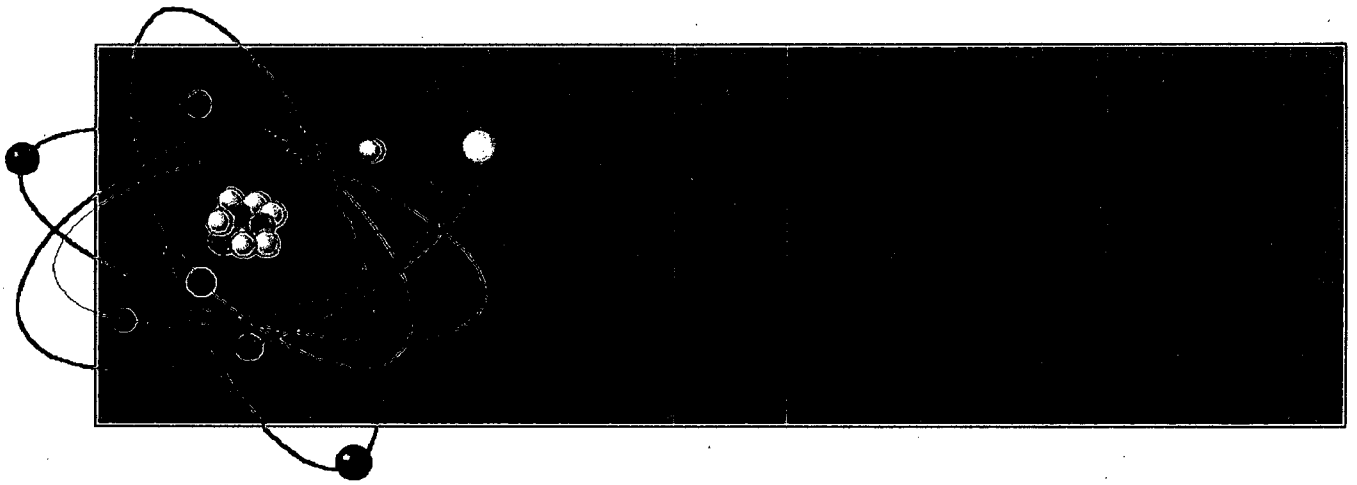

UNITED STATES NUCLEAR REGULATORY COMMISSION

ADVISORY COMMITTEE ON THE MEDICAL USES OF ISOTOPES

October 22-23, 2007
NRC Headquarters
Rockville, Maryland

MEETING AGENDA
ADVISORY COMMITTEE ON THE MEDICAL USES OF ISOTOPES

OCTOBER 22-23, 2007
Two White Flint North (T2-B3), Rockville, Maryland

Monday, October 22, 2007 CLOSED SESSION			
8:00 – 8:45	**1.**	**Opening Statements** Ms. Schlueter will discuss internal Committee business.	**J. Schlueter, NRC**
8:45 – 9:15	**2.**	**Ethics Briefing** Mr. Szabo will provide annual ethics briefing for Committee members.	**J. Szabo, NRC**
9:15 – 9:45	**3.**	**Self-Evaluation Report** Ms. Tull will provide the 2007 evaluation for an open discussion.	**A. Tull, NRC**

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

9:45 – 10:00		**BREAK**	

Monday, October 22, 2007 OPEN SESSION			
10:00 – 10:15	**4.**	**Opening Statements** Ms. Wastler will formally open the meeting. Ms. Schlueter will present opening remarks.	**S. Wastler & J. Schlueter, NRC**
10:15 – 11:15	**5.**	**Old Business** Ms. Tull will present previous Committee recommendations and the NRC responses.	**A. Tull, NRC**
11:15 – 12:00	**6.**	**Recent Security Activities** Ms. Schlueter will update the Committee on the GAO sting & fingerprinting orders.	**J. Schlueter, NRC**
12:00 – 1:00		**LUNCH**	
1:00 – 1:30	**7.**	**AU Approval for Byproduct Material** Dr. Welsh will provide information on the differences among licensees requiring Authorized User (AU) approval prior to ordering byproduct material.	**J. Welsh, ACMUI**
1:30 – 2:00	**8.**	**NARM** Mr. White will update the Committee on the NARM transition plan, rule, & guidance.	**D. White, NRC**
2:00 – 2:45	**9.**	**Elekta Perfexion** Dr. Howe will provide information on the new Leksell Gamma Knife® PERFEXION.	**DB. Howe, NRC**
2:45 – 3:00		**BREAK**	
3:00 – 4:30	**10.**	**Potential Changes to 10 CFR Part 35** Dr. Howe will continue the discussion of potential changes to 10 CFR Part 35.	**DB. Howe, NRC**

Tuesday, October 23, 2007
OPEN SESSION

8:00 – 9:00	**11.**	**NMED**	**M. Burgess, NRC**
		Ms. Burgess will provide information on the Nuclear Materials Events Database (NMED) and follow-up on Committee recommendations regarding NMED from the October 2006 meeting.	
9:00 – 10:15	**12.**	**Medical Events**	**R. Lieto, ACMUI & DB. Howe, NRC**
		Mr. Lieto and Dr. Howe will provide a summary of recent medical events and seek Committee advice, recommendations, and insights.	
10:15 – 10:30		**BREAK**	
10:30 – 12:30	**13.**	**Microspheres Guidance**	**A. Tull, NRC**
		Ms. Tull will update the Committee on the status and propose additional changes for Y-90 microspheres guidance.	
12:30 – 1:30		**LUNCH**	
1:30 – 2:00	**14.**	**Specialty Boards**	**C. Flannery, NRC**
		Ms. Flannery will update the Committee on the approval status of specialty boards.	
2:00 – 3:15	**15.**	**T&E Implementation Issues Cont.**	
		ACMUI members, specialty boards, representatives of professional societies, Agreement States, and NRC staff will continue to discuss 10 CFR Part 35 training & experience implementation issues in the medical community.	
3:15 – 3:30		**BREAK**	
3:30 – 4:45	**16.**	**Petition for Rulemaking (PRM 35-20)**	**D. Rathbun, NRC**
		Mr. Rathbun will provide a briefing on the status of the AAPM petition.	
4:45 – 5:00	**17.**	**Closing**	**A. Tull, NRC**
		Ms. Tull will provide a meeting summary, review action items, and propose dates for the next meeting.	

ACMUI MEETING
SPEAKERS AND PARTICIPATING NRC STAFF
October 22-23, 2007

Michele Burgess ..... NRC

Cindy Flannery..... NRC/Alt. Designated Federal Official

Donna-Beth Howe, Ph.D..... NRC

Andrew Kennedy, M.D. ..... (on behalf of) Sirtex Medical

Ralph Lieto..... ACMUI

Leon Malmud, M.D. ..... ACMUI Chairman

Duane White ..... NRC

Subir Nag, M.D. ..... ACMUI

Dennis Rathbun ..... NRC/DILR Director

Janet Schlueter..... NRC/DMSSA Director

John Szabo..... NRC

Ashley Tull ..... NRC

Sandra Wastler ..... NRC/Designated Federal Official

James Welsh, M.D..... ACMUI

PLEASE DO NOT REMOVE FROM T2-B3

ACMUI VISITOR LIST

OCTOBER 22, 2007

NAME	ORGANIZATION	SIGNATURE
Will Davidson	Univ of Penn	
Lynne Fairobent	AAPM	
Nat Geissel	Sirtex	
Andrew Kennedy	Sirtex	
Richard Martin	ASTRO	
Doug Pfeiffer	AAPM	
Samuel Putnam	Sirtex	
Riad Salem,	Northwestern Univ	
Ken Thurston	Sirtex	
Ann Warbick Cerone	MDS Nordion	
Gloria Bonanelli	ACR	
Michael Peters	SNM	
CHRIS GALLAGHER	ASNC	
HUGH CANNON	SNM	

PLEASE DO NOT REMOVE FROM T2-B3

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Samuel Putnam	Sirtex	
Riad Salem,	Northwestern Univ	
Ken Thurston	Sirtex	
Ann Warbick Cerone	MDS Nordion	
Craig Reed	Oncologix	
Mike Peters	SNM	

NO HANDOUT

NO HANDOUT

SECY 07-0166: ADVISORY COMMITTEE ON THE MEDICAL USES OF ISOTOPES 2007 STAFF EVALUATION AND SELF-EVALUATION

NON-PUBLICLY AVAILABLE

NO HANDOUT

UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D.C. 20555-0001

October 11, 2007

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

FROM: Sandra Wastler, Designated Federal Officer /RA/
Advisory Committee on the
Medical Uses of Isotopes

SUBJECT: RESPONSE TO RECOMMENDATIONS FROM THE JUNE 12-13, 2007 MEETING OF THE ADVISORY COMMITTEE ON THE MEDICAL USES OF ISOTOPES

Below are recommendations and action items from the June 12-13, 2007, 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.

MOTION (1): NRC staff should issue an Information Notice (IN), which describes errors previously made and provides examples of best practices with regards units of Air Kerma Strength (AKS) vs. apparent activity (mCi) for brachytherapy sources. The IN should incorporate the American Association of Physicists in Medicine (AAPM) position and be coordinated with Agreement States.

NRC staff will issue an IN, which describes errors previously made and provides examples of best practices with regards units of Air Kerma Strength (AKS) vs. apparent activity (mCi) for brachytherapy sources. The IN will incorporate the AAMP position on this issue.

MOTION (2): NRC staff should remove the attestation requirement for board certified individuals and rewrite the attestation requirement for individuals seeking authorization under the alternate pathway. The rewritten attestation should not include the word "competency" but should instead read "has met the minimum training and experience requirements."

NRC staff is considering the ACMUI recommendation to remove the attestation requirement for board certified individuals and to rewrite the attestation requirement for individuals seeking authorization under the alternate pathway.

MOTION (3): NRC staff should revise the regulations so that previously board certified individuals, who were certified prior to the effective date of recognition, are grandfathered.

NRC staff action on this ACMUI recommendation to revise the regulations so that previously board certified individuals, who were certified prior to the date of recognition, are grandfathered, will be based on the outcome of the petition for rulemaking, PRM 35-20 (AAPM petition).

MOTION (4): NRC staff should reduce the 200-hour radiation safety training requirement to 120 hours for individuals seeking authorization under the alternate pathway in 10 CFR 35.390.

NRC staff is considering the ACMUI recommendation to reduce the 200-hour radiation safety training requirement to 120 hours for individuals seeking authorization under the alternate pathway in 10 CFR 35.390.

MOTION (5): NRC staff should not change the current definition for a preceptor RSO in 10 CFR 35.2.

NRC staff accepts the ACMUI recommendation and will not propose revising the current definition for an RSO in 10 CFR 35.2.

MOTION (6): NRC staff should add the words "or equivalent" to 10 CFR 35.12(c) so it is clear that information included in a letter is the same as that which would have been submitted in NRC Form 313A.

NRC staff accepts the ACMUI recommendation to propose revising 10 CFR 35.12(c) and will add this item into a request for future rulemaking.

MOTION (7): NRC staff should revise 10 CFR 35.50(c)(2) to include AUs, AMPs, or ANPs identified on any license or permit that authorizes similar types of use of byproduct material. Additionally, the AU, AMP, or ANP must have experience with the radiation safety aspects of similar types of use of byproduct material for which the individual is seeking RSO authorization.

NRC staff accepts the ACMUI recommendation to propose revising 10 CFR 35.50(c)(2) and will add this item into a request for future rulemaking.

MOTION (8): NRC staff should remove the attestation requirement from 10 CFR 35.50(d) for AUs, AMPs, and ANPs seeking RSO status, if the AU, AMP, or AMP seeking RSO status will have responsibilities for similar types of uses for which the individual is authorized.

NRC staff accepts the ACMUI recommendation to propose revising 10 CFR 35.50(d) and will add this item into a request for future rulemaking.

MOTION (9): ACMUI tabled the following issues until the next full ACMUI meeting: 35.57(a), 35.75; 35.491(b)(2); and 35.400, 35.500, and 35.600.

NRC staff will add the following issues to the October ACMUI meeting agenda: 35.57(a), 35.75; 35.491(b)(2); and 35.400, 35.500, and 35.600.

MOTION (10): NRC staff should allow more than one RSO on a license with a designation of one RSO as the individual in charge.

NRC staff will seek an Office of General Counsel interpretation to determine whether or not more than one RSO on a license is allowable.

MOTION (11):
Note: Motion (11) received five favorable votes, three abstentions, and one opposition.

(a) NRC staff should include the three-case work experience requirement for individuals seeking authorization for Y-90 microsphere use; however, the three cases do not have to be with the particular type of microsphere for which the individual is seeking authorization.

NRC staff considered the ACMUI recommendation, and the revised microspheres guidance was published on September 25, 2007.

(b) Furthermore, ACMUI recommends the training and experience does not have to be performed under the supervision of an AU, and NRC staff should replace the proposed supervision paragraph with similar language from 10 CFR 35.690(c).

NRC staff accepts the ACMUI recommendation, and this change was incorporated in the revised microspheres guidance published on September 25, 2007.

MOTION (12): NRC staff should delete the attestation requirement for Y-90 microspheres users and incorporate a requirement in the second paragraph of the guidance for individuals seeking authorization to provide and retain documentation of the completion of training.

NRC staff accepts the intent of the ACMUI recommendation, and this change was incorporated in the revised microspheres guidance published on September 25, 2007.

MOTION (13): NRC staff should incorporate the proposed wording for the team approach section of the Y-90 microspheres guidance with one exception: ACMUI recommends the word "oncology" be replaced by "cancer management."

NRC staff accepts the ACMUI recommendation, and this change was incorporated in the revised microspheres guidance published on September 25, 2007.

MOTION (14): NRC staff should incorporate the proposed wording that notification under 10 CFR 35.14 does not apply for specific medical use licensees.

NRC staff has reconsidered this issue and will present it to the Committee with additional information at the October ACMUI meeting.

MOTION (15): ACMUI tabled the absorbed dose vs. administered activity issue for Y-90 microspheres until the next full ACMUI meeting.

NRC staff will add the dose vs. administered activity issue to the October ACMUI meeting agenda.

MOTION (16): NRC staff should revise the current guidance to conclude that the surgical removal of the sentinel lymph node is an independent procedure and should not be regulated by NRC.

NRC staff will seek an Office of General Counsel interpretation to determine whether or not the current guidance for sentinel lymph node biopsies can be revised to conclude that the surgical removal of the sentinel lymph node is an independent procedure and should not be regulated by NRC.

ACTION (1): NRC staff committed to consult legal counsel to determine the feasibility of discussing PRM 35-20 with ACMUI members in a closed executive session.

NRC staff consulted with the Office of General counsel and determined the feasibility of discussing PRM 35-20 with ACMUI members. PRM 35-20 has been added as a topic for the October ACMUI agenda.

ACTION (2): NRC staff should arrange a briefing for ACMUI members regarding the Increased Controls Orders to be issued later this year for fingerprinting.

NRC staff invited two ACMUI members, who represented the full Committee, to NRC Headquarters on July 31, 2007. The two ACMUI members briefed the full Committee during a teleconference on August 15, 2007. This action item is closed.

ACTION (3): NRC staff should engage ACMUI in a discussion regarding the review of operational events and data and work towards a goal of minimizing therapeutic medical events, if directed by the Commission to do so in the final Staff Requirements Memorandum (SRM).

The final SRM-SECY 07-0066 did not include this item. NRC staff retains the option to perform this review at a future date.

ACTION (4): NRC staff should provide detailed background information for the current and future presentations on the subject of potential changes to 10 CFR Part 35.

NRC staff will make every effort provide detailed background information for potential changes to 10 CFR Part 35 in the members' briefing binders prior to each meeting.

ACTION (5): NRC staff should email the ACMUI members a copy of the memo summarizing action items and motions made during the meeting.

This action will be added to the Policy and Procedure document for the ACMUI Coordinator.

TELECONFERENCE MEETING OF THE
ADVISORY COMMITTEE ON THE
MEDICAL USES OF ISOTOPES

August 15, 2007

MEETING SUMMARY

PURPOSE: To discuss issues related to the implementation of the Fingerprinting Orders for Increased Controls medical licensees.

OUTCOME: Dr. Richard Vetter and Mr. Ralph Lieto briefed the remaining Advisory Committee on the Medical Uses of Isotopes (ACMUI) members on the Fingerprinting Orders issues they discussed with NRC staff at an Increased Controls Fingerprinting Orders Working Group Meeting on July 31, 2007. The Nuclear Regulatory Commission (NRC) staff gained a better understanding of the views and opinions of the ACMUI. The ACMUI will send a letter to the Commission to offer its opinion and assistance with regards to NRC issuing Fingerprinting Orders to medical licensees.

FINGERPRINTING ORDERS

Dr. Vetter's and Mr. Lieto's concerns with the implementation of the Fingerprinting Orders for Increased Controls medical licensees are listed below:

1. Direct and indirect cost of fingerprinting (hundreds to thousands of dollars) in addition to the expenses already incurred by licensees to implement increased controls
2. Issuance of Orders with no justification
3. Grandfathering for individuals who have already been determined to be trustworthy and reliable and given unescorted access
4. Extended length of time between issuance of Orders and opportunity for stakeholder comment during rulemaking

Dr. Vetter and Mr. Lieto also summarized answers NRC staff had provided for their questions on July 31, 2007. The questions and answers are outlined below:

1. Can fingerprints be sent directly from the licensee to the FBI?
   Answer: No, there is no current method for licensees to send fingerprints directly to the FBI. Fingerprints must be submitted to NRC for forwarding to FBI.
2. Will licensees set the criteria to determine whether individuals granted unescorted access are trustworthy and reliable, or will NRC provide guidelines?
   Answer: NRC staff is considering this issue.

Dr. Subir Nag, ACMUI, asked the members if the fingerprinting Orders would provide additional information, since fingerprints are commonly taken for employment or driver's license purposes. Dr. Vetter explained that the local fingerprinting generally done for employment purposes would determine whether or not the individual had any issues with the local or state police. Dr. Vetter also indicated that the FBI database is national, so submitting fingerprints to the FBI would be an enhancement to the security of sources. Dr. Vetter also stated that NRC did not know

whether or not they would be able to use fingerprints previously taken for employment or other purposes. Mr. Lieto added that it is unknown at this time, if fingerprints will need to be resubmitted after a certain time period.

Dr. Leon Malmud, ACMUI Chair, stated he had been fingerprinted for many reasons (i.e. hospital work, NRC, Air Force, etc.) and asked the ACMUI to restrict its discussion to how the Fingerprinting Orders could potentially impact the practice of physicians and other professionals handling radioactive material. Dr. Nag stated that if the cost issue could be addressed there would be minimal impact on patient care.

MOTION 1: Dr. Nag made a motion to support grandfathering for individuals who had previously been determined to be trustworthy and reliable and granted unescorted access.

Dr. Vetter seconded the motion and added that the NRC Increased Controls Fingerprinting Orders Working Group indicated the system would be able to handle the influx of fingerprints.

Dr. Darrell Fisher, ACMUI, stated that the Energy Policy Act of 2005 did not have a provision for grandfathering. Dr. Fisher also noted that that the ACMUI had an opportunity to make recommendations to the Commission to aid the Commission in making the determination as to what radioactive materials or sources are of significance to require fingerprinting.

Dr. Orhan Suleiman, ACMUI, opposed the motion. Dr. Malmud's opinion was that it is a better option to start with uniform fingerprinting and not grandfather individuals. Dr. Fisher agreed. Dr. Nag requested to withdraw the motion, but the motion carried.

MOTION 2: Dr. Fisher made a motion that the ACMUI agree to assist the Nuclear Regulatory Commission, if requested, to determine those levels and types of material that could be of such significance to public health and safety to warrant fingerprinting and background checks.

Dr. Nag seconded the motion, and after considerable discussion, the ACMUI passed the motion unanimously.

Dr. Vetter suggested the ACMUI send a letter to the Commission with regards to the ACMUI's position on the Fingerprinting Orders issues. Dr. Malmud asked Dr. Vetter to compose a letter for his co-signature stating ACMUI would offer its services and opinion for consideration by the Commission on Fingerprinting Orders issues with regard to medical licensees.

MEETING OF THE
ADVISORY COMMITTEE ON THE
MEDICAL USES OF ISOTOPES

August 16, 2007 and September 20, 2007

MEETING SUMMARY

PURPOSE: To continue the discussion on training and experience issues related to the implementation of the medical regulations in 10 CFR Part 35, "Medical Use of Byproduct Material."

OUTCOME: The Nuclear Regulatory Commission (NRC) staff gained a better understanding of the views and opinions of the Advisory Committee on the Medical Uses of Isotopes (ACMUI), as well as other stakeholders' views and opinions. The staff will consider these views in its continuing effort to make 10 CFR Part 35 more useful, practical, and not overly burdensome on licensees, while maintaining public health and safety.

TRAINING AND EXPERIENCE

Unintended Consequence of Prescriptive Requirements on Certification Boards Resulting in NRC Setting Curriculum

Summary of Issue

Individuals who wish to be an Authorized User (AU) but have not yet passed the board certification exam must meet the requirements of the alternate pathway. Approximately 10-20 percent of those individuals who sit for the board certification exam do not pass on the first attempt; therefore, the unintended consequence is that the boards must teach to the alternate pathway. The ACMUI has no objection to the NRC indicating which topics should be covered for board certification; however, the ACMUI feels the determination for the number of hours for each topic should be under the purview of the certification boards.

Discussion

Dr. Welsh suggested that individuals who are eligible to take the board examination should not have to satisfy the alternate pathway but should be eligible as an authorized user if they have completed the requirements of board certification, even though they have not passed the exam.

Dr. Vetter raised the point that there are individuals who have passed the board certification exam; however, since the boards are only recognized for certain years, not all individuals who have passed the exam would meet the criteria to be an AU. Dr. Guiberteau of the American Board of Radiology (ABR) supported Dr. Vetter's statement and offered information on recently trained physicians who received their board certification in 2004 or 2005 but are currently not eligible through the board certification pathway to be an AU. Dr. Guiberteau explained that there are approximately 400 to 500 individuals who have written to or informed the ABR that they are ineligible under the board certification pathway and must meet the criteria of the

alternate pathway. Gerald White of the AAPM also described several classes of individuals who are impacted by the new board certification recognition. Mr. White estimated that there are potentially thousands of physicists and a large number of physicians who are unable to use their board certifications from prior to 2007.

Drs. Nag and Williamson provided personal examples and engaged NRC staff to determine whether or not they would be eligible to be an AU under various circumstances.

Conclusion

Drs. Malmud, Nag, Welsh, Williamson, Vetter, and Mr. Lieto engaged representatives from the certification boards and other stakeholders to amend motion (3) from the June 12, 2007 meeting summary to read as follows:

MOTION 1: NRC staff should revise the regulations so that board certified individuals, who were certified prior to the effective date of recognition or were certified by previously recognized boards listed in Subpart J of the previous editions of Part 35, are grandfathered.

The motion was seconded and passed unanimously.

Canadian Trained Authorized Users Not Eligible Under the Board Certification Pathway

Summary of Issue

A nuclear medicine physician certified by the American board of Nuclear Medicine but trained in Canada cannot currently be recognized as an AU by the NRC because the individual's training was not completed under the supervision of an AU. The physician must qualify for AU status under the alternate pathway even though they are board certified.

Discussion

Dr. Welsh proposed NRC staff amend the current regulations to include training under the Canadian equivalent of an AU. Dr. Henry Royal of the American Board of Nuclear Medicine (ABNM) stated that the boards regard the Canadian training program as being equivalent to the United States (U.S.). Sandra Wastler of the NRC indicated that NRC had recently received an application for recognition from the Canadian College of Physicists in Medicine (CCPM). Dr. Eggli raised the issue of a Canadian trained physician finding a preceptor to sign for their work experience. Ms. Wastler explained that currently individuals may come to the U.S., work under the supervision of an AU, and then obtain a preceptor statement from the supervising AU.

Conclusion

After a discussion with ACMUI members, other stakeholders, and NRC staff, Dr. Welsh's motion was formalized and seconded by Dr. Nag.

MOTION 2: NRC staff should revise the current regulations to include Canadian trained individuals who have passed the ABNM certification exam.

The motion carried unanimously.

Compatibility Category B vs. C for Training and Experience Requirements

Summary of Issue

The ACMUI desires Compatibility Category B for regulations so that individuals may practice anywhere in the U.S. without inconsistency in the training and experience requirements. Compatibility Category C allows states to have different training and experience requirements, allowing inconsistency among multiple jurisdictions. Some states currently have more restrictive requirements and wish to retain the flexibility of Compatibility C level regulations.

Discussion

Dr. Ron Zelac of the NRC informed the ACMUI and stakeholders that the Commission specifically directed NRC staff to assign Compatibility B for training and experience requirements for all categories of authorized users to ensure that training and experience requirements for the medical use of byproduct material are consistent between NRC and the Agreement States. NRC staff clarified the meaning of Compatibility B and C for ACMUI members.

Conclusion

MOTION 3: NRC staff should maintain Compatibility B for training and experience requirements to ensure that authorized individuals may cross state borders and practice throughout the U.S.

The motion carried unanimously.

Unavailability of Preceptor for Authorized Individuals

Summary of Issue

ACMUI and stakeholders are concerned that if a preceptor is not available or has passed on, an authorized individual may not be able to easily obtain the signature of another preceptor who is willing to attest to an individual's past training and experience that the preceptor did not personally supervise.

Discussion

Dr. Donna-Beth Howe of the NRC summarized many aspects of preceptor statements and clearly defined "preceptor" for the ACMUI and stakeholders. Dr. Eggli stated his unwillingness to sign a preceptor statement for training or experience that he did not personally supervise. This means an individual must repeat the training and experience under the supervision of the new preceptor. The ACMUI reaffirmed their dissatisfaction with the NRC's use of the word "competency" in preceptor statements. Ms. Schwarz asked that Dr. Malmud and Dr. Vetter discuss this topic directly with the Commissioners. Drs. Malmud and Vetter agreed that this is a high priority item to discuss with the Commission.

Dr. Darlene Metter of the Texas Radiation Advisory Board (TRAB) provided examples and stated issues with preceptor statements in the state of Texas. Salli Cheever with Physics Consultants, Inc. in Maine stated this issue comes up frequently. Ms. Cheever stated that authorized individuals might have obtained board certification over seven years ago and have not been listed on a radioactive materials license, and in Ms. Cheever's specific example, the individual must have the preceptor statement signed by the AU under whom they are currently working. Ms. Cheever added that this is acceptable in the state of Maine. Dr. Williamson stated that individuals previously trained at his facility have requested preceptor statements regarding their competency to function independently, and those individuals have been denied. Dr. Eggli supported Dr. Williamson's statement and confirmed the same situation occurs at his institution. Debbie Gilley of the state of Florida stated that not all Agreement States have implemented the new Part 35, and, therefore, have no current experience with this issue.

Dr. Howe confirmed that, in lieu of the NRC Form 313A, individuals can submit equivalent information to include a preceptor statement. Dr. Howe also stated that NRC has not received any requests from the NRC Regional Offices to address this issue, so NRC is unaware of any specific examples. Jackie Cook from NRC Region IV stated there was a potential issue with individuals obtaining preceptor statements; however, Roberto Torres of RIV stated he had only seen approximately one or two individuals fall into this category. In both cases the individuals gained work experience under a current AU and obtained preceptor statements within a few months.

Lynne Fairobent of the American Association of Physicist in Medicine (AAPM) and Dr. Metter of TRAB stated they both had several board certified individuals who could not practice due to the current regulations. Dr. Sue Langhorst of Washington University in St. Louis (WUSTL) stated, as the RSO, that she would not submit an application to the Radiation Safety Committee, if the individual did not currently meet the qualifications.

Dr. Eggli suggested that the ACMUI offer no further comment since motion (2) from the June 12, 2007, meeting summary fully encompassed the issue. Dr. Nag suggested the group refocus the discussion to non-board certified individuals who cannot obtain a preceptor statement due to unavailability of a preceptor.

Conclusion

After a lengthy discussion with ACMUI members and stakeholders, Dr. Nag made a motion that was seconded by Dr. Williamson.

MOTION 4: NRC staff should accept a preceptor statement from another AU for a non-board certified individual if the AU who supervised the training and work experience is not available as a preceptor.

The motion carried; however, Mr. Williamson abstained.

Seven Year Recency of Training for Individuals Seeking Authorization

Summary of Issue

10 CFR 35.59 states that training and experience must have been obtained within seven years preceding the date of the application or the individual must have had related continuing education and experience since the required training and experience was completed.

Discussion

Drs. Nag, Williamson, and Mr. Lieto provided example scenarios for individuals who would not meet the seven year training and experience requirement. Ms. Gilley of the state of Florida and Michael Ford of TRAB provided comments from the Agreement State perspective. Ms. Wastler of the NRC added that although the Agreement States do not consult with the ACMUI for license applications or amendment requests, Agreement States can use their own internal processes to determine if the individual seeking authorization has the appropriate continuing education and experience.

Conclusion

Dr. Nag stated that the ACMUI currently addresses this issue adequately and no further discussion was needed. Ms. Schwarz seconded his statement. The ACMUI did not make a formal motion or vote.

The ACMUI generally agreed that NRC staff should continue to use a case-by-case approval process for individuals who do not meet the seven-year recency of training requirement and consult the ACMUI, as needed.

Increased Complexity vs. Additional Benefit of the New 10 CFR Part 35 Training & Experience Requirements

Summary of Issue

ACMUI believes the new 10 CFR Part 35 training and experience requirements do not increase public health and safety, and the additional cost and complexity of the new regulations is not justified. Additionally, ACMUI believes the new regulations make it difficult or possibly exclude certain groups of individuals from practicing.

Discussion

Dr. Williamson summarized the issue for ACMUI members, NRC staff, and stakeholders. Dr. Langhorst of WUSTL agreed with ACMUI that there was no added health and safety benefit for Radiation Safety Officers. Dr. Nag added that the increased complexity of the regulations is less beneficial since individuals, who could otherwise be treating patients, are excluded. Dr. Thomadsen agreed with the other ACMUI members and stated his recollection of a concern about freestanding units, in which there was no hospital credentials reviewing committee. Dr. Williamson provided additional insight and stated at one time there was a concern that the board certification mechanisms did not adequately address the technical aspects of radiation safety practices; therefore, the regulations needed to be amended to be more prescriptive, and a set of criteria to accept board certification mechanisms was added to the rule language. Dr. Williamson proposed a motion which stated the current revision of the training and experience regulations has not improved public health and safety and has actually diminished safety or possibly patient access to health care. Mr. Ford of TRAB supported Dr. Williamson's statement

and added that the TRAB viewed the revisions to the training and experience requirements as a very complex solution to a non-existent problem. Dr. Nag agreed with Dr. Williamson and Mr. Ford but clarified that the new regulations have not necessarily reduced patient safety but have not increased patient safety. Dr. Metter of TRAB later added that she was unaware of any negative impact on patient care.

Conclusion

Mr. Lieto suggested this topic be discussed at the October ACMUI meeting. Dr. Fisher formally made the motion, and Mr. Lieto seconded.

MOTION 5: NRC staff should add 'increased complexity vs. additional benefit' as an agenda item for the October ACMUI meeting, so that ACMUI may continue the discussion on this topic.

The ACMUI did not vote on this motion.

Update on Increased Controls Activities and Lessons Learned

ACMUI Meeting
October 22, 2007

Janet Schlueter, Division Director
Division of Materials Safety and State Agreements
Office of Federal and State Materials

Original presentation by Tim Harris
OAS Meeting September 25, 2007

Purpose

- Provide an update to activities associated with the issuance of the Increased Controls (IC) requirements
- Provide any lessons learned from the first year inspections

Increased Controls (IC)

- Issued Jointly with Agreement States
- Require specific Actions to Enhance Control:
  - Access Controls
  - Background Checks for Unescorted Access
  - Monitor, Detect and Respond to Unauthorized Access
  - Advance Coordination with Local Law Enforcement
  - Transportation Controls
  - Protection of Sensitive Physical Protection Information
  - Nov. 14, 2005, Order EA-05-090, Published Dec. 1, 2005, 70FR72128

Implementation of the Increased Controls Working Group (IICWG)

- **Provides guidance on implementation issues**
- **Co-Chaired between NRC and Organization of Agreement States (OAS)**
  - Rob Lewis, NRC, Office of Federal and State Materials and Environmental Management Programs
  - Pete Myers (TX), Representing OAS
- **NRC Representatives**
  - Frederick Sturz, Office of Nuclear Security Incident Response
  - Brad Jones, Office of the General Counsel
  - Marie Miller, Region I Office
  - Steve Reynolds, Region III Office
  - Vivian Campbell, Region IV Office
- **Agreement State Representatives**
  - Robert Gallaghar (MA) – CRCPD

IICWG (continued)

- Sub-group formed to provide guidance on continued IC inspections
  - Interim guidance letter on continued IC inspections, dated 9/?/07
  - Developing IC inspection procedure
  - Revising Inspection Manual Chapter 2800

Interim Guidance

- Provides interim guidance for continued inspection of IC licensees
- Scheduling guidance:
  - If initial IC inspection was clear – IC inspection may be performed with routine due date for health and safety inspection
  - If initial IC inspection resulted in escalated enforcement, follow-up inspection within six months
  - Initial inspections of new or amended licenses implementing IC requirements conducted as soon as practical when notified that the licensee possess radioactive material

Inspections of IC Licensees

- NRC Regions and Agreement States have completed first year inspections
- Approximately 1100 IC inspections conducted out of 1700 licensees that are required to implement
- Information Notice 2007-16, "Common Violations of Increased Controls Requirements and Related Guidance Documents" issued on May 2, 2007
  - Informs licensees of available guidance to assist in implementing IC requirements
- Approximately 50% of NRC performed inspections resulted in violations

Examples of Common Violations

- Most violations have occurred in IC 2, IC1 and IC6
- Failure to document actions or program is a common throughout the ICs
- IC1: Allowing unescorted access to radioactive material quantities of concern without proper trustworthiness and reliability determinations
- IC2: Inadequate installation of equipment, dysfunctional equipment, or lack of monitoring of storage areas.
- 1C6: Access and handling of physical protection information according to IC 6.
- Information Notice 2007-16:
  - http://nrc-stp.ornl.gov/asletters/program/sp07042.

Integrated Materials Performance Evaluation Program (IMPEP)

- Purpose: Assess Agreement State and NRC Regional radioactive material licensing and inspection programs
- FY07: ME, NY, TX, FL, ND, UT, SC, MD, IA and Region III
- FY08: MN, RI, OR, TN, AZ, CA, WA, LA, NH, KY, GA

Training

- FY 2007 Training:
  - October 2006 – Albuquerque, NM
  - November 2006 – Albuquerque, NM
  - August 2007 – Albuquerque, NM
- FY 2008 Training:
  - 2 courses tentatively planned
    - Florida
    - Pennsylvania

Looking Forward - Fingerprinting

- Staff Requirements Memorandum, SRM-SECY-07-0011, dated March 12, 2007 instructed the NRC staff to:
  - Engage the Agreement States to develop a plan to require fingerprinting of IC licensees
  - To issue fingerprinting requirements to non-M&D service provider licensees who prefer unescorted access at IC facilities

Conclusion

- OAS and NRC partnership in implementing IC requirements has been a success.
- Fingerprinting will be our next opportunity for success.

Radioactive Materials Security and Licensing

ACMUI Meeting
October 22, 2007

Janet Schlueter, Division Director
Division of Materials Safety and State Agreements
Office of Federal and State Materials

Original presentation by John Kinneman
Commission Briefing September 4, 2007

Outline

- Actions to Improve Security (2001-2007)
- GAO Investigation and Senate Hearing
- Recommendations
- Action Plan to Further Improve Security

Actions to Improve Security (2001-2007)

- Staff Has Improved Security Posture to Reflect Post-9/11 Environment
- Security Assessments in 2002
- Materials Security Working Group
- Orders to Improve Security

Actions to Improve Security (2001-2007) (Continued)

- Consistently Employed Risk-Informed, Graded Approach
- Highest Risk Sources Considered First
- Graded Requirements

2007 GAO Investigation

- Formed Bogus Company and Obtained NRC License
- Altered NRC License
- Two Suppliers Agreed to Sell Material
- Parallel Attempt to Obtain Agreement State License Aborted When Notified of Site Visit

Short Term Actions Taken

- Discussed with GAO Investigators
- Terminated the NRC License
- Stopped Issuing New NRC Licenses Until Interim Guidance Issued
- Pre-Licensing Visits or Meetings for New Applicants
- Restarted Pre-Licensing Working Grou

Short Term Actions Taken

- Coordinated with Federal and State Partners
- Performed Consequence Assessment and Shared with GAO
- Retrospective Examination to Assure Licensees are Legitimate

GAO Recommendations

- Mandatory Pre-Licensing Visits
- Periodic Oversight of License Reviewers
- Explore Prevention of License Counterfeiting

Senate Staff Recommendations

- Permanent Subcommittee on Investigations:
  - Reevaluate "Good Faith" Presumption
  - Regulate Category 3 More Closely
  - Ensure Only Authorized Persons Get Radioactive Material

OIG Recommendation

- Independent External Panel to:
  - Identify Vulnerabilities in Material Licensing
  - Validate the Agency's Byproduct Material Security Efforts

Commission SRM

- Aug. 17, 2007
- Comprehensive Plan by Sept. 4, 2007
- Needed Changes in Licensing Process
- Include Short Term Actions
- Align with Agreement States

Action Plan Overview

- External Review
- Pre-Licensing Working Group
- Materials Program Working Group
- NSTS and WBL
- General Licenses and Outreach
- Agreement State Partnership

External Review Panel

- Three Independent Experts
- 120 Days to Review Licensing Process
- Identify Vulnerabilities and Effectiveness
- Review "Good Faith" Presumption

Pre-Licensing Working Group

- Reconstitute 2005-2006 Working Group
- Regional and Agreement State Co-Chairs
- To Develop Revised Guidance on Pre-Licensing Reviews and Visits
- Product due November 30, 2007

Materials Program Working Group

- FSME and Agreement State Co-Chairs
- Regional Participation
- Develop and Evaluate Solutions to:
  - Verification of Authorization
  - Counterfeiting
  - General Licensees

Materials Program Working Group

- Review Results of External Review
- Comprehensive Program Assessment
  - Pre-Licensing Guidance (Broader Look)
  - Not Limited to Licensing
  - IMPEP Process
- Reports/Recommendations Phased Over Next Year

NSTS and WBL

- Expand Rulemaking to Consider Smaller Sources (Category 3.5)
- Interface between NSTS and WBL
  - Effective Solution for Assuring Authorization
  - Impact for the Agreement States
- Partner with Agreement States to Achieve Broad Participation

General Licenses

- Staff-Identified Vulnerability
- Short-term Action Will be Developed
- Framework Review
- Ongoing Rulemaking

Resources

FY08 Unbudgeted		FY09 Unbudgeted	
FTE	$(Thousands)	FTE	$(Thousands)
15.5	2,580	12.0	8,260

Staff's Plan

- Comprehensive and Responsive
- Short-term, Mid-Term and Long-Term Actions
- Independent, External Program Review
- Comprehensive Internal Assessment

Acronyms Used

- DNMS – Division of Nuclear Materials Safety
- GAO – Government Accountability Office
- FSME – Office of Federal and State Materials and Environmental Management Programs
- WBL – Web-Based Licensing
- NSTS – National Source Tracking System
- SRM – Staff Requirements Memorandum

September 18, 2007

MEMORANDUM TO: Luis A. Reyes
Executive Director for Operations

FROM: Annette L. Vietti-Cook, Secretary */RA/*

SUBJECT: STAFF REQUIREMENTS - SECY-07-0147– RESPONSE TO GAO RECOMMENDATIONS AND OTHER RECOMMENDATIONS TO ADDRESS SECURITY ISSUES IN THE NRC MATERIALS PROGRAM

The Commission has approved the staff's Action Plan to respond to recommendations for addressing security issues associated with the NRC materials program, subject to the comments below.

The Independent External Review Panel should be chartered by and report directly to the Executive Director for Operations. The Independent External Review Panel should brief the Commission offices with their interim and final findings and provide the Commission with a copy of it's draft and final reports.

The most pressing issues involve trustworthiness of applicants for new licenses and authenticity of transactions involving licensees. In evaluating potential solutions to these issues the staff should consider developing practical common sense approaches such as requiring site visits to potential applicant's businesses and phone calls between the appropriate regulatory agency and one or both licensees involved in a transaction to verify the validity of the parties' licenses.

Many of the issues dealing with security cross state boundaries and require a consistent national implementation program. In those circumstances in which the States appear to lack authority to implement solutions – as in the recent challenges with implementing the fingerprinting requirements for unescorted access to nuclear materials – the staff should immediately inform the Commission of the problems and the staff's plans for resolving any impediments to implementing the requirements.

The staff should continue its efforts to fund Agreement States activities, to the maximum extent allowed under current law and explore the possibility of other federal programs providing support to implement security actions, including the possibility of requesting specific legislation.

Successful implementation of this action plan in a timely manner is essential for the NRC. The staff must identify interim actions which are tracked, completed, and documented. The Agreement States should be heavily involved in this activity to ensure practical solutions are implemented quickly. The staff should complete actions as soon as practical and not wait for perfect solutions. The staff should keep the Commission appropriately informed of the progress of the independent external review panel, the pre-licensing working group, and the materials program working group. The staff should provide periodic status reports on the progress of the Plan.

POLICY ISSUE
(Notation Vote)

August 25, 2007 SECY-07-0147

FOR: The Commissioners

FROM: Luis A. Reyes
Executive Director for Operations /RA/

SUBJECT: RESPONSE TO U.S. GOVERNMENT ACCOUNTABILITY OFFICE RECOMMENDATIONS AND OTHER RECOMMENDATIONS TO ADDRESS SECURITY ISSUES IN THE U.S. NUCLEAR REGULATORY COMMISSION MATERIALS PROGRAM

PURPOSE:

To request Commission approval of the staff's proposed Action Plan and associated funding to respond to recommendations to address security issues in the U.S. Nuclear Regulatory Commission's (NRC's) and Agreement States' materials programs.

SUMMARY:

Early in 2007, the U.S. Government Accountability Office (GAO) staff used the name of a bogus company to obtain a valid NRC materials license authorizing the possession of portable gauges containing radioactive sources. Following notification of this fact by GAO, the staff took immediate actions to respond to the identified vulnerability. After a Congressional hearing in July, the NRC received recommendations from the GAO and the Senate Committee on Homeland Security and Governmental Affairs, Permanent Subcommittee on Investigations (PSI) staff. As directed by the Commission in the Staff Requirements Memorandum (SRM) dated August 17, 2007, the staff has developed a proposed Action Plan to address needed changes in NRC's process for issuing licenses for radioactive sources.

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Janet R. Schlueter, FSME/DMSSA
(301) 415-3340

The plan includes specific actions and recommends that three working groups develop additional recommendations: a proposed independent panel, a Pre-Licensing Guidance Working Group (already working), and a proposed Materials Program Working Group. In order to implement the plan, the staff requests additional resources: 15.5 Full Time Equivalent (FTE) and $2.58 million in FY08 and 12.0 FTE and $8.26 million in FY09.

BACKGROUND:

In late May 2007, staff members from the GAO notified the NRC staff of the results of an investigation, where GAO staff used the name of a bogus company to obtain a valid NRC materials license authorizing the possession of portable gauges containing radioactive sources. The GAO staff then modified the license using computer software to make it appear that a much greater number of gauges were authorized than allowed by the original license.

In the same time frame, GAO attempted to obtain a license from the State of Maryland using a similar bogus application. GAO investigators abandoned the effort when Maryland informed them that Maryland would conduct a pre-licensing visit prior to issuing a license.

Previously, in a 2006 Congressional hearing, GAO presented testimony (GAO-06-583T), which described a 2005 GAO investigation where GAO staff successfully brought small radioactive sources into the U.S. using counterfeit documentation, even though the sources were exempt and did not require a license. Also, in 2003, GAO issued a report (GAO-03-804) that concluded that NRC needed to improve the security of radioactive sources.

The Energy Policy Act of 2005 required the establishment of the Radiation Source Protection and Security Task Force, which is chaired by the NRC. The Task Force issued its first report on August 15, 2006. The report contains 10 recommendations and 18 actions, some of which relate to verification issues similar to those raised by the GAO investigation. Appropriate reference is made to them in the Action Plan that is the subject of this Commission Paper.

In response to the GAO notification in late May 2007, the NRC staff promptly took the following actions:

- We immediately informed our Federal partners and the Agreement States of GAO's findings.
- We promptly terminated the license issued to the bogus company.
- Within 24 hours, we suspended issuance of all new materials licenses for about two weeks, pending issuance of revised interim procedures to address the GAO concerns.
- In mid-June, we issued revised interim procedures that require on-site inspections or in-office meetings for new materials license applicants. Exceptions may be made for applicants who already possess, or are listed on, an NRC or Agreement State license.

- We completed a retrospective examination of certain licenses issued by the NRC to verify that the licensees are legitimate.

When members of the Senate were notified of the GAO investigation, a hearing was scheduled by the PSI for July 12, 2007, entitled "Dirty Bomb Vulnerabilities: Fake Companies, Fake Licenses, Real Consequences." Commissioner McGaffigan and representatives of GAO testified at the hearing. In its testimony, GAO made three recommendations, calling for: (1) improved pre-licensing guidance, including consideration of mandatory site visits for new applicants; (2) periodic oversight of license application reviewers; and (3) improved measures to prevent counterfeiting of licenses (GAO-07-1038T).

In conjunction with the July 12, 2007, hearing, the PSI released a staff report, "Dirty Bomb Vulnerabilities," which contained four additional recommendations to improve NRC's materials program. The recommendations called for NRC to: (1) re-examine its apparent "good-faith" presumption in the licensing process; (2) physically inspect applicants' facilities before issuance of licenses for Category 3 radioactive sources; (3) consider including Category 3 sources in the proposed National Source Tracking System (NSTS); and (4) quickly establish the planned Web-Based Licensing (WBL) system.

Earlier in 2007, the NRC Office of the Inspector General (OIG) released its Audit Report "Summary Report and Perspectives on Byproduct Material Security and Control" (OIG-07-A-12, March 30, 2007). The OIG report concluded that, while NRC has taken a number of steps to improve security of byproduct material, the efforts are incomplete. The OIG report recommended that NRC convene an independent panel of experts external to the agency to identify agency vulnerabilities concerning NRC's material licensing and tracking programs, and validate the agency's byproduct material security efforts.

Since the initial GAO notification in May 2007, the Commission and staff have continued to pursue both short-term and long-term actions to address materials security vulnerabilities. As part of these efforts, the staff discussed the issues with the Executive Boards of the Organization of Agreement States (OAS) and the Conference of Radiation Program Control Directors (CRCPD), and coordinated with the Federal Nuclear Government Coordinating Council (GCC) through contacts with the Department of Homeland Security (DHS).

In addition, the staff is preparing a generic communication to material licensees, which will provide updated guidance on verifying license and possession authorizations prior to transfers of licensed material. (Verification requirements have already been imposed by orders issued to licensees who transfer higher risk sources, and general verification guidance was included in an information notice (IN 2006-12) to all materials licensees in 2006.) In conjunction with preparation of the new notice, the staff is considering suggestions from a major portable gauge vendor on how to improve the verification process for licensees.

The staff discussed these security issues with the Commission in a closed meeting on July 18, 2007. Following the meeting, the Commission issued a SRM dated August 17, 2007, directing the staff to prepare a comprehensive plan to address needed changes in NRC's process for issuing licenses for radioactive sources, including the role of pre-licensing visits to verify applicant authenticity and mechanisms for source suppliers to verify the authenticity of a license; appropriate strategies for aligning Agreement State licensing with recommended

changes; and an independent review of NRC's licensing process. This paper responds to that SRM and presents a comprehensive Action Plan.

DISCUSSION:

Reasons for Continuing Concerns About Materials Security

Although NRC has worked continuously since the 9/11/01 attacks to improve security for all licensees, the GAO, PSI, and OIG reports illustrate continuing concerns about security vulnerabilities in the NRC's materials licensing process. Two of the key reasons for these continuing concerns are:

1. NRC efforts have focused on higher risk sources. This is consistent with the agency's policy of risk-informed regulation, and with the International Atomic Energy Agency (IAEA) Code of Conduct on the Safety and Security of Radioactive Sources. However, both the GAO and PSI reports raised questions as to why lower risk sources are not being protected to the same degree as higher risk sources. It is difficult to explain the differences to a large segment of the stakeholder population, who may not generally think in terms of the relative risks associated with varying levels of radiation exposure, and the relative costs and benefits involved in reducing the risk.

2. As pointed out by the PSI report, NRC retains an apparent "good faith" presumption in its licensing approach, which assumes that applicants do not harbor malicious motives. According to the PSI report, this presumption is manifested not just by the lack of pre-licensing visits for applicants involving low-risk licensees, but also by NRC licensing guidance which provides applicants with model language and stock responses.

The implications of the security concerns are broad. Some solutions to these concerns are straightforward - for example, increasing pre-licensing visits - but some are not. For example, 10 CFR Section 30.41(d) is a longstanding regulation which specifies acceptable methods for verification of authorization to receive a particular amount and form of licensed material. This regulation allows transfers based on copies of licenses, written certifications from transferees, and even (for emergency shipments) oral certifications from transferees. This regulation may have to be revised to strengthen the verification requirements, and, if so, Agreement States would need to make compatible revisions. The impact of revisions to this regulation would be broad, because many small vendors and other licensees who transfer material directly to other licensees would be affected, as well as large vendors and their customers.

The Comprehensive Action Plan

As directed by the Commission in the SRM dated August 17, 2007, the staff has developed a proposed Action Plan (enclosed) to address needed changes in NRC's process for issuing licenses for radioactive sources. The Action Plan contains short-term, mid-term, and long-term actions, with timeframes ranging from a few months to more than two years. A milestone chart for the planned actions is included in the plan.

The Action Plan addresses all eight recommendations contained in the recent GAO, PSI, and OIG reports. Six of the recommendations are specific, and two are broad. In developing the

Action Plan, the staff took a comprehensive approach. Therefore, some of the proposed actions address issues that go beyond the recommendations, but that are nevertheless appropriate in order to address potential security vulnerabilities.

One of the broad recommendations (from OIG) calls for an independent review by an external panel of experts. The staff has developed a proposed charter for this panel (attached to the Action Plan), and, following Commission approval, will convene the panel in accordance with the agency's advisory committee process including consultation with the U.S. General Services Administration in accordance with 10 CFR 7.5. The panel will be chaired by a former Agreement State program manager, and will include another member who has not had substantial involvement in design or implementation of the current NRC materials program. The staff has identified specific individuals to fill these roles. These individuals have been selected based on their individual qualifications, knowledge of NRC regulatory programs, and impartiality with respect to the existing NRC materials policies and procedures. It is expected that another Federal agency, most likely the Defense Threat Reduction Agency, will provide a third qualified member.

The second broad recommendation (from the PSI report) calls for a reevaluation of the apparent "good-faith" presumption in the licensing process. As reflected in the enclosed Action Plan, the staff recommends that this issue be assigned to the external panel, because it challenges a fundamental premise of NRC's regulatory approach.

The plan proposes that the report of the independent review be completed by January 31, 2008. The panel's report will be provided to the Director, Office of Federal and State Materials and Environmental Management Programs (FSME) and a newly formed Materials Program Working Group, to consider adoption of the findings and recommendations for changes in the materials regulatory program. FSME and the working group will provide recommended actions to the Commission by Spring 08.

The Action Plan envisions two phases: development and implementation. Initially, proposals and actions must be developed to respond to recommendations and other known vulnerabilities. In addition to specific actions already identified, at least three working groups will be developing additional recommendations: the proposed independent panel, the Pre-Licensing Guidance Working Group, and the proposed Materials Program Working Group. Further, the plan recommends that consideration be given to expanding the NSTS and the associated rulemaking to include Category 3.5 sources, which are an order of magnitude smaller in amount of radioactivity than Category 3 sources. Category 3.5 does not appear in the IAEA Code of Conduct on Safety and Security of Radioactive Sources and is not well understood outside the agency. Adding Category 3.5 will require explanation and coordination with other government agencies to assure consistent implementation of the final NSTS. Also, in addition to the planned general license rulemaking, the plan recommends that a review be undertaken to identify any gaps or modifications that might be appropriate to ensure a consistent, risk-informed, graded approach for the general license program based on both safety and security.

As described in more detail in the Action Plan, the Pre-Licensing Guidance Working Group will develop and issue revised guidance to address pre-licensing reviews and visits, while the proposed Materials Program Working Group will identify other short-term and long-term

measures to be implemented for both specific and general licensees. Subsequently, the additional activities and recommendations arising from these groups must be evaluated, and implementation actions must be determined. Therefore, the proposed Action Plan focuses on the developmental phase, because full information on implementation will not be available until further progress is made by the working groups.

Strategies for Attaining Alignment with the Agreement States and NRC Regional Offices

To assure the consistent, nationwide implementation of the plan, it is likely that many of the actions implemented by the NRC will involve consideration of Agreement State compatibility. The resources required for the Agreement States to implement the recommendations and additional activities as a result of the Action Plan will be significant, because the Agreement States administer a much larger number of licenses than NRC (about 17,500 State licenses vs. about 4,500 NRC licenses). Funding for these activities will need to come from existing budgets which, in most States, are already stretched. In addition to programmatic changes, the plan also proposes enhancements to information technology systems (i.e., NSTS and Web-based Licensing (WBL)) that would include participation by Agreement States.

Coordination with other Federal agencies and the States during the development of these systems is ongoing and will continue. The elements of the Action Plan have been discussed with the Office of Infrastructure Protection, DHS and the major elements of the plan were entered into a list of important actions to improve security of radioactive sources discussed at a meeting of the GCC.

The staff initially coordinated with the Agreement States by discussing the Action Plan with a State program manager who oversees the license for a major portable gauge vendor, and with the Executive Boards of the OAS and the CRCPD. The State manager indicated a willingness to work with NRC to make improvements on license verifications. The OAS Executive Board recently sent a letter dated August 10, 2007, to Senator Carl Levin, which expresses concerns that the GAO testimony and PSI staff report do not provide adequate evidence or other basis to support the GAO and PSI recommendations, and that those recommendations could have a serious impact on the regulation of radioactive materials nation-wide. However, discussions with representatives of the OAS and CRCPD Boards indicate their willingness to work with the NRC staff to develop solutions in response to the Action Plan. Working groups established in conjunction with the plan will include Agreement State representatives. The staff will continue to coordinate closely with the Agreement States, to assure consistent, nation-wide implementation.

The plan has also been coordinated with the NRC Regions; regional representatives will participate in proposed Materials Program Working Group and in the planning and implementation of actions developed in response to the Action Plan.

The staff believes that implementation of the Action Plan and resulting regulatory improvements will improve safety, security, and public confidence by reducing the risk of fraudulent transfers, and establishing a more integrated, comprehensive regulatory framework for all radioactive sources.

RESOURCES:

While some of the activities in the Action Plan are ongoing and budgeted, the majority are unplanned activities that were not included in either the FY08 or FY09 budget process. The following table summarizes the unbudgeted NRC resources required for the Action Plan. Further details for each action item and the associated resources are included in the enclosed Action Plan.

FY08 Unbudgeted		**FY09 Unbudgeted**	
FTE	$ (Thousands)	FTE	$ (Thousands)
15.5	2,580	12.0	8,260

The table includes 1.0 FTE and $400,000 in FY08 for the independent panel activities.

The resource estimates in this paper are a subset of the resource estimates recently provided to the Commission. Resource estimates for a few items, such as NSTS Categories 1 and 2, that were previously provided, have been excluded from this Action Plan, based on further reexamination of their relationship to the GAO findings. Estimates for comparable items in this paper have increased from the resource estimates previously provided by 3.0 FTE and $110,000 in FY 2008.

The staff does not believe that the needed additional resources can be reallocated from other activities in the key program offices (FSME, the Office of Nuclear Security and Incident Response (NSIR), and the Office of Information Services (OIS)) without significantly impacting ongoing programs, given current resource constraints and the large amount of unbudgeted resources involved.

In addition to resource impacts for the NRC, the Agreement States will likely incur substantial unbudgeted costs to carry out recommendations coming from implementation of the Action Plan.

RECOMMENDATION:

That the Commission:

Approve the enclosed Action Plan to respond to the recommendations from the GAO, PSI, and OIG to address security issues in the NRC materials program.

Approve, as part of its review of the FY09 budget proposal and the supplemental information provided by the staff, the allocation of resources to fund the Action Plan.

Note that if the Action Plan is approved, the staff will prepare a communication plan in conjunction with its implementation.

COMMITMENTS:

The proposed commitments, subject to Commission approval, are included in the enclosed Action Plan.

COORDINATION:

This paper has been coordinated with the Office of the General Counsel which has no legal objection. The Action Plan involves significant unbudgeted resources, and the resource estimates have been coordinated with the Office of the Chief Financial Officer.

The Action Plan has also been coordinated with the Agreement States and Regions as discussed above.

/RA/

Luis A. Reyes
Executive Director
for Operations

Enclosure:
Action Plan to Respond to
Recommendations to Address Security
Issues in the NRC Materials Program

COMMITMENTS:

The proposed commitments, subject to Commission approval, are included in the enclosed Action Plan.

COORDINATION:

This paper has been coordinated with the Office of the General Counsel which has no legal objection. The Action Plan involves significant unbudgeted resources, and the resource estimates have been coordinated with the Office of the Chief Financial Officer.

The Action Plan has also been coordinated with the Agreement States and Regions as discussed above.

/RA/

Luis A. Reyes
Executive Director
for Operations

Enclosure:
Action Plan to Respond to
Recommendations to Address Security
Issues in the NRC Materials Program

ADAMS Accession No.: ML072360070 **WITS 20070294/EDATS: SECY-2007-0294**

OFC	FSME	NSIR	OIS	OIP
NAME	JKinneman	PHolahan for RZimmerman	EBaker	CAbrams for MDoane
DATE	08/20/07	08/23/07	08/23/07	08/20/07
OFC	OPA	OGC	CFO	TechEd
NAME	EBrenner	PMoulding for KCyr	WMcCabe	CPoland
DATE	08/23/07	08/23/07	/ /07	8/24/07
OFC	FSME	FSME	EDO	
NAME	GPangburn	GPangburn for CMiller	LAReyes	
DATE	8/24/07	8 /24/07	08/25/2007	/ /07

OFFICIAL RECORD COPY

ACTION PLAN TO RESPOND TO RECOMMENDATIONS TO ADDRESS SECURITY ISSUES IN THE U. S. NUCLEAR REGULATORY COMMISSION MATERIALS PROGRAM

INTRODUCTION

This action plan provides a comprehensive, integrated set of proposed staff actions to respond to recommendations from three reports:

1. U.S. Government Accountability Office (GAO) Testimony, GAO-07-1038T, "Actions Taken by NRC to Strengthen Its Licensing Process for Sealed Radioactive Sources Are Not Effective," July 12, 2007

2. Senate Homeland Security and Governmental Affairs Committee, Permanent Subcommittee on Investigations (PSI) Staff Report: "Dirty Bomb Vulnerabilities," July 12, 2007

3. U.S. Nuclear Regulatory Commission (NRC) Office of the Inspector General (OIG) Audit Report, OIG-07-A-12, "Summary Report and Perspectives on Byproduct Material Security and Control," March 30, 2007

The reports contain eight recommendations. For reference purposes, the recommendations are numbered as follows:

1. GAO Testimony: G-1, G-2, and G-3

2. PSI Staff Report: S-1, S-2a, S-2b, and S-3

3. NRC OIG Report: N-1

Also, two additional actions, which are not specifically covered by the eight recommendations, are included as Additional Actions A-1 and A-2:

A-1. Enhance communication with the public on the risk of exposure to radioactive materials

A-2. General license rulemaking (ongoing, budgeted) and review of the general license regulatory framework (unbudgeted)

For each recommendation, the Action Plan presents the proposed action, completion date, discussion, office lead and supporting offices, and unbudgeted resources. If the action is already budgeted, this is indicated in the resources section.

The total unbudgeted resources to implement the Action Plan are as follows:

Recommendation	FY08 Unbudgeted		FY09 Unbudgeted	
	FTE	$ (Thousands)	FTE	$ (Thousands)
G-1, G-2, G-3, S-2a (Increase from previous estimate: 2.0 FTE and $100,000 in FY08)	11.5	310	9.0	500
S-2b	1.0	760	1.0	5,910
S-3	1.5	1,100	2.0	1,850
N-1, S-1 (Increase from previous estimate: 0.5 FTE for FY08)	1.0	400	0.0	0
A-1		(Budgeted)		(Budgeted)
A-2 (Not included in previous estimate)	0.5	10	0.0	0
TOTAL (Increase from previous estimate: 3.0 FTE and $110,00 for FY08)	**15.5**	**2,580**	**12.0**	**8,260**

Recommendation G-1: The NRC should develop improved guidance for examining NRC license applications, in order to avoid allowing a malevolent group to obtain a license. The improved criteria should consider whether pre-licensing site visits to new licensees should be mandatory.

Action:

1. A Pre-Licensing Guidance Working Group has been convened, with an Agreement State program director as co-chair. The Group will develop and issue revised guidance to address pre-licensing reviews and visits. Exceptions will be addressed. The staff will coordinate with Agreement States to assure that the States implement compatible guidance.

2. A Materials Program Working Group will be formed, composed of NRC Headquarters, NRC Regional, and Agreement State representatives. The Group will identify short-term and long-term measures to be implemented for both specific and general licensees, pending completion of the Web-Based Licensing (WBL) system, the National Source Tracking System (NSTS), the interface between NSTS and WBL, the NSTS rulemaking and the

general license rulemaking. Licensing of imports and exports will be included, as well as prevention of counterfeiting as discussed under Recommendation G-3. The measures to be considered will include guidance or other actions to source suppliers with the objective of preventing unauthorized transfers. The staff will coordinate to assure that compatible compensatory measures are implemented in all Agreement States. The working group will also address the recommendations from the independent panel discussed under Recommendation N-1. A proposed charter for the group is Attachment 1 to this plan.

Completion Dates:

1. Compete revised guidance for pre-licensing visits: November 30, 2007
2. Develop corrective measures:
   a. Short-term measures:
      Improve license verification: October 30, 2007
      Reduce counterfeiting: December 31, 2007
      Reduce vulnerabilities in GL program: March 30, 2008
   b. Follow-up to independent review: April 30, 2008
   c. Issue final corrective measures: September 30, 2008

Discussion:

Based on recently revised interim procedures, the staff is currently conducting pre-licensing visits or in-office meetings with new materials applicants, except those who already possess or are listed on an NRC or Agreement State license. The Pre-Licensing Guidance Working Group will further develop and issue revised guidance to address pre-licensing reviews and visits. This guidance would be implemented in FY08 after training of the Regional staff.

With respect to potentially broader requirements, the 2006 Radiation Source Protection and Security Task Force Report, Action 6-1, states that NRC should expeditiously implement fingerprinting provisions for Category 1 and 2 sources. NRC has already imposed fingerprinting requirements for a large number of Category 1 and 2 licensees, and is coordinating with the Agreement States to impose similar requirements on the remaining Category 1 and 2 licensees. In addition, in a followup to Action 6-3 in the Task Force Report, the staff is pursuing a Memorandum of Understanding with the Department of Homeland Security, which would allow access to the Systematic Alien Verification for Entitlements (SAVE) database in connection with background checks for materials licensee personnel.

Office Leads:

1. Revised Pre-licensing Guidance: Region I
2. Materials Program Working Group: FSME

Support: NSIR, OIP, OGC, ADM, Regions, Agreement States

Resources:

Action	FY08 Unbudgeted		FY09 Unbudgeted	
	FTE	$ (Thousands)	FTE	$ (Thousands)
Pre-Licensing Working Group	0.5	10	0.0	0
NRC Inspection Resources to Conduct Additional Site Visits	3.0	0	1.0	0
Development of Corrective Measures by the Materials Program Working Group (Increase from previous estimate: 2.0 FTE and $100,000 for FY08)	4.0	200	0.0	0
NRC Implementation of Corrective Measures	4.0	100	8.0	500
TOTAL (Increase from previous estimate: 2.0 FTE and $100,000 for FY08)	**11.5**	**310**	**9.0**	**500**

Recommendation G-2: The NRC should conduct periodic oversight of license application examiners so that NRC will be assured that any new guidance is being appropriately applied.

Action: The Materials Program Working Group (see G-1 above) will develop recommendations addressing current training and oversight procedures for both NRC and Agreement State licensing programs and staff, in order to assure effective, consistent implementation.

Completion Date: March 31, 2008

Discussion: NRC materials license reviewers undergo a rigorous, structured training and qualification program that takes approximately 24 months, with formal course work and on-the-job training. The Integrated Materials Performance Evaluation Program (IMPEP) periodically evaluates license reviewer training and qualification programs, as well as the actual performance of license programs and reviewers, in both NRC offices and the Agreement States. Also, the NRC Regions engaged in materials licensing conduct internal performance assessments at least twice per year. Until the working group completes its review and makes recommendations, the Regions will place emphasis in their

performance assessments to assure that pre-licensing guidance is consistently followed.

The working group will evaluate the existing training provided to reviewers, and the effectiveness of IMPEP procedures and regional assessments, and make recommendations for improvements. With regard to IMPEP, the working group will consider the topics that are addressed, the depth of the review, and the frequency of the review.

Office Lead: FSME

Support: NSIR, Regions, OGC

Resources: (Included in G-1 above.)

Recommendation G-3: The NRC should explore options to prevent individuals from counterfeiting NRC licenses, especially if the counterfeiting allows the purchase of more radioactive materials than authorized.

Action: The Materials Program Working Group (see G-1 above) will address and make recommendations on the issue of counterfeiting, as well as related verification issues. Import and export licenses will be included.

Completion Date: March 31, 2008

Discussion: As discussed in the PSI Staff Report, licenses may be copied or faxed, so it is not sufficient to prevent counterfeiting of the original license alone. Other verification methods must also be implemented. The 2006 Radiation Source Protection and Security Task Force Report, Action 4-1, states that NRC should consider imposing additional measures to verify the validity of licenses prior to transfers of risk-significant sources. NRC regulation 10 CFR Section 30.41(d) currently allows transfers of licensed material based on copies of licenses, written certifications from customers, or (for emergency shipments) oral certifications from customers. (Manufacturers and distributors have been issued orders which impose more stringent verification requirements for transfers of Category 1 and 2 sources.) This regulation and similar provisions will be reviewed. The working group's efforts will be coordinated with the Agreement States to assure development of a nation-wide solution to the counterfeiting issue. However, this is a short-term measure and is not comprehensive; the long-term solution requires the development of the integrated WBL and NSTS and associated rulemaking, and the inclusion of Agreement State licenses in WBL. Completion of these activities will make counterfeiting ineffective (see Recommendation S-3).

Office Lead:	FSME
Support:	ADM, OIP, NSIR
Resources:	(Included in G-1 above.)
Recommendation S-1:	The NRC should reevaluate the apparent good-faith presumption that pervades its licensing process.
Action:	Include this topic within the scope of the independent, external review to be conducted under Recommendation N-1 below.
Completion Date:	January 31, 2008
Discussion:	This recommendation is broad in scope and calls into question a fundamental premise of the licensing approach used by the NRC staff and the Agreement States. Therefore, the staff has included it in the proposed charter for the independent, external panel (Attachment 2) to this Action Plan.
Office Lead:	FSME
Resources:	(Included in N-1 below.)
Recommendation S-2a:	The NRC should physically inspect applicants' facilities before the issuance of a Category 3 Materials License.
Action:	See G-1 above. Based on recently revised interim procedures, the staff is currently conducting pre-licensing visits or in-office meetings with new materials applicants, except those who already possess or are listed on an NRC or Agreement State license. The Pre-Licensing Guidance Working Group will further develop and issue revised guidance to address pre-licensing reviews and visits.
Completion Date:	November 30, 2007
Office Lead:	Region I
Support:	FSME, OIP, NSIR, OGC, Regions, Agreement States
Resources:	(See G-1 above.)
Recommendation S-2b:	The NRC should consider including Category 3 sources in the proposed NSTS.

Action: As previously directed by the Commission in the Staff Requirements Memorandum (SRM) dated June 9, 2006, the NSTS rulemaking will include consideration of Category 3 sources. The staff currently plans to expand the NSTS to include Category 3 sources. (This is consistent with Action 11-3 of the Radiation Source Protection and Security Task Force Report.)

The staff recommends that the scope of the NSTS rulemaking be expanded to include Category 3.5 sources. This will require the additional resources listed in the table below. Note that Category 3.5 sources are a factor of 10 smaller in amount of radioactivity than Category 3 sources.

Completion Dates: For Category 3 Sources:

Proposed Rule to the Commission: March 2008
Final Rule : Late 2008 - Early 2009

Implement Expanded NSTS - Category 3: October 2009

Note: The schedule listed above is to complete the expansion of the NSTS and rulemaking to include Category 3, as directed by the SRM. If the recommendation in this Action Plan to include Category 3.5 sources is approved, the additional resources listed below will be needed. The staff is developing the technical basis that will allow the rulemaking including Category 3.5 to meet or exceed the dates above.

Discussion: The current budget covers inclusion of Category 3 sources in the NSTS rulemaking. Even though the recommendation covers Category 3 sources only, the staff's resource estimates below would allow for inclusion of additional sources, down to Category 3.5, in order to more comprehensively address the concerns underlying the recommendation; that is, that smaller sources could be aggregated into larger sources which would pose a significant safety and security hazard.

Most of the additional cost to expand the NSTS is not associated with the rulemaking or the NSTS database itself, but rather the cost of adding and certifying a larger number of additional licensees, who will be authorized to access the system to enter or verify data.

Office Lead: FSME

Support: OIS, NSIR, Agreement States

Resources:

Action	FY08 Unbudgeted		FY09 Unbudgeted	
	FTE	$ (Thousands)	FTE	$ (Thousands)
Expand Scope of NSTS Rulemaking from Category 3 to Category 3.5 Sources	0.5	10	0.5	10
Maintain Interim Inventory Database Down to Category 3.5, Pending Launch of NSTS	0.0	250	0.0	300
Expansion of NSTS to Include Category 3 and 3.5 Sources (Note: These resources do not include additional resources needed for initial development of the NSTS to include Category 1 and 2 sources.)	0.5	500	0.5	5,600*
TOTAL	**1.0**	**760**	**1.0**	**5,910**

*A large part of this amount reflects the cost of adding and certifying additional licensees, so that they can access the system to enter or verify data.

Recommendation S-3: The NRC should act quickly to establish a WBL system to ensure that source materials can be obtained only in authorized amounts by legitimate users.

Actions: The staff will expand the WBL system to allow on-line verification of licenses, establish an interface with NSTS, and make the system externally accessible to licensees and government agencies who need to enter or verify data.

Completion Dates:

1. Develop and implement external WBL, including NRC licensees: October 2009

2. Add Agreement State licensees to WBL: FY-2010 and FY-2011

Discussion: If the action to expand the WBL system is approved and budgeted, the externally accessible system would be implemented in October 2009, with NRC licensees included in the database. Addition of the much greater number of Agreement State licensees would begin in FY10 and extend through FY11, costing about $6 million. Most of the cost for FY09 and beyond would be for verification of outside parties authorized to access the WBL system. The WBL activities will require extensive coordination

with Agreement States and other Federal agencies, so resources are included for that purpose. In addition to expenditures by NRC, the Agreement States will incur unexpected costs to support entering their data into WBL.

Recommendation S-3 addresses the concern that licensees could "shop around" and exceed their authorized quantities by buying authorized quantities from multiple vendors, a concern that intersects with the license counterfeiting considered in Recommendation G-3. The proposed solution includes an interface between the NSTS and WBL to allow vendors to review proposed purchases against the licensee's current inventory and license possession limits. This interface, along with establishment of current information about NRC and Agreement State active licenses in WBL, will require the ongoing cooperation of the Agreement States to continually update the database. Other Federal agencies, including the Domestic Nuclear Detection Office and Customs and Border Protection are interested in assisting with the development of and using such a system. In addition, the Radiation Source Protection and Security Task Force Report, Action 6-2, states that the NRC should evaluate the feasibility of establishing a national database for materials licensees that would contain information on pending applications and information on individuals cleared for unescorted access. Action 11-2 states that NRC should consider programming the NSTS to provide automatic daily information to Customs officials on export/import shipment notifications. External accessibility will allow direct access by licensees and government agencies to verify or enter data.

Office Lead: FSME

Support: OIS, NSIR, Agreement States

Resources:

Action	FY08 Unbudgeted		FY09 Unbudgeted	
	FTE	$ (Thousands)	FTE	$ (Thousands)
Expand WBL System to Allow On-line Verification, Establish an Interface with NSTS, and Allow Access by Outside Parties	0.5	1,000	1.0	1,750
Coordination with Agreement States	1.0	100	1.0	100
TOTAL	**1.5**	**1,100**	**2.0**	**1,850**

Recommendation N-1: The NRC should convene an independent panel of experts external to the agency to identify agency vulnerabilities concerning NRC's material licensing and tracking programs, and validate the agency's byproduct material security efforts.

Action: NRC will arrange the independent, external review, as recommended. The proposed charter for this independent panel includes Recommendation S-1 above. As noted earlier, the panel's recommendations will be provided to the Materials Program Working Group for implementation.

Completion Date: January 31, 2008

Discussion: The panel will be chaired by a former Agreement State program manager, and will include and another person who has not had substantial involvement in design or implementation of the current NRC materials program. The staff has identified specific individuals to fill these roles who have been selected based on their individual qualifications, knowledge of NRC regulatory programs, and impartiality with respect to the existing NRC materials policies and procedures. It is expected that another Federal agency, most likely the Defense Threat Reduction Agency, will provide a third qualified member. The panel will be convened in accordance with the agency's advisory committee process including consultation with the General Services Administration in accordance with 10 CFR 7.5. The panel's review will include an assessment of the existing and potential security vulnerabilities related to the NRC specific, import, export and general license programs. Their assessment will include, as a minimum, pre-licensing guidance, licensing procedures, the licensing process, possession limits on licenses, and license reviewer training and oversight. The panel will gather data by reviewing NRC licensing procedures and appropriate background documents, interviewing staff and selected licensees, visiting NRC Regional Offices and Agreement State Offices, evaluating business processes, etc.

Office Lead: FSME

Support: ADM

Resources:

Action	FY08 Unbudgeted		FY09 Unbudgeted	
	FTE	$ (Thousands)	FTE	$ (Thousands)
Independent Panel Review (Increase from previous estimate: 0.5 FTE for FY08)	1.0	400	0.0	0

Additional Action A-1: Enhance communication with the public on the risk of exposure to radioactive materials.

Action:

1. The staff will continue to participate on the interagency Public Education Subcommittee, chaired by the Department of Homeland Security, established under the Chairman's Radiation Source Protection and Security Task Force. This subcommittee is preparing an Action Plan to improve public education on radioactivity and potential radiological attacks.

2. As directed in the Staff Requirements Memorandum dated June 25, 2007, the staff will support OPA to upgrade the NRC website to improve information on radiation and radiation risk.

Completion Dates:

1. Interagency Public Education Subcommittee Action Plan: December 31, 2007

2. NRC website improvements: Ongoing

Office Lead: OPA, FSME

Support: NSIR, RES

Resources: (Budgeted)

Additional Action A-2: General License Rulemaking and Regulatory Framework Review

Action: The staff, with the additional resources shown below, will conduct a review of the regulatory framework associated with the general license program for byproduct material, and prepare a report specifying the desired "end state" for that program.

The staff will continue planned, budgeted efforts in the current general license rulemaking for byproduct material. The scope of this rulemaking includes consideration of specifically licensing certain sources, devices and materials that are currently eligible for a general license.

Completion Dates: 1. Review general license regulatory framework: June 2008

2. General license rulemaking for Byproduct Material:
   Proposed Rule: September 2008
   Final Rule: September 2009

Discussion: The review of the general license regulatory framework will be undertaken to identify any gaps in regulatory control or modifications that might be appropriate to ensure a consistent, risk-informed, graded approach for these sources, devices, and materials, based on both safety and security. This review will also include examining whether various types of sources and devices should be regulated through general or specific licenses, and whether other mechanisms, such as a more formal registration process, should be considered. The information and recommendations developed will be used as input to the general license rulemaking. The recommendations from this effort will also be provided to the Materials Program Working Group for its consideration and integration into its recommendations. Such an examination is important to ensure that the long-term result of the combined set of activities in this Action Plan create a defensible, complete system of regulatory controls for sources, devices, and materials which are currently generally licensed. Although these actions are outside the scope of the recommendations considered in this Action Plan, they are relevant, because general licensees by definition can obtain radioactive material without prior approval or screening by NRC. Therefore, the same security concerns that prompted the recommendations for specific licensees need to be considered for general licensees.

The general license rulemaking could result in a significant increase in the number of specific licenses. If this occurs, significant additional, ongoing costs would be incurred for both the NRC and Agreement States for licensing, inspection, enforcement, allegation resolution, etc.

Office Lead: FSME

Support: NSIR, Agreement States

Resources:

Action	FY08 Unbudgeted		FY09 Unbudgeted	
	FTE	$ (Thousands)	FTE	$ (Thousands)
Review of General License Regulatory Framework (not included in previous estimates)	0.5	10	0.0	0
General License Rulemaking		(Budgeted)		(Budgeted)

Attachments:
1. Proposed Charter for Materials Program Working Group
2. Proposed Charter for Independent External Review to Identify Vulnerabilities in the NRC Material Licensing Program
3. Action Plan Milestones

MATERIALS PROGRAM WORKING GROUP

PROPOSED CHARTER

PURPOSE

The working group will identify short and long term measures in response to security vulnerabilities[1] identified in the reports discussed below and through its own assessment.

The Working Group is to assess specific and potential security vulnerabilities and weaknesses in the NRC Materials Program and provide recommendations to address them. The Group is to consider potential vulnerabilities in Agreement State Programs and the effect and likely effectiveness of its recommendations on Agreement State Programs.

BACKGROUND

In late May 2007, staff members from the U. S. Government Accountability Office (GAO) notified the NRC staff of the results of an investigation, where GAO staff used the name of a bogus company to obtain a valid NRC materials license authorizing the possession of portable gauges containing radioactive sources. The GAO staff then modified the license using computer software to make it appear that a much greater number of gauges were authorized than allowed by the original license.

Previously, in a 2006 hearing, GAO presented testimony (GAO-06-583T), which described a 2005 GAO investigation where GAO staff successfully brought small radioactive sources into the U. S. using counterfeit documentation. Also, in 2003, GAO issued a report (GAO-03-804) that concluded that NRC needed to improve the security of radioactive sources.

When the Senate was notified of the GAO investigation, a hearing was scheduled for July 12, 2007, entitled "Dirty Bomb Vulnerabilities: Fake Companies, Fake Licenses, Real Consequences." GAO and Commissioner McGaffigan testified at the hearing. In its testimony, GAO made three recommendations, calling for: (1) improved pre-licensing guidance, including consideration of mandatory site visits for new applicants; (2) periodic oversight of license application reviewers; and (3) improved measures to prevent counterfeiting of licenses (GAO-07-1038T).

In conjunction with the July 12, 2007 hearing, the Senate released a staff report, "Dirty Bomb Vulnerabilities," which contained four additional recommendations to improve NRC's materials program. The recommendations called for NRC to: (1) re-examine its apparent "good-faith" presumption in the licensing process; (2) physically inspect applicants' facilities before issuance of licenses for Category 3 radioactive sources; (3) consider including Category 3 sources in the

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[1]Security Vulnerability, as used in this charter, means a weakness which would allow or significantly increase the possibility that an entity could obtain radioactive material and use it to harm the public, the environment or the national interest.

proposed National Source Tracking System; and (4) quickly establish the planned web-based licensing system.

Earlier in 2007, the NRC Office of the Inspector General (OIG) released an audit report (OIG-07-A-12, March 30, 2007). The OIG report concluded that, while NRC has taken a number of steps to improve security of byproduct material, the efforts are incomplete. The OIG report recommended that NRC convene an independent panel of experts external to the agency to identify agency vulnerabilities concerning NRC's material licensing and tracking programs, and validate the agency's byproduct material security efforts. That recommendation is being addressed by a separate independent panel, which may interact with this group.

The Energy Policy Act of 2005 required the establishment of the Radiation Source Protection and Security Task Force, which is chaired by the NRC. The Task Force issued its first report on August 15, 2006. The report contains 10 recommendations and 18 actions, some of which relate to verification issues similar to those raised by the GAO investigation. Reference is made in the Action Plan, to those actions which are similar to tasks assigned to this working group. The group should take into consideration the activities undertaken by other groups as part of the Task Force.

MEMBERSHIP

The working group will operate as an NRC/Agreement State working group as described under NRC's Management Directive 5.3 "Agreement State Participation in Working Groups." The working group will be co-chaired between NRC and a representative from the Organization of Agreement States (OAS). In addition to the co-chair, the OAS and Conference of Radiation Control Program Directors (CRCPD) will be requested to provide a staff member between them for the group. If CRCPD participates, the applicability of the Federal Advisory Committee Act (FACA) to the group must be considered.

The following personnel will serve on the working group:

NRC personnel:
FSME
Regions
NSIR
ADM
OIS
OGC
OIP
(Not all will contribute full time members, some offices may provide resource representatives as noted below.)

Agreement State Personnel:

CRCPD Representation:

Resource Representatives: At least representatives from offices listed above, that are not included in Working Group.

OBJECTIVES

This Working Group has three tasks:

1. Review the following areas and recommend specific actions that can be taken quickly to respond to the security vulnerabilities contained in them. The recommendations should focus on achieving reductions in vulnerabilities in the quickest possible time:

   a. Improve verification of authorization before transfer of radioactive material to a new licensee or licensee who has recently had a significant increase in their possession limit. Assess, among other possibilities, the effectiveness of issuing additional Orders to Manufacturers and Distributors that would require them to use specific methods, such as direct contact with the regulator, to verify authenticity/legitimacy of a license prior to making such a transfer. Recognize that existing Orders address verification for Category 1 and 2 sources. Determine what amount of radioactive material should require additional verification. Consider whether additional verification should apply to portable gauges.

   b. Reduce the ability to successfully counterfeit NRC and Agreement State licenses. Assess NRC's and Agreement States' license documentation (specific, import and export) for vulnerability to modification, use after an amendment, etc. Consider what actions could be taken to reduce those vulnerabilities such as special paper or special stickers. Note that many such solutions will require a change to 10 CFR 30.41 for the affected licensees and might be best accomplished in coordination with Task 1.a above. The working group should focus on changes that can be accomplished quickly, even if they are not fully effective; long term changes will be considered as part of the NSTS.

   c. Evaluate the NRC's general license (GL) program including: appropriateness of devices required to be registered as specified in 10 CFR 31.5 (c)(13)(I); ease of purchasing multiples of devices; ease of obtaining a large aggregate activity; controls that could be implemented in the short term to prevent aggregation; device/source transfer requirements; and Agreement State differences. The staff is engaged in rulemaking on this issue. The working group should coordinate staff preparing the rule to avoid duplicating the analysis involved in the rulemaking, but rather focus on short term actions such as requiring compliance with Increased Controls for general licensees possessing appropriate quantities of material. The working group should consider whether additional controls should be placed on the distribution of a subgroup of generally-licensed devices until the rulemaking is completed.

2. Review the results provided by the Independent Advisory Panel to Identify Vulnerabilities in the NRC Materials Licensing Program. Recommend to Division of Materials Safety and State Agreements (DMSSA) management what actions recommended by that panel should be implemented and describe actions to respond to any identified security vulnerabilities for which the Independent Advisory Panel did not make a specific

recommendation. Coordinate this activity with Task 3, below, to reduce duplication of effort.

3. Conduct a comprehensive review to assess the existing and potential security vulnerabilities in the NRC materials program including specific, import, export and general licenses. The review will include licensing, inspection and management control aspects of the program. The working group is to conduct the assessment using a risk-informed/significance approach and will take into consideration the Congressional and public perception of security as reflected in the reports discussed in the Background Section of this Charter. The working group will identify and propose resolutions for each vulnerability identified. The working group should identify those elements of the existing program that are effective in mitigating security vulnerabilities.

   The working group should include in its review, as a minimum:

   a. NRC's specific licensing process for existing and potential vulnerabilities and weaknesses. The assessment will include pre-licensing guidance, procedures, the licensing process, pre-licensing inspection, possession limits, renewal frequency and license reviewer training. The review of the prelicensing guidance should be broader than that conducted by the recent Pre-Licensing Working group, including consideration of more extensive and expensive background checks, fingerprinting for smaller quantities of radioactive material, background checks by another agency or other entity before applying to NRC. Should NRC require additional documentation or information in support of a license application? Should there be additional training for reviewers in how to identify applicants with intentions to misuse radioactive material? Should additional attention be paid to license transfers or significant personnel changes by a licensee? Should procedures that broad licenses or Master Materials Licensees use to issue permits to their own personnel be strengthened to provide a level of assurance similar to NRC procedures?

   b. NRC's Inspection Manual Chapter 2800 and the inspection process. Determine whether inspection frequencies are appropriate in light of concerns about security vulnerabilities and the possible misuse of radioactive material. Note that Manual Chapter 2800 has been reviewed by the Increased Controls subgroup which is recommending inspection frequency changes.

   c. Integrated Material Performance Evaluation Program (IMPEP). Consider the appropriateness of IMPEP frequency, procedures, and whether there are additional areas that should be reviewed or areas that should receive more scrutiny. Particularly consider the effectiveness of the oversight of license reviewers.

   d. NRC's import and export licensing process.

   e. The importance of identifying radionuclides that are not already included in the International Atomic Energy Agency Categories, (e.g., Po-210) as needing

additional security controls. This subject is addressed in the Radiation Source Protection and Security Task Force Report, Recommendation 3-1.

f. Review appropriate studies of safety and economic consequences of a radiological dispersal device to provide perspective on those events.

g. To the extent consistent with accomplishing Task 1 rapidly, evaluate the effect of short-term actions on long-term recommendations and minimize undesired effects.

h. The ongoing general license rulemaking and regulatory framework review that will be conducted by the staff.

i. The expected effect of each recommendation on Agreement States and the regulated community.

SCHEDULE

Offices, Agreement States and CRCPD identify representatives by October 1, 2007.

For Task 1, above, provide a complete report to the Director, DMSSA by March 31, 2008.

For Task 2, above, provide a complete report to the Director, DMSSA within 45 days of receiving the External Panel's report.

Meet with Director DMSSA and Steering Committee monthly to discuss progress and seek guidance. Additional interactions with the Steering Committee should take place as necessary.

Complete and submit a comprehensive report with recommendations to the Director, DMSSA by September 30, 2008.

In addition to documenting recommendations and the bases for those recommendations, the working group is to be particularly careful to document other options or recommendations which were considered and the reasons for not adopting them.

LEVEL OF EFFORT EXPECTED OF PARTICIPANTS

It is expected that the working group will consist of NRC staff and Agreement State Co-chairs and 3 NRC staff and one Agreement State staff member who will work essentially full time on this working group until completed. Clerical support will be provided by DMSSA.

STEERING COMMITTEE

A steering committee will be established for this working group. The steering committee will be composed of NRC management from DMSSA, NSIR, OIS and ADM as well as representatives from OAS.

MEETINGS

Working group meetings are not subject to the requirements of the FACA, but they will be announced in advance through the NRC Public Meeting Notice System. (If CRCPD participates, the applicability of the FACA to the working group must be considered.) Maximum use will be made of other appropriate media for facilitating interaction with the working group, for example, conference calls, facsimiles, and electronic mail. Working group meetings will be open to the public (unless predecisional information not normally publicly disclosed will be discussed) and will be held in the Washington, D.C., area or other locations as agreed upon by the working group members. Other persons attending working group meetings will be welcome to provide comments to the working group for its consideration in either written form or orally at times specified by the working group chair. Meeting minutes and draft and final documents produced by the working group will be publicly available from the NRC Public Electronic Reading Room, with the exception of exempt information.

UNITED STATES NUCLEAR REGULATORY COMMISSION

INDEPENDENT EXTERNAL REVIEW TO IDENTIFY VULNERABILITIES IN THE U.S. NUCLEAR REGULATORY COMMISSION MATERIAL LICENSING PROGRAM

PROPOSED CHARTER

1. **Committee's Official Designation**:

   Independent Advisory Panel to Identify Vulnerabilities in the NRC Materials Licensing Program

   This committee is 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**:

   As stated in the Action Plan to Respond to Recommendations to Improve the U.S. Nuclear Regulatory Commission Materials Program (Action Plan), the principal objective of this panel is to respond to the NRC Office of the Inspector General (OIG) recommendation (OIG-07-A-12), "...that the Executive Director for Operations convene an independent panel of experts external to the agency to identify agency vulnerabilities concerning NRC's material licensing and tracking programs and validate the agency's ongoing byproduct material security efforts."

   The OIG report also stated, "Such an assessment should necessarily include examination of the management, operational, and technical security controls and the extent to which these controls are: (1) implemented correctly, (2) operating as intended, and (3) producing the desired outcome with respect to mitigating security vulnerabilities."

   In responding to this recommendation, the panel will include in its review an assessment of the existing and potential security vulnerabilities related to NRC's specific, import, export and general license programs.

   The panel is to also evaluate the apparent good-faith presumption that pervades the NRC licensing process (See Recommendation S-1 in the Action Plan).

   The panel is expected to develop an agenda and plan for the review; this plan will include, as a minimum, assessment of pre-licensing guidance, licensing procedures, the licensing process, possession limits on licenses, and license reviewer training and oversight.

   The panel will document each significant issue identified and make appropriate recommendations and propose corrective actions.

The panel will establish criteria for identifying vulnerabilities and will rank-order the vulnerabilities identified on a risk-informed basis and the perceived security risk based on the members' knowledge and experience.

The panel will also identify elements of the existing program that are effective in mitigating security vulnerabilities and should, therefore, be preserved.

The panel will provide a project plan to the Director, Office of Federal and State Materials and Environmental Management Programs (FSME) for comment within 30 days of initiating work.

The panel will complete and submit a report with recommendations to the Director of FSME by January 31, 2008. In addition to documenting its recommendations and the bases for those recommendations, the panel should be particularly careful to document other options that were considered and the reasons for not adopting them.

3. **Time period (duration of this Committee):**

Approximately 120 days.

4. **Official to whom this Committee reports:**

Director,
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. **A description of the duties for which the the Committee is responsible, and, if such duties are not solely advisory, a specification of the authority for such functions:**

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, FSME as Special Government Employees (SGEs). Approximately 3 members will utilize 1 FTE (includes approximately 0.75 FTE for working group members and 0.25 FTE for NRC staff). It is estimated that $400,000 will be expended for travel and other expenses of the panel.

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

There will be between four and six meetings of the panel, including an initial meeting with the Director of FSME to provide the charge to the panel, a meeting when the panel presents its plan and another when it presents its findings. Additional meetings will likely be held to develop recommendations, as well as to prepare an early draft report, interim updates and a final report.

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

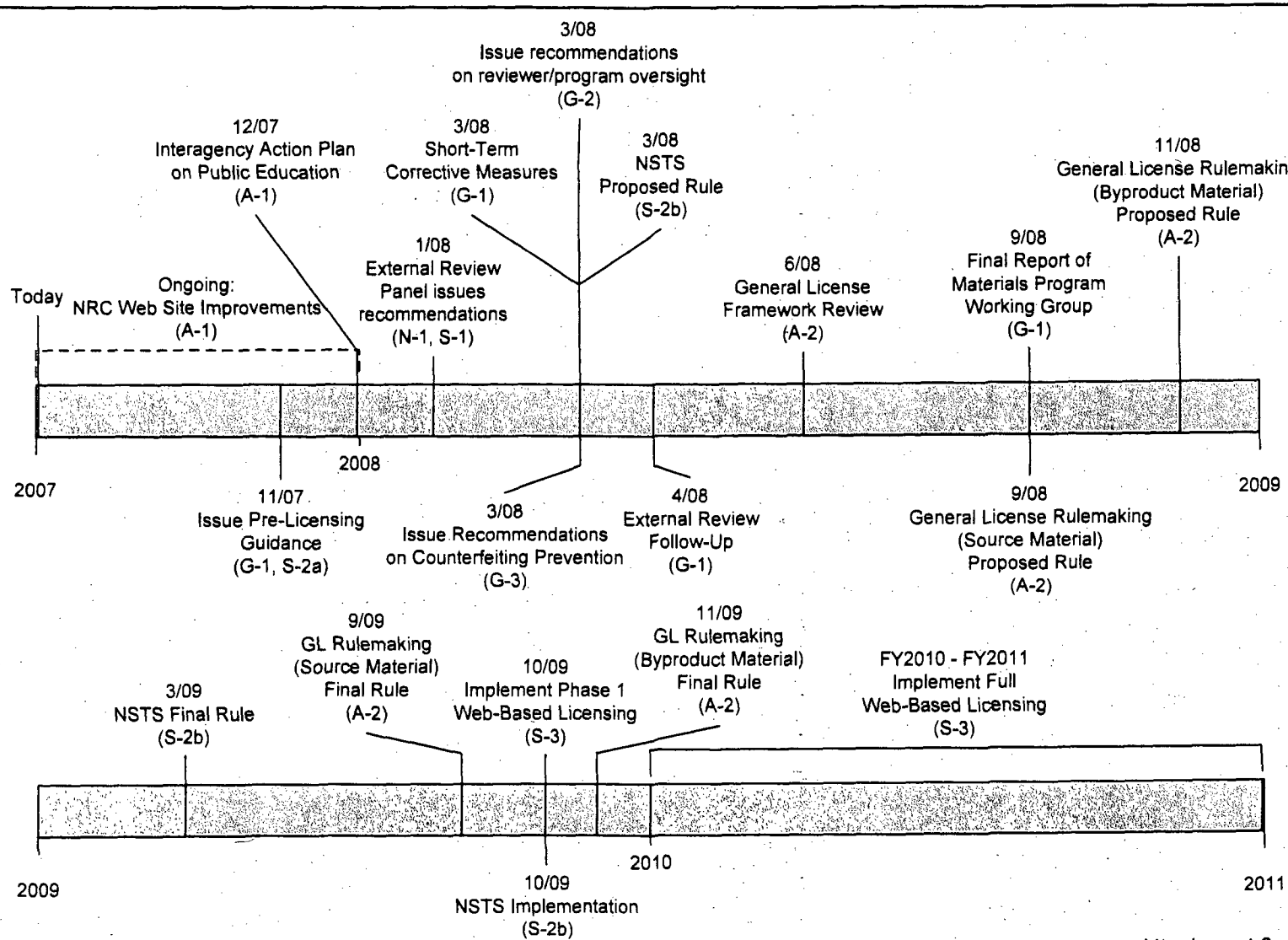
No later than two years after the work begins.

10. **Filing date:**

September ??, 2007

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

Action Plan Milestones



Attachment 3

United States Government Accountability Office

GAO

Testimony

Before the Permanent Subcommittee on Investigations, Committee on Homeland Security and Governmental Affairs, U.S. Senate

For Release on Delivery
Expected at 9:00 a.m. EDT
Thursday, July 12, 2007

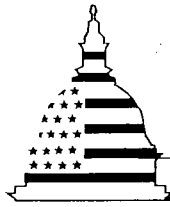
NUCLEAR SECURITY

Actions Taken by NRC to Strengthen Its Licensing Process for Sealed Radioactive Sources Are Not Effective

Statement of Gregory D. Kutz, Managing Director
Forensic Audits and Special Investigations

Gene Aloise, Director
Natural Resources and Environment

John W. Cooney, Assistant Director
Forensic Audits and Special Investigations



G A O

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July 12, 2007

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Highlights

Highlights of GAO-07-1038T, a testimony before the Permanent Subcommittee on Investigations, Committee on Homeland Security and Governmental Affairs, U.S. Senate

NUCLEAR SECURITY

Actions Taken by NRC to Strengthen Its Licensing Process for Sealed Radioactive Sources Are Not Effective

Why GAO Did This Study

The Nuclear Regulatory Commission (NRC) regulates domestic medical, industrial, and research uses of sealed radioactive sources. Organizations or individuals attempting to purchase a sealed source must apply for a license and gain the approval of either NRC or an "agreement state." To become an agreement state, a state must demonstrate to NRC that its regulatory program is compatible with NRC regulations and is effective in protecting public health and safety. NRC then transfers portions of its authority to the agreement state.

In 2003, GAO reported that weaknesses in NRC's licensing program could allow terrorists to obtain radioactive materials. NRC took some steps to respond to the GAO report, including issuing guidance to license examiners. To determine whether NRC actions to address GAO recommendations were sufficient, the Subcommittee asked GAO to test the licensing program using covert investigative methods.

What GAO Recommends

GAO recommends that NRC develop improved screening criteria to evaluate new license applications, conduct periodic reviews of license examiners to ensure the criteria are properly applied, and explore options to prevent license counterfeiting.

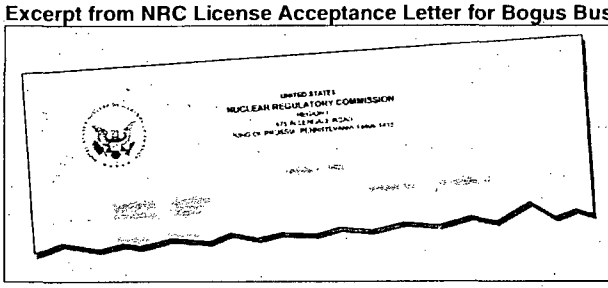
www.gao.gov/cgi-bin/getrpt?GAO-07-1038T.

To view the full product, including the scope and methodology, click on the link above. For more information, contact Gregory D. Kutz at (202) 512-7455 or kutzg@gao.gov or Gene Aloise at (202) 512-3841 or aloisee@gao.gov.

What GAO Found

By using the name of a bogus business that existed only on paper, GAO investigators were able to obtain a genuine radioactive materials license from NRC. Aside from traveling to a non-agreement state to pick up and send mail, GAO investigators did not need to leave their office in Washington, D.C., to obtain the license from NRC. Further, other than obtaining radiation safety officer training, investigators gathered all the information they needed for the license from the NRC Web site.

Excerpt from NRC License Acceptance Letter for Bogus Business



"This refers to your application dated February 2, 2007, for an NRC license. Enclosed with this letter is the license. Please review the enclosed document carefully and be sure that you understand all conditions..."

Source: GAO.

After obtaining a license from NRC, GAO investigators altered the license so it appeared that the bogus company could purchase an unrestricted quantity of radioactive sealed sources rather than the maximum listed on the approved license. GAO then sought to purchase, from two U.S. suppliers, machines containing sealed radioactive material. Letters of intent to purchase, which included the altered NRC license as an attachment, were accepted by the two suppliers. These suppliers gave GAO price quotes and commitments to ship the machines containing radioactive materials. The amount of radioactive material we could have acquired from these two suppliers was sufficient to reach the International Atomic Energy Agency's (IAEA) definition of category 3. According to IAEA, category 3 sources are dangerous if not safely managed or securely protected. Importantly, with patience and the proper financial resources, we could have accumulated substantially more radioactive source material.

GAO also attempted to obtain a license from an agreement state, but withdrew the application after state license examiners indicated they would visit the bogus company office before granting the license. An official with the licensing program told GAO that conducting a site visit is a standard required procedure before radioactive materials license applications are approved in that state.

As a result of this investigation, NRC suspended its licensing program until it could determine what corrective actions were necessary to resolve the weaknesses GAO identified. On June 12, 2007, NRC issued supplemental interim guidance with additional screening criteria. These criteria are intended to help a license examiner determine whether a site visit or face-to-face meeting with new license applicants is required.

Mr. Chairman and Members of the Subcommittee:

Thank you for the opportunity to discuss our covert testing of the Nuclear Regulatory Commission's (NRC) licensing process for sealed radioactive sources. Under the Atomic Energy Act of 1954, NRC regulates domestic medical, industrial, and research uses of sealed radioactive sources through a combination of regulatory requirements, licensing, inspection, and enforcement. Organizations or individuals attempting to purchase a sealed source must apply for a license and gain the approval of either NRC or an "agreement state." To become an agreement state, a state must first demonstrate to NRC that its regulatory program is compatible with NRC regulations and is effective in protecting public health and safety. Through an agreement between NRC and the state governor, NRC then transfers portions of its regulatory and licensing authority to the state. According to NRC, there are approximately 22,000 licenses in the United States—NRC administers about 4,400 licenses, and the rest are administered by regulatory authorities in the 34 agreement states.

Given that terrorists have expressed an interest in obtaining nuclear material, the Congress and the American people expect licensing programs for these materials to be secure. However, in 2003, we reported that weaknesses in the licensing program could allow terrorists to obtain radioactive materials. We recommended that NRC close this vulnerability by modifying its licensing process.[1] Among other things, we recommended that "NRC modify its process for issuing specific licenses to ensure that sealed radioactive sources cannot be purchased before NRC's verification—through inspection or other means—that the materials will be used as intended." NRC agreed with this recommendation and referred the issue to a working group composed of NRC and state representatives to coordinate NRC's response. In December 2005, the working group delivered its recommendations to NRC senior management. In December 2006, NRC issued new guidance to agreement states and NRC regional offices meant to strengthen the radioactive materials licensing process.[2] Although these are important steps forward, the Subcommittee remained concerned about whether, almost 6 years after September 11, 2001,

[1]GAO, *Nuclear Security: Federal and State Action Needed to Improve Security of Sealed Radioactive Sources*, GAO-03-804 (Washington, D.C.: Aug. 6, 2003).

[2]The guidance was also sent to officials in New Jersey, Pennsylvania, and Virginia—states that are not yet agreement states but have filed statements of intent with NRC to achieve agreement state status.

terrorists could still exploit weaknesses in the government's licensing process and obtain radioactive material. To determine whether NRC actions to address our 2003 recommendations were sufficient, the Subcommittee asked us to use covert investigative methods to test the licensing program.

To perform this investigation, we incorporated two bogus businesses—one in a non-agreement state and one in an agreement state. We selected these two states based on their proximity to the Washington, D.C., metro area. Using the names of the bogus businesses, we then prepared and submitted one application for a byproduct materials license to NRC and a second application to the department of the environment of the agreement state. In creating these applications, we only used publicly available information. Our investigators did not actually purchase radioactive materials for several reasons—first, the primary intent of our work was to test the licensing process rather than the purchasing process; second, we did not think the cost borne by the government would be necessary to prove the point of our work; and third, we did not have the proper facilities to safely store the radioactive materials. In performing research for this work, we reviewed our previous reports on nuclear security and learned about the licensing process from NRC's Web site. We altered the license we received from NRC, which enabled us to obtain agreements to purchase more radioactive material than the original license permitted. We conducted our investigative work from October 2006 through June 2007 in accordance with standards prescribed by the President's Council on Integrity and Efficiency.

In summary, we found the following:

- The license application we submitted to NRC was approved. We received a license in the mail from NRC about 4 weeks after submitting the application. Aside from traveling to a non-agreement state to pick up and send mail, our investigators did not need to leave their office in Washington, D.C., to obtain the license from NRC. Further, other than obtaining radiation safety officer training, investigators gathered all the information they needed for the license from the NRC Web site.

- After obtaining a license from NRC, we sought to purchase, from two U.S. suppliers, machines containing sealed radioactive material. Our letters of intent to purchase, which included an altered version of the NRC license as an attachment, were accepted by the suppliers. These suppliers gave us price quotes and commitments to ship the machines containing radioactive materials. The amount of radioactive material

we could have acquired from these two suppliers was sufficient to reach the International Atomic Energy Agency's (IAEA) definition of category 3. According to IAEA, category 3 sources are dangerous if not safely managed or securely protected and "could cause permanent injury to a person who handled them, or was otherwise in contact with them, for some hours. It could possibly—although it is unlikely—be fatal to be close to this amount of unshielded radioactive material for a period of days to weeks."[3] Importantly, with patience and the proper financial resources, we could have accumulated from other suppliers substantially more radioactive source material than what the two suppliers initially agreed to ship to us.

- We withdrew our second application from the agreement state department of the environment after license examiners indicated they would visit our company office before granting the license. Since we did not have a company office or the proper storage equipment, we asked the state to withdraw our application to obtain a license in this state. According to an official with the licensing program for this state, the completion of a site visit is a standard procedure before the state department of the environment approves a radioactive materials license application.

Background

Since the September 11, 2001, terrorist attacks there has been concern that certain radioactive material could be used in the construction of a radiological dispersion device (RDD). An RDD disperses radioactive material over a particular target area, which could be accomplished using explosives or by other means.[4] The major purpose of an RDD would be to create terror and disruption, not death or destruction. Depending on the type, form, amount, and concentration of radioactive material used, direct radiation exposure from an RDD could cause health effects to individuals in proximity to the material for an extended time; for those exposed for shorter periods and at lower levels, it could potentially increase the long-

[3]International Atomic Energy Agency, *Code of Conduct on the Safety and Security of Radioactive Sources* (Vienna, Austria: 2004).

[4]According to NRC, a dirty bomb is one type of RDD that combines a conventional explosive, such as dynamite, with radioactive material. The terms dirty bomb and RDD are often used interchangeably in the media. Most RDDs would not release enough radiation to kill people or cause severe illness—the conventional explosive itself could be more harmful to individuals than the radioactive material. However, depending on the scenario, an RDD explosion could create fear and panic, contaminate property, and require potentially costly cleanup.

term risks of cancer. In addition, the evacuation and cleanup of contaminated areas after dispersal could lead to panic and serious economic costs on the affected population. In 2003, a joint NRC/Department of Energy (DOE) interagency working group identified several radioactive materials (including Americium-241 and Cesium-137) as materials at higher risk of being used in an RDD, describing these as "materials of greatest concern."[5]

In its risk-based approach to securing radioactive sources, NRC has made a commitment to work toward implementing the provisions of IAEA's Code of Conduct. This document provides a framework that categorizes the relative risk associated with radioactive sources.[6] While NRC has recently focused on upgrading its capacity to track, monitor, and secure category 1 and 2 sources, which are considered high risk, category 3 sources are not a primary focus of NRC regulatory efforts. Category 3 sources include byproduct material, which is radioactive material generated by a nuclear reactor, and can be found in equipment that has medical, academic, and industrial applications. For example, a standard type of moisture gauge used by many construction companies contains small amounts of Americium-241 and Cesium-137. According to NRC, it would take 16 curies of Americium-241 to constitute a high-risk category 2 quantity, and 1.6 curies of Americium-241 is considered a category 3 quantity.

Results of Investigation

In October and November 2006, using fictitious names, our investigators created two bogus companies—one in an agreement state and one in a non-agreement state. After the bogus businesses were incorporated, our investigators prepared and submitted applications for a byproduct materials license to both NRC and the department of the environment for the selected agreement state. The applications, mailed in February 2007,

[5]The DOE/NRC Interagency Working Group on Radiological Dispersal Devices, *Radiological Dispersal Devices: An Initial Study to Identify Radioactive Materials of Greatest Concern and Approaches to Their Tracking, Tagging, and Disposition* (Washington, D.C.: 2003).

[6]NRC has endorsed the IAEA *Code of Conduct* and is working toward the implementation of its various provisions. On November 8, 2006, NRC issued a rule to require licensees to report information on the manufacture, transfer, receipt, disassembly, and disposal of all category 1 and 2 sources throughout their entire life cycle in the National Source Tracking System (NSTS). NRC's latest estimate is that the NSTS will be operational in May 2008. NRC told us that it has plans to consider including category 3 sources in the NSTS after the system becomes operational.

were identical except for minor differences resulting from variations in the application forms. Using fictitious identities, one investigator represented himself as the company president in the applications, and another investigator represented himself as the radiation safety officer. The license applications stated that our company intended to purchase machines with sealed radioactive sources.

According to NRC guidance finalized in November 2006 and sent to agreement states in December 2006, both NRC and agreement state license examiners should consider 12 screening criteria to verify that radioactive materials will be used as intended by a new applicant.[7] For example, one criterion suggests that the license examiner perform an Internet search using common search engines to confirm that an applicant company appears to be a legitimate business that would require a specific license. Another screening technique calls for the license examiner to contact a state agency to confirm that the applicant has been registered as a legitimate business entity in that state. If the examiner believes there is no reason to be suspicious, he or she is not required to take the steps suggested in the screening criteria and may indicate "no" or "not applicable" for each criteria. If the license examiner takes additional steps to evaluate a criterion, he or she should indicate what publicly available information was considered. If there is concern for a potential security risk, the guidance instructs license examiners to note the basis for that concern.

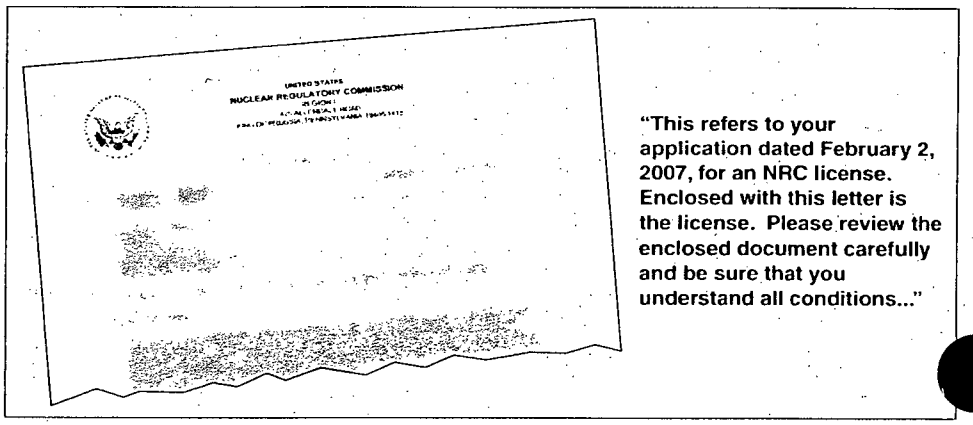
Application to NRC

Nine days after mailing their application form to NRC, our investigators received a call from an NRC license examiner. The NRC license examiner stated that the application was deficient in some areas and explained the necessary corrections. For example, the license examiner asked our investigators to certify that the machines containing sealed radioactive source material, which are typically used at construction sites, would be returned to the company office before being transported to a new construction site. The license examiner explained that this was a standard security precaution. Even though we did not have a company office or a construction site, our investigators nevertheless certified their intent to bring the machines back to their office before sending them to a new location. They made this certification via a letter faxed to NRC. Four days

[7]Nuclear Regulatory Commission, *Checklist to Ensure that Radioactive Materials Will Be Used As Intended*, NUREG-1556, Vol. 20, C (Washington, D.C.: Nov. 2006).

after our final correction to the license application, NRC approved our application and mailed the license to the bogus business in the non-agreement state. It took a total of 4 weeks to obtain the license. See figure 1 for the first page of the transmittal letter we received from NRC with our license.

Figure 1: Excerpt from NRC License Acceptance Letter for Bogus Business



Source: GAO.

The NRC license is printed on standard 8-1/2 x 11 inch paper and contains a color NRC seal for a watermark. It does not appear to have any features that would prevent physical counterfeiting. We therefore concluded that we could alter the license without raising the suspicion of a supplier. We altered the license so that it appeared our bogus company could purchase an unrestricted quantity of sealed source materials rather than the small amounts of Americium-241 and Cesium-137 listed on the original license. We determined the proper language for the license by reviewing publicly available information.

Next, we contacted two U.S. suppliers of the machines specified in our license. We requested price quotes and faxed the altered license to the suppliers as proof that we were certified to purchase the machines. Both suppliers offered to sell us the machines and provided us price quotes. One of these suppliers offered to provide twice as many machines as we requested and offered a discount for volume purchases. In a later telephone call to one of the suppliers, a representative of the supplier told us that his company does not check with NRC to confirm the terms listed on the licenses that potential customers fax them. He said that his company checks to see whether a copy of the front page of the license is faxed with the intent to purchase and whether the requested order

exceeds the maximum allowable quantity a licensee is allowed to possess at any one time.

Although we had no legitimate use for the machines, our investigators received, within days of obtaining a license from NRC, price quotes and terms of payment that would have allowed us to purchase numerous machines containing sealed radioactive source materials. These purchases would have substantially exceeded the limit that NRC approved for our bogus company. If these radioactive materials were unsealed and aggregated together, the machines would yield an amount of Americium-241 that exceeds the threshold for category 3 materials.

As discussed previously, according to IAEA, category 3 sources are dangerous if not safely managed or securely protected and "could cause permanent injury to a person who handled them, or was otherwise in contact with them, for some hours. It could possibly—although it is unlikely—be fatal to be close to this amount of unshielded radioactive material for a period of days to weeks." Importantly, with patience and the proper financial resources, we could have accumulated, from other suppliers, substantially more radioactive source material than what the two suppliers initially agreed to ship to us—potentially enough to reach category 2. According to IAEA, category 2 sources, if not safely managed or securely protected, "could cause permanent injury to a person for a short time (minutes to hours), and it could possibly be fatal to be close to this amount of unshielded material for a period of hours to days."

Application to the Agreement State

Ten days after mailing their application form to the agreement state's department of environment, our investigators received a call from a department license examiner. The license examiner stated that the application was deficient in some areas and said that she would send us a letter outlining what additional information the state required before approving the license. The examiner further stated that before the license was granted, she would conduct a site visit to inspect the company office and storage facilities cited in our application. Our investigators subsequently decided not to pursue the license in this state and requested that their application be withdrawn. According to an official in the department of environment for this state, the license examiner followed the required state procedure in requesting a site visit. The official told us that as a matter of long-standing state policy, license examiners in this state conduct site visits and interview company management (especially radiation safety officers) before granting new licenses for radioactive materials. This state policy is more stringent than the guidance NRC

provided agreement states in December 2006. The NRC guidance identified a site visit as one possible screening criterion to use in evaluating a new license application, but, as discussed above, a site visit is not required under the NRC guidance.

Corrective Action Briefing

On June 1, 2007, we contacted NRC and discussed the results of our work. An NRC official indicated that NRC would take immediate action to address the weaknesses we identified. After this meeting, we learned that NRC suspended its licensing program for specific licenses until it could determine what corrective actions were necessary to resolve the weaknesses. NRC also held a teleconference with a majority of the 34 agreement states to discuss our work. On June 12, 2007, NRC issued supplemental interim guidance with additional screening criteria. These criteria are intended to help a license examiner determine whether a site visit or face-to-face meeting with new license applicants is required. NRC told us that it planned to convene a working group to develop improved guidance addressing the weaknesses we identified.

Conclusions and Recommendations for Executive Action

NRC's goal is to provide licenses to only those entities that can demonstrate that they have legitimate uses for radioactive materials. However, our work shows that there continues to be weaknesses in the process NRC uses to approve license applications. In our view, a routine visit by NRC staff to the site of our bogus business would have been enough to reveal our lack of facilities and equipment. Furthermore, if NRC license examiners had conducted even a minimal amount of screening—such as performing common Web searches or making telephone calls to local government or business offices—they would have developed serious doubts about our application. Once we received our license, the ease with which we were able to alter the license and obtain price quotes and commitments to ship from suppliers of radioactive materials is also cause for concern. Accordingly, we are making the following three recommendations to the Chairman of the NRC:

- First, to avoid inadvertently allowing a malevolent individual or group to obtain a license for radioactive materials, NRC should develop improved guidance for examining NRC license applications. In developing improved screening criteria, NRC should consider whether site visits to new licensees should be mandatory. These improved screening criteria will allow NRC to provide reasonable assurance that licenses for radioactive materials will only be issued to those with legitimate uses.

- Second, NRC should conduct periodic oversight of license application examiners so that NRC will be assured that any new guidance is being appropriately applied.

- Third, NRC should explore options to prevent individuals from counterfeiting NRC licenses, especially if this allows the purchase of more radioactive materials than they are approved for under the terms of the original license.

Mr. Chairman, this concludes our statement. We would be pleased to answer any questions that you or other Members of the Subcommittee may have at this time.

Contacts and Acknowledgments

For further information about this testimony, please contact Gregory D. Kutz at (202) 512-7455 or kutzg@gao.gov or Gene Aloise at (202) 512-3841 or aloisee@gao.gov. Contacts points for our Offices of Congressional Relations and Public Affairs may be found on the last page of this testimony.

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UNITED STATES
NUCLEAR REGULATORY COMMISSION
OFFICE OF FEDERAL AND STATE MATERIALS
AND ENVIRONMENTAL MANAGEMENT PROGRAMS
OFFICE OF NUCLEAR MATERIAL SAFETY AND SAFEGUARDS
WASHINGTON, DC 20555-0001

August 31, 2007

NRC REGULATORY ISSUE SUMMARY 2007-13 VERIFICATION OF THE AUTHENTICITY OF MATERIALS POSSESSION LICENSES

ADDRESSEES

All U.S. Nuclear Regulatory Commission (NRC) materials licensees. All Agreement State Radiation Control Program Directors and State Liaison Officers.

INTENT

NRC is issuing this regulatory issue summary (RIS) to emphasize the importance of licensees maintaining situational awareness before and during all transfers of radioactive material. This RIS requires no action, or written response.

BACKGROUND

In July 2006, the NRC issued Information Notice (IN) 2006-12. This IN informed addressees that since September 11, 2001, NRC has taken aggressive measures to secure and control radioactive materials because of the risk associated with their potential use in malevolent activities. The purpose of the IN was to reiterate the requirements that a licensee seeking to transfer licensed material must verify that the transferees' license authorizes the receipt of the type, form, and quantity of material to be transferred, pursuant to 10 CFR 30.41(c), 40.51(c), and 70.42(c). The IN provided examples of encounters when transferors of the material should take extra care.

In May 2007, the U.S. Government Accountability Office (GAO) Forensic Audits and Special Investigations team fraudulently obtained a license from the NRC authorizing the use of six portable moisture density gauges. Using commercially available software, GAO altered the license to increase the maximum possession limits and obtain quotes for the purchase of a total of 45 portable moisture density gauges from two companies. GAO concluded that individuals seeking to use the material for malevolent activities could have completed the purchases and obtained the gauges.

ML072390092

SUMMARY OF ISSUE

As a result of the GAO activities, NRC staff promptly issued internal guidance that requires either on-site inspections or in-office meetings for many new materials license applicants.

Since the GAO notified the NRC about obtaining a license through fraud, the NRC has continued to pursue both short-term and long-term actions to address potential materials security vulnerabilities. These efforts include an action plan which will review licensing guidance as well as programs designed to track radioactive material and research ways to make it more difficult to counterfeit NRC licenses. The NRC has also formed a working group that will develop and issue revised guidance to address pre-licensing reviews and site visits. Rulemaking to codify these actions is also being pursued. The NRC believes that a more robust licensing process will minimize the potential for individuals to acquire radioactive material to conduct malevolent activities.

While the NRC works to close potential security vulnerabilities in its materials licensing process, materials licensees transferring material are asked to, in addition to the requirements in 10 CFR 30.41(c), 40.51(c), and 70.42(c), practice increased vigilance to ensure that radioactive material is not used for malevolent purposes.

As stated in IN 2006-12, when transferring licensed material, licensees should be vigilant, especially when a long period of time has transpired since the last transfer of material. IN 2006-12 also encourages licensees to remain vigilant any time there is a change in procedure or routine that may raise reasonable suspicion about the legitimacy of the order or the transferee's identity. The licensee should look for changes in routine (i.e. an established pattern of conduct) such as: 1) a significant increase in the quantity of material ordered; 2) a change in location where the material is to be delivered; 3) a change in type or form of material; or 4) a change in key personnel, without prior notice. If these changes are unexplained in the transfer request or purchase order, or if the request or order is on letterhead which is different from previous orders, or does not match the identity of the transferee, care should be exercised to verify the legitimacy of the licensee. Any of these changes could be (and generally are) legitimate, but they could also be precursors to the diversion of materials for other than their authorized use. In the event that a licensee transferring material has questions about the authenticity of the transferee, the licensee should pursue further information to alleviate the concern.

Licensees should contact the NRC or licensing agency of an Agreement State with any concerns regarding the legitimacy of any licenses or any suspicious requests. Particular attention should be given to new customers.

***FEDERAL REGISTER* NOTIFICATION**

A notice of opportunity for public comment on this RIS was not published in the *Federal Register* because this RIS is informational and does not represent a departure from current regulatory requirements.

CONGRESSIONAL REVIEW ACT

This (RIS, IN, etc.) is not a rule as designated by the Congressional Review Act (5 U.S.C. §§ 801-886) and, therefore, is not subject to the Act.

PAPERWORK REDUCTION ACT STATEMENT

This RIS does not contain any information collections and, therefore, is not subject to the requirements of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 et seq.).

The information collections contained in the Regulatory Issue Summary are covered by the requirements of 10 CFR Parts 30, 40, and 70, which were approved by the Office of Management and Budget, approval numbers 3150-0017, 3150-0020, and 3150-0009.

Public Protection Notification

The NRC may not conduct or sponsor, and a person is not required to respond to, a request for information of an information collection requirement unless the requesting document displays a currently valid OMB control number.

CONTACT

This RIS requires no specific action nor written response. If you have any questions about this summary, please contact (one of) the individual(s) listed below or the appropriate regional office.

//RA//

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Office of Federal and State Materials and Environmental Management Programs

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Enclosure: List of Recently Issued
FSME/NMSS Generic Communications

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Enclosure: List of Recently Issued
FSME/NMSS Generic Communications

DISTRIBUTION:
DMSSA r/f FSME r/f

ML072390092 (Single) **ML072390169 (Package)**

OFC	DMSSA/SSSB	DMSSA/SSSB	DMSSA/SSSB	DMSSA/SAIS	DMSSA/MSEA
NAME	CEinberg::tyh	THererra	THarris	ADWhite	AMcIntosh
DATE	8/30/07	8/30 /07	8/30 /07	8/30 /07	8/31/07

OFC	NMSS/HLW	NMSS/FCSS	NMSS/SFST	FSME/DWMEP	NSIR
NAME	WFord	RPierson	EWBach	LCamper	MShaffer
DATE	08/27/07	08/30/07	08/30/07	08/27/07	8/31/07

OFC	OIS	OGC-CRA	OGC	Org. Agrmt States	FSME/DMSSA
NAME	TDonnell	TRothschild	FCameron	CCardwell	JRSchlueter
DATE	8/31/07	8/31/07	8/31/07	9 /06/07	8/31/07

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Recently Issued FSME/NMSS Generic Communications

Date	GC No.	Subject	Addressees
02/02/07	IN-07-03	Reportable Medical Events Involving Patients Receiving Dosages of Sodium Iodide Iodine-131 less than the Prescribed Dosage Because of Capsules Remaining in Vials after Administration	All U.S. Nuclear Regulatory Commission medical use licensees and NRC Master Materials Licensees. All Agreement State Radiation Control Program Directors and State Liaison Officers.
02/28/07	IN-07-08	Potential Vulnerabilities of Time-reliant Computer-based Systems Due to Change in Daylight Saving Time Dates	All U. S. Nuclear Regulatory Commission licensees and all Agreement State Radiation Control Program Directors and State Liaison Officers.
03/13/07	IN-07-10	Yttrium-90 Theraspheres® and Sirspheres® Impurities	All U.S. Nuclear Regulatory Commission (NRC) Medical Licensees and NRC Master Materials Licensees. All Agreement State Radiation Control Program Directors and State Liaison Officers.
04/04/07	IN-07-13	Use of As-Found Conditions to Evaluate Criticality-related Process Upsets at Fuel Cycle Facilities	All licensees authorized to possess a critical mass of special nuclear material.
05/02/07	IN-07-16	Common Violations of the Increased Controls Requirements and Related Guidance Documents	All licensees who are implementing the U.S. Nuclear Regulatory Commission (NRC) Order Imposing Increased Controls (EA-05-090), issued November 14, 2005 and December 22, 2005.
05/21/07	IN-07-19	Fire Protection Equipment Recalls and Counterfeit Notices	All holders of operating licenses for nuclear power reactors and fuel cycle facilities; except those licensees for reactors that have permanently ceased operations and who have certified that fuel has been permanently removed from the reactor vessel; and except those licensees for decommissioned fuel cycle facilities.
06/11/07	IN-07-20	Use of Blank Ammunition	All power reactors, Category I fuel cycle facilities, independent spent fuel storage installations, conversion facility, and gaseous diffusion plants.

Date	GC-No.	Subject	Addressees
	IN-07-23	Inadvertent Discharge of Halon 1301Fire-suppression System from Incorrect and/or Out-of-date Procedures	All holders of operating licenses for nuclear power reactors, except those who have permanently ended operations and have certified that fuel has been permanently removed from the reactor vessel. All holders of licenses for fuel cycle facilities.
07/19/07	IN-07-25	Suggestions from the Advisory Committee on the Medical Use of Isotopes For Consideration to Improve Compliance With Sodium Iodide I-131 Written Directive Requirements in 10 CFR 35.40 and Supervision Requirements in 10 CFR 35.27	All U.S. Nuclear Regulatory Commission (NRC) medical-use licensees and NRC Master Materials Licensees. All Agreement State Radiation Control Program Directors and State Liaison Officers.
08/13/07	IN-07-26	Combustibility of Epoxy Floor Coatings at Commercial Nuclear Power Plants	All holders of operating licenses for nuclear power reactors and fuel cycle facilities except licensees for reactors that have permanently ceased operations and who have certified that fuel has been permanently removed from the reactor vessel.
03/01/07	RIS-07-03	Ionizing Radiation Warning Symbol	All U.S. Nuclear Regulatory Commission licensees and certificate holders. All Radiation Control Program Directors and State Liaison Officers
03/09/07	RIS-07-04	Personally Identifiable Information Submitted to the U.S. Nuclear Regulatory Commission	All holders of operating licenses for nuclear power reactors and holders of and applicants for certificates for reactor designs. All licensees, certificate holders, applicants, and other entities subject to regulation by the U.S. Nuclear Regulatory Commission (NRC) of the use of source, byproduct, and special nuclear material
03/20/07	RIS-07-05	Status and Plans for Implementation of NRC Regulatory Authority for Certain Naturally-occurring and Accelerator-produced Radioactive Material	All NRC materials licensees, Radiation Control Program Directors, State Liaison Officers, and NRC's Advisory Committee on the Medical Uses of Isotopes
04/05/07	RIS-07-07	Clarification of Increased Controls for Licensees That Possess Collocated Radioactive Material During Transportation Activities	All U.S. Nuclear Regulatory Commission (NRC) licensees issued NRC's Order Imposing Increased Controls and all Radiation Control Program Directors and State Liaison Officers

Date	GC No.	Subject	Addressees
05/04/07	RIS-07-09	Examples of Recurring Requests for Additional Information (RAIs) for 10 CFR Part 71 and 72 Applications	All holders of, and applicants for, a: (1) 10 CFR Part 71 certificate of compliance (CoC) for a radioactive material transportation package; (2) 10 CFR Part 72 CoC for a spent fuel storage cask; and (3) 10 CFR Part 72 specific license for an independent spent fuel storage installation (ISFSI).
06/27/07	RIS-06-27, Suppl. 1	Availability of NRC 313A Series of Forms and Guidance for Their Completion	All U.S. Nuclear Regulatory Commission (NRC) medical-use licensees and NRC Master Materials licensees. All Radiation Control Program Directors and State Liaison Officers.
05/15/07	RIS-07-10	Subscriptions To New List Server For Automatic Notifications Of Medical-Related Generic Communications, *Federal Register* Notices And Newsletters	All U.S. Nuclear Regulatory Commission (NRC) medical-use licensees and NRC Master Materials licensees. All Radiation Control Program Directors and State Liaison Officers.

Note: A full listing of generic communications may be viewed at the NRC public website at the following address: http://www.nrc.gov/Electronic Reading Room/Document Collections/Generic Communications.

Should the Authorized User be required to sign all orders for byproduct material?

James S. Welsh, MS, MD

Background

- Currently there is no NRC guidance regarding the ordering of byproduct material
- Radioisotope uses under 10 CFR 35 Subparts E, F and H require review, approval and signature of the AU before administration to the patient

Background

- Presently some institutions will have all orders for byproduct material signed by the AU
  - provides proof that this individual is aware that a shipment of radioactive material for medical use for which he/she is responsible will be arriving at the institution
- Other institutions do not have the AU acknowledge that such a shipment has been ordered
  - In principle this could lead to problems

10 CFR 35.27

- 10 CFR 35.27 Supervision
  - Allows delegation of tasks (e.g. ordering radioisotope from vendors) to non-AU's
  - Such individuals must be properly instructed and supervised
  - AU is presumed to be the one best suited to determine what tasks the delegate is capable of performing and what the level of supervision is appropriate

10 CFR 35.27 Supervision

- For balance between NRC responsibility to assure public health/safety and licensee's responsibility for the safe use of byproduct material, 35.27 intentionally excludes
  - prescriptive requirements
  - listing of tasks that can be delegated

Potential problems

- In principle this could lead to shipment of radioactive material without expressed knowledge of the AU
- Unlikely to happen in single department clinical applications (e.g. Rad Onc or Nuc Med radiopharmaceutical treatment)
  - but <u>might</u> be possible in the increasing number of interdisciplinary applications (eg Microsphere therapy involving IR, Nuc Med, Rad Onc; Prostate brachytherapy involving Urology and Rad Onc; Radioimmunotherapy involving Med Onc and Rad Onc or Nuc Med; etc)

Simple Solution

- In a post 9-11 era, where there is appropriately heightened concern about any shipments of byproduct material…
- All orders for byproduct material **should** have the signature of the Authorized User
- Whether this be a ***must*** is open for discussion

Status of Activities for NARM

Presentation for ACMUI
October 22, 2007

Duane White
Division of Materials Safety and State Agreements
Office of Federal and State Materials and
Environmental Management Programs (FSME)

Purpose

- To provide an update on NRC's efforts to implement the requirements of Section 651 (e) of the Energy Policy Act of 2005 (EPAct) for certain naturally-occurring and accelerator-produced radioactive material (NARM).
- Topics of discussion will include:
  - NRC's final regulations
  - Associated guidance in support of the regulations
  - The transition plan to facilitate an orderly transition of regulatory authority

Status of Final NARM Regulations

- The final regulations were published on October 1, 2007, and will become effective on November 30, 2007.
- The final regulations are responsive to stakeholder comments and incorporate model state standards.

Status of NARM Guidance

- NUREG-1556, Vol. 21, "Program-Specific Guidance About Possession Licenses for Production of Radioactive Material Using an Accelerator" is being finalized.
- NRC is also currently finalizing the revisions to NUREG-1556, Vol. 9, "Program-Specific Guidance About Medical Use Licenses" and Vol. 13, "Program-Specific Guidance About Commercial Radiopharmacy Licenses."
- A thirty day public comment period was provided for each of these NUREGs.
- Minor revisions to other guidance documents and inspection procedures are also planned.

Waiver / Transition Plan

Waiver

- On August 31, 2005, the Commission issued a waiver to allow States and individuals to continue their activities involving NARM. The Commission plans to terminate the waiver in phases.
- Once the waiver is terminated, all persons that possess the new byproduct materials in NRC jurisdiction must be in compliance with NRC regulations, and will need to apply for a license amendment within 6 months, or apply for a new license within 12 months.

Transition Plan

- Transition plan addresses the different transition scenarios and was coordinated with the States.
- Will be published without substantive change in between the time that the final regulations are published and become effective (i.e., 60-day window).

Transition Plan – Agreement States

- The NRC has received governor certifications from all 34 Agreement States, which document that their State has a program for licensing the new byproduct material that is adequate to protect public health and safety and that they intend to continue to regulate these materials.
  - Alabama, Arizona, Arkansas, California, Colorado, Florida, Georgia, Iowa, Illinois, Kansas, Kentucky, Louisiana, Maryland, Massachusetts, Maine, Minnesota, Mississippi, Nebraska, New Hampshire, New Mexico, Nevada, New York, North Carolina, North Dakota, Ohio, Oklahoma, Oregon, Rhode Island, South Carolina, Tennessee, Texas, Utah, Washington, and Wisconsin.
- The NRC Chairman will sign the responses to the Governors in conjunction with the effective date of the rulemaking and the waivers will be terminated.

Transition Plan – Non-Agreement States, Federal Agencies, and Tribes

- On the effective date of the rule, the Commission intends to terminate the waiver for Federal Government agencies, Federally Recognized Indian Tribes, Delaware, District of Columbia, Puerto Rico, U.S. Virgin Islands, Indiana, Wyoming, and Montana.
- The NRC plans to terminate the waiver for the remainder of Non-Agreement States in phases.
  - The 2nd phase is expected to occur in Summer-Fall 2008.
  - The 3rd phase is expected to occur in Spring-Summer 2009.
- States that become Agreement States by August 2009 will have their waiver terminated coincident with the effective date of their Agreement.

Transition Plan - Miscellaneous

- NRC will assume authority for NARM exempt distribution licenses upon waiver termination.
- NRC will assume authority for all SS&D evaluations and registrations for NARM in Agreement States without SS&D authority and Non-Agreement States upon waiver termination.

Communication

- A follow-up RIS (RIS 2007-22) of the 3/20/2007 RIS (RIS 2007-05) will be issued, which will provide a current update on the NARM related activities.
- Federal Register Notices will be published to indicate publication of the transition plan and proceeding waiver terminations.
- For additional information on NARM related activities you may access the "NARM Toolbox" at:

  http://nrc-stp.ornl.gov/narmtoolbox.html

Elekta Perfexion®

ACMUI Meeting

October 22, 2007

Donna-Beth Howe, Ph.D.

Perfexion® 35.1000 USE

Leksell Gamma Knife® Perfexion™ gamma stereotactic radiosurgery unit

Meets some of the gamma stereotactic radiosurgery specific regulations in 10 CFR Subpart H

291 cobalt sources with approximately 34 curies of activity per source

Substantially redesigned and re-engineered

no longer has components required for test in Subpart H

Perfexion® 35.1000 USE

Major Features

- formerly manual movements and settings are computer driven
- the sources are not stationary
- no collimator helmets
- patient bed movement is positioning device to put the treatment site in the radiation focal point

Perfexion® 35.1000 USE

Written directive

- **calculation of the dose to the treatment site is dependent on the shaping of the radiation field at the focal point by selection of different collimators for each of the 8 sectors.**
- **The positions of the sectors is needed to assure the dose is delivered in accordance with the AU's direction and is needed in the written directive.**
- **Commit to include the sector positions in addition to the target coordinate settings f each shot in written directive:**

Perfexion® 35.1000 USE

Spot-checks and full calibration.

- **The Perfexion™ unit does not have helmets, relative helmet factors, helmet microswitches, hydraulic backups, trunnions, trunnion centricity,**
- **The requirements in 10 CFR 35.635 and 35.645 to determine these values or test these components cannot be performed and the results of such determinations and tests cannot be recorded as described in 10 CFR 35.2632 or 35.2645.**

Perfexion® 35.1000 USE

The purpose of the test

assess whether the patient docking systems functioned correctly

to place the mechanical center of the stereotactic frame (x= 100 mm, y= 100 mm, z= 100 mm) at the radiation focal point,

know the size of the radiation focal point by confirming the collimator sizes, and

test the precision with which the treatment site could be placed at the radiation focal point and the accuracy of the dose calculations.

Perfexion® 35.1000 USE

Training and experience

- **Authorized User (AU)**
- **Authorized Medical Physicist**
- **Radiation Safety Officer**

Two Categories of individuals

- experienced gamma stereotactic radiosurgery unit
- not authorized for gamma stereotactic radiosurgery unit

Perfexion® 35.1000 USE

Each Individual:

- listed as authorized individual for gamma stereotactic radiosurgery unit; or
- is board certified by a board listed on NRC's web site under 10 CFR 35.50, 35.51, or 35.690," or
- meets the training and supervised work experience criteria in alternate pathway; and

Perfexion® 35.1000 USE

All Individuals

Training in topics listed in 35.50(e), 35.51(c), or 35.690(c) for the Perfexion™ unit.

For experienced individuals it must include the differences for each of the topics in 35.50(e), 35.51(c), or 35.690(c) between the Perfexion™ and other gamma stereotactic radiosurgery units the individual was authorized to use or had responsibility for.

- device operation, safety procedures, and clinical use
- device operation, safety procedures, clinical use, and the operation of a treatment planning system
- radiation safety, regulatory issues, and emergency procedures

Perfexion® 35.1000 USE

Written attestation for new individuals

- **before July 1, 2009 satisfactorily completion of training [and for RSO completed or committed to complete the supplemental hands on training]**
- **on or after July 1, 2009, a written attestation, signed by a preceptor (RSO, AMP, or AU) authorized for the Perfexion™, that the individual has satisfactorily completed the above training and has achieved a level of competency or radiation safety knowledge sufficient to function independently as a authorized individual for the Perfexion™ unit.**

Perfexion® 35.1000 USE

Spot-check and full calibration

Commit to follow the full calibration requirements of 10 CFR 35.635 and the spot-check requirements in 35.645 except for those involving helmets, helmet factors, helmet microswitches, trunnions, hydraulic backup of the treatment table retraction system, or source exposure indicator lights on the unit

Commit to perform test on location of the radiation focal point with respect to table position, location and/or function of the sectors, the patient bed, the docking device, the frame adaptor, and source exposure indicator light on the wall of the treatment room.

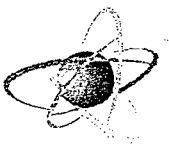
Perfexion® 35.1000 USE

Additional Items being considered:

Exposure indicator light location

Emergency timer circuits

Clarity for written procedures for the issue of pausing treatment and checking the patient set-up if a patient is observed to move during the course of a treatment shot



Potential Changes to 10 CFR Part 35

ACMUI Meeting

October 22, 2007

Donna-Beth Howe, Ph.D.

10 CFR 35.57(a)

Problem: An experienced Radiation Safety Officer, or a teletherapy or a medical physicist, or a nuclear pharmacist that is listed on license or permit before certain dates is grandfathered and 35.57(a) specifically states the individual "need not comply with the training requirements of 35.50, 35.51, or 35.55, respectively."

The effect of is that when an RSO or AMP listed on a license moves to a new license with different medical uses or the current licensee adds new medical uses that they will be responsible for, they are not required to have the additional training or a preceptor statement that they can function independently as an RSO or AMP for that use.

During review of a license amendment to add HDR authorization to an existing license, the reviewer noted that the licensee requested that the individual currently named as the RSO remain authorized as the RSO on the license once the amendment is issued. Specifically, since the RSO was named as the RSO on an NRC, non-HDR, medical license between October 24, 2002, and April 29, 2005, the RSO met the "grandfathering provisions" and pursuant to 10 CFR 35.57(a)(2) it appears the RSO does not need to met the any of the current requirements in 10 CFR 35.50 including the training requirements in 10 CFR 35.50(e) for the new type of use, i.e., HRD use..

Item 7 of the Checklist on page C-7 of Appendix C to NUREG-1556, Vol. 9, Rev. 1, included a more conservative provision for grand fathered RSOs. Specifically, the guidance states that, for an individual previously identified as an RSO on an NRC license, the applicant must provide the previous license number or a copy of the license that authorized the uses requested and on which the individual was named as the RSO.

The question was whether 10 CFR 35.57(a)(2) allows an individual who was named as an RSO on an NRC license which did not authorize a certain use (in this case, HDR) between October 24, 2002, and April 29, 2005, to be named as RSO on the licensee's amended license, which will authorize such use (in this case the use of HDR), without requiring him to comply with the training requirements in 10 CFR 35.50(e)?

A close review of the regulations indicates that an individual who was named as an RSO on a Commission license which did not authorize a certain use (in this case, HDR) between October 24, 2002, and April 29, 2005, can be named as RSO on the amended license authorizing such use (in this case, the use of HDR), without requiring that individual to comply with the training requirements in 10 CFR 35.50. If the guidance in NUREG Volume 9 Revision 1 conflicts with this the guidance is in error. The regulatory history of the regulations appear to support the approach in the guidance. Rulemaking would be needed to have the requirements align with the staffs guidance in NUREG 1556, Vol. 9, Appendix C, if the staff believes that that when a licensee amends its license to add a new use, the RSO should be required to meet the T&E requirements in 10 CFR 35.50(e).

Staff agreed to add this to the "user need memo." The proposal will be to revise 10 CFR 35.57 to only grandfather RSOs for uses listed on the license. The proposal will include a requirement that the RSOs be required to obtain additional training under 35.50(e) for uses for which he or she was not previously authorized (either for same license or another license). However, the proposal will not require a preceptor statement.

10 CFR 35.57(a) cont.

Recommend revising 10 CFR 35.57(a) to read:

(1) An individual identified as a Radiation Safety Officer, a teletherapy or medical physicist, or a nuclear pharmacist on a Commission or Agreement State license or a permit issued by a Commission or Agreement State broad scope licensee or master material license permit or by a master material license permittee of broad scope when using or responsible for the same materials and uses before October 24, 2002, need not comply with the training requirements of 35.50, 35.51, or 35.55, respectively.

(2) An individual identified as a Radiation Safety Officer, an authorized medical physicist, or an authorized nuclear pharmacist on a Commission or Agreement State license or a permit issued by a Commission or Agreement State broad scope licensee or master material license permit or by a master material license permittee of broad scope when using or responsible for the same materials and uses between October 24, 2002 and April 29, 2005 need not comply with the training requirements of 35.50, 35.51, or 35.55, respectively.

10 CFR 35.57(a) cont.

Problem: If the previous revision is made, the staff's intent is that the attestation for the new training not be required for the experienced RSO.

Recommend adding the following to 35.57(a):

An experienced RSO responsible for a new medical use will be required to successfully complete the training in 10 CFR 35.50(e) but not required to meet the other requirements in 10 CFR 35.50(d) for the new medical us[redacted]

10 CFR 35.75

Problem: Patients are permitted to be released if the total effective dose equivalent to any other individual from exposure to the released individual is not likely to exceed 5 mSv (0.5 rem). In reviewing the statements of consideration it is clear that the intent was that NRC did not expect a patient to receive more than one treatment in a year from the licensee and that the release criteria was 5 mSv (0.5 rem) for the year or 5 mSv/year (0.5 rem/year).

A state informed us that one of its licensees is using a new treatment in which a patient with a brain tumor is given a series of Iodine-131 administrations after removal of the tumor in a series of about six closely-spaced treatments. The licensee estimated that the resulting dose to a member of the public would be about 250 millirem (mrem) per release. The question is whether the patient release criteria in 10 CFR 35.75 would apply to each of the six treatments separately, in which case the total dose to a member of the public would be about 1.5 rem, or whether the criteria applies to an annual dose limit.

A discrepancy was identified between the intent and the current rule language. The intent was 500 mrem/year. But licensees are interpreting it as 500 mrem/release. The current rule as written is flawed and ambiguous and needs a revision to clarify that patient release is based on a limit of 500 mrem/year. We have a sound basis for the rule change because it is clear in the Supplementary information that the intent was based on an erroneous assumption (i.e., the 500 mrem/yr limit was based on the assumption that a patient would not be released more than once in a year). An article will be published in an upcoming newsletter to correct the previous article published in the December, 2006 newsletter. A RIS on this topic will also be published. These communications will inform the stakeholders that NRC plans to change Part 35.75 to reflect that the dose to the members of the public exposed to radiation emitted by patients who have been administered unsealed byproduct material or implants containing byproduct material shall not exceed 5 mSv per year.

10 CFR 35.75 cont.

Recommend revision of 10 CFR 35.75(a) to read:

(a) A licensee may authorize the release from its control of any individual who has been administered unsealed byproduct material or implants containing byproduct material if the total effective dose equivalent to any other individual from exposure to the released individual is not likely to exceed 5 mSv per year (0.5 rem per year).

10 CFR 35.491

Problem: The training and experience requirements in 35.491 were developed based on the use of an strontium-90 ophthalmic eye applicator for treatments of superficial eye conditions. This particular technology had been used for decades. Recently a new strontium-90 ophthalmic intra-ocular device was developed that is inserted into the eye. Its structure and treatment site uses differ significantly from that of the older device. Training in the use of the old device is not applicable for the safe use of the new device.

Options:

1. Put into 35.1000 and develop web based guidance that can be easily revised as experience is gained with the device, or
2. Revise 35.491 to address training of the 2 types of ophthalmic devices.

10 CFR 35.491 cont.

Recommend 35.491(b)(2) be revised to read:

(b)(2) Supervised clinical training in superficial ophthalmic radiotherapy under the supervision of an authorizeduser at a medical institution, clinic, or private practice that includes the use of strontium-90 for the superficial 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 history; or**

10 CFR 35.491 cont.

(b)(3) Supervised clinical training in intraocular ophthalmic radiotherapy deviceunder the supervision of an authorized user at a medical institution, clinic, or private practice that includes the use of strontium-90 for the internal eye 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; and

(3) Has obtained written attestation, signed by a preceptor authorized user that the individual has satisfactorily completed the requirements in paragraphs (a), or (b)(1)and (2), or (b)(1)and (3) of this section and has achieved a level of competency sufficient to function independently as an authorized user for the type of strontium-90 for ophthalmic use requested. The preceptor authorized user must be authorized for the same type of ophthalmic use as the individual requesting authorized user status.

10 CFR 35.400, 35.500, and 35.600

Problem 10 CFR 35.400, 35.500, and 35.600 require licensees to only use the sealed sources and devices in these sections as approved in the Sealed Source and Device Registry.

Some of the SSDR certificates include specific medical procedures or treatment of specific diseases or treatment areas listed by the manufacturer. If "only as approved in the SSDR" means only for the treatments described in the SSDR, other accepted uses under the practice of medicine would be either research or not permitted by the regulations.

The Regions mentioned the new Perfexion applications indicate the device will be used for treatments (e.g. neck tumors and other areas of the head) other than what it is approved for in the 510(k) submission or included in the SSDR. Specifically treatment of the Trigeminal Neuralgia was not included as an intended use for the new Perfexion in the 510(k) and the SSDR states it is used for abnormalities in the cranium but the license application indicates it can be used for treatment of the neck tumors.

Staff contacted FDA concerning uses of the device for treatments not included in the 510(k). FDA confirmed that treatment of trigeminal neuralgia and neck treatment are in fact off-label use. The reason why trigeminal neuralgia is an off-label use, rather than falling under "head structure ranging from very small target sizes of a few millimeters to several centimeters" is because Elekta had specifically requested trigeminal neuralgia as an intended use but FDA denied it based on lack of supported studies. FDA pointed out that it is not illegal to use a device for something other than what it is approved for in the "intended use" of the 510K. Also use a device for something other than what it is approved for in the 510(k), does not make it investigational. and was informed FDA does not have regulatory oversight for off-label use once it is approved because they do not get involved in the medical practice. FDA only intervenes if a company's standard language in advertising is for something other than what it is approved. Trigeminal Neuralgia was not included in the 510(k) as intended use for the new Perfexion. The Regions were concerned about the off-label use and wanted to ask the ACMUI's opinion about off-label use of the Perfexion.

10 CFR 35.400, 35.500, and 35.600 require licensees to use sources and devices "As approved in the Sealed Source and Device Registry." In this case the use in the SSDR did not include the neck region. Staff indicated this was a problem with the requirements and had been recognized as a potential problem for a while.

The topic of revising 35.400, 35.500, and 35.600 to allow more flexibility in use of the device for treatments other than listed in the SSDR as a potential Part 35 change was presented at the last ACMUI meeting. Because the ACMUI was behind schedule, this topic was tabled until the October meeting. With regards to whether a regulatory change is needed, the Regions stated that the "Principle Use" for many but not all of the SSDRs may be written to be general enough that this may be a non-issue. Uses not in SSDR will be discussed at the October 2007 ACMUI meeting.

10 CFR 35.400, 35.500, and 35.600

Revise 35.400, 35.500, 35.600 to exclude the specific medical indications for use provided by the manufacturer while retaining the type of medical use (35.400, 35.500, 35.600,), the physical conditions for use, or other important factors.

10 CFR 35.290

Problem: Not all facilities providing generator elution supervised work experience training to physicians have generators available or prepare kits.

The effect is that these facilities usually make arrangements with a nuclear pharmacy to obtain this hands-on training from an ANP. Although the supervising AU can make an arrangement for the ANP to provide the training under the AU's supervision, it would be simpler if the ANP providing the training could be recognized as the supervising individual.

35.290 users typically don't have generators available and do not do any kit prep. Several applicants send the physician to a nuclear pharmacy to obtain this hands-on training from an ANP. The T&E for an ANP (35.55)(b) doesn't specify any experience with generators, and the regulations in 35.290(c)(1)(ii) require the work experience to be obtained under the supervision of an AU that meets the T&E requirements in 35.290 or 35.290(c)(1)(ii) and 35.390 . A consultant request a response on this issue of whether the ANP can supervise the generator elution and kit preparation work experience.

T&E for an ANP (35.55)(b) requires supervised work experience preparing dosages which is primarily eluting Mo-99/Tc-99m generator and preparing kits. These are the primary activities of an ANP that prepares Tc-99m radioactive drugs. Currently the ANP cannot be recognized as the supervising individual. The AU at the medical facility is the supervising individual but may delegate the task to the ANP.

Since few physicians elute generators and prepare kits, it is appropriate for this part of the physician's training and work experience to be provided and supervised by an ANP.

10 CFR 35.290

Recommend revising 35.290 to read:

(b)(ii) Work experience, under the supervision of an authorized user, who meets the requirements in 35.290, or 35.290(c)(1)(ii)(G), and 35.390, or equivalent Agreement State requirements, involving–

...

(G) Eluting generator systems appropriate for preparation of radioactive drugs for imaging and localization studies, measuring and testing the eluate for radionuclidic purity, and processing the eluate with reagent kits to prepare labeled radioactive drugs (the work experience for the tasks in this paragraph may be under the supervision of an ANP) ;

NMED Overview

ACMUI Presentation
October 23, 2007
Michele Burgess, NRC

Purpose

- To overview the National NMED website
- To show how NMED can be a useful tool

Overall NMED System

- Starts with licensees (immediate and 30 day reports, and updates) and inspectors (followups and updates, inspections)
- Event reports and inspection information is collected
- Data is supplied to the NMED (via Op Center or INL)
- National data available on website- https://nmed.inl.gov (no "www")

NMED National Website

- Allows access to national data from all States for a national perspective on events
- Use as a technical tool to gather data to:
  - evaluate generic issues (e.g., product failures)
  - look for trends (including confirming that there are no changes to practice

NMED National Website (cont.)

- Quarterly Reports posted each calendar quarter to provide overviews of national data
- Newsletters posted each calendar quarter providing information and updates to NMED users
- *Online Tutorial available under the Help section* at the top of the screen (use the one marked "Online Training for All Other Users")

NMED National Website (cont.)

- Live online demonstration

Other Important Items

- Remember that some events are reportable on a longer timeframe, such as 30 days. In addition, Agreement States also need time to collect the information from their licensees and get it to NMED. Therefore, more accurate trending and conclusions can be gained by using a longer the timeframe for input – i.e., the farther back you go, the more complete data you have to base decisions or analysis on.
- Remember that search results are a tool for analysis, not conclusions. Different search criteria will (and should) result in different search results. Remember to consider the search criteria and implications of differ search criteria sets when making conclusions.

Other Important Items (cont.)

- Key fields to consider in crafting your searches:
  - Reportability
  - NRC only, Agreement only, or both
  - Date range, and which date type you really want
- **Questions??**

Wrap-up

- We hope you find the new website
  - easy to use
  - flexible enough to meet ACMUI needs
  - powerful enough for the more complex searches you need
- Please always feel free to contact us for:
  - assistance in using the website
  - checking numbers for important searches
  - suggestions for improvement

Contacts

- Reporting requirements, policy, and access:
  - ACMUI Coordinator Ashley Tull (NRC) 301-415-5294 or 918-488-0552
- Use of NMED website:
  - Tom Smith (INL) 208-526-6904
  - Robert Sant (INL) 208-526-6134
  - Dante Huntsman (INL) 208-526-0497
  - Michele Burgess (NRC) 301-415-5868

Status of Medical Events & Other Reported Events

ACMUI Meeting
October 23, 2007

Donna-Beth Howe, Ph.D.
Office of Federal and State Materials
Division of Materials Safety and State Agreements

Diagnostic Medical Events

35.200 1

Misdrawn and Mislabeled dose from the pharmacy

Technologists only read the number, not the units when using the dose calibrator

Status of Medical Events 2006

33 Medical Events reported - FY 2006

35.200		3
35.300		9
35.400		8
35.600		13
HDR	11	
MAMMOSITE	(3)	
Gamma Knife	2	
35.1000 Y-90 Microspheres		1

Therapy Medical Events

35.300 6

4 NaI-131
- 2 - Ordered wrong procedure
- Two Capsules
- Administered wrong dosage

1 Bexxar I-131
- Delivery system setup

1 Zevelin Y-90
- Dose calibrator Y-90 calibration error

Status of Medical Events

- 40 Medical Events Reported – FY 2007

	FY 2007	Change
35.200	1	- 2
35.300	6	- 3
35.400 (24)	10	+ 2
35.600	15	+ 2
• HDR	13	
• MAMMOSITE	(4)	
• Gamma Knife	2	
35.1000 Y-90 Microspheres	8	+ 7

Brachytherapy Medical Events

35.400 10

2 GYN
- Entered mg-Ra eq program required air kerma
- Tandem insert shorter than required

8 PROSTATE (22 patients)
- 6 - Dose rate constant error
- 10 - Air kerma mg-RA eq
- 4 - Failure to correctly visualize prostrate
- 2 - Mick applicator failure

HDR Medical Events

HDR 12

6 Varian
- Bloody fluid in connector
- Wrong isodose choosen for treatment plan
- Wrong catheter connector type*
- Wrong travel distance input*
- Wrong catheter length entered*
- Mammosite
  - Entered wrong catheter length*

Y-90 Microsphere Medical Events

35.1000 8

2 SIR-Spheres®
- Delivery system manufacturing problem
- 20 % to gallbladder

6 Thera-Sphere®

HDR Medical Events cont.

HDR Continued

7 Nucletron
- Wrong catheter length entered*
- Isodose line did not match written directive
- Entered wrong dose in treatment plan
- Reference source position entry error*
- Mammosite
- Wrong film magnification
- Treatment plan entered into computer wrong
- Imported wrong treatment plan

Y-90 Microsphere Medical Events cont.

35.1000 cont.

6 Thera-Sphere®
- 2 - Stopcock orientation error
- Assembly error – leak
- Failure to verify dose delivered
- Difference in prescribed and received from Nordion – calculation error
- Catheter failed/leaked

Gamma Knife Medical Events

Gamma Knife 2
- Prescribed at one percent maximum dose equivalent calculated at another percent
- Entered wrong treatment dose

Other Reported Events

- Involving Patients (160+) 7
  - 2 NARM
  - 1 Patient intervention
  - 1 Wrong units gave wrong dose below reportable limit
  - 1 Microsphere clumping/stasis
  - 2 Information only – linear accelerator (145+)

10 CFR 35.200 **I-131**

NMED Item Number: 070263

Narrative: **Last Updated:** 08/13/2007

The licensee reported that a 19-year-old female patient received 1.25 GBq (33.9 mCi) of I-131 instead of the prescribed 1.11 MBq (30 uCi) for a diagnostic thyroid scan. The incident involved a misdrawn and mislabeled dose from Shertech Pharmacy. The written directive was for 1.11 MBq (30 uCi). Two different nuclear medicine technologists at the licensee's facility measured the dosage in the dose calibrator; however, both read the number but missed the units. The calibrator printed the results, which were attached to the dose without review. Additionally, the dosage was placed into a neck phantom for a third check, but those results were not evaluated. The dose was administered on 4/24/2007 and the error was discovered on 4/26/2007. The patient and physician were notified. The licensee is following up with Shertech Pharmacy. The physician indicated that the patient had a normally functioning thyroid prior to the administration. The patient is expected to be on synthetic thyroid hormone for the remainder of her life. Investigations were performed by the North Carolina Radioactive Materials Branch and the North Carolina Board of Pharmacy on 5/8 and 5/9/2007. It was determined that both the licensee and the pharmacy were at fault. Corrective actions taken by the licensee included providing additional training to personnel.

Event Date:	**Discovery Date:**	**Report Date:**
04/24/2007	04/26/2007	04/26/2007

Licensee/Reporting Party Information:

License Number:	NC-011-0091-6	Name:	MISSION HOSPITALS
Docket Number:	NA	City:	ASHEVILLE

Site of Event:
Site Name: ASHEVILLE, NC

Reference Documents:

Reference Document Number:	Entry Date:	Retraction Date:	Type of Report:
LTR070501	05/02/2007		AGREEMENT STATE LETTER
EN43321	05/02/2007		EVENT NOTIFICATION REPORTED FROM AN AGREEMENT STATE
NC070022	06/12/2007		AGREEMENT STATE EVENT REPORT
LTR070809	08/13/2007		NRC LETTER

10 CFR 35.300

I-131

NMED Item Number: 070184

Narrative:

Last Updated: 09/19/2007

The licensee (dba VA Eastern Colorado Health Care System) reported that a patient received 1.11 GBq (30 mCi) of I-131 instead of the prescribed 0.56 GBq (15 mCi) on 5/31/2006. The incident was discovered on 3/28/2007. The clinical intent was for the patient to receive 1.11 GBq (30 mCi), but the written directive listed the prescribed dose of 0.56 GBq (15 mCi). The licensee implemented corrective actions to prevent a recurrence of the incident. The NRC reviewed the incident and determined that it is a reportable medical event. The INL has requested additional information for this event.

Event Date:	Discovery Date:	Report Date:
05/31/2006	03/28/2007	03/29/2007

Licensee/Reporting Party Information:

License Number: 03-23853-01VA
Name: V.A., DEPARTMENT OF
Docket Number: 03034325
City: NORTH LITTLE ROCK, AR

Site of Event:

Site Name: DENVER, CO

Reference Documents:

Reference Document Number:	Entry Date:	Retraction Date:	Type of Report:
EN43265	04/02/2007		EVENT NOTIFICATION
ML072540778	09/19/2007		NRC LETTER

10 CFR35.300 **I-131**

NMED Item Number: 070295

Narrative: **Last Updated:** 05/15/2007

The licensee reported that a patient prescribed to receive 5.55 GBq (150 mCi) of I-131 for thyroid cancer only received one-half of the intended dosage. The intended activity was stated to have been in two capsules in a single vial. The patient was presented with the vial containing the dosage. The patient was believed to have taken the dosage and then the vial and lead container were placed in storage. On 5/9/2007, a nuclear technician discovered a capsule in the vial. The technician reported the discovery to the RSO. The Oklahoma Radiation Management Section investigators interviewed licensee nuclear medicine technicians on 5/10/2007. The patient will be notified. The cause of the incident was determined to be a failure to verify that the entire dosage was administered. The unused capsule will decay in storage. The INL has requested additional information for this event.

Event Date:	**Discovery Date:**	**Report Date:**
04/27/2007	05/09/2007	05/09/2007

Licensee/Reporting Party Information:

License Number:	OK-01428-03	Name:	SAINT ANTHONY HOSPITAL
Docket Number:	NA	City:	OKLAHOMA CITY

Site of Event:
Site Name: OKLAHOMA CITY, OK

Reference Documents:

Reference Document Number:	Entry Date:	Retraction Date:	Type of Report:
OK070004	05/15/2007		AGREEMENT STATE EVENT REPORT
EN43356	05/15/2007		EVENT NOTIFICATION REPORTED FROM AN AGREEMENT STATE

10 CFR 35.300 **I-131**

NMED Item Number: 070276

Narrative: **Last Updated:** 05/08/2007

The licensee reported that a patient received 148 MBq (4 mCi) of I-131 for a whole body scan instead of the prescribed 5.6 MBq (150 uCi) for a thyroid uptake scan. The event was discovered by a consulting physicist on 3/9/2007. The event occurred after a scheduling person (who does not have a background in nuclear medicine) ordered the wrong scan. The licensee calculated that the dose to the patient's thyroid was approximately 14,000 cGy (rad) and the whole body effective dose equivalent was approximately 6.4 cSv (rem). If the prescribed I-131 amount had been administered, the doses would have been 525 cGy (rad) and 0.24 cSv (rem), respectively. Corrective actions taken by the licensee included generating policies requiring that further requests for I-131 procedures be verified directly with the referring physician.

Event Date:	**Discovery Date:**	**Report Date:**
01/16/2007	03/09/2007	03/09/2007

Licensee/Reporting Party Information:

License Number:	ME-03803-02	Name:	AROOSTOOK MEDICAL CENTER
Docket Number:	NA	City:	PRESQUIE ISLE

Site of Event:

Site Name: PRESQUIE ISLE, ME

Reference Documents:

Reference Document Number:	Entry Date:	Retraction Date:	Type of Report:
ME070016	05/07/2007		AGREEMENT STATE EVENT REPORT
EN43337	05/07/2007		EVENT NOTIFICATION REPORTED FROM AN AGREEMENT STATE

10 CFR 35.300 **I-131**

NMED Item Number: 070315

Narrative: **Last Updated:** 07/16/2007

The licensee reported that a patient with metastatic cancer and no thyroid received a therapeutic dose of 0.99 GBq (26.8 mCi) of I-131, instead of the prescribed whole body scan. The doctor prescribed the whole body scan, but the technologist administered the therapy dosage. The doctor and patient were notified of the error. A Florida Department of Health investigation revealed that no violation occurred and that no corrective actions were required.

Event Date:	**Discovery Date:**	**Report Date:**
05/17/2007	05/17/2007	05/21/2007

Licensee/Reporting Party Information:

License Number:	FL-1284-1	Name:	LARGO MEDICAL CENTER
Docket Number:	NA	City:	LARGO

Site of Event:

Site Name: LARGO, FL

Reference Documents:

Reference Document Number:	Entry Date:	Retraction Date:	Type of Report:
EN43377	05/29/2007		EVENT NOTIFICATION REPORTED FROM AN AGREEMENT STATE
FL07-081	07/16/2007		AGREEMENT STATE EVENT REPORT

10 CFR 35.300 **I-131**

NMED Item Number: 070181

Narrative: **Last Updated:** 06/11/2007

The licensee reported that a patient prescribed to receive 2.74 GBq (74 mCi) of I-131 during a Bexxar Therapy procedure only received between 0.19 and 0.37 GBq (5 and 10 mCi). The T-connector to the catheter was not fitted tight enough, causing the connector to come loose from the tubing. Some I-131 spilled on the floor. The patient and prescribing physician were notified of the dosing error. The licensee plans to conduct another procedure on 3/30/2007. The Florida Department of Health will follow up with the licensee on the incident. Corrective actions taken by the licensee included modifying procedures to require that two individuals verify that the T-connector is tightly connected to each tube before administration begins. The State is tracking the incident as FL07-054.

Event Date:	**Discovery Date:**	**Report Date:**
03/28/2007	03/28/2007	03/28/2007

Licensee/Reporting Party Information:

License Number:	FL-1319-1	Name:	MIAMI, UNIVERSITY OF, SCHOOL OF MEDICINE
Docket Number:	NA	City:	MIAMI

Site of Event:
Site Name: MIAMI, FL

Reference Documents:

Reference Document Number:	Entry Date:	Retraction Date:	Type of Report:
EN43260	04/02/2007		EVENT NOTIFICATION REPORTED FROM AN AGREEMENT STATE
LTR070611	06/11/2007		AGREEMENT STATE LETTER

10 CFR 35.300 **Y-90 Zevalin**

NMED Item Number: 070390

Narrative: **Last Updated:** 09/20/2007

The licensee reported that a patient received 1358 MBq (36.7 mCi) of Y-90 Zevalin (Ibritumomab Tiuxetan) for non-Hodgkin's lymphoma instead of the prescribed dose of 1073 MBq (29 mCi). The radiopharmacy prepared the dose but observed that the assay from the supplier was approximately 370 MBq (10 mCi) higher than their assay. They reviewed their data, including their most recent calibration of the dose calibrator with a NIST traceable syringe standard. They decided to use their NIST traceable calibration factor and associated assay. The dose was dispensed and the patient was treated. Another patient was scheduled to receive a similar treatment the next day and assay results of the dose revealed the same discrepancy. At that point, the licensee realized there was a problem and the second dose was not dispensed. The radiopharmacy identified the error. They had used an AEA Technology QSA source (model SIM.SY2) to calibrate their Capintec dose calibrator (model CRC-15R) as well as the hospital's dose calibrator. This source is specifically designed to calibrate Capintec CRC-15R units for Y-90 assays. The calibration source is labeled with an assay of 740 MBq (20 mCi) of Sr-90/Y-90 and a calibration date of 11/14/2004. However, the source certificate lists the Y-90 equivalent activity as 1135 MBq (30.68 mCi), which is the value that should have been used for the calibration. Apparently, this certificate was not available for the 6/8 and 6/10/2007 calibration. The radiopharmacy used the decay-corrected value on the source label rather than a decay-corrected value from the certificate's equivalent activity. Since the same calibration error was performed on the hospital's dose calibrator, the hospital's assay matched the radiopharmacy's and with the intended dosage. The patient's daughter and the referring physician were notified of the incident. Corrective actions taken by the licensee included using the source certificate information to perform the dose calibrator calibration.

Event Date:	**Discovery Date:**	**Report Date:**
06/19/2007	06/20/2007	06/22/2007

Licensee/Reporting Party Information:

License Number:	NR	Name:	NR
Docket Number:	NA	City:	NR

Site of Event:
Site Name: NR, NY

Reference Documents:

Reference Document Number:	Entry Date:	Retraction Date:	Type of Report:
EN43443 FROM AN AGREEMENT STATE	06/29/2007		EVENT NOTIFICATION REPORTED
LTR070918	09/20/2007		AGREEMENT STATE LETTER

10 CFR 35.400 **Prostate**

NMED Item Number: 070092

Narrative:

Last Updated: 05/01/2007

The licensee reported at least six medical events involving patient doses ranging from 21.6 to 36.5% more than prescribed for prostate gland permanent brachytherapy seed implant procedures using I-125. The medical table shows the pre-plan D90 (prescribed) doses and the post-plan D90 (received) doses to the six patients. All six patients were prescribed V100 doses of 14,500 cGy (rad). The patient procedures began on 1/4/2006 and the sixth patient received treatment on 8/14/2006. The medical events were discovered on 2/12/2007. The events occurred when an improper dose rate constant was used in treatment planning. The licensee investigated 28 patient procedures performed over the past year. The Texas Department of Health Services is also investigating the incident. Corrective actions taken by the licensee included password protecting the treatment planning system in order to limit access to source data, developing policies and procedures to address source data changes/corrections, developing policies and procedures to require that source data be reviewed on a regular basis by a physicist, and training dosimetry and physics staff regarding revisions.

Event Date:	Discovery Date:	Report Date:
01/04/2006	02/12/2007	02/13/2007

Licensee/Reporting Party Information:

License Number: TX-L05805 Name: CHRISTUS SANTA ROSA SURGERY CENTER

Docket Number: NA City: SAN ANTONIO, TX

Site of Event:

Site Name: SAN ANTONIO, TX

Reference Documents:

Reference Document Number:	Entry Date:	Retraction Date:	Type of Report:
TX-I-8391	02/19/2007		AGREEMENT STATE EVENT REPORT
EN43163	02/19/2007		EVENT NOTIFICATION REPORTED FROM AN AGREEMENT STATE
LTR070411	04/18/2007		AGREEMENT STATE LETTER
LTR070425	05/01/2007		AGREEMENT STATE LETTER

10 CFR 35.400 **Prostate**

NMED Item Number: 070183

Narrative:

Last Updated: 04/17/2007

The licensee reported that 10 patients received doses 27% higher than prescribed during I-125 prostate seed implant procedures. The licensee had changed from ordering I-125 doses in Air-Kerma to mCi. During the time period from 5/3/2006 to 3/27/2007, they used an incorrect dose count, which caused each of the 10 patients to receive doses 27% higher than written directives specified. The error was discovered on 3/28/2007 by a newly hired medical physicist. The patients are being informed. The Oklahoma Department of Environmental Quality will investigate the incident. The INL has requested additional information for this event.

Event Date:	**Discovery Date:**	**Report Date:**
05/03/2006	03/28/2007	03/29/2007

Licensee/Reporting Party Information:

License Number: OK-14046-02 Name: KAY COUNTY HOSPITAL

Docket Number: NA City: PONCA CITY, OK

Site of Event:

Site Name: PONCA CITY, OK

Reference Documents:

Reference Document Number:	Entry Date:	Retraction Date:	Type of Report:
EN43263	04/02/2007		EVENT NOTIFICATION REPORTED FROM AN AGREEMENT STATE
OK070003	04/17/2007		AGREEMENT STATE EVENT REPORT

10 CFR 35.400 **Prostate**

NMED Item Number: 070060

Narrative:

Last Updated: 04/18/2007

The Florida Agency for Health Care Administration reported that while performing an audit of the licensee, a medical event involving brachytherapy seeds was identified. The procedure involved the implant of 60 I-125 seeds totaling approximately 0.75 GBq (20.39 mCi). A review of preplanning, live planning, and post planning documents was conducted on 6/22/2006 and a wrong site administration was declared by the prescribing radiation oncologist and RSO. Their conclusion was supported by diagnostic films and physics calculations. The referring physician and patient were informed of the incident. The patient has undergone a diagnostic computed tomography exam and follow-up appointment. The medical event was determined reportable. The Florida Department of Health visited the licensee's facility to obtain details of the incident. It was determined that the written transrectal ultrasound-guided treatment plan had not been followed. A new plan was developed and implemented without the assistance of a certified sonographer and without a written change by the authorized user. The prostate was prescribed to receive 11400 cGy (rad) to 98% of its volume, but received only 1000 cGy (rad) to 46% of its volume. The penile bulb was estimated to have received approximately 14400 cGy (rad) to 11% of its volume. Corrective actions taken by the licensee included procedure modifications requiring a qualified ultrasound technologist to be present at all implants to ensure the visualization of the prostate. Also, if the urologist, radiation oncologist, or medical physicist have any questions concerning the location of the prostate and or the placement of the needles, the implant procedure will be stopped until those questions are resolved.

Event Date:	**Discovery Date:**	**Report Date:**
06/13/2006	06/22/2006	01/11/2007

Licensee/Reporting Party Information:

License Number: FL-3704-1 Name: SURGICAL CENTER OF CENTRAL FLORIDA
Docket Number: NA City: SEBRING, FL

Site of Event:

Site Name: SEBRING, FL

Reference Documents:

Reference Document Number:	Entry Date:	Retraction Date:	Type of Report:
EN43112	01/29/2007		EVENT NOTIFICATION REPORTED FROM AN AGREEMENT STATE
FL07-005	03/27/2007		AGREEMENT STATE EVENT REPORT
LTR070412	04/18/2007		AGREEMENT STATE LETTER

10 CFR 35.400 **Prostate**

NMED Item Number: 060742

Narrative: **Last Updated:** 01/31/2007

The licensee reported that a prostate gland seed implant procedure was not performed properly, resulting in a total shift of seeds from the intended treatment site. The dose to the intended site was 40% less than prescribed. The seeds (UROCOR model 125SL, batch 1B060245J) used for the implant procedure contained I-125 with a total activity of 725.2 MBq (19.6 mCi). The patient was notified at the time of the treatment. The licensee stated that the cause of the incident was human error. An Ohio Bureau of Radiation inspector performed an inspection on 12/12/2006 and determined that the incident occurred due to difficulty in visualizing the superior portion of the prostate gland. The licensee has instituted a policy to have both the urologist and the radiation oncologist agree on visualization of the superior portion of the prostate prior to implantation. The incident was reviewed by the NRC Medical Review Committee and determined to be a reportable medical event.

Event Date:	**Discovery Date:**	**Report Date:**
12/05/2006	12/05/2006	12/06/2006

Licensee/Reporting Party Information:

License Number:	OH-02200310002	Name:	UROLOGY CENTER
Docket Number:	NA	City:	CINCINNATI

Site of Event:

Site Name: CINCINNATI, OH

Reference Documents:

Reference Document Number:	Entry Date:	Retraction Date:	Type of Report:
EN43034	12/11/2006		EVENT NOTIFICATION REPORTED FROM AN AGREEMENT STATE
OH2006-100	12/19/2006		AGREEMENT STATE EVENT REPORT
OH2006-100A	01/31/2007		AGREEMENT STATE EVENT REPORT

10 CFR 35.400 **Prostate**

NMED Item Number: 060748

Narrative: **Last Updated:** 09/05/2007

The licensee reported implanting 104 I-125 brachytherapy seeds into a patient for treatment of prostate cancer on 10/25/2006. The total activity of the implanted seeds was 1.57 GBq (42.4 mCi). A post-implant CT scan performed on 12/8/2006 indicated that the seeds were misplaced approximately 1.5 cm inferior to the intended position. The patient and the prescribing physician were notified of the incident. Calculations showed the D90 value (the minimum dose received by 90% of the prostate volume) to be 6% of the prescribed dose or 800 cGy (rad) versus the prescribed dose of 14,500 cGy (rad). Also, an unintended tissue volume of 76.7 cc received 100% of the prescribed prostate dose. The patient required further treatment of the prostate gland, which was performed using a linear accelerator. This event was caused by the failure to accurately identify the position of the prostate. Corrective actions included having a radiologist review the volume study during implant procedure, filling the Foley catheter balloon with contrast to better identify the prostate base, and using fluoroscopy to confirm needle depth before depositing the seeds and fluoroscopic confirmation of seed position intermittently during the procedure. A medical consultant was contracted by the NRC to review the incident. It was concluded that no significant adverse effect was expected.

Event Date:	**Discovery Date:**	**Report Date:**
10/25/2006	12/08/2006	12/08/2006

Licensee/Reporting Party Information:

License Number:	29-15459-01	Name:	KENNEDY MEMORIAL HOSPITALS
Docket Number:	03009149	City:	TURNERSVILLE

Site of Event:
Site Name: TURNERSVILLE, NJ

Reference Documents:

Reference Document Number:	Entry Date:	Retraction Date:	Type of Report:
EN43039	12/12/2006		EVENT NOTIFICATION
ML070440431	02/26/2007		INSPECTION REPORT
ML070440431	02/26/2007		NRC LETTER
ML071000445	05/31/2007		CONSULTANT REPORT
ML071000445	05/31/2007		LICENSEE REPORT
ML071000445	05/31/2007		REGION REPORT
LTR070828	09/05/2007		NRC LETTER

10 CFR35.400 **Prostate**

NMED Item Number: 070024

Narrative: **Last Updated:** 08/23/2007

The licensee reported that an error occurred during a brachytherapy seed implant procedure, resulting in a dose less than prescribed to the intended site and doses greater than prescribed to unintended sites. The patient was prescribed a total dose of 12,000 cGy (rad) to the prostate using 41 I-125 seeds, with each seed containing 11.84 MBq (0.32 mCi). The patient moved after seven seeds had been implanted (two of the 14 treatment needles). The procedure was delayed to allow additional anesthesia to take affect. The lineup was checked using ultrasound and, once the urologist, radiation oncologist, and medical physicist were comfortable with the situation, the implant procedure was resumed. After the procedure was completed, radiographs revealed that 34 of the 41 seeds (needles 3 through 14) were inadvertently deposited approximately 4 cm inferior to the prostate into the penile bulb. As a result, the prostate received a dose of 1,300 cGy (rad). In addition, the penile bulb received approximately 11,000 cGy (rad), and the patient's skin received approximately 240 cGy (rad), more than 50% greater than prescribed. The dose to the penile bulb could result in scarring, fibrosis, erectile dysfunction, and impotency. The patient was notified of the error. This event was caused by the failure to have adequate procedures and a lack of communication. The NRC contracted a medical consultant, who concurred with the licensee's evaluation. Corrective actions included procedure revision, including performing imaging during the treatment rather than only at the end of the treatment.

Event Date:	**Discovery Date:**	**Report Date:**
01/08/2007	01/08/2007	01/08/2007

Licensee/Reporting Party Information:

License Number:	21-04125-01	Name:	HACKLEY HOSPITAL
Docket Number:	03002044	City:	MUSKEGON

Site of Event:
Site Name: MUSKEGON, MI

Reference Documents:

Reference Document Number:	Entry Date:	Retraction Date:	Type of Report:
EN43082	01/15/2007		EVENT NOTIFICATION
ML070960431	04/17/2007		ADAMS DOCUMENT PACKAGE
ML070820067	04/17/2007		CONSULTANT REPORT
ML070960426	04/17/2007		INSPECTION REPORT
ML070960426	04/17/2007		NRC LETTER
LTR070430	05/02/2007		NRC LETTER
LTR070625	06/25/2007		NRC LETTER
ML071730448	07/09/2007		NOTICE OF VIOLATION
ML071730448	07/09/2007		NRC LETTER
ML071290394	08/23/2007		LICENSEE REPORT
ML071340044	08/23/2007		LICENSEE REPORT

10 CFR35.400 **Prostate**

NMED Item Number: 070025

Narrative: **Last Updated:** 05/30/2007

The licensee reported an underdose to a patient's prostate after a Mick applicator malfunctioned during treatment. The patient was scheduled to receive 44 I-125 brachytherapy seeds (Best Medical), each containing an activity of 9.25 MBq (0.25 mCi). However, only 33 seeds had been implanted when the malfunction occurred. The seeds not implanted were accounted for and were placed in storage. The patient was notified of the incident on 1/10/2007. The patient received 11,000 cGy (rad) to the prostate gland. In the future, the operating room team will be more aware of the seed count. The dosimetrist will monitor the seed count and the physicist will not be distracted with interruptions. The Mick applicator was sent to the manufacturer for inspection/repair.

Event Date:	**Discovery Date:**	**Report Date:**
01/09/2007	01/09/2007	01/09/2007

Licensee/Reporting Party Information:

License Number: SC-0646 Name: CARE ALLIANCE HEALTH SERVICES ROPER HOSPITAL

Docket Number: NA City: CHARLESTON

Site of Event:

Site Name: CHARLESTON, SC

Reference Documents:

Reference Document Number:	Entry Date:	Retraction Date:	Type of Report:
EN43087	01/15/2007		EVENT NOTIFICATION REPORTED FROM AN AGREEMENT STATE
SC070001	03/01/2007		AGREEMENT STATE EVENT REPORT
LTR070314	03/19/2007		AGREEMENT STATE LETTER
LTR070524	05/30/2007		AGREEMENT STATE LETTER

10 CFR 35.400 **Prostate**

NMED Item Number: 070327

Narrative: **Last Updated:** 08/16/2007

The licensee reported that they ruptured a Pd-103 seed that contained an activity of 0.11 GBq (2.92 mCi), causing interruption of a medical procedure. The incident occurred while performing a patient implant in room 11 of the operating room. Preliminary evaluation by the licensee indicated that the Mick applicator jammed and failed to advance. Efforts to free the device may have damaged the seed. The patient procedure was stopped after 60 seeds were successfully implanted; the written directive prescribed 83 seeds. The oncologist stated that the 60 seeds implanted were adequate for successful therapy and that no additional seeds would be implanted. Radiation surveys revealed contamination on the applicator and surrounding absorbent chucks. Contaminated items were controlled and stored in the nuclear medicine department. The Mick applicator was removed from service for decay in storage. Following decay, the licensee with send the applicator to the manufacturer for a full evaluation. Smear tests of adjacent operating room surfaces and floor were negative. The operating room was released at approximately 1900 hours the same day. The licensee notified the manufacturer of the incident and a new Mick applicator was purchased. The INL has requested additional information for this event.

Event Date:	**Discovery Date:**	**Report Date:**
05/24/2007	*05/24/2007*	*05/25/2007*

Licensee/Reporting Party Information:

License Number:	MD-31-002-03	Name:	HOLY CROSS HOSPITAL
Docket Number:	NA	City:	SILVER SPRINGS

Site of Event:
Site Name: SILVER SPRINGS, MD

Reference Documents:

Reference Document Number:	Entry Date:	Retraction Date:	Type of Report:
EN43390	05/31/2007		EVENT NOTIFICATION REPORTED FROM AN AGREEMENT STATE
MD070006	07/10/2007		AGREEMENT STATE EVENT REPORT
LTR070814	08/15/2007		AGREEMENT STATE LETTER
LTR070816	08/16/2007		AGREEMENT STATE LETTER

10 CFR 35.400 **GYN**

NMED Item Number: 070215

Narrative: **Last Updated:** 06/27/2007

The licensee reported that a 31-year-old female patient with a history of vaginal cancer was prescribed 2,500 cGy (rad) via interstitial brachytherapy to the 50 cGy (rad) isodose line, but received 4,590 cGy (rad). The patient's anterior rectal dose was approximately 7,300 cGy (rad). The licensee used both Cs-137 and Ir-192 for the treatment. The medical physicist developed a treatment plan as directed by the authorized user/radiation oncologist using a commercial treatment planning software application. The licensee used 11 seed ribbons, each containing eight Ir-192 seeds (Best Industries), and each seed contained an activity of 1.855 mgRaEq or 1.18 MBq (3.19 mCi). A Syed template was used to place the Ir-192 ribbons, and the Cs-137 sources were loaded into a tandem applicator. The treatment was initiated on 3/6/2007. The medical physicist performed a manual check of the treatment plan calculations on 3/7/2007 and identified a significant discrepancy. It was noted that the hand calculations indicated a significantly higher dose rate than what was generated by the treatment planning software. After several hours of investigation, it was determined that the original treatment plan was in error. After 27 hours of the intended 50-hour treatment time, the sources were removed from the patient. The primary error was the use of an inappropriate dose rate factor in the treatment planning software. The value used corresponded to the dose rate factor for air Kerma; however, the source strength was entered in milligram radium equivalent. During the physics review, it was determined that acceptance testing of this treatment planning software did not include Ir-192; the acceptance testing covered only Cs-137 and I-125. There was no check of the preplan prior to obtaining the Ir-192 seeds, although there was sufficient time. Neither the physicist nor the radiation oncologist had prepared a treatment using Ir-192 in six years and the physicist had not used this particular treatment planning software for Ir-192. It would have been prudent to have an additional review or outside review. The double check was not performed until the day after the treatment began. Corrective actions taken by the licensee included changing the policy and procedures to require a check of calculations for any single fraction brachytherapy treatment. The radiation oncologist disclosed that the patient is at risk for radiation cystitis, rectal proctitis, and, more importantly, fistula formation between the rectum and the vagina. The patient will be monitored closely over the next year by both her gynecologic oncologist and the radiation oncologist. The patient was treated with broad spectrum antibiotics along with daily treatments in a hyperbaric oxygen chamber. Department of Health staff performed a reactive inspection on 3/21/2007. Licensee staff was interviewed and radiation therapy quality assurance policies, procedures, and patient records were reviewed. The patient's record was sent for review by a radiation oncologist and medical physicist. Their report identified several issues which the Department of Health will follow-up on.

Event Date:	**Discovery Date:**	**Report Date:**
03/06/2007	03/07/2007	03/21/2007

Licensee/Reporting Party Information:

License Number:	NR	Name:	NR
Docket Number:	NA	City:	NR

Site of Event:
Site Name: NR, NY

Reference Documents:

Reference Document Number:	Entry Date:	Retraction Date:	Type of Report:
NYS-DOH 07-001	04/11/2007		AGREEMENT STATE EVENT REPORT
EN43301	04/17/2007		EVENT NOTIFICATION REPORTED FROM AN AGREEMENT STATE
LTR070425	04/30/2007		NRC LETTER
LTR070608	06/11/2007		AGREEMENT STATE LETTER
LTR070626	06/27/2007		AGREEMENT STATE LETTER

10 CFR 35.400 **GYN**

NMED Item Number: 070074

Narrative: **Last Updated:** 06/18/2007

The licensee reported that a patient received 770 cGy (rad) to the cervix instead of the prescribed 3,000 cGy (rad). The patient also received doses to unintended locations. A Fletcher-Suit tandem and ovoid applicator containing 6.29 GBq (170 mCi) of Cs-137 was loaded into the patient on 2/2/2007 for a treatment time of 48.5 hours. Upon removal of the device, it was observed that the tandem applicator had been loaded with a plastic radioactive source carrier insert (tandem insert) that was approximately 4 cm shorter than the required 24 cm. This caused the sources in the tandem applicator to be displaced from the intended position, resulting in a lower than intended dose to the treatment site and higher than intended doses to other locations. There were three areas of unintended dose. The rectum area was prescribed to receive 930 cGy (rad) and received 2,472 cGy (rad), the vaginal mucosa area was prescribed 411 cGy (rad) and received 1,484 cGy (rad), and a second vaginal mucosa area was prescribed 265 cGy (rad) and received 1,414 cGy (rad). The licensee administered external beam treatment to compensate for the underdose. The NRC contracted a medical consultant to review this event. The consultant concluded that no significant adverse impact is expected. Corrective actions included additional training for applicable personnel and procedure modification.

Event Date:	**Discovery Date:**	**Report Date:**
02/02/2007	02/04/2007	02/05/2007

Licensee/Reporting Party Information:

License Number:	45-00034-26	Name:	VIRGINIA, UNIVERSITY OF
Docket Number:	03003296	City:	CHARLOTTESVILLE

Site of Event:
Site Name: CHARLOTTESVILLE, VA

Reference Documents:

Reference Document Number:	Entry Date:	Retraction Date:	Type of Report:
EN43145	02/07/2007		EVENT NOTIFICATION
ML071280817	05/16/2007		INSPECTION REPORT
ML071280817	05/16/2007		NOTICE OF VIOLATION
ML071280817	05/16/2007		NRC LETTER
LTR070615	06/18/2007		NRC LETTER
LTR070615A	06/18/2007		NRC LETTER

10 CFR 35.600 **HDR Varian**

NMED Item Number: 070392

Narrative: **Last Updated:** 07/02/2007

The licensee reported that a patient received 17.8% of the prescribed dose during an HDR treatment using a Miami vaginal cylinder and tandem. The HDR (Varian model VariSource, serial #600379) utilized an Ir-192 source (Alpha-Omega model VS2000, serial #02-01-0588-001-041907-10089-97) with an activity of 373.29 GBq (10.09 Ci). The treatment was initiated, but the device computer indicated the source wire positioning was not reproducible (error code 18 – wire drift detected) and the treatment was paused. The QA positioning test was conducted and was within acceptable limits. The treatment was continued, but the device again indicated positioning errors. The treatment was discontinued without being completed. Varian was contacted and a field engineer was dispatched the following day. The source and dummy wire transport systems were cleaned and tested. The medical physicists performed several QA tests and certified the HDR was ready for patient treatment. The patient and physician were notified of the incident immediately after the treatment was terminated. The licensee stated that while connecting the Miami vaginal cylinder to the HDR with seven separate connecting tubes, bloody fluid was noted on one of the connectors. It was determined that the protective caps covering the tubes were removed in surgery instead of waiting until the patient arrived in the department. In the future, the licensee will leave the protective caps on the applicator as long as possible to reduce or preclude any fluid from entering the closed system. The INL has requested additional information for this event.

Event Date:	**Discovery Date:**	**Report Date:**
06/25/2007	06/25/2007	06/26/2007

Licensee/Reporting Party Information:

License Number:	OR-91035	Name:	PROVIDENCE MEDFORD MEDICAL CENTER
Docket Number:	NA	City:	MEDFORD

Site of Event:

Site Name: MEDFORD, OR

Reference Documents:

Reference Document Number:	Entry Date:	Retraction Date:	Type of Report:
EN43445	07/02/2007		EVENT NOTIFICATION REPORTED
FROM AN AGREEMENT STATE			

10 CFR 35.600 **HDR Varian**

NMED Item Number: 070547 **Last Updated:** 09/04/2007

Narrative:
The licensee (dba Texas Oncology at Klabzuba) reported that a patient being treated with a Varian high dose rate afterloader (model VariSource) and Ir-192 received 2,500 cGy (rad) during the first of five fractions instead of the prescribed dose of 500 cGy (rad). The patient was prescribed to receive five fractions with 500 cGy (rad) per fraction. The incident was discovered following an independent physicist's review of the treatment plan. The incident occurred as a result of the incorrect isodose line being chosen and entered into the treatment planning system. The treatment planning system then normalized the calculations to the incorrect isodose line and the resulting treatment. The Oncologist signed and approved the plan and the RSO performed a second calculation check on the plan. The calculation error was identified by an independent physicist prior to administration of the second fraction.

Event Date:	**Discovery Date:**	**Report Date:**
08/22/2007	08/29/2007	08/29/2007

Licensee/Reporting Party Information:
License Number: TX-L05545 Name: PHYSICIAN RELIANCE
Docket Number: NA City: FORT WORTH

Site of Event:
Site Name: FORT WORTH, TX

Reference Documents:

Ref. Doc. Number:	Entry Date:	Retraction Date:	Type of Report:
TX-I-8439	09/04/2007		AGREEMENT STATE EVENT REPORT
TX-I-8439A	09/04/2007		AGREEMENT STATE EVENT REPORT
TX-I-8439B	09/04/2007		AGREEMENT STATE EVENT REPORT
EN43606	09/04/2007		EVENT NOTIFICATION REPORTED FROM AN AGREEMENT STATE

10 CFR35.600 **HDR Varian**

NMED Item Number: 070137

Narrative: **Last Updated:** 04/10/2007

The licensee reported that a patient was administered 2,400 cGy (rad) instead of the prescribed dose of 3,192 cGy (rad) during a series of fractional treatments using a Varian high dose rate afterloader (serial #262T) with an Ir-192 source containing an activity of 261.4 GBq (7.066 Ci). The treatments occurred between 2/13/2007 and 2/20/2007. The patient also received dose to an incorrect site. The treatment plan did not include a correction for the catheter connector type (disposable vs. reusable), resulting in a 1.4 cm source positioning error. The error was identified during the review process following the last dose fraction. The patient was informed of the incident on 3/6/2007. The patient will likely have a skin reaction to the treatment, which is expected to heal with time. Corrective actions taken by the licensee included instituting new procedures and checklists.

Event Date:	**Discovery Date:**	**Report Date:**
02/13/2007	02/20/2007	02/23/2007

Licensee/Reporting Party Information:

License Number: CO-197-02 Name: CENTURA HEALTH PENRONSE SAINT FRANCIS HOSPITAL

Docket Number: NA City: COLORADO SPRINGS

Site of Event:

Site Name: COLORADO SPRINGS, CO

Reference Documents:

Reference Document Number:	Entry Date:	Retraction Date:	Type of Report:
EN43220	03/09/2007		EVENT NOTIFICATION REPORTED FROM AN AGREEMENT STATE
CO07M07-01	04/10/2007		AGREEMENT STATE EVENT REPORT

10 CFR 35.600 **HDR Varian**

NMED Item Number: 070014

Narrative: **Last Updated:** 05/24/2007

The licensee reported that a patient received a high dose rate (HDR) treatment to the wrong site. The Varian HDR unit (model VariSource) contained an Ir-192 source (model VS2000, serial #020113680011120061O1) with an activity of 370 GBq (10 Ci). A series of fractions were conducted on 11/29, 12/6, 12/13, and 12/20/2006. A portion of the patient's inner thighs were treated instead of the intended cancerous target. The delivered dose to the skin was 2,000 cGy (rad) and the dose to the intended site was zero. The medical physicist stated that the error had been identified as part of a chart audit that was conducted prior to performing the next similar treatment of a subsequent patient. Computerized dosimetry planning records showed that the prescribed treatment was to occur with an automated source travel distance of 120 cm. The actual data point used during treatment was a travel distance of only 100 cm. The authorized radiation oncologist confirmed reddening of the skin on both inner thighs of approximately 3 cm2. HDR treatments have been rescheduled. The cause was determined to be human error, not equipment malfunction. Illinois Department of Health investigation also determined that the licensee failed to ensure that both an authorized user and an authorized medical physicist were present for the treatments and that the treatment plan did not receive the routine review during any of the subsequent treatment fractions to ensure the prescribed dose was being administered. The NRC had a medical consultant investigate the incident. The consultant found that personnel required additional operational training and that safety controls were missing. Corrective actions taken by the licensee included procedural modifications to assure catheter lengths are verified prior to treatment, providing additional training to personnel, and generating new procedures.

Event Date:	**Discovery Date:**	**Report Date:**
11/29/2006	01/04/2007	01/04/2007

Licensee/Reporting Party Information:

License Number:	IL-01289-01	Name:	SAINT JAMES HOSPITAL & HEALTH CENTER
Docket Number:	NA	City:	OLYMPIA FIELDS

Site of Event:
Site Name: OLYMPIA FIELDS, IL

Reference Documents:

Reference Document Number:	Entry Date:	Retraction Date:	Type of Report:
EN43078	01/09/2007		EVENT NOTIFICATION REPORTED FROM AN AGREEMENT STATE
IL070001	02/12/2007		AGREEMENT STATE EVENT REPORT
IL070001A	04/23/2007		AGREEMENT STATE EVENT REPORT
LTR070416	04/23/2007		AGREEMENT STATE LETTER
IL070001B	05/24/2007		AGREEMENT STATE EVENT REPORT

10 CFR35.600 **HDR Varian**

NMED Item Number: 070211

Narrative: **Last Updated:** 09/10/2007

The licensee reported that a patient did not receive the prescribed dose scheduled for a single fraction interstitial treatment using a Varian HDR remote afterloader (model VariSource) containing an Ir-192 source (model VS2000) with an activity of 230.9 GBq (6.24 Ci). The patient was scheduled to receive 900 cGy (rad) to the vagina. An incorrect applicator length of 100 cm was input into the treatment plan. The actual applicator length was 120 cm. The licensee determined that the source was at least 10 cm from the patient's thigh and calculated an excess dose to the thigh of 50 cGy (rad). No reddening of the skin was observed. The authorized user and patient were notified on 4/4/2007 and the patient will return for re-treatment on 4/12/2007. A State inspector was dispatched to the facility on 4/6/2007. Corrective actions taken by the licensee included providing additional training to personnel and generating new policies and procedures. The authorized user and authorized medical physicist will spot check the length of at least 20% of the applicators after treatment planning and prior to patient treatment. The patient was retreated on 4/12/2007.

Event Date:	**Discovery Date:**	**Report Date:**
04/04/2007	04/04/2007	04/05/2007

Licensee/Reporting Party Information:

License Number:	WI-09-1303-01	Name:	SAINT VINCENT HOSPITAL
Docket Number:	NA	City:	GREEN BAY

Site of Event:

Site Name: GREEN BAY, WI

Reference Documents:

Reference Document Number:	Entry Date:	Retraction Date:	Type of Report:
EN43288	04/10/2007		EVENT NOTIFICATION REPORTED FROM AN AGREEMENT STATE
WI070008	05/07/2007		AGREEMENT STATE EVENT REPORT
WI070008A	07/09/2007		AGREEMENT STATE EVENT REPORT
WI070008B	09/10/2007		AGREEMENT STATE EVENT REPORT

10 CFR 35.600 **HDR Nucletron**

NMED Item Number: 070309

Narrative: **Last Updated:** 08/20/2007

The licensee reported that a patient received only about 10% of the prescribed dose to the intended treatment site during HDR brachytherapy treatment. The patient was prescribed to receive 500 cGy (rad) to the vagina. The HDR unit (Nucletron model microselectron, serial #31148) used a 297.85 GBq (8.05 Ci) Ir-192 source (Nucletron model 105.002, serial #D36B-1574). The cause of the incident was an error in the catheter measurement used in the treatment plan. The dose was delivered approximately 54 mm from the intended target area. The error was discovered by the chief radiotherapy physicist during an audit. The catheter was retrieved from waste, re-measured, and the treatment plan was altered to address the problem. Corrective actions taken by the licensee included re-measurement of catheters prior to treatment. The patient's physician was informed of the incident; however, the patient was not.

Event Date:	**Discovery Date:**	**Report Date:**
05/10/2007	05/11/2007	05/11/2007

Licensee/Reporting Party Information:

License Number:	RI-7D-051-01	Name:	RHODE ISLAND HOSPITAL
Docket Number:	NA	City:	PROVIDENCE

Site of Event:
Site Name: PROVIDENCE, RI

Reference Documents:

Reference Document Number:	Entry Date:	Retraction Date:	Type of Report:
RI070001	05/23/2007		AGREEMENT STATE EVENT REPORT
EN43478	07/13/2007		EVENT NOTIFICATION REPORTED FROM AN AGREEMENT STATE
RI070001A	08/20/2007		AGREEMENT STATE EVENT REPORT

10 CFR 35.600 **HDR Nucletron**

NMED Item Number: 070471 **Last Updated:** 09/05/2007

Narrative:
The licensee reported that a patient only received 1,030 cGy (rad) during three fractionated HDR brachytherapy treatments instead of the prescribed 1,500 cGy (rad). The treatments were administered on 7/10, 7/17, and 7/24/2007. The HDR unit (model MicroSelectron, serial #31558) was manufactured by Nucletron Corporation and contained an Ir-192 source with an activity of 281.2 GBq (7.6 Ci). Following the third fraction, the licensee determined that the 500 cGy (rad) isodose line was at the surface of the cylinder, rather than 5 mm from the cylinder. Therefore, the patient only received 1,030 cGy (rad) instead of the dose prescribed in the written directive. On 7/31/2007, the physician revised the written directive and gave the patient a fourth treatment, which put the total dose at 2,000 cGy (rad). Corrective actions taken by the licensee included revising their procedures to require dual verification that the cylinder and isodose lines match with the written directive. In addition, all future treatment plans will be reviewed and approved by the physician prior to treatment.

Event Date:	**Discovery Date:**	**Report Date:**
07/10/2007	07/24/2007	07/24/2007

Licensee/Reporting Party Information:

License Number:	24-01143-06	Name:	LESTER E. COX MEDICAL CENTER
Docket Number:	03009784	City:	SPRINGFIELD

Site of Event:
Site Name: SPRINGFIELD, MO

Reference Documents:

Reference Document Number:	Entry Date:	Retraction Date:	Type of Report:
EN43516	07/30/2007		EVENT NOTIFICATION
LTR070806	08/08/2007		NRC LETTER
ML072290544	08/23/2007		INSPECTION REPORT
ML072290544	08/23/2007		NOTICE OF VIOLATION
ML072290544	08/23/2007		NRC LETTER
ML072290472	09/05/2007		LICENSEE REPORT

10 CFR 35.600 **HDR Nucletron**

NMED Item Number: 070015

Narrative: **Last Updated:** 02/01/2007

The licensee reported that a dose delivered to part of the target organ exceeded the prescribed dose by more than 50% during the first of four high dose rate (HDR) brachytherapy fractions. The licensee was using a Nucletron HDR (model MicroSelectron) and an Ir-192 source with an activity of 370 GBq (10 Ci). The patient was prescribed to receive four HDR brachytherapy fractions to a 7 cm length of the vaginal mucosa of 500 cGy (rad) each. About halfway through the first treatment fraction, it was determined that the inferior 3 cm of the treatment length received 756 cGy (rad). The medical physicist had entered 1,220 cGy (rad) into the HDR treatment planning computer instead of 500 cGy (rad). The physicist also entered 1,220 cGy (rad) on his HDR dosimetry check. He then completed the HDR dosimetry check, not realizing the incorrect dosage was entered on the checklist. Standard protocol is to check the treatment dose on the prescription plan, but that did not occur. The authorized user reviewed the treatment plan and isodose distribution curves and approved the plan for a dose of 1,220 cGy (rad) instead of 500 cGy (rad), which was stated on the written directive. As the patient was treated, the medical physicist gathered the pertinent medical documents for the patient file and noticed that the authorized user's checklist (physician's HDR dosimetry checklist) had 500 cGy (rad) for the prescribed dose. The medical physicist immediately terminated treatment. The patient received 756 cGy (rad) instead of the planned 500 cGy (rad), 51% over the prescribed dose. The patient received the prescribed total dose during the four fractions. The Wisconsin Department of Health and Family Services dispatched a team on 1/8/2007 for investigation. The patient was notified of the incident on 12/27/2006. Corrective actions taken by the licensee included modifying existing procedures and writing new policies and procedures.

Event Date:	**Discovery Date:**	**Report Date:**
12/27/2006	12/27/2006	12/27/2006

Licensee/Reporting Party Information:

License Number:	WI-025-1323-01	Name:	UNIVERSITY OF WISCONSIN
Docket Number:	NA	City:	MADISON

Site of Event:
Site Name: MADISON, WI

Reference Documents:

Reference Document Number:	Entry Date:	Retraction Date:	Type of Report:
LTR070110	01/10/2007		AGREEMENT STATE LETTER
EN43074	01/10/2007		EVENT NOTIFICATION REPORTED FROM AN AGREEMENT STATE
WI070002	02/01/2007		AGREEMENT STATE EVENT REPORT

10 CFR 35.600 **HDR Nucletron**

NMED Item Number: 060760

Narrative: **Last Updated:** 09/05/2007

During an NRC inspection on 12/18/2006, it was determined that a patient received a dose of 137 cGy (rad) to the intended site instead of the prescribed 600 cGy (rad) during HDR treatment for cervical carcinoma. The Nucletron HDR unit (model microSelectron, serial #31469) used an Ir-192 source with an activity of 236.99 GBq (6.405 Ci). The patient was prescribed five fractions at 600 cGy (rad) per fraction, for a total dose of 3,000 cGy (Rad). This was prescribed as a ring and tandem treatment to be performed using a 4-cm tandem. During the second of five fractions, the reference source position for the tandem applicators was entered incorrectly into the treatment console (the source position for the ring applicator was entered correctly). Consequently, the tandem source was displaced by 18 cm from the intended dwell position and was outside the patient's body during this fraction. The licensee added an extra fraction to the patient's treatment plan, which resulted in a total dose of 3,137 cGy (rad) and was within 20% of the total prescribed treatment. The maximum dose to unintended tissue was approximately 47 cGy (rad). The incident was reviewed by the NRC Medical Review Committee and was determined to be a reportable medical event. Corrective actions included procedure modification, personnel training, and increased program oversight.

Event Date:	**Discovery Date:**	**Report Date:**
11/09/2006	12/18/2006	12/18/2006

Licensee/Reporting Party Information:

License Number:	29-08285-01	Name:	COOPER HEALTH SYSTEM
Docket Number:	03002512	City:	CAMDEN

Site of Event:
Site Name: CAMDEN, NJ

Reference Documents:

Reference Document Number:	Entry Date:	Retraction Date:	Type of Report:
EN43057	12/21/2006		EVENT NOTIFICATION
ML071420244	06/18/2007		INSPECTION REPORT
ML071590326	06/18/2007		NOTICE OF VIOLATION
ML071420244	06/18/2007		NRC LETTER
ML071590326	06/18/2007		NRC LETTER
LTR070831	09/05/2007		NRC LETTER

10 CFR 35.600 **HDR Mammosite**

NMED Item Number: 060659 **Last Updated:** 08/23/2007

Narrative:
The licensee reported a medical event involving a 67-year-old female patient that received a high dose rate afterloader (Varian HDR model VariSource, serial #600389) breast therapy (mammosite) treatment. At the time of the event, the HDR contained approximately 144.3 GBq (3.9 Ci) of Ir-192. While the physicist was verifying the source positions and dwell times prior to treatment number eight of ten, it was noted that the first (most distal) source position was different from the previous treatments. A subsequent investigation by the licensee revealed that the usable catheter length entered into the treatment planning computer was 93 cm rather than the correct value of 95 cm. This error in catheter length was used for the first seven treatments beginning on 10/23/2006, which resulted in an unplanned dose to tissue proximal to the mammosite balloon. The patient was prescribed to receive 340 cGy/fraction (rad/fraction) to the specified site, or 2,380 cGy (rad) for the first seven fractions, but received only 700 to 1,000 cGy (rad) to the specified site. The incorrect site received 10,000 cGy (rad). If the fractions would have been administered correctly, that site would have received 2,450 cGy (rad). The licensee believes that a typographical error occurred in entering the usable catheter length. The referring physician and patient were notified of the incident and the remaining treatment fractions were cancelled. Corrective actions included training and procedure revisions that require verification of treatment parameters. The NRC contracted a medical consultant to review this event, who determined that the patient will likely experience breast atrophy and fat necrosis in the overexposed region.

Event Date:	**Discovery Date:**	**Report Date:**
10/23/2006	10/26/2006	10/27/2006

Licensee/Reporting Party Information:
License Number: 24-00889-01 Name: SAINT LUKES HOSPITAL OF KANSAS CITY
Docket Number: 03002286 City: Kansas City

Site of Event:
Site Name: KANSAS CITY, MO

Reference Documents:

Reference Document Number:	Entry Date:	Type of Report:
EN42941	10/30/2006	EVENT NOTIFICATION
LTR061031	11/06/2006	NRC LETTER
LTR061106	11/07/2006	NRC LETTER
ML063060100	11/15/2006	NRC LETTER
LTR061218	12/19/2006	NRC LETTER
ML063630381	01/04/2007	ADAMS DOCUMENT PACKAGE
ML063630404	01/04/2007	CONSULTANT REPORT
ML063630396	01/08/2007	INSPECTION REPORT
LTR070108	01/08/2007	NRC LETTER
ML063630396	01/08/2007	NRC LETTER
ML070780288	03/23/2007	NOTICE OF VIOLATION
ML070780288	03/23/2007	NRC LETTER
ML070370211	08/23/2007	LICENSEE REPORT

10 CFR 35.600 ***HDR Mammosite***

NMED Item Number: 070121

Narrative:

Last Updated: 07/11/2007

The licensee reported that a patient received 680 cGy (rad) per fraction for five fractions of MammoSite therapy instead of the prescribed 340 cGy (rad) per fraction for 10 fractions. However, the total prescribed dose of 3,400 cGy (rad) was administered. The licensee was using a Nucletron Corporation HDR (model microselectron, serial #31472) and an Ir-192 source (MFG QSA Global, model 105.002, serial #D36A-9791) that contained an activity of 219.78 GBq (5.94 Ci). This event occurred when the physician entered the wrong planning film magnification into the treatment system, which doubled the fractional dose. The patient was informed of the error on 9/27/2006. Although some tissue necrosis at the treatment site is expected with MammoSite therapy, the necrosis may have been exacerbated by the administered dosage scheme. The patient is being followed by her attending physician. The licensee has developed an extensive revision to the HDR Program. Effectiveness of the revisions will be evaluated by the State Agency in subsequent inspections.

Event Date:	**Discovery Date:**	**Report Date:**
09/27/2006	09/27/2006	02/26/2007

Licensee/Reporting Party Information:

License Number: OH-02120780000 Name: AKRON GENERAL MEDICAL CENTER

Docket Number: NA City: AKRON, OH

Site of Event:

Site Name: AKRON, OH

Reference Documents:

Reference Document Number:	Entry Date:	Retraction Date:	Type of Report:
EN43192	03/01/2007		EVENT NOTIFICATION REPORTED FROM AN AGREEMENT STATE
LTR070711	07/11/2007		AGREEMENT STATE LETTER

10 CFR 35.600 **HDR Mammosite**
NMED Item Number: 070403

Narrative: **Last Updated:** 09/17/2007

The licensee reported that a patient undergoing a mammosite HDR treatment received a dose that was 41.2% greater than prescribed. The licensee was using a Nucletron HDR unit (model V2, serial #31710) and an Ir-192 source (serial #D36B-0409) with an activity of 233.1 GBq (6.3 Ci). The treatment was halted and the patient was informed. The patient received an additional 350 cGy/day (rad/day) for four days, resulting in a total additional dose of 1,400 cGy (rad). The total prescribed dose for the four fractions was 3,400 cGy (rad) and the patient received 4,800 cGy (rad). The cause of the incident was determined to be human error. The treatment plan was incorrectly entered into the computer. Corrective actions taken by the licensee included the use of hand written QA checklists that must be filled out independently by the technologist, physicist, and attending physician prior to treatment. The licensee also developed an HDR prescription and dose tracking worksheet that must be filled out by the physician and updated after each treatment. In addition, the licensee updated the computer software to include typical doses for each HDR treatment plan. If the treatment dose entered into the computer is not within the typical dose range for that treatment type, the software questions the individual entering the data.

Event Date:	**Discovery Date:**	**Report Date:**
06/29/2007	06/29/2007	06/29/2007

Licensee/Reporting Party Information:

License Number:	LA-1121-L01	Name:	CHRISTUS SAINT FRANCIS CABRINI HOSPITAL
Docket Number:	NA	City:	ALEXANDRIA

Site of Event:

Site Name: ALEXANDRIA, LA

10 CFR35.600 **HDR Mammosite**

NMED Item Number: 070180

Narrative: **Last Updated:** 05/24/2007

The licensee (dba California Surgery Center) reported that a patient receiving mammosite treatment with a total prescribed dose of 3,400 cGy (rad) to be delivered in 10 fractions over the course of five days, only received 1,700 cGy (rad). The treatment was performed using a Nucletron high dose rate brachytherapy unit (model 105.999, serial #31703) and an Ir-192 source (serial #D36B-0632) with an activity of 151.7 GBq (4.1 Ci). The first five fractions were delivered uneventfully. During the last five fractions, the radiation therapy technologist accidentally imported the wrong treatment plan, resulting in an underdose to the treatment area. The dwell position of the source was actually fully outside of the patient, so the tumor received effectively no dose. The licensee is calculating the skin and whole body dose to the patient. The patient and referring physician were notified and re-treatment was scheduled. The incident was discovered upon review of the patient's chart when the patient returned for a follow-up exam. Corrective actions taken by the licensee included transferring all patient plans from the planning computer to the treatment control computer using a patient and date specific optical disk, verification and documentation of the dwell times and dwell positions for each mammosite fraction in writing by the treating therapist on a patient specific QA sheet prior to each fraction, and providing mandatory additional training to all clinical staff involved in HDR treatments including procedure review and treatment planning review for physics/dosimetry.

Event Date:	**Discovery Date:**	**Report Date:**
03/19/2007	03/26/2007	03/27/2007

Licensee/Reporting Party Information:

License Number:	CA-6833-15	Name:	RAVI PATEL, MD, INC.
Docket Number:	NA	City:	BAKERSFIELD

Site of Event:
Site Name: BAKERSFIELD, CA

Reference Documents:

Reference Document Number:	Entry Date:	Retraction Date:	Type of Report:
CA-XCA1088	04/02/2007		AGREEMENT STATE EVENT REPORT
EN43258	04/02/2007		EVENT NOTIFICATION REPORTED FROM AN AGREEMENT STATE
LTR070427	05/02/2007		AGREEMENT STATE LETTER
LTR070523	05/24/2007		AGREEMENT STATE LETTER

10 CFR35.600 **Gamma Knife**

NMED Item Number: 070157

Narrative: **Last Updated:** 07/12/2007

The licensee reported that a patient received a dose that was 20% less than prescribed during a gamma knife treatment. The gamma knife (Leksell Gamma System model 24001) was manufacturer by Elekta Instrument AB and contained 201 Co-60 sources with an activity of between 244.16 and 267.73 TBq (6,599 and 7,236 Ci). The treatment dose was prescribed as "40% of maximum dose equivalent equals 1,100 cGy (rad)," but was calculated as "50% of maximum dose equivalent equals 1,100 cGy (rad)". This event was discovered during a quality review by licensee staff. The Florida Bureau of Radiation Control determined this to be a medical event. Corrective actions taken by the licensee included adding a step to the gamma knife treatment plan for dose verification.

Event Date:	**Discovery Date:**	**Report Date:**
01/23/2007	03/03/2007	03/19/2007

Licensee/Reporting Party Information:

License Number:	FL-3823-2	Name:	DOCTORS HOSPITAL
Docket Number:	NA	City:	CORAL GABLES

Site of Event:
Site Name: CORAL GABLES, FL

Reference Documents:

Reference Document Number:	Entry Date:	Retraction Date:	Type of Report:
EN43252	03/21/2007		EVENT NOTIFICATION REPORTED FROM AN AGREEMENT STATE
LTR070611	06/11/2007		AGREEMENT STATE LETTER
FL07-046	07/12/2007		AGREEMENT STATE EVENT REPORT

10 CFR 35.600 **Gamma Knife**

NMED Item Number: 060716 **Last Updated:** 12/20/2006

Narrative:
The licensee reported that a patient prescribed to receive 18 Gy (1,800 rad) during a gamma knife treatment actually received 28 Gy (2,800 rad). The gamma knife (Elekta, Leksell model 24001 Type C) contained 267.7 TBq (7,236 Ci) of Co-60. The cause of the incident was determined to be human error. The prescribing physician, apparently in a hurry to leave for the day, had prescribed 18 Gy (1,800 rad). The physician then entered the prescribed value into the computer treatment plan rather than having the medical physicist do it as is the usual procedure. The physician erroneously entered 28 Gy (2,800 rad). The patient and referring physician were notified of the incident. Corrective actions taken by the licensee included a verification process to ensure the prescribed treatment value is transferred from the treatment planning computer to the gamma knife computer prior to patient therapy. A treatment plan signed by the treating oncologist, physicist, and neurosurgeon is now required. In addition, the treating oncologist and physicist will verify and initial the prescribed dose and isodose.

Event Date:	**Discovery Date:**	**Report Date:**
11/16/2006	11/16/2006	11/22/2006

Licensee/Reporting Party Information:
License Number: WA-WN-M0219-1 Name: UNIVERSITY OF WASHINGTON HARBORVIEW GAMMA KNIFE
Docket Number: NA City: SEATTLE

Site of Event:
Site Name: SEATTLE, WA

Reference Document Number:	Entry Date:	Retraction Date:	Type of Report:
WA-06-066	11/28/2006		AGREEMENT STATE EVENT REPORT
EN43008	11/28/2006		EVENT NOTIFICATION REPORTED FROM AN AGREEMENT STATE
WA-06-066A	12/12/2006		AGREEMENT STATE EVENT REPORT
WA-06-066B	12/20/2006		AGREEMENT STATE EVENT REPORT

10 CFR35.1000 **Y-90 Sir**

NMED Item Number: 070152

Narrative: **Last Updated:** 05/09/2007

The licensee reported that a patient received only 66% of a prescribed administration of 1.11 GBq (30 mCi) of Y-90 Sirtex Medical SIR-Spheres. The delivery catheter developed a leak around the c-line collar of the delivery set during administration. The authorized user unsuccessfully attempted to seal the leak. Leakage was contained within the plexiglas box containing the vial of microspheres. There was minimal contamination outside of the box. The licensee performed Bremsstrahlung measurements of the patient and the plexiglas box. Based on the differences, the administered dose was determined to be 66% of the prescribed dose. The licensee noted that this was the first of a two-part administration of the microspheres and the dose at the next treatment was adjusted to compensate for the difference. The incident was reported to the manufacturer. The problem with this delivery set lot number was known to the licensee. A new lot number was shipped to the licensee. The authorized user suspended these procedures until the new delivery systems were obtained and tested to verify satisfactory flow with no leakage. The device manufacturer traced the leaky units to one operator who had deviated from the normal assembly procedure. Sirtex destroyed the remainder of that lot number (batch #63000) and replaced them with a new, tested lot. Retraining was undertaken by all staff and increased inspections were carried out by Sirtex.

Event Date:	**Discovery Date:**	**Report Date:**
01/31/2007	01/31/2007	02/02/2007

Licensee/Reporting Party Information:

License Number:	NC-060-0014-3	Name:	CAROLINAS MEDICAL CENTER
Docket Number:	NA	City:	CHARLOTTE

Site of Event:
Site Name: CHARLOTTE, NC

Reference Documents:

Reference Document Number:	Entry Date:	Retraction Date:	Type of Report:
NC070002	03/20/2007		AGREEMENT STATE EVENT REPORT
EN43336	05/08/2007		EVENT NOTIFICATION REPORTED FROM AN AGREEMENT STATE
NC070002A	05/09/2007		AGREEMENT STATE EVENT REPORT

10 CFR 35.1000 **Y-90 Sir**

NMED Item Number: 070439 **Last Updated:** 09/06/2007

Narrative:
The licensee reported an inadvertent dose to a patient's gallbladder during a Y-90 SIR-Sphere procedure to treat liver carcinoma. The licensee administered 1 GBq (27.3 mCi) to the patient intending to deliver 26.1 Gy (2610 rad) to the carcinoma on the patient's liver. After review of the CT images on 7/12/2007, the physicist believes that 20% of the dose went to the gallbladder. The doctor and patient were notified on 7/12/2007. The licensee will follow up with the patient in future visits to determine if there is gallbladder damage. The Florida Department of Health investigated the incident and found no violations that caused the incident.

Event Date:	**Discovery Date:**	**Report Date:**
07/11/2007	07/12/2007	07/13/2007

Licensee/Reporting Party Information:

License Number:	FL-0031-1	Name:	UNIVERSITY OF FLORIDA SHANDS HOSPITAL
Docket Number:	NA	City:	GAINSVILLE

Site of Event:
Site Name: GAINSVILLE, FL

Reference Documents:

Reference Document Number:	Entry Date:	Retraction Date:	Type of Report:
EN43491	07/19/2007		AGREEMENT STATE EVENT REPORT
FL07-109	09/06/2007		AGREEMENT STATE EVENT REPORT

10 CFR 35.1000 **Y-90 Thera**
NMED Item Number: 070235

Narrative: **Last Updated:** 06/05/2007
The licensee reported that a patient undergoing Y-90 therasphere treatment of the liver received 5,440 cGy (rad) to the right lobe instead of the prescribed 12,000 cGy (rad). The patient received 3.28 GBq (88.65 mCi). The authorized user confirmed the setup was correct when queried during the pre-administration checklist. However, the stopcock was turned so that the dose was directed to the waste vial rather than into the patient delivery catheter. During administration, the interventional radiologist noted liquid in the waste vial tubing and directed the authorized user to stop treatment. The authorized user re-checked the delivery system and corrected the stopcock orientation. The remainder of the dose was delivered to the patient. The patient and referring physician were notified of the incident. Corrective action taken to prevent recurrence included requiring a second individual to check the delivery setup portion in addition to the individual actually delivering the dose. That second check was incorporated into the checklist.

Event Date:	**Discovery Date:**	**Report Date:**
04/18/2007	04/18/2007	04/18/2007

Licensee/Reporting Party Information:

License Number:	13-06009-01	Name:	COMMUNITY HOSPITALS OF INDIANA
Docket Number:	03001625	City:	INDIANAPOLIS

Site of Event:
Site Name: INDIANAPOLIS, IN

Reference Documents:

Reference Document Number:	Entry Date:	Retraction Date:	Type of Report:
EN43308	04/20/2007		EVENT NOTIFICATION
ML071430165	05/31/2007		INSPECTION REPORT
ML071430165	05/31/2007		NOTICE OF VIOLATION
ML071430165	05/31/2007		NRC LETTER
LTR070604	06/05/2007		NRC LETTER

10 CFR 35.1000 **Y-90 Thera**

NMED Item Number: 070270

Narrative: **Last Updated:** 06/12/2007

The licensee reported that a patient prescribed to receive 836.2 MBq (22.6 mCi) of Y-90 microspheres only received 595.7 MBq (16.1 mCi), which resulted in a 29% underdose. An MDS Nordion TheraSphere delivery system was being used to deliver the microspheres to the patient when a leak developed in the system. The licensee stated that the leak was caused by personnel error when assembling the administration set. They believe that the catheter was either screwed on too tight or not tight enough. The leak was not related to any manufacturing defect. Attempts to notify the patient have been made, but have not been successful. The patient's referring physician and the authorized user believe that the dose received was sufficient and are not planning a make-up administration. Corrective actions taken by the licensee included reviewing procedures.

Event Date:	**Discovery Date:**	**Report Date:**
04/20/2007	04/20/2007	04/23/2007

Licensee/Reporting Party Information:

License Number:	NC-068-0565-1	Name:	NORTH CAROLINA, UNIVERSITY OF, HOSPITAL
Docket Number:	NA	City:	CHAPEL HILL

Site of Event:

Site Name: CHAPEL HILL State: NC

Reference Documents:

Reference Document Number:	Entry Date:	Retraction Date:	Type of Report:
NC070020	05/03/2007		AGREEMENT STATE EVENT REPORT
LTR070503	05/03/2007		AGREEMENT STATE LETTER
EN43325	05/03/2007		EVENT NOTIFICATION REPORTED FROM AN AGREEMENT STATE
NC070020A	06/12/2007		AGREEMENT STATE EVENT REPORT

10 CFR 35.1000 **Y-90 Thera**

NMED Item Number: 070620

Narrative:

Last Updated: 10/11/2007

The University of North Carolina Hospital reported that a patient administered Y-90 microspheres for liver cancer received a 29% underdose on 9/13/2007. An MDS Nordion TheraSphere delivery system was being used to deliver the microspheres to the patient. The licensee stated that there was no equipment malfunction and no leakage of radioactive material. The patient was notified of the incident and there are no plans to perform a second administration. The cause was determined to be a failure to verify that the entire dose was administered. Corrective actions taken by the licensee included reviewing the procedure.

Event Date:	**Discovery Date:**	**Report Date:**
09/13/2007	09/13/2007	09/14/2007

Licensee/Reporting Party Information:

License Number: NC-068-0565-1 Name: NORTH CAROLINA, UNIVERSITY OF, HOSPITAL

Docket Number: NA City: CHAPEL HILL, NC

Site of Event:

Site Name: CHAPEL HILL, NC

Reference Documents:

Reference Document Number:	Entry Date:	Retraction Date:	Type of Report:
NC070048	10/11/2007		AGREEMENT STATE EVENT REPORT

10 CFR 35.1000 **Y-90 Thera**

NMED Item Number: 070350

Narrative: **Last Updated:** 09/10/2007

The licensee reported that a patient was prescribed by an authorized user's written directive to receive a Y-90 TheraSphere procedure of 1.05 GBq (28.3 mCi), but only received about 88.8 MBq (2.4 mCi). The patient was prescribed to receive 12,300 cGy (rad) to the tumor, but the RSO estimated that only about 700 cGy (rad) or 6% of the prescribed dose was received. During the procedure, the RSO was monitoring the radiation exposure rate in the room and did not observe the expected rise in the rate as the TheraSpheres enter the catheter and then the patient. The injection was stopped to evaluate the problem. The authorized user and RSO noticed that the blue stopcock was in the wrong position, directing the TheraSpheres into the waste vial and not into the patient. A radiation survey revealed that most of the radioactivity was in the waste vial and very little in the patient. Following the procedure, the activity in the waste vial was measured in a dose calibrator and revealed 0.96 GBq (25.9 mCi). The patient will be scheduled for re-treatment in the next few weeks. The licensee revised their TheraSphere checklist and retrained personnel.

Event Date:	**Discovery Date:**	**Report Date:**
05/31/2007	05/31/2007	05/31/2007

Licensee/Reporting Party Information:

License Number:	WI-079-1281-01	Name:	AURORA SAINT LUKE'S MEDICAL CENTER
Docket Number:	NA	City:	MILWAUKEE

Site of Event:
Site Name: MILWAUKEE, WI

Reference Documents:

Reference Document Number:	Entry Date:	Retraction Date:	Type of Report:
EN43398	06/06/2007		EVENT NOTIFICATION REPORTED FROM AN AGREEMENT STATE
WI070011	07/09/2007		AGREEMENT STATE EVENT REPORT
WI070011A	09/10/2007		AGREEMENT STATE EVENT REPORT

10 CFR 35.1000 **Y-90 Thera**

NMED Item Number: 070384

Narrative: **Last Updated:** 06/26/2007

The licensee reported that a patient was prescribed to receive 2.45 GBq (66.2 mCi) of Y-90 TheraSpheres for treatment of the liver, which would result in a delivered dose of approximately 11,000 cGy (rad). Only 1.74 GBq (47 mCi) was received from MDS Nordion and used for the treatment, resulting in approximately 8,000 cGy (rad) delivered to the liver. Calculation errors may have contributed to the under treatment. The licensee was concerned not to exceed a lung dose of 1,500 cGy (rad), which was achieved due to the treatment dose at the low end of the optimal range. The physician was notified and will consult the patient to decide if additional treatment is needed. The INL has requested additional information for this event.

Event Date:	**Discovery Date:**	**Report Date:**
06/18/2007	06/18/2007	06/20/2007

Licensee/Reporting Party Information:

License Number:	OR-90013	Name:	OREGON HEALTH SCIENCES UNIVERSITY
Docket Number:	NA	City:	PORTLAND

Site of Event:
Site Name: PORTLAND, OR

Reference Documents:

Reference Document Number:	Entry Date:	Retraction Date:	Type of Report:
EN43434	06/26/2007		EVENT NOTIFICATION REPORTED FROM AN AGREEMENT STATE

10 CFR 35.1000 **Y-90 Thera**

NMED Item Number: 070574 **Last Updated:** 09/17/2007

Narrative:
The licensee reported that a patient only received 1.74 GBq (47 mCi) of Y-90 during treatment of liver cancer instead of the prescribed 2.44 GBq (66 mCi). The treatment device was manufactured by MDS Nordion and an MDS Nordion representative was on site during the administration. The licensee is investigating the cause of the misadministration, but they believe the catheter used for the administration failed/leaked. The MDS Nordion representative will provide technical assistance in troubleshooting the problem. The physicians have been informed and they need to notify the patient.

Event Date:	**Discovery Date:**	**Report Date:**
09/10/2007	09/10/2007	09/11/2007

Licensee/Reporting Party Information:
License Number: 13-02752-03 Name: INDIANA UNIVERSITY MEDICAL CENTER
Docket Number: 03001609 City: INDIANAPOLIS

Site of Event:
Site Name: INDIANAPOLIS, IN

Reference Documents:

Reference Document Number:	Entry Date:	Retraction Date:	Type of Report:
EN43630	09/17/2007		EVENT NOTIFICATION

Non-Reportable

10 CFR35 **NARM**

NMED Item Number: 070101

Narrative: **Last Updated:** 02/26/2007

The licensee reported that a patient was administered a diagnostic dose of 1.11 MBq (30 uCi) of I-123 instead of the prescribed I-131 scan. The patient had no thyroid. The licensee counseled and disciplined the involved technologist. The licensee will review their medical directive for verification.

Event Date:	**Discovery Date:**	**Report Date:**
10/06/2006	10/06/2006	10/20/2006

Licensee/Reporting Party Information:

License Number: FL-3157-1 Name: SHANDS JACKSONVILLE MEDICAL CENTER, INC.

Docket Number: NA City: JACKSONVILLE

Site of Event:

Site Name: JACKSONVILLE, FL

Reference Documents:

Reference Document Number:	Entry Date:	Retraction Date:	Type of Report:
FL06-130	02/26/2007		AGREEMENT STATE EVENT REPORT

10 CFR35 **NARM**

NMED Item Number: 070138

Narrative: **Last Updated:** 03/15/2007

The licensee reported that a patient received 24% less than prescribed during treatment. A review of the event by the licensee and the State determined that the material involved (Pd-103) was accelerator produced and is not regulated by the NRC. Therefore, the incident is not reportable and was retracted on 3/14/2007.

Event Date:	**Discovery Date:**	**Report Date:**
11/01/2006	03/05/2007	03/05/2007

Licensee/Reporting Party Information:

License Number:	OR-90014	Name:	EMANUEL HOSPITAL
Docket Number:	NA	City:	PORTLAND

Site of Event:

Site Name: PORTLAND, OR

Reference Documents:

Reference Document Number:	Entry Date:	Retraction Date:	Type of Report:
EN43214	03/12/2007	3/14/2007	EVENT NOTIFICATION

REPORTED FROM AN AGREEMENT STATE

10 CFR 35.400 **Patient Intervention**

NMED Item Number: 070081

Narrative: **Last Updated:** 04/30/2007

The licensee reported that a 59-year-old female patient being treated for cervical cancer received 844.5 cGy (rad) to the intended area instead of the prescribed dose of 2046.5 cGy (rad). The planned dose was to be administered over a 39-hour time period using a low dose rate (LDR) Nucletron selectron afterloader and nine Cs-137 sources, each with an activity of 0.62 GBq (16.7 mCi). The procedure went as planned for the first 16.09 hours, but on 2/6/2007 between 0630 and 0717 EST, the patient pulled the applicator out approximately 4 cm. The licensee calculated the dose to the incorrect vaginal sites due to the displacement of the sources. If the full dose had been delivered as prescribed, the upper vagina would have received 2926.56 cGy (rad), but actually received 1225 cGy (rad). Likewise, the lower vagina would have received 465 cGy (rad), but actually received 267 cGy (rad). The patient and the patient's doctor were notified of the event and the patient refused further treatment. This event was determined to not be a reportable medical event due to patient intervention.

Event Date:	**Discovery Date:**	**Report Date:**
02/06/2007	02/06/2007	02/06/2007

Licensee/Reporting Party Information:

License Number: 06-00854-03 Name: SAINT FRANCIS HOSPITAL & MEDICAL CENTER
Docket Number: 03001246 City: HARTFORD

Site of Event:

Site Name: HARTFORD, CT

Reference Documents:

Reference Document Number:	Entry Date:	Retraction Date:	Type of Report:
EN43147	02/12/2007	3/7/2007	EVENT NOTIFICATION
LTR070305	03/05/2007		NRC LETTER
ML071010378	04/30/2007		LICENSEE REPORT
ML071010378	04/30/2007		REGION REPORT

10CFR 35.400 **Retracted**

NMED Item Number: 070174

Narrative: **Last Updated:** 03/29/2007

The licensee reported that a patient received I-125 seed implants for treatment of prostate cancer and the resulting dose that was 6.9% greater than intended. The prescribed dose for the treatment was 14,500 cGy (rad) and the given dose was 15,500 cGy (rad). It was determined that the wrong units were entered into the dose planning computer. The incident was retracted on 3/28/2007, based on the fact that the given dose was below the reporting criteria.

Event Date:	**Discovery Date:**	**Report Date:**
03/23/2007	03/23/2007	03/23/2007

Licensee/Reporting Party Information:

License Number:	37-11866-01	Name:	LANCASTER GENERAL HOSPITAL
Docket Number:	03003151	City:	LANCASTER

Site of Event:
Site Name: LANCASTER, PA

Reference Documents:

Reference Document Number:	Entry Date:	Retraction Date:	Type of Report:
EN43256	03/29/2007	3/28/2007	EVENT NOTIFICATION

10 CFR 35.1000 **Y-90 Sir**

NMED Item Number: 060688 **Last Updated:** 01/26/2007

Narrative:
The licensee reported that a patient receiving treatment for liver cancer using Y-90 microspheres was administered 0.24 GBq (6.5 mCi) instead of the prescribed 0.36 GBq (9.8 mCi). This resulted in the patient receiving 5,900 cGy (rad) to the left lobe of the liver rather than 10,000 cGy (rad). The licensee was using Y-90 SirTex Sirspheres and an intrahepatic catheter. Approximately half-way through the administration, the physician temporarily halted the procedure in order to flush the catheter and to verify positioning of the administered microspheres using angiography. As the physician attempted to inject the contrast media for the angiography, he noted resistance and slow flow, indicating that the patient's vasculature within the tumor could not accommodate additional microspheres. The physician elected to terminate the procedure and revised the written directive. As the physician halted treatment, the remaining microspheres in the delivery device and the catheter appeared to be clumped together. The licensee was unable to determine if the clumping of the microspheres contributed to this event. The licensee sent the delivery device to the manufacturer for examination. This event was retracted on 1/11/2007 after discussions with NRC Region III determined that this event did not meet the criteria for a reportable event because the physician terminated the procedure due to the medical condition of the patient.

Event Date:	**Discovery Date:**	**Report Date:**
11/07/2006	11/07/2006	11/08/2006

Licensee/Reporting Party Information:
License Number: 21-01333-01 Name: WILLIAM BEAUMONT HOSPITAL
Docket Number: 03002006 City: ROYAL OAK

Site of Event:
Site Name: ROYAL OAK, MI

Reference Documents:

Reference Document Number:	Entry Date:	Retraction Date:	Type of Report:
EN42975	11/13/2006	1/11/2007	EVENT NOTIFICATION
ML063250105	12/05/2006		LICENSEE REPORT
LTR070116	01/18/2007		NRC LETTER
ML070160316	01/26/2007		INSPECTION REPORT
ML070160142	01/26/2007		NRC LETTER

For information only – Linear Accelerator

NMED Item Number: 070372

Narrative:

Last Updated: 07/09/2007

The Toulouse University (dba Rangueil Hospital) reported a deviation between the delivered dose and the prescribed dose to 145 patients treated by stereotactic radiosurgery using a linear accelerator from 4/6/2006 to 4/17/2007. The manufacturer (BrainLAB AG) discovered a deviation concerning the beam calibration. ANS confirmed the deviations during a reactive inspection performed on 5/3/2007, which revealed that an inadequate beam calibration tool was used. An epidemiological survey will be organized to follow-up with the patients.

Event Date:	**Discovery Date:**	**Report Date:**
04/06/2006	04/17/2007	06/18/2007

Licensee/Reporting Party Information:

License Number: NON-LICENSEE Name: TOULOUSE UNIVERSITY
Docket Number: NA City: TOULOUSE, FR

Site of Event:

Site Name: TOULOUSE, FR

Reference Documents:

Reference Document Number:	Entry Date:	Retraction Date:	Type of Report:
LTR070620	06/20/2007		NRC LETTER
LTR070709	07/09/2007		NRC LETTER

For information only – Linear Accelerator

NMED Item Number: 070373

Narrative: **Last Updated:** 06/27/2007

A mechanical component/software incompatibility caused by using a combination of the BrainLAB target positioner (model 40700-3A) for Leksell headrings and BrainLAB planning software resulted in a 1.25 mm shift in target area alignment during radiosurgery treatment. Two hospitals in the USA were performing radiosurgery using the specified equipment configuration. The treatment is linear accelerator-based and is not regulated by the NRC. Upon confirmation of the cause, BrainLAB immediately notified all customers. Notification was received by the FDA and the two United States customers on 6/5/2007. It was concluded that there would be minimal risk of adverse effects because the target area alignment falls within the calculated safety margin used in treatments.

Event Date:	Discovery Date:	Report Date:
06/08/2007	06/08/2007	06/18/2007

Licensee/Reporting Party Information:

License Number:	NON-LICENSEE	Name:	BRAINLAB
Docket Number:	NA	City:	MUNICH

Site of Event:

Site Name: MUNICH , GE

Reference Documents:

Reference Document Number:	Entry Date:	Retraction Date:	Type of Report:
LTR070620	06/20/2007		NRC LETTER
LTR070625	06/27/2007		NRC LETTER

MEDICAL RADIOACTIVE MATERIAL EVENTS

Ralph P. Lieto, MSE
ACMUI Member
ACMUI Meeting, Oct. 23, 2007

Other Medical Radioactive Material Events

- Nuclear Materials Event Database (NMED)
  - FY 2007 (10/1/2006-10/1/2007)
  - Medical Events (patient) - 41?
  - Other reportable, medical use related Material Events – 26

Other Medical Radioactive Material Events

- Categories
  - Lost sources – sealed & unsealed
  - Leaking sealed sources
  - Landfill Alarms
    - DIS waste or unknown origin
    - Released patient (10 CFR 35.75) waste
  - Miscellaneous

Lost Sources - Sealed & Unsealed

1. Two shipments of Cs-131 seeds damaged by airport handling equipment. Only 3 of 63 seeds in one package recovered; second package – all seeds present & intact.
2. Cs-137 brachytherapy source lost after removed from patient; found in hospital laundry.
3. I-125 seed shipment (153 seeds/ 138 mCi) lost at Chicago airport; found 4 days later at Boston airport.
4. Radiopharmacy vehicle carjacked (540 mCi Tc-99m agents); found 4 days later with all containers intact.

Lost Sources - Sealed & Unsealed

5. Mo-99/Tc-99m generator (6 Ci) reported stolen from courier delivery vehicle at airport. Actually fell out of courier's vehicle during transit. Observing citizen picked up & took to local police after unsuccessful in contacting courier.
6. Three nuclear medicine quality control sealed sources (Cs-137, Co-57 < 0.2 mCi total) left abandoned in locked hospital x-ray room cabinet.
7. Lost one I-125 seed (0.13 mCi) after temporary implant from breast tumor localization.
8. 101 Pd-103 seeds (132 mCi) stolen from licensee transport vehicle.

Lost Sources - Sealed & Unsealed

9. Delivery container with Tc-99m (120 mCi) fell out of unsecured hatch of radiopharmacy delivery truck. Found intact 6 weeks later.
10. Six containers of Tc-99m agents (1.775 Ci) stolen from parked radiopharmacy vehicle during delivery.
11. Lost one I-125 seed left over from prostate implant.
12. Temporary loss of Ir-192 HDR source (6 Ci) at source vendor's facility.

Lost Sources - Sealed & Unsealed

13. Radiopharmacy delivery vehicle accident resulted in 18 containers being ejected. 1 container of F-18 (271 mCi) unrecovered from water.
14. Lost two I-125 seeds (0.68 mCi) during sterilization prior to implant.
15. Lost one I-125 seed left over from prostate implant.

Leaking Sealed Sources

- Two reports from same licensee: I-125 brachytherapy seed container wipe tested after sources removed & found contaminated. Therapies postponed. All sources returned to manufacturer. In one case, faulty weld found in one seed.

Landfill Alarms

- Six event reports
  - ➢3 events – Waste origin unknown
  - ➢2 events - Improper disposal of medical LLRW
  - ➢1 report involved residential waste from released patient (10 CFR 35.75)
- All involved I-131
- All events reported from 3 Agreement States (CA, FL, GA)

Miscellaneous

- Co-60 teletherapy machine source failed to retract to shielded position. Operator emergency intervention returned source into shield without medical event.
- 15 mCi NaI I-131 administered to woman 13-15 weeks pregnant. Fetal dose estimate: 5 cGy whole body; 13900 cGy thyroid. Categorized as Abnormal Occurrence.

Miscellaneous

- 19 persons given F-18 FDG, Tc-99m agents for nondiagnostic purposes – training employees & testing new imaging equipment.
  - ➢15 subjects > 100 mrem whole body limit.

  [F-18: 1.5-1.8 rem; Tc-99m: 0.15-0.46 rem]

Comparison Radioactive Material Events

	FY 2007	FY2006
Lost sources – sealed & unsealed	15	6
Leaking sealed sources	2	5
Landfill Alarms	6	27
Miscellaneous	3	6

Observations

- Search queries yielded different but incomplete results for same endpoint (e.g.,ME)
- Multiple search queries needed capture all(?) reported events involving medical use of RAM.
- NMED improvements
  - Report/query by specific licensee type
  - Search with multiple key words
  - Allow Boolean search criteria for "reportable" criteria of NRC vs. AS because of discrepancy

LOST SOURCES - SEALED & UNSEALED

NMED Item Number: 060630

Narrative: **Last Updated:** 06/12/2007

The licensee reported two damaged shipping packages containing IsoRay Cs-131 cancer therapy seeds (model CS-1). Federal Express discovered a flattened lead cap in their Spokane, Washington, terminal. A partial label on a lead container cap indicated it came from one of two packages containing 63 Cs-131 seeds with a total activity of 12.2 GBq (330 mCi). The second package was found crushed, but essentially intact; all seeds were present and undamaged. Scraps from the first package were found on the runway and on the floor of the tug; dayshift Federal Express staff had placed the damaged packages on the floor on the passenger side of the tug cab. Washington Department of Health (DOH) personnel responded to the scene on 10/4/2006. IsoRay also dispatched a team to the site. DOH personnel were able to recover three of the 63 seeds from the first package. Several areas of radioactive contamination were also found. Measurements on the floor of the tug's passenger side revealed 150 mR/hour with an Eberline RO2 ion chamber. Radiation measurements on the crushed pig lid were about 25 mR/hour. Using a GM instrument, contamination measurements of about 400 cpm were found on the crushed pig lid and 300 cpm on the crushed box. A spot on the tarmac was found reading about 12 mR/hour with an RO2. The undamaged stainless steel pig read about 5 mR/hour. Washington DOH requested that Federal Express management revise their hazardous material transportation handling procedures and provide refresher training to staff. The bottom half of the missing lead container was found by Federal Express on 11/28/2006. It had been pushed by a snow-plow to the rear of the Federal Express building. Federal Express believes that the squashed container had been caught in the loader until it worked its way out. Licensee personnel went to the airport on 11/28/2006 and retrieved the squashed container. No radioactive contamination was discovered. There was no radioactive contamination on the outside of the container although it still contained a number of seeds. A dose rate measurement revealed 35 mR/hour at 3 cm and 0.5 mR/hour at 30 cm. The licensee will perform an autopsy on the container to determine its contents.

Event Date:	Discovery Date:	Report Date:
10/03/2006	10/04/2006	10/04/2006

Licensee/Reporting Party Information:

License Number:	WA-WN-L0213-1	Name:	ISORAY
Docket Number:	NA	City:	RICHLAND, WA

Site of Event:

Site Name: SPOKANE, WA

Reference Documents:

Reference Document Number:	Entry Date:	Retraction Date:	Type of Report:
WA-06-053	10/10/2006		AGREEMENT STATE EVENT REPORT
LTR061005	10/10/2006		AGREEMENT STATE LETTER
EN42876	10/10/2006		EVENT NOTIFICATION REPORTED FROM AN AGREEMENT STATE
WA-06-053A	10/30/2006		AGREEMENT STATE EVENT REPORT
LTR061026	10/30/2006		AGREEMENT STATE LETTER
WA-06-053B	12/19/2006		AGREEMENT STATE EVENT REPORT
DOT2006101227	06/12/2007		OTHER
DOT2006111155	06/12/2007		OTHER

NMED Item Number: 060687

Narrative: **Last Updated:** 05/01/2007

The licensee reported the loss and recovery of a Cs-137 brachytherapy source that contained an activity of 0.56 GBq (15 mCi). Two radiation oncology residents were removing four Cs-137 sources from a patient, whereupon they discovered that one source was not in the ovoid source holder. The patient's bed sheets had been changed and taken out of the room. The source was recovered from the laundry and returned to safe storage. The patient had complained of some irritation on one of her legs. The licensee performed a complete investigation and the patient was followed closely to see if there were any medical consequences resulting from inadvertent exposure. It was

determined that the patient received within 5% of the prescribed dose to the intended site and no other organ or tissue received greater than 50 cGy (rad). The root cause was determined to be inadequate authorized physician supervision. Corrective actions taken by the licensee included a requirement that an authorized user will be present for each source loading, a new protocol for securing soiled sheets in the patient's room, and additional in-service for nursing staff. In addition, better signage will be posted on the two doors to the patient's room, which also reminds personnel that no item may leave the room until released.

Event Date:	Discovery Date:	Report Date:
11/05/2006	11/05/2006	11/05/2006

Licensee/Reporting Party Information:

License Number:	TX-L01303	Name:	BEN TAUB GENERAL HOSPITAL
Docket Number:	NA	City:	HOUSTON, TX

Site of Event:

Site Name: HOUSTON, TX

Reference Documents:

Reference Document Number:	Entry Date:	Retraction Date:	Type of Report:
TX-I-8371	11/13/2006		AGREEMENT STATE EVENT REPORT
EN42965	11/13/2006		EVENT NOTIFICATION REPORTED FROM AN AGREEMENT STATE
LTR070216	02/19/2007		AGREEMENT STATE LETTER
LTR070426	05/01/2007		AGREEMENT STATE LETTER

NMED Item Number: 060695

Narrative:

Last Updated: 02/12/2007

The licensee reported the loss and recovery of an overpack that contained two lead pigs holding I-125 brachytherapy seeds (model STM 1251). One lead pig contained 73 seeds with a total activity of 2.44 GBq (66 mCi) and the other pig contained 80 seeds with a total activity of 2.66 GBq (72 mCi). Milton Hospital contacted the licensee and stated that the package never arrived at their facility. The package had been picked up by Airnet for overnight delivery. Using the company's package tracking system, it was determined that the shipment had been transferred from Airnet to American Airlines at the O'Hare Airport Air Freight Hub in Chicago, Illinois. However, no record of the shipment's departure existed. Physical searches of the airport facility did not locate the shipment. The overpack was located at the airport in Boston, Massachusetts. The package was intact and was returned to the licensee. The licensee confirmed receipt on 11/13/2006.

Event Date:	Discovery Date:	Report Date:
11/09/2006	11/10/2006	11/10/2006

Licensee/Reporting Party Information:

License Number:	IL-02062-01	Name:	BARD BRACHYTHERAPY
Docket Number:	NA	City:	CAROL STREAM, IL

Site of Event:

Site Name: BOSTON, MA

Reference Documents:

Reference Document Number:	Entry Date:	Retraction Date:	Type of Report:
EN42984	11/15/2006		EVENT NOTIFICATION REPORTED FROM AN

IL060058 02/12/2007 AGREEMENT STATE
AGREEMENT STATE EVENT REPORT

NMED Item Number: 060709

Narrative: **Last Updated:** 01/30/2007

The licensee reported the theft and recovery of a radiopharmaceutical delivery vehicle that contained approximately 19.98 GBq (540 mCi) of Tc-99m. The vehicle was delivering radiopharmaceuticals to area hospitals and clinics and was car-jacked at a gas station located in Jackson, Mississippi. The Mississippi Department of Radiation Health notified the Flowood and Jackson police departments, the Mississippi Emergency Management Agency, and the FBI. The vehicle was recovered by the Jackson Police Department on 11/20/2006. The ammo boxes containing the Tc-99m were not tampered with (security seals were still attached) and all radioactive material was recovered. No corrective actions were taken for this incident. The State of Mississippi is tracking the incident as report number MS06014.

Event Date:	Discovery Date:	Report Date:
11/16/2006	11/16/2006	11/17/2006

Licensee/Reporting Party Information:

License Number:	MS-493-01	Name:	CARDINAL HEALTH
Docket Number:	NA	City:	FLOWOOD, MS

Site of Event:

Site Name: JACKSON, MS

Reference Documents:

Reference Document Number:	Entry Date:	Retraction Date:	Type of Report:
EN42999	11/27/2006		EVENT NOTIFICATION REPORTED FROM AN AGREEMENT STATE
LTR070125	01/30/2007		AGREEMENT STATE LETTER

NMED Item Number: 070027

Narrative: **Last Updated:** 06/12/2007

The Wisconsin Radiation Protection Section reported the loss and recovery of a radioactive material package containing 222 GBq (6 Ci) of Mo-99 (Tc-99m generator). The package was being transported by Tradewind Enterprises, Incorporated, and was initially reported to the National Response Center as being stolen from the carrier's vehicle at the Milwaukee, Wisconsin, airport. However, it was later determined that a private citizen observed the package fall from the carrier's vehicle while it was enroute to the Froedtert Hospital in Milwaukee. The package was a Type A box with Yellow II labels. The private citizen tried to contact the carrier company identified on the shipping label, but it was the weekend and no one was at the facility. The citizen took the package to the local police. The police subsequently took the package to Froedtert Hospital. The hospital evaluated the package and determined there was no damage and no contamination. The licensee no longer uses the carrier company involved in the incident.

Event Date:	Discovery Date:	Report Date:
01/14/2007	01/14/2007	01/14/2007

Licensee/Reporting Party Information:

License Number:	MA-60-0088	Name:	BRISTOL-MYERS SQUIBB MEDICAL IMAGING
Docket Number:	NA	City:	NORTH BILLERICA, MA

Site of Event:
Site Name: MILWAUKEE, WI

Reference Documents:

Reference Document Number:	Entry Date:	Retraction Date:	Type of Report:
EN43099	01/15/2007		EVENT NOTIFICATION REPORTED FROM AN AGREEMENT STATE
EN43105	01/23/2007		EVENT NOTIFICATION REPORTED FROM AN AGREEMENT STATE
WI070004	02/01/2007		AGREEMENT STATE EVENT REPORT
LTR070124	02/01/2007		AGREEMENT STATE LETTER
LTR070313	03/19/2007		AGREEMENT STATE LETTER
WI070004A	05/03/2007		AGREEMENT STATE EVENT REPORT
DOT2007020655	06/12/2007		OTHER

NMED Item Number: 070094

Narrative: **Last Updated:** 05/15/2007

Vista Hospital reported finding several radioactive sources in an x-ray room cabinet. The room had not been used for at least a year. A California Department of Health Services (DHS) inspector responded to the site on 2/8/2007. The inspector found three sources in an ammo can locked in a cabinet. The sources included a Cs-137 vial source (New England Nuclear model NES-356, serial #3561281A-22) with an activity of 4.29 MBq (116 uCi), a Cs-137 button source with an activity of 0.37 MBq (10 uCi), and a Co-57 vial source (CIS model CO-57-EGAG90) at background. Each of the sources were wipe tested for removable radioactivity and none was detected. The sources were each placed in their respective lead pigs and then placed in an ammo box. Radiation measurements on the outside of the ammo box revealed 2.5 mR/hour. The DHS attempted to locate the owner of the sources. The manufacturer (now Perkin-Elmer) was contacted, but because of the age of the source they did not have records of the original purchaser. The DHS could not locate the individual(s) responsible for abandoning the sources at Vista Hospital. The Los Angeles County Radiation Management took possession of the sources and will transfer them to the State storage facility pending disposal by a licensed broker.

Event Date:	**Discovery Date:**	**Report Date:**
01/01/2007	01/02/2007	02/07/2007

Licensee/Reporting Party Information:
License Number: NR Name: NR
Docket Number: NA City: NR, CA

Site of Event:
Site Name: BALDWIN PARK, CA

Reference Documents:

Reference Document Number:	Entry Date:	Retraction Date:	Type of Report:
CA-XCA1066	02/19/2007		AGREEMENT STATE EVENT REPORT
LTR070314	03/19/2007		AGREEMENT STATE LETTER
LTR070323	03/26/2007		AGREEMENT STATE LETTER
LTR070411	04/18/2007		AGREEMENT STATE LETTER
LTR070511	05/15/2007		AGREEMENT STATE LETTER

NMED Item Number: 070179

Narrative: **Last Updated:** 09/17/2007

The licensee reported the loss of an I-125 brachytherapy seed with an activity of 4.65 MBq (125.7 uCi) that was used as a temporary implant for a patient with a non-palpable breast lesion. The seed was implanted in the patient on 12/5/2006 and removed on 12/6/2006. The Nuclear Medicine Pharmacy was not contacted to retrieve the seed from Pathology following the surgical removal. On 12/13/2006, a nuclear medicine technologist discovered that one seed was missing when preparing to transfer I-125 seeds for disposal. The technician returned to the pathology suite, conducted a radiation survey of the suite, sink, drain traps, and waste baskets, but was unable to find the missing seed. A survey of the operating room and janitor's closet was also negative. It was determined that the seed was most likely lost while within the pathology laboratory. The licensee believes that the seed was either washed down the drain during cleaning of the area or was discarded as medical waste. The licensee stated that there were no radiation levels above background in any of the incineration ash. Corrective actions taken by the licensee included modifying procedures.

Event Date:	Discovery Date:	Report Date:
12/06/2006	12/13/2006	01/10/2007

Licensee/Reporting Party Information:

License Number:	MN-1047-201-55	Name:	MAYO CLINIC
Docket Number:	NA	City:	ROCHESTER, MN

Site of Event:

Site Name: ROCHESTER, MN

Reference Documents:

Reference Document Number:	Entry Date:	Retraction Date:	Type of Report:
MN070001	03/29/2007		AGREEMENT STATE EVENT REPORT
MN070001A	07/10/2007		AGREEMENT STATE EVENT REPORT
MN070001B	09/17/2007		AGREEMENT STATE EVENT REPORT

NMED Item Number: 070206

Narrative: **Last Updated:** 06/07/2007

The licensee reported that 101 Pd-103 seeds (Theragenics Corporation model 200), with a total activity of 4.88 GBq (132 mCi), were stolen from a truck parked at the residence of the RSO in Sunset, Louisiana. The RSO contacted the Saint Laundry Parish Sheriff and the Louisiana State Police. The seeds had been accepted by the licensee from the shipper and were going to be transported to the hospital by the licensee representative. The seeds were in the vehicle on the rear seat inside a red, padlocked, metal tool chest labeled as containing radioactive material. The seeds were contained in seven plastic sleeves and were inside two stainless steel containers. The Louisiana Department of Environmental Quality dispatched three inspectors to search the area where the sources were stolen. Corrective actions taken by the licensee included requiring the oncologist to get his own license and to write procedures for direct shipment from the site of receipt to the site of use on the day of use.

Event Date:	Discovery Date:	Report Date:
04/03/2007	04/03/2007	04/04/2007

Licensee/Reporting Party Information:

License Number:	LA-0581-L01	Name:	LAFAYETTE GENERAL MEDICAL CENTER
Docket Number:	NA	City:	LAFAYETTE, LA

Site of Event:
Site Name: SUNSET, LA

Reference Documents:

Reference Document Number:	Entry Date:	Retraction Date:	Type of Report:
EN43275	04/09/2007		EVENT NOTIFICATION REPORTED FROM AN AGREEMENT STATE
LTR070607	06/07/2007		AGREEMENT STATE LETTER

NMED Item Number: 070239
Narrative: **Last Updated:** 06/27/2007

The licensee reported the loss and recovery of a Malinckrodt Nuclear zippered delivery pouch that contained 4.44 GBq (120 mCi) of Tc-99m. When the delivery truck left the licensee's facility to deliver radiopharmaceuticals on 4/2/2007, the driver failed to properly secure the material or the rear hatch. The driver made a left hand turn approximately 0.5 miles from the office. The truck's rear hatch opened and two items fell from the truck, including the zippered delivery pouch and a brief case containing a survey meter, several syringes, and other miscellaneous medical materials. The delivery driver was unaware of the loss of the items. An individual in another vehicle witnessed the incident, followed the truck for two blocks, and alerted the delivery driver. The delivery driver drove back to the scene, but the items were gone. A search was conducted, but the items were not found. The zippered delivery pouch was subsequently found on 5/18/2007. The licensee received a call from Long Beach Community Health Center reporting that one of their patients had found the pouch in the City of Hawaiian Gardens, California. The licensee recovered the pouch and found everything intact; it did not appear to have been tampered with or opened. All radioactivity had decayed to background. Corrective actions taken by the licensee included holding an emergency mandatory meeting on 4/3/2007 for all employees that handle and transport radioactive material.

Event Date:	Discovery Date:	Report Date:
04/02/2007	04/02/2007	04/02/2007

Licensee/Reporting Party Information:

License Number:	CA-4313	Name:	PACIFIC MEDICAL IMAGING, INC.
Docket Number:	NA	City:	SANTA FE SPRINGS, CA

Site of Event:
Site Name: SANTA FE SPRINGS, CA

Reference Documents:

Reference Document Number:	Entry Date:	Retraction Date:	Type of Report:
CA-XCA1093	04/23/2007		AGREEMENT STATE EVENT REPORT
CA-XCA1093A	04/23/2007		AGREEMENT STATE EVENT REPORT
CA-XCA1093B	04/23/2007		AGREEMENT STATE EVENT REPORT
LTR070530	05/31/2007		AGREEMENT STATE LETTER
LTR070626	06/27/2007		AGREEMENT STATE LETTER

NMED Item Number: 070240
Narrative: **Last Updated:** 05/09/2007

The licensee reported the theft of six containers that contained a total of 65.67 GBq (1.775 Ci) of Tc-99m in the form of 49 unit dose syringes. A licensee courier made a delivery to Presbyterian Hospital in Charlotte, North Carolina, and upon returning to his truck found that the six containers were stolen. The courier had locked his truck and truck storage compartment prior to entering the hospital. The stolen containers were rigid black nylon cases that are about one square foot and weigh between 10 and 15 pounds. Inside the containers are shielded metal cylinders containing syringes. Each container was labeled with the radiation symbol and the word "Radioactive." The Radiation Protection Section of the North Carolina Department of Environment and Natural Resources notified the Charlotte-Mecklenburg Police and issued a press release.

Event Date:	**Discovery Date:**	**Report Date:**
04/20/2007	04/20/2007	04/20/2007

Licensee/Reporting Party Information:

License Number:	NC-006-0794-1	Name:	CARDINAL HEALTH, INC.
Docket Number:	NA	City:	CHARLOTTE, NC

Site of Event:

Site Name: CHARLOTTE, NC

Reference Documents:

Reference Document Number:	Entry Date:	Retraction Date:	Type of Report:
ML071100486	04/24/2007		PRELIMINARY NOTIFICATION REPORTED FROM AN AGREEMENT STATE
PN107005	04/24/2007		PRELIMINARY NOTIFICATION REPORTED FROM AN AGREEMENT STATE
EN43311	04/25/2007		EVENT NOTIFICATION REPORTED FROM AN AGREEMENT STATE
NC070019	05/09/2007		AGREEMENT STATE EVENT REPORT

NMED Item Number: 070320

Narrative: **Last Updated:** 09/17/2007

The licensee reported the loss of an I-125 seed (Oncura model 6711) that contained an activity of 18.46 MBq (0.499 mCi). The licensee received 101 seeds at their Nuclear Medicine hot laboratory on 4/23/2007, which were then transported to Radiation Oncology for assay on 4/24/2007. There were 10 strands, each containing 10 seeds, and one calibration seed. All seeds were account for. One of the strands was dismantled and all ten seeds were assayed and stored in a lead pig. The area was surveyed at the end of the assay process and the seeds were maintained under lock until the next morning when they were retrieved for a procedure. The 10 loose seeds were loaded into a Mick cartridge and then all the seeds were transported to the operating room. After the procedure, the nine seed strands and the cartridge as a whole were accounted for. All strands were stored in a lead pig and the cartridge was stored in a second pig. The package containing both pigs was transported to Radiation Oncology and stored under lock at all times. On 5/23/2007, a re-count of the seeds was completed prior to sending them back to the manufacturer. The calibration seed and the strands were accounted for. However, the cartridge only contained nine of the 10 seeds. The area where the cartridge was loaded and unloaded was surveyed, as well as the two units that were used to sterilize the seeds. The seed was not located. Surveys of other areas where the package was transported are in progress. The cause of the

incident was determined to be inadequate procedures. Corrective actions taken by the licensee included generating new procedures.

Event Date:	Discovery Date:	Report Date:
04/24/2007	05/23/2007	05/24/2007

Licensee/Reporting Party Information:

License Number:	MN-1025-200-07	Name:	IMMANUEL-SAINT JOSEPH'S HOSPITAL
Docket Number:	NA	City:	MANKATO, MN

Site of Event:

Site Name: MANKATO, MN

Reference Documents:

Reference Document Number:	Entry Date:	Retraction Date:	Type of Report:
EN43388	05/29/2007		EVENT NOTIFICATION REPORTED FROM AN AGREEMENT STATE
MN070002	07/10/2007		AGREEMENT STATE EVENT REPORT
MN070002A	09/17/2007		AGREEMENT STATE EVENT REPORT

NMED Item Number: 070426

Narrative: **Last Updated:** 09/11/2007

The licensee reported the loss of a 222 GBq (6 Ci) Ir-192 brachytherapy source (serial #02-01-0710-001-05180) during a Federal Express shipment from Saint Lukes Regional Medical Center in Twin Falls, Idaho, to the licensee's facility in Edgerly, Louisiana. The licensee initially reported that the box arrived, but that it contained a helicopter part and not a source. The following day, the licensee stated that the source was found at their facility and had been there since Federal Express delivery.

Event Date:	Discovery Date:	Report Date:
07/11/2007	07/11/2007	07/11/2007

Licensee/Reporting Party Information:

License Number:	LA-10025-L01	Name:	ALPHA OMEGA SERVICES
Docket Number:	NA	City:	EDGERLY, LA

Site of Event:

Site Name: EDGERLY, LA

Reference Documents:

Reference Document Number:	Entry Date:	Retraction Date:	Type of Report:
EN43484	07/13/2007		EVENT NOTIFICATION
EN43480	07/16/2007		EVENT NOTIFICATION REPORTED FROM AN AGREEMENT STATE
LA070018	09/11/2007		AGREEMENT STATE EVENT REPORT

NMED Item Number: 070436

Narrative: **Last Updated:** 07/19/2007

The licensee reported an accident involving a vehicle transporting radiopharmaceuticals in Chelmsford, Massachusetts. The vehicle had rolled over, emptying 18 Type A transport containers onto the highway and over an embankment. Six of the containers ended up in a stream of water at the bottom of the embankment. Radioactive materials included bulk and individual doses of Tc-99m, F-18 FDG for PET imaging, and I-131 for patient therapy. The Tc-99m was transported in an internally shielded Type A nylon covered container and the I-131 and F-18 were transported in Type A shielded ammo boxes. Seventeen of the 18 containers were recovered. One container that held 10.03 GBq (271.21 mCi) of F-18 was not found. There was no release of radioactive material during the incident. None of the containers showed any external contamination. Only one ammo box was damaged with a torn off lid, but the tungsten syringe shield containing the dose of F-18 was not breached. Attempts to recover the lost container included using divers and metal detectors.

Event Date:	**Discovery Date:**	**Report Date:**
07/06/2007	07/06/2007	07/13/2007

Licensee/Reporting Party Information:

License Number:	MA-41-0366	Name:	CARDINAL HEALTH PHARMACY SERVICES
Docket Number:	NA	City:	WOBURN, MA

Site of Event:

Site Name: CHELMSFORD, MA

Reference Documents:

Reference Document Number:	Entry Date:	Retraction Date:	Type of Report:
EN43489	07/19/2007		EVENT NOTIFICATION REPORTED FROM AN AGREEMENT STATE

NMED Item Number: 070534

Narrative: **Last Updated:** 08/22/2007

The licensee reported the loss of two I-125 brachytherapy seeds that contained an activity of 12.58 MBq (0.34 mCi), each. The seeds were discovered missing in Operating Room #10. Nine seeds were originally taken to surgery by a nuclear medicain technician to be sterilized. Only seven seeds were returned. A search was initiated but the seeds were not found. The Arizona Radiation Regulatory Agency (ARRA) dispatched a team to try to locate the missing seeds, but they have not been located. Searches for the sources will continue. The ARRA is tracking the incident as number AZ070011.

Event Date:	**Discovery Date:**	**Report Date:**
08/14/2007	08/17/2007	08/17/2007

Licensee/Reporting Party Information:

License Number:	AZ-07-138	Name:	WALTER BOSWELL MEMORIAL HOSPITAL
Docket Number:	NA	City:	SUN CITY WEST, AZ

Site of Event:

Site Name: SUN CITY WEST, AZ

Reference Documents:

Reference Document	Entry Date:	Retraction Date:	Type of Report:

Number:		
EN43576	08/22/2007	EVENT NOTIFICATION REPORTED FROM AN AGREEMENT STATE

NMED Item Number: 070562

Narrative: **Last Updated:** 10/04/2007

Wheaton Franciscan Healthcare reported the loss of an I-125 brachytherapy seed (North American Science model MED3631-A-M) that contained an activity of 9.62 MBq (0.26 mCi). The licensee had received 106 seeds, of which 93 were implanted into a patient's prostate. Prior to transporting the leftover seeds to the hot laboratory, the physicist performed a routine survey using a Ludlum 14C instrument with a thin window GM pancake probe. He surveyed the two physicians, the operating room, trash, linens, table surfaces, instruments, and the discarded needles that held the seeds. The leftover seeds were then transported to the hot laboratory for storage. The physicist recounted the seeds in the laboratory on 8/28/2007 and only counted 12 seeds. The physicist returned to the operating room and repeated the original surveys, but did not locate the missing seed. The lead transport container was searched to verify that the seed was not there. The seed was not found. Corrective actions taken by the licensee included modifying procedures to require confirmation of the number of seeds removed from the patient and placed in the lead container prior to leaving the operating room.

Event Date:	**Discovery Date:**	**Report Date:**
08/28/2007	08/28/2007	08/28/2007

Licensee/Reporting Party Information:

License Number:	WI-079-1285-01	Name:	WHEATON FRANCISCAN HEALTHCARE - SAINT FRANCIS, INC
Docket Number:	NA	City:	MILWAUKEE, WI

Site of Event:

Site Name: MILWAUKEE, WI

Reference Documents:

Reference Document Number:	Entry Date:	Retraction Date:	Type of Report:
WI070021	09/10/2007		AGREEMENT STATE EVENT REPORT
WI070021A	10/04/2007		AGREEMENT STATE EVENT REPORT

LEAKING SEALED SOURCES

NMED Item Number: 070311

Narrative: **Last Updated:** 06/20/2007

The licensee reported that one or more I-125 brachytherapy seeds may be leaking. They received a shipment of Best Industries seeds (2300 series) on 4/25/2007. The sources were counted, assayed, sterilized, and loaded into needles pending use in a treatment two days later. The next day, a routine smear of the storage container showed 5476 Bq (148 nCi) of activity. Checks of the receipt station, autoclave, and loading station revealed no radioactive contamination. A follow up smear of the needles individually revealed no contamination. After contacting the manufacturer and consulting with the patient's physician, the treatment was canceled. Appropriate packaging was provided to the licensee and the 92 seeds were returned to the manufacturer. Test performed by the manufacturer revealed no contamination. However, subsequent testing indicated a partially failed weld on one of the sources, which contained an activity of 22.2 MBq (0.6 mCi). The sources remain at the manufacturer's facility for disposal.

Event Date:	Discovery Date:	Report Date:
04/26/2007	04/26/2007	05/11/2007

Licensee/Reporting Party Information:

License Number:	IL-02015-01	Name:	CHICAGO PROSTATE CANCER CENTER
Docket Number:	NA	City:	WESTMONT, IL

Site of Event:

Site Name: WESTMONT, IL

Reference Documents:

Reference Document Number:	Entry Date:	Retraction Date:	Type of Report:
IL070022	05/23/2007		AGREEMENT STATE EVENT REPORT
IL070022A	06/20/2007		AGREEMENT STATE EVENT REPORT

NMED Item Number: 070514

Narrative: **Last Updated:** 08/14/2007

The licensee reported that one or more I-125 seeds (Best Industries, series 2300) may be leaking. Each seed contained an activity of 22.2 MBq (0.6 mCi). The licensee received the shipment of seeds on 7/17/2007. The seeds were counted, assayed, and sterilized that same day and then placed in storage pending use in a patient procedure scheduled for 7/23/2007. On the day of the procedure, the seeds were removed from their vial and loaded into needles. A routine smear sample of the storage container revealed over 888 Bq (24 nCi) of activity. Surveys of the receipt station, autoclave, and loading station revealed no contamination. Smear samples of the individually loaded needles did not reveal any radioactive contamination. After contacting the manufacturer and consulting with the patient's physician, it was determined to cancel the use of the seeds and return them to the manufacturer for analysis. A manufacturer's representative visited the site to evaluate the conditions of source preparation and sterilization. No unusual findings were reported.

Event Date:	Discovery Date:	Report Date:
07/23/2007	07/23/2007	07/23/2007

Licensee/Reporting Party Information:

License Number: IL-02015-01 Name: CHICAGO PROSTATE CANCER CENTER
Docket Number: NA City: WESTMONT, IL

Site of Event:

Site Name: WESTMONT, IL

Reference Documents:

Reference Document Number:	Entry Date:	Retraction Date:	Type of Report:
IL070042	08/14/2007		AGREEMENT STATE EVENT REPORT

LANDFILL ALARMS

NMED Item Number: 070089

Narrative: **Last Updated:** 08/21/2007

BFI Sunshine Canyon Landfill reported that a roll-off truck (BFI/Allied Waste #3005) from the licensee's facility triggered their radiation monitor alarms. BFI measured approximately 180 kcpm using a NaI probe (background was 1 kcpm). A Califronia Department of Health Services inspector responded to the landfill. Using a Bicron microRem meter, a net exposure rate of 0.29 mR/hour was detected at the surface, with 0.02 mR/hour at two feet (background was 0.01 mR/hour). Using an Exploranium multi-channel analyzer, the radionuclide was identified as I-131 and an activity of 11.1 MBq (0.3 mCi) was calculated. The licensee was informed of the incident. A release form was generated permitting burial of the load. The licensee performed an investigation and determined that a janitorial trainee had picked up trash from an I-131 patient's room. Additional training was provided to both Environmental Services and the nursing staff. The licensee will also install radiation detectors with alarms at the exit of the loading dock.

Event Date:	Discovery Date:	Report Date:
01/17/2007	01/17/2007	01/17/2007

Licensee/Reporting Party Information:

License Number:	CA-0404-19	Name:	CEDARS SINAI MEDICAL CENTER
Docket Number:	NA	City:	LOS ANGELES, CA

Site of Event:

Site Name: LOS ANGELES, CA

Reference Documents:

Reference Document Number:	Entry Date:	Retraction Date:	Type of Report:
CA-XCA1065	02/14/2007		AGREEMENT STATE EVENT REPORT
LTR070411	04/18/2007		AGREEMENT STATE EVENT REPORT
LTR070502	05/03/2007		AGREEMENT STATE LETTER
LTR070608	06/11/2007		AGREEMENT STATE LETTER
CA-XCA1070	08/21/2007		AGREEMENT STATE EVENT REPORT
LTR070821	08/21/2007		AGREEMENT STATE LETTER

NMED Item Number: 060652

Narrative: **Last Updated:** 11/29/2006

The Brea-Olinda Landfill reported that a truck load of waste from Taormina (CVT) set off their radiation monitor alarms. Landfill personnel surveyed the load using an Innovision 451B and found the highest radiation reading to be 9.2 uSv/hour (0.92 mrem/hour) on contact (background was 0.2 uSv/hour or 0.02 mrem/hour). A DOT Exemption (CA-CA-06-042) was issued and the load was returned to Taormina (CVT). The waste was separated and diapers were found that contained medical waste. A California Department of Health Services investigator responded to the site on 10/11/2006. Using a Ludlum 19, dose rates were 6 uSv/hour (0.6 mrem/hour) on contact, 1.8 uSv/hour (0.18 mrem/hour) at one foot, and 0.45 uSv/hour (0.045 mrem/hour) at three feet (background was 0.12 uSv/hour or 0.012 mrem/hour). Using an Exploranium GR-130, the radionuclide was identified as I-131 and an activity of 2.96 to 4.81 MBq (0.08 to 0.13 mCi) was estimated. The material will be allowed to decay until it is undistinguishable from background and then disposed of as regular waste.

Event Date:	Discovery Date:	Report Date:

10/10/2006 10/10/2006 10/10/2006

Licensee/Reporting Party Information:

License Number:	NON-LICENSEE	Name:	BREA-OLINDA LANDFILL
Docket Number:	NA	City:	BREA, CA

Site of Event:

Site Name: BREA, CA

Reference Documents:

Reference Document Number:	Entry Date:	Retraction Date:	Type of Report:
CA-XCA1004	10/24/2006		AGREEMENT STATE EVENT REPORT
LTR061122	11/29/2006		AGREEMENT STATE LETTER

NMED Item Number: 060698

Narrative: **Last Updated:** 02/26/2007

Waste Management of Orange reported that a transfer truck from the licensee's facility set off their radiation monitor alarms. A California Department of Health Services inspector visited the Waste Management facility. Using a Thermo Identifinder, the inspector measured an exposure rate of 5.44 uSv/hour (544 urem/hour) at the surface, 1.82 uSv/hour (182 urem/hour) at one foot, and 0.78 uSv/hour (78 urem/hour) at three feet (background was 0.18 uSv/hour or 18 urem/hour). The contaminated items were two bags that contained regurgitated food and medical waste. Using an Exploranium multi-channel analyzer, the radionuclide was identified as I-131 and an activity was calculated to be between 2.52 and 8.21 MBq (68 and 222 uCi). The waste was sent back to the licensee's facility where it will be allowed to decay to background before disposal. The licensee stated that the waste did not set off their portal monitor because it was not working properly. They will have the monitor repaired and will perform hand surveys on waste leaving their facility until it is fixed.

Event Date:	Discovery Date:	Report Date:
10/28/2006	10/28/2006	10/28/2006

Licensee/Reporting Party Information:

License Number:	CA-0379-30	Name:	SAINT JOSEPHS HOSPITAL
Docket Number:	NA	City:	ORANGE, CA

Site of Event:

Site Name: ORANGE, CA

Reference Documents:

Reference Document Number:	Entry Date:	Retraction Date:	Type of Report:
CA-XCA1019	11/15/2006		AGREEMENT STATE EVENT REPORT
LTR070221	02/26/2007		AGREEMENT STATE LETTER

NMED Item Number: 070557

Narrative: **Last Updated:** 09/06/2007

A side-loader garbage truck set off the radiation monitor alarms on multiple occasions at the City of Deerfield Beach. The Florida Department of Health investigator found syringes and radiation surveys revealed 1 mR/hour on contact. The State believes the waste to be medical and the radionuclide I-131. The material will be stored onsite to decay and then disposed.

Event Date:	Discovery Date:	Report Date:
07/30/2007	07/30/2007	07/31/2007

Licensee/Reporting Party Information:

License Number: NR Name: NR
Docket Number: NA City: NR, FL

Site of Event:

Site Name: DEERFIELD BEACH, FL

Reference Documents:

Reference Document Number:	Entry Date:	Retraction Date:	Type of Report:
FL07-113	09/06/2007		AGREEMENT STATE EVENT REPORT

NMED Item Number: 070039

Narrative:

Last Updated: 01/17/2007

The Taylor County Landfill reported that a truck/trailer transporting solid waste from Albany, Georgia, set off their radiation monitor alarms. The trailer was held inside a fenced area. State of Georgia personnel responded to the landfill on 11/29/2006 and provided radiological monitoring assistance. Using a Thermo-Identifinder, a maximum radiation level of 5 mR/hour was detected on contact with the trailer. The radionuclide was identified as I-131 using an Exploranium GR-135. Landfill personnel were advised to bury the load. State of Georgia personnel will contact licensees authorized to administer I-131 in the Albany area and advise them to place emphasis on patient instructions and hospital staff awareness regarding disposal of potentially contaminated waste.

Event Date:	Discovery Date:	Report Date:
11/28/2006	11/28/2006	11/28/2006

Licensee/Reporting Party Information:

License Number: NON-LICENSEE Name: TAYLOR COUNTY LANDFILL
Docket Number: NA City: BUTLER, GA

Site of Event:

Site Name: BUTLER, GA

Reference Documents:

Reference Document Number:	Entry Date:	Retraction Date:	Type of Report:
GA-2006-33I	01/17/2007		AGREEMENT STATE EVENT REPORT

NMED Item Number: 070559

Narrative:

Last Updated: 10/01/2007

Waste Management of Orange reported that a truck load of waste from the licensee's facility set off their radiation monitor alarms. Waste Management separated the waste and stored it in a locked radioactive material storage area. A California Health and Human Services Agency (HHSA) inspector responded to the site. Using a Ludlum 19, the inspector obtained readings of 50 uSv/hour (5 mrem/hour) on contact, with 18 uSv/hour (1.8 mrem/hour) at one foot and 4 uSv/hour (0.4 mrem/hour) at three feet (background was or 0.15 uSv/hour or 0.015 mrem/hour). The radioactive material appeared to be incinerated diapers. Using an Exploranium GR-130, the radionuclide was identified as I-131 and the activity was estimated as 25.9 to 51.8 MBq (0.7 to 1.4 mCi). DOT Exemption CA-CA-07-31 was issued and the licensee's RSO responded to the site, took control of the waste, and transported it back to their facility for decay in storage. Preliminary investigation by the RSO determined that the waste originated from an outpatient who lives at the Sister House, adjacent to their facility and that the waste had been placed in the licensee's waste stream at an unknown location. Further investigation confirmed that the waste had originated from

an out-patient who was a resident of the Regina Residence Special Care Unit, a contiguous facility to the licensee, but is not part of the hospital. The trash was removed from the patient's room and deposited into the licensee's trash container. Any trash originating from the hospital would pass through two sets of radiation detectors prior to being placed into the trash container. Since the waste was from Regina Residence, the waste did not pass through radiation detectors. The Regina Residence supervisor confirmed that standard procedure involved depositing trash in the licensee's container. The supervisor was informed of the requirement to isolate the trash from I-131 patients. Corrective actions included training the appropriate individuals at Regina Residence on proper procedures.

Event Date:	**Discovery Date:**	**Report Date:**
08/22/2007	08/22/2007	08/22/2007

Licensee/Reporting Party Information:

License Number: CA-0379-30
Docket Number: NA
Name: SAINT JOSEPHS HOSPITAL
City: ORANGE, CA

Site of Event:

Site Name: ORANGE, CA

Reference Documents:

Reference Document Number:	Entry Date:	Retraction Date:	Type of Report:
CA-XCA1150	09/06/2007		AGREEMENT STATE EVENT REPORT
LTR070926	10/01/2007		AGREEMENT STATE LETTER

MISCELLANEOUS

NMED Item Number: 070026

Narrative:

Last Updated: 07/25/2007

The licensee reported the malfunction of an MDS Nordion teletherapy unit (model Theratron-80, serial #2640986) that contained a Neutron Products Co-60 source (model NPTT, serial #T-1444) with an activity of 62.53 TBq (1,690 Ci). The Co-60 source did not return to the shielded position after completing a patient's treatment. The therapists immediately entered the room and retracted the source to a safe configuration. The patient was exposed for less than 30 seconds following the completion of the prescribed treatment and it was determined that no medical event occurred. The teletherapy unit was repaired by Neutron Products on 12/8/2006. The problem was identified as an old air cylinder and detent pin, which were replaced, returning the unit to normal operation.

Event Date:	Discovery Date:	Report Date:
12/01/2006	12/01/2006	01/02/2007

Licensee/Reporting Party Information:

License Number:	OH-02300140000	Name:	CLINTON MEMORIAL HOSPITAL
Docket Number:	NA	City:	WILMINGTON, OH

Site of Event:

Site Name: CLINTON, OH

Reference Documents:

Reference Document Number:	Entry Date:	Retraction Date:	Type of Report:
OH012007	01/15/2007		AGREEMENT STATE EVENT REPORT
EN43091	01/15/2007		EVENT NOTIFICATION REPORTED FROM AN AGREEMENT STATE
OH012007A	07/25/2007		AGREEMENT STATE EVENT REPORT

NMED Item Number: 060662

Narrative:

Last Updated: 05/09/2007

The licensee reported an unintentional dose to a fetus when the mother received thyroid ablation therapy. As a prelude to the thyroid ablation therapy, the patient was administered 555 MBq (15 mCi) of Tc-99m on 5/24/2006, and 0.518 MBq (14 uCi) of I-131 on 5/25/2006. Prior to these administrations, the patient denied the possibility of pregnancy and signed an informed consent specifically addressing pregnancy and fetal exposure. On 5/26/2006, the patient was administered 547.6 MBq (14.8 mCi) of I-131 for the thyroid ablation. The patient's OB/GYN physician notified the licensee on 10/9/2006 that the patent was currently 32 to 34 weeks pregnant. The baby was born in mid-November 2006. The baby was examined by an endocrinologist and placed on a treatment plan. The licensee and the South Carolina Department of Health and Environmental Control reviewed the event and determined that the thyroid ablation treatment was performed contrary to licensee procedures, which requires a mandatory pregnancy test prior to treatment for all women of child-bearing age. The licensee hired an independent consultant to assess the dose to the embryo. However, the consultant's dose assessment differed from the licensee's calculations by a factor of 4 to 5. The licensee hired a second consultant for an additional independent review. The final dose assessment to the fetus was 5.173 cGy (rad) to the whole body and a thyroid dose of approximately 13,920 cGy (rad). The fetus did not experience a total thyroid ablation. The child is currently receiving a small amount of thyroid supplement. Corrective actions included reiteration of the licensee's policy.

Event Date:	Discovery Date:	Report Date:
05/26/2006	10/09/2006	10/18/2006

Licensee/Reporting Party Information:

License Number:	SC-0139	Name:	MCLEOD REGIONAL MEDICAL CENTER
Docket Number:	NA	City:	FLORENCE, SC

Site of Event:
Site Name: FLORENCE, SC

Reference Documents:

Reference Document Number:	Entry Date:	Retraction Date:	Type of Report:
EN42935	11/01/2006		EVENT NOTIFICATION REPORTED FROM AN AGREEMENT STATE
ML063250461	11/22/2006		PRELIMINARY NOTIFICATION REPORTED FROM AN AGREEMENT STATE
PN106015	11/22/2006		PRELIMINARY NOTIFICATION REPORTED FROM AN AGREEMENT STATE
LTR070130	02/01/2007		AGREEMENT STATE LETTER
AS 06-06	05/09/2007		ABNORMAL OCCURRENCE NUMBER
ML071080195	05/09/2007		ABNORMAL OCCURRENCE NUMBER

NMED Item Number: 060732

Narrative: **Last Updated:** 01/30/2007

During a routine inspection of the licensee, the California Department of Health Services reviewed the prescription log and determined that 19 test subjects had been prescribed various nuclear medicine tests for non-diagnostic purposes. The purpose of the tests was to train employees and test new imaging equipment. Fifteen of the exams exceeded the public dose limits of 1 mSv (100 mrem) whole body; nine F-18 FDG-PET exams resulted in doses between 15.51 and 18.15 mSv (1,551 and 1,815 mrem) and six Tc-99m exams resulted in doses between 1.52 and 4.66 mSv (152 and 466 mrem – see source table for details). The prescribing physician was not an authorized user for the licensee; however, the RSO gave that physician temporary privileges as authorized user. Corrective actions taken by the licensee included requiring the RSO, medical physicist, and authorized user to sign statements acknowledging and agreeing that the authorization under the license was for human use for the purpose of medical diagnosis only, and not for testing, calibration, or other non-medical reasons.

Event Date:	Discovery Date:	Report Date:
11/09/2006	11/09/2006	11/20/2006

Licensee/Reporting Party Information:
License Number: CA-7481-36 Name: HI-DESERT PET & NUCLEAR MEDICINE IMAGING CENTER
Docket Number: NA City: VICTORVILLE, CA

Site of Event:
Site Name: VICTORVILLE, CA

Reference Documents:

Reference Document Number:	Entry Date:	Retraction Date:	Type of Report:
CA-XCA1027	12/06/2006		AGREEMENT STATE EVENT REPORT
CA-XCA1027A	12/06/2006		AGREEMENT STATE EVENT REPORT
LTR070126	01/30/2007		AGREEMENT STATE LETTER

Compiled by RP Lieto

Microsphere Use Guidance

ACMUI Meeting
October 23, 2007

Ashley M. Tull
Office of Federal and State Materials
Division of Materials Safety and State Agreements

Overview

TODAY
- Dr. Kennedy, Sirtex
- Dr. Nag, ACMUI
- Ms. Tull, NRC
  - Propose changes
  - Discuss issues
  - Receive ACMUI input

PATH FOWARD
- Revise guidance
- Obtain "No Legal Objection"
- Publish guidance to web

Dose vs. Dosage (35.2)

- Prescribed **dose** means

(1) For gamma stereotactic radiosurgery, the **total dose** as documented in the written directive;
(2) For teletherapy, the **total dose** and dose per fraction as documented in the written directive;
(3) For manual brachytherapy, either the total source strength and exposure time or the **total dose**, as documented in the written directive; or
(4) For remote brachytherapy afterloaders, the **total dose** and dose per fraction as documented in the written directive.

- Prescribed **dosage** means the **specified activity** or range of activity of unsealed byproduct material as documented

(1) In a written directive; or
(2) In accordance with the directions of the authorized user for procedures performed pursuant to 10 CFR 35.100 and 35.200

Dose vs. Dosage

- Should NRC staff revise microsphere guidance to state that activity administered (mCi) may be used in the written directive?

Medical Event Reporting (35.3045)

- Add paragraph (text pending dose/activity issue):

  A licensee shall report any event, except for an event that results from patient intervention, in which the administration of byproduct material or radiation from byproduct material results in a dose that differs from the prescribed dose by more than 5 rem effective dose or 50 rem to an organ or tissue...and total dose/dosage delivered is +/- 20% of prescribed dose/dosage.

Quantifying Dose

- Add paragraph (text pending dose/activity issue):
  Procedures for administrations requiring a written directive should, for Y-90 microsphere administrations, describe how to quantify the total dose to the treatment site as well as the total dose to other sites upon completion of the administration to confirm that the administration is in accordance with the written directive.

Note: paragraph was included in original guidance but was inadvertently removed during the September revision.

Notification for AUs (35.14)

- Add paragraph:
  "NRC recognizes that an AU who satisfies the training and experience listed above and is currently listed on a Commission or Agreement State license, a permit issued by a Commission master material license, a permit issued by a Commission or Agreement State licensee of a broad scope, or a permit issued by a Commission master material license broad scope permittee, may be allowed to work under a different license for the specific microsphere use listed on the license or permit provided the new licensee submits documentation of satisfactory completion of the training and experience listed above and a copy of the license or permit on which the AU was originally listed for the specific microsphere use. The licensee shall provide all required documentation to NRC for each AU no later than 30 days after the date that the licensee allows t work as an authorized user for the specific microspheres."

Training in Manufacturer's Procedures

- Add paragraph:
  "Training in the manufacturer's procedures commensurate with the individual's duties to be performed must be provided to individuals preparing, measuring, performing dosimetry calculations, or implanting microspheres."

Completion of Procedure

- Delete highlighted text (text pending dose/activity issue):
  "The written directive should include...after implantation but before completion of the procedure: the radionuclide (including the chemical/physical form [Y-90 microspheres]), the manufacturer, treatment site, and the total dose to the treatment site. If the implantation was terminated because of stasis, then the total dose is the value of the total dose delivered when stasis occurred and the implantation was terminated."

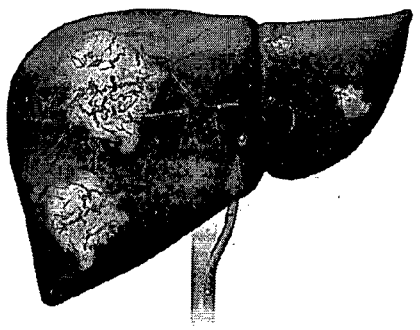
ADAMS

^{90}Y Microspheres Written Directive: Dose vs Activity

Andrew Kennedy, MD, FACRO
Co-Medical Director
Wake Radiology Oncology
Cary, North Carolina
USA

Disclosures

- Not affiliated with Sirtex Medical or MDS Nordion
- Private practice Radiation Oncologist
- Received honoraria from Sirtex Medical and MDS Nordion in 2006-7 for educational lectures
- A Director of Oncologix Tech, a research and development company of radioactive microparticle anticancer therapeutics



Microsphere Comparison

	Glass microspheres (TheraSpheres®)	Resin microspheres (SirSpheres®)
# spheres/tx	1 - 8 million spheres	40 - 80 million spheres
Activity per sphere:	2500 Bq	50 Bq
Stasis-related issues:	None	20-50% of all cases

Glass ^{90}Y Microspheres

Activity (GBq) glass = $\frac{\text{D (Gy) x M (kg)}}{\text{50 Gy*kg/GBq}}$

Dose (Gy)= assumes uniform distribution throught the whole volume (**MIRD**).

M = mass of liver volume (Kg)

$\text{Dose}_{\text{given}}$ (Gy) = $\frac{\text{50 [Injected Activity (GBq)][1-F]}}{\text{Mass of Selected Liver Target (kg)}}$

Radiation Dose Calc and Scheduling

Liver Volume (cc) 2354
Liver Mass (Kg) = 2.42
Desired Dose (Gy) = 150
Required Activity (GBq 7.27

Median mass = 2.05 Kg N=29
Median dose delivered = 140 Gy

Delivered Dose for Ordered Activity (GBq) = 10					
Time	Monday	Tuesday	Wednsday	Thursday	Friday
8:00 AM	166	128	99	76	59
12:00 PM	159	123	95	73	56
4:00 PM	152	118	91	70	54
8:00 PM	146	113	87	67	52

Delivered Dose for Ordered Activity (GBq) = 20					
Time	Monday	Tuesday	Wednsday	Thursday	Friday
8:00 AM	332	257	198	153	118
12:00 PM	318	246	189	146	113
4:00 PM	305	235	181	140	108
8:00 PM	292	225	174	134	104

Dosimetry Issues - Glass

- Based on MIRD model
  - But microsphere distribution is **not** uniform
- Actual absorbed dose unknown for normal or tumor tissue – integral estimate at best
- **Not based on tumor volume, liver function, or vascularity**

Resin Sphere Dose Selection

3 approaches can be used to select activity
- "**Empiric**" - tumor volume estimate
- "**Partition**" - limited usefulness but most accurate
- "**BSA**" body surface area and tumor volume

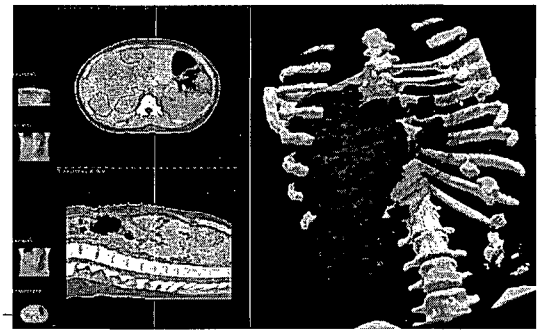
Not based on MIRD estimates
Not based on liver mass

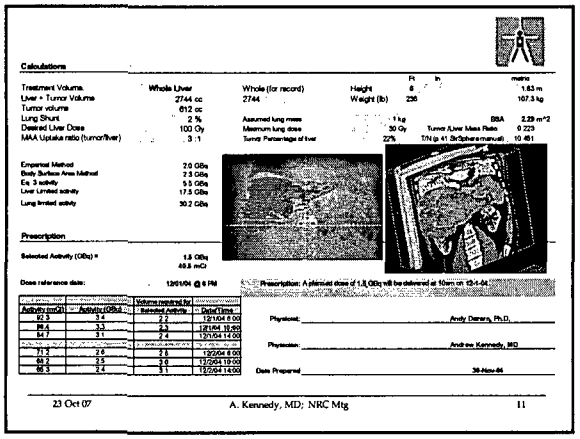
Activity recommended cannot be delivered due to vascular stasis in up to 50% of cases

Empiric Method Dosing

Tumor % of Whole Liver	Dose Recommended
< 25%	2 GBq
>25% - 50%	2.5 GBq
>50%	3.0 GBq

Tumor volume (GTV)





Stasis-Related Issues

- A Patient with metastatic colon cancer metastases = 22% of the liver volume
- AU determines 1.8 GBq for treatment
- Common activity delivery outcomes:
  - 1.1 GBq due to prior chemo+anti-VEGF therapy
  - 1.5 GBq if chemo given but not anti-VEGF agents
  - 1.8 GBq in second line therapy with chemo only

Technology Gap

- No available software, hardware or imaging products to reliably predict resin microsphere activity delivery
- No ability to verify absorbed dose in liver from either microsphere
- Activity pre and post is most reliable method for resin microspheres and is basis for all published reports on outcome

Int. J. Radiation Oncology Biol. Phys., Vol. 68, No. 1, pp. 13–23, 2007

0360-3016/07/$–see front matter

ELSEVIER

doi:10.1016/j.ijrobp.2006.11.060

REPORT

RECOMMENDATIONS FOR RADIOEMBOLIZATION OF HEPATIC MALIGNANCIES USING YTTRIUM-90 MICROSPHERE BRACHYTHERAPY: A CONSENSUS PANEL REPORT FROM THE RADIOEMBOLIZATION BRACHYTHERAPY ONCOLOGY CONSORTIUM

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Purpose: To standardize the indications, techniques, multimodality treatment approaches, and dosimetry to be used for yttrium-90 (Y90) microsphere hepatic brachytherapy.

Methods and Materials: Members of the Radioembolization Brachytherapy Oncology Consortium met as an independent group of experts in interventional radiology, radiation oncology, nuclear medicine, medical oncology, and surgical oncology to identify areas of consensus and controversy and to issue clinical guidelines for Y90 microsphere brachytherapy.

Results: A total of 14 recommendations are made with category 2A consensus. Key findings include the following. Sufficient evidence exists to support the safety and effectiveness of Y90 microsphere therapy. A meticulous angiographic technique is required to prevent complications. Resin microsphere prescribed activity is best estimated by the body surface area method. By virtue of their training, certification, and contribution to Y90 microsphere treatment programs, the disciplines of radiation oncology, nuclear medicine, and interventional radiology are all qualified to use Y90 microspheres. The panel strongly advocates the creation of a treatment registry with uniform reporting criteria. Initiation of clinical trials is essential to further define the safety and role of Y90 microspheres in the context of currently available therapies.

Conclusions: Yttrium-90 microsphere therapy is a complex procedure that requires multidisciplinary management for safety and success. Practitioners and cooperative groups are encouraged to use these guidelines to formulate their treatment and dose-reporting policies. © 2007 Elsevier Inc.

Radioembolization, Hepatic neoplasms, Yttrium-90, Microsphere, Brachytherapy.

INTRODUCTION

The key limitation of external beam radiotherapy in the treatment of primary or metastatic liver tumors is the tolerance of normal liver parenchyma to radiation. The dose required to destroy solid tumor, estimated at ≥70 Gy, is far greater than the liver tolerance dose of 35 Gy delivered to the whole liver in 1.8 Gy/d fractions (1).

Unlike most organs, the liver has a dual blood supply: the hepatic artery and the portal vein. Observations on vascular supply to hepatic malignancies have demonstrated that metastatic hepatic tumors >3 mm derive 80–100% of their blood supply from the arterial rather than the portal hepatic circulation (2). This fundamental concept is the foundation for the intra-arterial administration of brachytherapy with microspheres embedded with the beta-emitting isotope,

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Acknowledgments—The authors thank Mr. David Carpenter for editorial assistance; and Drs. James Andrews, David Berry, Keith Blanshard, Huan Giap, Thomas Helmberger, W. Scott Helton, Nasir Khan, Johannes Lammer, David Liu, Val Lewington, Bruno Sangro, James Welsh, and Christoph Johannes Zech for their expert review and valuable suggestions.

Conflict of interest: none.

Received May 8, 2006 and in revised form Nov 1, 2006. Accepted for publication Nov 20, 2006.

yttrium-90 (Y90). There are two components to this radioembolization procedure: embolization and brachytherapy. The angiographic endpoints of embolization and stasis and the need to modify the delivery according to angiographic findings under fluoroscopy define the treatment as an embolization procedure. The administration and delivery of radiation with modification of dose based on tumor and target volume define this treatment as a brachytherapy procedure.

At present, more than 3,000 patients have been treated with Y90 microsphere brachytherapy in more than 80 medical centers worldwide. Unfortunately, there are currently no large-scale, prospective clinical trials to guide practitioners on the use of this technology. Therefore it is important to carefully review the available clinical data regarding the indications, techniques, multimodality treatment approaches, and dosimetry used for liver microsphere brachytherapy and formulate guidelines to avoid toxicity and poor tumor response. The optimal management of these patients involves coordinated expertise from a variety of disciplines. The complex overlap of responsibilities and the skills required in Y90 microsphere brachytherapy emphasize the urgent need to establish guidelines for this treatment modality.

METHODS AND MATERIALS

The Radioembolization Brachytherapy Oncology Consortium (REBOC) is an independent group of experts from the fields of interventional radiology, radiation oncology, nuclear medicine, medical oncology, and surgical oncology involved with Y90 microsphere therapy. Selected members of the REBOC panel (chair and principal investigator, Dr. Subir Nag) met in Columbus, Ohio on April 6–8, 2006 to identify areas of consensus and controversy and issued clinical guidelines for Y90 microsphere brachytherapy after reviewing all available unpublished and published data. These recommendations were all in Category 2A, with the categories of consensus used by the panel being similar to those used in National Comprehensive Cancer Network guidelines:

Category 1: There is uniform panel consensus, based on high-level evidence, that the recommendation is appropriate.
Category 2A: There is uniform panel consensus, based on lower-level evidence including clinical experience, that the recommendation is appropriate.
Category 2B: There is nonuniform panel consensus (but no major disagreement), based on lower-level evidence including clinical experience, that the recommendation is appropriate.
Category 3: There is major disagreement among panel members that the recommendation is appropriate.

To safeguard against potential biases arising from conflict of interest, the panel required written disclosure of any potential conflict of interest. To guard against overemphasis of any individual bias or exclusion of expert opinion, members from all involved specialties were included on the panel. Costs associated with developing this report were borne by an unrestricted educational grant from Sirtex Medical (Lane Cove, Australia) and MDS Nordion (Kanata, Ontario, Canada) to the Ohio State University, with Dr. Subir Nag being the principal investigator. These corporate sponsors had no panel membership or review of the text. The American College of Radiation Oncology, American Brachytherapy Society, Society of Interventional Radiologists, Society of Nuclear Medicine, and the Cardiovascular and Interventional Radiologic Society of Europe had representatives in the panel; however, this report represents the opinions of the individual panel members and does not necessarily imply an official endorsement by the represented societies.

This initial report was sent for review and comments to the sponsoring societies and selected Y90 users who were not part of the panel for broader input. The report was then revised according to the comments of these external reviewers before journal submission. It should be noted that these broad recommendations are intended to be technical and advisory in nature; however, the responsibility for medical decisions ultimately rests with the treating physician. This is a constantly evolving field, and the recommendations are subject to modifications as new data become available.

RESULTS

The deliberations and recommendations of the panel are presented here to guide ongoing clinical practice and future investigations. An executive summary of the recommendations is listed in Table 1.

Y90 glass vs. resin microspheres

Currently two different Y90 microsphere products, glass microspheres and resin microspheres, are available in North America; only the resin type is available worldwide. In the United States, practitioners need to keep in mind that glass Y90 microspheres are approved by the U. S. Food and Drug Administration (FDA) for treatment of unresectable hepatocellular carcinoma under the provisions of a "humanitarian device exemption" (HDE no. H9800006), which includes unique restrictions on the medical use of the device. One of the conditions of approval for a humanitarian device exemption is that there be institutional review board initial review and approval before a humanitarian-use device is used at a facility, as well as continuing review of its use. Resin microspheres have received FDA premarket approval for hepatic metastases from colorectal cancer, concurrent with fluorodeoxyuridine (FUDR). Any other use of resin microspheres is an off-label use and, although it does not need institutional review board approval, the physician performing the treatment should understand their responsibilities in this regard. There has been no direct comparison of the efficacy of the two microsphere products. Similarities and differences between the glass and resin microspheres are outlined in Table 2 (3).

Radioembolization team

The REBOC panel strongly emphasizes that a multidisciplinary team approach, combining the expertise and skill of various specialties, is essential in the management of patients with primary and metastatic liver cancers. The team should include individuals with expertise necessary to (*1*) assume overall medical management of the cancer patient, (*2*) perform vascular catheterization, (*3*) perform and interpret radiologic scans, (*4*) assume responsibility for the de-

Table 1. Executive summary of the Radioembolization Brachytherapy Oncology Consortium Consensus Panel recommendations

No.	Recommendation
1	The panel believes that there is sufficient evidence to support the safety and effectiveness of yttrium-90 (Y90) microsphere therapy in selected patients.
2	A multidisciplinary team approach combining the expertise and skill of various specialties is essential in the management of patients with primary and metastatic liver cancers. This team approach can be achieved at different institutions by involving various combinations of personnel from the disciplines of interventional radiology, radiation oncology, nuclear medicine, medical physics, hepatology, surgical oncology, medical oncology, and radiation safety, depending on their availability at the local institution.
3	Candidates for radioembolization are patients with unresectable primary or metastatic hepatic disease with liver-dominant tumor burden and a life expectancy >3 months.
4	Absolute contraindications to Y90 microsphere treatment include pretreatment ^{99m}Tc macro-aggregated albumin (MAA) scan demonstrating the potential of >30 Gy radiation exposure to the lung or flow to the gastrointestinal tract that cannot be corrected by catheter techniques. It is important that liver injection of MAA is delivered with flow rates and catheter position that mimic the anticipated Y90 infusion rate and catheter position.
5	Relative contraindications to Y90 microsphere treatment include limited hepatic reserve, irreversibly elevated bilirubin levels, compromised portal vein (unless selective or superselective radioembolization can be performed), and prior radiation therapy involving the liver.
6	Essential pretreatment investigations include cross-sectional imaging with CT or MRI, serum chemistry, and tumor markers. [18]Fluorodeoxyglucose positron emission tomography may be a useful adjunct to determine the site of treatment failure in the presence of hepatic and extrahepatic disease, to rectify the inability to follow tumor markers, and to account for or clarify presence of discordant posttreatment findings on CT and/or MRI.
7	Flow characteristics in the hepatic artery and avoidance of extrahepatic deposition of the microspheres are optimally detected and prevented by percutaneously inserted arterial catheters under fluoroscopy rather than by indwelling intra-arterial catheters.
8	Meticulous angiographic techniques are required for patients under consideration for radioembolization. All extrahepatic vessels originating from the hepatic arteries that supply the gastrointestinal tract should, under most circumstances, be embolized to exclude extrahepatic deposition of the Y90 microspheres.
9	In the presence of bilobar disease, either a single whole liver infusion of Y90 microspheres or sequential unilobar liver treatment is acceptable. Patients with unilobar disease should receive therapy only to the affected lobe.
10	The prescribed activity estimated by the body surface area method for resin microspheres is more consistent with the delivered dose in clinical practice and therefore should be the method of choice. For glass microspheres, the prescribed activity calculation method described by the manufacturer is recommended.
11	It is recognized that there is wide geographic and institutional variation in the regulation of the use of Y90 microspheres. Users should comply with local and national regulations.
12	By virtue of their training, certification, involvement, and contribution to Y90 microsphere treatment programs, the disciplines of radiation oncology, nuclear medicine, and interventional radiology are all qualified to use Y90 microspheres. They need to fulfill the training and experience requirements set in Code of Federal Register 10, Part 35.390 or 35.490.
13	The panel strongly advocates the creation of a treatment registry with uniform reporting criteria.
14	Initiation of clinical trials is essential to further define the safety and role of Y90 microspheres in the context of currently available therapies.

livery of the Y90 microspheres and be the authorized user, and (5) monitor radiation safety. This team approach can be achieved at different institutions by involving various combinations of personnel from the disciplines of interventional radiology, radiation oncology, nuclear medicine, medical physics, hepatology, surgical oncology, medical oncology, and radiation safety, depending on their availability at the local institution. A treatment schema is shown in Fig. 1.

Table 2. Properties of resin and glass yttrium-90 microspheres

Parameter	Resin	Glass
Trade name	SIR-Spheres	TheraSpheres
Manufacturer and location	Sirtex Medical, Lane Cove, Australia	MDS Nordion, Kanata, Canada
Diameter	20–60 μ*	20–30 μ†
Specific gravity	1.6 g/dL	3.6 g/dL
Activity per particle	50 Bq	2500 Bq
Number of microspheres per 3-GBq vial	40–80 × 10^6	1.2 × 10^6
Material	Resin with *bound yttrium*	Glass with yttrium *in matrix*

* SIR-Spheres package insert. Sirtex Medical, Lane Cove, Australia.
† TheraSphere package insert. MDS Nordion, Kanata, Canada.

Indications and patient selection

Success in treatment of tumors in the liver by locoregional therapy, whether bland embolization, chemoembolization, or radioembolization, relies on the presence of appropriate indications to ensure that patients receive safe and effective therapy. Because the nature of primary and secondary hepatic malignancies differs, therapy should be tailored to the disease. The integration of combination therapy with irinotecan, oxaliplatin, and bevacizumab has improved response rates and survival of patients with metastatic colorectal cancer, as demonstrated in large randomized trials (4–6). It is also notable that the responses seen with newer combination regimens sometimes convert patients with un-

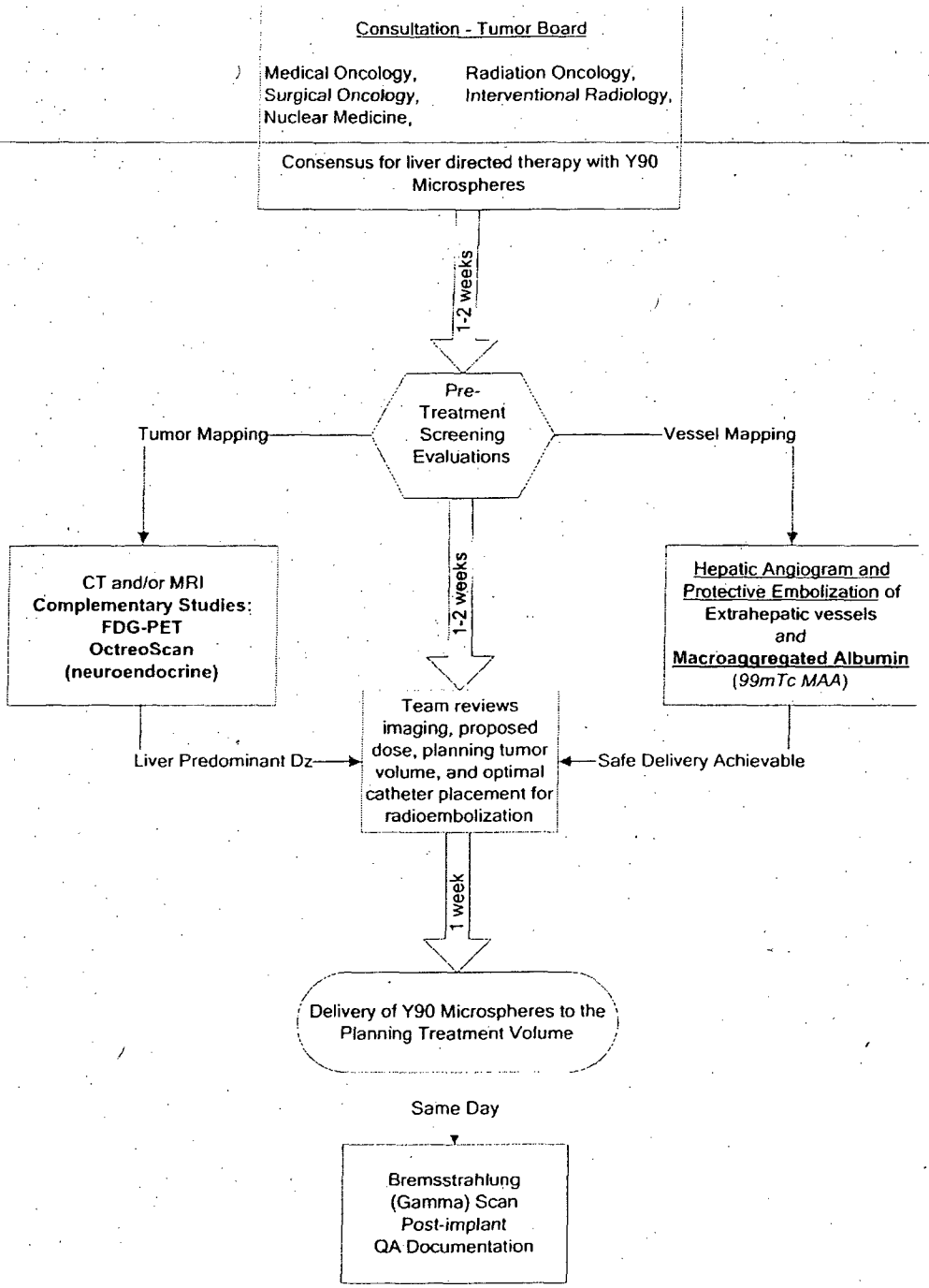


Fig. 1. Treatment algorithm for yttrium-90 microsphere brachytherapy.

resectable liver metastases to resectable status. Similarly, patients with hepatic metastases from other primary sites should be offered standard systemic treatment options with known survival benefit before Y90 treatment. In the case of primary liver tumors, patients should undergo hepatology and transplant evaluations to determine the optimal treatment strategy.

Patients considered for radioembolization therapy would include those with (*1*) unresectable hepatic primary or metastatic cancer, (*2*) liver-dominant tumor burden, and (*3*) a life expectancy of at least 3 months. In metastatic colorectal cancer, radioembolization therapy can be given (*1*) alone after failure of first-line chemotherapy, (*2*) with FUDR during first-line therapy, or (*3*) during first- or second-line chemotherapy on a clinical trial.

Contraindications for radioembolization therapy may include (*1*) pretreatment ^{99m}Tc macro-aggregated albumin (MAA) scan demonstrating the potential of $\geq$30 Gy radiation exposure to the lung or flow to the gastrointestinal tract resulting in extrahepatic deposition of ^{99M}Tc MAA that cannot be corrected by catheter embolization techniques, (*2*) excessive tumor burden with limited hepatic reserve, (*3*)

elevated total bilirubin level (>2 mg/dL) in the absence of a reversible cause, and (*4*) compromised portal vein, unless selective or superselective radioembolization can be performed. Patients with prior radiotherapy involving the liver should be carefully reviewed on a case-by-case basis. It is unclear whether capecitabine chemotherapy treatments represents a contraindication to Y90 treatment.

Investigations and workup

Treatment with Y90 microspheres must be based on cross-sectional images and arteriograms in the individual patient. The workup should include three-phase contrast CT and/or gadolinium-enhanced magnetic resonance imaging of the liver for assessment of tumoral and nontumoral volume, portal vein patency, and extent of extrahepatic disease. Whole body positron emission tomography (PET) can be very helpful. Serum chemical analyses should be performed to evaluate hepatic and renal function and to determine the presence and magnitude of elevation of tumor markers. Patients with irreversible elevations in serum bilirubin should be excluded. In the presence of renal insufficiency, care must be taken to avoid or minimize the use of iodinated contrast material. Pretreatment hepatic artery ^{99m}Tc MAA scan is performed to evaluate hepatopulmonary shunting.

Angiographic evaluation of hepatic vasculature

Once a patient has been selected as a candidate for radioembolization, an initial angiographic evaluation that includes abdominal aortogram, superior mesenteric and celiac arteriogram, and selective right and left hepatic arteriogram is to be performed within 1 h of treatment, primarily to document the visceral anatomy, provide information on perfusional flow characteristics of the targeted vascular territory, identify anatomic variants, and isolate the hepatic circulation by occluding extrahepatic vessels (7). Flow characteristics in the hepatic artery are optimally detected and extrahepatic deposition of the microspheres is prevented by percutaneously inserted arterial catheters under fluoroscopy rather than by the use of indwelling arterial catheters connected to an implanted device. Given the possibility of nontarget deposition of microspheres, this panel recommends the prophylactic embolization of all extrahepatic vessels at the time of MAA assessment, including the gastroduodenal, right gastric, and other extrahepatic vessels, to avoid extrahepatic deposition of microspheres. It is to be noted that these vessels/organs can revascularize quickly, and therefore the embolization should be performed close to the intended time of radioembolization, with a check arteriogram required before radioembolization to ensure that such revascularization has not occurred.

Lobar vs. whole liver treatment/MAA

Depending on the anatomic distribution of tumor, as well institutional preferences, whole liver or unilobar approaches may be considered. For the assessment of lung shunting fraction, unilobar or whole liver injection of MAA may be performed. Irrespective of the location of MAA injection, it is imperative that the MAA be delivered with flow rates and catheter position that mimic the anticipated Y90 infusion rate. Whole liver or unilobar infusions of Y90 may be considered at the discretion of the treating team, according to tumor characteristics and location. Scintigraphy should be performed within 1 h of injection of MAA to prevent false-positive extrahepatic activity due to free technetium.

Posttreatment radiologic evaluations

The most common change in the CT appearance of the liver after radioembolization is decreased attenuation in the treated hepatic parenchyma and is representative of liver edema, congestion, and microinfarction, a reversible process that is incidental and self-limiting. Early posttreatment CT imaging is often misleading at defining tumor response, owing to the time-dependent, partially reversible attenuation changes. As such, care must be taken to avoid misinterpretation of early imaging as progression of disease (8, 9). Computed tomography imaging may demonstrate Y90-associated effects on adjacent organs, which may include thickening of the duodenum, stomach, and gallbladder. The effects of Y90 microsphere therapy on liver metastases have been compared by CT, magnetic resonance, and PET in small cohort studies. Positron emission tomography imaging may show attenuated metabolic activity, a finding that suggests treatment response that may be discordant with findings on CT images (10). However, PET may be beneficial in monitoring treatment response for selected patients. A postprocedure Bremsstrahlung scan is recommended within 24 h after treatment to evaluate distribution of Y90.

Radiation safety issues

In the United States, Y90 therapy is regulated by the Nuclear Regulatory Commission (http://www.nrc.gov) under the Code of Federal Register (CFR) 10, part 35.1000, as a brachytherapy device (not a drug) used for permanent brachytherapy implantation therapy. Each microsphere treatment vial contains millions of spheres, and therefore individual sources cannot be counted or leak tested. They are only to be used under the supervision of an authorized user, who must meet the training and experience requirements for manual brachytherapy (set in CFR 10, part 35.490), as well as the specific vendor training in the use of the microspheres and the microsphere delivery system. For U.S. institutions performing brachytherapy under a broadscope license, the physician must be authorized by the institutional radionuclide committee. The REBOC panel believes that by virtue of their training, certification, involvement, and contribution to Y90 microsphere treatment programs, the disciplines of radiation oncology, nuclear medicine, and interventional radiology are all qualified to use Y90 microspheres. They would need to fulfill the training and experience requirements set in CFR 10, part 35.390 (for unsealed sources) or 35.490 (for manual brachytherapy), as well as the specific vendor training. As of April

2006, this possible amendment was under discussion at the Nuclear Regulatory Commission.

For Y90 microspheres, the "prescribed dose" means the total dose documented in the written directive. The written directive should include (*1*) before implantation: the treatment site, the radionuclide (Y90 microspheres), and dose (in gigabecquerels); and (*2*) after implantation but before completion of the procedure: the radionuclide (Y90 microspheres), treatment site, and the total dose. It is important to consider stopping the radioembolization procedure when there is slowed antegrade flow (before total vascular stasis has been reached) to prevent reflux of microspheres into unintended vessels. This is recognized as an acceptable reason to terminate the delivery of Y90 before the prescribed dose has been delivered. Hence, in addition to the dose, "stopped when there is slowed antegrade flow" should be included in the written directive. If the implantation was terminated because of slowed antegrade flow, then the total dose is the value of the total dose delivered when slowed antegrade flow occurred and the implantation was terminated. The written directive should specify the maximum dose that would be acceptable for a specified site (or sites) outside the primary treatment site to which the microspheres could be shunted (such as the lung and gastrointestinal tract). Procedures should describe measures taken to ensure that the Bremsstrahlung emissions from each patient or human research subject permits his/her release in accordance with local regulations.

Radiation precautions guidelines are as follows.

- Although Y90 is a beta emitter with limited penetration in tissues, it nonetheless represents a source of gamma emission—Bremsstrahlung that can interact with any tissue in the body. Microspheres can cause significant problems if spilled.
- Unlike liquid isotope spills, which can be mopped up, the tiny microspheres can become lodged in crevices from which they are difficult to remove, or they can disperse in the air and be inhaled.
- Pregnant staff and/or pregnant family members should be excluded from procedural or postprocedural care of Y90 patients.
- Infusion personnel must remain behind delivery apparatus containing the dose. Anyone assisting should remain clear of the tubing connected to the catheters.
- The angiographic suite area immediately underneath personnel involved in dose administration should be draped and plastic covers placed over pedals as a precautionary measure in case of spillage.
- Double gloves, double shoe covering, and protective eyewear are advised for administering staff.
- The delivery catheter should be considered radioactive and disposed of, observing radiation precautions. All other potentially contaminated material (*i.e.*, exit tubing from the dose vial, three-way valve, tube to catheter, needles, gloves, gauzes, hemostat, and drapes) should be considered radioactive and disposed of, observing radiation precautions, after catheter removal.
- Tubing and syringes to deliver and flush and the catheter sheath are not considered "hot" and therefore do not need special radiation precautions for disposal. However, they should be surveyed for radioactivity before routine disposal.
- All personnel within the angiography suite must have their shoe covers checked for radiation at the end of the procedure and before leaving the suite. The suite must be checked at the end of the procedure after all contaminated waste and the patient have been removed from the room to detect any radiation contamination.
- Special shielding requirements are not necessary for postprocedure nursing care.
- Yttrium-90 resin microspheres may have trace amounts of free Y90 on their surface, which can be excreted in the urine during the first 24 h. Patients are advised to wash their hands after voiding. Men should sit to urinate, and the urinal double-flushed after voiding. These precautions should be undertaken for 24 h after treatment. In contrast, Y90 glass microspheres are not known to have free Y90 in trace amounts in the treatment vial; therefore, no special precautions are necessary for handling of urine of patients treated with Y90 glass microspheres.
- A letter should be given to the patient at discharge confirming they have received radiation internally. Additionally, a wristband indicating the isotope given, date delivered, and a contact number for questions can be helpful. This wristband is to be worn by the patient for 1 week after discharge.

Figure 2 is a copy of the radiation safety instructions given to patients at Ohio State University after discharge from Y90 resin microsphere treatment. As noted, there is no need to make special arrangements for body fluids (urine, stool, blood, or vomit) for glass microsphere patients upon discharge.

Dosimetry

Yttrium-90 is produced by neutron bombardment of ^{89}Y in a commercial reactor, yielding a pure beta emitter with an average energy of 0.94 MeV, tissue penetration of 2.5 mm, and a maximum range of 1.1 cm. One gigabecquerel (27 mCi) of Y90 delivers a total dose of 50 Gy/kg in tissue. No significant amount of Y90 leaches from the sphere (11), and it decays to stable zirconium-90 with a half-life of 2.67 days (64.2 h).

Both single and multiple deliveries are safe and widely used, and some related terminology has developed. The intended portion of the liver for treatment is the *planning target volume* (PTV), as defined by the International Commission on Radiation Units and Measurements, which may be a solitary lesion, a segment, a lobe, or both lobes. Treating multiple tumors within the entire liver in a single treatment session is termed a *whole liver delivery*. Treating the entire liver by first treating one lobe and then the other

Radiation Safety Discharge Instructions for Patients with Radioactive Y90 Resin Microspheres for Liver Brachytherapy

Y90 resin microspheres are radioactive sources that, over time, become inactive. This means that for the next few days there will be a small amount of radioactivity near your liver. This does not represent a significant risk to others. However, to be on the safe side, these precautions and instructions should be followed:

1. Patients are advised not to be in close contact (< 1 meter) with others for extended periods of time during the first week after microsphere therapy.
2. If you have to go to a doctor or Emergency Room or need surgery within 3 days of this treatment, notify the medical staff that you have a small amount of radiation in your liver. Your physicians should give you any immediate and necessary medical or surgical treatments without concern for the radiation in the liver. They can call Radiation Medicine or Radiation Safety with any questions regarding the details of the treatment.
3. There is **NO** need to make special arrangements for body fluids (urine, stool, blood or vomit) for glass microspheres, or after 24 hours if resin microspheres.

If you have questions concerning radiation safety, please call the following contacts:

During normal working hours:

Radiation Medicine:

Radiation Safety Officer:

After hours:

I have read and understand the above radiation safety instructions and agree to abide by them.

_____ _____

Patient Signature Radiation Safety Signature

Date:_____ Date:_____

Fig. 2. Radiation safety discharge instructions for patients with radioactive yttrium-90 resin microspheres for liver brachytherapy.

separate sessions is termed *sequential delivery*; both are described in the literature. Treatment to a single lobe only is termed *lobar delivery*. A 90-day interval before retreatment of the PTV is recommended to allow for adequate hepatic healing. In sequential treatments, a 30–45-day interval is the generally accepted practice (10, 12, 13).

All patients are to have CT treatment planning with reconstruction of the liver volumes (whole liver, right lobe,

and left lobe). The required activity for treatment of each patient is to be calculated differently according to whether glass or resin microspheres are to be used.

Resin microspheres are received in bulk, and the individual medical centers extract the desired activity from a 3-GBq source vial that arrives on the day of treatment. This process differs from that for glass microspheres; these arrive a few days before the procedure, and the entire vial containing the spheres is delivered to the tumor. When choosing an activity, the significant physical differences between the two spheres must be considered. (*1*) Activity per microsphere: glass microspheres contain 2,500 Bq per sphere; thus, only 1–2 million spheres are delivered for the typical patient (11). This number of glass spheres is not sufficient to cause significant embolization in the main hepatic arteries. Resin microspheres contain approximately 50 Bq per sphere; thus, an average treatment contains 40–60 million spheres, a number that can cause embolic effects in the arteries (11). (*2*) Embolic effect on dose delivery: glass microspheres are received in the requested activity, and all of the spheres in the vial are completely infused. The prescribed activity of resin spheres cannot always be infused, owing to slowed antegrade hepatic arterial flow. When delivery of spheres is stopped earlier than planned, the residual activity in the delivery vial is measured and deducted from the activity present at the beginning of the procedure to obtain the amount infused.

Glass Y90 microsphere prescribed activity calculation

The activity determination for glass microspheres is based on a nominal target dose and the patient's liver mass, which is determined from the CT data and assumes uniform distribution of the microsphere throughout liver volume:

$$A\ (GBq)_{glass} = \frac{D(Gy) \times M(kg)}{50} \qquad (1)$$

In this equation, *A* is the activity, *D* the nominal target dose, and *M* the liver mass for the PTV (*i.e.*, segment, lobe, or whole liver) being treated. For a typical patient with a liver mass of 2 kg, the required activity is 6 GBq to achieve 150 Gy to the target tissue. It is recommended that the cumulative lung dose be kept to <30 Gy to prevent radiation pneumonitis. The target dose for any given solid tumor is not known; however, it is believed that doses of 100–120 Gy balance response rates and hepatic fibrosis risk when glass microspheres are used. Dose is not calculated similarly for resin microspheres, but an equivalent activity for treatment is approximately 1.5–2.0 GBq.

Resin Y90 microsphere prescribed activity calculation

There are two methods for prescribed activity determination provided by the resin microsphere user's manual (Sirtex user's manual, issued March 2002; pages 38–42): (*1*) the body surface area method (BSA), as outlined below in Eqs. 2 and 3, and (*2*) the empiric method. However, the panel strongly recommends the use of the BSA for resin microsphere dose calculation, on the basis of its more favorable toxicity profile, with response and survival outcome similar to the empiric method.

BSA method. The body surface area method is calculated as follows:

$$BSA\ (m^2) = 0.20247 \times height\ (m)^{0.725} \times weight\ (kg)^{0.425} \qquad (2)$$

$$Activity\ (GBq) = (BSA - 0.2) + \frac{Tumor\ volume}{Total\ liver\ volume} \qquad (3)$$

The activity prescribed can be reduced if the hepatic function is compromised. There are not accepted guidelines as to how much to reduce the activity if a patient's liver function or estimated reserve is only just good enough to be a candidate. Generally, more experienced users reduce dose by 30% for patients with poorer liver function but who are still candidates for this approach according to established eligibility criteria.

Empiric method (not recommended). According to the empiric method:

For tumor ≤25% of the total mass of the liver by CT scan, use 2 GBq whole liver delivery.
For tumor >25% but <50% of the liver mass by CT scan, use 2.5 GBq whole liver delivery.
For tumor >50% of liver mass by CT scan, use 3 GBq for whole liver delivery.

DISCUSSION

Yttrium-90 microsphere therapy has been studied in prospective clinical trials with encouraging results in Australasia (14–17). Important contributions from these studies have provided invaluable experience, shaping patient selection, treatment technique, and safety issues. Investigators in the United States have had access to Y90 microspheres since 2000 (18–22). Important clinical experiences have established encouraging response and survival data in a modest number of patients in each study. Acceptable toxicity is found in metastatic colorectal patients treated with Y90 for both microsphere types (10, 12, 13, 23). Acute side effects (within 30 days of treatment) are predominately constitutional (fatigue, fever), gastrointestinal (ulcer, nausea, emesis, abdominal pain), or hepatic (biochemical). Late radiation effects (30–90 days) are hepatic, with fibrosis/cirrhosis, ascites, portal hypertension, and development of varices, with permanently elevated liver function tests, termed *radiation-induced liver disease* (24).

Gray *et al.* (25) reported a phase III trial of resin microspheres in chemotherapy-naïve metastatic colorectal disease patients with liver metastases only, who received either

Table 3. Published data on yttrium-90 in hepatocellular carcinoma

First author, year (reference)	No. of patients	Treatment group	Sphere	No. of centers	Toxicity system
Salem, 2005 (13)	43	First line	Glass	1	CTC version 3.0*
Goin, 2005 (35)	121	First line	Glass	5	SWOG
Geschwind, 2004 (29)	80	First line	Glass	4	SWOG
Carr, 2004 (27)	65	First line	Glass	1	N/A
Dancey, 2000 (28)	22	First line	Glass	1	N/A
Lau, 1998 (17)	71	First line	Resin	1	N/A

Abbreviations: SWOG = Southwest Oncology Group; N/A = not available.
* Common Terminology Criteria for Adverse Events, version 3.0; http://ctep.cancer.gov; published December 12, 2003.

hepatic artery infusion of FUDR (32 patients) or FUDR plus a single treatment to the whole liver with microspheres (32 patients). In addition to response, time to liver disease progression, and overall survival, quality of life and treatment-related toxicity were measured. The partial and complete tumor response rate was significantly higher for patients who received Y90 in addition to hepatic arterial chemotherapy (44% vs. 17.6%; $p = 0.01$). The median time to progression in the liver was longer for the Y90 patients (15.9 months vs. 9.7 months; $p = 0.04$). Survival was improved for the Y90-treated patients who lived longer than 15 months, with a 5-year survival rate of 3.5% vs. 0. Quality of life was found to be similar for the two groups, as was toxicity.

A retrospective study from 7 U.S. centers by Kennedy *et al.* (12) reported response, toxicity, and overall survival in chemorefractory liver-predominant disease after resin Y90 treatment. More than two thirds of patients responded to treatment, despite a history of heavy chemotherapy treatments. Median survival for responders was 10.5 months, compared with 4.5 months for nonresponders. There were no cases of Grade 4 or 5 toxicity, venoocclusive disease, or radiation-induced liver disease. The most common side effects were fatigue, brief nausea, and transient elevation of liver enzymes. The carcinoembryonic antigen (CEA) response nadir occurred at 12 weeks, as did maximal response on CT scanning.

Yttrium-90 microspheres have been used extensively for the treatment of hepatocellular carcinoma. The acute and late toxicity profile, as well as the identification of high- and low-risk patients for Y90, has been previously reported (26). Safety, tumor response, and survival benefit have been compared with historical controls in reports by several centers (27–29). Surrogate markers for clinical benefits, including tumor marker reduction and quality of life, have also been described (30, 31). Treatment with Y90 as a bridge to transplantation, radiofrequency ablation, or resection has also been studied (32–34).

Substantial data are available on the acute and late side effects of Y90 microspheres in hepatocellular carcinoma patients. It is quite common for patients undergoing Y90 microsphere therapy to experience mild postembolization syndrome on the day of treatment and for up to 3 days after treatment. Symptoms include fatigue, nausea, and abdominal pain. Radioembolization to nontarget organs can also cause other acute damage, resulting in gastrointestinal ulceration, pancreatitis, and radiation pneumonitis. Late toxicity can include radiation-induced liver disease (radiation hepatitis) (26, 31, 35–39). The incidence of nontarget radiation will be minimized if meticulous angiographic and dosimetry techniques are used (40). Fatal radiation pneumonitis has only been reported in 2 cases. Strict adherence to accepted limits on radiation

Table 4. Published details of toxicities (Grade 3–4) of yttrium-90 therapy in hepatocellular carcinoma

	First author, year (reference)					
Category	Salem, 2005 (13)	Goin, 2005 (35)	Dancey, 2000 (28)	Geschwind, 2004 (29)	Carr, 2004 (27)	Lau, 1998 (17)
Gastrointestinal						
Nausea, emesis, pain	12	N/A	4.5	9	15	16.9
Ulcer	0	N/A	13.6	4	0	0
Constitutional						
Weight loss, fatigue, fever	6	27	0	1	N/A	14.1
Liver function						
Bilirubin	14	N/A	22.7	16	17	0
Alkaline phosphatase	0	3	9.1	1	N/A	N/A
Alanine aminotransferase	12	8	22.7	6	70.7	N/A
Aspartate aminostransferase	12	8	22.7	6	N/A	N/A
Ammonia	N/A	3	N/A	N/A	N/A	N/A

Abbreviation: N/A = not available.
Values are percentages.

dose (<30 Gy) to the lung prevents this complication (41). Radiation-induced liver disease and radiation fibrosis may be long-term sequelae of Y90 treatment. The peer-reviewed publications shown in Tables 3 and 4 describe early and late toxicities encountered with Y90 microspheres.

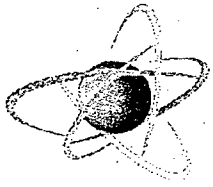
CONCLUSIONS

Yttrium-90 microsphere therapy is a complex procedure that requires multidisciplinary management for safety and success. The initial results and published literature suggest that there is sufficient evidence to support the safety and effectiveness of Y90 microsphere therapy in selected patients with primary and metastatic liver cancer. However, the role of this therapy must be investigated further to integrate and quantify the benefit when combined with other therapies. Modern combination chemotherapy and targeted systemic therapy have resulted in prolongation of survival for patients with metastatic colorectal cancer. Limited reports suggest that combination therapy may also increase the number of patients who subsequently can undergo complete surgical resection of liver metastases. These same antineoplastic agents are known radiosensitizers and therefore ideally could be given with Y90 microspheres in an attempt to further control metastatic liver disease and perhaps to increase the potential for surgical resection. Ongoing phase I and II clinical trials investigating combination chemotherapy with concomitant Y90 microsphere treatment should provide important data on the efficacy and toxicity of the combined modality approach and the optimum sequencing of treatments. Performance of clinical trials and creation of a treatment registry with uniform reporting criteria are essential for determining the safety and role of Y90 microspheres in the context of currently available therapies.

REFERENCES

1. Dawson LA, McGinn CJ, Normolle D, *et al.* Escalated focal liver radiation and concurrent hepatic artery fluorodeoxyuridine for unresectable intrahepatic malignancies. *J Clin Oncol* 2000;18:2210–2218.
2. Ackerman NB, Lien WM, Kondi ES, *et al.* The blood supply of experimental liver metastases. I: The distribution of hepatic artery and portal vein blood to "small" and "large" tumors. *Surgery* 1970;66:1067–1072.
3. Kennedy AS, Salem R. Comparison of two 90Yttrium microsphere agents for hepatic artery brachytherapy [Abstract]. *Proceedings of the 14th International Congress on Anti-Cancer Treatment* 2003;1:156.
4. Goldberg RM, Sargent DJ, Morton RF, *et al.* A randomized controlled trial of fluorouracil plus leucovorin, irinotecan, and oxaliplatin combinations in patients with previously untreated metastatic colorectal cancer. *J Clin Oncol* 2004;22:23–30.
5. Grothey A, Sargent D, Goldberg RM, *et al.* Survival of patients with advanced colorectal cancer improves with the availability of fluorouracil-leucovorin, irinotecan, and oxaliplatin in the course of treatment. *J Clin Oncol* 2004;22:1209–1214.
6. Hurwitz H, Fehrenbacher L, Novotny W, *et al.* Bevacizumab plus irinotecan, fluorouracil, and leucovorin for metastatic colorectal cancer. *N Engl J Med* 2004;350:2335–2342.
7. Liu DM, Salem R, Bui JT, *et al.* Angiographic considerations in patients undergoing liver-directed therapy. *J Vasc Interv Radiol* 2005;16:911–935.
8. Marn CS, Andrews JC, Francis IR, *et al.* Hepatic parenchymal changes after intraarterial Y-90 therapy: CT findings. *Radiology* 1993;187:125–128.
9. Murthy R, Xiong H, Nunez R, *et al.* Yttrium 90 resin microspheres for the treatment of unresectable colorectal hepatic metastases after failure of multiple chemotherapy regimens: Preliminary results. *J Vasc Interv Radiol* 2005;16:937–945.
10. Lewandowski RJ, Thurston KG, Goin JE, *et al.* 90Y microsphere (TheraSphere) treatment for unresectable colorectal cancer metastases of the liver: Response to treatment at targeted doses of 135–150 Gy as measured by [18F]fluorodeoxyglucose positron emission tomography and computed tomographic imaging. *J Vasc Interv Radiol* 2005;16:1641–1651.
11. Kennedy AS, Nutting C, Coldwell D, *et al.* Pathologic response and microdosimetry of 90Y microspheres in man: Review of four explanted whole livers. *Int J Radiat Oncol Biol Phys* 2004;60:1552–1563.
12. Kennedy AS, Coldwell D, Nutting C, *et al.* Resin 90Y-microsphere brachytherapy for unresectable colorectal liver metastases: Modern USA experience. *Int J Radiat Oncol Biol Phys* 2006;65:412–425.
13. Salem R, Lewandowski RJ, Atassi B, *et al.* Treatment of unresectable hepatocellular carcinoma with use of 90Y microspheres (TheraSphere): Safety, tumor response, and survival. *J Vasc Interv Radiol* 2005;16:1627–1639.
14. Gray BN, Anderson JE, Burton MA, *et al.* Regression of liver metastases following treatment with yttrium-90 microspheres. *Aust N Z J Surg* 1992;62:105–110.
15. Stubbs RS, Cannan RJ, Mitchell AW. Selective internal radiation therapy (SIRT) with 90Yttrium microspheres for extensive colorectal liver metastases. *Hepatogastroenterology* 2001;48:333–337.
16. Lau WY, Leung WT, Ho S, *et al.* Treatment of inoperable hepatocellular carcinoma with intrahepatic arterial yttrium-90 microspheres: A phase I and II study. *Br J Cancer* 1994;70:994–999.
17. Lau WY, Ho S, Leung TW, *et al.* Selective internal radiation therapy for nonresectable hepatocellular carcinoma with intraarterial infusion of 90yttrium microspheres. *Int J Radiat Oncol Biol Phys* 1998;40:583–592.
18. Coldwell D, Kennedy AS, Van Echo DA, *et al.* Feasibility of treatment of hepatic tumors utilizing embolization with yttrium-90 glass microspheres [Abstract]. *J Vasc Interv Radiol* 2001;12:S113.
19. Kennedy AS, Murthy R, Sarfaraz M, *et al.* Outpatient hepatic artery brachytherapy for primary and secondary hepatic malignancies. [Abstract]. *Radiology* 2001;221P:468.
20. Kennedy AS, Murthy R, Van Echo DA. Preliminary results of outpatient hepatic artery brachytherapy for colorectal hepatic metastases. [Abstract]. *Eur J Cancer* 2001;37:289.
21. Murthy R, Kennedy AS, Coldwell D, *et al.* Technical aspects of TheraSphere (TS) infusion. [Abstract]. *J Vasc Interv Radiol* 2002;13:S2.
22. Van Echo DA, Kennedy AS, Coldwell D. TheraSphere (TS) at 143 Gy median dose for mixed hepatic cancers: Feasibility and toxicities. [Abstract]. *Am Soc Clin Oncol* 2001;260a:1038.
23. Van Hazel G, Blackwell A, Anderson J, *et al.* Randomised phase II trial of SIR-spheres plus fluorouracil/leucovorin che-

motherapy versus fluorouracil/leucovorin chemotherapy alone in advanced colorectal cancer. *J Surg Oncol* 2004;88:78–85.
24. Lawrence TS, Robertson JM, Anscher MS, *et al.* Hepatic toxicity resulting from cancer treatment. *Int J Radiat Oncol Biol Phys* 1995;31:1237–1248.
25. Gray B, Van Hazel G, Hope M, *et al.* Randomised trial of SIR-Spheres plus chemotherapy vs. chemotherapy alone for treating patients with liver metastases from primary large bowel cancer. *Ann Oncol* 2001;12:1711–1720.
26. Goin JE, Salem R, Carr BI, *et al.* Treatment of unresectable hepatocellular carcinoma with intrahepatic yttrium 90 microspheres: A risk-stratification analysis. *J Vasc Interv Radiol* 2005;16:195–203.
27. Carr BI. Hepatic arterial 90Yttrium glass microspheres (Therasphere) for unresectable hepatocellular carcinoma: Interim safety and survival data on 65 patients. *Liver Transpl* 2004;10:S107–S110.
28. Dancey JE, Shepherd FA, Paul K, *et al.* Treatment of nonresectable hepatocellular carcinoma with intrahepatic 90Y-microspheres. *J Nucl Med* 2000;41:1673–1681.
29. Geschwind JF, Salem R, Carr BI, *et al.* Yttrium-90 microspheres for the treatment of hepatocellular carcinoma. *Gastroenterology* 2004;127:S194–S205.
30. Liu MD, Uaje MB, Al-Ghazi MS, *et al.* Use of Yttrium-90 TheraSphere for the treatment of unresectable hepatocellular carcinoma. *Am Surg* 2004;70:947–953.
31. Steel J, Baum A, Carr B. Quality of life in patients diagnosed with primary hepatocellular carcinoma: Hepatic arterial infusion of Cisplatin versus 90-Yttrium microspheres (Therasphere). *Psychooncology* 2004;13:73–79.
32. Kim DY, Kwon DS, Salem R, *et al.* Successful embolization of hepatocellular carcinoma with yttrium-90 glass microspheres prior to liver transplantation. *J Gastrointest Surg* 2006;10:413–416.
33. Kulik L, Atassi B, van Holsbeeck L, *et al.* Yttrium-90 microspheres (TheraSphere) treatment of unresectable hepatocellular carcinoma: Downstaging to resection, RFA and bridge to transplantation. *J Surg Oncol* 2006;94:572–586.
34. Kulik LM, Mulcahy MF, Hunter RD, *et al.* Use of yttrium-90 microspheres (TheraSphere) in a patient with unresectable hepatocellular carcinoma leading to liver transplantation: A case report. *Liver Transpl* 2005;11:1127–1131.
35. Goin JE, Dancey JE, Roberts CA, *et al.* Comparison of post-embolization syndrome in the treatment of patients with unresectable hepatocellular carcinoma: Trans-catheter arterial chemo-embolization versus yttrium-90 glass microspheres. *World J Nucl Med* 2004;3:49–56.
36. Goin JE, Salem R, Carr BI, *et al.* Treatment of unresectable hepatocellular carcinoma with intrahepatic yttrium 90 microspheres: Factors associated with liver toxicities. *J Vasc Interv Radiol* 2005;16:205–213.
37. Ho S, Lau WY, Leung TW, *et al.* Partition model for estimating radiation doses from yttrium-90 microspheres in treating hepatic tumours. *Eur J Nucl Med* 1996;23:947–952.
38. Ingold J, Reed G, Kaplan H. Radiation hepatitis. *Am J Roentgenol* 1965;93:200–208.
39. Thamboo T, Tan KB, Wang SC, *et al.* Extra-hepatic embolisation of Y-90 microspheres from selective internal radiation therapy (SIRT) of the liver. *Pathology* 2003;35:351–353.
40. Rhee TK, Omary RA, Gates V, *et al.* The effect of catheter-directed CT angiography on yttrium-90 radioembolization treatment of hepatocellular carcinoma. *J Vasc Interv Radiol* 2005;16:1085–1091.
41. Leung TW, Lau WY, Ho SK, *et al.* Radiation pneumonitis after selective internal radiation treatment with intraarterial 90yttrium-microspheres for inoperable hepatic tumors. *Int J Radiat Oncol Biol Phys* 1995;33:919–924.



U.S.NRC

Protecting People and the Environment

Status of Specialty Board Recognition

Cindy Flannery, CHP, Team Leader

U.S. Nuclear Regulatory Commission
Office of Federal and State Materials
and Environmental Management Programs
Division of Materials Safety and State Agreements
Medical Safety & Events Assessment Branch
Medical Radiation Safety Team

October 22, 2007

*Board is verifying the qualifications of diplomates who have obtained their certification prior to the recognition date.

Specialty Board:	Status:	Recog. Date:
Board of Pharmaceutical Specialties	35.55	March 6, 1996
American Board of Nuclear Medicine	35.190, 35.290, 35.390	October 20, 2005*
Certification Board of Nuclear Cardiology	35.290	October 29, 2000
American Board of Health Physics	35.50	Jan. 1, 2005
American Board of Science in Nuclear Medicine Nuclear Medicine Physics and Instrumentation Radiation Protection	 35.50 35.50	 June, 2006 June, 2006
American Board of Radiology (Radiation Oncology) American Board of Radiology (Diagnostic Radiology) American Board of Radiology (Radiologic Physics) Medical Nuclear Physics Diagnostic Radiologic Physics Therapeutic Radiologic Physics	 35.390, 35.490, 35.690 35.290, 35.392 35.50 35.50 35.51	 June, 2007 June, 2006* June, 2007* June, 2007* June, 2007*
American Osteopathic Board of Radiology (Rad. Onc.) American Osteopathic Board of Radiology (Diag.Rad.)	35.390, 35.490, 35.690 35.290, 35.392	May 1, 2007 July 1, 2000
American Osteopathic Board of Nuclear Medicine	35.290	May 18, 2006
American Board of Medical Physicists	Awaiting input	
Certification Board of Nuclear Endocrinology	Awaiting input	
Canadian College of Physicists in Medicine	Under review by NRC staff	

35.50	Radiation Safety Officer
35.51	Authorized Medical Physicist
35.55	Authorized Nuclear Pharmacist
35.190	Authorized User - uptake, dilution, and excretion studies
35.290	Authorized User - imaging and localization studies
35.390	Authorized User - use of unsealed byproduct material for which a written directive is required
35.392	Authorized User - oral administration of sodium iodide I-131 requiring a written directive in quantities less than or equal to 33 mCi
35.394	Authorized User - oral administration of sodium iodide I-131 requiring a written directive in quantities greater than 33 mCi
35.490	Authorized User - use of manual brachytherapy sources
35.590	Authorized User - use of sealed sources for diagnosis
35.690	Authorized User - use of remote afterloader units, teletherapy units, and gamma stereota radiosurgery units

Status of Specialty Board Recognition

Certification Board of Nuclear Endocrinology

- Applied for recognition under 35.190, 35.392, 35.394
- 35.190 Training for uptake, dilution, and excretion studies
- CBNE - partial recognition (i.e., uptake studies under 35.190)

Status of Specialty Board Recognition

CONTACT:

Cindy Flannery
(301) 415-0223
cmf@nrc.gov

Ashley Tull - Re: Seven year recentness of training

From: Ashley Tull
To: Subir.Nag@kp.org
Date: 10/19/2007 4:25:28 PM
Subject: Re: Seven year recentness of training
CC: Cynthia Flannery; Sandra Wastler; welsh@humonc.wisc.edu

Dr. Nag,

The Medical Radiation Safety Team has further reviewed your email, "Seven year recency of training", from 9/24/07 below. Please note that this is not an official NRC opinion, and this response has not been reviewed by NRC's Office of General Counsel.

If this case was an NRC licensee, based on the information provided, the NRC would require the following additional training and documentation:

1. Obtain training in the HDR operation, safety procedures, and clinical use. This training may be obtained by a vendor or by an AU or AMP authorized for the HDR use.
2. Obtain a written attestation that the individual has completed the HDR training and experience and has achieved a level of competency sufficient to function independently as an AU for HDR.

Let me know if I can be of further assistance.

As[redacted]y

Ashley M. Tull
Health Physicist
U.S. Nuclear Regulatory Commission
(301) 415-5294
(918) 488-0552

>>> <Subir.Nag@kp.org> 9/24/2007 12:59:48 PM >>>

Ashley:
I am forwarding you a specific instance of difficulty faced by board certified radiation oncologists due to the seven year recentness of training issue. Could we have this matter for discussion at the next ACMUI meeting (in October).
Thanks.
Subir

Subir Nag, MD, FACR, FACRO
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The following email was forwarded from an ACMUI member to NRC staff. The email provides a specific example of difficulty faced by board certified radiation oncologists due to the seven year recentness of training issue

---

I recently have been faced with our local Health Protection office (HPO) taking a position that the new NRC regulations forbid use of technologies such as HDR and/or radiopharmaceuticals if a physician is not on a license that includes these or without additional recent documentation of experience with these technologies and/or the AU qualification of boards
from June 2006. A new faculty trained at William Beaumont (extensive HDR) who has been at Upenn for some 7 years on faculty came and was refused certification of these things by the HPO locally because she was more than 7 years since training and Penn didn't have an HDR. I would have thought that being boarded would make eligibility acceptable. Below is the note from the local HPO.

The Hospital Radiation Safety Review Group has reviewed your request to add Dr. XXXX as an Authorized User, and approved her as an Authorized User for manual brachytherapy, intravascular brachytherapy, and external beam radiation therapy. At this time, HRSRG approval is limited to these modalities. Owing to the Nuclear Regulatory Commission?s changes in specialty board certification requirements, the Review Group could only approve her for those uses for which she was previously authorized under the radioactive materials licenses of the University of Pennsylvania and the Philadelphia VA Medical Center. In order to extend approval, as requested, to include the use of the high dose rate remote after-loader unit (HDR) and diagnostic/therapeutic use of radiopharmaceuticals, HRSRG would need the submission of a signed preceptor detailing her training and experience, or else American Board of Radiology certification issued from June 2006 forward (as detailed below).
Specifically, authorization for ordering PET studies will require ABR certification in Diagnostic Radiology? AU eligible dated from June 2006 forward, or a signed preceptor detailing that her training and experience within the last seven years meets the requirements for imaging and localization studies as specified in the Iowa Administrative Code (IAC) 641- 41.2(68) or the equivalent Code of Federal Regulations (CFR) 10 CFR 35.290. Authorization for radiopharmaceutical therapy requires ABR certification in Radiation Oncology ? AU eligible dated from June 2007 forward, or a signed preceptor detailing that her training and experience within the last seven years meets the requirements for unsealed by-product material for which a written directive is required as specified in the IAC 641- 41.2(69) or the equivalent 10 CFR 35.390. Authorization for HDR use requires ABR certification in Radiation Oncology ? AU eligible dated from June 2007 forward, or a signed preceptor detailing that her training and experience within the last seven years meets the requirements for use of remote afterloader units as specified in IAC 641-41.2(73) or the equivalent 10 CFR 35.690.
I would appreciate your thought on whether this is an appropriate interpretation of the regulation by our local HPO and whether there is movement to assure that we don't lose credentials that are certified by the ABR via an NRC based regulation.

NRC Petition Process

ACMUI Briefing

October 23, 2007

NRC Petition Process

- Any interested person may petition the Commission to issue, amend or rescind any regulation.
- The Office of Administration, following the regulatory requirements of 10 CFR 2.802, determines if the petition is complete or incomplete.

NRC Petition Process

10 CFR 2.802 requires each petition to:

(1) Set forth a general solution to the problem or the substance or text of any proposed regulation or amendment, or specify the regulation which is to be revoked or amended;

(2) State clearly and concisely the petitioner's grounds for and interest in the action requested;

(3) Include a statement in support of the petition which shall set forth the specific issues involved, the petitioner's views or arguments with respect to those issues, relevant technical, scientific or other data involved which is reasonably available to the petitioner, and such other pertinent information as the petitioner deems necessary to support the action sought. In support of its petition, petitioner should note any specific cases of which petitioner is aware where the current rule is unduly burdensome, deficient, or needs to be strengthened.

NRC Petition Process

If petition is determined to be incomplete:

1) The petitioner will be given an opportunity to submit additional data.

2) If the petitioner does not submit additional data to correct the deficiency within 90 days, the petition may be returned to the petitioner without prejudice to the right of the petitioner to file a new petition.

NRC Petition Process

A petition determined to be complete is:

1) Assigned a docket number.

2) Posted to the NRC Web site.

3) Published in the Federal Register for public comment period of 75 days.

NRC Petition Process

After the public comment period closes:

1) The public comments are posted in ADAMS and on the NRC website.

2) Copies of all the public comments are sent to the petitioner.

3) The petition and public comments are sent to the Division of Intergovernmental Liaison and Rulemaking.

NRC Petition Process

Division of Intergovernmental Liaison and Rulemaking:

1) Assigns a Project Manager.

2) Forms a Working Group that will review the petition and the public comments and develop a recommended resolution of the petition (i.e., to grant or deny the petition).

NRC Petition Process

In considering the merits of the petition, the Working Group:

1) Reviews the petition, any supporting information presented by the petitioner, and the public comments received.

2) Develops an analysis of the petition that:

a) identifies each regulatory issue raised.
b) describes the rationale for each request, including the supporting information
c) identifies the key points made by the commenters (can be in a summary form)
d) indicates how the petition supports the performance goals
e) identifies the pros and cons of each issue and recommends a course of action

NRC Petition Process

The Working Group will brief the Petition Review Board and make a recommendation to:

1) Deny the petition

2) Grant the petition

3) Grant in part and deny in part

NRC Petition Process

The Petition Review Board is composed of:

1) FSME Deputy Office Director

2) DILR Director

3) Programmatic Division Director

4) ADM/RDEB Branch Chief

5) Assistant General Counsel for Rulemaking and Fuel Cycle

NRC Petition Process

The Petition Review Board can vote to:

1) Accept the Working Group recommendation

2) Accept only part of the Working Group recommendation

3) Refer petition back to Working Group

NRC Petition Process

The Petition Review Board decision is considered to be the resolution of the petition.

If petition is granted in whole or part then a proposed rule goes into the rulemaking process

If petition is denied, the a denial package is prepared for the EDO or Chairman to sign

Denial is posted in the Federal Register

E. Russell Ritenour Petition

Ritenour Petition

Update

E. Russell Ritenour Petition

- September 13, 2006 — Docketed at NRC
- November 1, 2006 — Posted to Federal Register
- January 16, 2007 — Public comment closed
- April 11, 2007 — WG began analysis

E. Russell Ritenour Petition

The petitioner requested the NRC to amend 10 CFR § 35.57 to:

1. Recognize medical physicists certified by either the ABR or ABMP on or before October 24, 2005, as grandfathered for the modalities that they practiced as of October 24, 2005. This change should be independent of whether or not a medical physicist was named on an NRC or an Agreement State license as of October, 24, 2005. And
2. Recognize all diplomates that were certified by the named boards in Subpart J for RSO who have relevant timely work experience even if they have not been formally named as an RSO (or as either an "Assistant or Associate RSO"). These diplomates need to be grandfathered as an RSO by virtue of certification providing the appropriate preceptor statement is submitted.

E. Russell Ritenour Petition

Background

- Part 35 T&E was revised in 2002 and 2005
- Part 35, Subpart J was retained for a 2 year transition period in 2002 and extended 1 year in 2004 (expired 24 October, 2005)
- AMPs and RSOs listed on licenses prior to effective date were "grandfathered"
- Commission directed that all boards "both new and existing" must meet new requirements in Part 35

E. Russell Ritenour Petition

Public Comments

- 165 comments submitted
- 108 were form letters from members of AAHP
- 10 were from professional associations
- Most comments were in support of the petition

E. Russell Ritenour Petition

ACMUI Position

In the June 12, 2007 ACMUI meeting, the committee passed MOTION (3): NRC staff should revise the regulations so that previously board certified individuals, who were certified prior to the effective date of recognition, are grandfathered.

E. Russell Ritenour Petition

Working Group Membership

- Project Manager– Division of Intergovernmental Liaison and Rulemaking
- Medical Safety and Event Assessment Branch-Division of MSSA
- Office of General Counsel
- Office of Information Services
- Office of Administration
- NRC Region III
- NRC Region IV
- *Organization of Agreement States*

E. Russell Ritenour Petition

Current Status

- The petition and public comments are currently being analyzed by the Working Group.
- The Working Group anticipates making a recommendation to the Petition Review Board by the end of the year.

QUESTIONS?

NRC Petition Process

or

E. Russell Ritenour Petition

American Association of Physicists in Medicine
One Physics Ellipse
College Park, MD 20740-3846
(301) 209-3350
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http://www.aapm.org

Annette L. Vietti-Cook
Secretary
Attn: Rulemakings and Adjudications Staff
U.S. Nuclear Regulatory Commission
Washington, DC 20555-000 1

September 10, 2006

Dear Ms. Vietti-Cook:

On behalf of the American Association of Physicists in Medicine[1] (AAPM) and pursuant to 10 CFR § 2.802, the enclosed petition is submitted to the U.S. Nuclear Regulatory Commission (NRC) to amend 10 CFR § 35.57, *Training for experienced Radiation Safety Officer, teletherapy or medical physicist, authorized medical physicist, authorized user, nuclear pharmacist, and authorized nuclear pharmacist.* The purpose of this petition is to revise the "grandfather" provision of Part 35 to recognize individual diplomates of certifying boards that were previously named in Part 35 prior to October 25, 2005.

Thank you for your consideration. If you have need for any additional information we would be pleased to provide it. If you have additional questions, please contact Lynne Fairobent, AAPM's Manager of Legislative and Regulatory Affairs at 301-209-3364 or via email at lynne@aapm.org.

Sincerely,

E. Russell Ritenour, Ph.D.
President

1 Enclosure

[1] The American Association of Physicists in Medicine's (AAPM) mission is to advance the practice of physics in medicine and biology by encouraging innovative research and development, disseminating scientific and technical information, fostering the education and professional development of medical physicists, and promoting the highest quality medical services for patients. Medical physicists contribute to the effectiveness of radiological imaging procedures by assuring radiation safety and helping to develop improved imaging techniques (e.g., mammography CT, MR, ultrasound). They contribute to development of therapeutic techniques (e.g., prostate implants, stereotactic radiosurgery), collaborate with radiation oncologists to design treatment plans, and monitor equipment and procedures to insure that cancer patients receive the prescribed dose of radiation to the correct location. Medical physicists are responsible for ensuring that imaging and treatment facilities meet the rules and regulations of the U.S. Nuclear Regulatory Commission (NRC) and various State regulatory agencies. AAPM represents over 6,000 medical physicists.

PETITION FOR RULEMAKING
TO AMEND
10 CFR § 35.57, *Training for experienced Radiation Safety Officer, teletherapy or medical physicist, authorized medical physicist, authorized user, nuclear pharmacist, and authorized nuclear pharmacist.*

1. STATEMENT OF PETITIONER'S INTEREST

The American Association of Physicists in Medicine's (AAPM) mission is to advance the practice of physics in medicine and biology by encouraging innovative research and development, disseminating scientific and technical information, fostering the education and professional development of medical physicists, and promoting the highest quality medical services for patients. Medical physicists contribute to the effectiveness of radiological imaging procedures by assuring radiation safety and helping to develop improved imaging techniques (e.g., mammography, Computed Tomography, Magnetic Resonance, ultrasound, etc.). They contribute to development of therapeutic techniques (e.g., prostate implants, stereotactic radiosurgery, etc.), collaborate with radiation oncologists to design treatment plans, and monitor equipment and procedures to insure that cancer patients receive the prescribed dose of radiation to the correct location. Medical physicists are responsible for ensuring that imaging and treatment facilities meet the rules and regulations of the U.S. Nuclear Regulatory Commission (NRC) and various State regulatory agencies. AAPM represents over 6,000 medical physicists.

AAPM believes that medical physicists have demonstrated their competence to practice through certification by the American Board of Radiology (ABR) or the American Board of Medical Physics (ABMP). With the change in the NRC process for recognition of certifying boards, AAPM is concerned that only individuals certified after the effective date assigned by the NRC staff, once it recognizes a board's certification process, can use certification to meet the training and experience requirements of the rule. This requires individuals certified prior to the effective date to have to go through the alternate pathway. The medical physics community believes there is no evidence to support a rulemaking assertion that training and education (T&E) requirements for listing as an Authorized Medical Physicist (AMP) or Radiation Safety Officer (RSO) acceptable before October 25, 2005 are no longer acceptable as of October 25, 2005.

2. BACKGROUND

A revision of 10 CFR Part 35, *Medical Use of Byproduct Material*, was published on April 24, 2002. (67 *FR* 20249). This revision contained new T&E requirements for individuals to become authorized as an RSO, AMP, authorized user (AU), and/or authorized nuclear

pharmacist (ANP). These new requirements provided three pathways for an individual to become authorized. These pathways are:

(1) an individual may be certified by a specialty board whose certification process is recognized by the NRC or an Agreement State as meeting NRC's T&E regulation (a "recognized board");
(2) approval based on an individual's T&E (alternate pathway); or
(3) identification of an individual's listing on an existing NRC or Agreement State license (in essence the "grandfathering pathway").

As in the rulemaking, pathway (1) will be referred to as the certification pathway and (2) the alternate pathway.

As indicated by the "Background statement" in 67 *FR* 20249 and 70 *FR* 16335, during a briefing on February 19, 2002 to the Commission, the Advisory Committee on Medical Uses of Isotopes (ACMUI) expressed concern about requirements for T&E in the revised 10 CFR Part 35 approved by the Commission on October 23, 2000 (SRM-SECY-00-0118). The ACMUI was "concerned that if the requirements for recognition of specialty board certifications were to become effective as drafted, there could be potential shortages of individuals qualified to serve as RSOs, AMPs, ANPs, and AUs because they would no longer meet the requirements for T&E under the certification pathway. The ACMUI indicated that, without changes to the requirements for T&E in the final rule approved by the Commission in October 2000, the boards would no longer be qualified for recognition by NRC and, therefore, a **board's future diplomates could no longer be approved as RSOs, AMPs ANPs, or AUs."** [Emphasis added.]

The ACMUI also expressed the concern that the specialty boards might be "marginalized." "Based on these concerns, the ACMUI urged the Commission to implement measures to address the T&E issues associated with recognition of specialty boards by the NRC in the draft final rule and to find a permanent solution after publication of the final rule. Subsequently, the NRC modified the final rule by reinserting Subpart J (as contained in the proposed rule before publication of the revised Part 35 in April 2002) for a 2-year transition period. [This was subsequently extended for a third year until October 24, 2005 (69 *FR* 55736).] Subpart J provides for continuing recognition of the specialty boards listed therein during the transition period. The final rule was published in the Federal Register on April, 2002 (67 *FR* 20249) and became effective on October 24, 2002." This rule, as implemented, has in actuality "marginalized" the specialty boards that it intended to recognize.

The Commission directed the NRC staff to develop options for addressing the T&E issue further and to work with the ACMUI and stakeholders (SRM-COMSECY-02-0014). The final T&E rule was published in the Federal Register March 30, 2005 (70 *FR* 16335) and became effective on April 29, 2005. However, in accordance with 69 *FR* 55736, *Medical Use of Byproduct Material Minor Amendments: Extending Expiration Date for Subpart J,* Subpart J was extended to October 24, 2005.

3. PROPOSED ACTIONS

First, 10 CFR § 35.57, *Training for experienced Radiation Safety Officer, teletherapy or medical physicist, authorized medical physicist, authorized user, nuclear pharmacist, and*

authorized nuclear pharmacist, should be amended to recognize medical physicists certified by either the ABR or the ABMP on or before October 24, 2005, as grandfathered for the modalities that they practiced as of October 24, 2005. This change should be independent of whether or not a medical physicist was named on an NRC or an Agreement State license as of October 24, 2005.

Secondly, 10 CFR § 35.57 should be amended to recognize all diplomates that were certified by the named boards in Subpart J for RSO who have relevant timely work experience even if they have not been formally named as an RSO (or as either an "Assistant or Associate RSO"). These diplomates need to be grandfathered as an RSO by virtue of certification providing the appropriate preceptor statement is submitted.

4. RATIONALE FOR CHANGES

The AAPM, the ABR, and the ABMP believe that it was never the intent of the Commission to deny recognition to any medical physicist currently practicing, or to minimize the importance of certification by a certifying board. This belief is confirmed by our review of the Commission and the ACMUI transcripts. However, since the rule became final, the AAPM, the ABR and the ABMP remain concerned about the NRC's staff's method used to grant recognized status to the process used by certifying boards such as ABR and ABMP.

It has become clear during this review that new concerns regarding diplomates of the certifying boards listed in the original Subpart J have been identified by the medical community. During the review by NRC staff for recognizing the process in place for a certifying board, the NRC staff has assigned "effective dates" for that recognition. As a result, current diplomates of the ABR and the ABMP to serve as AMPs and RSOs must apply via the "alternate pathway" and cannot be listed on a license via the "certification pathway."

The ABR and ABMP believed that the review of their current process was only for diplomates certified after the October 24, 2005, the final date for which Subpart J regulations are effective (see 69 *FR* 55736 *Medical Use of Byproduct Material Minor Amendments: Extending Expiration Date for Subpart J*). We have affirmed with the boards that they believed that their existing diplomates' certifications (*i.e.*, certificates issued before October 25, 2005) would continue to be recognized by the Commission or an Agreement State. AAPM believes that medical physicists have demonstrated their competence to practice through certification by the ABR or the ABMP. We are concerned that the effective date assigned by the staff once it recognizes a board's process may force individuals certified prior to that date to have to pursue the alternate pathway. AAPM believes that this will place an undue burden on the medical community and potentially result in an insufficient number of AMPs and RSOs.

4.1 Authorized Medical Physicists Amendment

During the revision of 10 CFR Part 35, the NRC added the concept of a medical physicist to be listed on a license. The term "AMP" is a recent construct in both the NRC and Agreement State regulatory structure. Prior to the concept of "AMP" licensing authorities:

1. may have requested a medical physicist to be named on the initial license;
2. may not have required all medical physicists to be listed on a license;
3. may not have required licensees to add additional medical physicists if they joined a

practice or replaced a "named medical physicist; and

4. Qualified medical Physicists may not have been listed in connection with manual brachytherapy procedures.

This inconsistency in the regulation was the basis for the requirement to list an AMP on licenses, however the requirement also specifies that an individual must have a statement signed by a "preceptor AMP" attesting that the individual is capable of acting independently for the modality specified. Without medical physicists listed on licenses prior to the new regulation, there is limited opportunity for a medical physicist to serve as a preceptor. In order for a medical physicist to be "grandfathered" in accordance with the new regulation, the medical physicist must have been listed on a license as of the effective date of the regulation.

By amending §35.57 in the first case, medical physicists would be recognized by virtue of their certification by the boards listed originally in Subpart J prior to October 24, 2005. This would allow individuals to serve as AMPs or preceptor AMPs without having to be recognized via the alternate pathway. This would not result in grandfathering the boards' processes but would recognize the diplomates that were certified by the named boards in Subpart J and found competent on or before October 24, 2005, *i.e.*, a "true grandfathering of individuals." AAPM believes that there have been no health and safety concerns raised by these individuals practicing in medical institutions.

4.2 Radiation Safety Officer Amendment

By regulation, licensees can have only one individual named as a RSO, unlike the position of AU for which there are typically multiple individuals named on a license. This circumstance makes it far more difficult for an AMP or other Board diplomates to have acquired the requisite grandfather status prior to October 24, 2005. Radiation safety and training has been part of the certification exams for physicists for both the ABR (since at least 1979) and the ABMP (since inception of the exam). AAPM believes that the NRC should recognize individuals that were certified by a board that was listed in Subpart J of the old regulations for both §§ 35.50 (RSO) and 35.51 (AMP) prior to October 24, 2005.

5. CONCLUSION

AAPM believes that these proposed solutions should be expedited. Although the certifying bodies are concerned with receiving recognized status, AAPM is concerned about ensuring that the diplomates of the Boards listed in Subpart J are able to continue practicing medical physics and serving as RSOs to assure the continuation of high quality patient care.

AAPM believes that the proposed amendment to 10 CFR § 35.57, *Training for experienced Radiation Safety Officer, teletherapy or medical physicist, authorized medical physicist, authorized user, nuclear pharmacist, and authorized nuclear pharmacist,* should be enacted expeditiously to ensure that diplomates of the Boards listed in Subpart J are able to continue practicing medical physics and serving as RSOs in order to assure the continuation of high quality patient care. Further, AAPM believes that this action eliminates the marginalization of specialty boards.

NO HANDOUT

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

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.

1. Scheduling and Conduct of Meetings

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

1.1 Scheduling of Meetings:

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

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

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

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

1.2 Meeting Agenda:

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

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

1.3 Conduct of the Meeting:

1.3.1 All meetings will be held in full compliance with the Federal Advisory Committee Act. Questions concerning compliance will be directed to the NRC Office of the General Counsel.

1.3.2 The Chair will preside over the meeting. The Vice Chair will preside if the Chair is absent or if the Chair is recused from participating in the discussion of a particular agenda item. The Designated Federal Officer will preside when both the Chair and the Vice Chair are absent and/or recused from the discussion, or when directed to do so by the Commission.

1.3.3 A majority of the current membership of the ACMUI will be required to constitute a quorum for the conduct of business at an ACMUI meeting.

1.3.4 The Chair has both the authority and the responsibility to maintain order and decorum, and may, at his or her option, recess the meeting if these are threatened. The Designated Federal Officer will adjourn a meeting when adjournment is in the public interest.

1.3.5 The Chair may take part in the discussion of any subject before the ACMUI, and may vote. The Chair should not use the power of the Chair to bias the discussion. Any dispute over the Chair's level of advocacy shall be resolved by a vote on the Chair's continued participation in the discussion of the subject. The decision shall be by a majority vote of those members present and voting, with a tie permitting continued participation of the Chair in the discussion.

1.3.6 When a consensus appears to have developed on a matter under consideration, the Chair will summarize the results for the record. Any members who disagree with the consensus shall be asked to state their dissenting views for the record. Any ACMUI member may request that any consensus statement be put before the ACMUI as a formal motion subject to affirmation by a formal vote. No ACMUI position will be final until it has been formally adopted by consensus or formal vote, and the minutes/transcript written and certified.

2. MINUTES/TRANSCRIPTS

2.1 Minutes/transcripts of each meeting will be prepared by the ACMUI Chair, with assistance from the FSME staff, in accordance with the requirements in 10 CFR Part 7. The Commission staff will prepare minutes/transcripts of ACMUI meetings with the Commission.

2.2 The ACMUI Chair will certify the minutes/transcripts in accordance with 10 CFR Part 7.

2.3 In accordance with the requirements of the NRC's Operating Plan, FSME staff will prepare a meeting summary. The FSME staff will e-mail the meeting summary document or web link to the ACMUI members.

2.4 Copies of the certified minutes/transcripts will be made available to the ACMUI members, and to the public, not later than 90 days after the meeting.

3. APPOINTMENT OF MEMBERS

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

3.2 The Chair will be appointed by the Director, FSME, from the membership of the ACMUI. The Chair will serve at the discretion of the Director, FSME.

3.3 The Vice Chair will be appointed by the Director, FSME, from the membership of the ACMUI. The Vice Chair will serve at the discretion of the Director, FSME.

4. CONDUCT OF MEMBERS

4.1 If a member believes that he or she may have a conflict of interest with regard to an agenda item to be addressed by the ACMUI, this member should divulge it to the Chair and the Designated Federal Officer as soon as possible, but in any case before the ACMUI discusses it as an agenda item. ACMUI members must recuse themselves from discussion of any agenda item with respect to which they have a conflict of interest.

4.2 Upon completing their tenure on the ACMUI, members will return any privileged documents and accountable equipment (as so designated by the NRC) provided for their use in connection with ACMUI activities, unless directed to dispose of these documents or equipment.

4.3 Members of the ACMUI are expected to conform to all applicable NRC rules and regulations, and are expected to attend meetings regularly and perform all assigned duties.

5. ADOPTION AND AMENDMENTS

5.1 Adoption or approval of an amendment of these bylaws shall require an affirmative vote of two-thirds of the current ACMUI membership and the concurrence of the Director of the Office of Federal and State Materials and Environmental Management Programs.

5.2 Any member of the ACMUI or FSME staff may propose an amendment to these bylaws. The proposed amendment will be distributed to the members by the Chair and scheduled for discussion at the next regular ACMUI meeting.

5.3 The proposed amendment may be voted on as early as the next ACMUI meeting after distribution to the members.

5.4 The ACMUI shall consult with the Office of the General Counsel regarding conflicts that arise from the interpretation of the bylaws. After consultation, the ACMUI shall resolve interpretation issues by a majority vote of the current membership of the ACMUI.

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

1. **Committee's Official Designation**:

   Advisory Committee on the Medical Uses of Isotopes

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

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

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

3. **Time period (duration of this Committee):**

   Continuing Committee.

4. **Official to whom this Committee reports:**

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

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

   U.S. Nuclear Regulatory Commission.

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

7. **Estimated annual direct cost of this Committee:**

   Members are appointed by the Director, Office of Federal and State Materials and Environmental Management Programs as Special Government Employees (SGEs). Approximately 13 members utilize 1 FTE (includes approximately 0.6 FTE for NRC staff and 0.4 FTE for ACMUI members 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, 2008.

10. **Filing date:**

March 15, 2007

/RA/

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

ADVISORY COMMITTEE ON THE MEDICAL USES OF ISOTOPES

Position	Name	Phone	Email	Title	Address	Fax	Assistant	Comments
Nuclear Medicine Physician	**Douglas F. Eggli, M.D.**	(717) 531-8940	deggli@psu.edu	Dept of Radiology, H066, Penn State Univ Hospital, The Milton S. Hershey Med Center	Room HG300B, PO Box 850, 500 University Dr., Hershey, PA 17033	(717) 531-5596	Debra Pavone (717) 531-5341 dpavone@psu.edu	
Patient Advocate	**Darrell R. Fisher, Ph.D.**	(509) 373-2000 *Restricted PII* cell	dr.fisher@pnl.gov	Sr Scientist, Radioisotopes Program, Pacific Northwest National Lab	*Home: Restricted PII* 902 Battelle Blvd., P7-27, Richland, WA 99354	(509) 373-2001		mail all items home
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Health Care Administrator	**Leon S. Malmud, M.D.** CHAIRMAN	(215) 707-7074 (215) 885-0756	malmudls@tuhs.temple.edu	Dean Emeritus, Temple Univ School of Med, Temple Univ Health System	3401 N. Broad St., Philadelphia, PA 19140	(215) 707-3261	Pat Martin (215) 707-7078 martinp@tuhs.temple.edu	
Nuclear Pharmacist	**Steve Mattmuller**	(937) 298-3399 x57682	Steve.Mattmuller@kmcnetwork.org	Chief Nuclear Pharmacist, Dept of Nuc Med/PET, Kettering Memorial Hospital	3535 Southern Blvd., Kettering, OH 45429			
Radiation Oncologist	**Subir Nag, M.D.**	(408) 851-8085 (408) 851-8000 *Restricted PII* cell	subir.nag@kp.org	Kaiser Permanente Radiation Oncology	3800 Homestead Rd., Santa Clara, CA 95051	(408) 851-8010		
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FDA Representative	**Orhan H. Suleiman, Ph.D.**	(301) 796-1471	orhan.suleiman@fda.hhs.gov	Senior Science Policy Advisor, Office of Oncology Drug Products, Office of New Drugs, Center for Drug Evaluation and Research (CDER), FDA	USFDA, White Oak Building 22, Room 2206, 1093 New Hampshire Ave., Silver Spring, MD 20993	(301) 796-9909		
Medical Physicist Therapy	**Bruce R. Thomadsen, Ph.D**	(608) 263-4183 (608) 263-8500	thomadsen@humonc.wisc.edu	University of Wisconsin-Madison, University of Wisconsin Medical School, Associate Professor	1530 Medical Science Center, 1300 University Avenue, Madison, WI 53706	(608) 262-2413		
Nuclear Cardiologist	**William A. Van Decker, M.D.**	(215) 707-3347 (215) 707-9857	vandecwa@tuhs.temple.edu	Dir of Nuc Card and Assoc Prof of Med, Temple Univ School of Med	1051 Montgomery Ave., Narberth, PA 10972 3401 N. Broad St. 945 Parkinson Pavilion Philadelphia, PA 19140	(215) 707-3946	Tanya Santiago 215-707-9587 tanya.santiago@tuhs.temple.edu	
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Radiation Oncologist	**James S. Welsh, M.D.**	(715) 421-7442 *Restricted PII* cell	welsh@humonc.wisc.edu	Med Dir, UW Cancer Center, Riverview	410 Dewey St., P.O. Box 8080, Wisconsin Rapids, WI 54495-8080	(715) 421-7408	Barbara Schmalz (715) 422-9208 schmba@rhahealthcare.org	
State Government Representative	Vacant							