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**October 13-14, 2004
NRC Headquarters**

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ACMUI Meeting
October 13, 2004
U.S. Nuclear Regulatory Commission
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PRINTED NAME	ORGANIZATION
1 RALPH SHUPING	FDA
2 DONNA-BETH HOWE	USNRC
3 KEN MAYNARD	SNM
4 ROBERT GALLAGHER	MA DPH/RCP OAS
5 LYNN FANOHANT	AAPM
6 JERRY WHITE	AAPM
7 DAVIS LEWIS	USNRC
8 ROSHUNDA DRUMMOND	ASTRO
9 CHRISTINE WILLIAMS	SNM
10 GIORGIO ROMANO III	ACIC
11 LISA DIMMICK	Nucletron
12 RAYMOND HORN	Nucletron
13 HUGO CANIDON	SNM
14 MELISSA MARTIN	AAPM
15 TERENCE BEVEN	SNM
16 SUSAN B. CING	NRE
17	
18	
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**ACMUI Meeting
October 14, 2004
U.S. Nuclear Regulatory Commission
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PRINTED NAME	ORGANIZATION
1 Lynne Fairbent	AARM
2 TERENCE BEVEN	SNM
3 Ken MAYNARD	SNM
4 JAMES BOXALL	ACC
5 Roshunda Drummond	ASTRO
6 JERRY WHITE	AAPM
7 Ralph Shuping	FDA
8 Donna Beth Heuser	USNRC
9 Michael Maricley	USNRC
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**SPEAKERS and PARTICIPATING NRC STAFF
ACMUI MEETING
OCTOBER 13-14, 2004**

Roger W. Broseus, PhD, NMSS/IMNS/RGB

Leon S. Malmud, MD, ACMUI Chairman

Thomas H. Essig, NMSS/IMNS/MSIB, Designated Federal Official

Robert Gallagher, Massachusetts

Linda M. Gersey, NMSS/IMNS/MSIB

Timothy Harris, NMSS/IMNS/MSIB

Patricia K. Holahan, PhD, NMSS/IMNS

Merri Horn, NMSS/IMNS/RGB

Donna-Beth Howe, PhD, NMSS/IMNS/MSIB

Andrea Jones, RES

Charles L. Miller, PhD, NMSS/IMNS

Subir Nag, MD, ACMUI

Sami Sherbini, PhD, NMSS/IMNS/MSIB

John Szabo, OGC

Richard J. Vetter, PhD, ACMUI

William Ward, NMSS/IMNS/MSIB

Ronald E. Zelac, PhD, NMSS/IMNS/MSIB

**AGENDA
ACMUI MEETING
OCTOBER 13-14, 2004**

**WEDNESDAY, OCTOBER 13, 2004, CONFERENCE ROOM, T-2B3, TWO WHITE FLINT NORTH,
ROCKVILLE, MARYLAND**

- 1) 8:00 – 8:15 Opening Remarks (Closed Session) (Presenter: C. Miller, PhD, NRC)
Dr. Miller will open the closed session with a status update of ACMUI/
NRC staff interactions, and will also provide an outline of the topics to
be discussed during the closed session.
- 2) 8:15 – 8:45 Ethics Briefing (Closed Session) (Presenter: J. Szabo, NRC)
Mr. Szabo, Office of the General Counsel, will provide the ACMUI its
required annual ethics briefing.
- 3) 8:45 – 9:45 Administrative Issues (Closed Session) (Presenter: T. Essig, NRC)
Mr. Essig will brief the ACMUI on issues related to committee
management, logistics, and the roles and responsibilities of the ACMUI
and the NRC staff.
- 4) 9:45 – 10:15 Interim Source Database (Closed Session) (Presenter: W. Ward, NRC)
Mr. Ward will brief the ACMUI on the purpose and the status of
the interim radioactive source database.

NOTE: The above sessions may be closed pursuant to 5 U.S.C. 552b(c)(2), (6) and (9)(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."

10:15 – 10:30 *BREAK*****

- 5) 10:30 - 10:35 Opening Remarks (Open) (Presenter: T. Essig, DFO, NRC)
Mr. Essig, Designated Federal Officer, ACMUI, will commence the open
session with introductory remarks explaining the purpose of the
meeting and welcoming all in attendance.
- 6) 10:35 – 11:05 Radioimmunotherapy and Microsphere Therapy (Open)
(Presenter: D.B. Howe, PhD, NRC)
Dr. Howe will discuss current NRC policy, regulations, and training and
experience (T&E) requirements regarding antibody-linked radionuclide
therapy and microsphere therapy.

- 7) 11:05 – 12:00 Radioimmunotherapy and Microsphere Therapy (Open)
(Presenter: S. Nag, MD, ACMUI)
Dr. Nag will present his views on issues regarding regulation of these therapies.
- 12:00 – 1:00 *****LUNCH*****
- 8) 1:00 – 1:30 Registration of Brachytherapy Sources (Open) (Presenter: T. Harris)
Mr. Harris will discuss the background on existing registration of brachytherapy seeds and current guidance.
- 9) 1:30 – 2:00 Radiation Safety Aspects of I-125 Therapeutic Seeds Used as Markers in Breast Cancer Tumors (Open) (Presenter: Robert Gallagher, Mass.)
Mr. Gallagher will discuss the regulatory issues encountered with the off-label use of I-125 radioactive seeds as markers to delineate tumors in breast cancer patients.
- 10) 2:00 – 3:00 Staff Findings and Followup to the ACMUI Report on the NRC Method of Dose Reconstruction (Open) (Presenter: S. Sherbini, PhD, NRC)
Dr. Sherbini will present the NRC staff response to the ACMUI's recommendations related to the staff's method of reconstructing doses.
- 3:00 – 3:15 *****BREAK*****
- 11) 3:15 – 4:15 Status of Medical Events (Standing Item) (Open)
(Presenters: T. Essig, NRC; L. Gersey, NRC; and DB Howe, PhD, NRC)
Staff will seek the ACMUI's advice, recommendations, and insights regarding the cause of medical events, and possible methods to reduce them.
- 12) 4:15 – 5:00 Update to Medical Event Criteria Definition (Open)
(Presenter: R. Zelac, PhD, NRC)
Dr. Zelac will discuss possible efforts to update the medical event criteria definition.
- 5:00 **ADJOURN**

THURSDAY, OCTOBER 14 2004, CONFERENCE ROOM, T-2B3, TWO WHITE FLINT NORTH, ROCKVILLE, MARYLAND

- 13) 8:00 – 8:15 Draft Final 10 CFR 35 T&E: Status of Rulemaking (Open)
(Presenter: R. Broseus, PhD, NRC)
Dr. Broseus will brief the ACMUI with the status of the training and experience (T&E) draft final rule, which proposes the addition of specified training hours to the T&E.
- 14) 8:15 – 10:00 Discussion/Preparation of ACMUI Comment Letter on the Draft Final 10 CFR 35 T&E Rulemaking (Open)
The ACMUI will discuss the proposed changes as presented in the draft

final rule; reach consensus on ACMUI comments; and prepare a letter stating the committee's position on the draft final rule.

- 10:00 – 10:15** *****BREAK*****
- 15) 10:15 – 11:15 Proposed Changes to AO Criteria (Open) (Presenter: A. Jones, NRC)
Ms. Jones will present proposed changes to the Abnormal Occurrence criteria for the medical events.
- 16) 11:15 – 12:00 National Source Tracking (Open) (Presenter: M. Horn, NRC)
Ms. Horn will provide an overview of NRC's system to account for radioactive sources nationwide.
- 12:00 – 1:00** *****LUNCH*****
- 17) 1:00 – 3:00 2005 ICRP Recommendations (Open)
(Presenter: R. Vetter, PhD, ACMUI)
Dr. Vetter will brief the ACMUI on the International Commission on Radiological Protection's (ICRP) recommendations for 2005. Dr. Vetter will seek an ACMUI consensus position on the 2005 recommendations, for presentation to the ACNW Working Group discussion on October 19, 2004.
- 18) 3:00 – 3:30 Administrative Closing/Action Item Review (Open)
The NRC staff and the ACMUI will discuss miscellaneous items of interest arising from the October 13-14, 2004 meeting; will review action items arising from this meeting, will discuss other non-sensitive administrative matters related to committee business, if any; and will discuss proposed meeting dates for the Spring 2005 meeting.
- 3:30** **ADJOURN**

**OPENING REMARKS
(ACMUI ONLY)**

NO HANDOUT

**ETHICS BRIEFING
(ACMUI ONLY)**

NO HANDOUT

**ADMIN ISSUES
(ACMUI ONLY)**

NO HANDOUT

**INTERIM SOURCE
DATABASE
(ACMUI ONLY)**

NO HANDOUT

OPENING REMARKS

NO HANDOUT

**Radioimmunotherapy and
Microsphere Therapy**

October 2004

ACMUI MEETING

Donna-Beth Howe, Ph.D.

**Radioimmunotherapy -Monoclonal
Antibodies**

**FDA regulates them as radioactive biologicals
a subset of radioactive drugs**

**Licensed for manufacture and commercial
distribution pursuant to 10 CFR 35.72. or
equivalent Agreement State requirements**

Licensed for medical use under 10 CFR 35

**Therapeutic procedure - requires a written
directive**

Y-90 Microsphere Therapy

FDA regulates them as medical Devices

They are sealed sources

**Licensed for Manufacture and commercial
distribution pursuant to 10 CFR 35.74. or
equivalent Agreement State requirements**

Licensed for medical use under 10 CFR 35

**Therapeutic procedure - requires a written
directive**

Radiation Safety Considerations of New Modalities

- Y-90 microspheres
- Radiolabelled antibody therapy
- Pulse Dose Rate
- I-125 permanent afterloader
- Ceslum-131 permanent seeds

Nag

⁹⁰Y-Microspheres For Primary and Metastatic Liver Cancers

- Yttrium-90 microspheres suspended in solution
- Permanently injected into liver via hepatic A
- Y-90 - high-energy pure beta-emitter
- Max. energy = 2.27MeV (mean 0.93MeV).
- Mean range in tissue = 2.5mm
- Half-life = 64 hours
- 94% of the radiation is delivered in 11 days
- SIR-Spheres® by Sirtex and Theraspheres by MDS Nordion

Nag

Microspheres



Glass microspheres - HCC

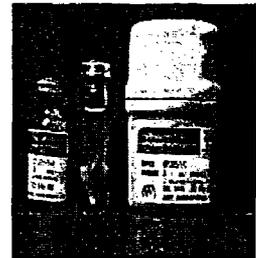


Resin microspheres - Colorectal

Nag

SIR-Spheres®

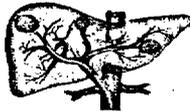
- Supplied in a vial containing 3 GBq of yttrium-90 (at the time of calibration) in a total of 5 cc water for injection
- Each vial contains 40 - 80 million resin microspheres 20-60 μ diameter.
- Average no. of particles implanted = 30 - 60 x 10⁶



Nag

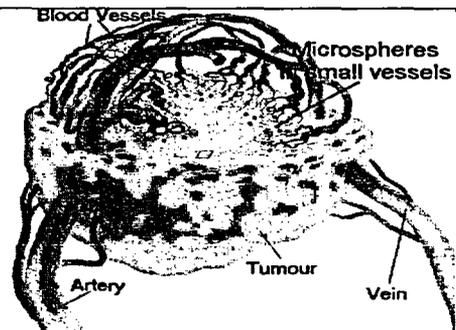
Hepatic Artery Infusion

- Injected into common, right, or left hepatic artery via chemotherapy catheter port
- Distributes non-uniformly in the liver
- Tumor usually gets higher density (x5-6) of SIR-Spheres than normal liver due to blood flow
- Not metabolized or excreted; stays permanently in the liver.
- Tumor vessels 25 μ m -75 μ m diameter
- End arterioles to venous 8 μ m diameter



Nag

Liver vasculature



Nag

Advantages of Pulsed Brachytherapy

- Only a single Ir source is necessary, reducing the need for an extensive, expensive inventory of sources
- Intermediate half-life of Ir (74 days): the source may be kept for up to 3 months before replacement
- Storage is simplified by location of source within the shielded unit.
- Since the maximum activity of the source is 1.0 Ci, additional shielding may be required to meet governmental standards in some rooms, but the source is only 1/10th of that used in the high dose-rate units.

Nag

Advantages of Pulsed Brachytherapy

- Risk of exposure to radiation oncology personnel, nursing staff, physicians from other disciplines or visiting family members is eliminated.
- The source is safely isolated after treatment, allowing the nursing staff to work more extensively with the patient.
- The pulse is generally timed to end precisely at the hour, reducing confusion as to when the nursing staff may enter the room.

Nag

Disadvantages of PDR

- PDR treatments require several days to deliver the desired dose
 - requiring prolonged hospital stays.
- Risks of prolonged bedrest (e.g. deep venous thromboses, pulmonary emboli, stasis ulcers, etc.)
- During the hospital stays, there is the potential for movement of the instrumentation.
- Significant movement of the patient in the bed may impede transit of the cable-driven source.

Nag

Radiobiologic Issues

- Is a dose delivered to a volume as a brief pulse of a single stepping source at very high instantaneous dose rates biologically equivalent to the same average dose delivered constantly by a series of sources at a much lower instantaneous dose rate?
- Is the dose equivalent both in terms of its effect on early reacting tissues (including tumor) and late-reacting tissues?

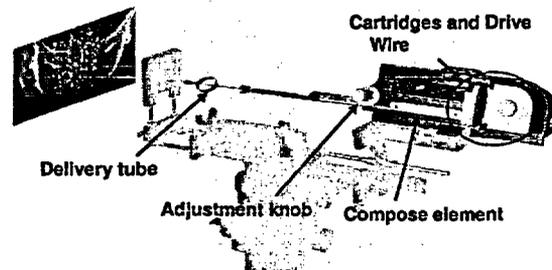
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Radiation Safety Consideration

- Source activity is one tenth of HDR source
- Is it necessary to have a physicist/authorized user to be present throughout the treatment?
- If so, not practical to use PDR

Nag

I-125 afterloader - seedSelectron



Nag



ACMUI Briefing Revisions to Part 35 – Recognition of Board Certifications

October 14, 2004

Roger W. Broseus, CHP, Ph.D.
Office of Nuclear Material Safety and Safeguards,
Division of Industrial and Medical Nuclear Safety

Extension of Subpart J

- Subpart J: Effective date extended one year to October 24, 2005 (69 FR 55736, Sep 16, 2004)
- Allow time for boards to apply for recognition of certifications under forthcoming revisions to Part 35

Public Comments on Proposed Rule

- Preceptors should not be required to attest to candidates passing board administered exams
- Use of “attest” vs. “certify” in preceptor statements

Public Comments on Proposed Rule (cont.)

- Proposed § 35.390(c) implies preceptor must attest to passing of certification examination
- Allow for authorization of radiation oncologists who complete residency programs (§ 35.390)

Public Comments on Proposed Rule (cont.)

- Agreement States seek full 3 years to develop a compatible rule
- Hours of training – want more specificity, e.g., for number of hours of **didactic training** to qualify as
- Authorized users – 35.190, 35.290, 35.390
- Authorized nuclear pharmacists under 35.55

Working Group Recommendations

- Draft-final rule to require a minimum numbers of hours of 'didactic' training of the total hours
- Applies only to the "alternate pathway"
- Would not apply to requirements for recognition of specialty board certifications by the NRC or an Agreement State

Requirements for Minimum Number of
'Didactic' Hours of T&E
(draft-final rule)

Section	Total Hrs	Didactic
35.55	700	200
35.190	60	8
35.290	700	80
35.390	700	200

Status of Rulemaking

- Resolve comments from ACMUI, AS
 - Comment period ends Oct 18, 2004
- Draft-final rule to Commission ~mid-Nov
- Anticipate publication in 2005

Radiation Safety Aspects of I-125 Therapeutic Seeds Used as Markers in Breast Cancer Tumors

Robert Gallagher
Chairman, National Materials Program Pilot 4
Supervisor, Materials Inspection and Enforcement Branch
Massachusetts Radiation Control Program

INTRODUCTION

- Brief description of NMP Pilot 4
 - One of 5 pilot projects under NMP
 - Goal: Have an Agreement State, or group of Agreement States, assume responsibility for development of licensing and inspection guidance for a new use of material not previously reviewed and approved.

How Radioactive Seed Localization was Selected

- Reviewed regulatory needs identified by NMP Pilot 1 Working Group;
- Surveyed Agreement States, NRC HQ and Regional offices;
- Contacted major medical institutions in the United States

Why Radioactive Seed Localization was Selected

- Iodine-125 is an AEA material, regulated by both NRC and Agreement States;
- Use in this application does not fit under 10 CFR 35.200 or 35.400;
- Therefore use does fit into 10 CFR 35.1000, Other medical uses
- No review by the NRC or an Agreement State has been performed.

Status of Guidance Development

- Draft of licensing and inspection document submitted to NRC/STP on September 9, 2004;
- Received comments from NRC and OAS which are currently under review by the Working Group.

Description of Radioactive Seed Localization (RSL)

- Calls for the use of currently available seeds previously approved for permanent implantation;
- I-125 seed, typically 200-300 μCi /seed, implanted into breast lesion using 18-gauge needle;
- Seeds are then located using hand-held gamma probe by surgeon and surgically removed;

Description of Radioactive Seed Localization (RSL) - continued

- Seed may be removed from specimen in surgery;
- Or specimen with seed may be sent to pathology for removal of seed and analysis of the tissue;
- Seeds are then disposed of per 10 CFR 35.92 or equivalent Agreement State regulations.

Radiation Safety Aspects of RSL

- Facility diagrams - include all areas of use
 - Administration;
 - Excision;
 - Removal from tissue;
 - Analysis
 - Storage for disposal.

Radiation Safety Aspects of RSL

- Authorized Users
 - Identify all authorized users and document his or her training;
 - 10 CFR 35.490
 - 10 CFR 35.290 and preceptorship training
 - General surgeons - 8 hours radiation safety training under guidance of AU described above.

Records

- Applicant may simplify by confirming that it will meet the brachytherapy requirements appropriate for a temporary implant in 10 CFR Part 35 Subparts F, L and M.

Safety Precautions for RSL

- Licensees should provide procedures addressing:
 - Safety procedures and instructions, including survey procedures;
 - Identifying individuals who must be present;
 - Source accountability and leak testing;
 - Verification of source activity.

Safety Precautions for RSL

- Applicant should supply procedures for responding to an abnormal situation:
 - Monitoring area using appropriate instruments;
 - Restricting access and posting;
 - Description of equipment and process for recovery of any dropped or mishandled seeds;

Safety Precautions for RSL

- Applicant should supply procedures for responding to an abnormal situation:
 - Patient follow-up should they not return;
 - Description of length of time seeds remain in patient;
 - Notification of medical emergency of patient.

Change in Physical Conditions of Use

- If the conditions of use exceed those stated in the SS&D certificate, limited scope licensee will have to amend its license to allow for use *under new conditions*
- Some states will not allow variations unless the original SS&D registration is amended or custom evaluation is performed

Comments Received from the NRC

- Primarily involve pathology specimens
 - Delineate program for specimens going to pathology laboratory. Should specify:
 - Tissues with seed processed at external pathology laboratory?
 - Description of radiation safety program
 - Program to assure samples transferred to licensed facility

Comments Received from the NRC

- New conditions of use
 - Applicant must be instructed to address why the sources are safe to use in the normal and emergency conditions of use associated with this procedure

Comments Received from the NRC

- Authorized Users
 - Addition of clinical experience should be considered for addition to the training and experience of the authorized users criteria
 - At least one Part 30 Authorized User should be identified in the Pathology Laboratory

Comments Received from the NRC

- Patient Dose
 - Guidance needs to address the patient dose and regulatory issues associated with the dose to patient from the seeds
 - Applicant needs to provide definition of prescribed dose for procedure and commit to document prescribed dose for each patient

Comments Received from the NRC

- Patient Safety
 - Guidance does not convey potential for source rupture during procedure
 - Discussion should be included about possibility for pre-treatment to mitigate I-125 uptake from a ruptured source

Areas Needing Further Discussion within NRC

- Format
 - NRC currently evaluating a number of different formats to determine a standard format for guidance for 10 CFR 35.1000 uses

Areas Needing Further Discussion within NRC

- Submission of Procedures
 - Reconciliation is needed on which procedures must be provided and which ones the applicant can commit to

Summary

- Described radiation safety aspects of use of I-125 therapeutic seeds used as markers and guidance developed by Pilot 4
- Described comments received from NRC
- Working Group received the comments only recently
- Discuss comments by teleconference October 14, 2004

St. Joseph Mercy Hospital Case

Unplanned exposures of members of
the public

Background Time Line

- Exposures occurred during July 1-7, 2002.
- Exposures involved up to 35 people who visited the patient.
- Doses to a few of the visitors may have exceeded the applicable regulatory limit.
- The dose to one visitor was estimated to be greater than 10 times the limit.

Background Time Line

- NRC was notified on August 15, 2002.
- Two NRC inspectors conducted an inspection at the facility on October 4 - 16, 2002.
- The NRC inspection report was issued December 10, 2002.

**Background
Findings**

- The licensee estimated the dose to be 3 – 6 rem based bedside survey data and an exposure duration of about 40 hours.
- NRC estimated the dose to be 15 rem based on bedside survey data and an exposure duration of 77 hours.

**Background
Time Line**

- The President, Society of Nuclear Medicine, sent a letter to the NRC Chairman, December 2, 2003, expressing concern that the 15 rem estimate is far too conservative.
- The letter submitted an alternative reconstruction in which the dose was estimated to be about 1 rem.

**Background
Time Line**

- ACMUI was chartered to conduct an independent review of the dose assessments and report to the Commission.
- NRC staff conducted their own reviews and calculations.
- ACMUI submitted its report May 14, 2004.
- Staff submitted their report to the Commission June 4, 2004.

Conclusions

- ACMUI estimated the dose to be 9 rem using NRC's exposure duration estimates and scenario, and 4 rem using the licensee's estimates and scenario.
- NRC concluded that the original dose estimate of 15 rem is probably the best estimate for this case.

Outcomes

- The alternative dose assessment submitted by the SNM alerted NRC to several important factors that should be noted in future reporting on dose assessments.
- ACMUI's review and report also pointed out some important considerations that would help improve NRC's regulatory programs.

Planned Actions

- Institute a required review by Headquarters staff of all reports involving dose assessment prior to issue. This is to continue at least for a period until the areas of concern are routinely addressed.
- Issue a communication to licensees describing methods and precautions that may help improve the quality of dose assessments in the future.

Planned Actions

- Issue guidance to licensees, and NRC staff, on acceptable methods to assess the effective dose in situations such as the St. Joseph case.
- Revise NRC's procedures to rapidly and efficiently permit licensees to increase allowable doses to members of the public, under certain conditions, to levels that are much higher than are currently permitted.

Planned Actions

- Provide continuing training to NRC technical staff on issues raised in this case, and more generally on advanced radiation concepts and quantities and advanced techniques of dose assessment.

END



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POLICY ISSUE NOTATION VOTE

June 25, 2004

FOR: The Commissioners

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

SUBJECT: ST. JOSEPH MERCY HOSPITAL: RADIATION EXPOSURES OF MEMBERS OF THE PUBLIC - REVIEW C RECONSTRUCTIONS

- [PURPOSE](#)
- [SUMMARY](#)
- [BACKGROUND](#)
- [DISCUSSION](#)
- [INSIGHTS](#)
- [RECOMMENDATIONS](#)
- [COORDINATION](#)

PURPOSE:

To report to the Commission the results of staff's reviews of the dose reconstructions for the most exposed member of the public in the St. Joseph Mercy Hospital case, and to obtain Commission approval of the staff's recommendation from insights gained during analysis of this case.

SUMMARY:

Based on its reviews, the staff of the Office of Nuclear Material Safety and Safeguards (NMSS) has concluded that the 15 centisievert (cSv) (15 rem) dose estimated by Region III for the member of the public is the estimate that appears supported by available data and, based on this data, does not appear to be overly conservative and is probably the true dose.

This conclusion is based on NMSS' determination that Region III used an appropriate method to calculate the dose and obtained the necessary data by direct and detailed interviews with the exposed member of the public and the licensee on duty at the time of the exposures, and confirmed that the information provided by the exposed member of the public and the hospital staff was consistent. Still, the licensee's data is at variance with parts of Region III's findings, a different dose estimate, and it has not proven possible to resolve these differences.

The reconstructions proposed by Drs. Marcus and Siegel (supported by SNM) and by the ACMUI were found to be reasonable approaches, but the methods used and assumptions made are likely to result in estimates with greater uncertainty than that provided by Region III. The estimates were 1 cSv (1 rem) obtained by Drs. Marcus and Siegel, 3-6 cSv (3-6 rem) obtained by the licensee, 4-9 cSv (4-9 rem) calculated by the ACMUI, and 15 cSv (15 rem) estimated by Region III.

The reconstructions that were reviewed included the alternative dose reconstruction proposed by the Society of

Medicine (SNM) and prepared by Drs. Carol Marcus and Jeffrey Siegel ([Attachment 3](#)); the calculations and estimates submitted by the Advisory Committee on the Medical Use of Isotopes (ACMUI) ([Attachment 5](#)); and the original estimates reported by the US Nuclear Regulatory Commission's (NRC's) Region III ([Attachment 2](#)).

BACKGROUND:

A hospitalized patient with metastatic thyroid cancer and severely depressed renal function was administered 1 gigabecquerel (285 millicurie) ^{131}I on July 1, 2002, and subsequently died on July 7, 2002. During that period, members were believed to have visited the patient. The licensee estimated that, as a result of their proximity to the patient, about 10-12 of the visitors may have received a dose over the regulatory limit of 0.1 cSv/yr (100 mre) if the licensee's estimate of time at bedside was estimated by Region III to have received a dose of 15 cSv (15 rem). The licensee estimated the dose to that person to be 3-6 cSv (3-6 rem). Region III conducted a special inspection of the licensee's facility on July 4-16, 2002. Region III coordinated with NMSS staff during all phases of the inspection, documentation of findings, and assessment of dose, as is normal agency policy for this type of event.

In a December 2, 2003, letter to the NRC Chairman, the SNM President expressed concern that NRC might have been excessively conservative in its assessment of the dose to the family member, and might have overestimated the dose to this family member by at least an order of magnitude. The letter also submitted, for NRC review, an alternative reconstruction prepared by Drs. Carol Marcus and Jeffrey Siegel. The reconstruction concluded that Region III had overestimated the dose to the family member by a factor of up to 17.

The Chairman advised SNM that the NRC staff would review the reconstruction prepared by Drs. Marcus and Siegel. In addition, the ACMUI would be tasked with preparing an independent review of the Region III's dose assessment and comparing it to Drs. Marcus and Siegel's dose reconstruction. ACMUI submitted its report to NMSS on May 14, 2004 ([Attachment 5](#)). This paper summarizes the staff's reviews of the reconstruction prepared by the licensee and Drs. Marcus and Siegel, as well as the staff's conclusions based on that evaluation and the independent evaluation performed by the ACMUI.

DISCUSSION:

Based on its own calculations, and after detailed reviews of Drs. Marcus and Siegel's and ACMUI's reconstruction report, NMSS staff has concluded that Region III's estimate is reliable and as accurate as circumstances permit. Region III's reconstruction is overly conservative and is not supported by the available data. The bases for this conclusion are presented in detail in [Attachment 1](#) to this paper. NMSS considers Region III's dose estimate (15 rem), as well as the licensee's estimate of 3-6 cSv (3-6 rem), to be plausible estimates. While both Region III and the licensee used identical methods to estimate the dose, the differences in this case were caused by conflicting reconstructions. Review of the case led NMSS staff to conclude that Region III's dose estimate is probably closest to the actual dose. This conclusion is based on NMSS' determination that Region III used an appropriate method to calculate the dose. Region III obtained the necessary data by direct and detailed interviews with the exposed member of the public and the licensee on duty at the time of the exposures, and confirmed that the information provided separately by the exposed member of the public and by the hospital staff was consistent.

The method used by Region III and by the licensee is based on the assumption that the bedside dose rates measured by the hospital staff are representative of the average radiation fields to which the family member was exposed. Justification for this assumption is a statement made by the Radiation Safety Officer (RSO) on duty at the time the bedside measurements were made at the location of the family member's head and torso. The family member was expected to move from this location during her visit, but observations made by the hospital staff indicated that she was nearly all the time at the edge of the bed, at the location where the surveys were made, and at times approached the patient much more closely than the survey locations. The dose estimates were obtained by multiplying the dose measured on each visiting day by the estimated "stay time" (i.e., the time during which the family member stayed at the patient's bedside) for that day, and adding the daily doses to obtain the total dose.

It is important to stress that the disparity in Region III and the licensee's dose estimates does not represent a comparison of possible doses, nor does it reflect different levels of conservatism in assessing the doses; rather, these dose estimates were obtained on the basis of two different, and mutually exclusive, exposure scenarios for the period July 2-7, 2002. The family member and members of the staff were interviewed separately by Region III and the licensee. Based on that interview, Region III estimated the stay time as 77 hours, starting from July 2 until the patient's death on July 7, while the licensee estimated the stay time as 39 hours, starting from July 5 until the patient's death on July 7. This disparity in stay times

accounts for the difference in Region III and the licensee's dose estimate. The accounts provided during the interviews differed in some detail and, in some respects, were inconsistent. However, the stay time estimates in both cases obtained directly from what the family member and the hospital staff said that the family member did during the visits and the different estimates reflect different accounts of these activities.

The staff has not been able to reconcile these differences. However, it is not surprising that the different accounts have not been entirely consistent, since the interviews took place about 3 months after the incident. It is unreasonable to expect that under the circumstances surrounding her visits, the family member would be able to clearly recall during those visits, accounting for each hour of each visit. Region III's estimates of exposure times were based on accounts provided not only by the family member, but also confirmed by accounts of hospital staff who had observed the family member's activities during her visits, and by the RSO who was on duty between July 2 and July 7, 2002. Region III's dose estimate is supported by the available data. Nevertheless, the licensee maintains that its scenario is accurate because, it asserts, its interviews were more thorough.

Both Drs. Marcus' and Siegel's and ACMUI's reconstructions viewed the measured dose rates as not being representative of the dose rates to which the family member was exposed. Both approaches used measured dose rates as starting points to normalize calculated radiation fields around the patient. They then postulated a reasonable distance at which the family member would have been expected to sit during her visits, and used that distance to calculate the dose rates to which the family member was exposed.

The methods used by Drs. Marcus and Siegel and by ACMUI to perform their dose rate calculations differed considerably, with the former's tending to be fairly simplified, and the latter's more complex. To calculate dose rates, and in the absence of reliable data on which to base these calculations, both reconstructions assumed, in varying degrees, values for important parameters that are required to complete the calculations. In addition to these assumptions, both also used simplifications in their calculations, to render the calculations manageable. NMSS staff considers that, taken together, these assumptions and simplified methods yielded results that are likely to be much more uncertain than those obtained by Region III and by the licensee. Drs. Marcus' and Siegel's reconstruction led to a dose estimate on the order of 1 cSv (1 rem), and ACMUI's calculations yielded an estimate of 4-9 cSv (4-9 rem).

The different dose estimates, although spanning a large range, are not expected to have a significant impact on the family member's health. This impact is expected, under any of the dose estimates, to be minimal. In addition, the lowest estimate of about 1 cSv (1 rem) provided by Drs. Marcus and Siegel still yields a dose that is at least an order of magnitude higher than the regulatory dose limit that was allowed at the time. Enforcement action using either Dr. Marcus' or Dr. Siegel's estimate rather than Region III's estimate, would not be any different. NMSS staff agrees with Drs. Marcus and Siegel, as well as with ACMUI, that attempts should always be made to obtain the most accurate dose estimate possible and justified by the circumstances of the case. In the present case, NMSS staff believes that Region III used a reasonable method to estimate the dose, given the information that was available.

INSIGHTS:

NMSS determined that the results of the inspection by Region III staff, as documented in the associated inspection report, were adequately justified and the report was in accordance with agency policy. However, retrospective consideration of the case suggests that more documentation might have avoided many of the questions and doubts raised by Drs. Marcus and Siegel and by the ACMUI. One of the recommendations proposed in this paper is designed to address this issue.

NMSS believes that timely recognition by the licensee of the potential for exceeding the applicable dose limit in this case might have prompted appropriate corrective actions and more timely collection of data that might have been used to estimate doses. A second recommendation is designed to improve the gathering of data promptly after an event has taken place.

NMSS staff and ACMUI discussed situations in which it is advantageous for family members to participate in a manner that will most likely cause the family members to exceed the current 0.5 cSv (0.5 rem) limit. A third recommendation is for the staff to develop procedures that would address such situations.

RECOMMENDATIONS:

Based on the insights gained while reviewing this case, as well as on suggestions made by Drs. Marcus and Siegel and ACMUI, staff proposes the following recommendations for the Commission's consideration. NMSS believes that the current procedures in place to document inspection findings and dose assessments are sound, but may benefit from some

modifications based on the insights gained from this case. The recommendations are intended to improve performance reporting dose reconstructions in future cases, and are expected to involve relatively small changes. The staff recommends that the Commission approve the following staff actions:

1. The licensee bears the prime responsibility for recognizing that an unplanned event has occurred, and for assessing doses and other consequences of such an event. Title 10 of the Code of Federal Regulations, 101.11 requires that surveys be made that may be necessary to assess and report doses to workers and members of the public who may be exposed to radiation arising from licensed activities. The licensee is normally the one with the most timely access to the data, and therefore, be encouraged to develop guidance or other means that (1) will alert them to the fact that an event is occurring or has just occurred, and (2) will ensure that their staff rapidly collect the information needed in a future dose reconstruction. This information would include interviews with the people involved; measurements of distances, source strengths, and radiation fields; bioassay data if the incident involves radioactive materials; and blood samples for biological dosimetry, if indicated. Supporting documentation would include calibration certificates for any instruments or sources used; training records; photographs of the equipment and affected areas; and any other information that may help improve the accuracy and reliability of dose assessments. This information should also be collected.

To assist licensees in understanding this responsibility, the staff intends to issue an appropriate communication alerting licensees to these considerations and suggesting possible approaches for compiling necessary information and data. Achieving this goal should improve the quality of data available in cases requiring dose reconstructions and should, therefore, result in more accurate and less controversial results.

2. Staff believes that some of the questions by SNM might have been avoided in the present case, if the dose reconstruction had provided more detail. The NMSS staff will review applicable inspection report guidance and determine what modifications should be made to better accommodate the special information requirements in situations like the St. Joseph Mercy Hospital case. Actions to be considered include presenting all the activities that were used in the reconstruction; describing and justifying the calculation methods and models used; listing any assumptions that were found necessary, and the reasons for selecting those assumptions; discussing points of view that are in disagreement with NRC's, e.g., a licensee's assessment; and explaining in the report why, if such is the case, NRC did not accept a licensee's assessment. The staff intends to develop guidance and training on methods to more fully document findings and dose estimates. The staff will also institute a policy for cases involving dose estimates above a trigger level that require higher than normal levels of review in cases of significant disagreement between NRC and a licensee. This would be similar to the approach now used in cases requiring escalated enforcement actions.
3. The staff is considering developing procedures that could be used to quickly grant approval of exemptions for licensees to permit members of the public to be exposed to doses up to the occupational limit, if certain conditions are met. Restricting a member of the public to a limit of 0.5 cSv (500 mrem) in situations where it is important for that person to take part in a patient's care and comfort, may protect against radiation exposure, but the licensee may fail to consider the person's overall well-being, and may thus fail to minimize detriment, as defined by the International Commission on Radiological Protection. In that definition, detriment is understood in a wider sense than just radiation detriment, and must consider all aspects of the situation, including any non-radiological considerations affecting a person's well-being. The cancer risk to a member of the public at the occupational limit must be viewed in this context as fairly small, in comparison with the emotional hardship, and possibly physical harm, that may result in a situation where meeting the 0.5 cSv (500 mrem) limit, effectively limits the licensee's ability to provide for a patient's care and comfort. This dose restriction may also place licensees in situations where they have great difficulty enforcing the limit when a member of the public refuses to observe that limit.

The staff intends to develop a set of conditions that would be considered sufficient to grant licensees such exemptions, and submit them for Commission approval. Licensees would be required to provide affected members of the public with appropriate dosimetry that would provide a running total dose, thereby permitting close monitoring of exposures and timely adjustments in exposure rates as needed, in order to be granted such exemptions. The staff would issue a generic communication informing licensees of this policy. No rulemaking would be required because this policy would be instituted as case-by-case exemptions, and the exposures would be required to be carefully controlled and monitored. The exemptions would also be time-limited.

In addition, the staff recommends that:

4. The Commission approve, and the Chairman sign, the proposed letter from the Chairman to Dr. Henry F.

President of SNM, ([Attachment 6](#)) informing him of NRC's conclusions, and of the public availability of the detailed report on this case.

NOTE: The proposed staff actions are expected to be completed within the existing budget, as part of the ongoing program performance, and no additional resources will be required.

COORDINATION:

The Office of the General Counsel has reviewed this Commission Paper and has no legal objections.

/RA Martin J. Virgilio Acting For/

Luis A. Reyes
Executive Director for Operations

Attachments:

1. [Staff review of the Marcus\Siegel and ACMUI dose reconstructions](#)
2. [NRC Inspection Report](#)
3. [Absorbed Dose Reconstruction by Drs. Carol Marcus and Jeffrey Siegel](#)
4. [ACMUI Dose Review Subcommittee Charter](#)
5. [ACMUI Report](#)
6. [Proposed letter from the Chairman to the Society of Nuclear Medicine](#)

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Last revised Monday, September 27, 2004

ATTACHMENT 1

**ST. JOSEPH MERCY HOSPITAL
ANN ARBOR - MICHIGAN**

**RADIATION EXPOSURE OF A MEMBER OF THE PUBLIC
JULY 1-7, 2002**

**A REVIEW OF THE DOSE RECONSTRUCTIONS PREPARED BY THE
LICENSEE; REGION 111; DRS. CAROL MARCUS AND JEFFERY
SIEGEL; AND THE ADVISORY COMMITTEE ON THE MEDICAL USE OF
RADIOISOTOPES (ACMU)**

1.0 INTRODUCTION

A report dated August 15, 2002, was submitted to the NRC by St Joseph Mercy Hospital, Ann Arbor, Michigan, notifying the agency of exposures of members of the public to radiation that likely resulted in doses in excess of the applicable regulatory dose limit of 0.1cSv/yr (100 mrem/yr). This report was followed by reports dated September 11, 2002 and October 1, 2002, containing additional details of the case and providing dose estimates for the exposed members of the public. These reports prompted a special NRC inspection of the facility, which was conducted from October 4 through 16, 2002. The report for this inspection is available to the public on NRC's Agency-wide Documents Access and Management System (ADAMS), accession number ML023440102. In that report, the NRC detailed its findings and its assessment of the dose to the highest exposed member of the public, which was estimated by the NRC to be 15 cSv (15 rem).

In a letter dated December 2, 2003, and addressed to the Chairman of the NRC, the President of the Society of Nuclear Medicine (SNM) expressed concern that the NRC may have overestimated the dose to the highest exposed member of the public in this case by at least an order of magnitude. The letter also provided a dose reconstruction in support of this claim, which had been commissioned by the SNM and prepared by Drs. Carol Marcus and Jeffrey Siegel. In response, the Chairman, in a letter dated January 12, 2004, advised SNM that the staff would review the reconstruction proposed by Drs. Marcus and Siegel, and that the Advisory Committee on the Medical Use of Isotopes (ACMUI) would also be tasked with preparing an independent review of NRC's dose assessment as well as Drs. Marcus' and Siegel's dose reconstruction.

The reviews by the NRC staff and by the ACMUI have been completed, and this report provides NRC's comments and conclusions.

2.0 SUMMARY OF THE CASE

This section provides a brief summary of the case; additional details may be found in the NRC inspection report, which is accessible to the public as indicated in Section (1.0) above.

A patient with metastatic thyroid cancer was admitted to the St Joseph Mercy Hospital in Ann Arbor, Michigan, and was orally administered 10.5 GBq (285 mCi) of sodium iodide-131 (¹³¹I) on July 1, 2002. The patient at that time was suffering from significantly depressed renal function. Soon after administration of the dose, the patient's condition deteriorated, and she died on July 7, 2002. On each day during that period, the hospital's radiation safety staff measured the radiation levels at the patient's bedside and at 1 meter from the patient.

The hospital's radiation safety staff took precautions to minimize radiation exposure to the public by not allowing visitors into the patient's room for the first 24 hours after administration of the ¹³¹I, after which visitors were allowed into the room. No restrictions were imposed on the duration of the visits, but visitors were instructed to remain behind shields provided by the hospital. A total of about 20-35 family members were estimated to have visited the patient during her hospital stay. On July 5, 2002, after the patient's condition worsened and it became evident that she would not survive, family members were permitted to go to the patient's bedside, bypassing the shields, to visit for the last time.

An estimated 10-12 persons stood or sat close to the bed on occasion during that period, and are thought to have received doses up to approximately 0.2 cSv (200 mrem). The other family members were estimated to have received doses below the dose limit for members of the public of 0.1 cSv/yr (100 mrem/yr). An exception was a close family member who had apparently on many occasions ignored instructions to stand behind the shields provided. That person was observed to be at bedside essentially continuously during the period between July 5 and 7, 2002, when the patient died. Her actions during the period July 2 to July 5 are controversial, and it is uncertain whether she did or did not stay behind the shields. The NRC inspectors' interviews led them to believe that she did not avail herself of the protection provided by the shields, and that her unshielded exposure to the patient started on July 2. On that basis, Region III estimated her stay time at bedside to be about 77 hours, and the resulting dose, based on the bedside radiation survey results, was estimated to be 15 cSv (15 rem). The licensee, on the other hand, concluded based on their independent interviews that the family member did observe shielding precautions during the period July 2 to July 5, and that her unshielded exposure to the patient started on July 5. As a result, they estimated the bedside stay time to be about 39 hours, and the dose, again based on the bedside radiation survey data, was estimated to be 3-6 cSv (3-6 rem). The dose estimates are not linearly proportional to the exposure durations because the radiation fields varied during this time period.

It is difficult now to resolve the difference in the NRC and licensee exposure scenarios, because the interviews took place about 3 months after the incident, and accounts provided by the family member would not be expected to be very accurate; they are known to be inconsistent in some parts. The Region III inspectors are confident that their reconstruction of what actually happened is reliable and as accurate as circumstances permit. A review by NMSS of available data did not suggest any reason to doubt the validity of this position, which is also supported by statements made by the hospital staff, including the radiation safety officer (RSO), who had observed this family member's behavior during the period in question. However, the data also does not provide compelling reasons to reject the licensee's position. It should be noted that the two dose estimates represent estimates based on two different, mutually exclusive, exposure scenarios, and not a range of estimated doses. The principal differences in this case lie with conflicting reports of what happened, and not with the dose reconstructions themselves.

Both NRC's as well as the licensee's dose estimates are based on two premises: that the accounts provided to them by the family member and by the hospital staff are true and accurate to the extent that details can be remembered, and that the bedside surveys represent the average radiation fields in which the family member was exposed during her bedside visits. The survey data, which was obtained by the RSO on duty during this period, was stated by the RSO to have been made at the location where the daughter was observed to sit during her visits, and in the vicinity of her head and torso. One may question the validity of the accounts on which the dose estimates are based, but NRC is unaware of any reliable information that would prompt reassessment of its position. In addition, the lack of data on which to base any reliable, detailed, theoretical modeling of the radiation fields around the patient support the approach to dose assessment use by both Region III and by the licensee.

NRC recognizes that its dose estimate may be high. On the other hand, this estimate does not take into account activities engaged in by the visitor that likely contributed a significant dose. It

was established during interviews with hospital staff that the family member actively participated in patient care, such as by provided her with food and drink, taking part in bathing and dressing her, and providing hygiene and comfort services. The participation was apparently triggered by the family member's dissatisfaction with the care being provided by the hospital. All of these activities would have brought the family member into much closer contact with the patient than "bedside", and would have placed her in radiation fields that may have exceeded 1 cSv/hr (1 rem/hr). The contribution from these activities were not included in the 15 cSv (15 rem) estimate because there is no data available that would have permitted reliable estimation of its magnitude. If such a contribution was significant, then the 15 cSv (15 rem) estimate may be on the low side of the true dose. In addition, it was discovered that the family member had been sitting during some of her visits close to an unshielded urine bag containing ¹³¹I-contaminated urine, and that the radiation fields from that bag were significant. There is no data available to quantify this contribution to the family member's dose, however, and it was therefore not included in the 15 cSv (15 rem) estimate.

3.0 COMMENTS ON DRS. MARCUS' and SIEGEL'S DOSE RECONSTRUCTION

In the following discussion, the close family member who received the highest dose will be referred to as the "visitor" for brevity. Drs. Marcus's and Siegel's dose reconstruction starts with the premise that the survey data described by the hospital staff as having been made at "bedside" should not be used directly in dose assessment because bedside is not a well-defined location. Instead, the authors believed that the dose estimate should be based on calculation of the dose rate to which the visitor was exposed. The reconstruction, however, does not discuss why it is important to know the exact position of the survey relative to bedside if the surveys were made at the visitor's exposure location, as stated by the RSO on duty at the time.

To calculate the dose rate to which the visitor was exposed, the reconstruction used the dose rate measurement at 1 meter made soon after administration of the ¹³¹I, which was 0.04 cSv/hr (40 mrem/hr), as the starting point for the assessment. Using this 1 meter reading, together with the inverse square law¹, the distance at which a dose rate of 0.4 cSv/hr (400 mrem/hr) would be measured was calculated to be 31.6 cm. The 0.4 cSv/hr is the "bedside" dose rate measured at that time. The authors then make the assumption that the visitor's distance of closest approach, or bedside, was realistically somewhere between 31.6-100 cm, with an average distance of 65.8 cm. Again using the inverse square law, the authors estimated that the dose rate at 65.8 cm is a factor of 4.3 lower than that at 31.6 cm, and therefore that NRC's dose estimate, which was based on the bedside measurements, must be high by that factor.

The authors then went on to note that they had re-enacted the bedside situation and concluded that the centerline-to-centerline distance between the patient and the visitor must have been in the range of 65-70 cm. They then concluded that the visitor must have sat at a distance in the range of 65-100 cm, with an average of 82.5 cm. Again using the inverse square law, the dose rate at 82.5 cm was estimated to be a factor of 6.8 lower than that at 31.6 cm, and hence NRC's dose estimate was high by that factor.

¹ The inverse square law states that the intensity of the radiation field from a point source in a vacuum decreases as the square of the distance from the source.

The reconstruction also identifies what it believed to be errors that the NRC committed and factors that NRC neglected to take into account. Together with the factor of 6.8 noted above, these additional items led the authors to conclude that NRC had overestimated the dose to the visitor by a factor of 17. The following comments consider each of the items raised in the reconstruction as weaknesses or errors in NRC's approach, and point out the reasons NMSS does not entirely agree with them and therefore with the conclusions based on them.

3.1 USE OF THE BEDSIDE SURVEY DATA

One point that should be noted is that the reconstruction used the radiation field at the mathematical average of the assumed range of distances as representative of the mean radiation field to which the visitor was exposed. However, the radiation field changes non-linearly with distance, and for such a function, the field at the arithmetic mean distance is not representative. A more appropriate mean value to use in this case might be the geometric mean. The geometric mean is closer to the patient than the arithmetic mean, and the dose rate at that distance would therefore be higher than that calculated at the arithmetic mean distance. It should also be noted that use of the mean distance in this manner to estimate dose implies that the visitor spent equal amounts of time at various distances within the specified range, since the average dose rate was not time-weighted. Data obtained from interviews with the visitor and the hospital staff indicate that this is not a valid representation of the actual situation.

Another point to note is that distances in the reconstruction, such as 31.6 cm, 65.8 cm, and 82.5 cm, are given to the nearest millimeter. Although valid mathematically, NMSS staff believes that this practice may lead readers to conclude, erroneously, that the analysis was done to a much higher level of accuracy than was in fact the case. These numbers are rough estimates at best, and one significant figure is all that can justifiably be used in this type of analysis.

A third point that should be noted is that the factors of 4.3 and 6.8 derived by this method are based on data measured soon after administration of the ^{131}I , at which time the activity was in the patient's stomach. However, the activity would soon be taken up into the blood and distributed in the body's organs and tissues. This would change the radiation fields around the patient, and the factor derived for the first day may no longer be valid, and should therefore not be applied to the dose estimate for the entire exposure period without demonstrating the validity of such an approach. The reconstruction did not show how that factor would be expected to change with time, nor did it demonstrate that the factor can be considered approximately constant. It is noted here that the visitor did not receive any exposure during the first 24 hours after administration of the ^{131}I , which is the period for which these factors were calculated.

The use of the inverse square law in a field as complex, and close to a source of radiation as large, as that in the present case is also very questionable, and will provide invalid dose estimates. The inverse square law is strictly applicable only to point sources in a vacuum. It may serve as a rough approximation in air when volume sources are involved, as in this case, but only at distances large enough that the volume source appears as essentially a point. Conventionally, the inverse square law is considered not to be applicable at distances less than about 10 times the largest linear dimension of the source. For a source distributed in the stomach, this would mean a distance of not less than about 2 meters. This distance becomes

larger when the activity is distributed in the body. It should not be used at bedside, as was done in this reconstruction, because it will produce incorrect estimates.

NMSS staff conducted a series of Monte Carlo calculations to determine the shape of the radiation fields around the patient. The Monte Carlo transport code MCNP, Version 5, was used (1). This code was developed and is maintained by the Los Alamos National Laboratory (LANL). The patient was modeled by the Medical Internal Radiation Dose (MIRD) anthropomorphic phantom (2), which was developed at Oak Ridge National Laboratory (ORNL). The phantom contains all the important tissues, organs, and bones in the human body, and has been updated by NRC based on recent data published by ORNL.

Drs. Marcus' and Siegel's reconstruction applied its analysis to the survey data taken soon after administration of the ^{131}I , at which time the activity would be located in the stomach. The Monte Carlo calculations carried out by NMSS therefore uniformly distributed the ^{131}I activity in the stomach contents. Dose rates were calculated at various distances from the patient along a transverse plane passing through the center of the stomach. The results are shown in Figure (1), together with the dose rates calculated using the inverse square law. The inverse square curves were generated using distances of 1.0 and 1.2 meters from the source, which was taken to be at bedside. The MCNP calculations were made for the left side of the patient, which was necessary because there is a considerable difference between the radiation fields on the left and right sides of the patient when the activity is in the stomach. The visitor sat on the left side of the patient.

The two inverse square curves highlight the fact that the particular inverse square curve obtained is sensitive to the assumed position of the source with respect to the survey location. The point at which a dose rate of 0.4 cSv/hr (400 mrem/hr) would be expected, according to these curves, is at about 30 cm from the edge of the bed for the lower inverse square curve, and at about 40 cm from the edge of the bed for the upper inverse square curve, assuming the source is at the edge of the bed. The curves show dose rates close to the edge of the bed that are well into the cSv/hr (rem/hr) range. Other curves could be obtained by changing the position of the source or of the "1-meter" reading location, neither of which are known exactly in this case.

In addition to its sensitivity to the exact location of the "1-meter" survey with respect to the source, the inverse square law is not valid close to a volume source, in this case the patient, and the two curves give incorrect results at all distances within a few meters of the patient, with the error becoming larger at closer distances, such as bedside. The MCNP dose rate curve shows a very different distribution from that predicted on the basis of the inverse square law, and illustrates the inapplicability of that law in this case. The dose rate at the edge of the bed predicted by the MCNP curve shown in Figure (1) is about 0.45 cSv/hr (450 mrem/hr), which is consistent with the reported "bedside" dose rate at that time of 0.4 cSv/hr (400 mrem/hr). Other MCNP curves could have been obtained by making small changes in the assumptions that went into the calculations.

The above considerations show that attempts to calculate the dose rate to the visitor, even using sophisticated Monte Carlo techniques, involve large uncertainties because of the absence of sufficient data to accurately model the radiation fields around the patient and at the location of the visitor. Use of the inverse square law compounds these uncertainties to the

point where the results must be viewed as only qualitative, order of magnitude estimates.

NMSS does not disagree with the statements in Drs. Marcus' and Siegel's report regarding what might be considered reasonable patterns of behavior and reasonable distances at which a visitor may have sat when visiting the patient. Region III determined during its inspection that the visitor's behavior was significantly different from the scenario postulated in Drs. Marcus' and Siegel's report as reasonable. Region III has also determined that, although the distance at which the "bedside" measurements were made was not measured, the hospital staff who made the measurements stated that the locations of these measurements were selected partly because they were the locations at which the visitor was observed to sit at bedside during her visits. The staff, including the RSO on duty at the time, stated that the surveys were made at the location of the visitor's torso and head. It is NRC's judgement that this type of information is more reliable as a basis for dose assessment than the use of the dose rate at 1 meter on the day of administration, the inverse square law, and assumed ranges of distances at which the visitor would reasonably have been expected to sit. Because of these considerations, NMSS views the factors of 4.3 and 6.8 calculated in Drs. Marcus' and Siegel's report to be subject to large uncertainties, and should not be used as reliable indicators of dose.

It should be noted that the bedside dose rate measurements were also used by the hospital radiation protection staff in making their own assessments of the dose to the visitor, in a manner identical to that used by Region III. Although the hospital's dose estimate of 3-6 cSv (3-6 rem) is much lower than the 15 cSv (15 rem) calculated by the Region III, the disagreement is caused by differences in stay time estimates; the dose rates used in both calculations were the same.

3.2 FAILURE TO CORRECT THE SURVEY RESULTS FOR DECAY AND AN ERROR IN THE SURVEY DATA

Drs. Marcus' and Siegel's report states that the survey data should have been decayed to account for exponential decay with an apparent 3.1-day half-life before being used in the dose assessments. The report also stated that "there is an obvious mistake in the dose rate on Day 4, which cannot be the same as it was on Day 3." The results of the daily bedside and 1 meter surveys made by the hospital staff during the patient's stay are shown in Figure(2). The figure shows that, although there is a general trend of decreasing dose rates, the trend is neither constant nor exponential, and is not the same for the bedside and the 1-meter readings. The decrease is uneven, and the bedside readings stabilize on days 4 and 5. An exponential decay would be represented by a straight line with negative slope in Figure (2). A half-life assignment is appropriate for an exponential function, but should clearly not be assigned to the pattern shown in Figure (2).

Regarding the corrections for decay, assuming that the 3.1 day half-life does in fact reflect exponential decay, it can be shown that the difference in dose assessed over a 12-20 hour period with and without decay correction is less than 10 percent. This is probably the worst case situation, because the surveys were not all made at the beginning of each exposure period, and some were made late in the day. The actual decay correction will therefore be less than 10 percent.

NMSS, however, does not believe that the observed pattern of dose rate variation with time is due mainly to decay or excretion. This is partly because the radiological half-life of ^{131}I is about 8 days, and therefore cannot account for the observed changes. In addition, the patient's renal function was severely depressed, and she was therefore not excreting the activity at a rate that would account for the observed changes, nor for the pattern of change. NMSS suspected that the observed changes in dose rate were due mainly to a re-distribution of activity in the body, which started in the stomach following ingestion, was absorbed into the blood, and was then distributed amongst the organs and tissues in the body. This distribution would be affected at least in part by the distribution of the metastatic cancer cells. The differences in the two observed patterns of change in measured dose rates shown in Figure(2) are due partly to the fact that the exact survey locations with respect to the patient probably varied somewhat from day to day, but also because the readings at bedside are much more sensitive to the details of the distribution of activity in the body than they are at 1 meter. The bedside readings would be expected to respond to changes in this distribution in a manner that is different from the readings at 1 meter.

To verify this hypothesis, NMSS performed a series of Monte Carlo calculations, with each set of calculations being performed with the radioactive material located in a different organ or tissue. All calculations were performed using the same total ^{131}I activity. The results are shown in Figure (3). The calculations show the radial distribution of dose rate in a transverse plane through the center of the stomach and at a radial distance of 35 cm from the long axis of the patient. A different set of curves would have been obtained if different transverse planes were used, but the trends would be similar.

The curves clearly show that changes in the distribution of activity in the body have a very large impact on the radiation field outside the body. For example, at an angle of -90 degrees, which corresponds to the left side of the patient, the dose rate falls from about 0.5 cSv/hr (500 mrem/hr) when the activity is in the stomach, to 0.25 cSv/hr (250 mrem/hr) when it is uniformly distributed in the torso, such as in the blood pool, to about 0.05 cSv/hr (50 mrem/hr) if the activity is located in the liver. In other words, moving the activity from the stomach to the liver changes the dose rate at this location by an order of magnitude. The dose rate may also rise after it had fallen if the activity moves from the torso to the ribs and arm bones. The distributions shown in Figure (3) are idealized in that it is unlikely for all of the radioactive material to concentrate in one tissue or organ. The actual distribution would most likely be a distribution amongst a number of tissues and organs. However, the figure clearly shows that the observed changes in bedside dose rates with time were not due mainly to decay but to re-distribution. Decay would have an impact, but it would be secondary in comparison. It is therefore unwarranted to assert that the survey data contain an error, nor is it warranted to make the suggested decay corrections, which are in any case very small. The change in dose rate with time was taken into account in Region III's calculations by using the daily survey data on each day to assess the dose received on that day. The decay effects were stated in the Marcus/Siegel reconstruction to account for an NRC dose overestimation by a factor of 1.5, but based on the above considerations, NMSS believes that this factor is much smaller, and is probably very nearly one.

3.3 FAILURE TO ASSESS THE TOTAL EFFECTIVE DOSE EQUIVALENT INSTEAD OF THE DEEP DOSE EQUIVALENT

Drs. Marcus' and Siegel's dose reconstruction states that the effective dose equivalent is a more relevant quantity in assessing risk to a person than is the deep dose equivalent. To obtain the effective dose equivalent, the reconstruction applied a correction factor of 0.6 to NRC's dose estimate, and concluded that NRC's dose estimate is therefore high by a factor of 1.7 (1/0.6). The factor of 0.6 was obtained from work published by Dr Siegel on patient release after administration of ¹³¹I (4). It is based on the observed ratio of the dose rate measured at 1 meter from patients after administration of ¹³¹I to the calculated dose rate expected from such patients. It is interesting to note that the authors of the reconstruction assumed that the dose estimate shown in Region III's inspection report was a deep dose equivalent, even though the report does not state that, nor does it specify the type of dose it estimated. Although it is likely that the deep dose equivalent was the intended quantity, it would have been appropriate to raise the issue as a question rather than a statement of fact.

NMSS agrees that the effective dose is a more suitable quantity for assessing risk than the deep dose equivalent, and has in fact provided guidance to its licensees to encourage the use of effective dose rather than deep dose equivalent whenever doses are calculated, such as in this case. Such guidance was provided in NRC's Regulatory Issues Summary (RIS) 2003-04, which is accessible using NRC's ADAMS system (ML030370122). In that RIS, NRC advised its licensees that when dose is calculated, rather than measured using personnel dosimetry, the effective dose equivalent rather than the deep dose equivalent should be used in calculation of the total effective dose equivalent (TEDE). NMSS does not, however, agree with the approach used in Drs. Marcus' and Siegel's report for correcting the survey data to obtain an estimate of the effective dose equivalent for the following reasons.

The first point to note is that the factor of 0.6 is a mean value that has a large uncertainty associated with it. Dr Siegel's published report lists the factor of 0.6 as having a range of 0.37 - 0.9. In addition, the data in this published work was based on patients administered ¹³¹I for non-Hodgkin's lymphoma in the form of ¹³¹I-tositumomab. There is no reason to suppose, however, that the distribution of activity in such patients, and therefore the radiation fields outside of these patients, would be the same as that for patients with metastatic thyroid cancer and depressed renal function administered sodium-¹³¹I, or that the factor is applicable to this particular patient. In addition, the location of the dose rate measurements with respect to the patient may not be the same in the two situations; in one case the survey was from the front of the patient, in the other from the side. Finally, the factor of 0.6 was determined using the theoretical dose rates calculated at 1 meter assuming the patient to be adequately represented by a point source. This may be acceptable for patient release, but it is not for this situation, where the visitor sat much closer to the source than 1 meter. It therefore appears that the factor of 0.6 assumed to apply in this case may not be appropriate, and should not be used to estimate the effective dose rate from the survey data.

The survey data are reported in units of millirem per hour, but NRC does not have the information necessary to determine with confidence the quantity for which the survey instrument was calibrated. Most survey instruments are still calibrated to indicate the exposure rate in roentgens per hour (R/hr), and for purposes of this analysis, it will be assumed that this was the case for the survey instrument used to make the surveys. The conversion from R to effective dose is easily made using published dose coefficients. Using these coefficients and assuming the survey data was in units of R/hr, the effective dose per R, at the photon energies emitted by ¹³¹I, is found to be about 0.93. Therefore, using the exposure rate meter readings as an

indicator of effective dose rate will overestimate that dose by a factor of about 1.07 ($1/0.93$), or essentially 1, rather than the factor of 1.7 indicated in the Marcus/Siegel report. If the meter was in fact calibrated to read millirem per hour directly, then the factor of 1.07 would be much smaller, and probably equal to one. It should be pointed out that this analysis is based on two assumptions: that the visitor was exposed in a more or less uniform radiation field over her body, incident on the front of the body, and that the survey data was taken at a location that was representative of the average radiation field to which the visitor was exposed. Interviews with licensee personnel, including the RSO, indicated that the survey data is representative of the dose rates to which the visitor was exposed. The radiation field, however, was probably not uniform over the visitor's body because of her proximity to the source of radiation. The effect of this non-uniformity cannot be determined because it depends on the degree of non-uniformity, the shape of the radiation field, as well as the exact relationship between the survey location and the visitor's body. The effective dose may therefore be higher or lower than the survey results suggest, but the difference in this case is probably not large.

3.4 CONCLUSIONS

The scenario and arguments presented in Drs. Marcus' and Siegel's reconstruction are quite reasonable, and may be viewed as representing a realistic description of the behavior of a typical visiting family member. However, the information available to NRC indicates that the actual behavior was quite different from that described in the reconstruction, and was, in some respects, atypical. The approach used in the reconstruction is dependent on the ability to calculate dose rates very close to the patient, to compare these with the measured values. NMSS staff believes that the calculational methods used in the reconstruction were not adequate to permit reasonably accurate calculations of these dose rates, and the results of such calculations therefore probably contain large uncertainties.

4.0 ACMUI CALCULATIONS AND RECOMMENDATIONS

4.1 DOSE RECONSTRUCTION

The ACMUI took a position similar to that in the Marcus/Siegel reconstruction, namely that the survey data should not be used directly, and that a dose rate should be calculated. As in the Marcus/Siegel case, the ACMUI did not indicate why the bedside survey data should not be used directly in estimating dose. The calculational methods used were different from those in the Marcus/Siegel reconstruction, and were, in many respects, much more sophisticated and appropriate for this case. However, simplifications were made that likely introduced large uncertainties in the dose estimates.

In estimating the dose rate, the ACMUI plotted the bedside survey data as a function of time. Monte Carlo calculations of dose rates were made at different distances from the patient, ranging from 15 cm to 31.6 cm. The distance that best fit the survey data, using a decay half-time of 3.26 days, was found to be 20 cm, and on that basis it was concluded that the bedside surveys must have been made at that distance from the patient. It was next reasoned that the visitor sitting at bedside probably had her forearms about 37 cm from the patient, based on the width of a typical hospital bed, and the dose rate at that distance was calculated to be 0.65 of the dose rate at 20 cm. This led to the conclusion that NRC's dose estimate, which was based on the survey data, is high by a factor of $1/0.65$, or about 1.5. Multiplying NRC's dose estimate of

15 cSv (15 rem) by 0.65 gives a dose estimate of about 10 cSv (10 rem). In these calculations, the patient was modeled as a water-filled cylinder with activity uniformly dispersed in it.

In addition to the factor of 1.5, ACMUI also stated that the survey data should have been decay corrected, and the absence of this correction led to overestimation of the dose by NRC by an additional factor of 1.1. ACMUI concluded that NRC's dose estimate is therefore 1.7 times too high, and the dose estimate should therefore be about 9 cSv (9 rem) rather than 15 rem. This is ACMUI's upper limit of their estimated dose range.

ACMUI also assumed that the visitor stood behind shields during her visit between July 2 and July 4. The shields were 1" of lead and, taking this shielding into account, further reduced the dose estimate from 8.8 cSv (rem) to 4.3 cSv (5.6 rem), rounded to 4 cSv (4 rem). ACMUI's final estimated range is 4-9 cSv (4-9 rem).

ACMUI's methods and approach were found by NMSS staff to be sophisticated and appropriate, but several areas of concern were noted, and these are discussed below.

- (1) The modeling assumed that the ^{131}I activity was uniformly distributed in the patient's body throughout the period in question. This may not be a valid assumption, and the results of the calculations based on it may therefore contain excessive uncertainties. This is particularly important because the calculations were performed for locations that are very close to the patient. These are the locations that would be expected to be very sensitive to the details of this distribution. NMSS's more detailed Monte Carlo calculations, which permitted placement of the activity in any organ or combination of organs, showed that the assumed distribution of the ^{131}I in the organs has a very significant effect on the radiation fields around the patient. This is clearly shown in Figure(3).
- (2) The assumption of a 3.2 day half-life in the calculations may overestimate this effect on the calculated dose rates. As discussed in Section 3.2 above and illustrated in Figures(2) and (3), the apparent changes in survey results may not have been due mainly to decay but most likely resulted from a re-distribution of activity in the patient's body. Since the details of this distribution are not known, it is difficult to reconstruct an accurate profile of the dose rate as a function of time. Taking these changes into account is also not possible if the patient is modeled as a water-filled cylinder with uniformly distributed activity. The changes in dose rate from day to day were taken into account in Region III's assessment by using each day's survey results with that day's occupancy time to estimate the dose for that day. Any deviations due to changes in between surveys were quite small, as was shown in Section 3.2, and corrections for this effect are negligible. Assuming a constant decay half-life of 3.2 days over the exposure period may lead to errors in the result, because the dose rate did not decrease uniformly in this manner, as shown in Figure (2) above.
- (3) The ACMUI's assumption that the visitor remained behind the shields during the period of July 2 to July 4 is reasonable but conflicts with information available to the Region III inspectors. The inspectors' reconstruction of events is supported by statements made by several hospital staff, including the RSO and patient care staff on duty during the

period in question. ACMUI does not acknowledge that there is an equally strong alternative scenario, and that there is little basis to make a choice between the two.

- (4) The ACMUI reconstruction assumed that Region III estimated the deep dose equivalent in assessing the dose to the visitor, stated that the Region and the licensee should have reported effective dose equivalent instead of deep dose equivalent, and concluded that had this been done, the dose estimate would have been reduced by as much as a factor of 4. The factor of 4 was based on surmise and not on calculations. NMSS notes that Region III's inspection report does not mention deep dose equivalent or total effective dose equivalent, but provides only a dose, without qualification. Although the intended quantity was likely the deep dose equivalent, a question, rather than an assumption, would have been appropriate. It is also unclear how the ACMUI arrived at the factor of 4 reduction in using effective dose in place of deep dose equivalent.

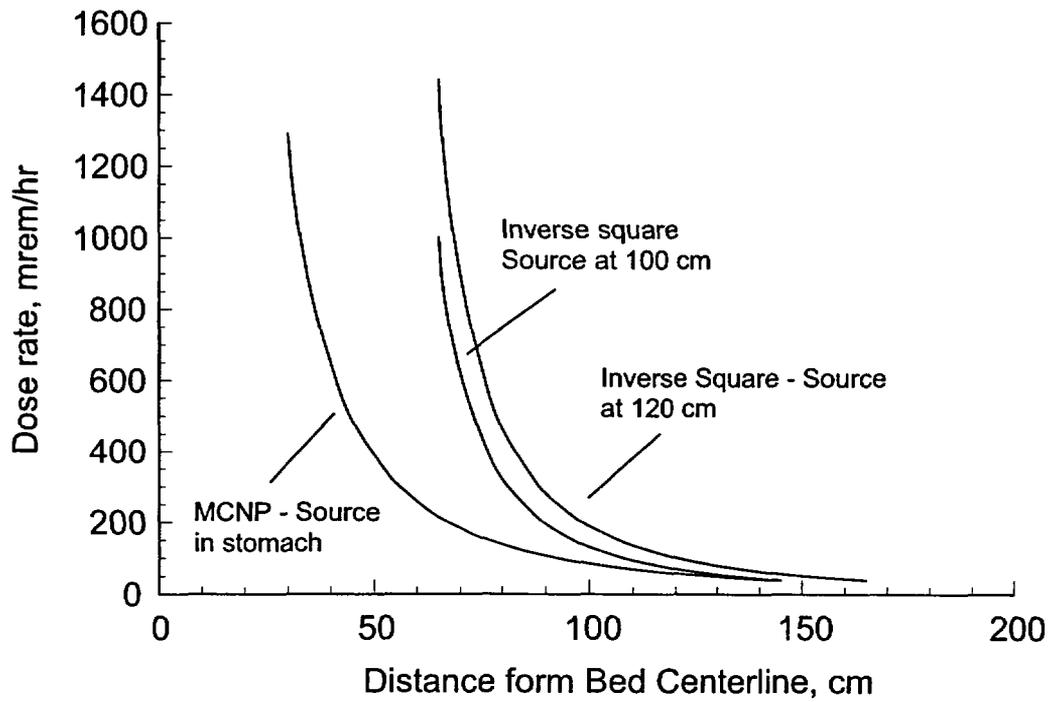
Based on published data (3), the deep dose equivalent at the ^{131}I photon energies is about a factor of 1.3 higher than the effective dose for anterior-posterior exposure in a uniform field. The field in this case was probably not uniform, and therefore the deep dose equivalent would probably be more than a factor of 1.3 higher than the effective dose. However, because the exact relationship of the survey location with respect to the visitor's body is not known, it is not possible to determine if using the survey data as a surrogate for the deep dose equivalent or for the effective dose will lead to over- or under-estimation of the effective dose. If the body was closer to the source than the survey location, then the effective dose will be underestimated. In this case, neither the survey location, nor the position of the visitor with respect to the source are known. What is known is that the surveys were made at the location where the visitor sat, and at a position that corresponded to that of the visitor's torso and head. It is therefore a good approximation to use the survey results as providing reasonable estimates of the visitor's effective dose. The uncertainty in this approach is likely to be much smaller than attempting to determine the relationship between the survey data, the deep dose equivalent, and the effective dose without knowing the location of the surveys or of the visitor, nor the shape of the radiation field at these locations.

The ACMUI method and assumptions were found by NMSS staff to be quite reasonable. However, as in the Marcus/Siegel reconstruction, the method depends on the ability to accurately calculate dose rates very close to the patient. The ACMUI Monte Carlo calculations, although much more appropriate in this case than use of the inverse square law, involved simplifications that, in the view of NMSS staff, introduce significant uncertainties in the results. The assumed location of the visitor with respect to the patient is also likely to involve large uncertainties.

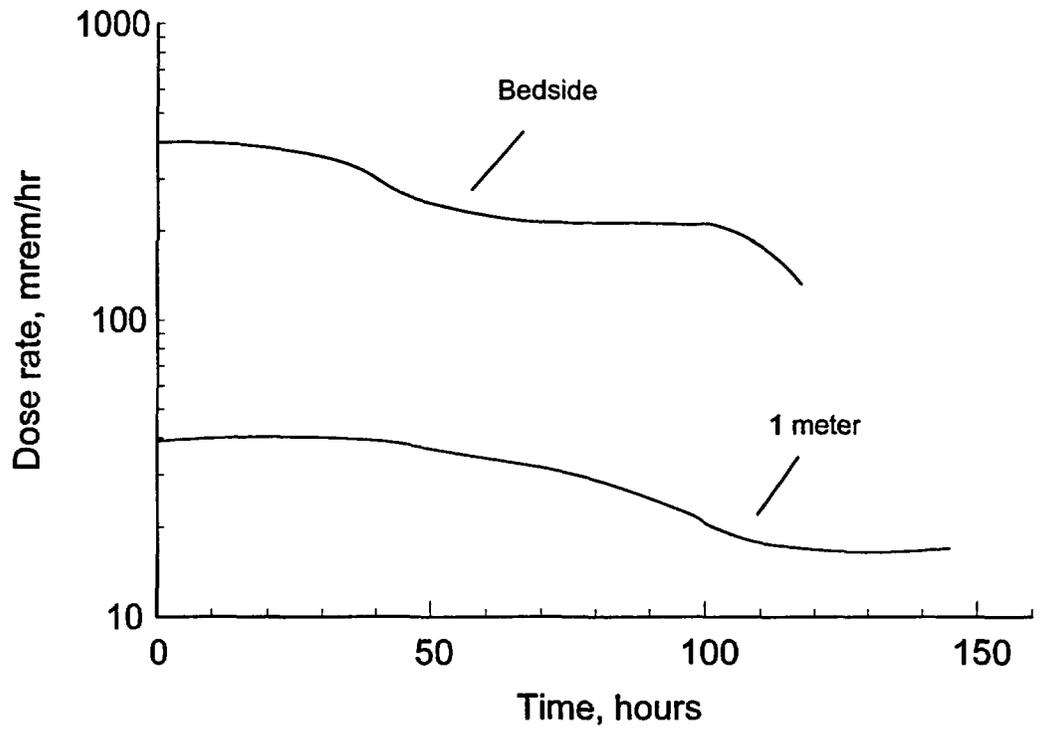
4.2 CONCLUSIONS

The approach taken by the ACMUI to estimate the dose to the visitor were found by NMSS staff to be reasonable and valid. However, the approach depended on the ability to calculate dose rates very close to the patient. It also depended on an assumed location for the visitor with

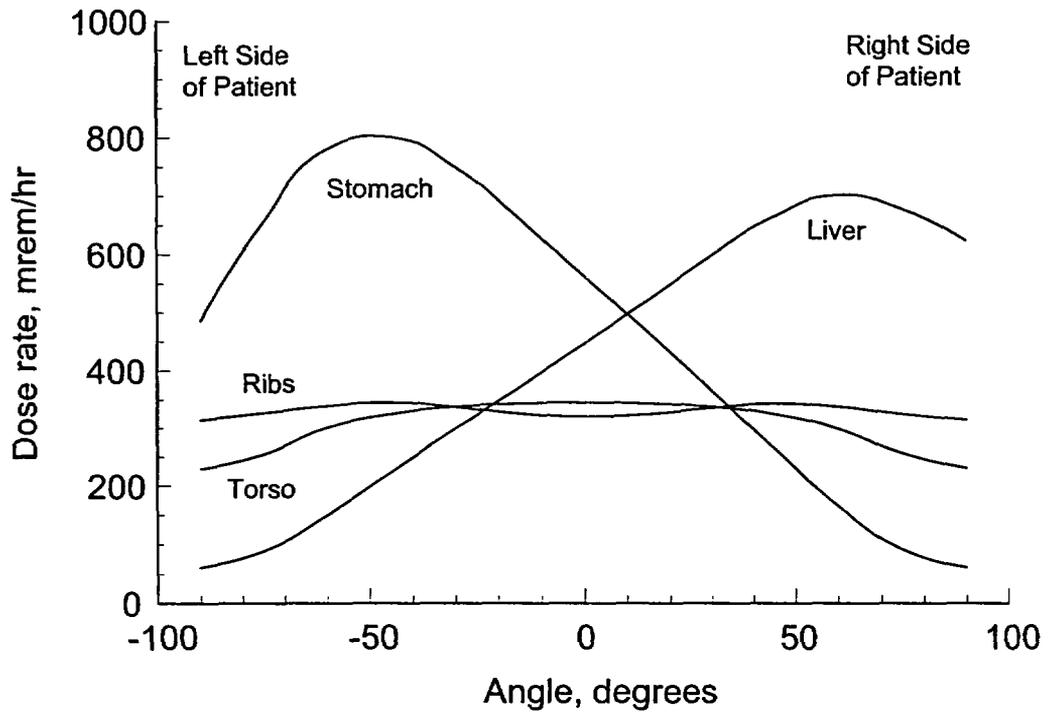
respect to the patient. NMSS staff believes that the methods used in calculating the dose rates close to the patient were not sufficiently detailed for the intended purpose, and were therefore not capable of estimating dose rates close to the patient with adequate accuracy. In addition, the assumptions made in the calculations, particularly regarding the visitor's location, were reasonable but to some degree arbitrary, and may not reflect the actual situation. In the opinion of NMSS staff, these factors, taken together, probably result in uncertainties in the dose estimates that exceed those inherent in the approach taken by Region III and the licensee.



Figure(1) - Variation of dose rate with transverse distance from patient centerline. The activity is uniformly distributed in the stomach.



Figure(2) - variation of measured dose rates at bedside and at 1 meter following administration of the I-131



Figure(3) - Radial dose distribution around the patient in a transverse plane through stomach. All curves were calculated using the same total activity.

REFERENCES

1. MCNP - A General Purpose Monte Carlo N-Particle Transport Code, Version 5, LA-CP-03-0245, Los Alamos National Laboratory, Los Alamos, New Mexico.
2. Snyder, W.S., Form, M.R., and Warner, G.G., Estimates of Specific Absorbed Fractions for Photon Sources Uniformly Distributed in Various Organs of a Heterogeneous Phantom, Society of Nuclear Medicine: Medical Internal Radiation Dose (MIRD) Pamphlet No. 5 Revised; New York, 1978.
3. Conversion Coefficients for Use in Radiological Protection against External Radiation, ICRP Publication 74, Pergamon Press, New York, 1995.
4. Siegel, JA; Kroll, S; Regan, D; Kaminski, MS; and Wahl, RL; A Practical Methodology for Patient Release After Tositumomab and ¹³¹I-Tositumomab Therapy; J. Nucl. Med., Vol. 43, No. 3, 2002.

ATTACHMENT 2

NRC INSPECTION REPORT 030-01997/2002001 (DMNS)
ST. JOSEPH MERCY HOSPITAL

December 10, 2002

EA-02-248

Julie MacDonald
Senior Vice President & Chief Operating Officer
St. Joseph Mercy Health System
St. Joseph Mercy Hospital
5301 East Huron River Drive
Ann Arbor, MI 48106-0995

SUBJECT: NRC INSPECTION REPORT 030-01997/2002001(DNMS)
ST. JOSEPH MERCY HOSPITAL

Dear Ms. MacDonald:

This refers to the special inspection conducted from October 4 through 16, 2002, at St. Joseph Mercy Hospital, Ann Arbor, Michigan, with continued in-office review through November 15, 2002. The purpose of the inspection was to review the circumstances, root and contributing causes, and proposed corrective actions regarding your radiation safety officer's October 1, 2002, written report of exposures to several members of the public in excess of the NRC's annual limit of 100 millirem, and to determine whether activities authorized by the license were conducted safely and in accordance with NRC requirements. The members of the public were family members of a radiopharmaceutical therapy patient who had been hospitalized for compliance with 10 CFR Part 35.75. Our inspectors determined from calculations that the patient's daughter, who was the maximally exposed member of the public, received an exposure of 15 rem total effective dose equivalent. The in-office review included a review of the results of the NRC medical consultant's evaluation of the exposure to the patient's daughter.

The enclosed copy of our inspection report identifies areas examined during the inspection. Within these areas, the inspection consisted of a selective examination of procedures and representative records, observations, independent measurements, and interviews with personnel and members of the public. On October 16, 2002, the preliminary inspection findings were discussed with you and members of your staff. The inspection findings and conclusions were discussed with you during a telephone conference call with Gary Shear and Darrel Wiedeman of my staff on November 21, 2002.

Based on the results of our inspection, we identified three apparent violations, which are being considered for escalated enforcement action in accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions" (Enforcement Policy), NUREG-1600 (enclosed). These apparent violations include the failure to: (1) limit the dose to individual members of the public to 0.1 rem in a year; (2) use procedures and engineering controls, to the extent practical, based upon sound radiation protection principles, to achieve doses to members of the public that are as low as is reasonably achievable; and (3) investigate an overexposure to a member of the public and implement corrective actions. In addition, we identified three potential violations which are not being considered for escalated enforcement

action. These violations include the failure to: (1) include estimates of each individual's dose in your initial August 15, 2002, written report; (2) measure the dose rates in the contiguous unrestricted areas following the administration of a radiopharmaceutical therapy dosage requiring hospitalization; and (3) limit the dose in unrestricted areas to 2 millirem in any one hour.

The NRC contracted with a medical consultant to review the circumstances of this event, specifically with regard to the exposure to the daughter of the therapy patient. Our consultant determined that the exposure to the daughter may result in less than a one percent increase in the lifetime risk of cancer. Enclosed with this letter is a copy of the consultant's report for your review.

Since the NRC has not made a final determination in this matter, no Notice of Violation is being issued for these inspection findings at this time. In addition, please be advised that the number and characterization of apparent violations may change as a result of further NRC review.

A predecisional enforcement conference, open for public observation, to discuss these apparent violations has been scheduled for January 16, 2003, at 1:00 p.m. (CDT) in the Region III office in Lisle, Illinois. The decision to hold a predecisional enforcement conference does not mean that the NRC has determined that a violation has occurred or that enforcement action will be taken. This conference is being held to obtain information to assist the NRC in making an enforcement decision. This may include information to determine whether a violation occurred; information to determine the significance of a violation; information related to the identification of a violation; and information related to any corrective actions taken or planned. The conference will afford you an opportunity to provide your perspective on these matters and any other information that you believe the NRC should take into consideration in making an enforcement decision. In presenting your corrective action, you should be aware that the promptness and comprehensiveness of your actions will be considered in assessing any civil penalty for the apparent violations. The guidance in the enclosed excerpt from NRC Information Notice 96-28, "SUGGESTED GUIDANCE RELATING TO DEVELOPMENT AND IMPLEMENTATION OF CORRECTIVE ACTION," may be helpful.

You will be advised by separate correspondence of the results of our deliberations on this matter. No response regarding these apparent violations is required at this time.

In accordance with 10 CFR Part 2.790 of the NRC's "Rules of Practice," a copy of this letter and Enclosure 1 will be made available electronically for public inspection in the NRC Public Document Room or from the Publicly Available Records (PARS) component of NRC's document system (ADAMS). ADAMS is accessible from the NRC Web site at <http://www.nrc.gov/reading-rm/adams.html> (the Public Electronic Reading Room).

J. MacDonald

-3-

We will gladly discuss any questions you have concerning this inspection.

Sincerely,

/RA/

Marc Dapas, Acting Director
Division of Nuclear Materials Safety

Docket No. 030-01997
License No. 21-00943-03

- Enclosure 1: Inspection Report 030-01997/2002001(DNMS)
- Enclosure 2: NUREG 1600
- Enclosure 3: Excerpt from Information Notice 96-28
- Enclosure 4: Medical Consultant's Report

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U.S. NUCLEAR REGULATORY COMMISSION

REGION III

Docket No.: 03001997

License No.: 21-00943-03

Report No.: 03001997/2002001(DNMS)

Licensee: St. Joseph Mercy Health System
Ann Arbor, MI 48106-0995

Locations: St. Joseph Mercy Hospital
5301 East Huron River Drive
Ann Arbor, MI

Dates: October 4 - 16, 2002
w/continued in-office review through November 15, 2002

Exit Meeting: October 16, 2002 (Preliminary)
November 21, 2002 (Final Exit)

Inspector: Jamnes L. Cameron, Team Leader
Darrel Wiedeman, Senior Health Physicist

Approved By: Gary L. Shear, Chief
Materials Inspection Branch
Division of Nuclear Materials Safety

EXECUTIVE SUMMARY

St. Joseph Mercy Health System Ann Arbor, Michigan Inspection Report 03001997/2002001(DNMS)

This was a special inspection to review the circumstances, root and contributing causes, and proposed corrective actions associated with an event involving exposures to individual members of the public in excess of 0.1 rem (100 millirem) total effective dose equivalent. The overexposures resulted from close contact, over several days, with a hospitalized patient who had been administered 285 millicuries of sodium iodide iodine-131. The licensee's report indicated that the event may have involved as many as 20 individuals. The licensee's radiation safety officer estimated the highest exposure to be between 3000 and 5600 millirem. The remaining overexposures, involving approximately ten other individuals, were estimated to be between 100 and 500 millirem total effective dose equivalent. The doses to the remaining members of the public were not expected to exceed 100 millirem total effective dose equivalent.

A patient who was administered a therapeutic quantity of sodium iodide iodine-131 on July 1, 2002, and hospitalized in accordance with 10 CFR Part 35.75, retained a significant portion of the administered dosage due to poor renal function, during her hospital stay. As such, radiation levels near the patient remained relatively high during this period. During the treatment period, hospital staff, including the former radiation safety officer (RSO), observed the patient's adult daughter frequently at the patient's bedside. Licensee staff, including the former RSO, did not take prudent precautions to maintain the daughter's dose as low as is reasonably achievable. The inspectors calculated the dose to the patient's daughter to be 15 rem total effective dose equivalent due to her proximity to the patient during her treatment, and the amount of time that she spent in areas of elevated radiation levels. The NRC's medical consultant, Dr. Edward Silberstein, determined that the exposure may result in less than a one percent increase in her lifetime risk of cancer.

After initially determining that public exposures likely exceeded regulatory limits, licensee staff, particularly the former RSO, were slow to investigate the circumstances associated with the overexposure. Licensee management did not initiate their investigation of the overexposures until July 26, 2002, 19 days after the event. The initial investigation was limited to interviews of hospital staff and a review of records of daily patient room surveys, and did not include interviews of the former RSO. The investigation was not conducted in a probing manner commensurate with the potential significance of the exposures.

The licensee's initial written report regarding exposures to members of the public in excess of the regulatory limit was limited to generalities regarding the radiological conditions pertinent to the exposures and the resultant doses to individuals. The report did not include the required information regarding doses to individuals, and included only a reference to exposure from a diagnostic radiology procedure, which was not in any units of dose (e.g., rem, rad, Gray, or Sievert). The licensee's October 1, 2002, follow-up report, provided nearly seven weeks after the initial report, required significant NRC staff involvement in order to obtain a specific dose estimate for any of the members of the public involved, and the technical bases for the estimate.

The inspectors identified three apparent violations of NRC regulatory requirements. The apparent violations included the failure to: (1) limit the dose to individual members of the public to 0.1 rem in a year; (2) use procedures and engineering controls, to the extent practical, based

upon sound radiation protection principles, to achieve doses to members of the public that are as low as is reasonably achievable; and (3) investigate an overexposure to a member of the public and implement corrective actions. In addition, the inspectors identified three potential violations of NRC regulatory requirements. The potential violations included the failure to: (1) include estimates of each individual's dose in the licensee's August 15, 2002, written report; (2) measure the dose rates in the contiguous unrestricted areas following the administration of a radiopharmaceutical therapy dosage requiring hospitalization; and (3) limit the dose in unrestricted areas to 2 millirem in any one hour.

The root cause of the apparent and potential violations was inattention to licensed responsibilities on the part of the former RSO. The former RSO stated that she had become distracted by other duties and responsibilities that affected her ability to focus on the regulatory and safety issues associated with the sodium iodide iodine-131 therapy procedure and the resultant public doses. Furthermore, the former RSO did not communicate her belief that public dose limits had been exceeded until the radiation safety committee meeting on July 17, 2002. After that meeting, licensee management did not investigate the exposures until after the former RSO's termination on July 26, 2002. This was not considered to be timely. The root cause of the potential violation associated with the August 15, 2002, report contents was unfamiliarity with NRC reporting requirements. The licensee's proposed corrective actions were adequate to address the potential violations. The adequacy of the licensee's corrective actions to address the apparent violations will be determined following the predecisional enforcement conference.

Report Details

1. Program Scope and Inspection History

License No. 21-00943-03 authorized St. Joseph Mercy Health System (licensee) to possess and use licensed materials for human medical purposes at the licensee's facilities located at St. Joseph Mercy Hospital, Ann Arbor, Michigan (hospital). The authorization included radiopharmaceuticals for diagnosis and therapy, and sealed sources for therapy.

The NRC last inspected the licensee on January 12, 2000, and identified one violation for failure to include all required information on written directives for radiopharmaceutical therapy. The NRC inspectors confirmed that the licensee's corrective actions for the violation have been adequate to prevent recurrence. This violation is closed. The licensee's failure to include all required information on the written directive did not result in any misadministrations or recordable events. During the previous inspection on February 11, 1997, the NRC identified one violation, involving the licensee's failure to secure from unauthorized access or removal, waste containing technetium-99m. This violation was closed during the January 12, 2000, inspection.

2. Sequence of Events

a. Inspection Scope

The inspection included a review of the sequence of events that resulted in exposures in excess of 100 millirem to several members of the public. The inspection also included tours of licensee facilities; interviews of selected licensee personnel; and reviews of the licensee's August 15, 2002, September 11, 2002, and October 1, 2002, written reports and other associated records.

b. Observations and Findings

On June 12, 2002, the licensee admitted a patient for treatment of metastatic thyroid carcinoma. During the treatment, a licensee authorized user physician prepared a written directive for the administration of 300 millicuries of sodium iodide iodine-131. The authorized user physician initially considered a dosage of 600 millicuries; however, due to the patient's poor renal function, he decreased the dosage to 300 millicuries.

On July 1, 2002, the licensee's former radiation safety officer (RSO) administered the radiopharmaceutical therapy dosage in accordance with the provisions of the written directive. The actual administered dosage was 285 millicuries. The patient remained hospitalized due to her other health problems and the patient control requirements in 10 CFR Part 35.75. The licensee provided the patient a private room with private sanitary facilities, posted the patient room door with the appropriate radiation warning signs, positioned shields at the foot of the bed and between the bed and door to the room, and provided radiation safety instructions to patient care staff, including instructions for the control of visitors. In addition, following administration of the therapy dosage, the RSO measured the radiation levels in the patient's room, the adjoining room, and the hallway outside the patient's room.

Typically, for patients with normal renal function, 90 to 95 percent of the administered dosage of sodium iodide iodine-131, which has not been taken up by the residual and metastatic thyroid tissues, is rapidly filtered from the blood stream (i.e., within 24 to 48 hours post-administration) via the kidneys and excreted in the urine. For such patients, there is a rapid reduction in the external radiation profile commensurate with the biological elimination of the unbound iodine-131. Following this initial rapid decline in external radiation levels, the levels would normally further diminish according to an effective half-life (due to a combination of physical radiological decay and biological elimination) of seven days.

During each day that the patient was hospitalized, the RSO measured radiation levels at the patient's bedside and at one meter from the patient. Due to the patient's poor renal function, typical biological elimination of the iodine-131 did not occur, and there was no initial rapid reduction in radiation levels. Radiation levels measured on July 1, 2002, post-administration of the therapy dosage, were 400 millirem per hour at the bedside and 40 millirem per hour at one meter. Radiation levels measured on subsequent days diminished according to an effective half-life of three to four days.

On July 1, 2002, all of the patient's visitors adhered to the radiation safety precautions instituted by the licensee. The primary precaution taken by the licensee was to not allow any visitors inside the patient's room during the first day after administration of the therapy dosage. This was confirmed through interviews of patient care staff and the patient's daughter. In keeping with its usual practice, the licensee relaxed visitor restrictions 24 hours after the administration of the dosage, and allowed visitors in the room. Hospital staff instructed the visitors to remain behind the shields during visitation; however, the licensee did not impose any stay time restrictions on the visitors.

Between July 2 and 7, 2002, several patient care staff and the RSO observed the patient's adult daughter frequently at the patient's bedside, near the window, where a shield was not located. When they observed this, they reminded the daughter to position herself on the other side of the bed so that she was protected from unnecessary radiation exposure. On July 5, 2002, the patient's physical condition worsened. The RSO and the authorized user physician approved the temporary removal of the bedside shields so that the patient's family members (estimates provided by hospital staff and the daughter vary between 20 and 35 individuals) could visit with the patient for the last time. Based on observations of the patient's room, the inspectors estimated that 10 - 12 individuals could have stood in close proximity to the bed, and received a dose of approximately 200 millirem total effective dose equivalent. Doses to all other family members in the patient's room would not likely have exceeded 100 millirem total effective dose equivalent.

The patient's condition declined until she died on July 7, 2002. Licensee patient care staff and the RSO observed the daughter at the bedside essentially continuously between July 5 and 7, 2002. The former RSO did not recommend further precautions to the daughter to maintain her radiation exposure as low as is reasonably achievable. Suggested precautions could have included maintaining an arm's length from the side of the patient's bed (since radiation levels at one meter were approximately one-tenth of those at the bedside), the use of additional shielding, minimizing the daughter's time at the bedside, or the use of a digital dosimeter to self-monitor the daughter's exposure, which the licensee had available. Part 20.1101(b) to Title 10 of the Code of Federal Regulations (10 CFR) requires that the licensee use, to the extent practical, procedures

and engineering controls, based upon sound radiation protection principles, to achieve occupational doses and doses to members of the public that are as low as is reasonably achievable. The licensee's failure to use procedures and engineering controls, to the extent practical, based upon sound radiation protection principles, to achieve doses to members of the public that are as low as is reasonably achievable, is considered an apparent violation of 10 CFR Part 20.1101(b).

The former RSO stated that during the weekend of July 6 -7, 2002, she repeatedly attempted to contact her supervisor to relay her concern regarding potential exposures to members of the public. Interviews of the supervisor indicated that he had not received any pages or telephone calls to his residence. The supervisor stated that upon his return to work on July 8, 2002, he did not have any messages on his office telephone from the former RSO. Furthermore, he stated that the former RSO did not mention her concerns regarding public doses when she interacted with her supervisor following the patient's death.

Following the patient's death, the former RSO assisted a mortician during the embalming process. The embalming was performed in the hospital morgue. The former RSO provided the mortician with a digital dosimeter to monitor his exposure during the process. The dosimeter recorded an exposure of 35 millirem for the nine-hour procedure. Contaminated body fluids from the decedent were disposed to the sanitary sewer. Based on surveys conducted by the former RSO in the morgue and the patient's room, the licensee did not identify any significant residual contamination.

On July 17, 2002, the licensee's radiation safety committee convened for a regularly scheduled meeting. During the meeting, the committee members discussed the radiopharmaceutical therapy procedure that occurred on July 1 through 7, 2002, and the unique issues associated with it, including visitor control and the death of a patient during therapy. During those discussions, the former RSO indicated for the first time her belief that a member of the public received a dose in excess of 500 millirem, but she had not yet evaluated the extent of the exposure.

Parts 35.21(a) and (b) to 10 CFR require, in part, that the licensee appoint an RSO responsible for implementing the radiation safety program. The licensee, through the RSO, is required to ensure that radiation safety activities are being performed in accordance with approved procedures and regulatory requirements in the daily operation of the licensee's byproduct material program. The RSO is required to, among other things, investigate overexposures and deviations from approved radiation safety practices, and implement corrective actions as necessary.

The licensee's former RSO became aware that the daughter of a patient being treated with a radiopharmaceutical was not following the licensee's approved safety practices. In addition, the former RSO suspected that the patient's daughter had received an exposure to radiation in excess of the NRC's regulatory limits and failed to investigate the potential exposure and implement corrective actions. The former RSO's failure to investigate the potential overexposure and implement corrective actions is considered an apparent violation of 10 CFR Parts 35.21(a) and (b).

On July 26, 2002, the licensee terminated the former RSO's employment. Licensee management representatives stated that the termination was not related to the July 1 through 7, 2002, therapy treatment. At the time of her termination, the former RSO had

not yet evaluated the potential exposure to the patient's family members, including the patient's daughter.

c. Conclusions

A patient, who was administered a therapeutic quantity of sodium iodide iodine-131 on July 1, 2002, and hospitalized for compliance with 10 CFR Part 35.75, retained a significant portion of the administered dosage during her hospital stay. As such, radiation levels around the patient remained relatively high during this period. During the treatment period, hospital staff, including the licensee's former RSO, observed the patient's daughter frequently at the patient's bedside. Licensee staff, including the former RSO, did not take prudent precautions to maintain the daughter's dose as low as is reasonably achievable. Two apparent violations of regulatory requirements were identified, including the failure to: (1) use procedures and engineering controls, to the extent practical, based upon sound radiation protection principles, to achieve doses to members of the public that are as low as is reasonably achievable; and (2) investigate an overexposure to a member of the public and implement corrective actions as necessary.

3. **Licensee Investigation**

a. Inspection Scope

The inspection included a review of the results of the licensee's investigation of an event involving exposures in excess of 100 millirem to several members of the public. The inspection also included tours of facilities; interviews of selected licensee personnel; and a review of applicable procedures, associated records, and written reports.

b. Observations and Findings

Prior to the July 17, 2002, radiation safety committee meeting, the former RSO did not share with others her belief that a member of the public had received a radiation dose in excess of 500 millirem total effective dose equivalent. Before her termination on July 26, 2002, the former RSO had not evaluated the extent of the radiation exposure to the patient's daughter. The former RSO stated that she was focused on other activities, including shielding calculations for diagnostic radiology rooms and State registration of radiation producing devices (i.e., x-ray tubes).

Following termination of the former RSO, licensee management and the newly appointed RSO initiated an investigation into the exposures to members of the public associated with the July 1, 2002, administration of a radiopharmaceutical therapy dosage to a hospitalized patient. The investigation included a review of the records of the results of daily surveys conducted in the patient's room by the former RSO, and interviews of licensee staff who provided care to the patient. Based on anecdotal information obtained from patient care staff, licensee management bounded the maximum exposure received by a member of the public to approximately 3 rem total effective dose equivalent, and equated this to the dose received during a computed tomography (CT) scan.

c. Conclusions

Licensee staff, particularly the former RSO, were slow to investigate the circumstances associated with overexposures to members of the public resulting from the radiopharmaceutical therapy procedure performed on July 1 through 7, 2002. Licensee management did not initiate the investigation until July 26, 2002, nineteen days after the event. The initial investigation was limited to interviews of hospital staff and a review of records of daily patient room surveys, and did not include interviews of the former RSO or members of the patient's family. The investigation was not conducted in a probing manner commensurate with the potential significance of the exposures.

4. **Notifications and Reporting**

a. Inspection Scope

The inspection included a review of the notifications and reporting to the NRC of an event involving exposures to members of the public which resulted in doses in excess of 100 millirem in a year. The inspection also included interviews of selected licensee employees and a review of associated records and reports.

b. Observations and Findings

Title 10 CFR Part 20.2203(a) requires that each licensee submit a written report within 30 days of becoming aware that an individual member of the public received a dose in excess of the limits in 10 CFR Part 20.1301. Licensee staff initially determined that a member of the public likely received a dose in excess of 100 millirem total effective dose equivalent during the July 17, 2002, radiation safety committee meeting. Licensee staff provided a written notification to the NRC of this event in a letter dated August 15, 2002.

Title 10 CFR Part 20.2203(b) requires that each report required by 10 CFR Part 20.2203(a) describe the extent of exposure of individuals to radiation, including estimates of each individual's dose. The licensee's August 15, 2002, written report described the general radiological conditions in the patient's room, but did not provide specific dose estimates for any of the visitors. Licensee staff stated that the maximum likely dose to the visitors was the same as the dose expected from a CT scan, namely, 3 rem total effective dose equivalent. The licensee's failure to include estimates of each individual's dose in its August 15, 2002, written report is considered a potential violation of 10 CFR Part 20.2203(b).

On August 27, 2002, an NRC inspector contacted the licensee's current RSO to discuss the August 15, 2002, written report and obtain additional information. Since this individual had not been in the RSO position during the time that the event occurred, he was not familiar with any of the event details. The RSO indicated that he would need additional time to obtain the requested information.

On September 11, 2002, the RSO provided a follow-up written report regarding the public exposure event. The report included additional event details; however, the estimate for the maximally exposed individual was "... less than or equal to 3000 (millirem)." In addition, the RSO continued to rely on anecdotal information from patient care staff in developing the dose estimate. The inspector again requested that the RSO re-evaluate the dose estimate, and suggested that he use more definitive information regarding the duration of exposure and proximity of the daughter to the patient.

On October 1, 2002, the RSO submitted a third written report containing the detailed information requested by the inspector. In the subject report, the RSO revised his dose estimate for the patient's daughter to between 3000 and 5600 millirem total effective dose equivalent. The report provided the technical basis for the exposure estimate, including the results of interviews with the daughter.

c. Conclusions

The licensee's initial written report regarding exposures to members of the public in excess of the regulatory limit was limited to generalities regarding the radiological conditions pertinent to the exposures and the resultant doses to individuals. The report did not include the required information regarding doses to individuals, and included only a reference to exposure from a diagnostic radiology procedure, which was not in any units of dose (e.g., rem, rad, Gray, or Sievert). The licensee's October 1, 2002, follow-up report, provided nearly seven weeks after the initial report, required significant NRC staff involvement in order to obtain a specific dose estimate for any of the members of the public involved, and the technical bases for the estimate. One potential violation of regulatory requirements was identified involving the failure to include estimates of each individual's dose in the licensee's August 15, 2002, written report.

5. **Public Dose Assessments**

a. Inspection Scope

The inspection included a review of the licensee's assessments of doses to members of the public resulting from the July 1, 2002, radiopharmaceutical therapy dosage administration. The inspection also included interviews of selected licensee employees and the therapy patient's daughter, observations of facilities, and a review of associated records and reports.

b. Observations and Findings

Title 10 CFR Part 20.1301(a)(1) requires that the licensee conduct operations so that the total effective dose equivalent to individual members of the public from the licensed operations does not exceed 0.1 rem (100 millirem) in a year. The licensee estimated the daughter's dose to be 3 to 5.6 rem (3000 to 5600 millirem) total effective dose equivalent. The estimate was based on information provided by the daughter regarding her activities between July 5 and 7, 2002. The RSO, who performed the dose estimate, was not aware that the daughter had been near the patient's bedside periodically between July 2 through 5, 2002.

During the inspectors' interviews of the patient's daughter, she provided the following information regarding her proximity to the patient and duration of exposure:

- On July 1, 2002, following administration of the therapy dosage, all family members remained at the doorway to the patient's room during visitation, as instructed by hospital staff.
- Beginning approximately mid-day on July 2, 2002, through the late afternoon of July 5, 2002, the daughter remained at the patient's bedside approximately half of each day.

- Beginning at approximately 5 p.m. on July 5, 2002, after the patient's condition worsened, the daughter remained at the bedside continuously, except for approximately 3.5 hours, until the patient's death on July 7, 2002.
- When at the patient's bedside, the daughter sat against the bed, with her elbows or forearms on the bed.
- No other family members remained in the patient's room for as long, or positioned themselves as close, as the daughter did.

Based on bedside radiation level surveys performed by the former RSO, and the information provided by the patient's daughter, the inspectors calculated the daughter's dose at 15 rem total effective dose equivalent, as follows:

July 2, 2002: 6 hours @ 348 millirem per hour

July 3, 2002: 12 hours @ 250 millirem per hour

July 4, 2002: 12 hours @ 210 millirem per hour

July 5, 2002 (through 5 p.m.): 8.5 hours @ 210 millirem per hour

July 5, 2002 (after 5 p.m.): 7 hours @ 210 millirem per hour

July 6, 2002: 20.5 hours @ 132 millirem per hour

July 7, 2002: 11.5 hours @ 107 millirem per hour

The main difference between the licensee's estimate of the daughter's dose as provided in the October 1, 2002, written report, and the inspectors' estimate was additional detail provided by the daughter during the inspectors' interview on October 4, 2002. The additional detail concerned the daughter's bedside proximity during July 2, 2002 through July 5, 2002, which she had not recalled during earlier conversations with licensee staff. The licensee's failure to limit the dose to individual members of the public from licensed operations to 0.1 rem in a year is considered an apparent violation of 10 CFR Part 20.1301(a)(1). At the time of the inspection, the licensee did not dispute the inspectors' estimate of the daughter's exposure, but the RSO stated that he would need additional time to review the inspectors' assumptions and the outcomes of their calculations.

The former RSO did not measure the radiation levels in an emergency exit stairwell next to the patient's room and along the wall where the head of the patient's bed was located; however, all entry points to the stairwell were via alarmed fire/emergency exit doors. In addition, the former RSO did not survey the area outside the window of the patient's room, which was on the ground floor. The former RSO did not place any shields between the patient's bed and the window. The stairwell and the area outside the patient's window were not restricted for purposes of radiation protection. Title 10 CFR Part 35.315(a)(4) requires that the licensee promptly measure the dose rate in contiguous restricted and unrestricted areas, with a radiation measurement survey instrument, to demonstrate compliance with the requirements of 10 CFR Part 20, after administration of a radiopharmaceutical therapy dosage requiring hospitalization in

order to comply with 10 CFR Part 35.75. The licensee's failure to measure the dose rates in the contiguous unrestricted areas, located in the stairwell and outside the window, following the administration of a radiopharmaceutical therapy dosage requiring hospitalization to comply with 10 CFR Part 35.75 is considered a potential violation of 10 CFR Part 35.315(a)(4).

Title 10 CFR Part 20.1301(a)(2) requires that the licensee conduct operations so that the dose in any unrestricted area from external sources does not exceed 2 millirem in any one hour. The inspectors requested that the licensee evaluate the likely radiation levels in the unrestricted areas that were not surveyed following the administration of the radiopharmaceutical therapy dosage on July 1, 2002. The current RSO determined, based on surveys performed in the patient's room, that the radiation levels in the stairwell adjacent to the room ranged from 10 millirem in an hour on July 1, 2002, to 4 millirem in an hour on July 7, 2002. The current RSO also determined that outside the patient's window, the radiation levels ranged from 17 millirem in an hour on July 1, 2002, to 8 millirem in an hour on July 7, 2002. The licensee's failure to limit the dose in unrestricted areas from licensed operations to 2 millirem in any one hour during the period from July 1 through 7, 2002, is considered a potential violation of 10 CFR Part 20.1301(a)(2).

c. Conclusions

Based on additional information obtained during the inspection, the inspectors calculated the dose to the patient's daughter to be 15 rem total effective dose equivalent, due to her proximity to the patient during the patient's treatment, and due to the amount of time that she spent in areas of elevated radiation levels. At the time of the inspection, licensee staff were not able to re-evaluate their earlier dose estimates based on the recency of the additional information. In addition, the inspectors identified that elevated radiation levels existed in two unrestricted areas during the patient's radiopharmaceutical therapy treatment. However, due to the nature of the areas, exposure to members of the public was not likely. One apparent violation of regulatory requirements was identified for failing to limit the dose to individual members of the public to 0.1 rem in a year. In addition, two potential violations of regulatory requirements were identified, including the failures to: (1) limit the dose in unrestricted areas to 2 millirem in any one hour, and (2) measure the dose rates in the contiguous unrestricted areas following the administration of a radiopharmaceutical therapy dosage requiring hospitalization.

6. **Quality Management Program Implementation**

a. Inspection Scope

The inspection included a review of the licensee's implementation of its written quality management program procedures which consisted of interviews of selected licensee personnel and reviews of applicable procedures and associated records.

b. Observations and Findings

The written directive for the July 1, 2002, administration of a therapeutic quantity of sodium iodide iodine-131 included a prescribed dosage of 300 millicuries. The administered dosage was 285 millicuries. The written directive was signed and dated by an authorized user physician and included all of the information specified in 10 CFR Part 35.2. Licensee staff verified the dosage in a dose calibrator prior to administration, and confirmed that the dosage was within ten percent of the prescribed dosage.

The inspectors reviewed selected administrations of therapeutic radiopharmaceuticals. The administrations reviewed included nine signed and dated written directives completed prior to July 1, 2002. In each case, licensee staff verified the dosage in a dose calibrator and the identity of the patient prior to administering the dosage. The former RSO audited all administrations of therapeutic quantities of radiopharmaceuticals at least once each year to ensure that the administrations were in accordance with the associated written directive. The former RSO had not identified any recordable events or misadministrations as a result of previous audits.

c. Conclusions

The licensee adequately implemented the written procedures of its quality management program for therapeutic radiopharmaceutical administrations. The inspectors did not identify any problems with regard to those administrations in general, or specifically with regard to the July 1, 2002 administration, which was the subject of this inspection.

7. Licensee Corrective Actions

a. Inspection Scope

The inspection included a review of the licensee's proposed corrective actions for the event involving exposures in excess of 100 millirem to several members of the public. The review included interviews of selected licensee personnel.

b. Observations and Findings

The licensee provided its initial corrective actions in its August 15, 2002, written report of the event involving several public exposures in excess of the regulatory limit. The actions were limited to documenting agreement between the authorized user and anyone visiting patients that have been hospitalized for compliance with 10 CFR Part 35.75, that the visitors will comply with the controls established by the licensee. The licensee also committed to enhancing documentation of visitor stay times within the rooms of patients hospitalized for compliance with 10 CFR Part 35.75, providing larger radiation warning signs for the patient's room door, and making individual education sheets available to visitors.

During the inspection, the licensee provided additional corrective actions in an October 8, 2002 letter. The additional actions included establishing a policy of not allowing visitors into hospitalized therapy (radiopharmaceutical and sealed source) patient rooms. In those instances when an authorized user deems it appropriate for visitors to enter such patient rooms, the licensee will provide more formalized instruction to the visitors regarding visitation restrictions; use available resources to develop a

balanced solution that meets the needs of patients and their families, while fulfilling regulatory responsibilities; and ensure that management is promptly notified of any concerns regarding patient or visitor compliance with radiation safety restrictions or precautions.

c. Conclusions

The licensee's proposed corrective actions were adequate to address the problems associated with the exposures to members of the public arising from the July 1 through 7, 2002 radiopharmaceutical therapy procedure.

8. **NRC Medical Consultant's Review**

The NRC staff contracted with a medical consultant, Edward Silberstein, M.D., to review the possible health effects associated with the dose to the patient's daughter as a result of this event. Dr. Silberstein opined that the exposure to the patient's daughter may result in less than a one percent increase in her lifetime risk of cancer.

9. **Exit Meeting**

On October 5, 2002, the inspectors summarized the initial findings at a preliminary exit meeting with licensee representatives. The summary included the inspectors' understanding of the sequence of events, the preliminary dose assessment for the patient's daughter, and the licensee's proposed corrective actions. On October 16, 2002, the Chief, Materials Inspection Branch, and the inspectors summarized the inspection findings at a second preliminary exit meeting with licensee representatives. The summary reiterated the findings from the first preliminary exit meeting, included the identified apparent violations, and described the NRC's process for use of a medical consultant. The final exit meeting was conducted by telephone on November 21, 2002, to discuss the apparent violations. The licensee did not identify any material reviewed during the inspection and proposed for inclusion in this report as proprietary in nature.

PARTIAL LIST OF PERSONS CONTACTED

Elizabeth Beger, R.N., Service Delivery Leader, 1000 Oncology Unit
Rayma Bilicki, M.S., Radiation Safety Officer (through July 26, 2002)
Sharlene Campbell, Director, Radiology
John E. Freitas, M.D., Authorized User Physician
Amy S. Harrison, M.S., Medical Physicist
Michelle Hazard, Manager, Radiation Oncology and Radiation Safety
Timothy G. Kensora, M.S., Radiation Oncology Physicist, and
Radiation Safety Officer (after July 26, 2002)
Julie MacDonald, M.S., RN, Senior Vice President, Patient Care Services and
Chief Operating Officer
Mandi A. Murray, Assistant General Counsel
Leonard A. Sullivan, Service Delivery Leader, Environmental Health
patient's daughter* - name withheld to protect personal privacy

ATTACHMENT 3

**ABSORBED DOSE RECONSTRUCTION FOR FAMILY
MEMBER OF 1-131 PATIENT**

CAROL S. MARCUS AND JEFFRY A. SIEGEL

**NUCLEAR REGULATORY COMMISSION RADIATION
ABSORBED DOSE RECONSTRUCTION FOR FAMILY MEMBER
OF I-131 PATIENT**

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Running Title: NRC dose calculation from I-131 patient

NRCdosereconstri-131pt10-21-03

**NUCLEAR REGULATORY COMMISSION RADIATION
ABSORBED DOSE RECONSTRUCTION FOR FAMILY MEMBER
OF I-131 PATIENT**

Abstract: A terminally ill patient with metastatic thyroid cancer and severe renal insufficiency was treated as an inpatient with 10,545 MBq (285 mCi) Na^{131}I . The patient died six days after radiopharmaceutical administration while still in the hospital. A close relative of the patient disregarded the instructions of the Radiation Safety Officer (RSO) and insisted upon staying close to the patient for long periods of time until the patient's death. The licensee later reported to the Nuclear Regulatory Commission (NRC) that this member of the public had likely received a dose in excess of the 1 mSv (100 mrem) regulatory limit. The NRC subsequently performed a dose reconstruction and determined that the family member received an exposure of 15 cSv (rem) total effective dose equivalent (TEDE). An analysis of the NRC's approach and an alternative dose reconstruction, in which the TEDE was determined to be approximately a factor of as much as 17 lower, is presented.

Key Words: Nuclear Regulatory Commission; radiation dose calculation

Case Presentation: A patient with terminal metastatic thyroid cancer and severe renal insufficiency was treated with 10,545 MBq (285 mCi) Na^{131}I and hospitalized in accordance with NRC requirements pursuant to 10 CFR

Part 35.75. The patient died six days after radiopharmaceutical administration while still in the hospital. The RSO measured radiation levels in the patient's room each day, both at 1 meter from the patient and at the patient's bedside. The initial dose rate measurements following radiopharmaceutical administration were 0.040 cSv/h (rem/h) and 0.400 cSv/h (rem/h) at 1 meter and at the bedside, respectively. According to the NRC, these radiation levels diminished with an effective half-time of 3 to 4 days.

A close adult relative of the patient disregarded the instructions of the RSO and insisted upon staying close to the patient for long periods of time until the patient's death. The relative was reminded by licensee staff, including the RSO, to take a position behind a bedside shield. As a result of the relative's proximity to the patient and the amount of time spent in areas of elevated radiation levels, the licensee later reported to the NRC that the relative likely received a dose in excess of the 1 mSv (100 mrem) regulatory limit.

The NRC subsequently performed a dose reconstruction using the RSO's measured dose rate values at the bedside and the daily stay times for the

relative that were determined from interviews with the relative and licensee staff. Details of this analysis are publicly available in NRC's AgencyWide Documents Access and Management System (ADAMS), accession number ML023440102. The NRC assumed that the relative was at the bedside position for the total amount of stay time each day. NRC determined TEDE by multiplying the measured dose rates by the estimated stay times. The dose rates, stay times, estimated TEDE during each day, and the total TEDE are presented in Table 1. As shown in the Table, the TEDE was estimated to be 15 cSv (rem) for the relative. Only the external dose component was considered; no mention is made concerning the possibility or likelihood of internal intake. Therefore the TEDE is equal to the deep dose equivalent (DDE).

SNM/ACNP Concern Over NRC Dose Reconstruction: The Society of Nuclear Medicine (SNM) and the American College of Nuclear Physicians (ACNP) were concerned that NRC's dose reconstruction in this case might be overly conservative. Meetings with NRC Commissioners McGaffigan and Merrifield were held to discuss NRC dose reconstructions as well as to suggest the formation of an independent committee composed of experts from the SNM/ACNP and other dosimetry experts to conduct peer reviews

of NRC's dose calculations. On September 9, 2003, NRC Chairman Diaz sent a letter to Henry Royal, M.D., President of the SNM, making the following statements of interest:

(1). "In this particular case, the hospital had performed daily dose rate measurements at the bedside. The NRC estimated the stay times next to the bed based on interviews with the [relative] and the hospital staff. The dose to the [relative] was then calculated using these stay times and the measured exposure rate for each day. Since the NRC staff was able to use measured dose rates and did not have to perform a complex dose reconstruction analysis, the Commission does not feel that the staff's results were overly conservative."

(2). "While we appreciate your offer to have an independent SNM/ACNP Committee review our calculations, we believe the staff gets sufficient support from its existing medical and scientific consultants, contractors, and the ACMUI [Advisory Committee on Medical Uses of Isotopes] in performing and reviewing its dose reconstructions."

(3). "The staff will also continue to evaluate the state-of-the-art in dose reconstruction in order to keep its determinations as realistic as possible."

The NRC thus maintains that its dose reconstruction in this case is accurate, and states that its methods are not overly conservative and are essentially "state-of-the-art". However, the authors present below an alternative dose reconstruction based on the same dose rate and stay time data.

Alternative Dose Reconstruction: The initial dose rate measurement at 1 meter from the patient was 0.040 cSv/h (rem/h). The reasonableness of this measurement can be ascertained by theoretical calculation, according to:

$$\text{Dose rate at 1 meter (cSv/h)} = \Gamma \times A_0 \times \text{SF}$$

where Γ = specific gamma ray constant for ^{131}I at 1 m (= $5.95\text{E-}6$ cSv-m²/MBq-h); A_0 = 10,545 MBq; and SF = shielding factor due to patient attenuation. For ^{131}I this has been reported to be 0.6 (1).

Thus, dose rate at 1 meter = $(5.95\text{E-}6)(10,545)(0.6) = 0.038$ cSv/h.

According to this theoretical calculation, the 0.040 cSv/h measurement at 1 meter is therefore realistic and reasonable. (Note: This simple calculation illustrates that even if no dose rate measurements had been obtained, no "complex dose reconstruction analysis" would have been needed.)

No such theoretical calculation can be used to directly verify the initial 0.400 cSv/h dose rate measurement at the patient's bedside since no distance was given. The NRC did not attempt to estimate this distance and apparently assumed that the relative's location corresponded to dose rate levels measured at the patient's bedside. "Bedside" is imprecise and not a standard unit of length. We believe that it is imperative to reconstruct the distance before you reconstruct the dose. The initial measured dose rate at 1 m can be used to estimate the distance at which the bedside dose rate measurements were taken. Using the inverse square law, $(40/400)^{1/2}$, the bedside dose rate is estimated to be at a distance of 31.6 cm from the patient. Since this initial dose rate measurement was performed at a time when the activity was mainly confined to the stomach, a point source assumption and use of inverse square is an adequate approximation. Does 31.6 cm realistically represent the distance between the relative and the

patient? If not, the bedside dose rate measurements can not be used to estimate the relative's exposure.

From the NRC's dose reconstruction in the ADAMS document, it is reported that the relative's closest position to the patient was sitting against the bed, with elbows or forearms on the bed. The NRC approach to dose calculation is precisely defined in 10 CFR Part 20. Pursuant to 10 CFR 20.1003, arms distal to the elbow and legs distal to the knee, as well as hands, elbows, feet, and knees, are extremities; doses to extremities are reported as shallow-dose equivalents. For purposes of external exposure, head, trunk, and arms and legs proximal to elbow and knee, respectively, are considered "whole body parts" for which DDEs are calculated. Since TEDE in this case is equivalent to DDE, and pursuant to 10 CFR 20.1201(c) the assigned DDE must be for the part of the body receiving the highest exposure, we first assumed that the patient's proximal arms were at the closest distance to the patient and therefore received the highest exposure. It is reasonable to assume that this patient-to-relative's proximal arm distance could be on the order of 31.6 cm. If the patient's proximal arms remained in this position for the entire stay times, then the bedside dose rates used by NRC to estimate TEDE is a reasonable approach.

It is, however, likely that the relative's body, including proximal arms, was at a further distance for some of the time, due to comfort considerations from prolonged stay times. For example, it is likely that the relative sat back in the chair at least part of the time, instead of being continually hunched forward over the bed. It is not unlikely that this comfort distance could be comparable to 1 meter, while still being "at bedside". It is therefore realistic to assume that the relative's closest distance was at an average "bedside" distance between 31.6 cm and 100 cm, i.e., an average distance of 65.8 cm. That is, the proximal forearm averaged a distance of 65.8 cm from the patient. In this case, the NRC dose estimate is overly conservative by a factor of $(65.8/31.6)^2 = 4.3$.

Up to now, we have used NRC regulatory definitions and criteria for the TEDE calculation. TEDE can also be determined in this case for the relative's trunk as the surrogate for "whole body" TEDE. While this approach is not specifically addressed in NRC regulations, we believe it would be prudent to determine this additional dose estimate, especially in this case since the proximal arms and trunk of the body were at significantly different distances from the patient. Thus, if TEDE values are to be used in

a risk assessment, it may be important to differentiate the estimated dose values for the individual's arms from that of the trunk.

Simulated measurements of the patient-relative geometry performed independently by the authors yielded a center-of-gravity to center-of-gravity (umbilicus-to-umbilicus) distance of 65-70 cm. On average, the umbilicus-to-umbilicus distance was therefore between 65 cm and 100 cm, for an average distance of 82.5 cm. Using this scenario, the NRC dose estimate is overly conservative by a factor of $(82.5/31.6)^2 = 6.8$ using the relative's trunk as the "whole body" part of interest.

Another important factor to consider is attenuation by the exposed individual's body. The NRC has taken into account the shielding by the patient's body by using a measurement instead of using the specific gamma ray constant for an unshielded point source. However, NRC did not take into account the shielding (i.e., attenuation) by the body of the family member, which requires essentially the same shielding factor as that which applies to the patient. TEDE is not equivalent to dose rate multiplied by time; attenuation by the exposed individual must be taken into account. For ^{131}I , the shielding factor is 0.6 for the patient, as previously discussed (1),

and also 0.6 for the family member's body (2). The attenuation factor for the DDE according to NRC regulation, however, is different. According to 10 CFR 20.1003, the DDE, "...which applies to whole body exposure, is the dose equivalent at a tissue depth of 1 cm...". Using the linear attenuation coefficient for ^{131}I in tissue-equivalent material (4), and a depth of 1 cm, the corresponding attenuation factor for the DDE is $e^{-0.11(1)} = 0.9$. Thus, the NRC overestimated the relative's TEDE, based on its own regulatory criteria, by an additional factor of $1/0.9 = 1.1$ based on use of the proximal arm. The TEDE overestimate is $1/0.6 = 1.7$ based on the use of the trunk of the body.

The NRC's dose reconstruction also did not take several other important factors into account. The NRC assumed that the exposure rate at one point in time measured by the RSO was constant for 24 hours, instead of exponentially decreasing. While it is reasonable to ignore decay if the effective half-time is long, in this case it was only 3.1 days based on the time-bedside dose rate data. In addition, there is an obvious mistake in the dose rate on Day 4, which cannot be the same as it was on Day 3 (see Table 1). Finally, at times shortly after dose administration, this patient is not really a point source, but more closely resembles a line source (3). This is

especially important at short distances from the patient, since it decreases the exposure relative to that which is calculated using the inverse square law. These three considerations taken together potentially represent an additional NRC dose overestimate by a factor of 1.5.

Thus, the NRC's dose calculation is conservative by a factor of only $(1)(1.1)(1.5) = 1.6$ using the proximal arms as the body part receiving the highest exposure under the assumption that the proximal arms are always at a distance of 31.6 cm from the patient. If the proximal arms are at an average distance of 65.8 cm, the NRC calculation is conservative by a factor of $(4.3)(1.1)(1.5) = 7.1$. If umbilicus-to-umbilicus calculations are used, the NRC dose calculation is potentially overly conservative by a factor on the order of $(6.8)(1.7)(1.5) = 17$. The relative's TEDE may well be a maximum of only 0.9 cSv if umbilicus-to-umbilicus calculations are used.

Discussion/Conclusion: A specific dose reconstruction performed by The NRC has been reported. An analysis of the NRC's dose reconstruction methods indicates a potential dose estimate that is overly conservative by a factor of approximately 1.6, 7.1, or 17, depending upon calculation methods

and assumptions. NRC regulations require that the TEDE calculated be for the body part receiving the highest exposure. Nothing in the regulations, however, precludes use of other body parts for the TEDE calculation. We believe that the factor of 17 realistically applies to the true whole body dose in this case, while the factors of 1.6 and 7.1 more accurately reflect the proximal arm dose. If a dose estimate is to be used to determine risk, as was done by the NRC in this case, then we recommend use of not only the regulatory-mandated TEDE value but also the most appropriate TEDE value based on the specific circumstances.

We recognize that "state-of-the-art" dose reconstruction should result in a probability distribution rather than a single dose estimate. The uncertainty for each parameter in the calculation should be modeled and Monte Carlo simulation could then be used to get a frequency distribution of the likely dose. This, however, is beyond the scope of this case report.

All licensees should expect that the NRC performs dose calculations using state-of-the-art dosimetry methods that result in realistic and not overly conservative dose estimates. This is especially important since these dose estimates are used for risk assessment. The large discrepancy in

methodology, criteria used, and estimated dose demonstrated in this case raises important issues. We therefore recommend that the Commissioners consider a case-by-case review of staff dose calculations by an outside expert panel to gain valuable perspectives and alternative calculation strategies.

References

1. Siegel JA, Kroll S, Regan D, Kaminski MS, Wahl RL: A practical methodology for patient release after tositumomab and I-131-tositumomab therapy. *J Nucl Med* 2002; 43:354-363.
2. Sparks RB, Siegel JA, Wahl RL: The need for better methods to determine release criteria for patients administered radioactive material. *Health Phys.* 1998; 75:385-388.
3. Siegel JA, Marcus CS, Sparks RB: Calculating the absorbed dose from radioactive patients; the line-source versus point-source model. *J Nucl Med* 2002; 43:1241-1244.

4. Schleien B, Slaback LA, Jr., Birky, BK: Handbook of Health Physics and Radiological Health, 3rd edition, 1998, Table 5.1, Williams and Wilkins, Baltimore, MD.

Acknowledgements

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Torrance, CA 90502.

TABLE 1. Bedside dose rates, stay times, and NRC TEDE calculations.

<u>Day</u>	<u>Dose rate at bedside (cSv/h or rem/h)</u>	<u>Stay time (h)</u>	<u>TEDE (cSv or rem)</u>	
0	0.400	0	0	
1	0.348	6	2.088	
2	0.250	12	3.000	
3	0.210	12	2.520	
4 (through 5 PM)	0.210	8.5	1.785	
4 (5 PM - midnight)	0.210	7	1.470	
5	0.132	20.5	2.706	
6	0.107	11.5	1.231	
			<u>Total</u>	<u>14.800</u>

ATTACHMENT 4

ADVISORY COMMITTEE ON THE MEDICAL
USE OF ISOTOPES

CHARTER FOR THE SUBCOMMITTEE TO REVIEW
THE DOSE RECONSTRUCTIONS

ATTACHMENT D

**ADVISORY COMMITTEE ON THE MEDICAL
USE OF ISOTOPES**

**CHARTER FOR THE SUBCOMMITTEE TO REVIEW
THE DOSE RECONSTRUCTIONS**

Formation of ACMUI Dose Evaluation Subcommittee

On January 29, 2004, Thomas Essig, ACMUI Designated Federal Official, sent an e-mail message to the ACMUI caused the formation of a Dose Evaluation Subcommittee. Details of the Subcommittee's function is as follows.

Purpose: A Dose Evaluation Subcommittee has been formed to enable the full Committee to provide its advice to the NRC staff regarding a dose reconstruction for the daughter of a patient who had received a radiation exposure in excess of the public dose limit while comforting her dying mother who was undergoing radioiodine therapy at the St. Joseph Mercy Hospital in Ann Arbor, Michigan.

Subcommittee membership:

Dr. Leon Malmud, Chair. Will oversee the Subcommittee and ensure that product delivery schedule is met, including vetting of the Subcommittee's product with the full ACMUI.

Dr. Jeffrey Williamson, Member. Will evaluate the technical details of the dose evaluation, with an eye toward assessing the reasonableness of the 15 rem dose estimate.

Dr. Douglas Egli, Member. Will provide insights from his perspective as a nuclear medicine physician.

Ms. Sally Schwarz, Member. Will provide radiopharmaceutical insights, as appropriate.

Ms. Nicki Hobson, Member. Will provide patient advocate insights, as appropriate.

Approach: The attached inspection report prepared by NRC Region III contains an assessment of the dose received by the daughter while comforting her mother during her final days. The Dose Evaluation Subcommittee is requested to prepare independent views of the evaluation of radiation exposure received by the daughter. Input data are contained in the attached file. The Subcommittee is specifically requested to evaluate the approach to the dose reconstruction taken by the NRC Region, as well as the critique of the inspection report prepared by Drs. Carol Marcus and Jeffry Siegel (this critique is not available electronically and will be faxed to you). In preparing its report, the Subcommittee should indicate, for each aspect of the dose reconstruction and the Marcus/Siegel critique, whether it agrees or not with the evaluations and representations presented and why.

ATTACHMENT 5

ADVISORY COMMITTEE ON THE MEDICAL
USE OF ISOTOPES

REPORT



ADVISORY COMMITTEE
ON THE MEDICAL
USES OF ISOTOPES

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

MEMORANDUM TO: Charles L. Miller, PhD, Director
Industrial and Medical Nuclear Safety
Nuclear Materials Safety and Safeguards

FROM: Leon S. Malmud, MD, Chairman *Leon S. Malmud*
Dose Reconstruction Subcommittee
Advisory Committee on the Medical Uses of Isotopes

DATE: May 14, 2004

SUBJECT: TRANSMITTAL OF THE ACMUI DOSE
RECONSTRUCTION SUBCOMMITTEE REPORT TO
NRC STAFF

On January 29, 2004, Nuclear Regulatory Commission (NRC) staff requested, under the direction of the Commission, that the Advisory Committee on the Medical Uses of Isotopes (ACMUI) perform an independent evaluation of the NRC staff's method to reconstruct an overdose of radiation to a member of the public, who received the overdose at St. Joseph Mercy Hospital in Ann Arbor, Michigan. The Commission instructed this action because of assertions by Carol Marcus, MD, and Jeffrey Siegel, PhD, who claimed that the NRC's dose reconstruction method was overly conservative in this case.

In its charter, the ACMUI's Dose Reconstruction Subcommittee (DRS) was asked to prepare independent views of the evaluation of radiation exposure the daughter received. The DRS was specifically requested to evaluate the approach to the dose reconstruction taken by the NRC, as well as the critique of the inspection report prepared by Drs. Carol Marcus and Jeffrey Siegel. In preparing its report, the DRS was requested to indicate, for each aspect of the dose reconstruction and the Marcus/Siegel critique, whether it agrees or not with the evaluations and representations presented, and why.

The ACMUI's DRS has performed its independent review and is now submitting to the NRC staff a report of its findings. See attached.

Attachment: ACMUI DRS Report

Memorandum

TO: Members of the ACMUI

FROM: Jeffrey F. Williamson, Ph.D., acting Chair
ACMUI Dose Reconstruction Subcommittee

DATE: April 29, 2004

SUBJECT: Report to ACMUI

This memo summarizes the Dose Reconstruction Subcommittee's (DRS) recommendations to the ACMUI regarding the St. Joseph Hospital incident. The chronology of this event is fully described in the attached Region III inspection report (Appendix A) and is not repeated here. The charges of DRS, as specified by the Commission and NRC staff were to:

- o Independently review Region III's evaluation of dose to the member of the public in question (the patient's daughter) and assess its reasonableness.
- o "Review the alternate dose reconstruction methodology submitted by the Society of Nuclear Medicine and provide the results of its assessment." The specific document reviewed by DRS was entitled "Nuclear Regulatory Commission Radiation Absorbed Dose Reconstruction For Family Member Of I-131 Patient" and authored by Drs. Carol S. Marcus and Jeffrey A. Siegel.
- o Provide analysis and recommendations, as appropriate, regarding dose-reconstruction methodology.

Review of Region III's dose-calculation methodology.

During the patient's hospitalization, the licensee performed "bedside" measurements and 1 m measurements at approximately daily intervals. Based on documents submitted to Region III by the Licensee and on their own interviews with the individuals involved, Region III concluded that the patient's daughter remained at the patient's bedside for intervals ranging from 6-21 hours per day essentially positioned at the point of licensee bedside measurement. Thus a completely empirical methodology was used.

DRS findings and Recommendations

1. DRS performed independent calculations as described in the attached technical report (Appendix B) and Dr. Williamson's slides presented at the ACMUI meeting of 2 March 2004. The DRS analysis is based upon a computational rather than empirical methodology.

DRS estimates the range of radiation deep dose equivalent (DDE) to the patient's daughter, a "member of the public", to be 4-9 rem in a "best case-worst case" scenario. . Even at the lowest estimate ("best case") of 4 rem, the radiation burden exceeded the 100 mrem allowed.

2. The difference between the DRS upper limit of 9 rem and NRC's 15 rem dose arose from use of a computational methodology, which allowed a more realistic distance to be inferred from the measurements. The discrepancy between the 4 and 9 Rem estimates had to do with the assumptions of the time spent by the daughter near the patient and use of shielding.
3. There was agreement among members of the DRS that the calculations performed by the regional office of the NRC, which produced a radiation burden of 15 rem represented the most conservative scenario that could be plausibly assumed. They were overly conservative, in the sense that they assumed extended, close contact between the patient and the daughter at an unrealistically close distance for extended times, and ignored use of local shielding. More specifically,
 - Use of Monte Carlo simulation to reconstruct the bedside measurement distance, suggested that the bedside measurement distance was an unrealistically short distance for mean patient center-to-daughter surface distance. This methodology was necessary because the Licensee failed to adequately document the daughter's location relative to the point of measurement. Use of this methodology lowered the estimated dose by about 35% for the same exposure times and positions assumed by region III.
 - Use of continuous decay would lower the dose estimate by about 10%.
 - Most importantly, the Licensee post-incident interviews and dose reconstruction led to a different scenario regarding use of body shields and daughter dwell- time distribution than that derived from the Region III interviews. Assuming conservative scenarios consistent with the Licensee's claims that local shielding was used by the daughter during the period 7/2/02 until 7/4/02, DRS estimates an additional reduction of TEDE between 36% and 51%. DRS strongly feels that these differences should have been outlined in the Inspection Report and used to define lower and upper exposure bounds.
 - When the NRC requests that a consultant assess medical risk, the NRC should provide to the consultant an estimate of effective dose equivalent (EDE) as well as TEDE, since EDE is better correlated with any adverse medical effects associated with the exposure.
 - We suggest that a discrepancy, if any, between the licensee and the NRC inspectors, should be described in the final inspection report with data and "high dose-low dose" estimates.
4. The Region III methodology involved multiplying Licensee exposure-rate measurements, presumed to be made at the average position occupied by the exposed subject, and the duration of exposure. This is an appropriate method of dose estimation for many cases. In particular, given the time-distance-shielding scenario assumed by the Region III inspectors, it was an appropriate methodology. However, it relies on the premise that the Licensee has taken adequate steps to measure exposure at the average location occupied by the daughter and to closely monitor the daughter's duration of exposure and utilization of shielding. In

this situation, the Licensee failed to prospectively document the exposure scenario, despite a clear indication that the daughter's 100 mrem limit was clearly exceeded well before the patient's death.

5. Perhaps, prompt contemporaneous notification to the NRC regional office of the unwillingness of the member of the public to comply with the directions of the RSO would have had the desirable effect of assisting in the better documentation of the event.
6. The DRS dose reconstruction effort utilized Monte Carlo simulation, a tool not normally available in the field. Use of such simulations provided a basis for reducing Region III's estimate by 35%. DRS does not recommend that NRC and Licensees use such computing tools for all cases of dose reconstruction. Cases where more sophisticated approaches, including many of the suggestions made by the Marcus-Siegel report, are warranted include the following:
 - o Situations in which adverse medical effects in the exposed individual are possible
 - o The reconstructed dose is near the regulatory limit and a regulatory decision depends upon the reconstructed dose.
 - o The Licensee contests NRC's reconstructed dose.
 - o Inadequate documentation of the location of the irradiated subject relative to the radiation source and/or points of dose measurement
 - o Situations where inverse square law and other widely used approximations are likely to be inaccurate

Thus, in the SJH case, DRS believes NRC should have supported their empirical dose estimates by an independent computational dose assessment because (a) the licensee disputed NRC's dose estimates and (b) documentation of the daughter position relative to the measurement point was lacking. Because of the short distances involved relative to the size of the source (patient), relatively sophisticated computational tools, capable of modeling patient attenuation and large distributed sources, are indicated. While DRS believes that Monte Carlo tools are certainly useful in this case, DRS believes that uncertainties in (a) duration of the daughter's exposure, (b) use of shielding, and (c) average location of daughter exposure relative to the patient are more significant than uncertainties associated with the dose computation methodology itself.

7. A review of the alternative dose reconstruction by Drs. Marcus and Siegel (M&S) is attached (Appendix C). In summary,
 - o DRS agrees with M&S that Region III should have supported their measurement-based dose estimation with an independent computational estimate.
 - o DRS does not agree with the large errors (factors of 1.6 and 6.8 for integrated DDE at the measurement point and reconstruction distance proposed by M&S, respectively). By comparison, the corresponding overestimates identified by DRS are factors of 1.1 and 1.7 respectively. The main reason for the discrepancies is use of insufficiently accurate approximations by M&S to model the effects of distance and patient attenuation in the presence of an extended volume source.
 - o M&S state "All licensees should expect that the NRC performs dose calculations using state-of-the-art dosimetry methods that result in realistic and not overly conservative dose estimates." However, their paper does not define "state-of-the-art." In the

opinion of DRS, the specific computational methods used by M&S fall short of any reasonable interpretation of this standard. In section 6 above, DRS describes a range of circumstances in which more sophisticated dose calculation tools are indicated.

- o M&S by implication associate inaccurate or non-“state-of-the-art” dose calculation methodologies with “overly conservative” dose estimates. DRS agrees that modeling inaccuracies can contribute to dose overestimates as well as underestimates. However, by far the most significant contribution to conservatism are assumptions regarding duration of exposure, distance of exposure and use of local shielding.
8. A concern of the committee is how such a similar situation in the future might be handled in a more optimal manner for both the public and licensee. Therefore, the subcommittee recommends that the ACMUI recommend that the NRC develop guidance or rule changes in collaboration with the ACMUI regarding (1) prompt notification of the regional NRC office of non-compliance by a member of the public and (2) maximum permissible dose levels for caregivers, family members, and friends of radioactive patients who choose to ignore dose limits for members of the public.
 9. Region III, the Licensee, and the published M&S commentary all appear to accept DDE is the appropriate dose-reconstruction endpoint for assessing regulatory compliance. Recently Dr. Marcus has brought to DRS’ attention Regulatory Issues Summary 2003-04 (RIS03-04) and its relevance to the SJH case. RIS03-4 clearly allows, if not encourages, Licensees and NRC inspectors to use EDE Licensees are encouraged to use the effective dose equivalent in place of the DDE in all situations that do not involve direct monitoring of external exposures using personnel dosimetry. DRS believes that the Licensee could have evaluated the daughter’s radiation exposure in terms of EDE and that its use should have been considered by Region III. Because of the radiation field nonuniformity and the unidirectional exposure of the daughter, reporting EDE rather than DDE would have reduced the daughter’s calculated exposure significantly (possibly by as much as a factor of 4).

In general, DRS believes that EDE is a better surrogate for medical risk and therefore a more rationale choice as a regulatory compliance endpoint. While its implementation for uniform isotropically distributed sources is straightforward, there are no accepted industry-wide medical practice guidelines for EDE estimation from point measurements or from first principles for situations such as the SJH case, wherein the radiation field is neither uniform over the subject’s body nor uniformly incident on the subject’s body surface. DRS recommends that at ACMUI’s next face-to-face meeting, it consider the problems of practical estimation of EDE and how to encourage adoption of EDE in dose reconstructions and other radiation safety scenarios involving members of the general public as specified by Regulatory Issues Summary 2003-04.

ACMUI Dose Reconstruction Subcommittee (DRS)
Appendix B: Technical Report
15 April 2004

Interview of Region III Inspectors by DRS members

- DRS interviewed Mr. Cameron and Mr. Wiederman (C&W) from Region III, who performed St. Joseph's Hospital inspection
- Additional information gleaned
 - Licensee found minimal or no contamination in patient room
 - C&W provided times/dates of bedside and "1 m from bedside" measurements performed by licensee. However, exit and entry times of the daughter are not available.
 - C&W reported that a urine collection bag, placed near the patient bed, contained a significant radiation burden. During part of the daughter's exposure, this bag may have been separately shielded. DRS did not include the urine bag as an additional radiation burden, but assumed that it was included in the Licensee's bedside and 1 m dose measurements.
 - C&W stated they interviewed daughter for about 90 minutes: pertinent findings
 - Daughter did indeed "move around": bathed, fed and provided other basic care to patient. However, daughter insists she sat in the position assumed by the Region III calculations.
 - Daughter sat in chair facing the bed and patient's left side. Daughter's knees were placed against lowered bed rail and sat leaning forward with her elbows on edge of mattress.
 - C&W stated that licensee personnel performed bedside measurements at the point where they believed daughter's forearms were positioned
 - C&W had the impression that daughter was so attached to her mother (the patient), that using the "general rationale person model," a person who seeks to minimize discomfort, would not yield a good approximation to the daughter's time-space distribution around the patient.
 - Nursing notes are insufficient to provide definitive factual confirmation of the daughter's dwell times or distance assumptions
 - C&W believed that sometimes the daughter was closer than the stated distance and sometimes further. Also, the daughter was exposed by a urine reservoir, which was not otherwise included in the calculations. Hence they still believe that their assumption is a reasonable average.
- The DRS achieved consensus on the following issues:
 - C&W beliefs notwithstanding, that the daughter could have sat rigidly in a single position for so long still seems implausible.
 - C&W were unable to provide any factual basis for assuming other average distances or non-unity occupancy factor.
 - DRS is not aware of any industry guidance or scientific studies (e.g., time motion studies) which are applicable to this case and could provide the basis for an alternative set of time-distance assumptions.

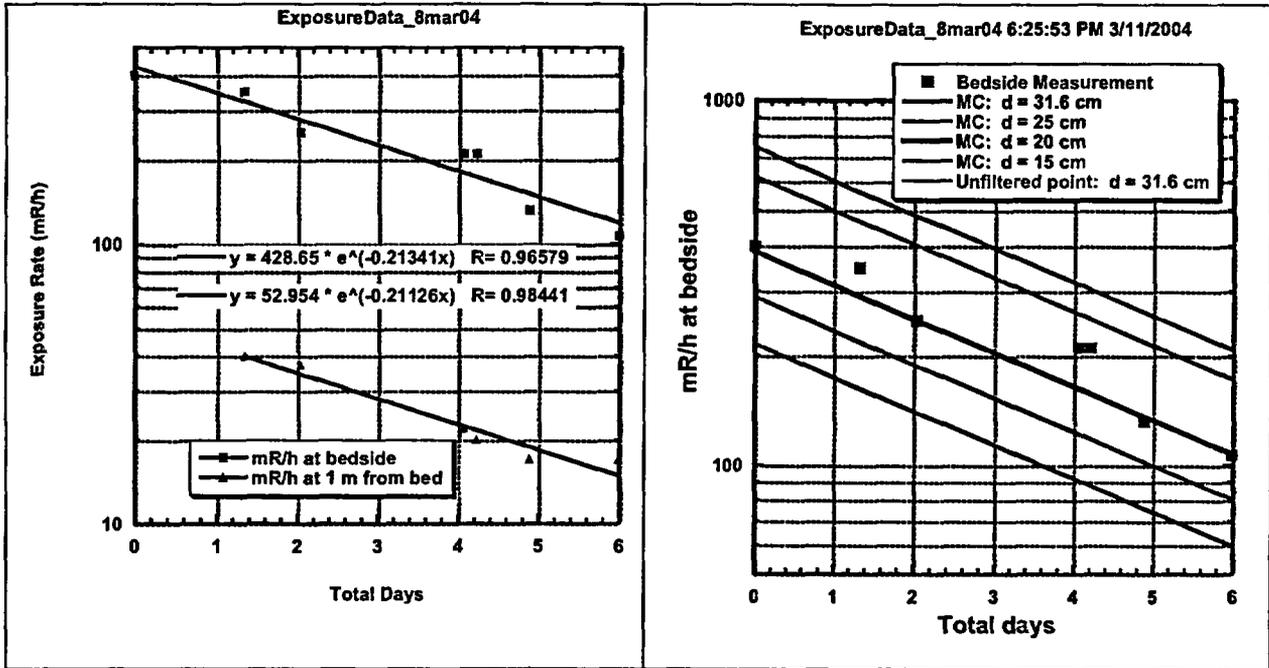
- Data available from this interview do not permit quantitative assessment of dose estimation uncertainty due to dwell time and distance uncertainties.
- Given the data available to inspectors and lacking an objective basis for constructing plausible alternative scenarios factual basis, their assumptions seemed reasonable.

Interview of Ralph Lieto on 3/12/04 and review of SJH written materials

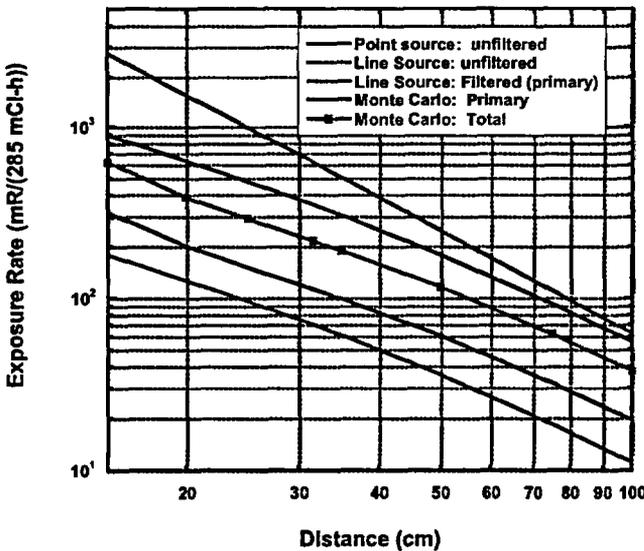
- Interview with Ralph Lieto (by J. Williamson) yields following findings
 - SJH continues to contest NRC dose reconstruction. They believe that NRC has willfully ignored their far more intensive reconstruction efforts. The crux of the dispute is how long the daughter was positioned near the patient without the use of portable shields.
 - Based on recollections of two eye witnesses to J. Cameron interview of daughter, ~~Mr. Lieto~~ the licensee claims
 - Interview was superficial and lasted only 15 minutes
 - JC “led” patient on” by asking questions such as “were you positioned like this?” rather than asking her “tell me what happened in your own words”
 - Contradictions between this brief interview and more extensive multiple witness interviews were ignored by NRC.
- Other findings
 - During 7/2, 7/3 and 7/4 up until 7/5 3 PM, licensee maintains that bedside shields were in place and that daughter followed instructions to stay behind them. Region III claims that shields were not being used or positioned properly. No licensee documentation exists to dispute Region III daughter dwell times.
 - Shields were 1” thick, 36” wide and 46.5” tall providing 24 inches vertically of protection. Shields could be positioned such that shield surface was in contact with mattress edge.
 - Licensee information based on detailed staff interviews conducted two weeks after incident and daughter telephone interview conducted in Sept 2002.
 - To what extent shields were used after 7/5 is contradictory: Licensee interview summary is contradictory and daughter claims in 9/02 interview that they were not used after 7/5 but were used before.

Technical Issues

Effective half life and Reconstructed distance of bedside readings



The more complete data consistently reveal $\lambda = 0.212 \text{ da}^{-1}$, equivalent to a half-life of 3.26 days. Based on Monte Carlo simulations, the patient-to-detector center distance best accounting for the measurements is about 20 cm. This suggests readings were taken with detector a few cm from lateral surface of the patient. Monte Carlo simulation is warranted in this particular case because the patient was known to have impaired renal function and because the fraction of thyroid uptake is typically small in metastatic thyroid cancer patients. This assumptions warrants treating the patient as a cylindrical volume source in which radioactivity is uniformly distributed.



Since a typical hospital bed is about 37 inches wide, the mattress edge-to-patient center is about 47 cm. Assuming that the daughter placed her forearms on the lateral aspect of the mattress edge, a distance of 37 cm would seem to be the shortest distance between the daughter's forearms and the patient center that could be maintained for a long period of time. Hence, DRS suggests that 37 cm is a more appropriate distance to apply to the Region III scenario rather than the estimated 20 cm measurement distance. Based on the ratio of MC air-kerma rates at 35 cm and 20 cm, it is reasonable to scale the bedside readings downward by a 0.65 factor.

Continuous vs. Stepwise decay.

Region III simply multiplied the patient dwell time by the measured beside reading without correcting for decay either during the interval between the measurement time and beginning of the daughter's exposure, or during the interval of exposure. Let t = time between measurement and start of daughter's exposure of duration t . Then

$t = 0$ and $T = 21$ hr implies Region III/True exposure = 1.09 (exposure measurement at beginning of daughter's visit)

$t = 0$ and $T = 6$ hr implies Region III/True exposure = 1.03

$t = -10.5$ h and $T = 21$ hr implies Region III/True exposure = 1.045 (exposure measurement during midpoint of daughter's visit)

$t = 18$ h and $T = 6$ hr implies Region III/True exposure = 1.204

$t = 6$ h and $T = 18$ hr implies Region III/True exposure = 1.14

This leads to an overestimate for individual exposure segments of 3-20% assuming that measurements were always performed prior to the midpoint of the daughter's visit. The NRC staff could have included this correction, since measurement times were available and since estimates of daughter initiation and ending times of exposure were available. DRS believes the effect could be as large as 10% effect, an estimate which NRC staff could attempt to confirm by performing a more detailed reconstruction based upon availability of measurement times and estimates of the daughter's visiting hours. However, for general practice, such efforts are probably not warranted since the 10% improved achieved is small in relation to the total uncertainty of the reconstructed dose.

Daughter Tissue attenuation

Marcus et al. suggests that an attenuation correction (attenuation of I-131 gamma rays through 1 cm tissue) should have been applied. DRS believes that this correction is negligible or even > 1 , due to compensation of primary photon attenuation by backscatter from the daughter.

DRS estimated dose assuming Region III scenario

Based on this review, DRS estimates TEDE to be

$$\text{TEDE} = 15 \text{ Rem} \times 0.65 \times 0.90 = 8.8 \text{ Rem}$$

This estimate assumes the same distance-dwell time distribution as Region III

Reconciliation of SJH and Region III dose-reconstruction efforts

Based on review of material submitted by the Licensee, it is clear to DRS that the Licensee made significant efforts through retrospective interviews and records review to reconstruct the daughter dwell times and used of shielding. This reconstruction is both more detailed and closer in time to the incident than NRC's Region III effort. In addition, SJH continues to challenge NRC's calculations on technical grounds. DRS believes that NRC can be criticized for not making a more thoughtful and balanced effort to reconcile the two reconstruction scenarios.

Based on our admittedly relatively superficial view, DRS proposes the following alternative reconstruction scenario:

- During the period 7/2-7/4, we can assume the shields were in place and the daughter was standing behind them.
- Approximating I-131 by Ir-192, NCRP 49 indicates the transmission through 1" Pb shields to be about 0.02
- In a best case scenario, DRS assumes the daughter's body core was fully behind the shield
- In a worst-case scenario, DRS assumes that the daughter leaned over the shields with elbows, head and neck exposed to unshielded radiation field. DRS assumes a 50% occupancy ratio in this position, although no data are available to justify this or any other assumption.
- In both the worst and best case scenarios, DRS assumes that the daughter's minimum distance is limited by the shield, the distal surface of which can be no closer than 55 cm to the patient's center.
- The unshielded 55 cm exposure is given by MC to be about 41% of the 20 cm (beside measurement point) rate.

DRS notes that its postulated distance and dwell time scenarios are extremely conservative. Basically, the daughter was assumed to have positioned herself as close to the patient as geometrically possible and remained there 100% of the exposure time. On the other hand, neither Region III nor the Licensee are able to provide factual data justifying other scenarios. Region III inspectors believe that the daughter performed routine care duties, such as bathing the patient, and may have been even closer to the patient than the bedside measurement distance.

$$\text{Best case} = 0.9 \times (0.02 \times 0.41 \times (2.088 + 3.0 + 2.52)) + 0.65 \times (3.25 + 2.71 + 1.23) = 4.3 \text{ Rem}$$

$$\text{Worst case} = 0.9 \times (0.51 \times 0.41 \times (2.088 + 3.0 + 2.52)) + 0.65 \times (3.25 + 2.71 + 1.23) = 5.6 \text{ Rem}$$

Summary

- DRS believes that the 15 Rem estimate represents the most conservative estimate one could make that is not totally implausible. More sophisticated distance reconstruction techniques and common-sense evaluation of geometry (bed widths, etc) suggests that reducing this estimate by 40% is reasonable, assuming the Region's dose-time-distance scenario.
- DRS believes that the NRC should have considered the licensee's more detailed and contemporaneous dose reconstruction efforts. Where a dispute arises over dwell times, shield usage, etc. between NRC inspector reports and licensee interviews, both versions should be described in the inspection report and a range calculated based on bracketing scenarios. Of course, DRS assumes that both licensee and NRC inspectors are acting in good faith and that no one is intentionally trying to distort the truth.
- While details of space-time occupancy are very difficult to reconstruct retrospectively, both NRC inspectors and licensees are obligated to apply common sense in selecting distances, accounting for geometric constraints imposed by bed sizes and shield positions.

- In this particular case, DRS is comfortable citing a 4-9 Rem figure based on testimony from various parties. In routine cases where MC is not available, use of analytic line source or extended volume source formulas should be used since inverse square law will underestimate exposures near extended sources.
- In contrast to the Marcus-Siegel report, which challenges the Region III calculation mostly on methodological grounds, DRS finds that the greatest source of uncertainty is associated with assumed daughter dwell times and use of body shields. The assumed distance is also highly uncertain. However, neither Region III nor the licensee are able to provide factual data upon which an uncertainty analysis could be based.
- As suggested by the Marcus-Siegel paper, DRS used a computational approach (Monte Carlo simulation) to estimate a patient center-to-bedside detector distance. This reconstructed distance provides a rational basis for reducing NRC's dose estimate by 35%. However, DRS believes that inverse-square law, as proposed by Marcus and Siegel, applied to a single measurement is not appropriate in this case.
- The DRS reconstruction effort used Monte Carlo tools and more elaborate computational models than are normally applied in the field. These efforts were undertaken at the request of the Commission because this individual case has prompted a National debate. In routine cases, DRS believes that such efforts may not be warranted. It believes that effort should be directed more towards the "basics" of time, distance, and shielding utilization. The uncertainties associated with these assumptions overwhelm the issues of computational methodology.

Appendix C:
**ACMUI Dose-Reconstruction Subcommittee (DRS) Comments on "Nuclear
 Regulatory Commission Radiation Absorbed Dose Reconstruction For Family
 Member Of I-131 Patient" by Drs. Carol S. Marcus and Jeffrey A. Siegel**

Marcus-Siegel Comment	DRS response
<p>"We believe that it is imperative to reconstruct the distance before you reconstruct the dose."</p>	<p>DRS agrees that a computational dose reconstruction is a useful tool complementing the empirical dose estimation technique used by Region III and the Licensee. DRS believes theoretical dose estimation in this case is warranted for two reasons (a) the Licensee contests NRC's analysis (although not on grounds of methodology) and (b) No observations are available to determine where the daughter was positioned in relation to the bedside measurement.</p> <p>However, DRS does not believe that inverse square law and using only one data point, as proposed by M&S, to be either state-of-the-art or adequate for this case.</p>
<p>The bedside distance (31.6 cm per M&S estimates) is implausibly short. A distance of 66 cm is suggested, which M&S claim reduces NRC's dose estimate by factor of 4.3.</p>	<p>While DRS believes that the bedside distance is implausibly short, it disagrees with the M&S critique in several important respects</p> <ul style="list-style-type: none"> o There is no factual basis or industry standard to justify doubling the distance. DRS believes that using the measurement without modification is preferable to an arbitrary unjustified choice. In contrast, DRS increased the distance from 20 to 35 cm based upon geometric plausibility arguments. o Simple point source or even line source approximations are invalid so close to the patient. Near a large volume source, dose fall-off is much less rapid than inverse square law. Hence, DRS estimates only a 35% reduction in dose, not 77% as proposed by M&S.
<p>Evaluating whole body dose as well as DDE would have been prudent. M&S believe this would have reduced NRC's dose estimate by a 6.8-fold factor.</p>	<p>DRS agrees that whole body dose is a better surrogate for medical risk and agrees it should be supplied to medical consultants.</p> <p>Based on highly limited Monte Carlo calculations, DRS believes that mean and maximum physical dose differ by about a factor of 4 assuming a cylindrical source and subject geometries and a center-to-center distance of 50 cm. However, this simplified simulation falls short of the definition of EDE.</p>
<p>Failing to account for tissue attenuation over the 1 cm tissue depth overestimates DDE by 10%.</p>	<p>M&S derive this factor by considering only primary photon attenuation. DRS believes that backscattered radiation from the daughter would likely compensate for decrease in the primary photon DDE, although detailed Monte Carlo</p>

	simulations were not performed. In any case, this correction is small in relation to other uncertainties.
(a) Failing to use line source approximation; (b) – stepwise daily rather than continuous decay and (c) equality of two successive measurements together imply that NRC overestimated total bedside DDE by 1.5 assuming patient elbows were actually positioned at the point of measurement.	(a) Since no inverse square law corrections are made by NRC, it is unclear why the adequacy of inverse square law is relevant here. (b) DRS believes continuous decay might reduce the dose by as much as 10%. (c) More detailed information available to DRS indicates that the measurements were performed 4 hours apart, so that their equality is well within experimental error. Overall, DRS believes the dose estimation factor is only 1.1 not 1.5 in this context.
NRC estimate of integrated bedside DDE measurement is in error by 1.1×1.5 factor = 1.6	DRS rejects the attenuation correction, and the 1.5 correction above. DRS believes NRC's error in this calculation is about 10% due to ignoring continuous decay.
Based on distance implausibility, NRC estimate of DDE is in error by $4.3 \times 1.1 \times 1.5 = 6.8$	For reasons explained above, DRS estimates that Region III overestimated DDE by a factor of $1.5 \times 1.0 \times 1.1 = 1.7$ Basic reasons: DRS believes M&S theoretical calculations are too approximate and that their choice of mean daughter-patient distance too arbitrary.
Using mean body dose, NRC estimate is too high by following factors $(6.8) \times (1.7) \times (1.5) = 17$	DRS does not believe that the approximations and rules of thumb used by M&S are accurate enough to support quantitative estimates of mean whole body dose. DRS recommends Monte Carlo simulation or other more sophisticated radiation transport tools for estimating this quantity.

ATTACHMENT 6

**PROPOSED LETTER FROM THE CHAIRMAN TO THE
SOCIETY OF NUCLEAR MEDICINE**

June XX, 2004

Henry D. Royal, M.D.
President
Society of Nuclear Medicine
1850 Samuel Morse Drive
Reston, Virginia 20190-5316

Dear Dr. Royal:

In my letter to you dated January 12, 2004, concerning the St. Joseph Mercy Hospital dose reconstruction, I had indicated that the Nuclear Regulatory Commission (NRC) staff will review the reconstruction prepared by Drs. Carol Marcus and Jeffrey Siegel. I had also indicated that the Advisory Committee on the Medical Use of Isotopes (ACMUI) will also be asked to review that reconstruction, as well as NRC's dose assessments, and to perform its own calculations as necessary. These reviews have been completed, and this letter is to inform you of our conclusions.

Based on careful review and input from the ACMUI, as well as our staff's extensive calculations, NRC has concluded that the original dose estimate of 15 cSv (15 rem) obtained by NRC's Region III staff is the estimate that appears best supported by available data and, based on that data, does not appear to be overly conservative and is probably closest to the true dose. We have come to this conclusion because our reviews showed that Region III used an appropriate method to calculate the dose, obtained the necessary data by direct and detailed interviews with the exposed member of the public and the hospital staff on duty at the time of the exposures, and confirmed that the information provided separately by the exposed person and by the hospital staff was consistent.

It has not proven possible to resolve the differences between NRC's and the licensee's dose estimates. Both estimates used identical methods of dose assessment, based on the daily dose rate surveys made by the licensee at the patient's bedside. The difference between the two is due to differences in estimated exposure durations for the family member. This difference, in turn, arose from differences in the recollection of the details of the event by the family member during separate interviews with the NRC and the licensee. The details differed in some respects in the different interviews, and were not entirely consistent. This is not surprising considering the difficult circumstances for the family member during which the exposures occurred, and also the fact that the interviews took place as much as 3 months after the incident.

The dose reconstructions performed by Drs. Marcus and Siegel relied on a calculated dose rate to the family member considering the 285 curie source term, instead of using the survey data more directly. NRC has concluded based on its own detailed calculations that this approach carries a larger uncertainty than that based on the radiation surveys. The reason is that there is

little numerical data available in this case on which to base an accurate dose rate calculation, and assumptions therefore were necessary to substitute for the missing data. These assumptions were based on what was considered reasonable behavior on the part of the family member, as opposed to information collected from the people involved. Available evidence strongly indicates that the assumptions made do not represent the pattern of exposure that actually occurred. Furthermore, our own calculations show that the radiation fields around the patient were such that relatively small changes in such assumptions could have a large impact on the assessed dose rate.

The present case suggests that licensees need to be reminded that they have the prime responsibility for promptly recognizing that an event occurred, understanding the types of information that will likely be needed to perform accurate dose reconstructions, and promptly gathering this information. In the present case, the event was recognized some time after it happened, and interviews were delayed in some cases for several months. Not surprisingly, details could not be accurately remembered, and inconsistencies and disagreements were the result. We are also considering actions to ensure that more detail than is normally deemed necessary be included in future NRC reports on similar cases.

I would like to thank you for providing us with this opportunity to improve our procedures and documentation in situations such as this one. Details of the analysis performed by the staff of the various reconstructions may be found in the staff's report to the Commission, available on NRC's Agency-wide Documents Access and Management System(ADAMS), accession number ML041450268.

Nils J. Diaz

cc: Simin Dadparvar, M.D.
President
American College of Nuclear Physicians

Status of Medical Events

ACMUI Meeting
October 13, 2004

Linda M. Gersey
NMSS/IMNS
Regional Event Coordinator

Overview

- Communicating Medical Events to ACMUI
- Receiving ACMUI Recommendations
- Summary of Recent Events
- NRC Identified Event Issues –2 Questions

Communication of Medical Events

- Summary of past events
 - ◆ Provided at each ACMUI meeting
 - ◆ Events from past year
 - ◆ Organized by Event Type

ACMUI Input

- NRC asks ACMUI to review specific events to address a specific concern
- ACMUI may also identify issues NRC should address

Receiving Recommendations

- ACMUI: consolidated recommendations within 2 months
- ACMUI may recommend other focus areas
- NRC actions discussed at next ACMUI meeting

Past Event Summary

- 10/1/03 thru 9/22/04
- 33 medical events
- 35,300 Radiopharmaceutical
(10 total)
 - ◆ 1 Sm-153
 - ◆ 1 Sr-89
 - ◆ 8 I-131

Past Event Summary Cont.

- **35.400 Manual Brachytherapy**
 - (11 total)
 - ◆ 1 eye applicator
 - ◆ 1 I-125 leaking seed
 - ◆ 5 prostate implants
 - ◆ 1 Ir-192 ribbon
 - ◆ 2 OBGYN
 - ◆ 1 Mammosite

Past Event Summary Cont.

- **35.600 HDR**
 - ◆ 6 total
- **35.1000**
 - (6 total)
 - ◆ 1 Giasite
 - ◆ 1 Y-90 Microspheres
 - ◆ 4 IVB

NRC Concern 1

- **Eight I-131 medical events**
- **What could NRC communicate to licensees to aid them in preventing these types of events?**

NRC Concern 2

- Several medical devices not reviewed by NRC for safety issues (SS&D)
- Examples
 - ◆ MICK applicator
 - ◆ Brachytherapy seeds imbedded in suture material

NRC Concern 2 Cont.

- Should NRC change policy and require SS&D review for these types of medical devices?

ACMUI Recommendations

- Please provide consolidated response to 2 questions by December 17, 2004
- May include other ACMUI recommendations
- NRC to describe any actions at next ACMUI meeting

Any Questions?

Status of Medical Events

October 2004 ACMUI Meeting

Donna-Beth Howe, Ph.D.

Status of Medical Events

35 Medical Events reported - FY 2004 date

35.300		11
35.200 I-131	5	
35.400		9
35.600 (HDR)		8
35.1000		7
GliaSite	1	
Y-90 Microspheres	1	
IVB	5	

Novoste IVB Events

Licensee lost entire Beta Cath Device

- o device storage containers were found empty 26 days after last use
- o discovered device was missing 19 days after functional test

AGENDA TOPIC: STATUS OF MEDICAL EVENTS

**10 CFR 35.300 -RADIOPHARMACEUTICAL
SM-153**

NMED Item Number: 030921

Narrative:

Last Updated: 05/25/2004

The licensee reported that a patient was administered 0.35 GBq (9.39 mCi) of Sm-153 Quadramet instead of the prescribed dose of 3.44 GBq (93 mCi) for the treatment of bone pain. The licensee's dose calibrator indicated that the dose received from the Cardinal Health Pharmacy in Jenison, Michigan, contained 0.35 GBq (9.39 mCi). The label on the syringe indicated that it contained 3.47 GBq (93.9 mCi) of Sm-153. The licensee notified the pharmacy about the discrepancy and was told to use a multiplier of 10. The dose was then administered to the patient. About one hour later, the pharmacy called the licensee and stated that the dose that the patient received was in fact 0.35 GBq (9.39 mCi). The pharmacy mistakenly assumed that Sm-153 was a pure beta-emitter and could not be assayed correctly by the licensee's dose calibrator. The physician, RSO, and patient were notified of the event and the patient received the remainder of the prescribed dose on 11/12/2003. The lack of a specific protocol for assaying Sm-153 contributed to this event. The licensee added a procedure for assaying Sm-153 doses, which was reviewed by all technologists. An inspection of Cardinal Health Pharmacy revealed that several errors had been made during the processing and dispensing of this order. Their corrective actions included retraining of personnel and procedure modification.

Event Date:	Discovery Date:	Report Date:
11/10/2003	11/10/2003	11/11/2003

Licensee/Reporting Party Information:

License Number:	21-04177-01	Name:	LAKELAND MEDICAL CENTER SAINT JOSEPH
Docket Number:	03002049	City:	SAINT JOSEPH, MI

Reference Documents:

Reference Document Number:	Entry Date:	Retraction Date:	Type of Report:
EN40313	11/12/2003		EVENT NOTIFICATION
ML033170253	11/17/2003		PRELIMINARY NOTIFICATION
PN303043	11/17/2003		PRELIMINARY NOTIFICATION
LTR031231	01/06/2004		NRC LETTER
ML033580684	01/12/2004		INSPECTION REPORT
ML033510734	01/12/2004		LICENSEE REPORT
ML033580684	01/12/2004		NOTICE OF VIOLATION
ML033580684	01/12/2004		NRC LETTER
ML040890165	04/13/2004		INSPECTION REPORT
ML040890165	04/13/2004		NOTICE OF VIOLATION
ML040890165	04/13/2004		NRC LETTER
ML041310372	05/25/2004		LICENSEE REPORT

Sr-89**NMED Item Number: 040053****Narrative:****Last Updated: 04/21/2004**

During an NRC inspection, the inspector determined that a patient was administered 147.26 MBq (3.98 mCi) of Sr-89 chloride although the written directive specified 148 MBq (4 mCi) of Sr-90. The dose to the patient's bone surface was calculated to be 251 cGy (rad). The physician erroneously wrote Sr-90 on the written directive when Sr-89 was intended; therefore, the patient received the intended dose and no adverse impact to the patient is anticipated. The root cause of this event was the failure to follow written procedures. Corrective actions included revising the written directive form and retraining personnel.

Event Date:	Discovery Date:	Report Date:
12/29/2003	01/21/2004	01/22/2004

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:	ANN ARBOR	State:	MI
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Reference Documents:

Reference Document Number:	Entry Date:	Retraction Date:	Type of Report:
EN40465	01/26/2004		EVENT NOTIFICATION
ML040480294	03/09/2004		INSPECTION REPORT
ML040480294	03/09/2004		NRC LETTER
ML040630134	03/16/2004		LICENSEE REPORT
ML041000021	04/21/2004		INSPECTION REPORT
ML041000021	04/21/2004		NRC LETTER

I-131**NMED Item Number: 030987****Narrative:****Last Updated: 04/15/2004**

The licensee reported that a patient was administered a thyroid uptake dose of 36.26 MBq (0.98 mCi) instead of the prescribed dose of 0.56 MBq (15 uCi). The event occurred due to the prescription order being made incorrectly with no subsequent verification by the technologist. The patient and the patient's physician were notified of the event. An investigation determined that the licensee's policies and procedures were in place and deemed adequate. Corrective actions taken by the licensee included initial and annual training updates on the proper implementation of the existing procedures.

Event Date:	Discovery Date:	Report Date:
11/24/2003	11/24/2003	12/11/2003

Licensee/Reporting Party Information:

License Number:	KY-202-016-26	Name:	LEXINGTON CLINIC
Docket Number:	NA	City:	LEXINGTON, KY

Reference Documents:

Reference Document Number:	Entry Date:	Retraction Date:	Type of Report:
EN40387	12/16/2003		EVENT NOTIFICATION REPORTED FROM AN AGREEMENT STATE
ML033510313	12/18/2003		PRELIMINARY NOTIFICATION REPORTED FROM AN AGREEMENT STATE
PN103034	12/18/2003		PRELIMINARY NOTIFICATION REPORTED FROM AN AGREEMENT STATE
LTR040414	04/15/2004		AGREEMENT STATE LETTER

NMED Item Number: 040073

Narrative:

Last Updated: 04/21/2004

The licensee reported that a patient was administered 19.8 MBq (535 uCi) of I-131 instead of the prescribed 0.19 MBq (5 uCi). The verbal order from the authorized user for a 0.19 MBq (5 uCi) dose was misunderstood and an 18.5 MBq (500 uCi) dose was ordered. After the event was discovered, the patient was given a thyroid blocking solution. Based on the patient's resultant thyroid uptake, the licensee computed a dose to the thyroid of approximately 86 cSv (rem). The root causes of this event include inadequate procedures (the licensee's procedures did not include the use of I-131 for this procedure because I-123 is normally used), the failure of the nuclear medicine technologist to follow procedures for studies requiring a written directive, and the failure to communicate the dose order clearly. Corrective actions include procedure modification and a review of the education and competency training for nuclear medicine technologists.

Event Date:	Discovery Date:	Report Date:
01/29/2004	01/29/2004	01/30/2004

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:	BOSTON	State:	MA
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Reference Documents:

Reference Document Number:	Entry Date:	Retraction Date:	Type of Report:
EN40490	02/02/2004		EVENT NOTIFICATION
ML040620754	03/16/2004		LICENSEE REPORT
ML041000021	04/21/2004		INSPECTION REPORT
ML041000021	04/21/2004		NRC LETTER

NMED Item Number: 040352

Narrative:

Last Updated: 08/19/2004

The licensee reported that the wrong patient was administered 74 MBq (2 mCi) of I-131 for a thyroid cancer workup instead of the prescribed dose of 7.4 MBq (200 uCi) of I-123 for a thyroid uptake scan. The patient scheduled to receive the I-123 dose responded affirmatively to being the patient that was to receive the I-131 dose. The technologist did not follow procedures regarding proper identification of the patient, which requires two separate methods for verifying patient identification. Corrective actions taken by the licensee included disciplining the technologist in accordance with hospital policy. The need to thoroughly check patient identification using two approved methods was reiterated to all technologists. The Radiation Safety Committee modified the QMP at a 5/19/2004 meeting to delete personnel knowledge of the patient's identification as a mechanism of patient identification and replacing the method with verification using photo-ID. An investigation by the Ohio Department of Health occurred on 5/11-12/2004. The corrective actions suggested by the licensee were adequate.

Event Date:	Discovery Date:	Report Date:
05/10/2004	05/10/2004	05/13/2004

Licensee/Reporting Party Information:

License Number:	OH-02110310010	Name:	UNIVERSITY HOSPITAL
Docket Number:	NA	City:	CINCINNATI, OH

Reference Documents:

Reference Document Number:	Entry Date:	Retraction Date:	Type of Report:
EN40742	05/18/2004		EVENT NOTIFICATION REPORTED FROM AN AGREEMENT STATE
LTR040819	08/19/2004		AGREEMENT STATE LETTER

NMED Item Number: 040415

Narrative:

Last Updated: 08/10/2004

The licensee reported that a patient received 33.86 MBq (915 uCi) of I-131 sodium iodide for a thyroid uptake study instead of the prescribed oral dose of between 0.19 and 0.74 MBq (5 and 20 uCi). The root cause of the event was the lack of an adequate double check of the I-131 uptake dose prior to administration. A pipette contaminated with 74 MBq (2 mCi) of I-131 was inadvertently used to prepare the uptake dose. The radiopharmacy computer was programmed to detect volume errors but not activity errors, so it accepted the dose and printed the label. The radiopharmacy technologist did not detect the error when she assayed the dose, because she assumed that the activity displayed as "0.915 mCi" was "9.15 uCi". The nuclear medicine technologist that double-checked the dose mistook the "0.9 mCi" for "9 uCi" on the dose label and administered the dose. She had been working in an imaging room, but was needed to cover the thyroid uptake room near the end of the work shift (which may have contributed to the event). The absorbed dose to the patient's thyroid was 1219 cGy (rad) and the effective dose equivalent was 37 cGy (rad). The patient returned to the licensee's facility on 6/9/2004 for treatment of hyperthyroidism. Corrective actions included using a new pipette for drawing each I-131 uptake dose, reprogramming the computer to accept uptake dose activity rather than volume, not allowing the computer to print a label for the dose unless the activity is within the predefined range, training the radiopharmacy staff not to over-ride the failsafe mechanisms of the computer, and retraining the nuclear medicine technologist in the dose verification process prior to dose administration.

Event Date:	Discovery Date:	Report Date:
06/08/2004	06/08/2004	06/08/2004

Licensee/Reporting Party Information:

License Number:	21-01333-01	Name:	WILLIAM BEAUMONT HOSPITAL
Docket Number:	03002006	City:	ROYAL OAK, MI

Reference Documents:

Reference Document Number:	Entry Date:	Retraction Date:	Type of Report:
EN40797	06/09/2004		EVENT NOTIFICATION
ML041820368	07/16/2004		LICENSEE REPORT
ML042040298	08/10/2004		INSPECTION REPORT
ML042040298	08/10/2004		NRC LETTER

NMED Item Number: 040441

Narrative:

Last Updated: 08/23/2004

The licensee reported that a 19-year-old female patient, who was diagnosed with Grave's Disease of the thyroid, was administered 462.5 MBq (12.5 mCi) of I-131 instead of the prescribed dose of 0.444 MBq (12 uCi) of I-131. The intent of the procedure was to ablate the patient's thyroid. The physician wrote "12 uCi" on the prescription, but the technologist ordered "12 mCi" instead. The technologist received 462.5 MBq (12.5 mCi) of I-131 and administered it on 4/7/2004. This event was discovered on 6/7/2004 during the licensee's quarterly quality maintenance review. The licensee's review determined that the physician intended to prescribe "12 mCi", but wrote "12 uCi" by mistake. To prevent recurrence, the licensee modified their pre-printed prescription form such that physicians will be required to circle either "microCurie" or "milliCurie" when entering an isotope and activity. The licensee also re-emphasized with the technologist the importance of carefully checking the written directive and consulting with the authorized user of there are any discrepancies.

Event Date:	Discovery Date:	Report Date:
04/07/2004	06/07/2004	06/16/2004

Licensee/Reporting Party Information:

License Number:	44-14121-01	Name:	RUTLAND REGIONAL MEDICAL CENTER
Docket Number:	03007587	City:	RUTLAND, VT

Reference Documents:

Reference Document Number:	Entry Date:	Retraction Date:	Type of Report:
EN40825	06/18/2004		EVENT NOTIFICATION
LTR040621	06/21/2004		NRC LETTER
ML042180008	08/23/2004		INSPECTION REPORT
ML042320244	08/23/2004		LICENSEE REPORT
ML042180008	08/23/2004		NOTICE OF VIOLATION
ML042180008	08/23/2004		NRC LETTER
ML042320244	08/23/2004		REGION REPORT

NMED Item Number: 040491

Narrative:

Last Updated: 07/06/2004

The licensee reported that a patient was administered 103.6 MBq (2.8 mCi) of I-131 instead of the prescribed 74 MBq (2.0 mCi). The Woman's Hospital had ordered a 74 MBq (2 mCi) capsule of I-131. When the dose was sent it was 103.6 MBq (2.8 mCi). A verbal order was given to administer the dose to the patient. Woman's Hospital notified the licensee of the irregularity on 3/1/2004 when they received the dose. The RSO notified the licensee's corporate office by fax of the irregularity, but that person was not there and the event went unnoticed until 3/31/2004. The licensee changed their procedures so that two people are notified of events and the new pharmacist that made the dose received additional training on policies and procedures. Louisiana State event report number LA040006.

Event Date:	Discovery Date:	Report Date:
02/27/2004	03/01/2004	03/31/2004

Licensee/Reporting Party Information:

License Number:	LA-7096-L01	Name:	CARDINAL HEALTH
Docket Number:	NA	City:	HOUMA, LA

Reference Documents:

Reference Document Number:	Entry Date:	Retraction Date:	Type of Report:
EN40848	07/06/2004		EVENT NOTIFICATION REPORTED FROM AN AGREEMENT STATE

NMED Item Number: 040610

Narrative:

Last Updated: 08/27/2004

The licensee reported that a patient received 111 MBq (3 mCi) of I-131 instead of the prescribed dose of 0.93 MBq (25 uCi). The event was discovered on 8/12/2004. The imaging technologist misunderstood the referring physician's request and the authorized user did not approve the dose. Corrective measures included re-instructing personnel and ensuring that the authorized user approves all procedures.

Event Date:	Discovery Date:	Report Date:
08/10/2004	08/12/2004	08/17/2004

Licensee/Reporting Party Information:

License Number:	AL-0315	Name:	NORTHEAST ALABAMA REGIONAL MEDICAL CENTER
Docket Number:	NA	City:	MONTGOMERY, AL

Reference Documents:

Reference Document Number:	Entry Date:	Retraction Date:	Type of Report:
EN40979	08/27/2004		EVENT NOTIFICATION REPORTED FROM AN AGREEMENT STATE

NMED Item Number: 040611

Narrative:

Last Updated: 08/30/2004

The licensee reported that a patient received 3.7 GBq (100 mCi) of I-131 instead of a prescribed dose of 0.64 GBq (17.3 mCi). Three patients were scheduled for I-131 treatments on the same day. Two outpatients were scheduled to receive less than 0.11 GBq (33 mCi) and one inpatient was scheduled to receive 3.7 GBq (100 mCi). The wrong patient was injected with the inpatient dose and was also allowed to leave the facility without receiving proper instructions. The licensee did not discover the incident until after the patient had left the facility with her children. The authorized user who signed the written directive was at the facility when the dose was administered. The temporary RSO was at South Fulton Hospital, but was notified of the event. The licensee contacted the patient to notify her of the event, checked her into a room, and gave her proper instructions for release. The Georgia Department of Natural Resources (GDNR) received a written copy of the event, along with measures taken by the licensee to prevent recurrence. The GDNR also received a report from the licensee's medical physicist consultant (Alliance Medical Physics LLC) stating that the patient's two children would not have received overexposures or affects from radiation. The consultant estimated the most likely dose to the patient's children to be 0.5 mSv (50.2 mrem), with a maximum possible dose of 1.005 mSv (100.5 mrem).

Event Date:	Discovery Date:	Report Date:
07/01/2004	07/01/2004	07/01/2004

Licensee/Reporting Party Information:

License Number:	GA-1039-1	Name:	SOUTHERN REGIONAL MEDICAL CENTER
Docket Number:	NA	City:	RIVERDALE, GA

Reference Documents:

Reference Document Number:	Entry Date:	Retraction Date:	Type of Report:
GA-04-022I	08/27/2004		AGREEMENT STATE EVENT REPORT
LTR040720	08/30/2004		CONSULTANT REPORT
LTR040701	08/30/2004		LICENSEE REPORT
LTR040830	08/30/2004		NRC LETTER

35.400 - MANUAL BRACHYTHERAPY

Eye Applicator

NMED Item Number: 040213

Narrative:

Last Updated: 06/24/2004

The licensee reported that a 79-year-old male pterygium patient received 70.59 Gy (7,059 rad) during an eye treatment instead of the prescribed 20 Gy (2,000 rad). The patient was scheduled to receive a 42.5 second treatment using a 3M Company Sr-90 source (model 6D-1A) with an activity of 3.7 GBq (100 mCi). The dosimetrist programmed the manual timer for 42.5 seconds; however, the manual timer could not be set for fractions of seconds and interpreted the entry to be 4 minutes and 25 seconds. During the treatment, the physician questioned the treatment time and terminated the treatment after 2 minutes and 30 seconds. The patient and physician were notified of the event. The Tennessee Department of Radiological Health conducted an onsite inspection on 3/29/2004. Corrective actions taken by the licensee included updating procedures to incorporate the use of a second person operating a second timer during this type of treatment.

Event Date:	Discovery Date:	Report Date:
03/25/2004	03/25/2004	03/25/2004

Licensee/Reporting Party Information:

License Number:	TN-R-79104	Name:	SAINT FRANCIS HOSPITAL
Docket Number:	NA	City:	MEMPHIS, TN

Reference Documents:

Reference Document Number:	Entry Date:	Retraction Date:	Type of Report:
EN40611	03/31/2004		EVENT NOTIFICATION REPORTED FROM AN AGREEMENT STATE
LTR040331	03/31/2004		NRC LETTER
TN04035	04/12/2004		AGREEMENT STATE EVENT REPORT
TN04035A	05/04/2004		AGREEMENT STATE EVENT REPORT
TN04035B	06/24/2004		AGREEMENT STATE EVENT REPORT

I-125 Seeds**Cut Leaking Seeds****NMED Item Number: 030807****Narrative:****Last Updated: 10/30/2003**

The licensee reported that two Medi-Physics, Incorporated, brachytherapy seeds (model 6711 Oncoseed) were damaged during an implant procedure for a lung cancer patient. While implanting a source train (model 7000 Rapid Strand) of 31 I-125 seeds along the lining of the pleura, the licensee determined that the source train in use was longer than necessary. They decided to clip the unwanted part of the train, but snipped two seeds rather than the space between the seeds. Each seed contained an activity of 27 MBq (0.729 mCi). The licensee administered large quantities of SSKI within one hour of breaching the seeds and continued to administer SSKI for the next two weeks. The licensee took a pleural fluid sample from the patient and found a small amount of contamination, but a urinalysis of the patient revealed a significant amount of contamination. A thyroid bioassay of the patient on 10/10/2003 showed 2-3 cpm over the thyroid and 1800 cpm over the implant site, indicating that the SSKI had blocked any I-125 uptake by the thyroid. Licensee personnel involved in the procedure received thyroid bioassays, which were negative. Leak test results from a soak test showed significant leakage. The licensee assumed a worst-case scenario in which the entire contents of one seed and 50% of the second has or will leak. Radiation exposure was limited to the patient only. The licensee will attempt to quantify through both calculation and bioassay the extent of patient/thyroid exposure. The patient and referring physician were notified of the event. The INEEL has requested additional information for this event.

Event Date:	Discovery Date:	Report Date:
10/08/2003	10/08/2003	10/09/2003

Licensee/Reporting Party Information:

License Number:	WA-WN-M031-1	Name:	SACRED HEART MEDICAL CENTER
Docket Number:	NA	City:	SPOKANE, WA

Reference Documents:

Reference Document Number:	Entry Date:	Retraction Date:	Type of Report:
WA-03-043	10/10/2003		AGREEMENT STATE EVENT REPORT
WA-03-043A	10/10/2003		AGREEMENT STATE EVENT REPORT
EN40236	10/14/2003		EVENT NOTIFICATION REPORTED FROM AN AGREEMENT STATE
ML032880164	10/30/2003		PRELIMINARY NOTIFICATION REPORTED FROM AN AGREEMENT STATE
PN403043	10/30/2003		PRELIMINARY NOTIFICATION REPORTED FROM AN AGREEMENT STATE

Prostrate**NMED Item Number: 030947****Narrative:****Last Updated: 05/11/2004**

The licensee reported that a patient, implanted with 89 I-125 brachytherapy seeds for treatment of prostate cancer, received an estimated dose of 1,860 cGy (rad) instead of the intended dose of 14,500 cGy (rad) to the planned prostate target volume. Each I-125 seed contained an activity of 15.5 MBq (0.419 mCi). X-rays taken after surgery appeared to be normal. On 11/17/2003, a routine follow-up CT scan was performed and the results were made available to Radiation Oncology on 11/20/2003. Review of the CT scan showed that approximately 80% of the implanted seeds were in adjacent tissue and not in the intended location. The paraprostatic tissues and bulbous cavernosa received much of the dose and the patient may be at elevated risk for urethral stricture. The licensee notified the patient and treating physician of the event. The patient will require additional external beam radiation therapy. The licensee investigation revealed that the intra-operative ultrasound differed from the pre-plan ultrasound. The most likely cause was the identification of a portion of the bulbous cavernosa as the prostate gland on the intra-operative ultrasound. To prevent recurrence, the licensee modified their procedures to require more comprehensive imaging for prostate implant procedures.

Event Date:	Discovery Date:	Report Date:
10/16/2003	11/20/2003	11/21/2003

Licensee/Reporting Party Information:

License Number:	37-00448-19	Name:	ALBERT EINSTEIN HEALTHCARE NETWORK
Docket Number:	03007551	City:	PHILADELPHIA, PA

Reference Documents:

Reference Document Number:	Entry Date:	Retraction Date:	Type of Report:
EN40346	11/24/2003		EVENT NOTIFICATION
ML033280647	11/25/2003		PRELIMINARY NOTIFICATION
PN103033	11/25/2003		PRELIMINARY NOTIFICATION
ML033570322	01/08/2004		LICENSEE REPORT
ML033570327	01/08/2004		LICENSEE REPORT
ML040340655	02/13/2004		LICENSEE REPORT
ML040340655	02/13/2004		REGION REPORT
ML040650476	03/16/2004		INSPECTION REPORT
ML040560487	03/16/2004		NRC LETTER
LTR040316	04/01/2004		NRC LETTER
LTR040510	05/11/2004		REGION REPORT

NMED Item Number: 040001

Narrative:

Last Updated: 04/27/2004

The licensee reported that a patient received an underdose to the intended treatment site and radiation dose to an unintended area from an I-125 prostate seed implant procedure. The patient was prescribed to receive 122 I-125 seeds, each containing an activity of 13.3 MBq (0.36 mCi). During the patient's post-implant CT scan on 12/18/2003, the licensee discovered that the seeds had been implanted too low (approximately 2 cm inferior to the apex of the gland) and missed treating the upper portion of the prostate gland. As a result, an unintended area of 68 cc of tissue inferior to the prostate received the prescribed dose of 14,400 cGy (rad). The licensee has not estimated the actual dose to the prostate. The licensee is planning additional treatment to deliver the intended dose to the upper 2 cm of the gland. The patient and referring physician have been notified of the event. The cause of the event was attributed to personnel error associated with difficulty in clear delineation of the gland on the ultrasonic images used during the implant. Corrective actions included writing a new procedure to implement the use of fluoroscopic guidance to ensure the correct placement of seeds.

Event Date:	Discovery Date:	Report Date:
12/04/2003	12/18/2003	12/19/2003

Licensee/Reporting Party Information:

License Number:	AR-654	Name:	CENTRAL ARKANSAS RADIATION THERAPY INSTITUTE INC.
Docket Number:	NA	City:	CONWAY, AR

Reference Documents:

Reference Document Number:	Entry Date:	Retraction Date:	Type of Report:
EN40409	01/05/2004		EVENT NOTIFICATION REPORTED FROM AN AGREEMENT STATE
ML033570328	01/05/2004		PRELIMINARY NOTIFICATION REPORTED FROM AN AGREEMENT STATE
PN403053	01/05/2004		PRELIMINARY NOTIFICATION REPORTED FROM AN AGREEMENT STATE
AR-12-03-01	02/18/2004		AGREEMENT STATE EVENT REPORT
LTR040218	02/18/2004		AGREEMENT STATE LETTER
AR-12-03-01A	04/27/2004		AGREEMENT STATE EVENT REPORT

NMED Item Number: 040226

Narrative:

Last Updated: 07/08/2004

The licensee reported that 31 I-125 brachytherapy seeds were mistakenly implanted into a patient's bladder instead of his prostate at the V.A. Greater Los Angeles Healthcare System of Los Angeles, California. Each seed contained an activity of 12.95 MBq (0.35 mCi). The procedure prescribed implanting 109 seeds into the patient's prostate under ultrasound guidance. At the end of the procedure, it was discovered that 31 seeds had been placed in the bladder. These seeds were promptly removed. The likely cause of this event was misidentification of the base of the prostate and inadequate procedures. The licensee ceased performing prostate procedures pending an investigation and root cause determination. The patient was informed of this event.

Event Date:	Discovery Date:	Report Date:
03/31/2004	04/01/2004	04/02/2004

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:	LOS ANGELES	State:	CA
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Reference Documents:

Reference Document Number:	Entry Date:	Retraction Date:	Type of Report:
EN40634	04/05/2004		EVENT NOTIFICATION
ML041180329	05/10/2004		LICENSEE REPORT
LTR040707	07/08/2004		NRC LETTER

NMED Item Number: 040536

Narrative:

Last Updated: 07/26/2004

The licensee reported that a patient was prescribed placement of 74 I-125 seeds to the prostate. However, only 38% of the volume of the prostate received the prescribed dose of 16,000 cGy (rad). The radiation oncologist used poor technique in placing the iodine seeds in the prostate. There were no other safety issues related to the incident. The patient has been contacted and will receive consultation. The licensee will review the incident.

Event Date:	Discovery Date:	Report Date:
07/15/2004	07/15/2004	07/22/2004

Licensee/Reporting Party Information:

License Number:	45-15154-03	Name:	DANVILLE REGIONAL MEDICAL CENTER
Docket Number:	03013667	City:	DANVILLE, VA

Reference Documents:

Reference Document Number:	Entry Date:	Retraction Date:	Type of Report:
EN40892	07/26/2004		EVENT NOTIFICATION

NMED Item Number: 040566

Narrative:

Last Updated: 08/27/2004

The licensee reported that a patient injected with 73 I-125 brachytherapy seeds (Bard Brachytherapy, Incorporated) during a prostate implant did not receive the intended dose to a portion of his prostate. Each seed contained an activity 13.32 MBq (0.36 mCi) for a total activity of 972.36 MBq (26.28 mCi). A quality assurance CT scan revealed that a portion of the gland had not received the desired number of seeds. The patient was prescribed 145 Gy (14,500 rad) to the prostate. However, isodose curves were generated showing that less than 80% of the prescribed dose [less than 116 Gy (11,600 rad)] was delivered to a portion of the gland near the bladder base. It was determined that the treated portion of the gland received the intended dose. The licensee believes that the patient moved slightly in relation to the apparatus after the needles had been inserted, but before the seeds were inserted. Additional stabilization and evaluation of gland position by the urologist during the procedure should prevent recurrence. Such procedures have already been instituted. The treating urologist received additional in-service training in this regard on 7/2/2004. The patient was also notified of the event on 7/2/2004.

Event Date:	Discovery Date:	Report Date:
06/28/2004	07/02/2004	07/29/2004

Licensee/Reporting Party Information:

License Number:	NC-050-0503-2	Name:	MOUNTAIN REGIONAL CANCER CENTER
Docket Number:	NA	City:	SYLVA, NC

Reference Documents:

Reference Document Number:	Entry Date:	Retraction Date:	Type of Report:
NC040026	08/10/2004		AGREEMENT STATE EVENT REPORT
LTR040826	08/26/2004		AGREEMENT STATE LETTER
NC040026A	08/27/2004		AGREEMENT STATE EVENT REPORT

Ir- 192**NMED Item Number: 040154****Narrative:****Last Updated: 07/07/2004**

The licensee reported the loss and recovery of a ribbon containing seven Ir-192 seeds, each with an activity of approximately 27.4 MBq (0.74 mCi) for a total activity of approximately 191.7 MBq (5.18 mCi). The seed ribbon was implanted with seven others of the same activity on 2/19/2004 for a gynecological treatment. On 2/21/2004, the sources were removed from the patient. The waste from the removal procedure remained in the room while the sources were removed to a storage area in a shielded container. While inventorying the sources after removal, the licensee discovered that one ribbon was missing. The patient's room and other areas were searched to no avail. Following discussions with housekeeping personnel, the licensee found that the waste had been removed from the patient's room. Licensee Radiation Safety personnel surveyed the waste area and found the ribbon in a waste compactor approximately two and a half hours after removal from the patient. Due to skin reddening on the patient, the patient may have received an overexposure to the thigh. Calculations reveal that the patient received between 41 and 662 cGy (rad) skin dose. In the brief time (1 to 2 minutes) it took housekeeping to transport the lost ribbon with other trash to the dumpster, and during the time the ribbon was in the dumpster, any exposure to additional personnel would have been negligible. The root cause of this event was the use of a defective survey meter to survey the room following the procedure. Corrective actions included replacing the defective survey meter, procedure modification, and additional training for applicable personnel.

Event Date:	Discovery Date:	Report Date:
02/21/2004	02/21/2004	02/23/2004

Licensee/Reporting Party Information:

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

Reference Documents:

Reference Document Number:	Entry Date:	Retraction Date:	Type of Report:
EN40540	02/25/2004		EVENT NOTIFICATION
ML040550470	02/25/2004		PRELIMINARY NOTIFICATION
PN104007	02/25/2004		PRELIMINARY NOTIFICATION
ML041170489	05/06/2004		LICENSEE REPORT
ML041170489	05/06/2004		REGION REPORT
LTR040609	07/07/2004		REGION REPORT

10 CFR 35.600 - HDR

NMED Item Number: 030900

Narrative:

Last Updated: 05/11/2004

The licensee reported that a patient receiving her second of six treatments for cervical cancer was only given 200 cGy (rad) instead of the prescribed 600 cGy (rad). During planning of the third treatment, the Nucletron high dose rate afterloader unit (model Microselectron, serial #31469) displayed an error indicating that the treatment should be provided in two parts instead of one. The unit contained an Ir-192 source with an activity of 295.9 GBq (7.996 Ci). The licensee notified the manufacturer of the error and the manufacturer requested that the licensee review the previous two treatments. During the review of the previous two treatments, the licensee identified that the patient only received 200 cGy (rad) for her second treatment. The review of the treatment plan indicated that during transfer of the data to the high dose rate remote afterloader unit, the dwell times for the treatment locations were reversed, resulting in an underdose to the treatment site and dose to an unintended site. The unintended site that received the highest dose was the inner thigh. Dose to this area during normal treatment would have been 29.3 cGy (rad). Instead, the calculated dose to the inner thigh was 46 cGy (rad). The physician adjusted the remaining treatments so that the patient received the prescribed dose. The cause of the event was personnel error and both the patient and physician were notified. To prevent recurrence, the licensee modified their procedures to require additional checks of the treatment plan and equipment setup.

Event Date:	Discovery Date:	Report Date:
10/31/2003	11/03/2003	11/04/2003

Licensee/Reporting Party Information:

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

Reference Documents:

Reference Document Number:	Entry Date:	Retraction Date:	Type of Report:
EN40294	11/05/2003		EVENT NOTIFICATION
ML033080412	11/07/2003		PRELIMINARY NOTIFICATION
PN103032	11/07/2003		PRELIMINARY NOTIFICATION
ML040630594	03/10/2004		INSPECTION REPORT
ML040480352	03/10/2004		NRC LETTER
ML040540665	03/10/2004		OTHER
LTR040316	04/01/2004		NRC LETTER
ML040930422	04/13/2004		LICENSEE REPORT
ML040930422	04/13/2004		REGION REPORT
LTR040510	05/11/2004		REGION REPORT

NMED Item Number: 040150

Narrative:

Last Updated: 04/07/2004

The licensee reported that a patient receiving radiation treatments using a high dose rate remote afterloader did not receive the intended dose due to a therapy dose planning error. The patient was to receive 5,040 cGy (rad) from external beam treatment and 1,200 cGy (rad) from the remote afterloader for a total treatment dose of 6,240 cGy (rad). The patient was prescribed to receive three radiation treatments using a catheter that was 1,500 mm long. Each of the three treatments was to deliver 400 cGy (rad), for a total dose of 1,200 cGy (rad). The equipment involved in the treatment included a Nucletron high dose rate afterloader (model microselectron, serial #31021) and an Ir-192 source (model 105.002) with an activity of 222 GBq (6 Ci). The treatment planning system used a default catheter length value of 995 mm. When preparing the treatment plan for the first of three treatments, the medical physicist did not notice that the catheter length in the treatment plan was incorrect. When the radiation oncologist and the medical physicist were doing a pretreatment review and ensuring that the important parameters of the planned treatment were correct, they did not check the catheter length in the treatment plan. The first radiation treatment was performed, but instead of the source traveling to the intended site it never entered the patient's body. When the medical physicist began to plan the second treatment he noticed the error in the treatment plan for the first treatment. It was determined that the patient received approximately 2.2 cGy (rad) to the ankle and calf. The radiation oncologist notified the patient on the same day the error was discovered. The records of all patients previously treated by this same methodology were reviewed to determine if a similar error had occurred, but no other errors of this type were found. To prevent future errors, both the medical physicist and the radiation oncologist have to perform a formal cross check of the pretreatment printout that would include verifying that the catheter length specified in the treatment plan is correct. A new quality management checklist has been developed and is used before each treatment fraction is delivered. The licensee has contacted Nucletron for advice about this incident and the North Dakota Department of Health has conducted an on-site investigation of this incident.

Event Date:	Discovery Date:	Report Date:
01/28/2004	02/11/2004	02/12/2004

Licensee/Reporting Party Information:

License Number:	ND-33-01599-03	Name:	ALTRU HEALTH SYSTEM
Docket Number:	NA	City:	GRAND FORKS, ND

Reference Documents:

Reference Document Number:	Entry Date:	Retraction Date:	Type of Report:
ND040001	02/24/2004		AGREEMENT STATE EVENT REPORT
LTR040212	02/24/2004		LICENSEE REPORT
EN40543	02/27/2004		EVENT NOTIFICATION REPORTED FROM AN AGREEMENT STATE
ML040580083	03/02/2004		PRELIMINARY NOTIFICATION REPORTED FROM AN AGREEMENT STATE
PN404008	03/02/2004		PRELIMINARY NOTIFICATION REPORTED FROM AN AGREEMENT STATE
ND040001A	04/07/2004		AGREEMENT STATE EVENT REPORT
LTR040406	04/07/2004		AGREEMENT STATE LETTER

NMED Item Number: 040229

Narrative:

Last Updated: 08/12/2004

The licensee reported that a patient received three fractional brachytherapy doses of 818 cGy (rad) instead of the prescribed doses of 500 cGy (rad). The gynecological patient was prescribed five fractional treatments of 500 cGy (rad) each at the surface of a vaginal cylinder using a 0.25 TBq (6.7 Ci) Ir-192 brachytherapy source. On 3/15, 3/22, and 3/29/2004, the patient received 500 cGy/fraction (rad/fraction) at a depth of 5 mm beyond the surface of the treatment cylinder. This resulted in a delivered dose of 818 cGy/fraction (rad/fraction) at the surface of the cylinder. The error was discovered prior to delivering the fourth fraction. The prescribing physician and the patient's representative were informed. The written directive was modified to deliver a total dose of 2,954 cGy (rad), as opposed to the original total dose of 2,500 cGy (rad). No adverse health effects to the patient are expected. The licensee's investigation determined that this event was caused by the medical physicist's infrequent preparation of different or unusual treatment plans, the less than rigorous second verification of the treatment plan, and the failure to have adequate written procedures. To prevent recurrence, the licensee modified their procedures and re-trained personnel.

Event Date:	Discovery Date:	Report Date:
03/15/2004	04/05/2004	04/05/2004

Licensee/Reporting Party Information:

License Number:	13-00133-02	Name:	SAINT VINCENT HOSPITAL & HEALTH CARE
Docket Number:	03001579	City:	INDIANAPOLIS, IN

Reference Documents:

Reference Document Number:	Entry Date:	Retraction Date:	Type of Report:
EN40643	04/06/2004		EVENT NOTIFICATION
ML041320645	06/01/2004		INSPECTION REPORT
LTR040601	06/01/2004		NRC LETTER
ML041320645	06/01/2004		NRC LETTER
ML041660117	06/21/2004		INSPECTION REPORT
ML041550852	06/21/2004		LICENSEE REPORT
ML042150183	08/12/2004		NOTICE OF VIOLATION
ML042150183	08/12/2004		NRC LETTER

NMED Item Number: 040297

Narrative:

Last Updated: 07/30/2004

The licensee reported that a female patient received an unintended dose to the skin on the inner thigh during a high-dose-rate remote afterloader brachytherapy treatment for cervical cancer. The patient was prescribed to receive approximately 2,100 cGy (rad) to the cervix in three dose fractions of 700 cGy (rad) each, using a GammaMed HDR unit (model 12-It, serial #219) and a 129.5 GBq (3.5 Ci) Ir-192 source. The treatments occurred on 2/26, 3/4, and 3/11/2004. The event was discovered on 4/21/2004 when the patient returned for follow-up and two areas of reddening (about the size of a dime) on the upper inner thigh were noticed. The licensee believes that during the third treatment, the transfer tube shifted outward after localization films were taken to verify positioning. The patient and referring physician were informed of this event. The NRC contacted a medical consultant to review this event, who estimated that the dose to the inner thigh was approximately 600 to 1,000 cGy (rad) in the area of erythema, and as high as 1,500 to 2,000 cGy (rad) to a small area of blistering. No severe deterministic effects are expected. The estimated dose to the cervix was 1,450 cGy (rad). This event was caused by the licensee's failure to develop and implement written procedures for high-dose-rate remote afterloader brachytherapy treatments to ensure that the transfer tube was securely fastened to the vaginal cylinder. To prevent recurrence, the licensee developed procedures to determine whether the transfer tube is in place before and after treatment, marked the transfer tube as part of visual checks to determine if it moves during treatment, and trained the physics and nursing staffs on these procedures.

Event Date:	Discovery Date:	Report Date:
03/11/2004	04/21/2004	04/22/2004

Licensee/Reporting Party Information:

License Number:	24-11128-02	Name:	MISSOURI BAPTIST MEDICAL CENTER
Docket Number:	03008325	City:	SAINT LOUIS, MO

Reference Documents:

Reference Document Number:	Entry Date:	Retraction Date:	Type of Report:
EN40696	04/23/2004		EVENT NOTIFICATION
ML041140357	04/26/2004		PRELIMINARY NOTIFICATION
PN304005	04/26/2004		PRELIMINARY NOTIFICATION
ML041210305	05/13/2004		NRC LETTER
ML041460487	06/10/2004		CONSULTANT REPORT
ML041660044	06/24/2004		INSPECTION REPORT
LTR040624	06/24/2004		NRC LETTER
ML041660044	06/24/2004		NRC LETTER
LTR040707	07/08/2004		NRC LETTER
LTR040719	07/19/2004		NRC LETTER
ML041950198	07/30/2004		LICENSEE REPORT

NMED Item Number: 040342

Narrative:

Last Updated: 06/22/2004

The licensee reported that a patient received 1,800 cGy (rad) to the wrong site during prostate treatment using a Nucletron remote afterloading brachytherapy unit (model MicroSelectron) and an Ir-192 source with an activity of 270.7 GBq (7.315 Ci). It was determined that the input of information into the computer (Nucletron's PLATO program) was wrong. The dosimetrist clicked on the "catheter tip" but did not highlight and choose "catheter tip." Instead it stayed on "connector end," resulting in a 2 cm difference in source position. This led to the source stopping short of the target and the total prescribed dose was not delivered. There were a total of three fractions for the treatment (one on 3/31 and two on 4/1/2004). The event was compensated by external beam therapy. The cause of the event was attributed to operator error. The patient was informed of the event. Actions taken to prevent recurrence include implementing procedures for the addition of a visible check and documentation that the treatment plan was done with the source position calculated from the tip end of the catheter or needle. This will be added to the pretreatment checklist, which is performed and signed by the radiation oncologist, physicist, and dosimetrist. The checklist will be performed prior to initial treatment and at plan changes and is part of the patient's permanent record. The licensee also contacted Nucletron regarding the confusion of the default orientation and asked Nucletron to change it to what they use. Nucletron stated that it could not be done at this time, but are discussing the issue. Nucletron offered more training to the licensee's employees. The licensee is sending their employees to the training.

Event Date:	Discovery Date:	Report Date:
03/31/2004	04/07/2004	04/07/2004

Licensee/Reporting Party Information:

License Number:	LA-10853-L01	Name:	NEW ORLEANS CANCER INSTITUTE MEMORIAL MEDICAL CEN.
Docket Number:	NA	City:	NEW ORLEANS, LA

Reference Documents:

Reference Document Number:	Entry Date:	Retraction Date:	Type of Report:
EN40732	05/12/2004		EVENT NOTIFICATION REPORTED FROM AN AGREEMENT STATE
LTR040615	06/15/2004		NRC LETTER
LTR040621	06/22/2004		AGREEMENT STATE LETTER
LTR040505	06/22/2004		INSPECTION REPORT
LTR040622	06/22/2004		NRC LETTER

NMED Item Number: 040600

Narrative:

Last Updated: 08/25/2004

The licensee reported that a 93-year-old male patient received 10 cGy (rad) to the intended site instead of the prescribed 300 cGy/fraction (rad/fraction) during two separate high dose rate brachytherapy treatments for cancer. The intended treatment site was between the urethra and bladder wall. The prescribed dose was to a 7 mm radius distance from the source and the length of the treatment plan was 3 cm. The licensee used a Varian catheter and measuring wire. When they inserted the measuring wire, they thought they were at the end of the catheter, but they were actually about 20 cm short. The source for two treatments, on 8/18 and 8/19/2004, was actually located about 10 cm from the end of the penis, exterior to the body. The licensee estimated that the tumor site only got about 10 cGy (rad) and that the penis received approximately the same dose it would have received had the source been inserted into the correct location. The root cause appears to be an error on the part of the medical physicist. Both the radiation oncologist and the primary care physician believe the patient should not be informed of the event. The third treatment was performed correctly and the licensee has scheduled the patient for two additional treatments.

Event Date:	Discovery Date:	Report Date:
08/18/2004	08/19/2004	08/20/2004

Licensee/Reporting Party Information:

License Number:	CA-0059-19	Name:	PROVIDENCE SAINT JOSEPH MEDICAL CENTER
Docket Number:	NA	City:	BURBANK, CA

Reference Documents:

Reference Document Number:	Entry Date:	Retraction Date:	Type of Report:
EN40971	08/25/2004		EVENT NOTIFICATION REPORTED FROM AN AGREEMENT STATE

10 CFR 35.1000 - Gliasite

NMED Item Number: 040179

Narrative:

Last Updated: 05/13/2004

The licensee reported that a patient received 5,300 cGy (rad) instead of the prescribed 7,000 cGy (rad) during a therapeutic treatment of a brain tumor. The event involved Proxima Therapeutics GliaSite Radiation Therapy System and a liquid I-125 source with an activity of 15.76 GBq (426 mCi). The therapist calculated a dwell time of only 97 hours when the prescribed dwell time was 120 hours. Both the patient and referring physician were notified of the event. Based on investigation, it was determined that human error for improper dose calculation and a failure to perform a double check of the dose calculation as required by the Quality Management Program resulted in the event. Corrective actions taken by the licensee included developing a checklist to be attached to the patient's chart, which will be initialed, to ensure no step is missed, a second check by a qualified person will be performed prior to ordering the Iotrex, the signature of the dose calculation was moved to the front page of the written directive, a look-up table was developed to eliminate arithmetic errors, and QMP training/retraining of affected personnel. The licensee will make up for the under treatment by using a linear accelerator.

Event Date:	Discovery Date:	Report Date:
03/01/2004	03/04/2004	03/08/2004

Licensee/Reporting Party Information:

License Number:	OH-02110180013	Name:	CLEVELAND CLINIC FOUNDATION
Docket Number:	NA	City:	CLEVELAND, OH

Reference Documents:

Reference Document Number:	Entry Date:	Retraction Date:	Type of Report:
EN40575	03/11/2004		EVENT NOTIFICATION REPORTED FROM AN AGREEMENT STATE
LTR040513	05/13/2004		AGREEMENT STATE LETTER
IR-2004-020	05/13/2004		INSPECTION REPORT

10 CFR 35.1000 -Y-90 Microspheres

NMED Item Number: 040584

Narrative:

Last Updated: 08/18/2004

The licensee reported that a patient only received 22% of a prescribed treatment of Y-90 theraspheres. The physicians attempted to inject the prescribed treatment of 3.32 GBq (89.73 mCi) into the patient's liver, but only 0.72 GBq (18.92 mCi) was actually administered. The licensee is investigating the cause of the event. Initial investigation points to a tubing extension modification made to carry the dose to the targeted organ since the majority of the flow remained in the tubing. Licensee physicians have used the equipment five or six times without incident. The licensee will send the tubing back to the manufacturer for further investigation. The patient has been notified of the event.

Event Date:	Discovery Date:	Report Date:
08/11/2004	08/11/2004	08/13/2004

Licensee/Reporting Party Information:

License Number:	KY-202-029-22	Name:	UNIVERSITY OF LOUISVILLE
Docket Number:	NA	City:	LOUISVILLE, KY

Reference Documents:

Reference Document Number:	Entry Date:	Retraction Date:	Type of Report:
EN40947	08/18/2004		EVENT NOTIFICATION REPORTED FROM AN AGREEMENT STATE

10 CFR 35.1000 - IVB

NMED Item Number: 030933

Narrative:

Last Updated: 03/02/2004

The licensee reported that a patient received 1,378 cGy (rad) to an unintended site (healthy tissue). The patient was scheduled to receive an intravascular brachytherapy procedure that involved the use of a Novoste Beta-Cath device (model A1767, serial #91837) and an AEA Technology Sr-90 source train (model SICW.2, serial # ZB638) with a total activity of 2.91 GBq (78.56 mCi). The cardiologist was unable to insert the source train for the treatment because, as reported by the RSO, it was into a small artery and the routing did not follow a direct path. The source train was partially inserted into the patient, approximately 65 mm proximal of the intended site, when the cardiologist experienced difficulty. A 143-second exposure time elapsed before the cardiologist withdrew the source train, even though the licensee's procedure requires the sources to be immediately withdrawn once a problem occurs. The delay occurred as the cardiologist first worked to fully insert the source train and then discussed correcting the problem with the oncologist. The cause of the exposure was failure to follow established procedures. The catheter was examined and there were no kinks or bends. It was determined that there were no failures of the actual Beta-Cath device. It was suspected that the pressure from the artery and the tortuous route to the site caused a contraction on a portion of the catheter and resulted in the seeds being stuck at a particular location. The cardiologist was suspended from licensed activities until the details of the event were fully understood. The patient and referring physician were notified of the event.

Event Date:	Discovery Date:	Report Date:
11/18/2003	11/18/2003	11/18/2003

Licensee/Reporting Party Information:

License Number:	WA-WN-M008-1	Name:	SWEDISH MEDICAL CENTER
Docket Number:	NA	City:	SEATTLE, WA

Reference Documents:

Reference Document Number:	Entry Date:	Retraction Date:	Type of Report:
WA-03-054	11/19/2003		AGREEMENT STATE EVENT REPORT
EN40337	11/21/2003		EVENT NOTIFICATION REPORTED FROM AN AGREEMENT STATE
ML033240667	11/26/2003		PRELIMINARY NOTIFICATION REPORTED FROM AN AGREEMENT STATE
PN403049	11/26/2003		PRELIMINARY NOTIFICATION REPORTED FROM AN AGREEMENT STATE
LTR040204	02/04/2004		AGREEMENT STATE LETTER

NMED Item Number: 030956

Narrative:

Last Updated: 02/26/2004

The licensee reported that a patient received 500 cGy (rad) to the wrong area of the heart and that none of the prescribed dose of 1,840 cGy (rad) was received by the intended area of the heart. The event involved a Novoste Intravascular Brachytherapy device (model A1767, serial 91834) and a source train containing Sr-90 with a total activity of 1.79 GBq (48.4 mCi). The licensee RSO stated that during the procedure, the end of the 40-mm source train was not visible at the anticipated location at the end of the catheter. The sources were stuck in an apparent kink in the catheter. The source train was immediately retracted. A second attempt was then made but the sources became stuck in the same area and were again retracted. The procedure was terminated and analyses of the event and dose estimates were performed. An unintended area of the heart was exposed to radiation from the source train for approximately 47 seconds in the first attempt and 10 seconds in the second. The estimated radiation dose to the wrong area of the heart was approximately 500 cGy (rad). Essentially none of the prescribed dose of 1,840 cGy (rad) was delivered to the intended area of the heart. The patient was notified of the problem encountered. The licensee carefully reviewed this event and consulted with Novoste to determine the cause of the problem. Analysis showed that a kink in the catheter appeared under x-ray and was determined to be a sharp turn in anatomy of the patient that the sources could not pass. Corrective actions taken by the licensee included enhanced training for the IVB procedure and modified procedures to enhance awareness of sources not appearing at the intended treatment site.

Event Date:	Discovery Date:	Report Date:
11/24/2003	11/24/2003	11/25/2003

Licensee/Reporting Party Information:

License Number:	IL-01152-01	Name:	ADVOCATE LUTHERAN GENERAL HOSPITAL
Docket Number:	NA	City:	PARK RIDGE, IL

Reference Documents:

Reference Document Number:	Entry Date:	Retraction Date:	Type of Report:
EN40352	12/01/2003		EVENT NOTIFICATION REPORTED FROM AN AGREEMENT STATE
ML033300200	12/09/2003		PRELIMINARY NOTIFICATION REPORTED FROM AN AGREEMENT STATE
PN303044	12/09/2003		PRELIMINARY NOTIFICATION REPORTED FROM AN AGREEMENT STATE
LTR040209	02/09/2004		AGREEMENT STATE LETTER
IL030078	02/26/2004		AGREEMENT STATE EVENT REPORT

NMED Item Number: 040003

Narrative:

Last Updated: 02/04/2004

The licensee reported that a patient received a radiation dose to an unintended site of approximately 1840 cGy (rad) during an intravascular brachytherapy procedure. The event involved a Novoste Beta-Cath system (model A1767, serial #91828) using a 3.5 mm French catheter and an AEA Technology source train (model SICW.2, serial #ZA923) that contained Sr-90 with an activity of 2.0 GBq (53.8 mCi). The source train traveled to a location approximately 3 cm proximal of the intended treatment site. The cause of the event was determined to be a kink in the delivery catheter, which kept the source train from traveling to the correct site. The kink was not substantial enough to affect the flow of sterile water used to send/retrieve the source train. The kink was discovered the following day during medical physics quality checks. The attending physician was notified of the event. The Ohio Department of Health conducted an investigation during the week of 12/29/2003. Corrective actions incorporated by the licensee included additional cine films taken during procedures to verify the placement of the catheter. When there is any doubt of the placement of the catheter, the treatment will be aborted. The treatment team will then evaluate whether to attempt treatment with a different catheter.

Event Date:	Discovery Date:	Report Date:
12/22/2003	12/23/2003	12/24/2003

Licensee/Reporting Party Information:

License Number:	OH-02120180001	Name:	SOUTHWEST GENERAL HEALTH CENTER/IRELAND CANCER CEN
Docket Number:	NA	City:	MIDDLEBURG HEIGHTS, OH

Reference Documents:

Reference Document Number:	Entry Date:	Retraction Date:	Type of Report:
EN40413	01/05/2004		EVENT NOTIFICATION REPORTED FROM AN AGREEMENT STATE
ML033580644	01/05/2004		PRELIMINARY NOTIFICATION REPORTED FROM AN AGREEMENT STATE
PN303045	01/05/2004		PRELIMINARY NOTIFICATION REPORTED FROM AN AGREEMENT STATE
OH030014	01/27/2004		AGREEMENT STATE EVENT REPORT
OH030014A	02/04/2004		AGREEMENT STATE EVENT REPORT

NMED Item Number: 040051

Narrative:

Last Updated: 04/27/2004

The licensee reported that a source train did not reach the intended site during an intravascular brachytherapy treatment. The event involved a Novoste intravascular brachytherapy unit (model A1767, serial 90671) and an AEA Technology source train (model SICW.2, serial #ZA667) that contained 1.6 GBq (43.14 mCi) of Sr-90. During the advancement of the source train, some resistance was felt. After the source train was completely advanced, fluoroscopic confirmation was made that the source was in the proper position. The procedure lasted three minutes and eight seconds. When the treatment was completed and the source was retracted under fluoroscopic guidance, it was discovered that the source train had not been advanced into the correct location. A Toughey valve fitted on the guiding catheter had not been completely opened, causing the resistance felt during the advancement and ultimately the failure of the source train to reach the proper position. An Arrow sheath had not been placed through the Toughey valve to prevent this known problem. The licensee estimated the dose to the patient's thigh/groin area to be between 19.13 and 9.8 Gy (1,913 and 980 rad). The interventional cardiologist's left hand was positioned approximately 10 cm from the distal end of the anticipated source location and would yield a likely skin exposure of 15 cGy (rad). All other participants and observers to the procedure are not likely to have received greater than 1.91 mSv (191 mrem). The interventional cardiologist and radiation oncologist notified the patient of the event. A follow-up procedure was completed without problem. Corrective actions taken by the licensee included replacing the source with a source that is radiopaque along the entire train length, modifying procedures to require a team approach (when one member of the administering team believes there is a problem the source train is immediately retracted and the procedure aborted), adhering to the license requirement to use an Arrow sheath, and the requirement that the interventional cardiologist wear an extremity monitor.

Event Date:	Discovery Date:	Report Date:
01/19/2004	01/19/2004	01/21/2004

Licensee/Reporting Party Information:

License Number:	KY-202-124-26	Name:	BOWLING GREEN MEDICAL CENTER
Docket Number:	NA	City:	BOWLING GREEN, KY

Reference Documents:

Reference Document Number:	Entry Date:	Retraction Date:	Type of Report:
EN40460	01/26/2004		EVENT NOTIFICATION REPORTED FROM AN AGREEMENT STATE
ML040270155	01/28/2004		PRELIMINARY NOTIFICATION REPORTED FROM AN AGREEMENT STATE
PN104004	01/28/2004		PRELIMINARY NOTIFICATION REPORTED FROM AN AGREEMENT STATE
KY040001	04/27/2004		AGREEMENT STATE EVENT REPORT

Event Number: 40967

Licensee: THE METHODIST HOSPITAL

City: HOUSTON State: TX

License #: L00457

Notification Date: 08/18/2004

Notification Time: 15:21 [ET]

Event Date: 07/28/2004

Event Time: [CDT]

Last Update Date: 08/18/2004

Event Text

SOURCE TRAIN DID NOT RETRACT

"After IVB therapy the source train did not retract due to a kink in the IVB catheter, did not retract to the remote Beta-Cath device. The IVB catheter was immediately withdrawn and placed in the Novoste emergency plexiglass storage safe and then in the IVB storage room. No overexposure was received by the patient or attending staff. Novoste has been notified of the malfunction. The Novoste Beta Cath was returned to the manufacture on August 2, 2004. The IVB manufacturer is Novoste Beth Cath, source Sr-90, 1.71 GBq (46 millicuries). Transfer device Serial No. 92917, and Source train Serial No. ZA543. The device was packaged and returned to the manufacturer on August 2, 2004. This agency did not receive notice of the event within 24-hours"

Texas Incident No.: I-8155

Event Number: 41078

Licensee: SWEDISH MEDICAL CENTER

City: SEATTLE State: WA

License #: WN-M008-1

Notification Date: 09/28/2004

Notification Time: 15:08 [ET]

Event Date: 09/24/2004

Last Update Date: 09/28/2004

Event Text

AGREEMENT STATE REPORT

"Per Swedish Medical Center policy, post thyroid treatment patients are prescribed 74 mBq (2mCi (milliCuries)) for the treatment follow-up scan, and 185 mBq (5 mCi) for subsequent treatment if necessary. On 24 September 2004 a patient was prescribed 74 mBq (2 mCi) of NaI (Iodine-131) for a post treatment scan. Instead, 191 mBq (5.16 mCi) of NaI (Iodine-131) were administered. The prescribing physician realized that a misadministration had occurred on 27 September 2004 when the patient underwent the scan. A viable follow-up scan was able to be performed even though the misadministration had occurred.

"There are multiple procedural checks in place to assure medical technicians administer the prescribed dose. Human error appears to have lead to checks not being performed prior to this event.

"The Radiation Safety Officer for Swedish Medical Center notified the State of Washington, of the misadministration, on 27 September 2004.

"The treating physician notified the patient on Monday, 27 September 2004, when the physician discovered the patient had been administered 191 mBq (5.16 mCi) of NaI (Iodine-131) instead of the prescribed 74 mBq (2 mCi) of NaI (Iodine-131)."

Event Report Number WA-04--57

From: <SiegelB@mir.wustl.edu>
To: <rez@nrc.gov>
Date: 8/23/04 7:46AM
Subject: Re: Fwd: Consultancy, on Medical Event Criteria

Ron:

I have reviewed the material you sent to me and have discussed this matter briefly with Cathy Haney. Based on my recollections of the discussions by the ACMUI, during the Part 35 public workshops, and at the Part 35 Working Group meetings, there were no rigorous evidence-based criteria for retaining the 20% variance threshold in the revision of Part 35. In large part, the threshold was retained because it was in the prior version of the rule, because the reporting frequency associated with that threshold did not appear to be causing a significant burden for licensees, and because there was a general consensus that an error of 20% or more definitely had the potential to cause harm (although by no means was certain to do so). Thus, the Working Group's posture was to strike a balance such that the reporting burden would not be excessive, while nonetheless capturing all events likely to cause harm and capturing a large enough fraction of other signal events to provide NRC with information that could be evaluated and used to improve safety practices (through such mechanisms as Information Notices).

Whether a variance of more than 20% will cause harm to a patient is highly dependent on the modality. In general, the consensus of the ACMUI during my tenure as chair and that of the working group was that a 20% error in a cancer treatment regimen could lead to inadequate treatment of the cancer (underdosing) or to an increased likelihood of complications (overdosing). However, a threshold of only 10% was thought to be too low, since such differences were well within the range of standard of care variations from one practitioner to another. In contrast, a diagnostic radiopharmaceutical dosing error of more than 20% that led to an increase in EDE of just over 5 rem or to an organ dose of just over 50 rem would probably lead only rarely to actual harm, yet the magnitude of the error would likely be so large to cause such an excessive dose as to warrant reporting for that reason alone. For example, it would be of legitimate generic interest to the NRC to understand how a patient could be overdosed with Tc-99m MDP sufficient to cause an excess EDE of 5 rem, since this would require giving a dosage of nearly 240 mCi.

Finally, I think the Working Group recognized that there simply was not enough hard information in the scientific literature to allow for selection of different thresholds on a modality-by-modality basis that would be predicated on the risk of harm. If one realizes that such data would need to be specific to treatment site and radiopharmaceutical as well as to modality, it becomes clear that such an evidence-based approach would be daunting, if not simply impossible, to develop. Moreover, it would have been extremely confusing to licensees

Please let me know if you need additional information.

Barry A. Siegel, M.D.



Proposed Changes to the Abnormal Occurrence Criteria

Presented to:
Advisory Committee on Medical Uses of Isotopes
October 14, 2004

Presented by:
Andrea R. Jones, MSPH
Office of Nuclear Regulatory Research



Definition

- Section 208 of the Energy Reorganization Act of 1974 (Public Law 93-438) defines an abnormal occurrence as an unscheduled incident or event that the NRC determines to be significant from the standpoint of public health or safety.



Why Revise?

- To appropriately classify and report to Congress, in accordance with Section 208, only those events the Commission considers to have safety and security significance.
- To reduce potential misunderstanding by the public of actual health or safety significance from medical event occurrences.
- To acknowledge the introduction of evolving therapeutic treatment procedures delivering high radiation doses to localized portions of an organ or tissue.



Current Wording

IV. For Medical Licensees

A medical event that:

- (a) Results in a dose that is (1) equal to or greater than 1 Gy (100 rads) to a major portion of the bone marrow, to the lens of the eye, or to the gonads, or (2) equal to or greater than 10 Gy (1,000 rads) to any other organ; and
- (b) Represents either (1) a dose or dosage that is at least 50 percent greater than that prescribed in a written directive or (2) a prescribed dose or dosage that (i) is the wrong radiopharmaceutical, or (ii) is delivered by the wrong route of administration, or (iii) is delivered to the wrong treatment site, or (iv) is delivered by the wrong treatment mode, or (v) is from a leaking source or sources.



Proposed Wording

IV. For Medical Licensees

A medical event that:

- (a) Results in unintended permanent functional damage to any organ or tissue as determined by a physician; and
- (b) Results in a dose that is (1) equal to or greater than 1 Gy (100 rads) to a major portion of the bone marrow or the lens of the eye, or (2) equal to or greater than 2.5 Gy (250 rads) to the gonads, or (3) equal to or greater than 10 Gy (1,000 rads) to any other organ or tissue; and



Proposed Wording (con't)

IV. For Medical Licensees

- (c) Represents either (1) a dose or dosage that is at least 50 percent greater than that prescribed in a written directive, or (2) a dose or dosage administered in the absence of a written directive, for which a written directive was needed, and the dose or dosage is at least 50 percent greater than the intended dose or dosage; or (3) a prescribed dose or dosage that (i) is the wrong radiopharmaceutical or unsealed byproduct material; or (ii) is delivered by the wrong route of administration, or (iii) is delivered to the wrong treatment site, or (iv) is delivered by the wrong treatment mode, or (v) is from a leaking source or sources.



**If approved by the Commission,
the revised medical criterion will:**

- Ensure that medical events reported to Congress have resulted in permanent functional damage, as determined by a physician, to a specified target organ or surrounding tissue.
- Capture the current recommendations of International Commission on Radiological Protection (ICRP) - 60, "1990 Recommendations of the ICRP" reporting the dose threshold range causing sterility to the gonads.
- Include medical events where the dose was administered in error and a written directive was not required for the intended administration.
- Include "unsealed byproduct material" commensurate with the final rule revising 10 CFR Part 35, "Medical Use of Byproduct Material".



United States Nuclear Regulatory Commission



NATIONAL SOURCE TRACKING

October 14, 2004

Merri Horn

Division of Industrial Medical Nuclear Safety



United States Nuclear Regulatory Commission

National Source Tracking

- Structure and Key Players
- Background
- Elements
- Status
- Schedule



United States Nuclear Regulatory Commission

National Source Tracking System Structure and Key Players

- Interim Database
 - Initial - Merri Horn
 - Updates - Bill Ward
- NST Working Group
 - Co-Chairs - Merri Horn and Clayton Bradt, OAS-NYL
- NST Rulemaking Working Group
 - Task Leader - Merri Horn



United States Nuclear Regulatory Commission

**National Source Tracking System
(cont'n)**

- SafeSource Steering Committee
– Chair - Trish Holahan
- Interagency Coordinating Committee (ICC)
– Chair - Margaret Federline
- IT Team - Business Case Development
– IT Project Manager - Tammy Trocki



United States Nuclear Regulatory Commission

National Source Tracking - Background

- NRC and 33 Agreement States issue licenses for the medical, industrial, and academic uses of nuclear material
- Current regulations do not require tracking of sources
- Majority of licenses set possession limits
- No central database existed for high-risk sources



United States Nuclear Regulatory Commission

National Source Tracking - Background

- Joint NRC/DOE report on RDD recommends development of a national source tracking system
- IAEA Code of Conduct recommends establishment of a national register of radioactive sources
- US Government has made a non-legally binding commitment to the Code of Conduct
- NRC commitment to Congress to develop a tracking system



United States Nuclear Regulatory Commission

**National Source Tracking System -
Background**

- Be primarily Web-based
- Require licensees to report creation, transfer, receipt, and disposition of sources
- Cradle-to-grave account of sources
- Improve source accountability and give better information to decision-makers
- Will require rulemaking to implement



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National Source Tracking - Elements

Thresholds for Reporting

- 8/21/03 SRM M030716 directs staff to use the consolidated list of isotopes and thresholds as the basis for information collection and national registry
- IAEA Code of Conduct Categories 1 and 2
 - Commission added 7 isotopes to list



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National Source Tracking - Elements

- Licensees will be required to report
 - Creation of new sources
 - Transfer to another licensee
 - Receipt of sources
 - Endpoint of sources
- Licensees will be required to verify source inventory



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National Source Tracking - Elements

- **Basic Source Information to be captured**
 - Isotope
 - Activity and Date
 - Manufacturer
 - Model Number
 - Serial Number
 - Date created
 - Whether source is used in a device - voluntary





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National Source Tracking - Elements

- **Transfer/Receipt Information to be captured**
 - License number and company name of shipping company and receiving company
 - Specific sources to be transferred (make, model, serial number, isotope, activity)
 - Shipping date - transfer
 - Estimated arrival date - transfer
 - Carrier and tracking number - transfer voluntary
 - Receipt date - receipt





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National Source Tracking - Elements

- **Source endpoint Information**
- **Disposition Method**
 - Decay - system to calculate
 - Destroyed
 - Disposal
- **Disposition Date**
- **Comment field**





United States Nuclear Regulatory Commission

National Source Tracking - Elements

- **Verification of source inventory**
 - To keep system accurate, verification will be required
 - Frequency to be annually
 - Date certain to be established in rule



United States Nuclear Regulatory Commission

National Source Tracking- Status

Status:

- Working Group has developed use case descriptions
- ICC has finalized high-level interagency requirements
- Work on proposed rule has begun



United States Nuclear Regulatory Commission

National Source Tracking - Schedule

Schedule:

- **Rulemaking**
 - Proposed rule to ACMUI January 2005
 - Proposed rule to Commission spring 2005
 - Final rule to be in place by July 2006
- **Phased implementation of NSTS to begin Fall 2006**
 - Category 1 first, 90 days later Category 2
 - Maybe phased within Category 1 and 2

Potential Impact of ICRP 2005

Richard J. Vetter, Ph.D. CHP
ACMUI
October 14, 2005

ICRP Fundamental Aim

To provide an appropriate standard of protection for man without unduly limiting the beneficial actions giving rise to radiation exposure.

Intended Use

Influence

- regulatory agencies
- management bodies
- specialist advisors

Provide

- consistent basis for national and regional regulations
- encouragement for radiological safety culture

Safety Culture

Safety Culture: The assembly of characteristics and attitudes in organizations and individuals which establishes that, as an overriding priority, protection and safety issues receive the attention warranted by their significance.

ICRP Principles of Protection

- Restrictions on dose: **constraints**
- Achieving constraints: **obligatory**
- Not maintaining constraints: **failure**

Scope of Recommendations

- Apply to all "controllable sources" even emergencies
- Source: the cause of exposure, not necessarily physical source
- Exposure: the process of being exposed to radiation or radioactive materials
- Practice: sources that correspond to deliberate human activity that introduces, maintains, or increases exposure
- Judgements: responsibility for justification falls on governments or government agencies (except medical)

Scope of Recommendations

Justification of medical exposure:

- Do more good than harm to patients
- Practice must be justified
- Justification of practice lies more often with profession than government
- Justification also must be applied to procedures within a practice
- Justification of procedures falls on practitioners

Exclusions & Exemptions

- When annual effective dose of source is very low, it can be *excluded*, e.g. <0.01 mSv (1 mrem).
- When additional protective actions are not needed, *exemptions* may be granted through regulatory decision.

Classes of exposure

- **Occupational:** occurs at work, principally as a result of work (responsibility of management).
- **Medical:** exposure of persons as part of their diagnosis or treatment (no constraints, but procedures must be justified).
- **Public:** all other exposures (dose limits used as a basis for national policy).

Classes of exposure

- **Individual-related:** Within a single class an individual may be exposed to several sources, so an assessment of total exposure must be attempted.
- **Source-related:** Must consider the exposure of all the individuals exposed by a single source or group of sources.

Dose Constraints

To provide protection

- for the **most exposed individual**
- **within a class of exposure**
- from a **single source**
- optimization required

Dose Constraints: Maximum Values

National values normally will be lower than these maximum values. In addition, optimization is required.

	Maximum: mSv/year
Emergency Situations other than life saving, etc. (no direct benefit)	100 (10 rem)
Direct or indirect benefit, e.g. occupational, carers of radionuclide therapy patients	20 (2 rem)
Societal benefit (no information, training, or individual assessment)	1 (100 mrem)
Minimum constraint	0.01 (10 mrem)

Recommended Dose Limits

Individual dose limit from all sources within a class of exposure in normal situations only.

Class	Maximum: mSv/year
Occupational	20 (2 rem) averaged over 5 years; maximum of 50 mSv in one year
Public	1 (100 mrem) higher value allowed in special circumstances provided 5-year average does not exceed 1 mSv; constraint of 0.3 mSv/y in case of multiple dominant sources.

Exclusion of Radiation Sources

- Cosmic rays
- Artificial alpha emitters: 0.01 Bq/g
- Artificial beta emitters: 0.1 Bq/g
- Head of chain, e.g. U-238: 1 Bq/g
- K-40: 10 Bq/g

Effective Dose: New w_R

Type of Radiation	New w_R	Old w_R
Photons	1	1
Electrons & muons	1	1
Protons	2	5
Alpha, fission fragments, heavy nuclei	20	20
Neutrons (see report)	~2.5-22	5-20

Tissue Weighting Factors

Tissue	w_T
Bone marrow, breast, colon, lung, stomach	0.12
Bladder, esophagus, gonads, liver, thyroid	0.05
Bone surface, brain, kidneys, salivary glands, skin	0.01
Remainder tissues	0.1

ICRP 60: breast - 0.05; gonads - 20; brain, kidneys, salivary glands were included in remainder - 0.05

Practical Application

- Control exposures to low doses that give rise to stochastic effects (assumes linear, no-threshold response)
- Prevent exposures to high doses that cause tissue damage (deterministic effects)

Control of Stochastic Effects

- Protection quantity is effective dose (sum of doses from external and internal sources)
- Effective dose generally is not measurable (dose coefficients are derived from reference individuals)
- Thus, if doses approach or exceed dose constraints, investigations may be needed
- New models for internal dose estimates (voxel phantoms)

Application of Dose Constraints

Identification of exposed individuals:

- **Occupational:** workers in "controlled areas", well informed, specially trained. Administrative and support staff treated as members of the public
- **Medical:** voluntary; benefit and risk to the patient. Members of the public supporting patients in hospital or at home require individual consideration (constraints should be higher).

Application of Dose Constraints

Identification of exposed individuals:

- **Public:** critical group represents most highly exposed individuals. Use *average habits and mean characteristics* in calculating dose.

Definition of a single source:

- Use in a broad sense, e.g. the releases of radioactive material from an installation. Treat sources singly when considering action.

Application of Dose Constraints

The exposure of women:

- No reason to distinguish women from men in control of occupational exposure unless woman is pregnant. Once pregnancy is declared, protection of fetus should be considered. Working conditions should make it unlikely that dose to fetus will exceed 1 mSv during remainder of pregnancy.

Medical Exposure

- No limitation of dose to individual patient because it may reduce effectiveness of diagnosis or treatment.
- Constraints should apply to workers and public, but some exposure may occur in patient care and support by members of the public. Constraint of a few mSv is reasonable but should not be used rigidly, e.g. higher doses reasonable for parents of sick child.

Medical Exposure

- Public constraints are not appropriate for individuals who volunteer for research studies.
- Discharges to sewer and in airborne effluents should be assessed to ensure relevant national constraints for public exposure are met.
- Adventitious exposure of public in waiting rooms and on public transport is not high enough to require special restrictions on nuclear medicine patients, except for those treated with radioiodine.



Sealed Source and Device Registration

October 13, 2004

Timothy Harris

Section Chief, Section A

Materials Safety and Inspection Branch
Office of Nuclear Material Safety and Safeguards
U.S. Nuclear Regulatory Commission

Content of a Registration Certificate

- describes the design
- lists labeling and other identifying features
- specifies conditions of normal use
- shows prototype tests or classification per applicable standards

2

Content of a Registration Certificate (Continued)

- presents radiation profiles around the device
- safety criteria for approval are based on likely dose rates
 - in normal use of a single unit
 - in normal storage and handling of multiple units
 - in failure or disposal of a single unit
- sets limitations and/or other considerations of use
- all registrations are accessible at:

<http://www.hsrdo.nrc.gov/nrc/sources/index.cfm>

3

Brachytherapy Seed Registrations

- National Registry registrations:
 - 3 in NRC states
 - 19 in Agreement States
(CA, CO, FL, GA, IL, MA, TX, WA)
- Conditions of Normal Use:
 - fairly similar descriptions
 - e.g. permanent or temporary interstitial treatment, used as implant, by use of commercially-available implant tools

4

Prototype Testing of Sources

- Should verify that the source maintains its integrity when subjected to conditions of normal use and likely accident conditions (NUREG-1556, Vol.3, Section 10.5).
- Requires actual prototype testing of the sealed source (not engineering analysis), since sealed source is the primary containment of the radioactive material.
- Passing = source must maintain containment integrity.
- Could be tested in accordance with ANSI/HPS N43.6-1997, or ISO 2919-1999, and any variances must be evaluated.
- Registration certificate for the source should include its ANSI (or ISO) classification.

5

Source Standards

- ANSI/HPS N43.6-1997, "Sealed Radioactive Sources - Classification"
 - Status:
 - currently being updated (in 2004)
 - final draft was circulated to Working Group in July 2004
- ISO-2919:1999, "Performance Classification of Testing of Sealed Sources"
 - Status:
 - last updated in 1999
 - was not on the agenda of the Tech. Committee meeting in March, 2004, Buenos Aires, Argentina

6

Source Standards (Continued)

- ANSI 44.1-1977, "Integrity and Test Specifications for Selected Brachytherapy Sources"

Status:
 - issued in 1977
 - reaffirmed in 1984
 - withdrawn in 1995

- ANSI 44.2-1973, "Leak-Testing Radioactive Brachytherapy Sources"

Status:
 - withdrawn in 1984

ISO-2919:1999

Table 4 - Sealed source classification (performance) requirements for typical usage

Sealed source usage	Sealed source class	Sealed source class, according to test				
		Temperature	Pressure	Impact	Vibration	Penetration
Radiography - Industrial	Source to be used in device	4	3	3	1	3
	Radionuclide	3	3	3	1	3
Medical	Source laboratory	4	3	3	2	4
	Radionuclide	3	3	3	1	3
General purpose - Unprotected source	Source in device	4	3	3	1	3
	Source in device	4	3	3	2	4
General purpose - Unprotected source (medium and high energy)	Source in device	4	3	3	2	4
	Source in device	4	3	3	2	4
Special purpose and source for low-energy gamma (except for X-ray fluorescence analysis)	Source in device	3	3	3	2	3
	Source in device	3	3	3	2	3
Chromatography	Source in device	3	3	3	2	3
	Source in device	3	3	3	2	3
General purpose source application (including nuclear battery)	Source in device	4	3	3	2	4
	Source in device	4	3	3	2	4
Calibration source activity > 1 MBq	Source in device	3	3	3	2	3
	Source in device	3	3	3	2	3
General purpose source Category I	Source in device	4	3	3	2	4
	Source in device	4	3	3	2	4
General purpose source Category II, III and IV	Source in device	3	3	3	2	3
	Source in device	3	3	3	2	3
General purpose source Category V	Source in device	3	3	3	2	3
	Source in device	3	3	3	2	3

ISO-2919:1999

Table 2 - Classification of sealed source performance (5 digits)

Test	Class					Sealed source
	1	2	3	4	5	
Temperature	No test	-40 °C (23 min) + 60 °C (1 hr)	-40 °C (30 min) + 100 °C (1 hr)	-40 °C (30 min) + 100 °C (1 hr)	-40 °C (30 min) + 100 °C (1 hr)	Sealed test
External pressure	No test	10 MPa absolute to atmosphere	20 MPa absolute to 2 MPa absolute	20 MPa absolute to 2 MPa absolute	20 MPa absolute to 2 MPa absolute	Sealed test
Impact	No test	50 g from 1 m or equivalent impact energy	200 g from 1 m or equivalent impact energy	500 g from 1 m or equivalent impact energy	500 g from 1 m or equivalent impact energy	Sealed test
Vibration	No test	3 times 10 min at 200 Hz or 400 Hz or 800 Hz (5 g ²)	3 times 10 min at 200 Hz or 400 Hz or 800 Hz (5 g ²)	3 times 10 min at 200 Hz or 400 Hz or 800 Hz (5 g ²)	3 times 10 min at 200 Hz or 400 Hz or 800 Hz (5 g ²)	Sealed test
Penetration	No test	1 g from 1 m or equivalent impact energy	10 g from 1 m or equivalent impact energy	100 g from 1 m or equivalent impact energy	100 g from 1 m or equivalent impact energy	Sealed test

(1) Assessment maximum amplitude

ANSI N 43.6 Table 4. Sealed Source Performance Requirements for Typical Usage

Sealed Source Usage	Sealed Source Test and Class				
	Temperature	Pressure	Impact	Vibration	Penetration
Radiography - Industrial Source in device	4	3	3	1	3
	4	3	3	1	3
Medical Source laboratory	3	3	3	1	3
	3	3	3	1	3
General purpose (medium and high energy) Source in device	4	3	3	2	4
	4	3	3	2	4
Special purpose and source for low energy gamma (except for X-ray fluorescence analysis) (source)	3	3	3	2	3
	3	3	3	2	3
Chromatography Source in device	3	3	3	2	3
	3	3	3	2	3
General purpose source application (including nuclear battery)	4	3	3	2	4
	4	3	3	2	4
Calibration source - Activity greater than 1.11 MBq (30 µCi)	3	3	3	2	3
	3	3	3	2	3
General purpose source Category I	4	3	3	2	4
	4	3	3	2	4
General purpose source Category II, III and IV	3	3	3	2	3
	3	3	3	2	3
General purpose source Category V	3	3	3	2	3
	3	3	3	2	3

10

ANSI/HPS N43.6-1997 - Classification

- Based on performance specifications related to radiation safety. Does not consider radiation output.
- Actual testing of two prototype (or dummy) sources for each test in Table 4 or by derivation/comparison to previously tested source (similar design/construction).
- An example of a typical source designation is:
ANSI 96C43515, where,
- ANSI 96
|
year of standard
- C
|
meets max. activity allowed for the isotope
- 4
|
temp.
- 3
|
press.
- 5
|
impact
- 1
|
vibr.
- 5
|
punct.

Summary of Current Prototype Tests

- Most registrations list a standards classification, e.g.
 - C43211
 - CS3211
 - C63211
 - CS3X42
 - CX3212
- Some standards classifications are supplemented, e.g.
 - stepping and cart wheel crush test
 - autoclaving temperature and low pressure test
 - drop test
 - custom impact test
- Some are tested to a custom protocol

Registration of Brachytherapy Sources

**Timothy Harris
Section Chief, MSIB-A
301 415-6613
teh@nrc.gov**

Content of a Registration Certificate

- describes the design
- lists labeling and other identifying features
- specifies conditions of normal use
- shows prototype tests or classification per applicable standards
- presents radiation profiles around the device
- safety criteria for approval are based on likely dose rates
 - in normal use of a single unit
 - in normal storage and handling of multiple units
 - in failure or disposal of a single unit
- sets limitations and/or other considerations of use
- all registrations are accessible at:
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Brachytherapy Seed Registrations

- **National Registry registrations:**
 - 3 in NRC states
 - 19 in Agreement States
(CA, CO, FL, GA, IL, MA, TX, WA)

- **Conditions of Normal Use:**
 - fairly close descriptions
 - e.g. permanent or temporary interstitial treatment, used as implant, by use of commercially-available implant tools

Prototype Testing of Sources

- Should verify that the source maintains its integrity when subjected to conditions of normal use and likely accident conditions (NUREG-1556, Vol.3, Section 10.5).
- Should require actual prototype testing of the sealed source (not engineering analysis), since sealed source is the primary containment of the radioactive material.
- Passing = source must maintain containment integrity.
- Should be tested in accordance with ANSI/HPS N43.6-1997, or ISO 2919-1999, and any variances must be evaluated.
- Registration certificate for the source should include its ANSI (or ISO) classification.

Source Standards

ANSI/HPS N43.6-1997, "Sealed Radioactive Sources - Classification"

Status:

- currently being updated (in 2004)
- final draft was circulated to Working Group in July 2004

ISO-2919:1999, "Performance Classification of Testing of Sealed Sources"

Status:

- last update in 1999
- was not on the agenda of the Tech. Committee meeting in March, 2004, Buenos Aires, Argentina

ANSI 44.1-1977, "Integrity and Test Specifications for Selected Brachytherapy Sources"

Status:

- issued in 1977
- reaffirmed in 1984
- withdrawn in 1995

ANSI 44.2-1973, "Leak-Testing Radioactive Brachytherapy Sources"

Status:

- withdrawn in 1984

Table 4 — Sealed source classification (performance) requirements for typical usage

Sealed source usage		Sealed source class, depending on test				
		Temperature	Pressure	Impact	Vibration	Puncture
Radiography — Industrial	Sealed source	4	3	5	1	5
	Source to be used in device	4	3	3	1	3
Medical	Radiography	3	2	3	1	2
	Gamma teletherapy	5	3	5	2	4
	Brachytherapy [6] ¹⁾	5	3	2	1	1
	Surface applicators ²⁾	4	3	3	1	2
Gamma gauges (medium and high energy)	Unprotected source	4	3	3	3	3
	Source in device	4	3	2	3	2
Beta gauges and sources for low-energy gamma gauges or X-ray fluorescence analysis ²⁾		3	3	2	2	2
Oil-well logging		5	6	5	2	2
Portable moisture and density gauge (including hand-held or dolly-transported)		4	3	3	3	3
General neutron source application (excluding reactor startup)		4	3	3	2	3
Calibration source activity > 1 MBq		2	2	2	1	2
Gamma irradiation sources [3], [5]	Category I ²⁾	4	3	3	2	3
	Categories II, III and IV ³⁾	5	3	4	2	4
Ion generators ³⁾	Chromatography	3	2	2	1	1
	Static eliminators	2	2	2	2	2
	Smoke detectors ²⁾	3	2	2	2	2

¹⁾ Sources of this nature may be subject to severe deformation in use. Manufacturers and users may wish to formulate additional or special test procedures.

²⁾ Excluding gas-filled sources.

³⁾ "Source in device" or a "source assembly" may be tested.

Table 2 — Classification of sealed source performance (5 digits)

Test	Class						
	1	2	3	4	5	6	X
Temperature	No test	-40 °C (20 min) + 80 °C (1 h)	-40 °C (20 min) + 180 °C (1 h)	-40 °C (20 min) + 400 °C (1 h) and thermal shock to 20 °C	-40 °C (20 min) + 600 °C (1 h) and thermal shock to 20 °C	-40 °C (20 min) + 800 °C (1 h) and thermal shock to -20 °C	Special test
External pressure	No test	25 kPa absolute to atmospheric	25 kPa absolute to 2 MPa absolute	25 kPa absolute to 7 MPa absolute	25 kPa absolute to 70 MPa absolute	25 kPa absolute to 170 MPa absolute	Special test
Impact	No test	50 g from 1 m or equivalent imparted energy	200 g from 1 m or equivalent imparted energy	2 kg from 1 m or equivalent imparted energy	5 kg from 1 m or equivalent imparted energy	20 kg from 1 m or equivalent imparted energy	Special test
Vibration	No test	3 times 10 min 25 to 500 Hz at 49 m/s ² (5 g _n) ¹⁾	3 times 10 min 25 to 50 Hz at 49 m/s ² (5 g _n) ¹⁾ and 50 to 80 Hz at 0,635 mm amplitude peak to peak and 80 to 500 Hz at 98 m/s ² (10 g _n) ¹⁾	3 times 30 min 25 to 80 Hz at 1,5 mm amplitude peak to peak and 80 to 2 000 Hz at 196 m/s ² (20 g _n) ¹⁾	Not used	Not used	Special test
Puncture	No test	1 g from 1 m or equivalent imparted energy	10 g from 1 m or equivalent imparted energy	50 g from 1 m or equivalent imparted energy	300 g from 1 m or equivalent imparted energy	1 kg from 1 m or equivalent imparted energy	Special test

1) Acceleration maximum amplitude

ANSI N 43.6-1997 Table 4. Sealed Source Performance Requirements for Typical Usage

Sealed Source Usage		Sealed Source Test and Class				
		Temperature	Pressure	Impact	Vibration	Puncture
Radiography - Industrial	Unprotected source	4	3	5	1	5
	Source in device	4	3	3	1	3
Medical	Radiography	3	2	3	1	2
	Gamma teletherapy	5	3	5	2	4
Gamma gauges (medium and high energy)	Unprotected source	4	3	3	3	3
	Source in device	4	3	2	3	2
Beta gauges and sources for low energy gamma gauges or x-ray fluorescence analysis (excluding gas filled sources)		3	3	2	2	2
Oil Well logging		5	6	5	2	2
Portable moisture and density gauge (including hand held or dolly transported)		4	3	3	3	3
General neutron source application (excluding reactor startup)		4	3	3	2	3
Calibration sources - Activity greater than 1.11 MBq		2	2	2	1	2
Gamma Irradiators ⁹	Category I	4	3	3	2	3
	Categories II, III,	5	3	4	2	4
	Category IV	5	3	4	2	4
Ion generators ⁸	Chromatography	3	2	2	1	1
	Static Eliminators	2	2	2	2	2
	Smoke Detectors	3	2	2	2	2

⁸Source-device combination may be tested.

⁹For this Standard, gamma irradiators have been divided into four distinct categories.

Category I - Self-Contained-Dry Source Storage.

Category II - Panoramic-Dry Source Storage.

Category III - Self-Contained-Wet Source Storage.

Category IV - Panoramic-Wet Source Storage.

ANSI/HPS N43.6-1997 - Classification

- Based on performance specifications related to radiation safety. Does not consider radiation output.
- Actual testing of two prototype (or dummy) sources for each test in Table 4 or by derivation/comparison to previously tested source (similar design/construction).
- An example of a typical source designation is:
ANSI 96C43515, where,

ANSI	96	C	4	3	5	1	5
	year of	meets max.	temp.	press.	impact	vibr.	punct.
	standard	activity					
		allowed for					
		the isotope					

Summary of Current Prototype Tests

- Most registrations list a standards classification, e.g.
 - C43211
 - C53211
 - C63211
 - C53X42
 - CX3212

- Some standards classifications are supplemented, e.g.
 - stepping and cart wheel crush test
 - autoclaving temperature and low pressure test
 - drop test
 - custom impact test

- Some are tested to a custom protocol

UNITED STATES NUCLEAR REGULATORY COMMISSION
CHARTER FOR THE ADVISORY COMMITTEE ON MEDICAL USES OF ISOTOPES
(Pursuant to Section 9 of Public Law 92-463)

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

Advisory Committee on the Medical Uses of Isotopes

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

The Committee provides advice, as requested by the Director, Division of Industrial and Medical Nuclear Safety (IMNS), Office of Nuclear Material Safety and Safeguards, 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, IMNS

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

From March 18, 2004, to March 18, 2006

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

Charles L. Miller, Director
Division of Industrial and Medical Nuclear Safety
Office of Nuclear Material Safety and Safeguards
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:**

- a. \$160,000.00 (includes travel, per diem, and compensation)
- b. Total staff-year of support: 1.5 Full Time Equivalent

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

Three meetings per year except when active rulemaking is conducted, then five meetings per year.

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

March 18, 2006

10. **Filing date:**

March 18, 2004

/RA/

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

ACMUI BYLAWS

ACMUI
February 20, 2002

U.S. NUCLEAR REGULATORY COMMISSION
OFFICE OF NUCLEAR MATERIALS SAFETY AND SAFEGUARDS
ADVISORY COMMITTEE ON MEDICAL USES OF ISOTOPES
BYLAWS

CONTENTS

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5.	Amendments.....	5

PREAMBLE

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

These bylaws have as their purpose fulfillment of the Committee's responsibility to provide objective and independent advice to the Commission through the Office of Nuclear Material Safety and Safeguards, 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 Committee is capable. Any ambiguities in the following should be resolved in such a way as to support those objectives.

Bylaws - Advisory Committee on the Medical Uses of Isotopes

BYLAWS-ADVISORY COMMITTEE ON THE MEDICAL USES OF ISOTOPES

1. Scheduling and Conduct of Meetings

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

1.1 Scheduling of Meetings:

1.111 Meetings must be approved or called by the Designated Federal Officer. At least two regular meetings of the Committee will be scheduled each year. A spring meeting will be scheduled in April-May, and a fall meeting will be scheduled in October-November. Additionally, the Committee will meet with the Commission each year in the first or second quarter of each year.

1.1.2 Special 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 Committee 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 Committee 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 Committee (referred to below as "the Chair") in consultation with the Nuclear Materials Safety and Safeguards (NMSS) staff. The Designated Federal Officer must approve the agenda. The Chair will query committee members for agenda items prior to agenda preparation. A draft agenda will be provided to committee 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 committee will review the findings of the Office of the General Counsel regarding

Bylaws - Advisory Committee on the Medical Uses of Isotopes

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 Designated Federal Officer will preside if the Chair is absent, if the Chair is recused from participating from discussion of a particular agenda item, or if directed to do so by the Commission.

1.3.3 A majority of the current membership of the Committee will be required to constitute a quorum for the conduct of business at a committee 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 committee, 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 committee member may request that any consensus statement be put before the ACMUI as a formal motion subject to affirmation by a formal vote. No committee position will be final until it has been formally adopted by consensus or formal vote, and the minutes written and certified.

2. MINUTES

2.1 The Chair will prepare detailed minutes of each ACMUI meeting (excepting meetings with the Commission for which transcripts are prepared) based on the transcripts of the meeting.

Bylaws - Advisory Committee on the Medical Uses of Isotopes

- 2.2 A draft of the minutes will be prepared by the Chair, assisted by NRC staff, and made available as soon as practicable to the other members. After receiving corrections to the draft minutes from the committee members, the Chair will certify the minutes. By certifying the minutes, the Chair attests to the best of his or her knowledge to the completeness and technical accuracy of the minutes.
- 2.3 Copies of the certified minutes will be distributed to the ACMUI members. The staff will then forward the minutes to the Public Document Room, with only deletions authorized or required by law.

3. APPOINTMENT OF MEMBERS

- 3.1 The members of the committee are appointed by the Commission, which determines the size of the committee. 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 Commission. The Commission has the final authority for selection. The term of an appointment to the committee is three years, and the Commission has determined that no member may serve more than 2 consecutive terms (6 years).
- 3.2 The Chair will be appointed by the Commission. The Chair will serve for a period of two years, and will be eligible for reappointment by the Commission for two additional two-year terms.

4. CONDUCT OF MEMBERS

- 4.1 If a member feels that he or she may have a conflict of interest with regard to an agenda item to be addressed by the committee, he or she should divulge it to the Chair and the Designated Federal Officer as soon as possible, but in any case before the committee discusses it as an agenda item. Committee 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 committee, 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.

Bylaws - Advisory Committee on the Medical Uses of Isotopes

5. ADOPTION AND AMENDMENTS

- 5.1 Adoption of these bylaws shall require a vote of two-thirds of the current ACMUI membership and the concurrence of the Director of the Office of Nuclear Material Safety and Safeguards.
- 5.2 Any member of the committee or NRC 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 committee meeting.
- 5.3 The final proposed amendment may be voted on not earlier than the first regular meeting after it has been discussed at a committee meeting pursuant to Paragraph 5.2.
- 5.4 A vote of two-thirds of the current ACMUI membership and the concurrence of the Director of the Office of Nuclear Material Safety and Safeguards shall be required to approve an amendment.
- 5.5 Any conflicts regarding interpretation of the bylaws shall be decided by majority vote of the current membership of the committee.

OSHA Docket Office for information about materials not available through the OSHA Web page and for assistance using the Web page to locate docket submissions.

Electronic copies of this Federal Register notice as well as other relevant documents are available on OSHA's Web page.

II. Background

The Department of Labor, as part of its continuing effort to reduce paperwork and respondent (*i.e.*, employer) burden, conducts a preclearance consultation program to provide the public with an opportunity to comment on proposed and continuing information collection requirements in accordance with the Paperwork Reduction Act of 1995 (PRA-95) (44 U.S.C. 3506(c)(2)(A)).

This program ensures that information is in the desired format, reporting burden (time and costs) is minimal, collection instruments are clearly understood, and OSHA's estimate of the information collection burden is accurate. The Occupational Safety and Health Act of 1970 (the Act) (29 U.S.C. 651 *et seq.*) authorizes information to collection by employees as necessary or appropriate or enforcement of the Act or for developing information regarding the causes and prevention of occupational inquiries, illnesses, and accidents (28 U.S.C. 657).

The OSHA 70 Form is used by applicants seeking accreditation from OSHA to be able to test or examine certain equipment and material handling devices, as required under the maritime regulations, part 1917 (Marine Terminals), and part 1918 (Longshoring). The OSHA 70 Form application for accreditation provides an easy means for companies to apply for accreditation.

The OSHA 71 Form is required to be issued by the those accredited by OSHA to employers in the maritime industry to make known that certain equipment and material handling devices are safe to use of operate. The OSHA 72 Form is required to be issued by those accredited by OSHA to employers in the maritime industry when the equipment or material handling device is found to be unsafe to use.

The collection of the information needed to complete these forms is necessary to provide an affective and efficient means of enabling employers and employees to determine if cargo gear, equipment and/or other material handling devices are safe to use.

III. Special Issues for Comment

OSHA has a particular interest in comments on the following issues:

- OSHA has a particular interest in comments on the following times.
- Whether the proposed information collection requirements are necessary for the proper performance of the Agency's functions, including whether the information is useful;
- The accuracy of OSHA's estimate of the burden (time and costs) of the information-collection requirements, including the validity of the methodology and improvement used;
- The quality, utility, and clarity of the information collected; and
- Ways to minimize the burden on employers who must comply; for example, by using automated or other technological information collection and transmission techniques.

IV. Proposed Actions

OSHA is proposing to extend the information collection requirements in the Gear Certification Standard (29 CFR part 1919). The Agency will summarize the comments submitted in response to this notice and will include this summary in its request to OMB to extend the approval of these information collection requirements contained in the Standard.

Type of Review: Extension of currently approved information collection requirements.

Title: Gear Certification (29 CFR part 1919).

OMB Number: 1218-0003.

Affected Public: Business or other for-profit, not-for-profit institutions; Federal government; State, local, or Tribal governments.

Number of Respondents: 80.

Frequency of Response: On occasion, annually; quadrennially.

Total Responses: 82.

Average Time per Response: Varies from 2 minutes (.03 hour) for a supervisor to disclose forms to an OSHA Compliance Officer during an inspection to 45 minutes (.75 hour) for an accredited agency to complete the OSHA 70 Form.

Estimated Total Burden Hours: 61.

Estimated Cost (Operation and Maintenance): \$1,452,000.

V. Authority and Signature

John L. Henshaw, Assistant Secretary of the Labor for Occupational Safety and Health, directed the preparation of this notice. The authority for this notice is the Paperwork Reduction Act of 1995 (44 U.S.C. 3506 *et seq.*) and Secretary of Labor's Order No. 5-2002 (67 FR 65008).

Signed at Washington, DC, on August 23, 2004.

John L. Henshaw,
Assistant Secretary of Labor.
[FR Doc. 04-19630 Filed 8-26-04; 8:45 am]
BILLING CODE 4510-26-M

NUCLEAR REGULATORY COMMISSION

Advisory Committee on the Medical Uses of Isotopes: Meeting Notice

AGENCY: U.S. Nuclear Regulatory Commission.

ACTION: Notice of meeting.

SUMMARY: The U.S. Nuclear Regulatory Commission will convene a meeting of the Advisory Committee on the Medical Uses of Isotopes (ACMUI) on October 13 and 14, 2004. A sample of agenda items to be discussed during the public sessions includes: (1) Use of I-125 Brachytherapy Seeds as Markers; (2) Proposed Changes to Abnormal Occurrence Criteria; (3) Discussion of Medical Event Criteria; and, (4) Update on St. Joseph Mercy Hospital Dose Reconstruction Case. To review the agenda, see <http://www.nrc.gov/reading-rm/doc-collections/acmui/schedules/2004/> or contact arm@nrc.gov.

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

DATE AND TIME FOR CLOSED SESSION

MEETING: October 13, 2004, from 8 a.m. to 10 a.m. This session will be closed so that NRC staff can give the ACMUI its required annual ethics briefing.

DATES AND TIMES FOR PUBLIC MEETINGS: October 13, 2004, from 8:30 a.m. to 5 p.m.; October 14, 2004, from 8 a.m. to 5 p.m.

ADDRESS FOR PUBLIC MEETINGS: U.S. Nuclear Regulatory Commission, Two White Flint North Building, Room T2B3, 11545 Rockville Pike, Rockville, MD 20852-2738.

FOR FURTHER INFORMATION CONTACT: Angela R. McIntosh, telephone (301) 415-5030; e-mail arm@nrc.gov of the Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001.

Conduct of the Meeting

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

1. Persons who wish to provide a written statement should submit a

reproducible copy to Angela R. McIntosh, U.S. Nuclear Regulatory Commission, Two White Flint North, Mail Stop T8F5, 11545 Rockville Pike, Rockville, MD 20852-2738. Submittals must be postmarked by September 15, 2004, and must pertain to the topics on the agenda for the meeting.

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

3. The transcript and written comments will be available for inspection on NRC's Web site (<http://www.nrc.gov>) and at the NRC Public Document Room, 11555 Rockville Pike, Rockville, MD 20852-2738, telephone (800) 397-4209, on or about January 14, 2005. This meeting will be held in accordance with the Atomic Energy Act of 1954, as amended (primarily Section 161a); the Federal Advisory Committee Act (5 U.S.C. App); and the Commission's regulations in Title 10, U.S. Code of Federal Regulations, Part 7.

4. Attendees are requested to notify Angela R. McIntosh at (301) 415-5030 of their planned attendance if special services, such as for the hearing impaired, are necessary.

Dated at Rockville, Maryland, this 23rd day of August, 2004.

For the Nuclear Regulatory Commission.
Andrew L. Bates,
Advisory Committee Management Officer.
 [FR Doc. 04-19595 Filed 8-26-04; 8:45 am]
 BILLING CODE 7590-01-P

NUCLEAR REGULATORY COMMISSION

[License Nos. (as shown in Attachment 2);
 Docket Nos. (as shown in Attachment 2);
 EA-03-099]

Decommissioning Power Reactor Licensees Order Modifying License (Effective Immediately)

AGENCY: Nuclear Regulatory Commission.

ACTION: Issuance of order for implementation of additional security measures associated with access authorization.

FOR FURTHER INFORMATION CONTACT: John Hickman, Project Manager, Decommissioning Directorate, Division of Waste Management and Environmental Protection, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Rockville, MD 20852. Telephone: (301) 415-3017; fax number: (301) 415-5398; e-mail JBH@nrc.gov.

SUPPLEMENTARY INFORMATION:

I. Introduction

Pursuant to Code of Federal Regulations Title 10 part 2.106, the Nuclear Regulatory Commission is providing notice in the matter of decommissioning power reactor licensees order modifying license (effective immediately).

II. Further Information

I. The licensees identified in Attachment 2 to this Order hold licenses issued by the Nuclear Regulatory Commission (NRC or Commission) authorizing possession of nuclear power plants in accordance with the Atomic Energy Act of 1954 and Code of Federal Regulations Title 10 (10 CFR) part 50. Commission regulations at 10 CFR 50.54(p)(1) require these licensee to maintain safeguards contingency plan procedures in accordance with 10 CFR part 73, Appendix C. Specific safeguards requirements are contained in 10 CFR 73.55.

II. On September 11, 2001, terrorists simultaneously attacked targets in New York, N.Y., and Washington, DC, utilizing large commercial aircraft as weapons. In response to the attacks and intelligence information subsequently obtained, the Commission issued a number of Safeguards and Threat Advisories to its licensees in order to strengthen licensees' capabilities and readiness to respond to a potential attack on a nuclear facility. The Commission has also communicated with other Federal, State, and local government agencies and industry representatives to assess the adequacy of security measures at licensed facilities. In addition, the Commission conducted a comprehensive review of its safeguards and security programs and requirements.

As a result of its initial consideration of current safeguards and security requirements and the Order issued on May 23, 2002, as well as a review of information provided by the intelligence community, the Commission has determined that certain additional security measures are required to address the current threat environment. Therefore, the Commission is imposing requirements, as set forth in Attachment 1¹ of this Order, on all decommissioning power reactor licensees with spent fuel in the spent fuel pool. These requirements, which supplement existing regulatory requirements, provide the Commission with reasonable assurance that the public health and safety, and common defense and security continue to be

¹ Attachment 1 contains SAGEGUARDS information and will not be released to the public.

adequately protected in the current threat environment. These requirements will remain in effect until the Commission determines otherwise.

The Commission recognizes that licensees may have already initiated many of the measures set forth in Attachment 1 to this Order in response to previously issued advisories, the May 2002 Order, or on their own. It also recognizes that some measures may not be possible or may need to be tailored to accommodate the specific circumstances existing at the licensee's facility to achieve the intended objectives and avoid any unforeseen effect on safety.

Although the additional security measures implemented by licensees in response to the Safeguards and Threat Advisories and the May 2002 Order have been adequate to provide reasonable assurance of adequate protection of public health and safety, the Commission concludes that these security measures must be supplemented further because the current threat environment continues to persist. Therefore, it is appropriate to require additional security measures and these measures must be embodied in an Order, consistent with the established regulatory framework. In order to provide assurance that licensees are implementing prudent measures to achieve a consistent level of protection to address the current threat environment, all licenses identified in Attachment 2 to this Order shall be modified to include the requirements identified in Attachment 1 to this Order. In addition, pursuant to 10 CFR 2.202, I find that in the circumstances described above, the public health, safety and interest require that this Order be immediately effective.

III. Accordingly, pursuant to Sections 103, 104, 161b, 161i, 161o, 182 and 186 of the Atomic Energy Act of 1954, as amended, and the Commission's regulations in 10 CFR 2.202 and 10 CFR parts 50 and 73, it is hereby ordered, effective immediately, that all licenses identified in Attachment 2 to this order are modified as follows:

A. All licensees shall, notwithstanding the provisions of any Commission regulation or license to the contrary, comply with the requirements described in Attachment 1 to this Order except to the extent that a more stringent requirement is set forth in the licensee's security plan. The licensees shall immediately start implementation of the requirements in Attachment 1 to the Order and shall complete implementation no later than 180 days from the date of this Order with the exception of additional security

SUMMARY MINUTES FOR THE MEETING OF THE ADVISORY COMMITTEE ON THE
MEDICAL USES OF ISOTOPES
March 1-2, 2004

The Advisory Committee on the Medical Uses of Isotopes (ACMUI) held its semiannual meeting at the U.S. Nuclear Regulatory Commission (NRC) Headquarters in Rockville, Maryland, on March 1-2, 2004.

The ACMUI members present at the March 1 meeting were:

Manuel Cerqueira, MD	Nuclear cardiologist, ACMUI Chairman
Douglas F. Eggli, MD	Nuclear medicine physician
Nekita Hobson	Patients' rights advocate
Ralph P. Lieto	Medical physicist
Leon S. Malmud, MD	Healthcare administrator
Ruth E. McBurney	State representative
Subir Nag, MD	Radiation oncologist
Sally W. Schwarz, RPh	Nuclear pharmacist
Orhan Suleiman, PhD	Food and Drug Administration (FDA) representative
Richard J. Vetter, PhD	Radiation safety officer
Jeffrey F. Williamson, PhD	Radiation therapy physicist

ACMUI member absent:

David A. Diamond, MD	Radiation oncologist
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Staff from the Office of Nuclear Material Safety and Safeguards (NMSS); Division of Industrial and Medical Nuclear Safety (IMNS); Material Safety and Inspection Branch (MSIB), and the Rulemaking and Guidance Branch (RGB) participated in the meeting. Staff from the Office of Nuclear Security and Incident Response (NSIR) and the Office of the General Counsel (OGC) also participated. Specific participating staff members are listed below:

Roger W. Broseus, PhD	NMSS/IMNS/RGB
Thomas H. Essig	NMSS/IMNS/MSIB, Designated Federal Officer
Patricia K. Holahan, PhD	NMSS/IMNS
Michael Layton	NSIR
Charles L. Miller, PhD	NMSS/IMNS
Trip Rothschild	OGC
Angela R. Williamson	NMSS/IMNS/MSIB

Also present were:

Andrew Kang	Food and Drug Administration
Raymond Horn	Nucletron Corporation
James Goetz	St. Luke's Hospital, Bethlehem, Pennsylvania
Richard Fejka	Food and Drug Administration
Lynne Fairobent	American College of Radiology
James Boxall	American College of Cardiology

William D. Nelligan	Certification Board of Nuclear Cardiology
Gerald A. White	American Association of Physicists in Medicine
Lisa Dimmick	
John Coats	
Howard Griffith	
Roshunda Drummond	American Society of Therapeutic Radiology and Oncology

The meeting came to order at 10:22 a.m.

OPENING REMARKS

Thomas H. Essig, Designated Federal Officer, introduced each ACMUI member and presented certificates of appreciation to Ruth E. McBurney, State government representative, and Nekita Hobson, Patient advocate. Ms. McBurney's and Ms. Hobson's terms on the committee end after the March 2004 meeting.

DOSE RECONSTRUCTION SUBCOMMITTEE FINDINGS IN THE ST. JOSEPH MERCY HOSPITAL CASE

Jeffrey F. Williamson, PhD, gave a presentation on this topic.

Remarks: Dr. Williamson gave this presentation in response to a Commission request that the ACMUI review the staff's method of dose reconstruction. The Commission requested this activity in response to the Society of Nuclear Medicine's (SNM) assertions that the NRC uses excessively conservative methods to reconstruct doses in instances when overdoses have occurred. The particular event that triggered the SNM's assertions is the St. Joseph Mercy Hospital event, whereby a member of the public received excessive radiation exposure while caring for her dying mother. In response to the Commission request, the ACMUI formed a Dose Reconstruction Subcommittee, chaired by Dr. Leon S. Malmud. Dr. Williamson is a member.

As Dr. Williamson began reporting on his findings, he informed everyone that the findings were not fully reviewed by the other subcommittee members. Therefore, these findings were actually his independent views.

Dr. Williamson then gave an overview of his understanding of the particulars of the event. He also noted some of SNM's general assertions regarding what they believed were shortcomings in the NRC's approach to dose reconstruction. These assertions include:

- An unrealistic estimate of the daughter arm-to-patient center distance;
- The Iodine-131 source was not allowed to decay continuously;
- The total effective dose equivalent is an inappropriate endpoint for risk assessment;
- Tissue attenuation in the daughter should have been considered.

Dr. Williamson stated that he performed a Monte Carlo assessment of the dose the daughter may have received. He concluded that NRC's dose estimate to the daughter did seem a bit conservative. Nevertheless, a less conservative estimate would not have changed the outcome: that the daughter received a dose many times higher than the regulatory limit, which

is true even if the most liberal methods to assess her dose were applied. While Dr. Williamson agreed that the daughter was excessively exposed, he believed that a more "sophisticated" assessment of dose would "enhance the (NRC's) scientific credibility of future dose calculations."

After asking Dr. Williamson to clarify several points, the ACMUI expressed concern over possible overestimation of doses in cases where an overestimation may cause unnecessary patient notification, and/or excessive regulatory response. Nonetheless, the ACMUI acknowledged that the subcommittee needs more time so that it may thoroughly assess the NRC's method of dose reconstruction, and come to better defined conclusions. Charles Miller, NRC, suggested that the ACMUI delay reporting any findings to the Commission until such re-assessment is completed.

This discussion begins on Page 8 of the meeting transcript.

STATUS OF RULEMAKING

Roger Broseus, NRC, presented information on this topic.

Dr. Broseus explained that he would use this time to provide an overview of public comments that have been received to date, regarding the proposed 10 CFR Part 35, Medical Use of Byproduct Material. The official comment period ended February 23. At that date, NRC received approximately 15 letters and e-mails. By February 27, NRC had received a total of 25 public comments. Dr. Broseus noted that these comments can be viewed at the NRC website.

Dr. Broseus reminded the ACMUI that the Federal Register notice that announced the proposed rule posed three questions to the public. They were

1. Do the proposed changes adequately cover safety?
2. Should the Agreement States establish requirements in their rules by October 24, 2005, or should they be given three full years to develop compatible rules?
3. Regarding the preceptor's role in verifying the adequacy of training, should the word "attestation" or "attest" be used in place of "certification"?

Dr. Broseus explained that, of the initial 15 comments, five supported the proposed rule. Other comments made included the belief that preceptors should not be required to attest that a candidate passed a board certification. This comment was made in response to the language in 35.390(c), which can be interpreted to mean that preceptors must attest that a candidate took a board exam and passed it. However, several commenters agreed that preceptors should be required to attest that a candidate is able to adequately function as an authorized user (AU), but should not be required to "certify" that a person is competent.

Regarding the certification boards, Dr. Broseus explained the boards believed that if the new rule is made effective immediately after the expiration of Subpart J in the current rule, they will not have enough time to submit applications for recognition for NRC staff evaluation. Therefore, these boards suggest that staff allow them a grace period to apply for recognition.

One commenter suggested that radiation oncologists be exempt from the proposed training and experience (T&E) requirements in 35.390(b)(1)(ii).

Dr. Broseus then briefly overviewed comments submitted by the Agreement States. These include:

- ▶ A request for three full years to adopt any final rules;
- ▶ The NRC should specify the precise number of hours of training AUs must obtain to fulfill the requirements of 35.190, 35.290, and 35.390, so that there is an assurance of compatibility between the Agreement States and NRC in this area;
- ▶ The NRC should clarify the definitions in 35.2;
- ▶ Support for retention of the preceptor function;
- ▶ General support for the concept of requiring those who passed boards to independently obtain preceptor attestation, rather than requiring boards to ensure they have obtained attestation.

Next, Dr. Broseus reminded the ACMUI that staff had previously drafted some revised Part 35 implementation guidance that it passed to the ACMUI and the Agreement States for comment. Staff received ACMUI comments on December 15, and a few Agreement State comments as well. The ACMUI consensus position was the NRC does not understand clearly the purpose and process of board certification procedures and requirements. Furthermore the ACMUI believes the draft implementation guidance included redundant requirements (e.g., "boards must declare that candidates complete T&E to sit for an examination"). The ACMUI also believed that it is inappropriate for the NRC to examine board processes, such as reviewing examinations and grading procedures. Other ACMUI comments included:

- ▶ Why should certification boards be required to renew their certifying processes every 5 years, as proposed, when boards' certifying programs are static?
- ▶ NRC should individually address those boards who do not apply for recognition. NRC should not automatically refuse recognition of any board that did not respond to the NRC's written request that the board apply for recognition.
- ▶ NRC should invest time to interact with boards so as to better understand board processes. This may be accomplished via public workshops, for example.

Dr. Broseus stated that the Agreement States' comments tended to echo those of the ACMUI. Specific to obtaining AU status, the Agreement States requested common performance indicators to evaluate the training programs of board pathway to obtaining AU status, and to evaluate the alternate pathway to obtaining AU status.

Dr. Broseus then stated planned future actions, but stipulated that what was being presented is subject to adjustment. Dr. Broseus stated that staff will continue to compile and analyze comments, after which a final draft rule will be prepared. This final draft will be presented to the ACMUI and the Agreement States simultaneously. Staff will then forward ACMUI and Agreement State comments and present them to the Commission. Once comments are reconciled, they will be published in the Federal Register. Staff plans to publish these comments by the end of October, 2004, and post the revised board certification implementation procedures on the NRC web site in September, 2004. In closing, Dr. Broseus re-emphasized the staff's objectives - to publish supplementary information in the Federal Register that clearly

explains the rationale for the revised T&E rule and also addresses everyone's comments; to provide a clear basis for the rule change, and to have the rule in place before the expiration of Subpart J in the current 10 CFR Part 35.

The ACMUI asked a couple of clarifying questions, made a few additional comments, but offered no recommendations.

This discussion begins on Page 47 of the meeting transcript.

EMERGING TECHNOLOGY SUBCOMMITTEE DISCUSSION ON MISSION AND MEETING PROCEDURES

The Emerging Technology Subcommittee, chaired by Ruth McBurney, presented information on this topic to the ACMUI.

Ms. McBurney began by reminding everyone that the NRC staff sent the draft Seedselectron licensing guidance to the Subcommittee in December (2003) for review.

One committee member made a general statement about the nature of reviewing newer devices. He stated his belief that, because of the extreme technical nature of newer devices such as the Seedselectron, the ACMUI must be able to meet more often, via teleconference if necessary, to discuss these devices and provide effective advice to the NRC on how to best license them. He further noted that in order to be able to fully appreciate the capabilities of the Seedselectron, he had to make a site visit to the manufacturer.

This member further suggested that NRC staff form working groups when necessary, to review any draft guidance associated with these newer devices whose use is not regulated adequately under existing regulations. He believed that working groups will improve the accuracy of such guidance, as well as help in developing the guidance more quickly.

Ms. Burney then stated, that, in harmony with the working group idea just mentioned, she is part of the National Materials Program (NMP) pilot project working group, looking to establish priorities of regulatory needs. As part of that effort, the NMP is recommending that centers of expertise be identified, that alternate resources be identified, and that outside expertise be brought in when necessary.

A member of the public, Lynne Fairbent, stated that bringing in outside expertise is consistent with how NRC's other advisory committees, the Advisory Committee on Reactor Safeguards and the Advisory Committee on Nuclear Waste (ACRS/ACNW) operate. She believed that in this effort of providing recommendations on newer technologies, the ACMUI could benefit from following their example.

The ACMUI Chair, Dr. Cerqueira, then asked NRC staff for its position regarding the ACMUI's soliciting assistance from professional medical societies, in light of potential conflicts of interest (since many ACMUI members also serve on professional societies) and budget concerns. Thomas Essig, NRC, stated that ACMUI would have the same privilege as do ACRS and ACNW, with respect to solicitation of outside help, but that any such privilege is constrained by the ACMUI budget. (Any conflict of interest issues will be addressed as they emerge).

Since Ms. McBurney is rotating off the committee, it was suggested that Dr. Vetter replace her as the Emerging Technology Subcommittee Chair. Dr. Vetter agreed.

This discussion begins on Page 67 of the meeting transcript.

EMERGING TECHNOLOGY SUBCOMMITTEE DISCUSSION ON SEEDSELECTRON LICENSING GUIDANCE

Donna-Beth Howe, NRC discussed this subject with the ACMUI.

The ACMUI mentioned that a stakeholder, Nucletron Corporation, submitted a letter to them with concerns about how the NRC will license the Seedselectron device at St. Luke's hospital. Dr. Howe addressed this letter, in part, by mentioning that NRC staff recently completed a technical assistance request (TAR) submitted to NRC Headquarters by Region I, on behalf of St. Luke's Hospital. The Region requested assistance in licensing the SeedSelectron device for St. Luke. She stated that the TAR response addressed some of the concerns in Nucletron's letter. Dr. Howe further mentioned that staff recently put the SeedSelectron licensing guidance on the NRC website. Dr. Howe informed everyone that the SeedSelectron guidance should be considered a living document, subject to amending as necessary.

After the ACMUI and the NRC staff briefly discussed logistical issues associated with inviting vendors of new devices to brief the ACMUI, Dr. Jeffrey Williamson gave an summary of Nucletron's demonstration of its Seedselectron device to him.

Dr. Williamson explained that the SeedSelectron is basically an enhanced manual brachytherapy device. The primary method by which it delivers sources (to a position within the patient) is by automatic positioning of the needles, which are guided by a template. This is similar to manual brachytherapy, which uses a template to position the needles, but the positioning is done manually. Dr. Williamson mentioned that the version of the Seedselectron licensing guidance in his possession contains provisions that would (unnecessarily) burden users of the Seedselectron. An example he gave was the guidance's proposal for modifying the written directive. Staff believes that the written directive, as currently defined, may not be adequate for permanent seed implants. Although this may be true, according to Dr. Williamson, staff should not attempt to address this issue in the licensing guidance. In response, Dr. Howe replied that she had already removed the references to the written directive.

However, there were other issues associated with this guidance, according to Dr. Williamson. One was verifying the needle position. Dr. Williamson does not believe that using the SeedSelectron always mandates special precautions to verify needle positions. He believes that verifying needle positions is supportable only when using the Seedselectron's treatment planning system.

In response, Dr. Howe stated that this proposal was added to ensure the administration was performed in accordance with the written directive. However, the staff tried to stress that it was put into the notes to licensees. This section provides guidance the licensee should consider, but are neither requirements the licensee must implement nor information the licensee must provide to NRC. Even so, Dr. Williamson believed that including this language may give

licensees the impression that using the Seedselectron carries with it excessive regulatory burden (another ACMUI member agreed). Dr. Williamson went on to suggest his belief that the guidance should be crafted in such a way that there is a reasonable protocol for daily and quarterly quality assurance, to verify that seeds are inserted properly into needles. If staff has broader concerns about permanent seed implants, he suggests staff notify the public via using normal Agency processes, such as Information Notices, that do not name specific vendor products.

Dr. Williamson also mentioned the FIRST system (Fully Integrated Real-time Seed Treatment) , (This integrated system allows the physician to plan the treatment, image the treatment, and adjust the treatment in real time). Although Dr. Williamson believed that much of the guidance is appropriate, he stated that the staff's requirement regarding the positive confirmation of seed location cannot be implemented because quantitative localization of seeds in ultrasound images is not yet possible. This is an active area of research, according to Dr. Williamson. He suggested that staff remove that requirement from the guidance.

Finally, Dr. Williamson made comments regarding high-dose rate brachytherapy. He stated that 35.600 requires a series of tests to be performed daily, quarterly, and annually, to give licensees reasonable assurance that radioactive seeds are placed in the desired location within patients. Dr. Williamson said there is no reason to depart from this paradigm in guidance space. Dr. Howe agreed with Dr. Williamson's earlier points on confirmation of seed location, and had already modified the guidance to focus on initial visualization of the needle placement. She stated that crafting this guidance is in its developmental stage, and so it is subject to updates. She also confirmed that she expects comments on the "living document" and will be working with Dr. Williamson and the subcommittee to improve the guidance.

One ACMUI member suggested that, as staff develops guidance, it does so for system components rather than for any particular vendor's radioactive seeds. This would give the guidance broader applicability.

Dr. Williamson and staff then agreed that the Emerging Technology Subcommittee should undertake a detailed review of the existing version of the Seedselectron guidance and forward its views to NRC staff.

ACTION ITEM

The Emerging Technology Subcommittee will undertake a detailed review of the existing version of the Seedselectron guidance and forward its views to NRC staff.

Next, a Nucletron representative, Raymond Horn, spoke to the ACMUI. He stated that he was "enheartened" by the discussion on how to improve the Seedselectron guidance. However, he feels strongly that the pending guidance be reviewed. Mr. Horn also urged staff to amend St. Luke Hospital's license using current guidance, so they can begin using their Seedselectron device. He stated that St. Luke is willing to amend its license again if the guidance changes substantially. In further support of a quick amendment, Dr. Goetz, Director of the Cancer Center at St. Luke's Hospital, informed the ACMUI and the NRC staff that, in the past 6 months, St. Luke's has had to refer upwards of 15 individuals to outside locations, creating

inconvenience and potentially affecting quality of care. The ACMUI agreed that staff should license St. Luke's Seedselectron expeditiously.

This discussion begins on Page 83 of the meeting transcript.

REMOVING MODALITIES OUT OF PT. 35.1000

Donna-Beth Howe, NRC, led the discussion on this agenda topic.

Dr. Howe began by stating that to move modalities out of 10 CFR 35.1000, staff must undertake rulemaking. There are no other options.

There are two ways to initiate rulemaking: 1) staff initiates rulemaking, or 2) stakeholders initiate rulemaking via a 2.202 rulemaking petition. The question NRC wrestles with is "At what point in time is it appropriate to move modalities out of 10 CFR 35.1000?" In this case, calendar time is not the driving factor that answers this question. Rather, the following is considered: 1) the cost-effectiveness of rulemaking, and 2) whether NRC has enough licensees seeking the technology to justify rulemaking. Regarding the 2nd point, it is not cost effective to initiate rulemaking for a technology that only a few licensees are using, regardless of how advanced that technology may be. Further points staff must consider are:

- ✓ How clear and well-established the guidance is.
- ✓ If the staff creates rules in instances when the licensed community has little experience with the technology, then more rulemaking will be required, if modifications are needed.

Thus, for technologies that have not been widely used, it is better to leave them in §35.1000 and create web site guidance, which can be easily modified when necessary.

Dr. Howe expanded on things the staff looks for when determining a technology is not new and our guidance can be codified into regulation. These include:

- ▶ The guidance on the rule has stabilized.
- ▶ NRC has sufficient experience licensing the technology.
- ▶ NRC has sufficient experience inspecting the technology.
- ▶ There is adequate medical event experience.
- ▶ Licensees and other stakeholders have good medical use experience with the technology.

Dr. Howe then explained that, in relation to inspection experience, staff recently developed a new program code. This program code drives the frequency for NRC inspection of therapy-emerging technologies. Only those devices that staff believes should be placed into that program code are put there. Any licensee who has a device in that code will receive an inspection within 12 months of the license being issued for that device. Thereafter, the licensee will be inspected every 2 years. If inspection and use experience reveals that the device does not need to be categorized under that code, staff will remove that device from the code. The licensee will then be inspected according to its normal inspection schedule.

Dr. Howe then reiterated staff's preference for leaving newer technologies in §35.1000 and issuing regulatory guidance: it is much easier and simpler to adjust the regulatory environment

by updating the guidance as both staff and licensees gain insights and experience with the newer devices.

After complimenting Dr. Howe on a nice summary of this situation, an ACMUI member commented that there appears to be several advantages to leaving newer technologies in §35.1000. He wanted to know why anyone would want to remove newer technologies out of §35.1000. Another member responded that devices that are moved into regulation are given considerable public scrutiny and comment, therefore, there is an opportunity for the regulated community to have input into how the device will be regulated. Furthermore, Lynne Fairbent, representing the American College of Radiology, added two more reasons: 1) that NRC stated, and it was clearly understood by the public, that newer devices would be promptly removed from §35.1000, and 2) as long as devices remain in §35.1000, licensees who want to use those devices must apply for a license amendment, unless the license is a broad scope license. Thus, when devices are removed from §35.1000 into a permanent regulatory section, licensees do not need to apply for amendments.

Another issue with leaving devices in §35.1000 had to do with guidance. An ACMUI member stated that as guidance changes, licensees are not necessarily aware of the changes. Dr. Howe responded that licensees are held only to the commitments they made when they applied for a license amendment; they are not held to guidance that is later amended. However, staff received the point that staff may need to be more active in making licensees aware of changes to the guidance.

Everyone agreed that leaving newer technologies in §35.1000 is not necessarily inappropriate. The question was what is the appropriate length of time a device should remain in §35.1000, and "regulated" by guidance? With that question in mind, Lynne Fairbent believed that intravascular brachytherapy (IVB), having been in §35.1000 for three years, should be moved out of §35.1000 into a permanent regulatory section. An ACMUI member agreed.

Dr. Howe responded to this perceived need for urgent IVB rulemaking by pointing out that last year, it appeared that drug-coated stents would replace IVB use, and, in fact, one manufacturer ceased making IVB sources. While it is true that the new drug-coated stents caused a sharp decrease in the use of IVB, there have been problems with the new stents. Until this environment stabilizes, and IVB appears to be permanent, IVB should remain in §35.1000.

There was more discussion about the general climate of IVB, but ACMUI made no recommendations on this subject.

This discussion begins on Page 121 of the meeting transcript.

DEFINING MEDICAL EVENTS INVOLVING PROSTATE SEED IMPLANTS

Ronald E. Zelac, NRC, presented this topic to the ACMUI.

As Dr. Zelac began, he explained that staff does not really expect a resolution for this topic. It is being presented for the committee's information, and staff hoped to use this meeting to gather from the ACMUI some additional information that might be helpful.

Staff is having difficulty defining "medical event," as the term applies to permanent seed implants in the prostate. The regulation in 10 CFR Part 35.3045 defines medical event, in part, as a deviation from the prescribed dose by more than 50 rem to an organ or tissue; and a total dose that deviates from the prescribed dose by 20 percent or more. Regarding prostate seed implants, the ACMUI recommended, at its November 2003 meeting, to use D90 as the criterion to determine when a medical event occurred. ("D90" refers to 90 percent of the target organ receiving the prescribed dose. A medical event has occurred if there is an unacceptable percentage of dose that was delivered to 90 percent of the target organ).

Dr. Zelac explained that D90 is acceptable for defining under dosing. For a D90 that is less than 80 percent, it is clear a medical event occurred (i.e., if 90 percent of the organ receives less than 80 percent of the dose, a medical under dosing event has occurred). However, D90 does not work as well for determining whether an overdose occurred. In overdoses, a D90 that is greater than 120 percent meets the definition of a medical event; however, in many standard treatments, it is desirable to have a dose that exceeds 120 percent. Further compounding this issue is that in standard treatments, a significant portion of the target organ may receive a dose exceeding 200 percent of the prescribed dose. Dr. Zelac then asked the ACMUI to answer two questions regarding the standard practice of prostate implant doses: Are D90s that exceed 120 percent standard practice? Are D90s that exceed 200 percent standard practice?

The ACMUI responded that there is not a simple answer to these questions. Factors such as the volume of the target organ and characteristics of the tumor will determine if a medical event has occurred. Other factors mentioned are the limitations of computed tomography (CT), used to image the organ during treatment planning, and each institution's individual protocol regarding when to image the organ. With respect to CT, it does not produce images as clear as those that can be produced with ultrasound or magnetic resonance imaging. The use of CT, therefore, makes it difficult to determine the treatment volume within the target organ. With respect to post treatment planning imaging, some institutions image the organ the day of the treatment, some image it the day after treatment. Because maximum organ edema can occur the day after, this will affect the dose distribution within the organ.

This member suggested that, to determine when a medical overdose occurs, that the NRC err on the side of generosity to collect gross errors. Otherwise, the NRC will wind up including many events simply because of variations in clinical practice. The ACMUI stated that, for this particular procedure, the determination of a medical event should be based upon excessive dose to normal tissue, not excessive dose to the tumorous tissue.

There was much discussion regarding the clinical difficulties surrounding this issue. Finally, Dr. Zelac surmised that a way to approach defining a medical event for this modality would be to craft the written directive to state the number of seeds to be used and the total seed strength and exposure time desired, then the using those factors, determine the desired dose equivalent to the target organ. To determine if a medical event occurred, apply the existing rule criteria to dose equivalent rather than to dose. The ACMUI agreed with this approach, and Dr. Zelac thanked them for providing insight into the challenges surrounding this modality.

This discussion begins on Page 141 of the meeting transcript.

UPDATE: RECOMMENDATIONS FROM THE FALL 2003 MEETING

Angela R. Williamson, NRC, gave the ACMUI an update on this subject.

Ms. Williamson stated that the ACMUI gave the staff only one recommendation, and it was in response to an issue the staff brought before the committee. The issue was whether the staff should impose a threshold of dose for the treatment of hyperthyroidism, in response to licensee requests to use any activity of radioiodine they requested to use. The ACMUI recommended that the NRC staff allow licensees to use the activity they believed was necessary to treat their patients, and the NRC staff agreed with that recommendation.

The ACMUI and the NRC staff then launched into a general discussion about the ACMUI's March 2, 2004, briefing to the Commission. The ACMUI ended that discussion with no recommendations to the staff.

This discussion begins on Page 179 of the meeting transcript.

The meeting adjourned at 4.33 p.m.

The Advisory Committee on the Medical Uses of Isotopes (ACMUI) held its semiannual meeting at the U.S. Nuclear Regulatory Commission (NRC) Headquarters in Rockville, Maryland, on March 1-2, 2004.

The ACMUI members present at the March 1 meeting were:

Manuel Cerqueira, MD	Nuclear cardiologist, ACMUI Chairman
Douglas F. Eggli, MD	Nuclear medicine physician
Nekita Hobson	Patients' rights advocate
Ralph P. Lieto	Medical physicist
Leon S. Malmud, MD	Healthcare administrator
Ruth E. McBurney	State representative
Subir Nag, MD	Radiation oncologist
Sally W. Schwarz, RPh	Nuclear pharmacist
Orhan Suleiman, PhD	Food and Drug Administration (FDA) representative
Richard J. Vetter, PhD	Radiation safety officer
Jeffrey F. Williamson, PhD	Radiation therapy physicist

ACMUI member absent:

David A. Diamond, MD	Radiation oncologist
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Staff from the Office of Nuclear Material Safety and Safeguards (NMSS); Division of Industrial and Medical Nuclear Safety (IMNS); Material Safety and Inspection Branch (MSIB), and the Rulemaking and Guidance Branch (RGB) participated in the meeting. Staff from the Office of Nuclear Security and Incident Response (NSIR) and the Office of the General Counsel (OGC) also participated. Specific participating staff members are listed below:

Roger W. Broseus, PhD	NMSS/IMNS/RGB
Thomas H. Essig	NMSS/IMNS/MSIB, Designated Federal Officer
Patricia K. Holahan, PhD	NMSS/IMNS
Charles L. Miller, PhD	NMSS/IMNS
Angela R. Williamson	NMSS/IMNS/MSIB
Ronald E. Zelac, PhD	NMSS/IMNS/MSIB

Also present were:

Lynne Fairobent	American College of Radiology
James Boxall	American College of Cardiology
William D. Nelligan	Certification Board of Nuclear Cardiology
Gerald A. White	American Association of Physicists in Medicine
Roshunda Drummond	American Society of Therapeutic Radiology and Oncology

The meeting came to order at 8:05 a.m.

PREPARATION FOR THE COMMISSION BRIEFING

The ACMUI began by discussing Ralph Lieto's briefing to the Commission, "Proposed Rulemaking on Pt. 35 Revision." Mr. Lieto stated his intent to bring three ongoing issues to the Commission, Pt. 35 revision on proposed rulemaking: the obtaining of board certification and the regulated community's belief that it attests to the understanding of a body of knowledge, rather than determining competency; the issue of preceptor statements and the use of the term "attestation" as opposed to "certification"; and transitional issues associated with the proposed rule.

The ACMUI then discussed the particulars of each topic, to help Mr. Lieto fine tune his discussion points.

Next, Thomas Essig, NRC, discussed his presentation, "NRC Method of Dose Reconstruction." (During the March 1, 2004, ACMUI public meeting, Charles Miller clarified that the staff would not launch into a technical discussion of the dose reconstruction issue, since it is still a work in progress. Rather, Mr. Essig would provide an overview of the status of this effort.)

In this overview, Mr. Essig explained that he intended to tell the Commission that staff plans to use the ACMUI's evaluation of the NRC method of dose reconstruction, combined with the NRC's self-assessment of its dose reconstruction method, to respond to the Society of Nuclear Medicine/American College of Nuclear Physician's criticism that the NRC uses excessively conservative methods to reconstruct doses.

Dr. Malmud then briefly discussed what he planned to say to the Commission, as the Chairman of the ACMUI Subcommittee that is reviewing the NRC's method of dose reconstruction.

This discussion begins on Page 4 of the meeting transcript.

PROPOSED CHANGES TO ABNORMAL OCCURRENCE CRITERIA

Angela R. Williamson briefed the ACMUI on this topic.

Ms. Williamson began by clarifying that changes to the abnormal occurrence (AO) criteria are within the authority of NRC's Office of Nuclear Regulatory Research (RES). The staff at this time welcomes any recommendations that the ACMUI may have regarding changes to the criteria, but final decisions regarding whether the criteria will be changed is within the purview of RES.

Next, Ms. Williamson defined AO: "an unscheduled incident or event which the NRC determines to be significant from the standpoint of public health and safety." Then Ms. Williamson explained that the staff is considering adding language to the current criteria which would enable staff to capture events of a certain threshold that involve intravascular brachytherapy (IVB).

At this point, an ACMUI member asked Ms. Williamson to explain the purpose of the AO report to Congress. Ms. Williamson explained that the report, as far as can be established, is for their information. It is unclear if they use the report in any manner.

Ms. Williamson then briefly outlined the proposed change. The proposed change is to add, to the medical event criteria the phrase "or to tissue, which results in permanent functional damage." Ms. Williamson explained that this addition should capture only those IVB events, for reporting as AOs, where serious potential harm was done to the patient, but would exclude IVB events where the serious potential harm does not exist.

The ACMUI suggested this language: "...or to a portion of an organ, or part of an organ, which results in permanent functional damage to the tissue."

After some ensuing discussion, the ACMUI made a recommendation:

Insert a 3rd condition into the AO criteria to read as follows: "3) equal to or greater than 10 Gray to any portion of an organ which results in permanent functional damage."

The ACMUI suggests the above recommendation, conditional upon the agreement of the committee's two radiation oncologists, Dr. David Diamond and Dr. Subir Nag. Dr. Diamond was not present for the meeting, and Dr. Nag left early to attend another engagement.

This discussion begins on Page 72 of the meeting transcript.

TRANSITION ISSUES ON PT. 35 IMPLEMENTATION

Mr. Ralph Lieto ACMUI, gave a briefing on this topic.

Mr. Lieto discussed issues revolving around the new training and experience (T&E) rule, to become effective October 2004.

Regarding the preceptor issue, Mr. Lieto stated his belief that the preceptor requirement in the revised rule should apply to those professionals who are entering training programs this year, and not to individuals currently in training programs. Roger Broseus, NRC, clarified that under the proposed rule, anyone certified by a board that NRC recognizes, must submit a preceptor statement. The combination of the board certification and the preceptor statement would thus qualify the person for recognition (as an Authorized User, Authorized Medical Physicist, etc.) Dr. Donna-Beth Howe clarified that the preceptor statement must affirm that the person is board certified, and must include a statement that the individual is competent to function independently as an AU, AMP, etc. Regarding the alternate training pathway, Dr. Broseus clarified that a preceptor statement is needed, but the individual will need to submit detailed documentation of the training that was taken.

The ACMUI acknowledged that the structure of the new rule - with its risk informed stature - would put a new burden on the stakeholder community to determine when it is prudent to act as a preceptor for an individual. However, as the ACMUI supported the new risk-informed stature, they acknowledged that this new burden was preferential to a prescriptive rule.

Regarding the diagnostic use of Iodine-131, Mr. Lieto explained the focus of the revised rule is based on isotope activity, so that certain diagnostic uses now require a written directive. This may result in some AUs needing to meet therapy-related application criteria, for which they may not have documented T&E. Dr. Howe clarified that NRC no longer regulates according to diagnostic versus therapy uses. NRC now regulates according to whether a written directive is required. Accordingly, the NRC will grandfather those AUs experienced in 10 CFR 35.200 uses, who, because of the revised regulatory structure, will not otherwise be authorized to use Iodine-131, for which a written directive is required. Grandfathering these experienced AUs who were using I-131 for diagnostic whole body scans, will therefore enable them to keep their authorization to practice under the revised rule.

The ACMUI made the following recommendation:

That licenses be amended so that current authorized users of sodium iodide-131, in activities greater than 30 microcuries, for imaging and localization studies, be granted authority to continue operating in this manner.

The ACMUI then discussed the issue of grandfathering AMPs. One ACMUI member mentioned that this issue seems to be pretty much limited to concerns in Agreement States in which AMP is not a defined item; therefore, physicists who acted as AMPs were not listed on licenses as such. She stated that she is unsure how any more comments from ACMUI will affect the final rule. Nevertheless, other members believed that it was necessary that the ACMUI make a motion to encourage staff to think about the necessity of grandfathering AMPs so that those practicing in Agreement States will be able to continue practicing should they move to a state regulated by the NRC.

The ACMUI made the following recommendation:

That the NRC consider alternative rule language and/or guidance procedures to ensure that physicists currently practicing in Agreement States as HDR physicists; intravascular brachytherapy physicists; or Cobalt-60 teletherapy physicists, be grandfathered as AMPs, regardless of whether they are named on an Agreement State or NRC license.

Next, an ACMUI member brought up a related grandfathering issue, this one concerning uses under 10 CFR 35.200. This member believed there is a need to ensure that future practitioners of localization and imaging are able to practice I-131 imaging using non-sodium iodide, after completing the normal training pathway for 35.200 uses.

Toward that end, the ACMUI made the following recommendation:

That the NRC staff amend the revised 10 CFR Part 35.200 to allow future 35.200 practitioners to use any desired form and activity of I-131 for imaging - with the exception of sodium iodide in excess of 30 microcuries - without additional training and experience.

With regard to diagnostic use of sodium iodide, the ACMUI made another motion to "convey the spirit" of the committee.

The ACMUI made the following recommendation:

That diagnostic use of sodium iodide, falling under 35.392 be included in the 700 hours of training for 10 CFR Part 200 uses, as long as use is limited to diagnostic imaging and localization, and the AU meets the specific experience requirements listed In 35.392.

Later, the ACMUI made a motion to amend the current definition of preceptor. The current definition is "an individual who provides or directs the training and experience required for an individual to become an AU, an AMP, an ANP, or an RSO." As illustrated graphically below, the ACMUI desires to remove the article "the" that is between the words "directs" and "training." In doing so, the ACMUI believes the rule will become more flexible by allowing multiple persons to act as preceptor for different modalities.

Thus, the ACMUI made a recommendation to redefine preceptor as follows:

"An individual who provides or directs the training and experience required for an individual to become an AU, an AMP, an ANP, or an RSO."

In the ensuing discussion, the ACMUI moved again to redefine preceptor, this time to

Thus, ACMUI moved to again redefine preceptor as follows. (The redline/strikeout indications are meant to demonstrate the suggested change.)

"An individual who provides, or directs the or verifies training and experience required for an individual to become an AU, an AMP, an ANP, or an RSO."

In this extensive and detailed discussion, one more item related to T&E was mentioned. An ACMUI member mentioned that, as is currently worded, §35.390 can be construed to mean that a physician with a residency in radiation therapy or nuclear medicine need not satisfy to the letter, all the requirements in paragraph B.1, which includes 700 hours of T&E and lists various technical duties. However, since neither of the ACMUI radiation oncology representatives were present, the committee could not get their input. The ACMUI therefore, decided to discuss this issue with the NRC staff in a teleconference, in which the ACMUI's oncologist representatives can participate.

This discussion begins on Page 104 of the meeting transcript.

PROPOSED CHANGES TO 10 CFR PART 35

Donna-Beth Howe, NRC, presented this topic to the ACMUI.

Dr. Howe began by reminding the ACMUI that at the November 2003 meeting, she had brought to the committee's attention, 10 issues related to 10 CFR Part 35 implementation. Staff believes these issues require rulemaking.

Since that time, staff has identified additional issues. Some are relatively minor, involving changes to the rule. Others are a bit more involved. Below is a summary of the recommended changes.

Section	Suggested Change	ACMUI Reaction
32.74(a)	Revise to add "transmission sources" to the text in 32.74(a)	A motion for approval to add "transmission sources."
32.74(a)	Revise to add "§35.1000" to the list of regulatory sections in §32.74(a).	A motion for approval to add "§35.1000" to the list of regulatory sections. ¹
35.12(d)	Revise to specifically include "Subpart M"	The ACMUI agreed with the idea conceptually, but withheld supporting the suggested revision until staff makes the intent of the changes more clear. ¹
35.12(d)	Revise to specifically include appropriate radiation safety requirements in Subparts D through H	Same as above.
35.41(b)(4)	Revise to add "§35.1000"	The ACMUI supported this suggestion.
36.610(d)	This section discusses the requirement for initial training. Revise to add a new section that discusses the need for vendor training, and distinguishes vendor training from initial training.	The ACMUI agreed with the idea conceptually, but withheld supporting the suggested revision until staff can verbalize the changes such that the licensee has the flexibility to require vendor training when the licensee believes doing so is necessary.
35.26	Revise to §35.26 to permit changes based upon the §35.1000 guidance posted to the NRC website.	The ACMUI supported this suggestion.

¹As Dr. Howe discussed these suggested changes with the ACMUI, Charles Miller, NRC, clarified that these changes were preliminary. Therefore, the staff was searching for ACMUI's conceptual agreement on these suggested changes, and not necessarily motions to approve specific wording. This motion, therefore, will not be carried into the record as a formal motion at this time.

Section	Suggested Change	ACMUI Reaction
35.2026	This is the section that describes the records a licensee must keep. Suggest revision to include a requirement that licensees keep a copy of the old and new procedures; and keep a copy of the appropriate 35.1000 guidance upon which the licensee is basing his or her changes.	The ACMUI supported this suggestion.

This presentation begins on Page 231 of the meeting transcript.

NEXT MEETING DATE, AGENDA TOPICS, MEETING SUMMARY

The ACMUI tentatively scheduled the Fall 2004 meeting for October 13-14. The ACMUI also scheduled two teleconference calls: March 22, 2004; and May 13, 2004, with May 20 as a back up date to the May 13 date. These dates were proposed to discuss issues related to T&E and the NRC's method of dose reconstruction.

This presentation begins on Page 260 of the meeting transcript.

The meeting adjourned at 5:08 p.m.

AGENDA TOPIC: SPRING 2004 SUM MINUTES/RECOM.

ACMUI RECOMMENDATION AND ACTION ITEM TABLE - FY04								
Date	Item Number	ACMUI Recommendation (R) ACMUI Action Item (AA) Staff Action Item (SA)			Name and Description of Recommendation or Action Item	Staff Accepted Recommen- dation? Y, N, N/A or Partially	Staff Disposition/ Response	Remarks/Follow-up/ CLOSED OUT
		R	A A	S A				
Nov 2003	2004- A01		X		<p>ACMUI COMMENTS ON STAFF'S DRAFT BOARD RECOGNITION PROCEDURES</p> <p>The ACMUI will forward the NRC staff its comments regarding the draft procedures staff is developing for board recognition by the middle of December, 2003</p>	N/A	ACMUI forwarded the comments via e-mail to NRC staff on 12-15-03.	<p>RGB staff will disposition the comments.</p> <p>Update Jan 2004: The proposed rule discussing the steps staff will take to address issues regarding board certification (e.g., "marginalization" of certification boards) was published in the <u>Federal Register</u> on Dec 9, 2003. See 68 FR 68549.</p> <p>CLOSED OUT</p>
Nov 2003	2004- A02			X	<p>REDLINE/STRIKEOUT VERSION OF T&E RULE LANGUAGE</p> <p>NRC staff will forward the ACMUI a recent redline/strikeout version of the original rule language the committee forwarded to staff, and the changes staff made, by the end of December 2003.</p>	N/A	Staff sent ACMUI the redline/ strikeout version on 12-16-03. Staff informed ACMUI to provide comments as directed in the <u>Federal Register</u> (68 FR 68549.)	CLOSED OUT
Nov 2003	2004- A03			X	<p>MORE CLEAR VERSION OF RSO RULE LANGUAGE</p> <p>Staff will forward the ACMUI a clearer version of the revised RSO rule language.</p>	N/A	Staff sent ACMUI the redline/ strikeout version on 12-16-03. Staff informed ACMUI to provide comments as directed in the <u>Federal Register</u> (68 FR 68549.) Note: this action item is basically identical to Action Item 2004-02A.	CLOSED OUT

Date	Item Number	ACMUI Recommendation (R) ACMUI Action Item (AA) Staff Action Item (SA)			Name and Description of Recommendation or Action Item	Staff Accepted Recommen- dation? Y, N, N/A or Partially	Staff Disposition/ Response	Remarks/Follow-up/ CLOSED OUT
		R	A A	S A				
Nov 2003	2004- A04			X	<p>DRAFT SEEDSELECTRON LICENSING GUIDANCE</p> <p>So that the ACMUI can recommended an appropriate level of T&E needed for the use of the seedSelectron® therapy system, staff will give the ACMUI's Emerging Technology Subcommittee a copy of specific medical events involving the seedSelectron®; plus a copy of the staff's draft seedSelectron® licensing guidance.</p>	N/A	<p>Sent documents via e-mail to ACMUI on Dec 8, 2003. Sent reminder e-mail on Jan 8, 2004. Staff requested that ACMUI either forward a date when they would like to hold a teleconference to discuss the documents, or forward their comments on the documents. Requested response by February 2, 2004.</p> <p>Sent March 2004 version via e-mail on June 9, 2004, with comments due by COB June 25, 2004.</p> <p>Sent July 2004 version via e-mail on July 26, 2004, with request for comments by COB 8-9-04.</p>	Final comments submitted on
Nov 2003	2004- R01	X			<p>RADIOIODINE ACTIVITY THRESHOLD FOR THE TREATMENT OF HYPERTHYROIDISM</p> <p>That the NRC allow those licensees, who were previously authorized to use I-131 to treat hyperthyroidism under the previous regulation, continue to use I-131 under the revised regulation in 35.392 and 35.394; provided that those licensees submit a written statement that contains at least three cases documenting that they have experience using greater than 33 millicuries. This statement need not be from a preceptor AU.</p>	Y	<p>Staff has accepted this recommendation as the professional advice of the ACMUI. Staff specifically solicited this recommendation from the ACMUI so that staff can respond to technical assistance request (TAR) number 133633, submitted to NRC Headquarters from the Region 1 office of the NRC. Staff has forwarded this recommendation to Region 1. TAR 133633 may be viewed in the Agencywide Documents and Administration System under accession number ML033570442.</p>	CLOSED OUT

Date	Item Number	ACMUI Recommendation (R) ACMUI Action Item (AA) Staff Action Item (SA)			Name and Description of Recommendation or Action Item	Staff Accepted Recommen- dation? Y, N, N/A or Partially	Staff Disposition/ Response	Remarks/Follow-up/ CLOSED OUT
		R	A A	S A				
Jan 2004	2004- A05		X		<p>SUBCOMMITTEE: EVALUATION OF DOSE RECONSTRUCTION</p> <p>On January 29, 2004, staff requested, under the direction of the Commission, to have the ACMUI perform an independent evaluation of the staff's reconstruction of the dose received by a member of the public who received the dose at St. Joseph Mercy Hosp in Ann Arbor Michigan. The ACMUI independent review is due to NRC staff on February 20. On March 2, 2004, the ACMUI subcommittee should be prepared to brief the Commission on the results of its independent evaluation.</p>	N/A		<p>Dr. Williamson, member of the dose reconstruction subcommittee, presented preliminary findings to the ACMUI and NRC staff during the March 1, 2004 ACMUI public meeting. The subcommittee will refine its findings and present them to the full committee on March 30, and will present its final report to staff on or about April 9, 2004.</p> <p>The ACMUI held a public teleconference on March 22, 2004 to discuss and vote on the DRS's final report. However, the DRS had not finalized its report. Staff scheduled another teleconf for April 8, 2004.</p> <p>On April 8, 2004, the ACMUI held a public teleconference to discuss the DRS's final report. However, the report was not finalized. Staff scheduled another teleconference for May 13.</p> <p>Staff received the DRS report on May 21, 2004. CLOSED OUT</p>
Mar 2004	2004- A06		X		<p>ACMUI INPUT ON CHEN AMP REQUEST</p> <p>J. Williamson and R. Lieto reviewed Hung-Cheng Chen's AMP request</p>	N/A		<p>Staff requests response by March 15, 2004.</p> <p>On March 18, Dr. Williamson requested an extension to review this case.</p> <p>On April 2, 2004, Dr. Williamson e-mailed staff a request for additional time to review this case.</p>

Date	Item Number	ACMUI Recommendation (R) ACMUI Action Item (AA) Staff Action Item (SA)			Name and Description of Recommendation or Action Item	Staff Accepted Recommen- dation? Y, N, N/A or Partially	Staff Disposition/ Response	Remarks/Follow-up/ CLOSED OUT
		R	A A	S A				
								On April 5, 2004, Dr. Williamson provided his input. Mr. Lieto had provided his input March 12. CLOSED OUT
Mar 2004	2004- R02	X			<p>AMENDING THE ABNORMAL OCCURRENCE CRITERIA FOR MEDICAL EVENTS</p> <p>That NRC staff insert a condition "3" into the AO criteria to read as follows: "3) equal to or greater than 10 gray to any portion of an organ which results in permanent functional damage."</p>		Update (4-13-04): Did not receive agreement with suggested language from both oncologists. Will bring this issue back to the attention of ACMUI at a later public meeting.	<p>ACMUI gave this recommendation with the proviso that it be submitted to the committee's 2 oncologists, who were not present when the recommendation was made.</p> <p>Staff e-mailed this recommendation to the ACMUI's 2 oncologists, Dr. Nag and Dr. Diamond on 3-31-04, with a due date of 4-7-04.</p> <p>Staff will re-address this issue at the Oct 2004 ACMUI public meeting.</p>

Date	Item Number	ACMUI Recommendation (R) ACMUI Action Item (AA) Staff Action Item (SA)			Name and Description of Recommendation or Action Item	Staff Accepted Recommen- dation? Y, N, N/A or Partially	Staff Disposition/ Response	Remarks/Follow-up/ CLOSED OUT
		R	A A	S A				
Mar 2004	2004- R03	X			<p>AMEND 10 CFR PART 35 LICENSES TO ALLOW FOR CONTINUED USE OF I-131</p> <p>That licenses be amended so that current authorized users of sodium iodide-131, in activities greater than 30 microcuries, for imaging and localization studies, be granted authority to continue operating in this manner.</p>	Y	<p>At the Nov 2003 meeting, under the agenda topic entitled RADIOIODINE ACTIVITY THRESHOLD FOR THE TREATMENT OF HYPERTHYROIDISM, NRC sought ACMUI advise about granting broad authorization to AUs requesting authority to use > 33mCi. ACMUI recommended that NRC grant this authority and NRC agreed with that recommendation.</p> <p>Additionally, staff is currently making necessary changes to licenses to ensure that current authorized users of sodium iodide-131, in activities greater than 30 microcuries, for imaging and localization studies, are granted authority to continue operating in this manner.</p> <p>Thus, the NRC staff has already addressed this issue. (See Item #2004-01R in this table).</p>	CLOSED OUT FROM NOV 2003 MEETING

Date	Item Number	ACMUI Recommendation (R) ACMUI Action Item (AA) Staff Action Item (SA)			Staff Accepted Recommen- dation?	Staff Disposition/ Response	Remarks/Follow-up/ CLOSED OUT
		R	A A	S A	Name and Description of Recommendation or Action Item		
Mar 2004	2004- R04	X			N	<p>Only those medical physicists currently on an NRC or Agreement State license may be grandfathered for the uses in which they are currently authorized. NRC recognition of medical physicists not on Agreement State licenses is outside of the authority of the NRC to implement, because placing users on Agreement State licenses is the purview of the Agreement States.</p> <p>Once the Agreement States adopt the revised 10 CFR Part 35 training and experience criteria, they will be required to add the various categories of authorized users to Agreement State licenses.</p>	CLOSED OUT
Mar 2004	2004- R05	X			N	<p>NRC staff believes applicants should pursue authorized user (AU) status under both 35.290 and 35.392 independently. Staff believes that prospective AUs need the full 700 hours of training and experience (T&E) for 35.290 uses; as well as the full 80 hours of T&E under 35.390 uses, where a written directive is required.</p>	CLOSED OUT

Date	Item Number	ACMUI Recommendation (R) ACMUI Action Item (AA) Staff Action Item (SA)			Name and Description of Recommendation or Action Item	Staff Accepted Recommen- dation? Y, N, N/A or Partially	Staff Disposition/ Response	Remarks/Follow-up/ CLOSED OUT
		R	A A	S A				
Mar 2004	2004- R06	X			<p>REDEFINING THE PRECEPTOR STATEMENT IN 10 CFR 35</p> <p><i>The redline/strikeout indications in the following text demonstrate how the ACMUI recommends the preceptor statement in Part 35 be redefined.</i></p> <p>An individual who provides, or directs the or verifies training and experience required for an individual to become an AU, an AMP, an ANP, or an RSO.</p>	N	This is a proposed change to the proposed rule. It was submitted as a formal public comment. It will be addressed through the formal rulemaking process.	CLOSED OUT
Mar 2004	2004- R07	X			<p>REDEFINING PARAGRAPH (B)(1) OF 35.390, TRAINING FOR USE OF UNSEALED BYPRODUCT MATERIAL FOR WHICH A WRITTEN DIRECTIVE IS REQUIRED</p> <p>That NRC staff re-define the training requirement in 35.390(b)(1), by removing the reference to 700 hours of training, and replacing with a requirement to successfully pass the board exam by the Accreditation Council for Graduate Medical Education in the areas of oncology, nuclear medicine, diagnostic radiology, or a program in a related medical specialty.</p>	N	This is a proposed change to the proposed rule. It was submitted as a formal public comment. It will be addressed through the formal rulemaking process.	This recommendation was made at the March 22, 2004 ACMUI teleconference. CLOSED OUT

Date	Item Number	ACMUI Recommendation (R) ACMUI Action Item (AA) Staff Action Item (SA)			Staff Accepted Recommendation? Y, N, N/A or Partially	Staff Disposition/ Response	Remarks/Follow-up/ CLOSED OUT
		R	A A	S A			
Mar 2004	2004-R08	X			N	This is a proposed change to the proposed rule. It was submitted as a formal public comment. It will be addressed through the formal rulemaking process.	This recommendation was made at the March 22, 2004 ACMUI teleconference. CLOSED OUT
Mar 2004	2004-R09	X			N	This is a proposed change to the proposed rule. It was submitted as a formal public comment. It will be addressed through the formal rulemaking process.	This recommendation was made at the March 22, 2004 ACMUI teleconference. CLOSED OUT
Mar 2004	2004-R10	X			N	This allowance is already in the current rule.	CLOSED OUT
May 24, 2004	2004-A07	X			N	Sent request on May 24 with request for response by June 14, 2004.	Mr. Lieto provided a response on June 14, 2004. CLOSED OUT

Date	Item Number	ACMUI Recommendation (R) ACMUI Action Item (AA) Staff Action Item (SA)			Name and Description of Recommendation or Action Item	Staff Accepted Recommen- dation? Y, N, N/A or Partially	Staff Disposition/ Response	Remarks/Follow-up/ CLOSED OUT
		R	A A	S A				
July 2004	2004- A08		X		SAFEGUARDS REVIEW OF DRAFT PROTECTIVE MEASURES AND GUIDANCE REGARDING CERTAIN IRRADIATOR LICENSEES AND OTHER EQUIPMENT	N/A	Sent request to ACMUI on 7-21-04 with due date of 7-30-04. Contact: Richard Turtill, NSIR.	ACMUI responded 7-30-04 to Richard Turtill CLOSED OUT
Aug 2004	2004- A09		X		REVIEW UNIV OF PITTSBURG REQUEST FOR EXEMPTION TO 35.615(f)(3) D. Diamond and S. Nag to review request.	N/A	Sent e-mail request to Drs. Nag and Diamond on 8-20-04, with request for response on 8-25-04.	Response received 8-20-04. CLOSED OUT

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