the services of consulting radiation oncology physicians and medical physics for pre-treatment planning, implant preparations, implant treatments, post treatment planning, etc.



Sequence of Events

- February 2002, PVAMC initiated its prostate brachytherapy program and implanted its first patient.
- February 2003, during a seed prostate implant, many seeds (40 out of 74) were mistakenly implanted into the patient's bladder and subsequently recovered. NRC determined that because the written directive was revised, no medical event occurred.



Sequence of Events

- October 2005, during a seed prostate implant, many seeds (45 out of 90) were again mistakenly implanted into the patient's bladder and subsequently recovered. NHPP determined that because the written directive was revised, no medical event occurred.
- May 2008, the NHPP notified the NRC of a possible medical event involving a patient that received a dose to the prostate that was less than 80 percent of the prescribed dose.



Sequence of Events

- May 2008, the NHPP initiated an onsite reactive inspection at the PVAMC in response to the reported medical event.
- June 2008, the PVAMC prostate brachytherapy program suspended.
- The PVAMC commissioned an external review of the entire prostate brachytherapy program.



Sequence of Events

- July 2008, the PVAMC appointed an Administrative Board of Investigation (ABI) to review the facts and circumstances surrounding the medical events.
- As of October 2, 2008, the licensee identified and reported to the NRC a total of 92 medical events.



Medical Event Criteria

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



Basis for Medical Event Criteria

- 1) Rectum -The D1.33 (dose to 1.33 cc) was selected because it is the volume the VariSeed® treatment planning program used to identify high dose volume during the pre-treatment planning.
- 2) Tissue External to Prostate - A perimeter of 1cm was selected because it fully encompassed seeds positioned parallel and perpendicular to the external prostate surface. It was determined that any prostate brachytherapy seed protruding beyond the 1cm cloud around the prostate was counted as exterior to the prostate and evaluated for dose contribution to the perineum, rectum and bladder.



Basis for Medical Event Criteria

- 3) Tissue Inferior to Prostate - A determination was made that 10 percent (5) of the minimum number (53) of seeds implanted in the Phase II patients located more than 1 cm exterior to and inferior to the surface of the prostate was the criteria for a possible medical event.
- 4) Bladder - The criteria of 3 or more seeds located in the bladder wall was selected based on the review of a patient's post-treatment plan which identified that 2 seeds in the bladder contributed to less than 60 Gy (equivalent to 60 Sv) to the bladder wall. The dose to the bladder wall with the seeds in the wall was compared to the dose to the bladder wall with the seeds removed. This criterion was well below the bladder tolerance dose.



92 Total Medical Events

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



Causes of Medical Events

- 1) Incorrect Placement of Seeds
- 2) Inadequate Procedures
- 3) Poor Management Oversight of Contractors
- 4) Inadequate Training of Licensee staff



Causes of Medical Events

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



Corrective Actions Taken

The licensee instituted the following corrective actions:

- 1) Suspended the prostate brachytherapy program on June 11, 2008, and ordered an external review of the prostate brachytherapy program by a Administrative Board of Investigation;



Corrective Actions Taken

- 2) Amended the PVAMC Sealed Source Radiotherapy policy to include:
 - a. A comparison and evaluation of both treatment plans and associated calculations with the written directive;
 - b. Direction to allow prostate implant treatments to proceed only when the treatment planning computer is able to produce pre or post-treatment plans; and
 - c. Instruction to the Radiation Safety Officer (RSO) and quality management staff to immediately report all deviations that exceed ten percent of the prescribed dose or dose fraction.



Corrective Actions Taken

- 3) Provided radiation safety training to radiation oncology staff, nuclear medicine staff, new employees, trainees and contractors regarding NRC regulations for written directives and medical events, including training on PVAMC's open door policy for reporting concerns and suspected violations;
- 4) Instituted a medical center peer-review system for radiation oncology services and post-treatment evaluations.
- 5) Revised the contract for radiation oncology services to realign services under the PVAMC RSO;



Corrective Actions Taken

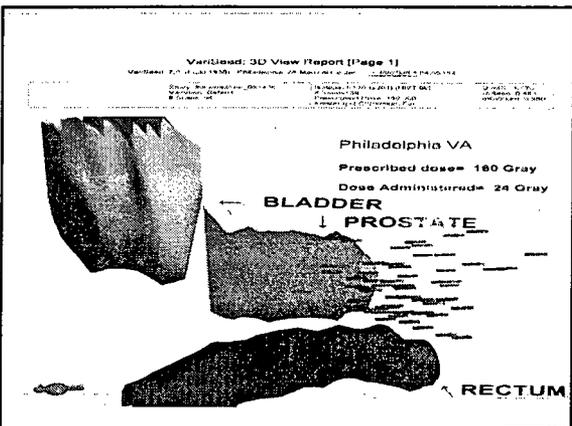
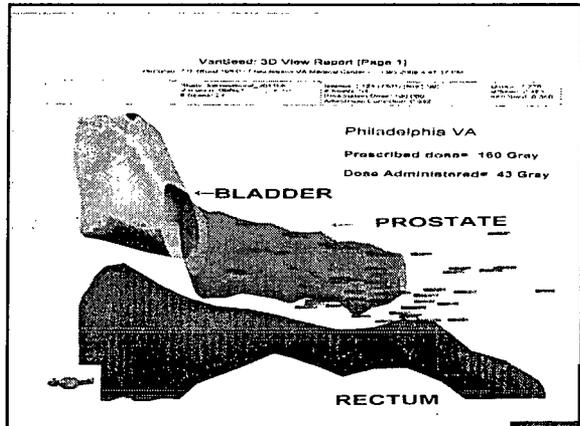
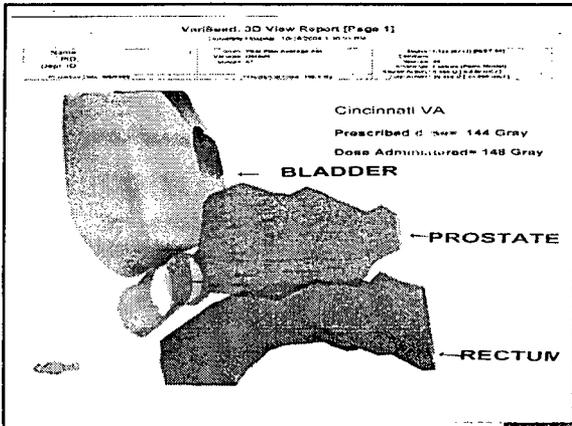
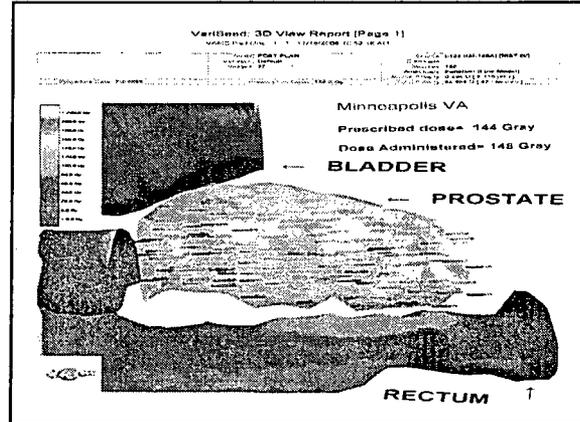
- 6) Instituted an internal quality assurance program to ensure communications between radiation oncology team members regarding safety and treatment concerns; and
- 7) Modified the PVAMC written procedures to incorporate a dual verification system and to clarify responsibilities.



Corrective Actions Taken

In addition, for patient care, the licensee:

- 1) Performed verification computed tomography (CT) scans on all patients that received prostate implants between CY 2002 and May 2008;
- 2) Re-evaluated the dose delivered to the treatment area;
- 3) Re-implanted brachytherapy seeds at a different VA location for at least four individuals; and
- 4) Removed at least one individual from performing brachytherapy treatments at the VA.



Questions?



Medical Use of ¹³⁷Cesium Chloride

Bruce Thomadsen, Ph.D.

Advisory Committee on the Medical Uses of Isotopes

June 25, 2009



Advisory Committee on the Medical Uses of Isotopes (ACMUI) Subcommittee on ¹³⁷Cesium Chloride (¹³⁷CsCl) Irradiators

- Darrell Fisher, Ph.D.
- Debbie Gilley
- Ralph Lieto
- Orhan Suleiman, Ph.D
- Bruce Thomadsen, Ph.D
- Richard Vetter, Ph.D.
- James Welsh, M.D.



Purpose of the Subcommittee

- The National Research Council's report, *Radiation Source Use and Replacement*, made several assumptions that seemed questionable to the ACMUI.
- The subcommittee investigated the concerns raised by the ACMUI



Concerns Addressed

- The need for ¹³⁷CsCl irradiators
- Viable alternatives
- Current Security



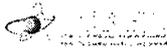
The Need for the Irradiators *Blood Products*

- The original report assumed that approximately 10% of the blood used in the United States (US) was irradiated.
- Discussions with hematologists and oncologists indicated that for these practices, the value ranged between 15% and 40%.
- The patients involved have depressed immune systems and need the irradiated blood.
- The lower number probably comes from a higher fraction of trauma cases, where irradiation is irrelevant.



The Need for the Irradiators *Animal Irradiation*

- Research on stem cells and other systemic therapies increasingly requires whole-body irradiation of the animals (usually mice) before infusion.
- This research is growing and may soon lead to treatments for currently untreatable conditions.



The Need for the Irradiators

Summary

- Without irradiators available, hematology and oncology patients would suffer potential death from the lack of irradiated blood.
- Without irradiators available, much of the stem-cell and systemic drug research would not be able to proceed.



Alternatives to ¹³⁷CsCl Irradiators

- The alternatives are conventional x-ray units or linear accelerators.
- Both have been and are used for blood, animal and material irradiation.



Conventional X-ray Units Blood Irradiation

- For blood irradiation, only one unit is approved by the U.S. Food & Drug Administration.
- The National Research Council listed the price as \$180,000, with \$10,000/year for the service contract.
- The current price is \$250,000 with \$33,000/year for the service contract.
- A replacement tube costs extra, as does calibration and quality management.



Conventional X-ray Units Blood Irradiation

- Throughput is lower for the x-ray unit.
- With 48,000 blood-product units / x-ray tube, a 50-unit per day operation would replace the tube every 3.7 years, adding to the cost of running the unit.



Conventional X-ray Units Animal Irradiation

- About 10 units are available.
- Few provide beams of 200 kV or higher, which limits their use with animals due to lack of penetration.
- Most prices range from \$146K - \$250K, plus the service contracts of about 10% per year.
- One low energy, short distance, small field size units markets for \$43K - \$87K.



Conventional X-ray Units Animal Irradiation

- Issues with the x-ray units for animal irradiators, other than price, include:
- The different Relative Biological Effectiveness (RBE) compared with ¹³⁷Cs – possibly a factor of 2 for the lower energy units.
 - The dose rates, which can have an effect on the biological effectiveness as well as make anesthesia more difficult.
 - Penetration may require irradiating animals from several directions.



Conventional X-ray Units Animal Irradiation

The RBE is the effectiveness of a type of radiation compared with a reference radiation.

- The RBE varies with the energy of the radiation;
- It also varies with the species and the biological endpoint.
- All of which makes the direct replacement of units using ^{137}Cs with x-rays a bit complicated.



Medical Linear Accelerators

- If the radiotherapy department's accelerator is used, time available for blood or animal irradiation become a problem.
- If not using a radiotherapy department's accelerator, price becomes a problem, at \$1.5M to start.



Security

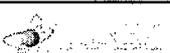
Since the National Research Council report raising the concerns about the security of these units, several things have changed.

- The security of the users has been enhanced through the required background checks and fingerprinting.
- The security of the facility has been enhanced following directives of the Nuclear Regulatory Commission (sometimes at great costs to the facility.)
- The security of the units is being enhanced through a program of the Department of Energy and Department of Homeland Security.



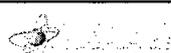
Security

- Following these three security enhancements, the units present little hazard for unauthorized source removal or disruption.
- The lack of such security was a major factor in the original report.



Summary

- Irradiation facilities are essential for irradiation of blood and in research.
- Forced replacement of $^{137}\text{CsCl}$ -based units would force many facilities to stop irradiations because of the large expense, since most of the facilities are non-profit and have few resources for funding a new x-ray unit or maintaining the unit.
- If not leading to the termination of the irradiations, the replacement would place a large financial burden on facilities which usually have little funding.



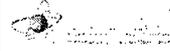
Summary

- While x-ray units have been used for blood, animal and material irradiation, the difference in the RBE complicates simple replacement of the ^{137}Cs .
- Finally, with the enhanced security programs for the $^{137}\text{CsCl}$ units, replacement is unnecessary.



Medical Isotope Shortages

Steve Mattmuller, MS, RPh, BCNP
Advisory Committee on the Medical Uses of Isotopes



Outline

- Needs
- Effects
- Causes
- Solutions



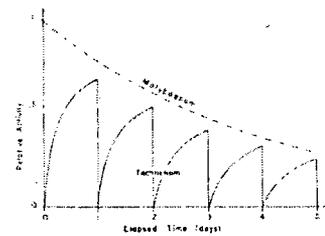
Needs: Patient Care

- More than 55,000 nuclear medicine procedures each day in the United States (US) depend on molybdenum-99 (Mo-99)
- Mo-99 (half-life = 66 hours) on a generator column, decays to technetium-99m (Tc-99m) (half-life = 6 hours)

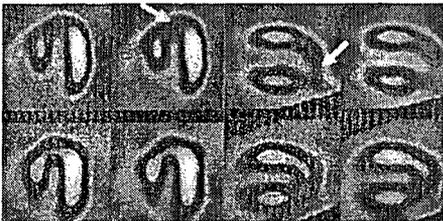


Needs: Patient Care

- Tc-99m eluted in chemical form pertechnetate
- Different radio-pharmaceuticals can be compounded using various kits for different nuclear medicine procedures



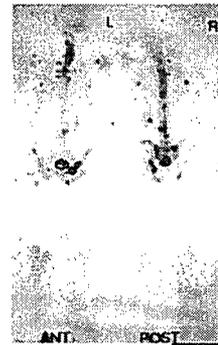
Needs: Patient Care



Cardiac perfusion single photon emission computed tomography (SPECT) study at stress (top row) and rest (bottom row) shows a defect in the heart due to reduced blood flow.



Needs: Patient Care



Effects: Patient Care

Since January 2007, the medical community has experienced five periods of supply disruptions.

Effects: Patient Care

Results from a Society of Nuclear Medicine (SNM) survey of effects on departments last November from the shortage that started August 2008:

- Postponed a procedure: 49%
- Cancelled a procedure: 19%
- Changed a procedure: 25%
- Recent shortage, 18% fewer procedures
- Referring physicians are frustrated by these interruptions and have/may choose inferior, sometimes more expensive alternate procedures for the care of their patients.

The worst of this recent shortage wasn't felt yet by the respondents; in early 2009 during two separate weeks were NO generators available!

Effects: Patient Care

Results of February survey of centralized nuclear pharmacies during the August 2008 - February 2009 shortage

% of Tc-99m doses able to dispense	% of Pharmacies
0-25%	4%
26-50%	17%
52-75%	29%
76-100%	50%

Effects: Patient Care

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

- are inferior in accuracy
- are usually more expensive
- may have a higher radiation dose
- may have a long term effect, since physicians are creatures of habit and will stay with the inferior procedure

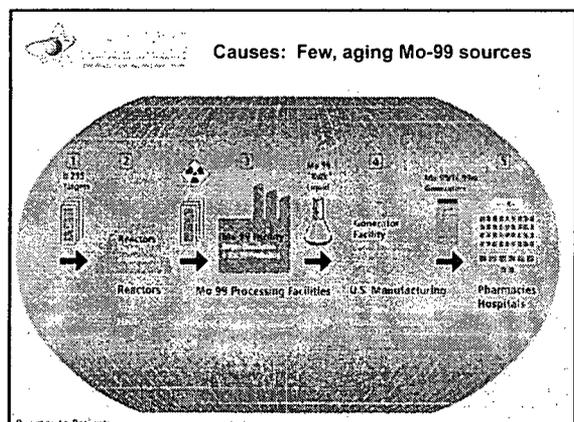
Effects: Patient Care

Our frustration is that we don't know:

- when the shortages will occur
- how severe the shortage will be or
- how long the shortage will last

Kettering Medical Center's own experience:

- Several weeks of 10% reduction in generator size
- Several weeks of generators reduced in size that arrived 3-4 days late
- Two weeks of NO generators





Causes: Fragile Supply

- National Research Universal (NRU) reactor in Canada and High Flux Reactor (HFR) in the Netherlands both supply 100% of US needs
- Both reactors use highly-enriched uranium (HEU) for Mo-99 targets
- The cost and potential of converting to low-enriched uranium (LEU) is unknown
- NRU - 52 years old, current license expires 2011
- HFR - 47 years old
 - August 2008: shutdown for maintenance, during restart found gas bubbles in the primary cooling system due to corrosion in a pipe encased in concrete
 - 2009: repairs will be made, **IF** it operates that long



Solution: New Mo-99 Suppliers

- + Babcock & Wilcox (B&W)
- + Partner with Covidien
- + Aqueous Homogenous Reactor (AHR)
 - No separate target, Mo-99 is processed from the fuel
 - Uses LEU
 - Domestic supplier
- BUT: Five years away...



Solution: New Mo-99 Suppliers

- + Missouri University Research Reactor (MURR)
- + Excellent track record in operations and radionuclide production
- + Testing is being completed for LEU targets
 - Needs to build a Mo-99 processing facility at an estimated cost of 40-50 million dollars
 - Uses HEU fuel, in process of changing to LEU fuel
 - BUT: 4-5 years away



Solution: New Mo-99 Suppliers

- Both B&W AHR and MURR have regulatory issues
- Reactor license category, B&W AHR reactor is designed for 100% radionuclide production
- MURR once converted to LEU fuel will need to operate at 12 Megawatts (MW) for efficient radionuclide production, 10 MW is the current limit.
- Flexibility will be needed during the licensing process in regards to construction plans and environmental issues, if time lines of 4-5 years are to be met.



Needs: Patient Care





Options to Revise Radiation Protection Regulations

SECY-08-0197

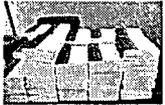
*Advisory Committee on Medical Uses of Isotopes
May 8, 2009*

Division of Compliance, Enforcement, and Enforcement Management Programs

1

Background

- Most recent rulemaking to incorporate the recommendations of the ICRP into 10 CFR 20 was completed in 1991, and was based primarily on ICRP Publications 26 (1977)
- Regulations that contained explicit dose criteria, rather than cross-references to Part 20, were not updated in 1991, and remain based primarily on ICRP Publications 1 (1958) and 2 (1959)




2

Background

- NRC staff recommended in 2001 that the Commission wait for next set of ICRP recommendations, and begin Technical Basis development
- Commission agreed in April, 2002, but did not approve Technical Basis efforts
- ICRP Recommendations published in December, 2007 as Publication 103, following considerable public consultation




3

SECY-08-0197

- Policy Issue Notation Vote paper provided to Commission on December 18, 2008
- Provided Options for next steps regarding NRC radiation protection standards
- Provided Background on technical issues in 10 CFR Part 20 and 10 CFR Part 50
- Recommended Commission approval for staff to undertake stakeholder dialogue and technical basis development



4

SRM-SECY-08-1097

- Commission approved staff recommendation to move forward with stakeholder dialogue and technical basis development, April 2, 2009
- Objective is to explore implications, as appropriate and where scientifically justified, of greater alignment with ICRP Publication 103.
- Given adequate protection, discussion is to focus on discerning the benefits and burdens associated with revising the radiation protection regulatory framework



5

Technical Issues for Part 20

- Total Effective Dose
- Dose limits
 - Occupational
 - Public
 - Embryo/fetus of Declared Pregnant Women
- Constraints
 - Occupational Exposure
 - Public Exposure
- Numerical values




6

Occupational Dose Limits

- ICRP Recommendation is 10 rem over 5 years, with a maximum of 5 rem in any one year.
- Part 20 limit is 5 rem per year.
- Options:
 - No change: 5 rem per year
 - ICRP recommendation
 - 2 rem per year
- Implications:
 - Impacts of reduced values?
 - Impacts of increased recordkeeping?



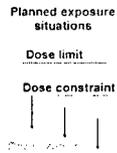
Dose Limit for Embryo/Fetus

- ICRP recommendation is 100 mrem after notification of pregnancy.
- 10 CFR 20.1208 is 500 mrem over gestation period
- Options:
 - No Change
 - ICRP Recommendation
 - Other single value, such as 50 mrem, after declaration
- Implications:
 - Impacts of reduced values?
 - Impacts of increased recordkeeping?



Constraints (1)

- ICRP recommends the consistent application of constraints as a tool in optimization of protection.
- Constraints are not to be limits.
- Part 20 already as a constraint for public exposure from airborne radionuclides from materials facilities.
- Many large licensees already use planning values in ALARA programs.



Constraints (2)

- Options:
 - No Change?
 - Require a licensee to use constraints as part of radiation protection program?
 - Specify a numeric value licensee is not to exceed?
- Implications:
 - Impacts to Programs?
 - Benefits in protection seen?
 - Relationship to Dose Limit?
 - Appropriate insertion of regulatory requirement?



Moving Forward

- NRC staff is looking to engage stakeholders on the technical issues and options for resolution
 - What are YOUR thoughts on the technical issues?
 - What are the impacts of different options?
 - Are there other options that should be considered?
 - What other issues need to be put on the table?
 - What information is needed to make decisions?



Planned Interactions

- Web page under development
- Press Release
- Scheduled Presentations
 - CRCPD, May 2009
 - SNM, June 2009
 - HPS, July 2009
 - State Liaison Officers, August 2009



How Can We Work Together?

- NRC Staff would like to work with, and through, ACMUI and its members to engage the medical communities
- What suggestions do you have for meetings we can make presentations to?
- What arrangement (subcommittee?) can we utilize for ongoing interactions with ACMUI?



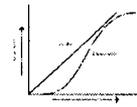
Questions? Questions?



Background Materials

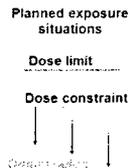
ICRP Publication 103

- Consolidated material from ICRP Publication 60 and subsequent publications
- Maintained fundamental principles of: Justification, Optimization, and Limitation
- Radiation risk remains as $\sim 5 \times 10^{-4}$ per rem
- LNT for prospective radiation control programs



ICRP Publication 103

- Moved to a "situation" based framework
 - Planned Exposure Situations
 - Emergency Exposure Situations
 - Existing Exposure Situations
- Emphasized Optimization using Dose Constraints
- Retained Dose Limits and values
 - Occupational Exposure: 10 rem / 5 years, max of 5 rem in any one year
 - Public Exposure: 100 mrem
 - Embryo/Fetus: 100 mrem



ICRP Continuing Work

- Assessment of new scientific information has resulted in new tissue and radiation weighting factors
- Efforts now underway to calculate new dose conversion factors using updated models and information
- Commonly used radionuclides to be available in 2011 ... Complete set 2014



International Standards Work

- IAEA continuing revision of Basic Safety Standards.
 - Draft reviewed by RASSC in November
 - Additional drafting in topical meetings
 - Further review at RASSC in June, 2009
 - Eventual Member State comment
- Draft moves to adopt ICRP Recommendations -



19

International Standards Work

- Revision of Euratom Basic Safety Standards
 - Revision of BSS Directive 96/29
 - Incorporate new ICRP recommendations
 - Consolidate all existing legislation
 - Integration of natural and artificial sources
 - Protection of the Environment
- Draft to Article 31 Group of Experts Plenary October, 2009



20

Technical Issues Part 50, App I

- Align App. I criteria concepts with Part 20
- Reconsider criteria in Sect. II.A, II.B, and II.C
- Update definition of dose receptors in Sect. II and IV
- Update cost-benefit criteria in Sect. II.D
- Assess whether Sect. I and V need qualifiers, i.e., existing fleet of reactors vs. new plants



21

Technical Issues Part 50, App I

- Revise Sect. I in differentiating applicability between LWR, Non-LWR, and NGNP
- Redefine compliance requirements for "licensed operation" for sites with multiple licensees
- Assess whether compliance with 40 CFR Part 190 needs further elaboration in Part 20 or guidance



22

NRC is requesting the ACMUI perform a review of NCRP Report 160, *Ionizing Radiation Exposure of the Population of the United States*, and advise NRC on policy issues that the report may raise for NRC's program, especially for machine produced radiation, diagnostic doses, and policy on practice of medicine.

April 14, 2009

Status of Training & Experience Subcommittee Report on American Board of Radiology (ABR) Certification

The Subcommittee has submitted the NRC's clarification questions to the ABR for comment. Dr. Mickey Guiberteau is the ABR representative. The Subcommittee will formulate a final recommendation as soon as a response is received from ABR.

The Subcommittee's goal is to make recommendation specific enough to satisfy NRC's concerns, but yet general enough that the solution could be applied to any recognized certification board confronting a time gap between diplomats completing residency training and final board certification.



**Advisory Committee on the
Medical Uses of Isotopes
Subcommittee Report**
Board Certification Pathway for AU Status

May 8, 2009

Douglas Eggli, M.D.
Subir Nag, M.D.
William Van Decker, M.D.
Mickey Guiberteau, M.D. (Consultant)



The Problem

- When there is a time delay between completion of training and final board certification, graduates of training programs leading to NRC recognized board certification cannot become NRC Authorized Individuals until board certification has been achieved.
- This has the potential of limiting employment possibilities for these graduates.
- The only way for these residency or fellowship graduates to obtain Authorized Individual status between completion of training and final board certification is via the alternate pathway.



Subcommittee Charge

- To recommend a potential solution that would allow an individual to become an Authorized User (AU) prior to final board certification when there is a significant time gap between completion of training and final board certification
- The subcommittee was specifically charged to make a recommendation pertinent to the change in training which will occur in Diagnostic Radiology residencies for the class entering 2010



Subcommittee Effort

- To make a recommendation that would address the specific case created by the change in training programs for the American Board of Radiology
- To offer a general enough solution to be applicable to any certification board where there is a significant delay between completion of training and board certification
 - The option would be available for use by any certifying board
 - Individual certifying boards would determine whether or not the option was necessary for its trainees
 - Certifying boards would not be required to implement the solution



Subcommittee Proposal to ACMUI

- Propose that NRC recognized certifying boards could issue a separate certificate at the end of training that attests to the trainees completion of Training & Experience (T&E) requirements necessary to achieve AU status
- Propose that NRC accept this certification for AU status by the board certification pathway



Effect of the Subcommittee's Proposal

- Proposal preserves the integrity, utility, and intent of the board certification pathway
- Proposal provides the same level of assurance of the quality and completeness of training as final board certification



Specific Detail Requested by NRC Staff

1. Provide clarification that the separate "AU-eligible" certificate issued by the American Board of Radiology (ABR) at the end of the training (which attests to the successful completion of the appropriate T&E requirements and NRC-tailored examination) is indeed an ABR-recognized certification; and not just a certificate.



Subcommittee Recommendation

- Subcommittee recommends that the certification of completion of T&E requirements provided by the certifying board "stands alone" and is fully recognized by the certifying board.



Specific Detail Requested by NRC Staff

2. Provide clarification that the proposed certification is indeed a separate, additional certification; and not just an interim certification. Also, confirm for which of the following T&E requirements the proposed separate, additional certification is being recommended: 35.290, 390, 392, and/or 394.



Subcommittee Recommendation

- Subcommittee recommends that the certifying boards clarify that the AU T&E certification is an additional independent certification, not just an interim certification
- Subcommittee recommends that the certifying board specifically state which specific T&E requirements the certification applies to



Specific Detail Requested by NRC Staff

3. Please clarify whether successful completion of the NRC-tailored examination will be required for ABR candidates who do not pursue or do not achieve the proposed certification. In other words, for those individuals, will the NRC-tailored examination be included in the ABR final certification exam offered at the end of the extended clinical experience?



Subcommittee Recommendation

- Subcommittee acknowledges that any one certifying board may take a slightly different approach to satisfying question #3
- Certification boards could take two possible pathways, each of which would lead to AU eligibility for trainees who successfully complete the T&E requirements, including any NRC-tailored examination(s)



Possible Pathway (A)

- All trainees would be required to acquire the necessary training and experience and to pass the required examinations to become an Authorized User
- If the trainee does not successfully complete the training, the trainee cannot become board certified



Possible Pathway (B)

- Training programs could offer two pathways, one leading to board certification with AU certification and a second leading to board certification without AU certification
- A trainee who obtains board certification without AU certification and subsequently desires to become AU eligible would have to obtain the necessary T&E by the alternate pathway



Specific Detail Requested by NRC Staff

3. We need to ensure that diplomats of the final ABR certification who did not receive the proposed certification (who either did not take or did not pass the NRC-tailored examination) will meet all of NRC's T&E for the certification pathway. Examples of such candidates include: a.) individuals who are not seeking AU status initially and therefore do not seek the certification after successful completion of the NRC-required T&E; or b.) candidates who fail the NRC-tailored exam.



Subcommittee Recommendation

- Candidates who either do not seek or do not obtain AU certification as part of their training program cannot achieve AU status by the board certification pathway
 - Since the AU T&E certification would be a separate document, applicants for AU status who do not possess this document could not become AUs by the board certification pathway
- Trainees who do not achieve AU certification by the board certification pathway must apply for AU status individually by the alternate pathway



Specific Detail Requested by NRC Staff

4. If the ABR wishes to pursue this approach, ABR will need to submit a request for NRC to review their proposal for additional certifications, since it is a change from the currently recognized certification processes. Additionally, ABR should confirm that each of its existing recognized certification processes will not change, or point out proposed changes.



Subcommittee Recommendations

- Certifying boards that wish to separate AU certification from final board certification would need to submit the proposed changes to NRC for evaluation
- Certifying boards would need to indicate whether the proposed change replaces their prior recognized certification process or represents an addition to the approved certification process(es)



Questions

ACMUI Subcommittee on Board Certification Pathway for AU Status

Douglas Eggli, MD
Subir Nag, MD
William Van Decker, MD
Mickey Guiberteau, MD (consultant)



ACMUI Subcommittee on Board Certification Pathway for AU Status Final Report

Introduction: Board certification has been an integral part of the training of Authorized Individuals recognized by NRC to safely handle radioactive materials for medical uses. NRC recognizes certification boards that provide training and experience (T&E) that meets the requirements defined in 10CFR35 and accepts board certification in granting authorized status to individuals trained and certified by recognized certification boards.

The Problem: When there is a time delay between completion of training and final board certification, graduates of training programs leading to NRC recognized board certification cannot become NRC Authorized Individuals until board certification has been achieved. This has the potential of limiting employment possibilities for these graduates. The only way for these residency or fellowship graduates to obtain Authorized Individual status between completion of training and final board certification is via the alternate pathway.

Although all recognized certification boards require their diplomats to be trained to the T&E requirements of 10CFR35, there are very different record keeping requirements between the board certification pathway and the alternate pathway. The alternate pathway was developed to provide a mechanism to allow qualified individuals in fields of medicine not covered by one of the NRC recognized certifying boards to achieve authorized individual status. These cases represent individual exceptions and are subject to a higher record keeping requirement than training programs leading to certification by one of the recognized certification boards. The alternate pathway was not intended to replace board certification.

Most employment opportunities for medical professionals who work in fields which use radioactive materials for diagnosis and treatment of disease require that the individual have NRC authorized status (or Agreement State equivalent). Most graduates cannot defer their employment until final board certifications and most practices cannot employ an individual who is not authorized to handle radioactive materials. This reality forces trained and qualified individuals to seek authorized status via the alternate pathway, invalidating the intent of the board certification pathway. Many training programs will be unable to provide alternate pathway preceptor statements because of the increased documentation requirement of the alternate pathway compared to the board certification pathway.

Although there are individuals currently affected by this dilemma, the problem will increase dramatically as the American Board of Radiology (ABR) changes its training and certification paradigm in 2010. For residents entering ABR diagnostic radiology training programs beginning in 2010, the time gap between completion of residency training and board certification will be 15 months. The ABR certifies between 1,300 and 1,500 diagnostic radiology graduates annually. These individuals will be functionally unemployable for 15 months after completion of training, if their employment depends on the ability to use radioactive materials. Rural and underserved areas will be most

affected, as they are more likely to be served by solo or small group practices unable to support a care provider who cannot obtain NRC authorized individual status.

The subcommittee was charged with proposing a solution to the problem outlined above. Specifically, the subcommittee was charged with developing a solution for American Board of Radiology diplomats that would allow trainees to become authorized users in the 15 months between completion of training (including all training and experience required for Authorized User (AU) status) and final board certification. The subcommittee decided to make its recommendation general enough that it could be employed by any certification board that determined that the time between completion of training and final board certification created a significant burden for its diplomats. *No certification board would be required to adopt this proposed solution.*

Proposed solution:

- NRC recognized certifying boards could issue a separate certificate/certification at the end of training which attests to the successful completion of the appropriate T&E requirements for the Authorized Individual status the graduate is seeking.
- The subcommittee proposes that NRC accept this certification for the board certification pathway.
- This solution preserves the integrity, utility, and intent of the board certification pathway and provides the same level of assurance of the quality and completeness of training as final board certification.

The American Board of Radiology has agreed in principle to this approach. The subcommittee proposes that the solution be proposed to any other NRC recognized certifying board which experiences a similar problem with the delay between completion of training and final board certification.

Since the initial proposal, NRC staff has asked for additional clarification and detail. Staff submitted a series of four questions which the subcommittee addresses as clarifications to its proposal. Question three was divided into two parts. Although the questions refer specifically to the American Board of Radiology, the subcommittee has generalized its recommendations to be applicable to any recognized certifying board.

NRC Staff Questions: (with bulleted subcommittee proposals)

1) *Provide clarification that the separate "AU-eligible" certificate issued by the ABR at the end of the training (which attests to the successful completion of the appropriate T&E requirements and NRC-tailored examination) is indeed an ABR-recognized certification; and not just a certificate.*

- Subcommittee recommends that the certification of completion of T&E requirements provided by the certifying board "stands alone" and is fully recognized by the certifying board.

2) *Provide clarification that the proposed certification is indeed a separate, additional certification; and not just an interim certification. Also, confirm for which of the following T&E requirements the proposed separate, additional certification is being recommended: 35.290, 390, 392, and/or 394.*

- Subcommittee recommends that the certifying boards clarify that the AU T&E certification is an additional independent certification, not just an interim certification
- Subcommittee recommends that the certifying board specifically state which specific T&E requirements the certification applies to

3a) *Please clarify whether successful completion of the NRC-tailored examination will be required for ABR candidates who do not pursue or do not achieve the proposed certification. In other words, for those individuals, will the NRC-tailored examination be included in the ABR final certification exam offered at the end of the extended clinical experience?*

- Subcommittee acknowledges that any one certifying board may take a slightly different approach to satisfying question #3a
- Certification boards could take two possible pathways, each of which would lead to AU eligibility for trainees who successfully complete the T&E requirements, including any NRC-tailored examination(s).
 - Possible Pathway A
 - All trainees would be required to acquire the necessary training and experience and to pass the required examinations to become an Authorized User
 - If the trainee does not successfully complete the AU training, the trainee cannot become board certified
 - Possible Pathway B
 - Training programs could offer two pathways, one leading to board certification with AU certification and a second leading to board certification without AU certification
 - A trainee who obtains board certification without AU certification and subsequently desires to become AU eligible would have to obtain the necessary T&E by the alternate pathway and would not be eligible to obtain AU status by board certification

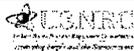
3b) *We (NRC) need to ensure that diplomats of the final ABR certification who did not receive the proposed certification (who either did not take or did not pass the NRC-tailored examination) will meet all of NRC's T&E for the certification pathway. Examples of such candidates include: a.) individuals who are not seeking AU status initially and therefore do not seek the certification after successful completion of the NRC-required T&E; or b.) candidates who fail the NRC-tailored exam.*

- Candidates who either do not seek or do not obtain AU certification as part of their training program cannot achieve AU status by the board certification pathway
 - Since the AU T&E certification would be a separate document, applicants for AU status who do not possess this document could not become AUs by the board certification pathway
- Trainees who do not achieve AU certification by the board certification pathway must apply for AU status individually by the alternate pathway

4) *If the ABR wishes to pursue this approach, ABR will need to submit a request for NRC to review their proposal for additional certifications, since it is a change from the currently recognized certification processes. Additionally, ABR should confirm that each of its existing recognized certification processes will not change, or point out proposed changes.*

- Certifying boards that wish to separate AU certification from final board certification would need to submit the proposed changes to NRC for evaluation
- Certifying boards would need to indicate whether the proposed change replaces their prior recognized certification process or represents an addition to the approved certification process(es)

The initial proposal, along with the clarifications in response to the NRC staff questions, comprises the subcommittee's recommendation to the ACMUI.



MEDICAL RADIOACTIVE MATERIAL EVENTS - FY2008

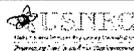
ACMUI Subcommittee Report
May 8, 2009

D. Gilley
R. Lieto, Chair
S. Nag, MD
O. Suleiman, PhD
B. Thomadsen, PhD



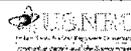
Medical Radioactive Material Events

- Nuclear Materials Event Database (NMED)
 - FY 2008 (Reported 10/1/2007-09/30/2008)
- Categories – Part 35 Medical Events (ME)
 - Part 35.300 - Unsealed Byproduct Material- Written Directive Required
 - §35.400 – Manual Brachytherapy
 - §35.600 - Remote Afterloaders, Teletherapy
 - §35.1000 – Other Medical Human Use
- Category - OTHER reportable, medical use related Material Events



Radiopharmaceuticals Requiring a Written Directive

- Part §35.200 – 3 events
 - Radionuclide
 - I-131 (patient) – 3
- Part §35.300 – 4 events
 - Radionuclide
 - I-131 (patients) - 4
 - Sm-153 (patients) - 8



CFR 35.200 Medical Events

reporting period October 1, 2007 – September 30, 2008

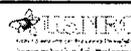
Radionuclide	Type of error	Actions	# patients
Nal I-131	Failure to write an adequate written directive	Additional training for staff responsible for scheduling.	1
Nal I-131	Failure to follow procedures	Policy and procedures modified to assure that the written directive is completed by the authorized use	1
Nal I-131	Failure to follow procedures	AU's written prescription was not what he intended. The patient received the correct dose. Additional training was provided to the technician and the written directive procedures were modified	1



CFR 35.300 Medical Events

reporting period October 1, 2007 – September 30, 2008

Radionuclide	Type of error	Actions	#patients
Nal I-131	Failure to follow the written procedure, failure to properly prepare package for shipment	Disciplinary action against the technologists, modification of procedures and retraining on preparing packages for shipment	1
Sm-153	Failure to follow written directive in verifying dose in calibrator	Procedure to verify dose used vial instead of syringe. Facility provided additional training and modified procedures	8
I-131 Bexxar	Failure to follow written directive; patient given Nal I-131	Changed procedures for receiving, handling and returning doses	1
Nal I-131	Failure to verify patient identity failure to follow written directive	Modification of procedures to verify patient before treatment	2



Comparison to previous year

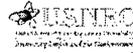
Radionuclide	2007	2008
Iodine-131	6	7
Y-90	1	0
Sm-153	0	8

	2007	2008
Number of Patients	7*	15



Radiopharmaceuticals Requiring a Written Directive

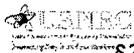
- Estimated frequency of radiopharmaceutical medical event (ME) occurrence
 - = 15 patients / 26176 treatments
 - = 5.7 E-4 (0.06%)
- Compares favorably to 0.04% reported last year.



Medical Events - §35.400 Manual Brachytherapy

- No. of §35.400 events: 9
- No. of patients: 111*
- Radionuclide involved:
 - I-125 7 events
 - Pd-103 1 event
 - Cs-137 1 event

* 2 VA events involved 102 patients



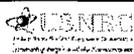
§35.400 - Manual Brachytherapy Summary of Events

Type of Error	Events	# Patients
Misidentification of prostate on TRUS	3	3
Faulty welding caused seeds to leak	1	2
Mick applicator jammed - leaking seeds	1	1
Wrong dose entered - calculation error	1	1
Wrong magnification used in planning	1	2
VA systemic errors (3 hospitals)	2	92+10 = 102
TOTAL	9	111



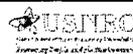
§35.400 - Manual Brachytherapy Observations

- Common issue with prostate implants was improper identification of gland boundaries by ultrasound (US).
- Most Mick applicator errors are user failure not applicator failure.
- Medical events at the VA to be discussed separately
 - the majority of the 102 MEs were from one center and due to misidentification of prostate on TRUS
 - it is possible that some of the other reported ME were due to differences in US volume at implant vs CT volume one month later



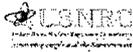
§35.400 - Manual Brachytherapy Observations

Estimated frequency of manual brachytherapy ME occurrence
= 111 patients/ 50,403 treatments
= 2.2E-3 (0.22%)



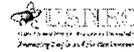
§35.400 - Manual Brachytherapy Recommendations

- Calculations and data entry to be checked by a second person.
- Use of nomogram as a secondary check.
- Better user training/practice with Mick applicator needed.
- Need adequate training in TRUS and use fluoroscopy for confirmation.



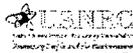
**Medical Events - \$35.600
Remote Afterloaders,
Teletherapy**

	FY2007	FY2008
All \$35.600	17	10
All HDR	14	8
MammoSite	4	3
Vaginal Cylinder	5(or7?)	2
LDR remote afterloader	1	0
Gamma Knife	2	1
Teletherapy	0	1



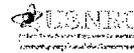
\$35.600 - HDR Medical Events

- Nucletron HDR - 4 events
(M=Breast intracavitary;
C=vaginal cylinders;
T=tandem and ovoids)
- Wrong catheter length entered (2M, 1C)
- Wrong step size manually entered (C)



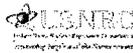
\$35.600 - HDR Medical Events

- Varian HDR – VariSource 2 events
(M=MammoSite; T=tandem and ovoids)
 - Wrong length (T)
 - Deflated MammoSite (M)
- Varian HDR – GammaMed 1 event
(M=MammoSite)
 - Wrong dose entered in plan (M)



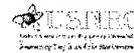
**\$35.600 - Gamma Knife
Medical Events**

- Gamma Knife - 1 events
 - Image reversed



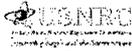
**\$35.600 - Teletherapy
Medical Events**

- Cobalt-60 units - 1 events
 - Therapist misread directive



**Medical Events - \$35.600
Observations**

- Only two types of HDR errors stood out:
wrong length and wrong dose.
- Compared with the number of procedures:
 - HDR - 8 failures / 62,000 procedures
= 1.3E-4 (0.013%)
 - GammaKnife - 1 failure / 13,000
procedures = 8E-5 (0.008%)
 - Teletherapy - 1 failure / 1900 procedures
= 5E-4 (0.05%)



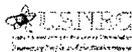
Other Medical Radioactive Material Events

- Part §35 – 6 events
 - §35.1000 (patient) – 4
 - Fetal/embryo patient doses – 2
- OTHER – 26 events
 - Lost sources – 11
 - Leaking Sources - 7
 - Contaminated Licensee Packages - 4
 - "Miscellaneous" - 6



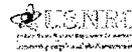
PART 35

- §35.1000 Uses
 - All 4 events were Y-90 microspheres caused by problems with equipment. Two were TheraSpheres; other two undocumented.
 - Four patients involved.
 - Estimated frequency of §35.1000 ME occurrence
 - = 4 patients/ 3586 treatments
 - = 1E-3 (0.1%)



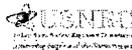
PART 35

- Pregnant patients administered I-131 therapies – 2
 - Patient received I-131 NaI two days after negative HCG pregnancy test. 32 cGy (rad) estimated embryo dose. No adverse effects expected because of stage of pregnancy.
 - Patient received I-131 NaI after two negative HCG pregnancy tests done within 5 days prior to administration. Patient failed to follow instructions. 35 cGy (rad) estimated embryo dose.



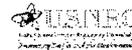
Lost Sources - Sealed & Unsealed

- 13 Events
 - I-131 capsule lost after use in thyroid neck phantom
 - Two events of Ir-192 seed ribbon lost from post-treatment inventory ; 1 found 3 days later in off-site laundry
 - Six events involving total of 24 I-125 seeds lost after implant or during autoclaving process.
 - Two Gd-153 transmission sources (194 mCi) lost when gamma camera disposed to scrap recycler.



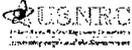
Lost Sources - Sealed & Unsealed

- 114 Pd-103 seeds (126.5 mCi) unused for implant, lost during storage in area undergoing renovation prior to return.
- Patient cremated within week after being implanted with 16 mCi of I-125 seeds.
- Loss and recovery of a Pu-238 cardiac pacemaker containing 74-148 GBq (2-4 Ci).



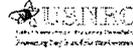
Leaking Sealed Sources

- Excludes leaking sources reported under medical event (ME)
 - All seven events involved I-125 seeds.
 - Three events where leakage found from wipe-testing/surveying/visual inspection of; wipe testing of storage pig, loading cartridge and one seed found contaminated. Two events found on seeds unused after implant; other done after autoclaving & cartridge loading.
- Returns to vendor for analysis found:
- seed likely damaged during use in applicator.
 - surface contamination but no defects (welds, encapsulation).
 - excessive force on stacked seeds during cartridge loading



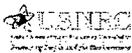
Leaking Sealed Sources

- I-125 seed jammed in applicator. Technician unloaded seed from cartridge with bare hands; survey found cartridge & hands contaminated.
- Two events discovered by vendors during seed strand assembly. Damaged seeds caused:
 - contamination of working/crimping tool;
 - cross-contaminated potentially 1500 seeds shipped to multiple customers.
- I-125 seed ruptured by cauterization tool 3 days after implant. Patient & equipment contaminated; thyroid bioassay < 1 rem (cSv).



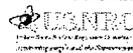
Miscellaneous - Packaging

- Four events
 - Inner pig with 51 I-125 seeds opened during shipment. Exposure levels significantly exceed limits; no contamination or loss or overexposures occurred.
 - Three events found Tc-99m contamination exceeding reportable limits
 - Three packages of Co-57 flood sources.
 - Five packages with cross-contamination from radiopharmacy courier who handled empty contaminated containers from previous stop. Significant vehicle and skin contamination.
 - Package from centralized radiopharmacy



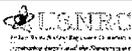
Miscellaneous - Machine Malfunctions

- Four events
 - Gamma Knife shielding doors failed to close after treatment; manually closed by medical physicist with negligible dose. No deviation from written directive.
 - High Dose Rate (HDR) source failed to retract properly during testing by manufacturer's field engineer. Source disconnected & top of source capsule clipped off by closing vault door.



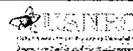
Miscellaneous - Machine Malfunctions

- During HDR source exchange by field engineer, old source failed to enter exchange container. Cause was dummy & active sources extended into same pathway became stuck outside safe. Vendor source recovery team sent to successfully retract source after engineer cuts wrong source (dummy instead of active) wire to place in emergency shielded container.
- Gd-153 attenuation correction source in SPECT gamma camera failed to retract to its shield. Cause was entanglement of cables moved by cleaning personnel. No personnel inadvertently exposed.



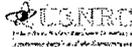
Miscellaneous - Overexposure

- Two workers for a radiopharmacy received extremity overexposures in the making of I-131 capsules. Doses ranged 53-105 rem (cSv). Lack of written procedures & proper handling tools cited.



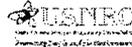
Radioactive MEDICAL EVENTS Comparison (events/patients)

	FY06	FY07	FY08
\$35.200/ \$35.300	9/9	7/7	7/15
\$35.400	7/7	7/7	9/111
\$35.600	14/19	17/17	10/10
\$35.1000	1/1	8/8	4/4



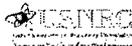
YEAR	FY04	FY05	FY06	FY07	FY08
MEDICAL EVENTS	43	34	35	37	28
ABNORMAL OCCURRENCES	12	7	6	10	10

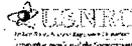
Ref: NMED Annual Report
INL/EXT-09-15284 (FY 2008)



OTHER Medical Radioactive Material Events Comparison

	FY06	FY07	FY08
Lost sources – sealed & unsealed	6	15	13
Leaking sealed sources	5	3	7
Fetal/Embryo Dose	1	2	2
Landfill Alarms	27	6	7
Miscellaneous	6	3	9

- 
- ### Recommendations
- Sr-90 eye applicator event involving 3 patients was initially reported as ME because thought to have wrong calibration resulting in 50% overdose. Later retracted because was determined that prescribed dose was received.
 - Sr-90 eye applicators must have a calibration by the current NIST traceable standard. Suggest reaffirmation of NRC IN 02-017 (May 2002).

- 
- ### Recommendations
- Event reporting needs to be improved. Often devoid of causes, remedial actions and info needed to analyze events for areas of improvement. Establish consistency requirements for the reporting of an event description.
 - Recognizing events are under reported (OIG Audit of NRC AS Program, 3/16/09), emphasizes importance of gaining value from reported events.
 - NMED improvements
 - Search with more than one key word
 - Report/query by specific licensee type (e.g. medical)

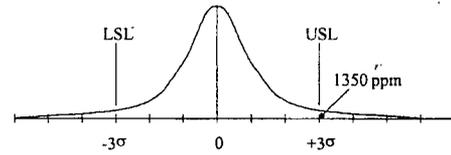
Six Sigma Concepts

From Harry Steudel
Professor Emeritus
University of Wisconsin

What is Six Sigma?

A Typical Scenario: Specification Limits at $\pm 3\sigma$

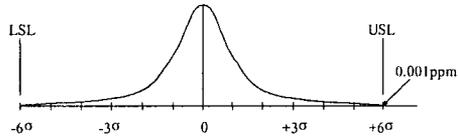
3 Sigma Case



What is Six Sigma?

Six Sigma Excellence: Specification Limits at $\pm 6\sigma$

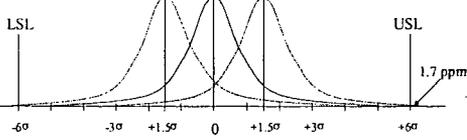
6 Sigma Case



What is Six Sigma?

Six Sigma Excellence

6 Sigma Case - 1.5 Sigma Shift of the Process Mean



PPM vs. DPMO

- PPM = Parts Per Million
- DPMO = Defects Per Million Opportunities

DPMO looks at the number of defects produced, while PPM traditionally reflects the number of defectives produced. What's the difference?

A single defective part may contain several defects - therefore DPMO requires greater control of your processes and, in many cases, a different way of accumulating data.

6 Sigma Conversion Table

Sigma Value	DPMO	Sigma Value	DPMO	Sigma Value	DPMO	Sigma Value	DPMO
0.00	933,103	1.50	500,000	3.00	66,807	4.50	1,350
0.05	926,473	1.55	480,061	3.05	60,571	4.55	1,144
0.10	919,243	1.60	460,172	3.10	54,700	4.60	960
0.15	911,492	1.65	440,362	3.15	49,471	4.65	816
0.20	903,190	1.70	420,740	3.20	44,565	4.70	687
0.25	894,350	1.75	401,294	3.25	40,050	4.75	577
0.30	884,930	1.80	382,088	3.30	35,930	4.80	483
0.35	874,928	1.85	363,168	3.35	32,157	4.85	404
0.40	864,334	1.90	344,578	3.40	28,716	4.90	337
0.45	853,141	1.95	326,350	3.45	25,588	4.95	280
0.50	841,345	2.00	308,538	3.50	22,750	5.00	233
0.55	828,944	2.05	291,160	3.55	20,182	5.05	193
0.60	815,940	2.10	274,253	3.60	17,864	5.10	150
0.65	802,338	2.15	257,846	3.65	15,776	5.15	131
0.70	788,145	2.20	241,904	3.70	13,903	5.20	108
0.75	773,373	2.25	226,627	3.75	12,224	5.25	88
0.80	758,026	2.30	211,855	3.80	10,724	5.30	72
0.85	742,154	2.35	197,662	3.85	9,387	5.35	50
0.90	725,747	2.40	184,060	3.90	8,198	5.40	40
0.95	708,840	2.45	171,056	3.95	7,143	5.45	30
1.00	691,402	2.50	158,655	4.00	6,210	5.50	22
1.05	673,645	2.55	146,850	4.05	5,386	5.55	26
1.10	655,422	2.60	135,648	4.10	4,661	5.60	21
1.15	636,831	2.65	125,072	4.15	4,025	5.65	17
1.20	617,911	2.70	115,070	4.20	3,467	5.70	13
1.25	598,706	2.75	105,650	4.25	2,980	5.75	11
1.30	579,260	2.80	96,801	4.30	2,550	5.80	9
1.35	559,618	2.85	88,508	4.35	2,185	5.85	7
1.40	539,828	2.90	80,757	4.40	1,866	5.90	5
1.45	519,939	2.95	73,529	4.45	1,589	5.95	4
This table reflects the loss from a 1.5 sigma shift in the process mean.							
						6.00	3

Sigma Level	Process With Most Potential Issues	Coding From Resolving Operation	Phone Calls Exceeding Two Minutes with Hold Level	Defects/Errors Opportunities	Process Year
3 Sigma	3,600 Every Day	770 Per Day	257 Each Day	66,800	63,32000
4 Sigma	340 Every Day	72 Per Day	24 Each Day	6,210	66,34000
5 Sigma	12 Every Day	13 Per Week	6 Each Week	230	66,07100
6 Sigma	6 Every Month	10 Per Year	3 Each Year	34	66,02066

Source: GE Healthcare
A Sampling of Six Sigma Success in Healthcare



Infiltration of Therapeutic Radiopharmaceuticals

Cindy Flannery, CHP, Team Leader

Office of Federal and State Materials
and Environmental Management Programs
Division of Materials Safety and State Agreements
Radioactive Materials Safety Branch
Medical Radiation Safety Team
May 8, 2009



Background

Nuclear Regulatory Commission (NRC) staff has determined that extravasation does NOT require reporting as a medical event under § 35.3045(a)(2)(ii) based on Supplementary Information on the general requirements of § 35.3045 based on prior § 35.33.



45 FR 31703, May 14, 1980

"Extravasation is the infiltration of injected fluid into the tissue surrounding a vein or artery. Extravasation frequently occurs in otherwise normal intravenous or intra-arterial injections. It is virtually impossible to avoid. Therefore, the Commission does not consider extravasation to be a misadministration."



Previous ACMUI Discussion

During the December 18, 2008 Advisory Committee on the Medical Uses of Isotopes (ACMUI) teleconference, ACMUI recommended that NRC should continue its policy of not requiring infiltrations of diagnostic dosages to be reported as medical events, even when the resulting dose exceeds the dose limits in 10 CFR 35.3045 (i.e., 50 rem)?



For Consideration

Given the higher doses from therapeutic administrations, should NRC consider an infiltration as a medical event if the infiltration occurred from an administration requiring a written directive (e.g. therapeutic administration)?



NRC Enforcement: Overview

Susanne Woods
Office of Enforcement
May 7, 2009



Outline

- Enforcement Process
 - Provides for:
 - Communication
 - Accuracy
 - Consistency/Fairness
 - Messages/Corrections
- Medical Enforcement



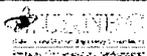
Materials Enforcement Process

- Inspection and/or investigation
- NRC review and licensee meeting (exit)
- Inspection report and apparent violations
- Enforcement panel (escalated)
- Predecisional enforcement conference (PEC)
- NRC reviews all information
- Agency decision



Escalated Enforcement

1. Enforcement Panel
 - Review information, 360° look, develop a strategy and path forward
 2. Licensee asked to provide:
 - Their perspective and considerations
 - Corrections to information
 - Identification and corrective actions
- Letter or PEC



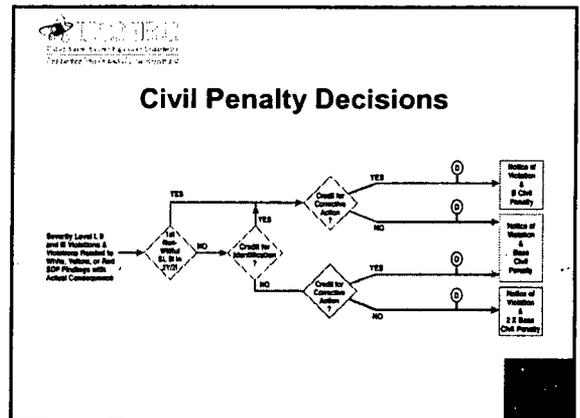
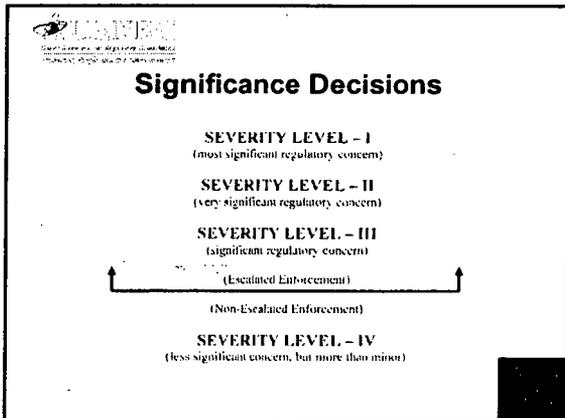
Escalated Enforcement

3. NRC reviews ALL information
4. Decisions:
 - Violation(s) occurred?
 - Significance (Severity Level)?
 - Enforcement action warranted? Type?
 - Civil Penalty warranted? Amount?



Possible Process Outcomes

No action
Notice of Violation (NOV)
NOV with Civil Penalty
Order (example: corrective action)
Criminal Penalty (Department of Justice)



-
- Escalated Enforcement Actions**
- Discretion - escalate/mitigate penalty
 - Public Information
 - Challenges and appeal rights
 - Enforcement Policy

-
- Willful Violations**
- Investigation
 - Panel
 - PEC and/or Dispute Resolution
 - Position, Safety Significance, Motivation, Benefit, Other
 - Outcome: Close-out letter NOV; Order

-
- Alternative Dispute Resolution**
- Post-investigation
 - Voluntary participation
 - Mediated
 - Between licensee and NRC
 - Offer begins early in the enforcement process

-
- Recent Medical Enforcement**
- Enforcement Statistics
 - Increased Control Enforcement Statistics

FDA's Radiation Associated Regulatory Responsibilities

Presented to the Nuclear Regulatory Commission's Advisory Committee on Medical Use of Isotopes (May 8, 2008)

Orhan H. Süleiman MS, PhD, FAAPM
Senior Science Policy Advisor
Office of Oncology Drug Products
Center for Drug Evaluation and Research

Food, Drug and Cosmetic Act (FDCA) - 1906

- Law has been amended many times over the last century.
- Subsequent laws have been incorporated into the FDCA, e.g. Radiation Control for Health and Safety Act 1968, and Medical Device laws (1976), Medical Device laws (1976), FDAMA (1997), FDAAA (2007)

FDA consists of many Centers

- Center for Drug Evaluation and Research (CDER) – Radiopharmaceuticals
- Center for Devices and Radiological Health (CDRH) – Medical Devices – accelerators, brachytherapy sources, etc.
- Center for Biologics Evaluation and Research (CBER) – Blood Irradiators
- Center for Food Safety and Nutrition (CFSAN) – Food irradiators

Other FDA Components

- Center for Veterinary Medicine
- National Center for Toxicological Research
- Office of Regulatory Affairs – FDA's field operations
- Office of the Commissioner- Office of Crisis Management (Emergency Operations)

Center for Devices and Radiological Health

Regulates most radiation products

- Medical Devices – regulated by Office of Device Evaluation (ODE) -analogous to CDER's Office of New Drugs (OND)
- Radiation emitting electronic products-regulated by Office of Communication, Education, and Radiation (OCER)
- Mammography- also regulated by OCER

Three different Statutes

- Electronic Products- 1968
- Medical Devices – 1976
- Mammography - 1992

Radiation Emitting Electronic Products (Radiation Control for Health and Safety Act of 1968)*

- Mandatory Emission Performance Standards
- Consumer and Medical Products
- Microwave ovens, lasers
- X-rays (medical and security products)

* Center for Devices and Radiological Health

7

Medical Device Act of 1976*

- 510 (k) – predicate device, substantial equivalency
- Class I – Minimal controls
- Class II- Special controls
- Class III
 - High risk devices
 - May require clinical trials for premarket approval (PMA).

– *Center for Devices and Radiological Health

8

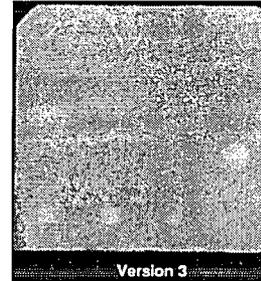
Mammography Quality Standards Act of 1992*

- Assures quality by establishing standards and regulating:
 - Quality control of equipment
 - Personnel
 - Image quality (Imaging and dosimetry phantom)

* Center for Devices and Radiological Health

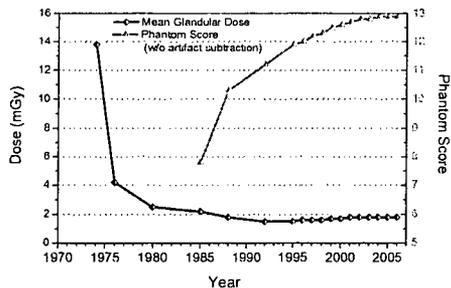
9

In order to detect change clinically, you need to assure the standard image remains constant.



10

Dose and Image Quality Trends in Mammography



11

Medical Isotopes (Radiopharmaceuticals)

- Center for Drug Evaluation and Research (CDER)
- Center for Biologics Evaluation and Research (CBER)

12

What does it take to get a drug approved? Research Phase

- Clinical Research under an Investigational New Drug (IND) Application
 - Phase I- Safety "n ~ 20 – 80"
 - Phase II- Efficacy "n < several hundred"
 - Phase III- Large scale studies for benefit – risk, dosing, and physician labeling information "n ~ several hundred to several thousand"

13

What does it take to get a drug approved? Manufacturing Standards

- Quality and purity of product
Good Manufacturing Practice (GMP) and
Chemistry Manufacturing Control.(CMC)

14

What does it take to get a drug approved?- Application process – New Drug Application

- NDA Process:
<http://www.fda.gov/cder/regulatory/applications/nda.htm#Related%20Topics>:
- Application Fee for NDA ~ \$1 M⁺

15

Radioactive Drug Research Committee Research (non-IND human research)

- Established in 1975
- Formally codified in 21 CFR 361.1
- Allows human research with radioactive drugs without an IND when:
 - Research is basic
 - RDRC approves
 - There is no clinically detectable pharmacologic effect from the administered
 - and radiation dose limits as specified are met

16

Manufacturing Responsibilities for medical isotope production?

Pharmaceuticals: Good Manufacturing Practice (GMP) – 21 CFR Parts 210, 211, 212 (proposed), 600-680

Medical Devices: Quality System (QS) regulations – 21 CFR Part 820

Guidance for Industry and FDA Current Good Manufacturing Practice for Combination Products
<http://www.fda.gov/cder/guidance/OCLOve1dft.htm>

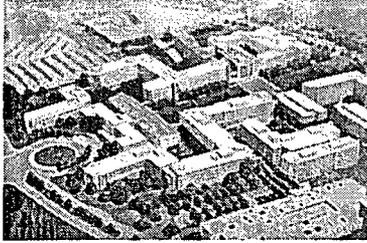
17

Licensing

- FDA does not license radioactive materials
- Radioactive materials licensed by the Nuclear Regulatory Commission (NRC) or
- Radioactive materials licensed by Agreement States (36 states with formal "agreements" with the NRC)
- FDA approves biological products via the Biological Licensing Application (BLA)
- FDA approves radiolabeled drugs via the New Drug Application (NDA)
- www.fda.gov/cder/guidance/5645fnl.htm

18

10903 New Hampshire Ave
Silver Spring, Maryland



19

Final Report Reflections

Richard J. Vetter, Ph.D CHP

Success

"Success is to be measured not so much by the position that one has reached in life as by the obstacles which he has overcome while trying to succeed."

Booker T. Washington,
American author & educator

Obstacles

- Board Certification
- T&E
- Dose Reconstruction
- Sentinel Nodes
- Increased Controls
- Fingerprinting
- Irradiators

Obstacles

- Personalities
- Parochialism
- Conflicting values
 - NRC: "Protecting People & the Environment"
 - ACMUJ: Needs of the patient come first
 - e.g. lymphoscintigraphy

Direction

"Quality is never an accident;
it is always the result of intelligent effort."

John Ruskin
English critic, essayist, & reformer
(1819 - 1900)

Appeal

Recognize that needs of the patient come first within a regulatory system that protects people and the environment.

New Challenges

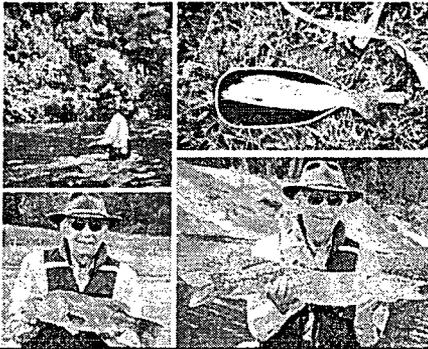
- Medicine: Increase quality; reduce cost
- All: Improve healthcare safety culture in face of cost reductions

FINIS

"For last year's words belong to last year's language and next year's words await another voice. And to make an end is to make a beginning."

**T.S. Eliot,
Nobel laureate in literature**

RE-ENTRY



An ACMUI Farewell

Ralph P. Lieto, MSE

"Mr. Lieto Goes to Washington"



2

I not only use all the brains I
have, but all that I can borrow.
- Woodrow Wilson

3

Opportunities for Improvement

- Training & Experience/Board Certification
- NRC Support for the ACMUI
- Patient Release Rule (10 CFR 35.75)

4

Opportunities for Improvement

- National Source Tracking System (NSTS)
- ICRP 2005 Recommendations
- Electronic Signature [EMR]

5

ACMUI - Members



6

**“Thank You”
and
Arrivederci!**

7

NO HANDOUT

**Advisory Committee on the Medical Uses of Isotopes May 2009 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. Cindy Flannery – 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. Duane White – NRC staff
9. Gretchen Rivera-Capella – NRC staff
10. Glenda Villamar – NRC staff
11. Leira Cuadrado – NRC staff

ACMUI

1. Douglas Eggli, M.D. – Nuclear Medicine Physician
2. Darrell Fisher, Ph.D. – Patients' Rights Advocate
3. Debbie Gilley – State Government Representative
4. Milton Guiberteau, M.D. – Diagnostic Radiologist (representative)
5. Ralph Lieto – Medical Physicist
6. Leon Malmud, M.D. – Chairman
7. Steve Mattmuller – Nuclear Pharmacist
8. Subir Nag, M.D. – Radiation Oncologist
9. Orhan Suleiman, Ph.D. – FDA Representative
10. Bruce Thomadsen, Ph.D. – Therapy Physicist
11. William Van Decker, M.D. – Nuclear Cardiologist
12. Richard Vetter, Ph.D. – Vice Chairman, Radiation Safety Officer
13. James Welsh, M.D. – Radiation Oncologist

Section 106 of the National Historic Preservation Act were met and provided the designated state liaison agency the opportunity to comment on the proposed action.

III. Finding of No Significant Impact

On the basis of the EA, NRC has concluded that there are no significant environmental impacts from the

proposed amendment and has determined not to prepare an Environmental Impact Statement.

IV. Further Information

Documents related to this action, including the application for amendment and supporting documentation, are available electronically at the NRC's Electronic

Reading Room at <http://www.nrc.gov/reading-rm/adams.html>. From this site, you can access the NRC's Agencywide Document Access and Management System (ADAMS), which provides text and image files of NRC's public documents. The ADAMS accession numbers for the documents related to this notice are:

Document	ADAMS Accession No.
License Renewal—Letter	ML063110083
—Application	ML063110089
—Environmental Report	ML063110087
NRC Letters to Confederate Tribes & Bands of Yakama Nation	ML073370055
	ML082470386
	ML090440136
NRC Letters to Confederated Tribes of the Umatilla Indian Reservation	ML080250134
	ML082610765
	ML090440128
NRC Letter to Washington State SHPO	ML073100238
	ML082470310
	ML090430370
NRC Letter to U.S. Fish and Wildlife Service	ML073100164
	ML082470214
Request for Additional Information (RAI) and Responses	ML080600457/ ML080640145
	ML081300403
	ML082330600
Tribal letters to NRC	ML080790549
	ML081620577
State Historic Preservation Office, letter to NRC	ML080560066
	ML082880314
Washington Department of Ecology letter to NRC	ML083040124
USFWS correspondence with NRC	ML090720616
	ML090720623
	ML090720581
Environmental Assessment	ML090700258

If you do not have access to ADAMS or if there are problems in accessing the documents located in ADAMS, contact the NRC Public Document Room (PDR) Reference staff at 1-800-397-4209, 301-415-4737 or by e-mail to pdr@nrc.gov.

These documents may also be viewed electronically on the public computers located at the NRC's PDR, O 1 F21, One White Flint North, 11555 Rockville Pike, Rockville, MD 20852. The PDR reproduction contractor will copy documents for a fee.

Dated at Rockville, Maryland this 27th day of March 2009.

For the Nuclear Regulatory Commission.

Andrea Kock,

Chief, Environmental Review Branch, Environmental Protection and Performance Assessment Directorate, Division of Waste Management and Environmental Protection, Office of Federal and State Materials and Environmental Management Programs.

[FR Doc. E9-7492 Filed 4-2-09; 8:45 am]

BILLING CODE 7590-01-P

NUCLEAR REGULATORY COMMISSION

Advisory Committee on the Medical Uses of Isotopes: Meeting Notice

AGENCY: U.S. Nuclear Regulatory Commission.

ACTION: Notice of meeting.

SUMMARY: NRC will convene a meeting of the Advisory Committee on the Medical Uses of Isotopes (ACMUI) on May 7-8, 2009. A sample of agenda items to be discussed during the public session includes: (1) Summary of the enforcement process and enforcement actions against medical licensees; (2) regulatory responsibilities of the U.S. Food and Drug Administration; (3) ACMUI subcommittee report on byproduct material events; (4) ACMUI subcommittee report on training and experience for yttrium-90 microspheres users; (5) National Academy of Science report on the production of medical isotopes using highly enriched uranium and low enriched uranium; (6) briefing on the Veterans Affairs medical events;

(7) infiltrations of therapeutic radiopharmaceuticals as medical events; (8) National Council on Radiation Protection & Measurements Report 160 "Ionizing Radiation Exposure of the Population of the United States" and its implications for NRC programs; (9) ACMUI subcommittee report on training and experience for American Board of Radiology certification; (10) medical event reporting to the International Nuclear Event Scale; and (11) potential changes to 10 CFR Part 35. A copy of the agenda will be available at <http://www.nrc.gov/reading-rm/doc-collections/acmui/agenda> or by e-mailing Ms. Ashley Cockerham at the contact information below.

Purpose: Discuss issues related to 10 CFR Part 35 Medical Use of Byproduct Material.

Date and Time for Closed Session: May 7, 2009, from 3:15 p.m. to 5:30 p.m. This session will be closed so that ACMUI can complete self-evaluations, discuss internal Committee business, and prepare for a meeting with the Commission.

Date and Time for Open Sessions: May 7, 2009, from 8 a.m. to 3:15 p.m. and May 8, 2009, from 8 a.m. to 4:30 p.m.

Address for Public Meeting: U.S. Nuclear Regulatory Commission, Two White Flint North Auditorium, 11545 Rockville Pike, Rockville, Maryland 20852.

Public Participation: Any member of the public who wishes to participate in the meeting should contact Ms. Cockerham using the information below.

Contact Information: Ashley M. Cockerham, e-mail: ashley.cockerham@nrc.gov, telephone: (240) 888-7129.

Conduct of the Meeting: Leon S. Malmud, M.D., will chair the meeting. Dr. Malmud will conduct the meeting in a manner that will facilitate the orderly conduct of business. The following procedures apply to public participation in the meeting:

1. Persons who wish to provide a written statement should submit an electronic copy to Ms. Cockerham at the contact information listed above. All submittals must be received by April 30, 2009, and must pertain to the topic on the agenda for the meeting.

2. Questions and comments from members of the public will be permitted during the meeting, at the discretion of the Chairman.

3. The draft transcript will be available on ACMUI's Web site (<http://www.nrc.gov/reading-rm/doc-collections/acmui/tr/>) on or about June 8, 2009. A meeting summary will be available on ACMUI's Web site (<http://www.nrc.gov/reading-rm/doc-collections/acmui/meeting-summaries/>) on or about June 22, 2009.

4. Persons who require special services, such as those for the hearing impaired, should notify Ms. Cockerham of their planned attendance.

This meeting will be held in accordance with the Atomic Energy Act of 1954, as amended (primarily Section 161a); the Federal Advisory Committee Act (5 U.S.C. App); and the Commission's regulations in Title 10, *U.S. Code of Federal Regulations*, Part 7.

Dated: March 30, 2009.

Andrew L. Bates,
Advisory Committee Management Officer.
[FR Doc. E9-7497 Filed 4-2-09; 8:45 am]
BILLING CODE 7590-01-P

NUCLEAR REGULATORY COMMISSION

Sunshine Federal Register Notice

DATE: Week of March 30, 2009.

PLACE: Commissioners' Conference Room, 11555 Rockville Pike, Rockville, Maryland.

STATUS: Public and closed.

ADDITIONAL ITEMS TO BE CONSIDERED:

Week of March 30, 2009

Wednesday, April 1, 2009

1 p.m.

Affirmation Session (Public Meeting) (Tentative), AmerGen Energy Company, LLC (License Renewal for Oyster Creek Nuclear Generating Station), Docket No. 50-219-LR, Citizens' Petition for Review of LBP-07-17 and Other Interlocutory Decisions in the Oyster Creek Proceeding (Tentative).

* * * * *

* The schedule for Commission meetings is subject to change on short notice. To verify the status of meetings, call (recording)—(301) 415-1292.

Contact person for more information: Rochelle Bavol, (301) 415-1651.

* * * * *

Additional Information

Affirmation of AmerGen Energy Company, LLC (License Renewal for Oyster Creek Nuclear Generating Station), Docket No. 50-219-LR, Citizens' Petition for Review of LBP-07-17 and Other Interlocutory Decisions in the Oyster Creek Proceeding, previously tentatively scheduled on February 4, 2009, has been tentatively rescheduled on March 31, 2009.

* * * * *

The NRC Commission Meeting Schedule can be found on the Internet at: <http://www.nrc.gov/about-nrc/policy-making/schedule.html>.

* * * * *

The NRC provides reasonable accommodation to individuals with disabilities where appropriate. If you need a reasonable accommodation to participate in these public meetings, or need this meeting notice or the transcript or other information from the public meetings in another format (e.g. braille, large print), please notify the NRC's Disability Program Coordinator, Rohn Brown, at 301-492-2279, TDD: 301-415-2100, or by e-mail at rohn.brown@nrc.gov. Determinations on requests for reasonable accommodation will be made on a case-by-case basis.

* * * * *

This notice is distributed by mail to several hundred subscribers; if you no longer wish to receive it, or would like to be added to the distribution, please contact the Office of the Secretary, Washington, DC 20555 (301-415-1969). In addition, distribution of this meeting

notice over the Internet system is available. If you are interested in receiving this Commission meeting schedule electronically, please send an electronic message to darlene.wright@nrc.gov.

Dated: March 31, 2009.

Rochelle C. Bavol,

Office of the Secretary.

[FR Doc. E9-7624 Filed 4-1-09; 11:15 am]

BILLING CODE 7590-01-P

NUCLEAR REGULATORY COMMISSION

[NRC-2009-0043]

Proposed Standard Review Plan Section 9.5.1.2 on Risk-Informed, Performance-Based Fire Protection Program, Correction

AGENCY: Nuclear Regulatory Commission (NRC).

ACTION: Solicitation of public comment, correction of proposed comment date.

SUMMARY: This document amends a notice appearing in the *Federal Register* on February 5, 2009 (74 FR 6181), that announced the proposed Standard Review Plan Section 9.5.1.2 on "Risk-Informed, Performance-Based Fire Protection Program." This action is necessary to extend the originally proposed end date for comment from April 5, 2009 to May 22, 2009.

FOR FURTHER INFORMATION CONTACT: Mr. Alexander R. Klein, Chief, Fire Protection Branch, Division of Risk Assessment, Office of the Nuclear Reactor Regulation, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001; telephone 301-415-2822 or e-mail at Alex.Klein@nrc.gov.

SUPPLEMENTARY INFORMATION: On page 6181, in the third column, Date Information, second line, the proposed period for comment of 60 days from the date of publication is extended to May 22, 2009.

Dated at Rockville, Maryland, this 25th day of March 2009.

For the Nuclear Regulatory Commission.

William F. Burton,

Chief, Rulemaking and Guidance Development Branch, Division of New Reactor Licensing, Office of New Reactors.

[FR Doc. E9-7495 Filed 4-2-09; 8:45 am]

BILLING CODE 7590-01-P

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

CONTENTS

Preamble.....	1
Scheduling and Conduct of Meetings.....	2
Minutes/Transcripts.....	4
Appointment of Members.....	4
Conduct of Members.....	5
Adoption and Amendments.....	5

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 12 members utilize 1 FTE (includes approximately 0.6 FTE for NRC staff and 0.4 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, 2010.

10. **Filing date:** March 17, 2008

/RA/

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