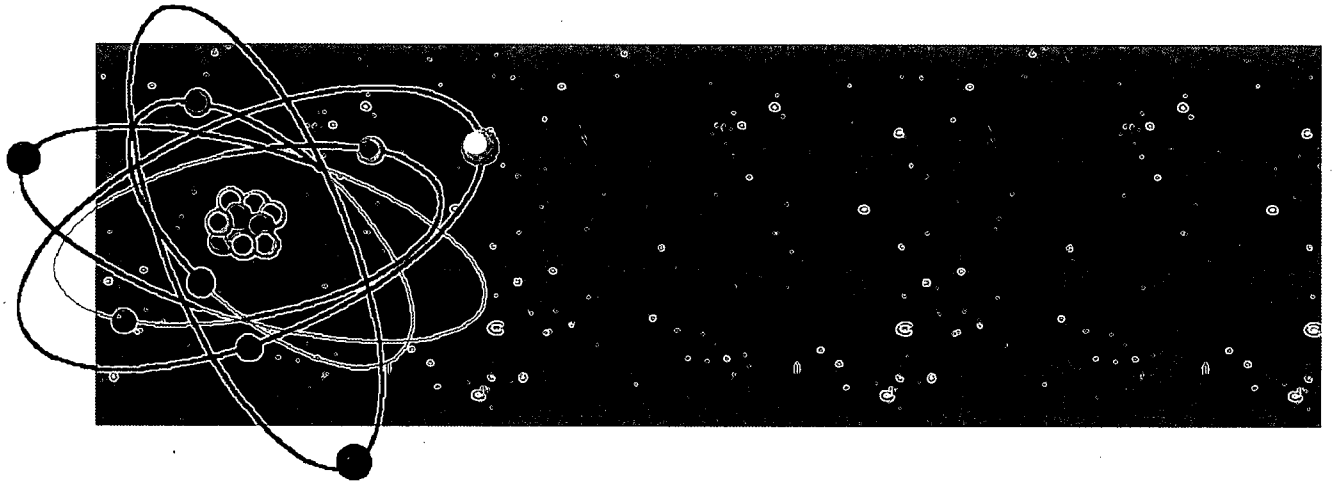

UNITED STATES NUCLEAR REGULATORY COMMISSION

ADVISORY COMMITTEE ON THE MEDICAL USES OF ISOTOPES

June 12-13, 2007
NRC Headquarters
Rockville, Maryland

ACMUI MEETING
SPEAKERS AND PARTICIPATING NRC STAFF
June 12-13, 2007

Armin Ansari, Ph.D. ..... CDC

Michele Burgess ..... NRC

Lydia Chang ..... NRC

Douglas Eggli, M.D. ..... ACMUI

Cindy Flannery ..... NRC

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

Luba Katz, Ph.D. ..... Abt Associates

Ralph Lieto ..... ACMUI

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

Andrew Mauer ..... NRC

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

Janet Schlueter ..... NRC/DMSSA Director

Orhan Suleiman, Ph.D. ..... ACMUI/FDA

Ashley Tull ..... NRC

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

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

Duane White ..... NRC

Ronald Zelac, Ph.D. ..... NRC

MEETING AGENDA

ADVISORY COMMITTEE ON THE MEDICAL USES OF ISOTOPES

June 12-13, 2007
Two White Flint North (T2-B3), Rockville, Maryland

Tuesday, June 12, 2007
OPEN SESSION

8:00 – 8:30	1.	**Opening** Ms. Wastler will formally open the meeting. Ms. Schlueter will present opening remarks.	**S. Wastler & J. Schlueter, NRC**
8:30 – 9:00	2.	**NARM Rule** Ms. Chang will update the Committee on the status of NARM rulemaking.	**L. Chang, NRC**
9:00 – 9:30	3.	**NARM Transition Plan** Mr. Mauer and Mr. White will update the Committee on the NARM transition plan.	**A. Mauer & D. White, NRC**
9:30 – 9:45		**BREAK**	
9:45 – 10:45	4.	**NARM Guidance** Dr. Howe and Mr. White will update the Committee on NARM guidance, NUREG 1556 Volumes 9, 13, and 21.	**DB. Howe & D. White, NRC**
10:45 – 11:30	5.	**Units of Air Kerma Strength (AKS) vs. Activity (mCi)** ACMUI members, NRC staff, and stakeholders will discuss issues regarding units for placement of orders for brachytherapy sources with manufacturers.	**TBD**
11:30 – 12:30		**LUNCH**	
12:30 – 12:45	6.	**Specialty Boards** Ms. Flannery will update the Committee on the approval status of specialty boards.	**C. Flannery, NRC**
12:45 – 2:45	7.	**T & E Implementation Issues** ACMUI members, specialty boards, representatives of professional societies, Agreement States, and NRC staff will discuss 10 CFR Part 35 training & experience implementation issues in the medical community.	**(Open)**
2:45 – 3:00		**BREAK**	
3:00 – 5:00	8.	**T & E Implementation Issues (Cont.)**	**(Open)**

Wednesday, June 13, 2007
OPEN SESSION

8:00 – 9:15	9.	**Potential Changes to 10 CFR Part 35** Dr. Howe will discuss potential changes to 10 CFR Part 35.	**DB. Howe, NRC**
9:15 – 9:45	10.	**One RSO on License** Mr. Lieto will provide comments on NRC policy for naming only one RSO on a license.	**R. Lieto, ACMUI**
9:45 – 10:00		**BREAK**	
10:00 – 10:30	11.	**Y-90 Microspheres Guidance** Ms. Tull will update the Committee on the Y-90 microspheres guidance.	**A. Tull, NRC**
10:30 – 11:15	12.	**Patient Release** Drs. Ansari and Katz will describe the results of a survey by NRC, AHRQ, and CDC focusing on release of individuals containing byproduct material in the context of radiation monitoring at security checkpoints.	**A. Ansari, CDC & L. Katz, Abt Associates**
11:15 – 11:30	13.	**Radiological Terrorism Event Response** Dr. Ansari will provide information on the potential roles and training needs of medical physicists in a nuclear/radiological terrorism event.	**A. Ansari, CDC**
11:30 – 12:00	14.	**Novel Radiotherapeutics** Dr. Suleiman will provide information on novel radiotherapeutics and challenges that may arise.	**O. Suleiman, FDA/ACMUI**
12:00 – 1:00		**LUNCH**	
1:00 – 2:00	15.	**Sentinel Lymph Node Biopsy** Dr. Eggli will provide technical safety information on the impact of NRC's position to require hospitals to be licensed for surgical removal of sentinel lymph nodes imaged with Tc-99m. Dr. Howe will present the technical basis for NRC's decision.	**D. Eggli, ACMUI & DB. Howe, NRC**
2:00 – 2:45	16.	**New Radiation Modalities** Dr. Nag will provide information on Cs-131 seeds for prostate cancer, Sr-90 eye applicators for age-related macular degeneration, and XOFT Axxent electronic brachytherapy.	**S. Nag, ACMUI**
2:45 – 3:00		**BREAK**	
3:00 – 3:30	17.	**Elekta Perfexion** Dr. Howe will provide information on the new Leksell Gamma Knife® PERFEXION.	**DB. Howe, NRC**
3:30 – 4:00	18.	**AU Approval for Byproduct Material** Dr. Welsh will provide information on the differences among licensees requiring Authorized User (AU) approval prior to ordering byproduct material.	**J. Welsh, ACMUI**
4:00 – 4:30	19.	**NMED** Ms. Burgess will provide information on the Nuclear Materials Events Database (NMED) and follow-up on ACMUI recommendations regarding NMED from the previous meeting.	**M. Burgess, NRC**
4:30 – 5:00	20.	**Closing** Ms. Tull will provide a meeting summary, review action items, and propose dates for the next meeting.	**A. Tull, NRC**

OPENING REMARKS

NO HANDOUT

NARM Rulemaking

ACMUI Meeting, June 12, 2007

Lydia Chang
U.S. Nuclear Regulatory Commission

NARM Rulemaking Update

- 7/28/06: Published Proposed Rule in the *Federal Register* (71 FR 42952)
- 8/22/06: Held Public Meeting in Las Vegas
- 9/11/06 Ended the Comment Period and Received 39 Comment Letters
- 4/3/07 Issued a Commission Paper for the Draft Final Rule (SECY-07-0062)
- 5/14/07 Approved by the Commission in an Affirmation Session and Issued an SRM

2

Public Comments

- Received a Total of 39 Comment Letters
- 14 Comment Letters are Associated With States: OAS, IL, TX, AR, NE, NH, NJ, WA, TN, NC, NY, CO, MI, OH
- 4 Comment Letters are From Other Federal Agencies: EPA, Air Force, Navy, Veterans Affairs
- Remaining Comment Letters are From Citizens, Professional Organizations, Universities, Medical Communities, and Industry

3

Highlights of Changes

- Definition of *Discrete Source*
- Addition of N-13 and O-15 to Part 20 Appendix B
- Items Containing Ra-226
- Production of Accelerator-Produced Radioactive Material
- Noncommercial Distribution of PET Radionuclides and PET Drugs
- Implementation Considerations

4

Definition of *Discrete Source*

- Proposed Rule: "A source with physical boundaries, which is separate and distinct from the radiation present in nature, and in which the radionuclide concentration has been increased by human processes, with the intent that the radionuclide concentrated radioactive material will be used for its radiological properties"
- SECY-07-0062: "A radionuclide that is distinct from the sources of radiation present in nature, and that has been processed so that its concentration within a material has been purposely increased for use for commercial, medical, or research activities"
- SRM: "A radionuclide that has been processed so that its concentration within a material has been purposely increased for use for commercial, medical, or research activities"

5

Part 20 Appendix B

- Occupational Value for Derived Air Concentration for Inhalation
  - N-13: 4E-6 μCi/ml
  - O-15: 4E-6 μCi/ml
- Effluent Concentration for Air
  - N-13: 2E-8 μCi/ml
  - O-15: 2E-8 μCi/ml

6

Items Containing Ra-226

- Exemption
  - Part 30: 1 μCi of Ra-226 per timepiece in intact timepieces
- General License (Acquire, Receive, Possess, Use, or Transfer)
  - Antiquities
  - Intact timepieces containing >1 μCi of Ra-226, nonintact timepieces, hands, & dials
  - Luminous items installed in air, marine, or land vehicles
  - <100 items of other luminous products used or stored at the same location at any one time
  - Small Ra-226 sources containing <1 μCi of Ra-226
- Specific License

7

Radionuclide Production Facility

- Part 30: Allows Noncommerical Transfer of PET Drugs to Medical Use Licensees within the Consortium in Accordance with §§ 30.32 & 30.34
- Part 32: Commercial Distribution of Byproduct Material
- Part 35: Allows Receipt From –
  - Commercial distributors
  - Noncommercial transfer from PET radionuclide production facilities within the consortium

8

Noncommercial Distribution

- Definition of *Consortium*: "An association of medical use licensees and a PET radionuclide production facility in the same geographical area that jointly own or share in the operation and maintenance cost of the PET radionuclide production facility that produces PET radionuclides used in producing radioactive drugs within the consortium for noncommerical distributions among its associated members for medical use. The PET radionuclide production facility within the consortium must be located at an educational institution or a Federal facility or a medical facility."

9

Specific Provisions for Part 35

- Include Effective Date (§ 35.10)
- Add Authorization for Continued Use of NARM (§§ 35.11 & 35.13)
- Relocate PET Radioactive Drug Production Area or Delivery Line (§ 35.13)
- Grandfather Certain Individuals (§§ 35.13, 35.14, & 35.57)
- Add Requirements for Sr-82/Rb-82 Generator (§§ 35.204 & 35.2204)

10

Specific Provisions for Part 35 (Continued)

- PET Radionuclides and Drugs
  - Activity values (§ 35.63)
  - Receipt of PET radionuclides and drugs (§§ 35.100, 35.200, & 35.300)
- Non-PET Radionuclides and Drugs
  - No Changes Needed

11

Implementation Considerations

- Waiver Termination
  - Agreement States (Final Transition Plan)
  - Federal Agencies & Indian Tribes (Effective Date)
  - Non-Agreement States (Phased Approach)
  - Waiver Expiration
- License for NARM
  - License Amendment (6 months)
  - New License Application (1 year)
- Start of the Clock
  - Effective Date
  - Waiver Termination Date
  - Waiver Expiration Date (08/07/09)

12

Next Steps

- Revise the Draft Final Rule per the Commission Direction as Stated in the Staff Requirements Memorandum Issued on 5/14/07
- Forward the Final Rule to the Office of Management and Budget for Review and Approval
- Publish the Final Rule in the *Federal Register*

13

NARM Guidance

Advisory Committee on the Medical Uses of Isotopes Meeting

June 12, 2007

Presented By:
Duane E. White
Office of Federal and State Materials and Environmental Management Programs

NARM Guidance Overview

- Established NARM Guidance Writing Team Summer 2006
  - Evaluated need for revision to NUREG-1556 series and/or development of any new licensing guidance to address the requirements of the NARM rule
- Revising two NUREGs at this time
  - NUREG-1556, Volume 9, "Program-Specific Guidance About Medical Use Licenses"
  - NUREG-1556, Volume 13, "Program-Specific Guidance About Commercial Radiopharmacy Licenses"

2

NARM Guidance Overview

- Developing new NUREG document
  - NUREG-1556, Volume 21, "Program-Specific Guidance about Possession Licenses for Production of Radioactive Material Using an Accelerator"

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- Draft NUREGs provided to ACMUI in November 2006 for comment
- Received comments on Volume 21 from Sally Schwartz
- Volume 21 revised to address draft NARM rule changes and Sally's comments

4

NUREG-1556, Vol. 13, Rev. 1

Main Revisions

- Added guidance for facility and equipment specific to PET radiopharmacies.
- Provide some radiation safety recommendations for handling high energy photon-emitting radionuclides (e.g., use of pocket dosimeters).
- Ensure applicants are aware that discrete sources of radium-226 now need to be identified and licensed by NRC.

5

NUREG-1556, Vol. 21

Main Topics

- Production of radioactive materials will be authorized under a separate possession license specific to production.
- Guidance will not use the term "Authorized User", but individuals may be listed on the license.
- Applicants have a choice to submit list of activated products or group them under atomic numbers 1-83.
- This document will also provide guidance to "consortium" members who will produce radioactive materials for members of the consortium.

6

NARM Guidance Schedule

- Publish for 30-day public comment
  - Volume 21: May 29, 2007
  - Volume 13: Late June
  - Volume 9: Mid July
- Will provide to ACMUI and States
  - Provide comments by end of comment period
- Staff will review and address comments
- Goal is to complete the final guidance in the Fall 2007

NARM TRANSITION PLAN

Presentation for ACMUI
June 12, 2007

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

1

Purpose

- To provide an update on NRC's efforts to publish and implement the transition plan to facilitate an orderly transition of regulatory authority for NARM.

2

Overview

- Section 651(e) of the EPAct expanded the definition of byproduct material in Sections 11e.(3) and 11e.(4) of the Atomic Energy Act of 1954 (AEA), as amended, and placed NARM under NRC's jurisdiction.
- The NRC was also required to publish a transition plan to facilitate an orderly transition of regulatory authority.

3

Waiver / Transition Plan

Waiver

- On August 31, 2005, the Commission issued a waiver to allow States and individuals to continue their activities involving NARM.
- The Commission plans to terminate the waiver in phases, starting from the effective date of the rule and ending August 7, 2009.

Transition Plan

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

4

Transition Plan – Agreement States

- The NRC has received governor certifications from 31 Agreement States, which document that their State has a program for licensing the new byproduct material that is adequate to protect public health and safety and that they intend to continue to regulate these materials.
  - Alabama, Arizona, Arkansas, California, Florida, Georgia, Iowa, Illinois, Kansas, Kentucky, Louisiana, Maryland, Maine, Minnesota, Mississippi, Nebraska, New Hampshire, New Mexico, Nevada, New York, North Carolina, North Dakota, Ohio, Oklahoma, Oregon, South Carolina, Tennessee, Texas, Utah, Washington, and Wisconsin.
- The NRC Chairman will sign the responses to the Governors in conjunction with the effective date of the rulemaking and the waivers will be terminated.
- Expect transparency in this aspect of the overall transition.

5

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

- Close coordination with affected States, licensees, and industry groups is necessary and ongoing.
- Once the waiver is terminated, all persons that possess the new byproduct materials in NRC jurisdiction must be in compliance with NRC regulations, and will need to apply for a license amendment within 6 months, or apply for a new license within 12 months.

6

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

- On the effective date of the rule, the Commission intends to terminate the waiver for Federal Government agencies, Federally Recognized Indian Tribes, Delaware, District of Columbia, Puerto Rico, U.S. Virgin Islands, Indiana, Wyoming, and Montana.

7

Transition Plan – Remainder of Non-Agreement States

- The NRC plans to terminate the waiver for the remainder of Non-Agreement States in phases.
  - The 2nd phase is expected to occur in Summer-Fall 2008, and impacted states will have at least 6 months notice.
  - The 3rd phase is expected to occur in Spring-Summer 2009, and impacted states will have at least 6 months notice.
- States that become Agreement States by August 2009 will have their waiver terminated coincident with the effective date of their Agreement.

8

Transition Plan - Miscellaneous

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

9

Communication

- Ongoing communications critical to ensuring success of overall transition.
- RIS with overall NARM status update and FAQs was issued on 3/20/2007 all NRC materials licensees, all states, and ACMUI.
- The information in this RIS is being widely disseminated through various trade journals and professional society newsletters.
- For additional information on NARM related activities you may access the "NARM Toolbox" at: http://nrc-stp.ornl.gov/narmtoolbox.html

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Source Strength Labeling Errors in Brachytherapy

ACMUI Spring Meeting
14 June 2007

Jeffrey F. Williamson, Ph.D.

VCU Radiation Oncology
Virginia Commonwealth University

Outline

- Describe concepts of apparent activity and air-kerma strength for low energy seeds in relation to
  - Primary standards and calibration practices
  - Dose calculation
- Review potential error pathways related to use of source strength quantities and units
- Review practical techniques for mitigating errors
- Discuss recommendations for future action

Trans-rectal Ultrasound-Guided Perineal Permanent Prostate Implant

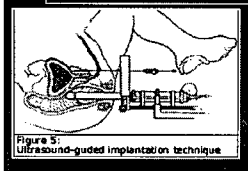
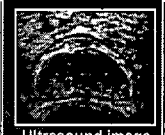


Figure 5: Ultrasound-guided implantation technique



Ultrasound image

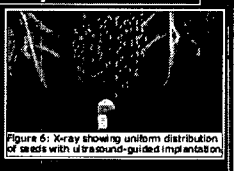
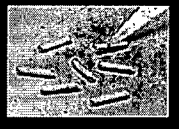


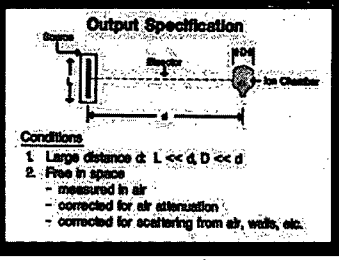
Figure 6: X-ray showing uniform distribution of seeds with ultrasound-guided implantation



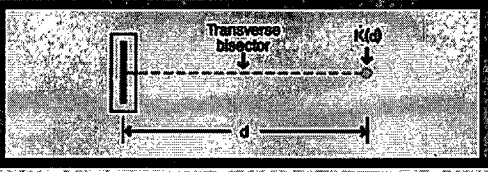
- Palladium-103 (^{103}Pd)
  - 17 day half life, mean energy = 22 keV
- Iodine-125 (^{125}I)
  - 59.6 day half life, mean energy = 28 keV
- 4.5 mm x 0.8 mm titanium-clad seeds

How is strength of clinical brachytherapy sources determined?

- Answer: by measuring air-kerma rate on transverse axis for all photon-emitting sources



2004 AAPM Definition of Air-Kerma Strength



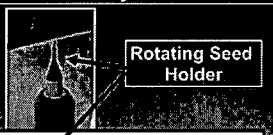
$$S_K = K_\delta(d)\, d^2 \quad [1\ \mu Gy \cdot m^2 \cdot h^{-1} = 1\ cGy \cdot cm^2 \cdot h^{-1} = 1\ U]$$

$K_\delta(d)$ is air-kerma rate in vacuo due to photons of energy $> \delta$ (~ 5 keV), $d \gg L$

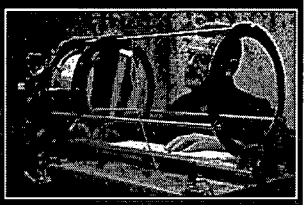
Cutoff designed to exclude low-energy contaminant radiation

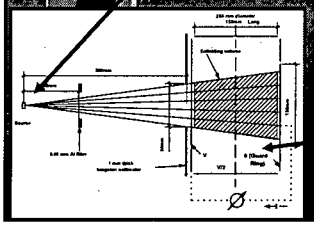
'WAFAC:' Wide Angle Free-Air Chamber

NIST Primary Standard for Low-Energy Seeds: $S_{K,N99}$



Rotating Seed Holder





Side View of WAFAC and Seed Holder

Apparent Activity: A_{app}

A_{app} = activity of hypothetical unfiltered point source of same radionuclide that gives same S_K as the given source

- Units: mCi, Ci, Bq, or MBq
- Applicable to all photon emitting radionuclides
  - Commonly used in interstitial implant dosimetry with I-125, Pd-103, & HDR Ir-192 sources

$$A_{app} \equiv S_K \Big/ \left[\Gamma_x \cdot \left(W/e\right)\right]$$

$$\left[\Gamma_X \cdot \left(W/e\right)\right] = \begin{cases} 1.45\ R \cdot cm^2 \cdot h^{-1} \times 0.876\ cGy/R = 1.27\ \mu Gy \cdot m^2 \cdot h^{-1}/mCi & \text{for } ^{125}I \\ 1.476\ R \cdot cm^2 \cdot h^{-1} \times 0.876\ cGy/R = 1.293\ \mu Gy \cdot m^2 \cdot h^{-1}/mCi & \text{for } ^{103}Pd \end{cases}$$

Values fixed by AAPM: Williamson, et al. Med. Phys. 26: 2529 (1999)

Traceability and AAPM Recommendations

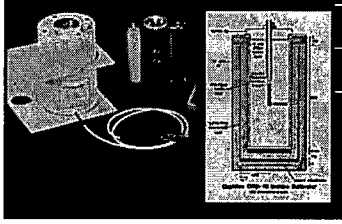
- ADCL: AAPM-accredited secondary lab which can calibrate a user's source against NIST standards
- Directly traceable calibration: source/instrument has NIST or ADCL calibration
- Secondarily traceable: source or instrument intercompared to a source with 'directly traceable' calibration.
- AAPM recommendations (TG 56, 40, and 43):
  - All clinical sources should have secondarily traceable calibrations
  - Each user should verify vendor calibrations with secondarily traceable S_K measurements
    - » Required for RTOG clinical trial participation

Status: Photon Brachytherapy Calibrations

- AAPM, ABS, and ICRU recommend that S_K be used for source ordering, planning, prescription, and recording treatments
- All source vendors and planning software use S_K
  - Most source certificates report both S_K and A_{app}
  - Dominant planning system (VariSeed): user can choose S_K or A_{app}
  - Most published dosimetry data is TG-43 and S_K compliant
- Nearly all sources have NIST traceable calibrations
  - AAPM maintains a Registry of sources that adhere to its recommendations
  - Most clinics maintain in-house calibration capability
- A_{app} in mCi units still widely used in clinical practice

Dose calibrators and Re-entrant ionization chambers

- Transfer standard: calibrate clinical sources by intercomparison to source with directly traceable calibration



- Stable and precise over large dynamic range
- Must have standard for each model of source used
- TG-56 recommends all BT practices have such a device and assay 10% of each source shipment

Quantitative Dosimetry: most current summary

Med. Phys 31: 531-674 (2004)

Update of AAPM Task Group No. 43 Report: A revised AAPM protocol for brachytherapy dose calculations

Mark J. Rivard
Department of Radiation Oncology, Tufts-New England Medical Center, Boston, Massachusetts 02111

Bert M. Coursey
Ionizing Radiation Division, National Institute of Standards and Technology, Gaithersburg, Maryland 20899

Larry A. DeWerd
Accredited Dosimetry and Calibration Laboratory, University of Wisconsin, Madison, Wisconsin 53706

William F. Hanson
Radiological Physics Center, M. D. Anderson Cancer Center, Houston, Texas 77030

M. Saiful Huq
Kimmel Cancer Center of Jefferson Medical College, Thomas Jefferson University, Philadelphia, Pennsylvania 19107

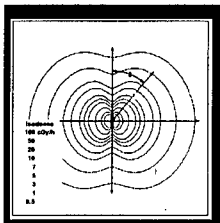
Geoffrey S. Ibbott
Radiological Physics Center, M. D. Anderson Cancer Center, Houston, Texas 77030

Michael G. Mitch
Ionizing Radiation Division, National Institute of Standards and Technology, Gaithersburg, Maryland 20899

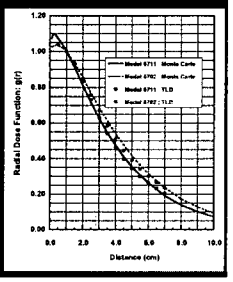
Ravinder Nath
Department of Therapeutic Radiology, Yale University, New Haven, Connecticut 06510

Jeffrey F. Williamson
Chair, Low-energy Interstitial Brachytherapy Dosimetry subcommittee of the Radiation Therapy Committee, Department of Radiation Oncology, Virginia Commonwealth University, Richmond, Virginia 23298

AAPM 2004 1-D Formalism



$$\dot{D}(r) = S_K \cdot \Lambda \cdot \left(\frac{1\ \text{cm}}{r}\right)^2 \cdot g_P(r) \cdot \phi_{an}(r)$$



Dose-rate constant

$$\Lambda = \frac{\dot{D}_{wat}\ (1\ \text{cm}, 90°)}{S_{K,N99}} \left[\frac{\text{cGy/h in water}}{\mu\text{Gy} \cdot \text{m}^2 \cdot \text{h}^{-1}}\right]$$

Radial dose function

$$g_P(r) = \frac{\dot{D}(r,90°)}{\dot{D}(1\ \text{cm},90°)} \cdot (r/1\ \text{cm})^2$$

TG-43 Dose Calculation Parameters

- All "living" RTP systems have adopted the TG-43 dose calculation system
- AAPM-endorsed and reviewed TG-43 data sets are available for nearly all low-energy sources
- TG-43 dose ratios (radial dose function, anisotropy corrections) are dimension less and do not depend on choice of strength quantity
- Only DRC (Λ) has absolute dose units and is normalized to S_K
  - Correction needed if A_{app} used

Using TG-43 Formalism With A_{app}

To use S_K in U

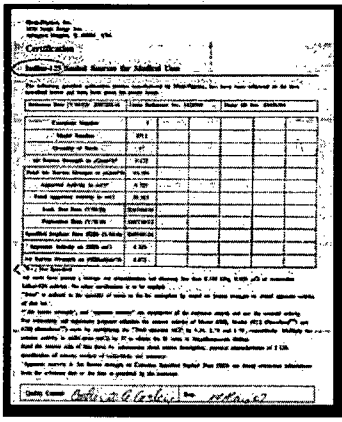
$$\dot{D}(r) = S_K \cdot \Lambda \cdot \frac{g_P(r)}{r^2} \cdot \phi_{an}(r)$$

To use A_{app} in mCi

$$\dot{D}(r) = A_{app} \cdot (S_K / A_{app}) \cdot \Lambda \cdot \frac{g_P(r)}{r^2} \cdot \phi_{an}(r)$$

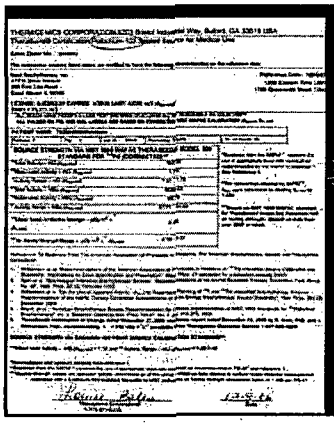
Where $\left(\frac{S_K}{A_{app}}\right) = \begin{cases} 1.27\ \text{U/mCi} & \text{for } ^{125}\text{I} \\ 1.293\ \text{U/mCi} & \text{for } ^{103}\text{Pd} \end{cases}$

- Numerically identical if same (S_K/A_{app}) used consistently



Oncura Model 6711 Calibration Certificate

- Both A_{app} and S_K are clearly stated
- Conversion factors for other quantities/units given
- Reference date is client-specified implant date
- Ordering quantity
  - Written: A_{app} or S_K
  - Telephone: A_{app} only



Theragenics/Bard Calibration Certificate

- Both A_{app} and S_K are clearly stated
- Three other quantities given + ranges
- Usually Reference date = implant date
- Ordering quantity
  - Written: A_{app} or S_K
  - Telephone: S_K only

Some Possible Error Pathways

- Vendor (V)-Client (C)-Physician (P) Interface
  - C's order matches prescription quantity, but not V's quantity (V-C miscommunication)
  - C's order matches V's ordering quantity, but not P's prescription quantity (C-P miscommunication)
  - C, V, and P all agree on quantity, but V fills order with wrong units (V operational error)
  - Reference-Implant date disagreement (V-C miscommunication)
- Treatment planning
  - Wrong quantity from V certificate input into computer
  - Select correct quantity from cert, but wrong RTP menu option
  - Wrong (S_K/A_{app}) correction stored in software
  - Incorrect decay correction for Ref vs Tx date differences

Some Possible Error Pathways

- Vendor (V)-Client (C)-Physician (P) Interface
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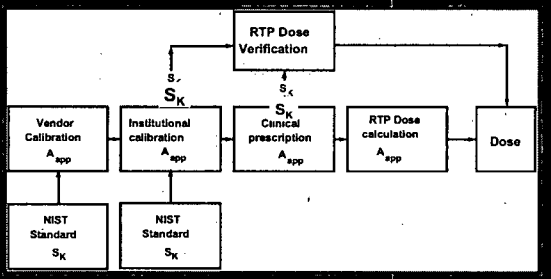
  - Wrong (S_K/A_{app}) correction stored in software
  - Incorrect decay correction for Ref vs Tx date differences

Avoiding Source Strength Errors

- Systematic Errors
  - Understand each V inventory system and use written order form to reduce miscommunication
  - Verify RTP dose calculation algorithm for accuracy and consistency with procedure
  - End-to-end testing: S_K assay + manual calc vs. single-seed plan
- Random Errors
  - Written procedures and forms to capture key data (dates, units)
    - » Have initial prescription in hand during ordering
  - Make V repeat order and fax cal certificate
  - Follow TG 56/43 S_K assay recommendations
  - Independent physicist review of plan per TG-56 guidelines

End-to-End Testing: first seed order

(Seed assay + manual dose calc) vs. (RTP + V source strength)



Recommendations/Conclusions

- Multiplicity of source strength quantities is a serious source of potential error
- Regulating A_{app} out of existence not warranted
  - About 50 patients affected over 3-4 years: risk $\approx 3 \times 10^{-4}$
  - Many other error pathways also worthy of attention
  - Community adaptation to outlawing of A_{app} may cause more errors in short term
  - Well documented and straightforward QA practices should be sufficient to address problem
- Recommendations
  - Draft Information notice highlighting potential problems, solutions
  - Ask NRC AAPM Liaison to discuss with Brachy SC Chairman

Units of AKS vs. Apparent Activity

Cindy Flannery, CHP, Team Leader
U.S. Nuclear Regulatory Commission
Office of Federal and State Materials
and Environmental Management Programs
Division of Materials Safety and State Agreements
Medical Safety & Events Assessment Branch
Medical Radiation Safety Team
June 12, 2007

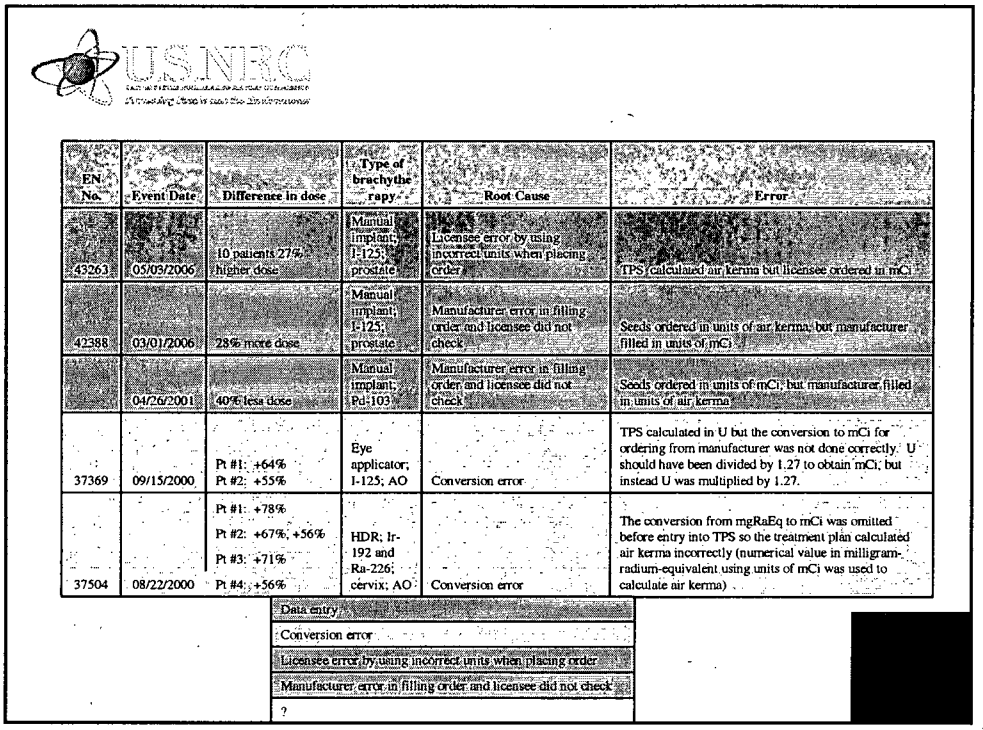
e-mail dated 10-25-06:

"... Modern planning systems use AKS; Guidance documents from the AAPM strongly recommend AKS; only some few vendors insist on selling sources in Apparent Activity. Given that transport documents, written directives and such require Contained Activity, using Apparent Activity is an additional variable that yields no benefit. **I strongly suggest that the Commission consider abandoning the concept and working with vendors to abandon it as well.**"

e-mail dated 10-27-06:

"I have received an email from a physicist colleague who is concerned about the confusion that can occur by the use of both Air Kerma source strength and Apparent Activity. .....I have been frustrated by the reluctance of some manufacturers and even some physicists to adopt the now recommended unit of Air Kerma source strength when ordering and calibrating radioactive materials used for patient implants. The AAPM and NIST now recognize Air Kerma Source Strength (AKS) as the unit to be used for such purposes. NIST and the calibration labs work only in AKS. *I order my sources in units of AKS and have occasionally had the order filled as if the numerical value I specified were in Apparent Activity.* **I encourage you to use your regulatory influence to move away from the obsolete Apparent Activity to the current unit Air Kerma Source Strength (AKS).**"

EN No.	Event Date	Difference in dose	Type of brachytherapy	Root Cause	Error
43256	03/23/2007	6.9% greater than intended	Manual implant; I-125; prostate	Data entry	The wrong unit of measurement was entered into the TPS
43301	03/07/2007	Patient received 4590 rad instead of the prescribed 2500 rad	interstitial brachytherapy; cervix	1. Conversion error. 2. Acceptance testing of Ir-192 in the TPS was not done so TPS did not have the correct dose rate factor (DRF) for Ir-192	1. The conversion from mgRaEq to air kerma was omitted before entry of the numerical value into TPS so the numerical value in mgRaEq was entered into TPS using the default units of air kerma. 2. Also the TPS did not have a DRF in the system for Ir-192 so the improper DRF was used in TPS calculation.
43163	01/04 - 08/14/2006	>6 patients with a range of 21 - 36% increase in dose	Manual implant; I-125; prostate	?	Improper dose rate constant in treatment planning
42729	07/10/2006	27% higher activity than intended	Manual implant; I-125; prostate	Licensee error by using incorrect units when placing order	TPS calculated 0.5 U (0.394 mCi) per seed but licensee order 0.5 mCi
42634	06/12/2006	27% increase in the activity of seeds. 100 seeds implanted instead of 80 seeds. 4% error in dose.	Manual implant; I-125; prostate	Data entry	The TPS default of Air Kerma Strength was used and the operator did not change the units to mCi in the TPS. If mCi had been selected, then TPS would have calculated fewer seeds to get to the desired total activity



EN No.	Event Date	Difference in dose	Type of brachytherapy	Root Cause	Error
43263	05/03/2006	10 patients 27% higher dose	Manual implant; I-125; prostate	Licensee error by using incorrect units when placing order	TPS calculated air kerma but licensee ordered in mCi
42388	03/01/2006	28% more dose	Manual implant; I-125; prostate	Manufacturer error in filling order and licensee did not check	Seeds ordered in units of air kerma; but manufacturer filled in units of mCi
	04/26/2001	40% less dose	Manual implant; Pd-103	Manufacturer error in filling order and licensee did not check	Seeds ordered in units of mCi; but manufacturer filled in units of air kerma
37369	09/15/2000	Pt #1: +64% Pt #2: +55%	Eye applicator; I-125; AO	Conversion error	TPS calculated in U but the conversion to mCi for ordering from manufacturer was not done correctly. U should have been divided by 1.27 to obtain mCi; but instead U was multiplied by 1.27.
37504	08/22/2000	Pt #1: +78% Pt #2: +67%; +56% Pt #3: +71% Pt #4: +56%	HDR; Ir-192 and Ra-226; cervix; AO	Conversion error	The conversion from mgRaEq to mCi was omitted before entry into TPS so the treatment plan calculated air kerma incorrectly (numerical value in milligram-radium-equivalent using units of mCi was used to calculate air kerma)

Data entry

Conversion error

Licensee error by using incorrect units when placing order

Manufacturer error in filling order and licensee did not check

?

Status of Specialty Board Recognition

Cindy Flannery, CHP, Team Leader
U.S. Nuclear Regulatory Commission
Office of Federal and State Materials
and Environmental Management Programs
Division of Materials Safety and State Agreements
Medical Safety & Events Assessment Branch
Medical Radiation Safety Team
June 12, 2007

1

Specialty Board:	Status:	Recog. Date:
Board of Pharmaceutical Specialties	35.55	March 6, 1996
American Board of Nuclear Medicine	35.190, 35.290, 35.390	October 20, 2005*
Certification Board of Nuclear Cardiology	35.290	October 29, 2000
American Board of Health Physics	35.50	Jan. 1, 2005
American Board of Science in Nuclear Medicine Nuclear Medicine Physics and Instrumentation Radiation Protection	 35.50 35.50	 June, 2006 June, 2006
American Board of Radiology (Radiation Oncology) American Board of Radiology (Diagnostic Radiology) American Board of Radiology (Radiologic Physics) Medical Nuclear Physics Diagnostic Radiologic Physics Therapeutic Radiologic Physics	35.390, 35.490, 35.690 35.290, 35.392 35.50 35.50 35.51	June, 2007 June, 2006* June, 2007* June, 2007* June, 2007*
American Osteopathic Board of Radiology (Rad. Onc.) American Osteopathic Board of Radiology (Diag.Rad.)	35.390, 35.490, 35.690 35.290, 35.392	May 1, 2007 July 1, 2000
American Osteopathic Board of Nuclear Medicine	35.290	May 18, 2006
American Board of Medical Physicists	Awaiting input	
Certification Board of Nuclear Endocrinology	Awaiting input	

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*Board is verifying the qualifications of diplomates who have obtained their certification prior to the recognition date.

§35.50	Radiation Safety Officer
§35.51	Authorized Medical Physicist
§35.55	Authorized Nuclear Pharmacist
§35.190	Authorized User - uptake, dilution, and excretion studies
§35.290	Authorized User - imaging and localization studies
§35.390	Authorized User - use of unsealed byproduct material for which a written directive is required
§35.392	Authorized User - oral administration of sodium iodide I-131 requiring a written directive in quantities less than or equal to 33 mCi
§35.394	Authorized User - oral administration of sodium iodide I-131 requiring a written directive in quantities greater than 33 mCi
§35.490	Authorized User - use of manual brachytherapy sources
§35.590	Authorized User - use of sealed sources for diagnosis
§35.690	Authorized User - use of remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units

Status of Specialty Board Recognition

CONTACT:

Cindy Flannery
(301) 415-0223
cmf@nrc.gov

T&E IMPLEMENTATION ISSUES

OPEN DISCUSSION

FEDERAL REGISTER NOTICE
VISITOR LIST

Dated: April 27, 2007.

Keith T. Sefton,

Deputy General Counsel, Administration and Management.

[FR Doc. 07–2243 Filed 5–7–07; 8:45 am]

BILLING CODE 7510–13–M

NUCLEAR REGULATORY COMMISSION

Advisory Committee on the Medical Uses of Isotopes: Meeting Notice

AGENCY: U.S. Nuclear Regulatory Commission (NRC).

ACTION: Notice of meeting.

SUMMARY: NRC will convene a public meeting of the Advisory Committee on the Medical Uses of Isotopes (ACMUI) June 12–13, 2007. A sample of agenda items to be discussed includes: (1) NARM legislation, transition plan, and guidance; (2) status of specialty board applications for NRC recognition; (3) units of air kerma strength vs. activity; (4) patient release and security checkpoints; (5) Y–90 microspheres guidance; (6) sentinel lymph node biopsies; (7) new modalities; (8) training and experience implementation issues. To review the agenda, see *http://www.nrc.gov/reading-rm/doc-collections/acmui/agenda/* or contact Ashley M. Tull. Contact information for Ms. Tull is provided below.

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

Date and Time: June 12–13, 2007, from 8 a.m. to 5 p.m.

ADDRESSES: U.S. Nuclear Regulatory Commission, Two White Flint North, Room T2–B3, 11545 Rockville Pike, Rockville, MD 20852–2738.

Contact: Ashley M. Tull by telephone (301) 415–5294; e-mail *amt1@nrc.gov*; or mail Office of Federal and State Materials, U.S. Nuclear Regulatory Commission, Mail Stop T8–F3, 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. 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.

2. Persons who wish to provide a statement should submit an e-mail or mail a reproducible copy to Ms. Tull at the contact information provided. Submittals must be e-mailed or postmarked by June 1, 2007, and must pertain to the topics on the agenda for the meeting.

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

4. The transcript and written comments will be available 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 September 12, 2007.

5. Attendees are requested to notify Ms. Tull, at the previously stated contact information, of their planned attendance if special services, such as those for the hearing impaired, are necessary.

Dated at Rockville, Maryland, this 2nd day of May 2007.

For the U.S. Nuclear Regulatory Commission.

Annette L. Vietti-Cook,

Secretary of the Commission.

[FR Doc. E7–8797 Filed 5–7–07; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

Notice of Sunshine Act Meetings

DATES: Weeks of May 7, 14, 21, 28, June 4, 11, 2007.

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

STATUS: Public and Closed.

MATTERS TO BE CONSIDERED:

Week of May 7, 2007

Monday, May 7, 2007

1:30 p.m. Briefing on Office of Federal and State Materials and Environmental Management Programs (FSME) Programs, Performance, and Plans (Public Meeting) (*Contact:* George Deegan, 301–415–7834).

This meeting will be webcast live at the Web address: *http://www.nrc.gov.*

Week of May 14, 2007—Tentative

There are no meetings scheduled for the Week of May 14, 2007.

Week of May 21, 2007—Tentative

There are no meetings scheduled for the Week of May 21, 2007.

Week of May 28, 2007—Tentative

Tuesday, May 29, 2007

1:30 p.m. NRC All Hands Meeting (Public Meeting) (Contact: Rickie Seltzer, 301–415–1728), Marriott Bethesda North Hotel, 5701 Marinelli Road, Rockville, MD 20852.

Wednesday, May 30, 2007

9:30 a.m. Briefing on Results of the Agency Action Review Meeting (AARM)—Materials (Public Meeting) (Contact: Duane White, 301–415-6272).

This meeting will be webcast live at the Web address: *http://www.nrc.gov.*

10:15 a.m. Discussion of Security Issues (Closed-Ex.1).

Thursday, May 31, 2007

9 a.m. Briefing on Results of the Agency Action Review Meeting (AARM)—Reactors (Public Meeting) (*Contact:* Mark Tonacci, 301–415–4045).

This meeting will be webcast live at the Web address: *http://www.nrc.gov.*

Week of June 4, 2007—Tentative

Thursday, June 7, 2007

1:30 p.m. Meeting with the Advisory Committee on Reactor Safeguards (ACRS) (Public Meeting) (*Contact:* Frank Gillespie, 301–415–7360).

This meeting will be webcast live at the Web address: *http://www.nrc.gov.*

Week of June 11, 2007—Tentative

There are no meetings scheduled for the Week of June 11, 2007.

* * * * *

*The schedule for Commission meetings is subject to change on short notice. To verify the status of meetings call (recording)—(301) 415–1292. Contact person for more information: Michelle Schroll, (301) 415–1662.

* * * * *

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

* * * * *

The NRC provides reasonable accommodation to individuals with disabilities where appropriate. If you need a reasonable accommodation to participate in these public meetings, or need this meeting notice or the transcript or other information from the public meetings in another format (e.g. braille, large print), please notify the NRC's Disability Program Coordinator, Deborah Chan, at 301–415–7041, TDD: 301–415–2100, or by e-mail at

PLEASE DO NOT REMOVE FROM T2-B3

ACMUI VISITOR LIST

JUNE 12-13, 2007

NAME	ORGANIZATION	SIGNATURE
Ann Warbick Cerone	MDS Nordion	
Bill Metzger	NeoVista	
Bruce Haffty, M.D.	ABR	
Candace Webb	Maryland	
Carlos Hamilton Jr., M.D.	AACE	
Craig Reed	Oncologix	
Dawn Edgerton	CBNC	
Dean Broga	ACMP	
Doug Pfeiffer	AAPM	
Emily Wilson	ASTRO	
Gloria Romanelli	ACR	
Henry Royal, M.D.	ABNM	
Herb Mower, Sc.D.	ACMP	
Hugh Cannon, Ph.D.	SNM	
Jean St. Germain	AAPM	
Jerry White	AAPM	
Ken Thurston	Sirtex	
Kent Lambert	ABHP	
Lynn Barnes	SNM	
Lynne Fairobent*	AAPM	
Melissa Martin*	ACR	
Mike Peters	SNM	
New Mexico†	Agreement State	--
North Dakota†	Agreement State	--
Nitesh Paryani	ASTRO	
Org. of Agreement States	OAS	--

*Wishes to make a statement

†Participating via conference line

PLEASE DO NOT REMOVE FROM T2-B3

ACMUI VISITOR LIST

JUNE 12-13, 2007

NAME	ORGANIZATION	SIGNATURE
Philip Alderson, M.D.	ABR	
Riad Salem, M.D.	Northwestern Univ	
Richard Fejka	FDA	
Richard Martin	ASTRO	
Richard Morin	ABR	
Sara Milo	AACE	
Steve King	AAPM	
Steve Thomas, Ph.D.	ABR	
Sue Langhorst, Ph.D.	WUSTL	
Terence Beven, M.D.*	SNM	
Texas†	Agreement State	--
TX Radiation Advisory Board†	Agreement State	--
William Vermeere	NeoVista	

*Wishes to make a statement

†Participating via conference line

Potential Changes to 10 CFR Part 35

ACMUI Meeting

June 13, 2007

Donna-Beth Howe, Ph.D.

10 CFR 35.2

Problem: By definition individuals that meet all the Board certification pathway are RSOs. Therefore they can sign attestations as preceptor RSO's even though they are not working as RSO's.

Should NRC revise the definition of an RSO to clarify the individual has to be listed on a license or the requirements for the RSO attestation to clarify the preceptor RSO has to be listed as an RSO on a medical use license.

10 CFR 35.12

Problem: 10 CFR 35.12(c)(1) indicates that the application will be either on NRC Form 313 or in a letter but does not indicate that the information submitted in the letter must be equivalent to the information submitted in the NRC Form 313.

By adding or equivalent the burden associated with the letter submission is captured in the information collection and recordkeeping burden of the NRC Form 313. This will also capture the burden in the NRC Form 313 for completing the NRC Form 313A series or letters containing equivalent information to that in the NRC Form 131A series.

10 CFR 35.12 cont.

- Revise 35.12(c)(1) to read
- (c) A request for a license amendment or renewal must be made by--
- (1) Submitting an original and one copy of either--
- (i) NRC Form 313, "Application for Material License" **or equivalent** ; or
- (ii) An **equivalent** letter requesting the amendment or renewal; and

10 CFR 35.50(c)(2)

Problem: As written the AU, AMP, ANP has to be listed on the licensees license. Individuals listed on a NRC or Agreement State license for the same materials and uses that they would have RSO responsibilities for should be eligible to be an RSO.

10 CFR 35.50(c)(2) cont.

Recommend revise 35.(c)(2) to read:

(c)(2) Is an authorized user, authorized medical physicist, or authorized nuclear pharmacist identified on a license or NRC Master Materials License Permit that authorizes similar types of use of byproduct material and the individual has experience with the radiation safety aspects of these similar types of use of byproduct material for which the individual has Radiation Safety Officer responsibilities; and,

10 CFR 35.50(d)

Problem A preceptor RSO's is required to provide attestations for AUs, AMPs, and ANPs qualifies under 35.50(c)(2) to be RSOs. RSO are reluctant to providing attestations for AUs, AMPs, and ANPs that they can function independently as RSO. The original intent of the NRC was not to require these individuals to need additional attestations to be RSOs and the RSO attestation requirements should be eliminated for AUs, AMPs, ANPs .

10 CFR 35.50(d) cont

Recommendation: Revise 35.50(d) to read:

- (d) Has obtained written attestation, signed by a preceptor Radiation Safety Officer, that the individual has satisfactorily completed the requirements in paragraph (e) and in paragraphs (a)(1)(i) and (a)(1)(ii) or (a)(2)(i) and (a)(2)(ii) or (b)(1) or (c)(1) of this section, and has achieved a level of radiation safety knowledge sufficient to function independently as a Radiation Safety Officer for a medical use licensee. **No attestation is required for those individuals meeting the requirements of or (c)(2) if they have RSO responsibilities for the similar types of use of byproduct material for which the individual is authorized.**

10 CFR 35.57(a)

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

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

10 CFR 35.57(a) cont.

Recommend revising 10 CFR 35.57(a) to read:

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

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

10 CFR 35.57(a) cont.

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

Recommend adding the following to 35.57(a):

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

10 CFR 35.75

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

10 CFR 35.75 cont.

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

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

10 CFR 35.491

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

10 CFR 35.491 cont.

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

(b)(2) Supervised clinical training in superficial ophthalmic radiotherapy under the supervision of an authorizeduser at a medical institution, clinic, or private practice that includes the use of strontium-90 for the superficial ophthalmic treatment of five individuals. This supervised clinical training must involve—

- **(i) Examination of each individual to be treated;**
- **(ii) Calculation of the dose to be administered;**
- **(iii) Administration of the dose; and**
- **(iv) Follow up and review of each individual's history; or**

10 CFR 35.491 cont.

(b)(3) Supervised clinical training in intraocular ophthalmic radiotherapy deviceunder the supervision of an authorized user at a medical institution, clinic, or private practice that includes the use of strontium-90 for the internal eye ophthalmic treatment of five individuals. This supervised clinical training must involve—

- **(i) Examination of each individual to be treated;**
- **(ii) Calculation of the dose to be administered;**
- **(iii) Administration of the dose; and**
- **(iv) Follow up and review of each individual's case history; and**

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

10 CFR 35.400, 35.500, and 35.600

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

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

10 CFR 35.400, 35.500, and 35.600

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

WHY ONLY ONE RSO?

Ralph P. Lieto
ACMUI Member

CURRENT Part 35 - RSO

§35.12 Application for license, amendment, or renewal
- –(b)(1) …training and experience qualifications of the Radiation Safety Officer…

§35.13(c) License amendments
- –Before it changes Radiation Safety Officers, except as provided in § 35.24(c);

CURRENT Part 35 - RSO

§35.24 Authority and Responsibilities for the Radiation Protection Program
- –(b) A licensee's management shall appoint a RSO, who agrees in writing to be responsible for implementing the radiation protection program. The licensee, through the RSO, shall ensure that radiation safety activities are being performed according to licensee-approved procedures and regulatory requirements.

CURRENT Part 35 – TEMP RSO

- –§35.24(c): ≤ 60 days each year, a licensee may permit an AU or an individual qualified to be a RSO, under §§ 35.50 and 35.59, to function and perform as a temporary RSO, if the licensee acts per §35.24(b), (e), (g), & (h) and notifies the NRC within 30 days.
- –(d): A licensee may simultaneously appoint more than one temporary RSO per §35.24(c), if needed to ensure that the licensee has a temporary RSO for each of the different types of uses of byproduct material

CURRENT GUIDANCE - NUREG

- Responsible for day-to-day oversight of the radiation protection program
- Permits consultants
- Not always full-time employee even for broad scope
- Meets qualifications & "…is available for advice and assistance on radiological safety matters."

[Ref: NUREG-1556, vols.9 &11]

MULTIPLE LISTING ON LICENSE

- AU
- AMP
- ANP
- RSO by "area" but discontinued
  - –Precedent?

NOT SPECIFIED ON LICENSE

- MANAGEMENT
  - Who has the ultimate responsibility for the radiation safety program
  - NEVER specified by name or office or title
- Health or medical physicist, technologists, technicians with daily program duties/ responsibilities

POLICY ORIGIN

- One RSO not specified in regulations
- NRC Staff HQ/Regional inquiry
  - Unable to provide any OGC or NRC document directing this licensing policy
- "officer" suggests AEC/military origin concept of singular person with duties for safety
- Existence predates NRC establishment of Management responsible for rad safety program

CONCERNS/ISSUES

- NRC:
  - multiple RSOs designated by area of expertise resulted in common duties not being done (citations)

CONCERNS/ISSUES

- Licensees
  - Multimodality/Broad Scope have staff who perform duties but unrecognized; qualified individuals in large programs compromised by new T&E interpretations of recognized boards & §35.59 (recentness of T&E).
    - Can't automatically replace RSO if leaves or unavailable
    - Moves to another license require lengthy documentation

CONCERNS/ISSUES

- Licensees
  - Single RSO on multiple licensees ⇒ not on-site
  - AU reluctance to be RSO, esp. rotating, teleradiology

SUGGESTIONS

- List "temp RSO" with some other designation to resolve hierarchy concern
  - Radiation safety specialist or
  - associate RSO
- If can meet "temp RSO" qualifications for 2 months why not recognize qualified & list with some other designation

SUGGESTIONS

- Permit listing of "other" RSO for high risk authorizations - HDR,brachytherapy, radiopharmaceutical therapy.
- Documented policy needed; OGC written interpretation, if needed, & ACMUI involvement
- Remove "officer" term?

Microspheres Guidance

Ashley M. Tull
Office of Federal and State Materials and
Environmental Management Programs
Division of Materials Safety and State Agreements

Advisory Committee on the Medical Uses of Isotopes
June 13, 2007

Overview

- Outline changes
- Discuss issues
- ACMUI input

- Obtain "No Legal Objection"
- Publish guidance to web
- Pursue additional discussion (teleconference or next meeting)

35.390 Users

"Authorized Users must meet the training and experience requirements of the specific vendor training in the use of the microspheres and the microsphere delivery system and either 10 CFR 35.390 or 10 CFR.490. The authorized user must have training and experience in radiation oncology, radiation dosimetry, and safe handling of unsealed byprodu material..."

Casework

"...individuals must have work experience including at least three cases for each type of Y-90 microspheres..."

"This work experience must be obtained under the supervision of an AU who is authorized for the type of microspheres for which the individual is seeking approval."

Written Attestation

"Individuals must also obtain written attestation, signed by a preceptor, stating that the individual has satisfactorily completed the training and experience requirements...and has achieved a level of competency sufficient to function independently as an authorized user for the medical use of Y-90 microspheres."

Team Approach

"Microsphere brachytherapy treatment is usually conducted using a multi-disciplinary team approach. The AU should consult , as necessary, with individuals with expertise in:

- Oncology
- Catheter placement
- Radiation dosimetry
- Safe handling of unsealed byproduct material

One individual may satisfy more than one of the listed areas of expertise."

Other

- Limited Specific Medical Use Licensees
  "An individual's qualifications to be an AU for Y-90 microspheres at a limited specific medical use licensee site must be reviewed and approved by the appropriate regulatory authority. The notification provision in 10 CFR 35.14 does not apply."
- Waste Disposal
  - Information Notice 2007-10
- Clarification, grammar, formatting

Discussion topics

- Dose vs. Activity
  - NRC : dose (rad or Gy)
  - Manufacturer : activity (mCi or GBq)
- "...but before completion of the procedure"

Questions?

Microsphere Brachytherapy Sources and Devices

Licensing Guidance – TheraSphere® and SIR-Spheres® Yttrium-90 Microspheres

Yttrium-90 (Y-90) microspheres are manual brachytherapy sources used for permanent implantation therapy. Y-90 microspheres are regulated under 10 CFR 35.1000 "Other Medical Uses of Byproduct Material or Radiation from Byproduct Material."

Authorized users must meet the training and experience requirements of the specific vendor training in the use of the microspheres and the microsphere delivery system and either 10 CFR 35.390 or 10 CFR 35.490. The authorized user must have training and experience in radiation oncology, radiation dosimetry, and safe handling of unsealed byproduct material applicable to microsphere use.

Additionally, individuals must have work experience including at least three cases for each type of Y-90 microspheres for which the individual is seeking authorized user status. This work experience must be obtained under the supervision of an authorized user who is authorized for the type of microspheres for which the individual is seeking approval.

Individuals must also obtain a written attestation, signed by a preceptor, stating that the individual has satisfactorily completed the training and experience requirements described above and has achieved a level of competency sufficient to function independently as an authorized user for the medical use of Y-90 microspheres. The preceptor authorized user must be authorized for and have clinical experience using the type of Y-90 microspheres for which the individual is requesting authorized user status.

Training in the manufacturer's procedures commensurate with the individual's duties to be performed must be provided to individuals preparing, measuring, performing dosimetry calculations, or implanting microspheres.

Leak tests are not required because the activity per microsphere (the sealed source) and Y-90 half life meet the criteria in 10 CFR 35.67(f); thereby relieving the licensee from the requirements of performing such tests.

The licensee shall follow all the requirements in 10 CFR Part 35 for brachytherapy sources and manual brachytherapy use except where the following licensing commitments provide regulatory relief:

For Y-90 microspheres, "prescribed dose" means the total dose documented in the written directive.

The written directive should include:

- before implantation: the treatment site, the radionuclide (including the chemical/physical form [Y-90 microspheres]), the manufacturer, and a dose of either XXX rad/Gray or the statement "dose delivered at stasis"; and

- after implantation but before completion of the procedure: the radionuclide (including the chemical/physical form [Y-90 microspheres]), the manufacturer, treatment site, and the total dose to the treatment site. If the implantation was terminated because of stasis, then the total dose is the value of the total dose delivered when stasis occurred and the implantation was terminated.

The written directive should specify the maximum dose that would be acceptable for a specified site (or sites) outside the primary treatment site to which the microspheres could be shunted (e.g. lung and gastrointestinal tract). The post-implantation written directive should specify the dose that will result to the specified site (or sites) due to shunting.

To confirm that the administration is in accordance with the written directive, procedures for Y-90 microsphere administrations should describe how to quantify the total dose to the treatment site as well as the total dose to other sites upon completion of the administration. The licensee should confirm if it will use the manufacturer's methodology or provide a copy of an alternative methodology.

The semi-annual physical inventory of microspheres aggregates (e.g. vials) should include:

- the radionuclide and physical form,
- the vial(s) in which the microspheres are contained
- the number of vials
- the total activity of each vial, and
- the location of the vial(s).

Procedures should describe measures taken to ensure that radiation emissions, which may include bremsstrahlung, from each patient or human research subject permits his/her release in accordance with 10 CFR 35.75; and

The following additional guidance applies when the Y-90 microspheres are placed in vials, syringes, or radiation shields that are not labeled by the manufacturer:

- Label vials and vial radiation shields with radionuclide and form (e.g., Y-90 microspheres).
- Label syringes and syringe radiation shields with the radionuclide, form, and therapeutic procedure (e.g., Y-90 microspheres, brachytherapy).

Microsphere brachytherapy treatment is usually conducted using a multi-disciplinary team approach. The authorized user should consult, as necessary, with individuals with expertise in:

- Oncology
- Catheter placement
- Radiation dosimetry
- Safe handling of unsealed byproduct material

One individual may satisfy more than one of the listed areas of expertise.

Notes to Licensees

Limited specific medical use licensees.

An individual's qualifications to be an authorized user for Y-90 microspheres at a limited specific medical use licensee site must be reviewed and approved by the appropriate regulatory authority. The notification provision in 10 CFR 35.14 does not apply.

Change in physical conditions of use.

If the physical conditions of use exceed those reported in the Sealed Source and Device (SSD) certificate, the limited specific medical use licensee should request an amendment for the new conditions, and broad scope licensee should perform its own engineering and radiation safety evaluation addressing those differences.

Use of other Y-90 microspheres.

The SSD safety evaluation for a specific manufacturer's Y-90 microspheres does not cover the use of any other Y-90 microspheres, including the preparation of Y-90 on other microspheres by a commercial nuclear pharmacy, the medical use licensee's authorized nuclear pharmacist, or a physician authorized user qualified to prepare radioactive drugs. The medical use of such a source will require a new SSD certificate (or safety evaluation by the broad scope medical use licensee) that addresses the conditions of use, safety of the new Y-90 microspheres, and compatibility of the new microspheres with microsphere delivery system(s).

The SSD safety evaluation for a manufacturer's Y-90 microsphere delivery system does not cover the use of any other delivery system with the Y-90 microsphere brachytherapy device. Before authorization, the medical use of such a delivery system will require a new SSD certificate (or safety evaluation by the broad scope medical use licensee) that addresses the conditions of use, safety of the microsphere delivery system, and compatibility of the new delivery system with the Y-90 microspheres.

TheraSphere® use outside Humanitarian Device Exemption (HDE) restrictions.

The MDS Nordion TheraSphere® Y-90 microspheres are approved by the U.S. Food and Drug Administration (FDA) under the provisions of a "Humanitarian Device Exemption" (HDE No. H9800006), which includes unique restrictions on the medical use of the devices. Nothing in the NRC license relieves the licensee from complying with those FDA requirements.

If the Institutional Review Board[1] that is required to approve and monitor the use of the MDS Nordion TheraSphere® Y-90 microspheres determines that the particular use of TheraSphere® Y-90 microspheres is for research purposes, the licensee must meet the requirements in 10 CFR 35.6, "Provisions for research involving human subjects." (Note: One of the conditions of approval for an HDE is that there be an Institutional Review Board initial review and approval before a humanitarian use device is used at a facility, as well as continuing review of its use.)

Revision of Y-90 Microsphere Radiation Safety programs to conform to changes in this licensing guidance.

The above licensing guidance may be revised as additional experience is gained regarding the medical use of TheraSphere® and SIR-Spheres® Y-90 microspheres. A licensee currently authorized to use these products that is committed by license condition to following provisions in this guidance existing at the time of commitment must apply for and receive an amendment to its license in order to make changes to conform with the revised provisions.

An applicant initially applying for authorization for the medical use of TheraSphere® and SIR-Sphere® Y-90 microspheres, or a licensee applying for an amendment to conform with revisions in this guidance, may request authorization to allow future changes to its radiation safety program, provided the following conditions are met:

- the revision is in compliance with the regulations;
- the revision is based upon NRC's current guidance for TheraSphere® and SIR-Spheres® Y-90 microspheres 35.1000 use posted on the NRC Web site;
- the revision has been reviewed and approved by the licensee's radiation safety officer and licensee's management;
- the affected individuals are instructed on the revised program before the change is implemented;
- the licensee will retain a record of each change for five years; and
- the record will include a copy of the appropriate Web site guidance, the old procedure, the new procedure, the effective date of the change, and the signature of the licensee management that reviewed and approved the change.

[1]Institutional Review Board approves and monitors the use of the MDS Nordion TheraShere® Y-90 microspheres.

If this authorization is approved, these conditions will be incorporated as license conditions in the licensee's license.

Waste Disposal Issues

In March 2007 NRC staff issued an Information Notice (IN 2007-10) to alert all medical licensees of the presence of radioactive contaminants and possible issues with disposal with the two variations of commercially available Y-90 labeled microspheres, TheraSphere® and SIR-Spheres®. Depending on the contaminants, licensees may need to:

- hold the remaining microspheres longer in decay-in-storage in accordance with 10 CFR 35.92;
- return the microspheres to the manufacturer, if the manufacturer is authorized to receive Y-90 microspheres; or
- transfer the microspheres to an authorized recipient.

IN 2007-10 is available on the NRC public website at
http://www.nrc.gov/reading-rm/doc-collections/gen-comm/info-notices/2007/

PATIENT RELEASE

HANDOUT TO BE PROVIDED AT MEETING

RADIOLOGICAL TERRORISM EVENT RESPONSE

HANDOUT TO BE PROVIDED AT MEETING

Novel Radiotherapeutics
(Dosimetry is the challenge)

Orhan H Suleiman, MS, Ph.D., FAAPM
Senior Science Policy Advisor
Office of Oncology Drug Products
Office of New Drugs
Center for Drug Evaluation and Research

Presented at Nuclear Regulatory Commission Advisory Committee on Medical Use of Isotopes
June , 2007
Rockville, Maryland

1

The opinions expressed today are those of the speaker and may not necessarily be official policy, or an official endorsement, or criticism, by the U.S. Department of Health and Human Services, the Public Health Service, or the U.S. Food and Drug Administration.

2

Current Radiotherapeutics

- SIR-spheres®: Yttrium-90 Microspheres (β)
- TheraSphere®: Yttrium-90 Glass Microspheres (β)
- Bexxar®: Tositumomab I-131 Tositumomab (β,γ)
- Zevalin®: Ibritumomab Tiuxetan (Indium-111)(γ) and Ibritumomab Tiuxetan (Yttrium-90) (β)
- Sr-89-chloride, Sm-153-EDTMP, I-131

3

Refractory or late stage illness

Most radiotherapeutics are indicated for refractory patients or late stage disease.

Why?

4

Dosimetry Issues

- Administered activity
  - Calibration accuracy (Manufacturer vs user)
  - NIST* is not always involved
- Radiation absorbed dose
  - Depends on administered activity
  - Biodistribution (within body, within organ and tissue)
  - Target volume

*National Institute of Standards and Technology

5

Radiation Dosimetry

Diagnostics

Stochastic Risk is low,

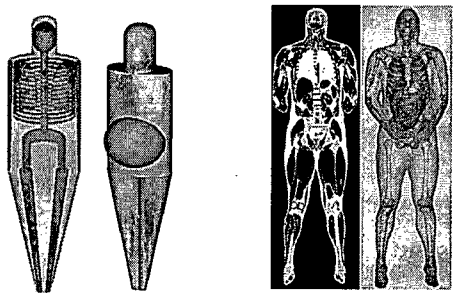
Relatively safe - Uncertainty in estimation is very high, but accepted in practice

Therapeutics

- External beam – Very good!
- Brachytherapy- Internal Sealed Source – Good.
- Internal Unsealed Sources – Generally acceptable for refractory, palliative, or humanitarian use

6

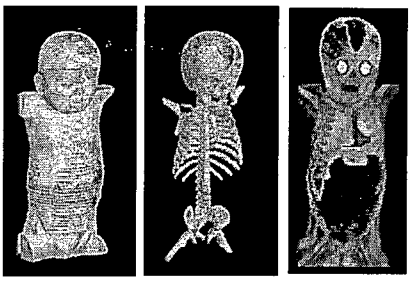
Patient Phantoms
Stylized versus Voxel



MIRD stylized phantoms *Voxel phantoms*

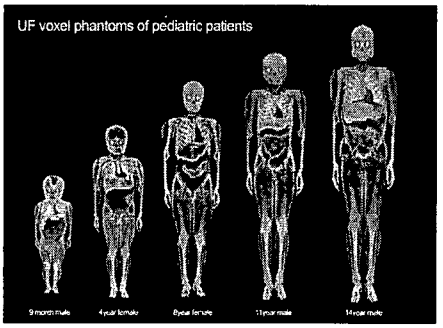
7

Patient Phantoms
UF 9-month male phantom



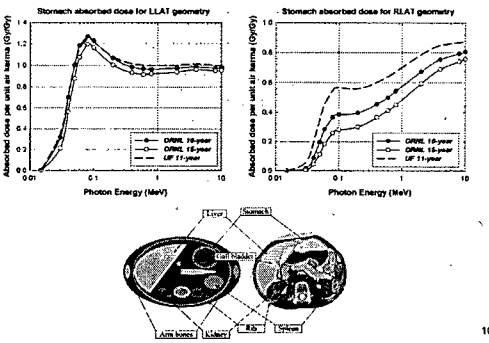
8

Patient Phantoms
UF Pediatric Phantom Series



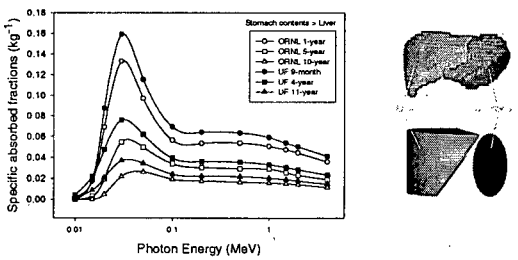
9

Stylized vs Voxel Phantom
External dosimetry



10

Stylized vs Voxel Phantom
Internal dosimetry



11

Radiation Dose

- Administered "dose"
  - Mass dose – pharmacologic, in mg
  - Radioactivity- in MBq (mCi)*
- Radiation Absorbed Dose (physical quantity)
  - mGy (rads)*
- Equivalent Dose or Dose equivalent (biological)
  - mSv (mRem)*

*Older non Standard Internationale Units

12

Radiotherapeutics -1

If radiotherapeutics are to eventually develop into a first-line therapy, then the dosimetry for determining (1) the administered activity and (2) the absorbed dose will have to improve over the current state of the practice. Standard reference patients are simply not acceptable, patient and organ specific modeling is essential.

13

Radiotherapeutics-2

In addition to absorbed dose in Gray (rads), the equivalent dose in Sv (rem) will be significantly different. Tissue modifying factors for dose rate effect and relative biological effectiveness (RBE) become critical, especially for particulate radiations such as beta (β) and alpha (α) emitters.

Doses are not always directly and independently verified or verifiable. Manufacturer stated accuracy is also a concern without traceable standards.

14

Why discuss now?

The state of the practice needs improvement.

The success or failure of these radiolabeled drugs (either in trials or clinical practice), and the ultimate efficacy of this future class of radiotherapeutics as a first line therapy may very well depend on application of new knowledge (radiobiology), and significant improvement in the level of dosimetry with respect to biodistribution, and precision and accuracy in determining the administered activity, and the planning and delivery of the target radiation absorbed dose.

15

Do members of this committee consider this a valid issue?

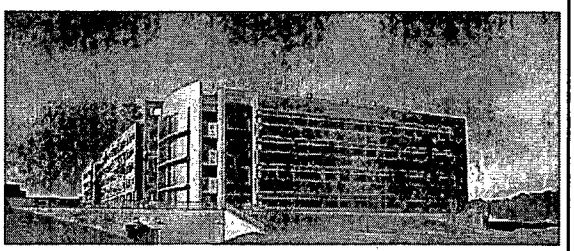
16

Acknowledgements

Wesley Bolch - University of Florida

17

FDA Campus @ White Oak, Silver Spring, Maryland



FDA

Sentinel Node Imaging and Lymphadenectomy

Douglas Eggli, M.D.
Richard Vetter, Ph.D.

Sentinel Node Imaging and Lymphadenectomy

Objectives

- Describe current practice
- Demonstrate safety of practice
- Identify inconsistencies in NRC guidance
- Propose consistent application of Regulatory Guide 8.39 "Release of Patients Administered Radioactive Materials"

Lymphoscintigraphy

Step 1: Lymphoscintigraphy: (less than 1 mCi ^{99m}Tc Sulfur Colloid) identifies sentinel lymph node; provides image for patient record.

Step 2: Patient released by Nuclear Medicine per Reg Guide 8.39, less than 150 mCi ^{99m}Tc.

Step 3: Patient may have surgery to remove tumor and sentinel lymph node.

Lymphoscintigraphy

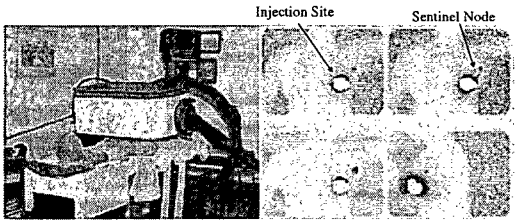
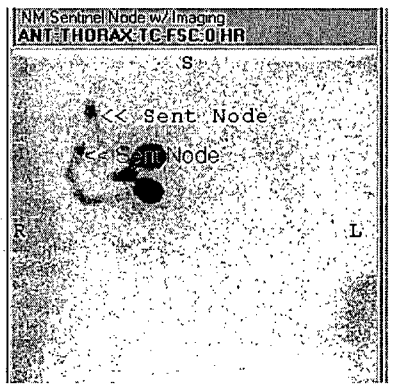


Figure 1. During SLN procedures those nodes infiltrated by tumor cells are identified. After the ^{99m}Tc injection, the patient is imaged with a conventional gamma camera.

From Michel and Hofer, 2004



Patient Release

- After imaging, patient is released per Regulatory Guide 8.39 which authorizes release if activity is less than 150 mCi ^{99m}Tc.
- Other medical procedures including surgery may be performed.
- Additional guidance is provided under NRC Health Physics Position Statement #156.

NRC Health Physics Position Statement #156

"If a licensee administers a radiopharmaceutical for a license authorized procedure, *it may conduct any number of additional procedures* whether they are authorized or not *provided that additional administrations are not performed for purposes of the unauthorized procedure* (although additional administrations may be needed for the authorized procedure). The basis for the above is that once a dose is administered to a patient for a procedure that is authorized, no additional harm from radioactive materials can result to the patient during the conduct of other medical procedures." [Emphasis added]

http://www.nrc.gov/about nrc/radiation/hppos/hppos156.html

Accessed 5/14/2007

Other Medical Procedures Include:

Scan	Other Procedure
Sestamibi or thallium heart scan:	Angiography
	Angioplasty
	Open heart surgery
Thyroid scan	Thyroidectomy
Tumor scan	Resection
Lymphoscintigraphy	Lymphadenectomy

Location of Other Medical Procedures

Imaging	**Surgery**
Hospital	Same Hospital
Hospital	Different Hospital
Outpatient Clinic	Different Hospital
Mobile Imaging	Customer Hospital

When Other Includes Surgery

Figure 2. Intra- and postoperative diagnosis is performed in ORs and pathology laboratories that are usually uncontrolled areas. They involve personnel such as surgeons, anesthesiologists, nurses, and pathologists who are usually neither trained in radiation safety practices nor monitored under their institutional personnel dosimetry program.

From Michel and Hofer, 2004

Why Surgery is Safe for Surgical Personnel

- Patient contains small fraction of releasable quantity per Reg. Guide 8.39
- Personnel doses are low (mrem/procedure):

Authors	Surgeons	Pathologists
Waddington, 2000	<0.2	neg.
Tosi, 2002	<1.2	<1.9
Kopp, 2002	<1.6	<2.2
Morton, 2003	0.2	0.25

New NRC Guidance

"The surgical removal of the radioactive tissue and its biopsy constitute the medical use of byproduct material in imaging and localization studies and must be performed at a licensed facility under the supervision of an authorized user." NMSS Quarterly Newsletter, March 2006.

http://www.nrc.gov/reading-rm/doc-collections/nuregs/brochures/br0117/06-01.pdf Accessed 05/14/2007

Consequences of the New Guidance

- Mobile nuclear medicine services can no longer provide lymphoscintigraphy if follow-up surgery is planned at a hospital not licensed to handle radioactive material, which decreases revenue and inconveniences the patient.
- Patients whose insurance restricts surgery to a hospital that doesn't possess radioactive material license cannot have lymphadenectomy within plan; this increases cost to the patient. Morbidity is increased if patient undergoes lymphadenectomy without image guidance.

Consequences of the New Guidance

- Increased patient morbidity
  - If image guided sentinel node biopsy cannot be performed, a formal axillary or inguinal lymph node dissection has to be performed.
  - Cost, operative risk, and recovery time are greater.
  - Persistent lymphadema of the affected extremity results. This is a significant medical management problem.

Consequences of the New Guidance

- Hospitals not licensed to handle radioactive material must purchase license from state or NRC and contract for services of authorized user and RSO, which increases cost.
- This guidance is inconsistent with Reg. Guide 8.39 which allows release of patients that contain less than 150 mCi ^{99m}Tc and directly contradicts NRC HPPOS #156.

Recommendations

To facilitate best practices in medicine and to put the needs of the patient first:

- Allow lymphoscintigraphy patients to be released unconditionally per Reg. Guide 8.39.
- Allow surgery of released patients at hospitals that do not possess radioactive material licenses.

Recommendations cont.

- Require hospital, clinic, or mobile nuclear service licensed to perform lymphoscintigraphy to educate applicable surgical and pathology personnel at unlicensed hospital in "Recommendations for Handling Radioactive Specimens Obtained by Sentinel Lymphadenectomy" published by Surgical Pathology Committee of the College of American Pathologists and the Association of Directors of Anatomic and Surgical Pathology (2000).

Questions??

New Modalities in Radiation Oncology

SUBIR NAG, M.D., FACR, FACRO
Director of Brachytherapy Services
Northern California Kaiser Permanente
Santa Clara, California

Presentation to the NRC
ACMUI Meeting, June 13, 2007

Nag

Disclosure/Acknowledgement

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  - Isoray Medical Inc.
  - Xoft Inc.
  - Neovista Inc.
- He has no financial interest in any of the above companies

Nag

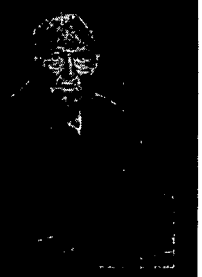
Radiation Safety Considerations of New Modalities

- Cesium-131 permanent seeds
- Xoft/Axxent electronic brachytherapy
- Neovista Sr-90 eye applicator

Nag

Low energy nuclides - historical perspectives

- Advantages of short half life and soft x-ray (20- 30 keV) – Harper 1958
  - –limited depth of radiation penetration in tissue
  - –minimal damage to distant normal tissue
  - –ease of shielding to limit dose to care givers
- 3 isotopes with suitable characteristics identified – I-125, Pd-103, Cs-131
- Donald Lawrence patented I-125 seed (1967) due to lower cost and ease of manufacture; marketed by 3M
- Pd-103 seed by Theragenics in 1980's (FDA approved in 1987)



Donald E. Lawrence

Nag

Disadvantages of current seeds for permanent implants

- I-125:
  - Rel. long half-life (60 days) – low dose rate
  - May be ineffective for faster growing tumors
- Pd-103:
  - Very low energy (21 KeV)
  - "cold spots" may occur if spaced more than 1.5 cm apart

Nag

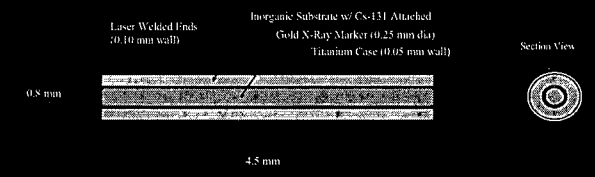
Cesium-131 – historical perspectives

- Chemist at Pacific Northwest National Lab (PNNL) - Lane A. Bray - process for economically separating and purifying Cs-131 (1998)
- IsoRay Medical co-founded in 1998 by Don Lawrence and Lane A. Bray
- Cs-131 seed FDA approved: March 28, 2003 - 510(k) No. K030162

Nag

Cesium-131 permanent seeds

- Seeds identical in size to I-125 or Pd-103 seeds
- Made by IsoRay - Model CS-1 brachytherapy seed
- Cs-131 adsorbed onto an internal inorganic substrate



Nag

Cesium-131 Indications

- Mainly for permanent prostate implants (as monotherapy or boost)
  - 540,000 cases per year worldwide
- Permanent implants at other sites eg. breast
  - 1.05 million cases worldwide
- As a removable implant
  - eye plaque
  - breast implant

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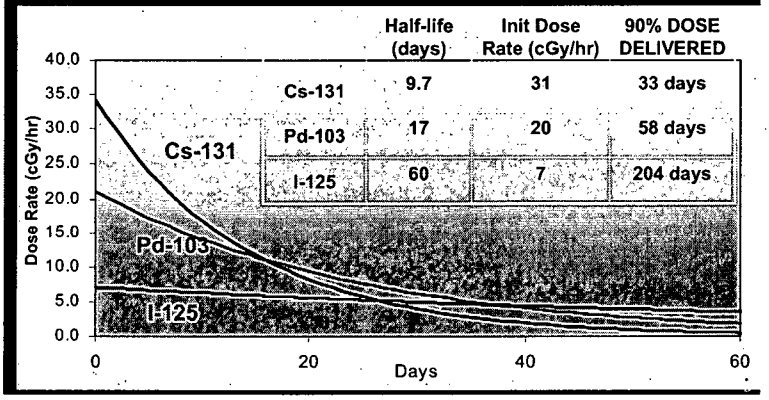
Physical characteristics of Cs—131 vs I-125 vs Pd-103

Cs-131 – short half-life: higher initial dose rates



Biological Effectiveness of Cs-131

- Optimum half-life for most tumors = 4 - 17 days
- Optimum half-life for fast repopulating tumors = 0- 5 days
- Cs-131 (T ½ = 9.7 days) predicted to be more efficacious for tumors with faster repopulation rates
- Less sensitive to variations in a/b ratio than I-125

*Armplilia, et.al., IJROBP 55(2):378-385 (2003)

Nag

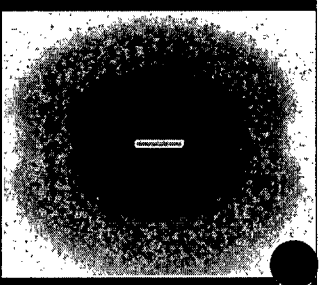
Cesium-131 – short half life

- Most (90 %) of radiation delivered in 1 month
  - vs 2 mo for Pd-103 and 6 mo for I-125
- Essentially all (99 %) of radiation delivered in 3 month for Cs
  - vs 6 mo for Pd-103 and 2 yrs for I-125
- Faster tumor regression – seeds come closer – increasing tumor dose delivered
- Side effects for a shorter duration
- Short shelf life – seeds need to be used within 2-3 days

Nag

Isotope Comparison - Dose Uniformity

ISOTOPE	TOTAL DOSE	ANISOTROPY FACTOR
Cs^{131}	105 Gy	.969
Pd^{103}	125 Gy	.877
I^{125}	145 Gy	.930

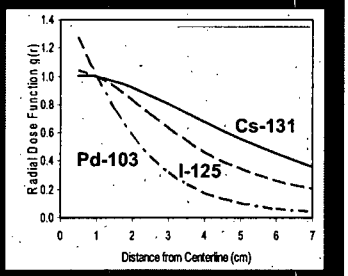


Autoradiograph

Nag

Cesium-131 - energy

- Energy (29 KeV)
  - consideration for penetration and radiation safety
  - similar to I-125
  - more penetration (vs Pd) – less risk of cold spots
  - minimal radiation hazards to medical workers, caregivers or surrounding organs



Radial Dose Function

Nag

Clinical History

- October of 2004 - patient first treated with Cesium-131 seeds at University of Washington, Seattle
- To date over 1200 patients treated
- Approx. 45 centers using Cs-131 seeds
- Another 25 centers about to use Cs-131 seeds

Nag

Radiation Safety and regulatory considerations

- Similar to Iodine-125 or Palladium-103
  - Source size identical to I or Pd
  - Similar energy
- Need shorter time for storage till decay (10 half lives - 3 months) due to shorter half life

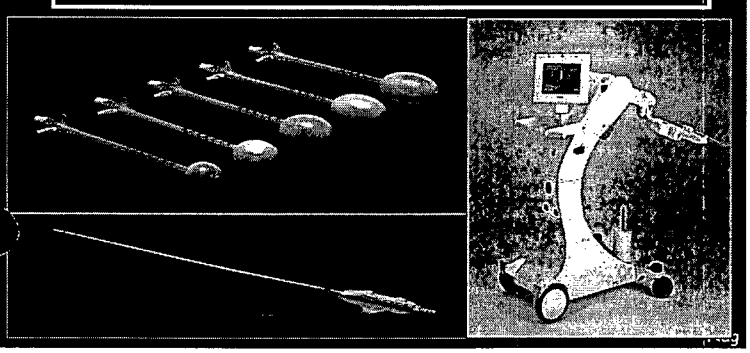
Nag

Clinical future

- Radiobiologically better than Iodine-125 or Palladium-103
- Not known if that will translate to better clinical outcome (better control and/or lower morbidity)
- Shorter half life may present a problem if case is postponed

Nag

Xoft Axxent Electronic Brachytherapy System

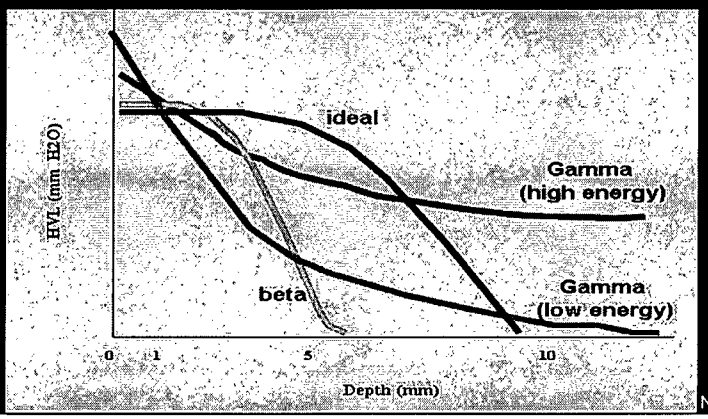


Brachytherapy definition

- Strict definition of Brachytherapy - Treatment of neoplastic diseases by radioisotopes placed inside or close to tumors
- "Brachy" (Gk) – close distance; therapia – treatment
- Broad definition of Brachytherapy - Treatment of diseases by sources placed inside or close to tumors

Nag

Ideal brachytherapy system - penetration



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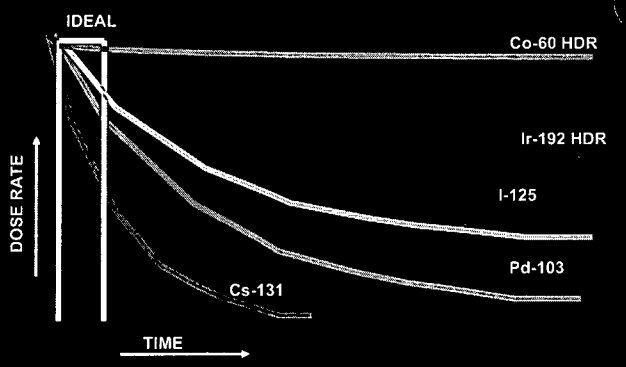
Ideal brachytherapy dose rate



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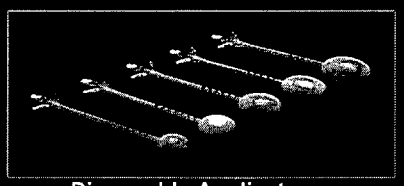
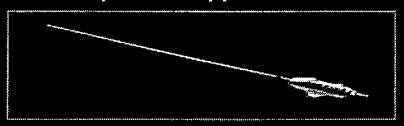
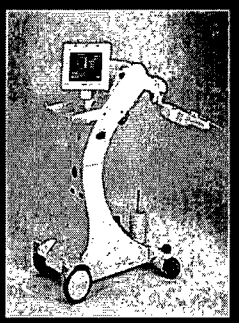
Xoft APBI System – an offshoot of intracoronary brachytherapy



Disposable Applicators



Disposable HDR X-Ray Source

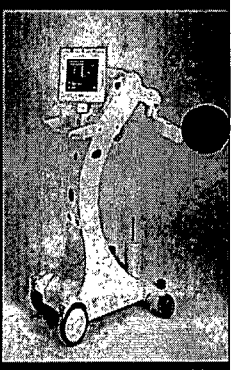


Xray Controller

Nag

Electronic Brachytherapy *Controller*

- Delivers power to electronic brachytherapy source
- Steps source dwell positions
- Uses output from conventional brachytherapy treatment planning systems



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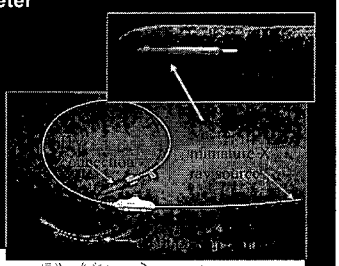
Disposable HDR X-Ray Source

- Miniaturized x-ray tube 2.2mm in diameter
- Fully disposable device
- Up to 50 kV operating potential
- NOT a radioactive source, yet
  - –Designed to closely mimic HDR ^{192}Ir dose rate
  - –Output: 0.6 Gy/min. measured in water, 3 cm from source axis
  - –Treatment times are comparable to ^{192}Ir

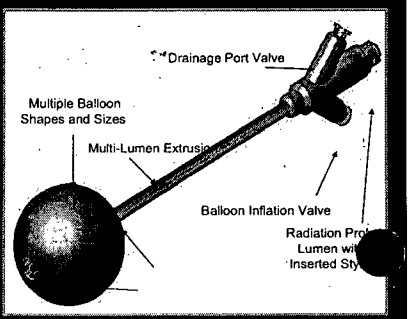


X-Ray Source Tip Detail

Nag

Axxent™ Balloon Applicator

- Like a mammosite balloon
- Integral drain built into applicator for seroma management
- Radiolucent Balloon Wall for improved visibility on planar film and in CT images.



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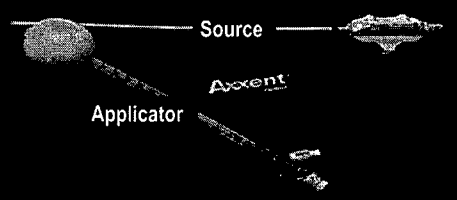
Disposable Flexishield, Applicator, Source

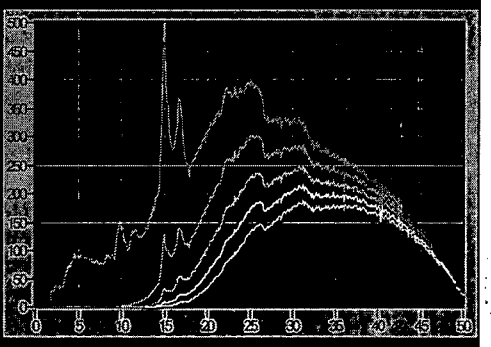


Flexishield:
flexible silicone-based radiation shield – 0.4mm Pb equiv

Nag

Spectral Characteristics and RBE

- Average energies: 26.7, 31.0, 32.6, 33.6 and 34.5 keV.
- RBE of Axxent x-ray source (vs 250 KeV) is about 1.2 (Fowler, J)
  - Similar to I-125 or Ir-192



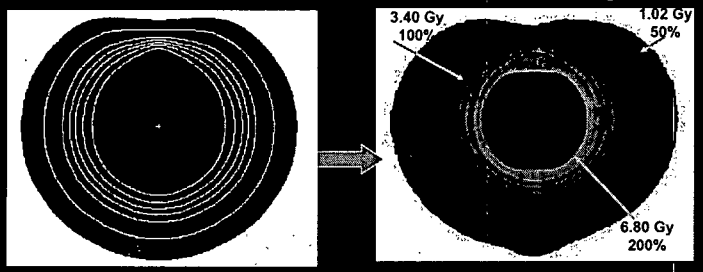
Spectrum (counts vs. energy) during 50kVp operation

Nag

X-Ray Source Distribution Pattern

BrachyVision® Isodose Contours

Radiochromic Film Image



34 mm Spherical Balloon 40kvP Calibrated to dose in Gy

Dose Plan Matches Dose Delivered

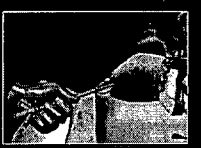
Nag

Xoft Balloon Applicator Implant

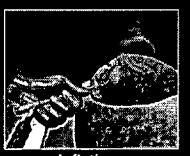
Typically performed by surgeon in office:

Lateral skin incision

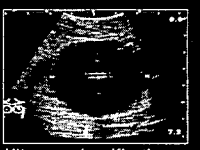
Trocar used to create pathway



Placement of Applicator into cavity



Inflation



Ultrasound verification (can also use X-ray or CT)

Inflated Applicator in position

Nag

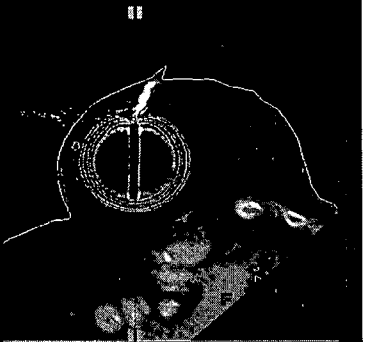
Radiation Treatment and Planning

- 50 kV operating voltage; max energy 50 keV
- Treatment plans developed from CT images with commercial treatment planning system
- Twice daily confirmatory imaging
- Total brachytherapy dose – 34 Gy
  - 3.4 Gy X 10 fractions
  - Delivered twice daily
  - (Same as implemented in NSABP B-39 trial)

Nag

Imaging and Treatment Planning

- Typically developed by physicist and/or dosimetrist:
- CT image is used to develop treatment plan of dwell positions and times

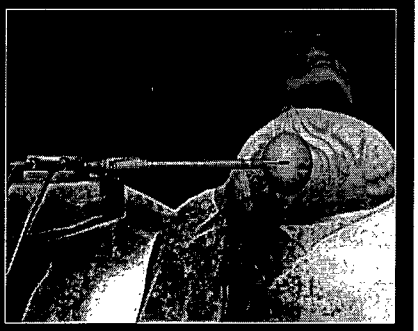


Plan shown is simulated. Isodose lines represent dose as determined by treatment planning system using Xoft TG-43 parameters. CTs of Xoft balloon in water bath are superimposed on patient CT images.

Nag

Treatment

- Similar to HDR
- Source automatically advanced into the applicator (stepping source)
- Typical treatment plan use 5-10 dwell positions
- Typical treatment time: 5-10 minutes



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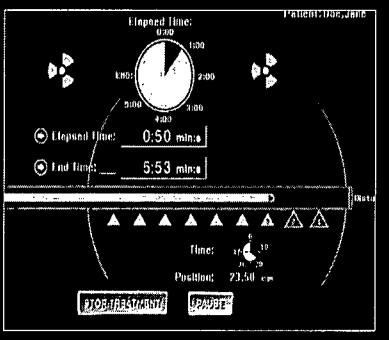
Treatment Controller displays



- total elapsed time (both digital and analog)
- planned total time
- visual display of source position
- time elapsed and remaining at current dwell position

Nag

Axxent Electronic Brachytherapy System Radiation Exposure Levels

- Does not require shielded room
- 15 mR/hr at a typical operator's location
  - did not include FlexiShield in all measurements
  - Attenuation consistent with expected for 50 keV maximum x-ray energy
- Each site to provide exposure rate data to the state as part of the license application

Nag

Quality Assurance / Quality Control

- No reports to specifically address electronic brachytherapy
- Utilize the concepts of AAPM brachytherapy reports for guidance to outline possible QA/QC program
  - TG-43 Brachytherapy dosimetry formalism (1995, 2004)
  - TG-56 Code of practice for brachytherapy (1997)
  - TG-59 High dose rate treatment delivery (1998)
  - CLA Subcommittee on source calibration (2004)

Nag

FDA status for Xoft device

- FDA cleared 12/22/05 – K050843
- "to deliver intracavitary or interstitial radiation to the surgical margins following lumpectomy for breast cancer."

Nag

Axxent Electronic Brachytherapy System Regulation status

- Not regulated by NRC (non-radioactive source)
- No specific QA or regulatory guidance for eBx from AAPM, State DPH, or CRCPD at this time;
- In development / In discussion with regulators in states slated for first human use study

Nag

Advantages of Axxent electronic brachytherapy

- Ability to switch the source on/off
- Adjustable radiation output
- Less shielding required compared to Ir-192 (does not need shielded room)
- Elimination of need for radioactive waste disposal
- Dosimetric characteristic mimics Ir-192 HDR afterloader
- But no NRC requirements or medical event consequences

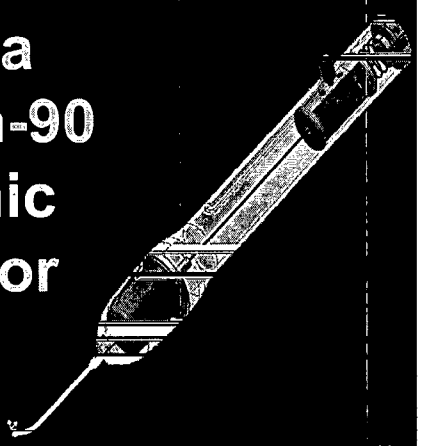
Nag

Summary / clinical future

- 2 sites treating now; plan 30 centers by end of 2007
- Currently FDA approved only for breast
- No off-label use as of now
- Potential for e-brachytherapy at other sites (eg vaginal applicators planned)
- Non-radioactive source a major advantage
- Reusable source/applicator can bring down cost
- Comparison to HDR analogous to linac vs Co-60 for external beam XRT

Nag

Neovista Strontium-90 Opthalmic Applicator



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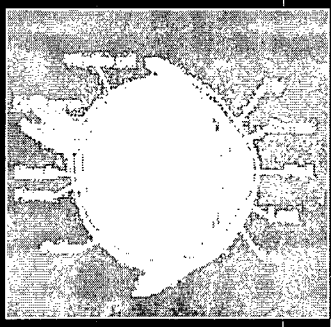
ERROR: undefined
OFFENDING COMMAND: ;O1n0M232L'W3^#8X

STACK:

Age-Related Macular Degeneration (AMD)

- Disease associated with aging that gradually destroys sharp, central vision
- AMD affects macula, (the part of the eye that allows you to see fine detail)
- Leading cause of vision loss in Americans 60 years of age and older
- AMD occurs in two forms: wet and dry



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Dry AMD
(non-neovascular)

- Early stage of AMD
- Light-sensitive cells in the macula slowly break down
- Gradually blurring central vision in the affected eye
- Over time, as less of the macula functions, central vision is gradually lost in the affected eye
- No treatment
- 10% can progress to wet AMD

Pre-AMD

Post-AMD

Nag

Wet AMD
(neovascular)

- Wet AMD – advanced AMD
- Abnormal blood vessels start to grow behind the retina (Choroidal NeoVascularization - CNV)
- These new blood vessels often leak blood and fluid which raise the macula
- Damage to the macula occurs rapidly – loss of central vision

Initial Symptoms

12 months later

Nag

Treatment of wet AMD

- Wet AMD can be treated by:
  - Laser surgery
  - Photodynamic therapy (PDT)
  - Injection of drugs into the eye
- None of these treatments is a cure
- The disease and loss of vision may progress despite treatment

Nag

Laser surgery

- Laser beam directly destroys the new blood vessels - preventing further loss of vision
- May also destroy some surrounding normal retina - some vision loss
- More effective if neovasculature developed away from fovea (central part of the macula)
- Risk of new blood vessels developing after laser treatment is high
- Repeated treatments may be necessary
- Only small percentage are candidates

Nag

Photodynamic therapy (PDT)

- Drug called verteporfin (Visudyne®) injected into arm - travels throughout the body, including new blood vessels in eye
- Drug tends to "stick" to the surface of new blood vessels
- Cold laser light directed into eye activates the drug
- Activated drug destroys new blood vessels - slows the rate of vision loss
- PDT does not stop vision loss or restore vision in eyes already damaged by advanced AMD
- Unlike laser surgery, does not destroy surrounding healthy tissue

Nag

Injection of anti-VEGF (Macugen®) into eye

- Abnormally high levels of a specific growth factor (VEGF) occur in eyes with wet AMD and promote the growth of abnormal new blood vessels
- Injection of anti-VEGF into back of eye blocks the effects of the growth factor
- Need multiple injections (9) that may be given as often as monthly
- Anti-VEGF treatment can help slow down vision loss from AMD and in some cases improve sight

Nag

Injection of anti-angiogenic drugs (®) into eye

- Anti-angiogenic drugs injected of into back of eye
  - Lucentis® - ranibizumab (Genentech)
  - Off label use of Avastin ® (FDA approved for colon ca)
- Prevents growth of abnormal new blood vessels
- Need multiple injections (9-12)
- Anti-angiogenic drug treatment can help slow down vision loss from AMD and in some cases improve sight

Nag

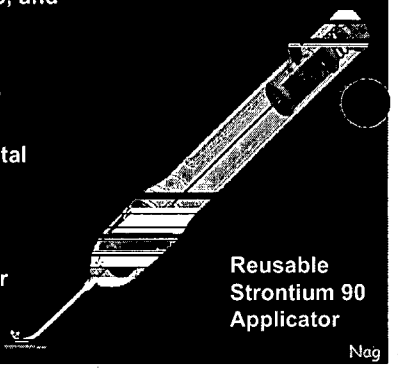
Rationale for radiation

- Proliferating choroidal neovascular cells have some similarity to neoplastic cells and benign cells like pterygium, neointimal hyperplasia cells
- Ionizing radiation has proven use in keloids, pterygium, neointimal hyperplasia etc
- Ionizing radiation has toxic effect on local pro-inflammatory and fibroblast cell populations

Nag

Neovista Strontium-90 Opthalmic Applicator

- Reusable device - size 20, 23, and 25 Gauge
- Hand-held applicator
- Delivers radiation directly to macula
- Strontium 90 attached to distal end of guide wire
- Lever extends wire to the cannula tip
- Retracts within housing after treatment



Reusable Strontium 90 Applicator

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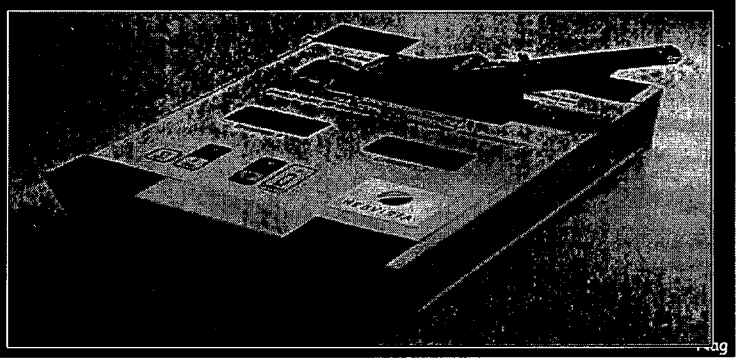
Multi-Channel Tester

- Used for source verification prior to each treatment



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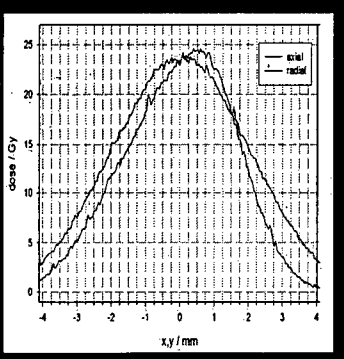
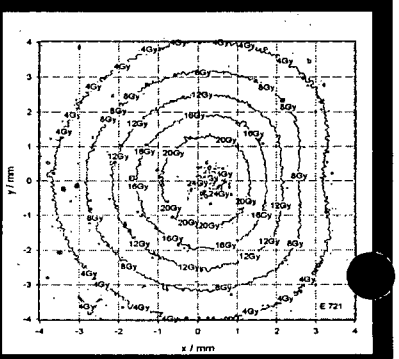
Dose Rate Profile



Isodose Curves



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Procedure

- Minimally invasive out-patient treatment
- Performed during Partial Vitrectomy procedure
- Local anesthesia
- 20-30 Minutes Total Treatment Time for Physician
- Controlled Penetration Depth - Approx 3mm
- Focal Therapy Irradiates Treatment Area

Nag

NeoVista Strontium-90 Opthalmic Applicator Clinical trials

- NeoVista proof of concept in Phase 2 radiation trials
- 28% of patients with 3 line gain (1 Radiation Tx alone) - *Comparable to Lucentis*
- Concomitant with Anti-VEGF may generate better results
- Entering Pivotal Phase 3 trials

Nag

CABERNET trial - Central Neo Vascularization secondary to AMD treated with Beta Radiation Epiretinal Therapy

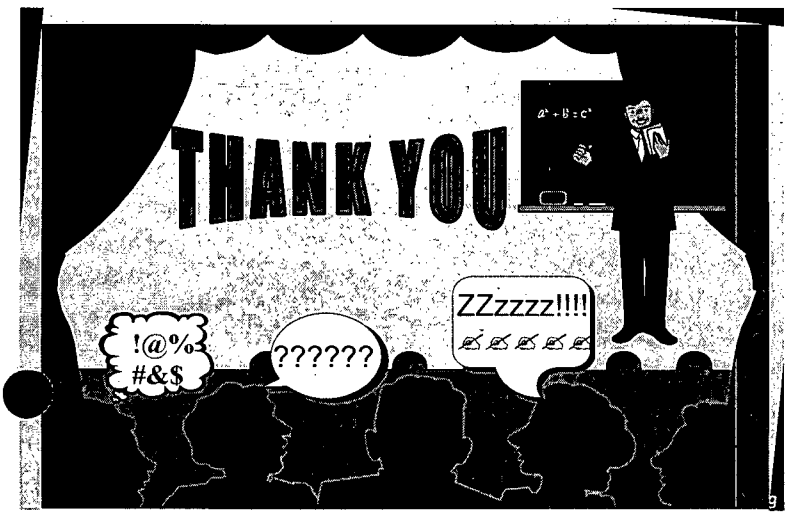
- Prospective, Randomized Phase 3, active controlled
- Non-Inferiority Design
  - Arm A- 24 Gy Neovista with ranibizumab (Lucentis)
  - Arm B (Active Control)- ranibizumab
- 450 Patients
  - 300 Surgical Arm
  - 150 ranibizumab Control Arm
- Approximately 30 Sites Worldwide
  - 20 US
  - 10 Outside US

Nag

Summary / concerns

- Used by opthalmologists with little or no radiation training
- Little or no radiation oncologist input
  - (similar to early days of intracoronary brachytherapy)
- Radiation used almost as a "burning" tool
- Hand held equipment
- No detailed dosimetry
- Need to develop the technology addressing above concerns

Nag



Elekta Perfexion®

ACMUI Meeting

June 13, 2007

Donna-Beth Howe, Ph.D.

Perfexion® 35.1000 USE

Leksell Gamma Knife® Perfexion™ gamma stereotactic radiosurgery unit

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

291 cobalt sources with approximately 34 curies of activity per source

Substantially redesigned and re-engineered

no longer has components required for test in Subpart H

Perfexion® 35.1000 USE

Major Features

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

Perfexion® 35.1000 USE

Written directive

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

Perfexion® 35.1000 USE

Spot-checks and full calibration.

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

Perfexion® 35.1000 USE

The purpose of the test

assess whether the patient docking systems functioned correctly

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

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

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

Perfexion® 35.1000 USE

Training and experience

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

Two Categories of individuals

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

Perfexion® 35.1000 USE

- To ensure the physician has work experience with the Perfexion™ unit, training must include completion of at least X clinical cases, as well as X clinical case studies in which the physician does the treatment planning, quality control steps, and simulated patient treatment. Additional clinical cases may substitute for the clinical case studies.

Perfexion® 35.1000 USE

Each Individual:

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

Perfexion® 35.1000 USE

All Individuals

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

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

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

Perfexion® 35.1000 USE

Written attestation

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

Perfexion® 35.1000 USE

Spot-check and full calibration

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

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

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

James S. Welsh, MS, MD

Background

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

Background

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

10 CFR 35.27

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

10 CFR 35.27 Supervision

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

Potential problems

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

Simple Solution

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

NMED Overview

ACMUI Presentation
June 13, 2007
Michele Burgess, NRC

Purpose

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

Overall NMED System

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

NMED National Website

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

NMED National Website (cont.)

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

NMED National Website (cont.)

- Live online demonstration

Other Important Items

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

Other Important Items (cont.)

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

Wrap-up

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

Contacts

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

CLOSING

NO HANDOUT

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

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

   Advisory Committee on the Medical Uses of Isotopes

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

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

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

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

   Continuing Committee.

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

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

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

   U.S. Nuclear Regulatory Commission.

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

7. **Estimated annual direct cost of this Committee:**

   Members are appointed by the Director, Office of Federal and State Materials and Environmental Management Programs as Special Government Employees (SGEs). Approximately 13 members utilize 1 FTE (includes approximately 0.6 FTE for NRC staff and 0.4 FTE for ACMUI members compensation and travel).

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

Five meetings per year, three of which are teleconferences.

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

Continuing Committee subject to Charter renewal on March 17, 2008.

10. **Filing date:**

March 15, 2007

/RA/

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

ACMUI
OCTOBER 24, 2006

U.S. NUCLEAR REGULATORY COMMISSION

OFFICE OF FEDERAL AND STATE MATERIALS AND ENVIRONMENTAL MANAGEMENT PROGRAMS

ADVISORY COMMITTEE ON MEDICAL USES OF ISOTOPES

BYLAWS

CONTENTS

PREAMBLE

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

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

1. Scheduling and Conduct of Meetings

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

1.1 Scheduling of Meetings:

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

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

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

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

1.2 Meeting Agenda:

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

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

1.3 Conduct of the Meeting:

1.3.1 All meetings will be held in full compliance with the Federal Advisory Committee Act. Questions concerning compliance will be directed to the NRC Office of the General Counsel.

1.3.2 The Chair will preside over the meeting. The Vice Chair will preside if the Chair is absent or if the Chair is recused from participating in the discussion of a particular agenda item. The Designated Federal Officer will preside when both the Chair and the Vice Chair are absent and/or recused from the discussion, or when directed to do so by the Commission.

1.3.3 A majority of the current membership of the ACMUI will be required to constitute a quorum for the conduct of business at an ACMUI meeting.

1.3.4 The Chair has both the authority and the responsibility to maintain order and decorum, and may, at his or her option, recess the meeting if these are threatened. The Designated Federal Officer will adjourn a meeting when adjournment is in the public interest.

1.3.5 The Chair may take part in the discussion of any subject before the ACMUI, and may vote. The Chair should not use the power of the Chair to bias the discussion. Any dispute over the Chair's level of advocacy shall be resolved by a vote on the Chair's continued participation in the discussion of the subject. The decision shall be by a majority vote of those members present and voting, with a tie permitting continued participation of the Chair in the discussion.

1.3.6 When a consensus appears to have developed on a matter under consideration, the Chair will summarize the results for the record. Any members who disagree with the consensus shall be asked to state their dissenting views for the record. Any ACMUI member may request that any consensus statement be put before the ACMUI as a formal motion subject to affirmation by a formal vote. No ACMUI position will be final until it has been formally adopted by consensus or formal vote, and the minutes/transcript written and certified.

2. MINUTES/TRANSCRIPTS

2.1 Minutes/transcripts of each meeting will be prepared by the ACMUI Chair, with assistance from the FSME staff, in accordance with the requirements in 10 CFR Part 7. The Commission staff will prepare minutes/transcripts of ACMUI meetings with the Commission.

2.2 The ACMUI Chair will certify the minutes/transcripts in accordance with 10 CFR Part 7.

2.3 In accordance with the requirements of the NRC's Operating Plan, FSME staff will prepare a meeting summary. The FSME staff will e-mail the meeting summary document or web link to the ACMUI members.

2.4 Copies of the certified minutes/transcripts will be made available to the ACMUI members, and to the public, not later than 90 days after the meeting.

3. APPOINTMENT OF MEMBERS

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

3.2 The Chair will be appointed by the Director, FSME, from the membership of the ACMUI. The Chair will serve at the discretion of the Director, FSME.

3.3 The Vice Chair will be appointed by the Director, FSME, from the membership of the ACMUI. The Vice Chair will serve at the discretion of the Director, FSME.

4. CONDUCT OF MEMBERS

4.1 If a member believes that he or she may have a conflict of interest with regard to an agenda item to be addressed by the ACMUI, this member should divulge it to the Chair and the Designated Federal Officer as soon as possible, but in any case before the ACMUI discusses it as an agenda item. ACMUI members must recuse themselves from discussion of any agenda item with respect to which they have a conflict of interest.

4.2 Upon completing their tenure on the ACMUI, members will return any privileged documents and accountable equipment (as so designated by the NRC) provided for their use in connection with ACMUI activities, unless directed to dispose of these documents or equipment.

4.3 Members of the ACMUI are expected to conform to all applicable NRC rules and regulations, and are expected to attend meetings regularly and perform all assigned duties.

5. ADOPTION AND AMENDMENTS

5.1 Adoption or approval of an amendment of these bylaws shall require an affirmative vote of two-thirds of the current ACMUI membership and the concurrence of the Director of the Office of Federal and State Materials and Environmental Management Programs.

5.2 Any member of the ACMUI or FSME staff may propose an amendment to these bylaws. The proposed amendment will be distributed to the members by the Chair and scheduled for discussion at the next regular ACMUI meeting.

5.3 The proposed amendment may be voted on as early as the next ACMUI meeting after distribution to the members.

5.4 The ACMUI shall consult with the Office of the General Counsel regarding conflicts that arise from the interpretation of the bylaws. After consultation, the ACMUI shall resolve interpretation issues by a majority vote of the current membership of the ACMUI.

MEETING OF THE
ADVISORY COMMITTEE ON THE
MEDICAL USES OF ISOTOPES

October 24, 2006

MEETING SUMMARY

PURPOSE: To discuss issues related to the implementation of the medical regulations in 10 CFR Part 35, "Medical Use of Byproduct Material."

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

TUESDAY, OCTOBER 24, 2006 (CLOSED SESSION[1])

ETHICS BRIEFING

Mr. Szabo, Office of General Counsel provided the ACMUI its required annual ethics briefing.

AMENDMENTS TO THE ACMUI'S BYLAWS

Ms. Flannery, NRC, presented proposed amendments to the ACMUI bylaws and the proposed changes were approved.

The following motion was made by the ACMUI during this presentation:

MOTION: ACMUI approve the proposed changes to the ACMUI bylaws.

REVISED SELF-EVALUATION QUESTIONS

Ms. MacIntosh, NRC, presented to the Committee the revised self-evaluation questions.

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[1] These sessions were 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."

The following actions items were recommended by the ACMUI during the closed session:

ACTION : The NRC staff should establish a system for evaluating proposed agenda items with a response back to the Committee member as to why a proposed topic was denied.

ACTION: The NRC staff should check on whether ACMUI members can access Informs on-line or whether editable PDF file of Financial Disclosure form can be obtained for the Committee members.

ACTION: The NRC staff should provide a copy of the Nuclear Material Safety and Safeguards (NMSS) reorganization slides to the ACMUI.

ACTION : The NRC should consider listing the ACMUI on the main NRC web page and add ACMUI to the Federal and State Materials and Environmental Management Programs (FSME) organization chart.

ACTION: The NRC should amend future ACMUI agenda to add a standing agenda item that allows the ACMUI a period of time to discuss emerging medical issues.

TUESDAY, OCTOBER 24, 2006 (OPEN SESSION)

NARM LEGISLATION UPDATE

Ms. Chang, NRC, made a presentation to inform the Committee of the activities associated with the NARM legislation that have occurred since last ACMUI meeting. These activities included the receipt of Staff Request Memorandum (SECY-06-0069), the Commission briefing with the stakeholders, publication of proposed rule in *Federal Register*(FRN Volume 79, No. 145), and the public meeting that was held in Las Vegas on August 22, 2006.

Ms. Chang explained that NRC had received 39 comments during the public comment period for the proposed rule. Four of those comments were from Federal Agencies and fourteen were associated with the Agreement States. The remaining comments were from individuals, professionals societies, universities, medical communities, and industries. The comments were in the area of compatibility designations; definition of discrete sources, regulations for items containing Ra-226; old contaminated sites; clarification on licensing practices, specific values of the DAC for N -13 and O -15; grandfathering of Authorized Users, Authorized Nuclear Pharmacists, Radiation Safety Officers; clarification on non-commercial distribution; decommissioning of accelerators, equipments, and facilities; financial assurance for decommissioning; fee categories; waver termination and transition plan.

The speaker also informed the ACMUI that the next steps are to address public comments, revise regulatory requirements, prepare a Federal Register Notice (FRN), send the draft FRN to the States and ACMUI for review and comment, and initiate the office concurrence process. The goal is to submit the Commission paper and the rulemaking package to the Executive Director for Operations on December 22, 2006.

The following actions were recommended by the ACMUI during this presentation:

ACTION: The NRC staff should send the draft final NARM rule to ACMUI for review at the same time that it is sent to Agreement States.

ACTION: The NRC staff should consider workshops regarding NARM implementation for licensees.

REVISIONS TO NUREG 1556 VOLUME 9, 13, and 21

Dr. Donna - Beth Howe, NRC made a presentation to update ACMUI on changes to NUREG 1556, Volume 9, Revision 2, "Consolidated Guidance about Material Licenses: Program Specific Guidance about Medical Licenses". The changes include: 1) revision of sample licenses, 2) addition of SI units, 3) an update to the Agreement State map, 4) addition of information about sensitive information, 5) incorporation of the changes in 10 CFR Part 35, 6) removal of all references to subpart J, and 7) addition of accelerator produced radioactive materials and Ra-226. NRC will publish the final guidance after incorporation of the changes in the regulations due to the NARM rulemaking.

Mr. Duane White, NRC, provided information to the Committee regarding the changes to NUREG 1556, Volume 13, " Consolidated Guidance about Material Licenses: Program Specific Guidance about Commercial Radiopharmacy Licenses" and the new NUREG 1556 Volume 21, Consolidated Guidance about Material Licenses: Program Specific Guidance about Possession of Licenses for Production of Radioactive Materials Using an Accelerator". The revision to Volume 13 include: 1) adding accelerator produced materials such as positron emission tomography (PET) radionuclides, 2) referring radiopharmacies, which use an accelerator to produce radioactive materials, to the new NUREG 1556 Volume 21, 3) providing some radiation safety recommendations for handling high energy photon-emitting radionuclides (e.g. pocket dosimeters), and 4) ensuring applicants are aware that discrete sources of Ra-226 now need to be identified and licensed by NRC.

NUREG 1556 Volume 21 addresses: 1) listing accelerator produced activation products to as radioactive materials, 2) radiation safety training for individuals who perform maintenance and repair on the accelerator, 3) requiring a detail description of the facility's layout, which would include method used to transfer radioactive material from the accelerator to other areas of the facility or to another licensee, and 4) raising awareness that discrete sources of Ra-226 now need to be identified and licensed by NRC.

The following action items and motion were recommended by the Committee during this presentation:

ACTION : The NRC staff should provide the three NARM-related guidance documents (NUREG 1556 Volumes 9,13, and 21) to ACMUI for review and comments.

ACTION : NRC should allow the Regions some flexibility from meeting their normal METRICS requirements in reviewing amendments requests that are NARM related. This action will assures NRC that some of the items will not fall through the cracks.

MOTION: NRC staff should follow-up with the ACMUI via e-mail regarding ACMUI's

proposed rewording of the statements in NUREG 1556, Volume 21 as presented in paragraph two of Mr. White's third slide.

PETITIONS FOR RULEMAKING

Petition Submitted by Mr. Peter Crane

Ms. Neelam Bhalla, NRC, updated the ACMUI on a petition regarding release of I-131 patients. The petition was filed by Peter Crane on September 21, 2005. A notice was published in Federal Register on December 21,2005 and comment period ended on March, 6, 2006. The petition review board is expected to make a determination on how to respond to the petition by December 20, 2006. The speaker informed the Committee that NRC has received 48 comments from patients, physicians, medical physicists, radiation safety officers, and professional organizations. Fourteen of the comments supported the petition and 31 opposed.

The petitioner requested to change 10 CFR 35.75 to reflect the NRC's patient release criteria prior to 1997. This criteria required the measured dose for release of I-131 patient to be less than 5 mrem per hour at a distance of one meter from the patient. Mr. Crane claimed that NRC has allowed for reduction of exposure to hospital employees at the expense of elevated exposure to family members. At the end, the speaker stated that a working group is reviewing the petition to determine whether there is a need to amend the current regulations.

Petition Submitted by William Stein III, PhD

Mr. James Firth, NRC, updated the ACMUI on the petition that was submitted by William Stein III, MD. The petition requested NRC to establish training and experience requirements for Authorized Users limited to parenteral administrations requiring a written directive of the following:

^{153}Sm-lexidronam (Quadramet),

^{131}I-tositumomab (Bexxar), and

^{90}Y-ibritumomab tiuxetan (Zevalin)

In addition to that request the petitioner requests that NRC recognizes the following adequate training and experience for the limited Authorized User status:

80 hours of classroom and laboratory training
Supervised work experience, and Written attestation.

NRC has received 23 comments from Agreement States, Organizations, and physicians.

The following motion was made by the ACMUI during this presentation:

Motion: That ACMUI opposed the petition as submitted by Dr. William Stein.

A Request for Petition for Rulemaking Submitted by Dr. E. Russell Ritenour

Dr. Ron Zelac, NRC, advised the Committee on the status of a request for petition for rulemaking

from the American Association of Physicists in Medicine. The petition was dated September 10, 2006 and will be noticed in the *Federal Register.* The comment period will end 75 days after the date noticed in the *Federal Register.* Resolution is anticipated approximately 1 year from the date noticed in the *Federal Register* or sooner.

Dr. Zelac explained to the Committee that the Dr. Riteneour requested NRC to revise 10 CFR 35.57 to "grandfather" as Authorized Medical Physicists all medical physicists certified by either the American Board of Radiology or the American Board of Medical Physicists on or before October 24, 2005, for the modalities that they practiced as of October 24, 2005. In addition the Dr Riteneour request that 10 CFR 35.57 be revised to "grandfather" as Radiation Safety Officers (RSO) all individuals certified by boards named for Radiation Safety Officer (RSO) training and experience requirements in the former 10 CFR 35 Subpart J who have relevant work experience, providing appropriate preceptor statements are submitted.

STAFF ACTIONS for AUTHORIZED MEDICAL PHYSICIST (AMP) and RADIATION SAFETY OFFICER (RSO) RECOGNITION

Ron Zelac, PhD, NRC, explained to the ACMUI the staff actions for recognizing amps and RSO. The speaker listed the available pathways to authorized (recognized) status as: 1) the certification pathway (10 CFR 35.50(a) and (c); 35.51(a)), 2) the "grandfather" provision pathway (35.57(a)), 3) the notification provision pathway (35.2 and 35.14); for AMP only, not for RSO), and 4) the alternate pathway (35.50(b); 35.51(b)).

Dr. Zelac explained why authorization of medical physicists MP as AMPS is a concern. Specifically, Dr. Zelac stated: 1) MP are not "grandfathered" if not listed on licenses or permits by April 29, 2005, 2) that some Agreement States currently don't list MP on licenses; all list RSO, but typically only one per license, and 3) the certification pathways are now time restricted in NRC states and will become so in Agreement States, in 2008.

The speaker described to the ACMUI what NRC is doing to reduce the impact of this issue as follows: 1) encouraging MP to get listed on licenses or permits Agreement States, to list MP whenever licensing actions occur, 2) encouraging Boards, to broaden recognition times, 3) encouraging Boards, to identify, upon request, diplomates from non-recognized years who meet current requirements for certification pathways to AMP, 4) issuance of All-Agreement States Letter (encouraging listing of MP on licenses), 5) issuing a Regulatory Issue Summary (RIS) (encouraging MP to request being listed), 6) providing copies of the RIS to MP professional organizations and Boards (suggesting that members and diplomates be notified of the RIS), 7) developing revised simplified NRC Forms 313A (for possible use by individuals applying for AMP or RSO status via the certification or alternate pathways), and 8) continuing discussions with Boards (about broadening recognition times and identifying earlier diplomates whose documented training and experience satisfy current requirements).

At the end the speaker added that the NRC staff has prepared a summary information paper on the results of the staff's action to identify problems in authorizing MP under 10 CFR Part 35 that should be with the Commission soon.

The following action item was recommended by the Committee during this presentation:

ACTION : The NRC staff should provide the ACMUI a copy of the pre-decisional paper

to the Commission regarding a summary on the results of staff actions to identify problems in authorizing medical physicists under 10 CFR Part 35 for review and comment.

AMERICAN ASSOCIATION of PHYSICISTS in MEDICINE (AAPM)

Gerald White, PhD, AAPM, made a statement on behalf of AAPM. Dr. White's concern was the issue with the NRC recognition of the boards for their certification process before 2005. The other concern was the certificates that are no longer offered by boards. He expressed concerns about physicists who move from one jurisdiction to another as these regulations changes from one state to another. Dr. White requests a uniform national criteria for authorized medical physicists and RSO. The commenter believes that alternate pathway is more cumbersome and there are a great number of physicists who desire to be listed on a license and have not submitted applications because they do not feel to meet the criteria. Also the commenter believes that the burden should not fall on the boards to evaluate individual applications for years prior to the effective date.

STATUS OF SPECIALTY BOARD

Ms. Cindy Flannery, NRC, summarized the status of specialty boards recognition in as shown in the following table:

Specialty Board:	Status:
Board of Pharmaceutical Specialties	Approved for 35.55
American Board of Nuclear Medicine	Approved for 35.190, 35.290, 35.390
American Board of Health Physics	Approved for 35.50
American Board of Science in Nuclear Medicine	Approved for 35.50
American Board of Radiology (Radiation Oncology)	Approved for 35.390, 35.490, 35.690
American Board of Radiology (Diagnostic Radiology)	Approved for 35.290, 35.392
American Board of Radiology (Radiologic Physics)	Approved for 35.50, 35.51
American Osteopathic Board of Radiology (Rad. Onc.)	Approved for 35.390, 35.490, 35.690
American Osteopathic Board of Radiology (Diag.Rad.)	Approved for 35.290, 35.392
American Osteopathic Board of Nuclear Medicine	Approved for 35.290
American Board of Medical Physicists	Awaiting input

Ms. Flannery explained to the Committee that NRC is discussing options with various specialty boards that are interested in recognizing diplomates certified prior to the effective dates, summarized as below:

American Board of Radiology (ABR) – Radiation Oncology recognized under 10 CFR 35.490 and 35.690 (Effective date of June, 2007). ABR modified their certification process to meet the requirements for recognition under 10 CFR 35.390 only. Since ABR did not need to revise their certification process for recognition under 35.490 and 35.690, ABR is determining an earlier effective date for recognition under 10 CFR 35.490 and 35.690.

The ABR is considering appending the certificates (or providing a letter) for diplomates who met NRC's current T&E requirements at the time of certification. This will be done on a case-by-case basis at the request of the diplomate. This method is under consideration for the following specialties:

American Board of Radiology – Diagnostic Radiology (Effective date of June, 2006)

American Board of Radiology – Radiologic Physics (Effective date of June, 2007)

American Board of Radiology – Radiation Oncology (35.390) (Effective date of June, 2007)

ATTESTATION FOR RADIATION SAFETY OFFICER (RSO)

Ken Brown, MD, American Society for Nuclear Cardiology (ASNC), opened up a discussion on perceptor requirements for authorized users seeking to serve as RSO. Dr. Brown expressed his concern regarding the new requirement in 10 CFR Part 35 that an authorized user (AU) must obtain written attestation, signed by a preceptor RSO, stating that he or she has the necessary radiation safety experience should that AU also wish to serve as the RSO on their license.

A second concern of ASNC revolves around the practicality of having AUs obtain a perceptor statement from an RSO. The statement required for board eligibility or the statement required for those individuals applying on the basis of training and experience criteria is adequate documentation for this purpose.

The speaker believed the result of this additional preceptorship requirement would be limiting patient access to nuclear diagnostic imaging – particularly in small facilities in suburban or rural areas where it is just not feasible or financially possible to employ a full time RSO. Should this requirement continue, it is likely that the patients will have to wait longer or travel farther to receive these critical diagnostic services.

Finally, ASNC believes that this additional mandate possibly resulted from clerical error between the December 9, 2003 proposed rule and the drafting of the March 30, 2005 final rule.

The following motion was made by the ACMUI during this presentation:

> **MOTION: The attestation requirements for all RSO pathways should be deleted from the regulations.**

INTERIM INVENTORY and NATIONAL SEALED SOURCE TRACKING

Interim Inventory

Mr. William Ward, NRC, updated the Committee of the development on interim inventory of the radioactive sources. The speaker explained that the reason for doing an interim inventory is that

NRC has interest in tracking International Atomic Energy Agency (IAEA) category 1 and 2. IAEA Code of Conduct recommends establishment of a national register. After the IAEA issued a Code of Conduct, NRC and Department of Energy (DOE) adopted the IAEA list. NRC develops the Interim Inventory with annual updates until replaced by National Source Tracking System (NSTS). The inventory provides "snapshot" of high-risk sources, includes NRC and Agreement State licensees, and includes IAEA Category 1 and 2 sources. The database has been used to: 1) locate sources following Gulf hurricanes, and 2) issue advisories and orders for enhanced control measures by licensees. Database will be used to inform the NSTS design parameters and provide baseline data.

The speaker also provided the ACMUI with additional information regarding the inventory that NRC performed in 2004 and 2005. With regard to 2006 and 2007 inventories, Mr. Ward explained that: 1) the inventory process for 2006 was similar to that of 2005, however, the data are not analyzed yet, 2) during the 2006 inventory, NRC contacted 3,122 licensees and reviewed 17,389 reports, and 3) the response rate was 97.4%. For 2007, the inventory will include: 1) category 3.5 which is $1/10^{th}$ of category 3 and is 1/100 of category 2, as directed by the Commission, 2) generally licensed devices, and 3) a significantly higher number of sources as compared to 2006.

National Source Tracking System

Mr. Paul Goldberg, NRC, gave an overview and the following reasons for the development of the NSTS: 1) Joint NRC/DOE report on Radiological Dispersal Devices recommends development of a NSTS, 2) IAEA Code of Conduct on Safety and Security of Radioactive Sources recommends establishment of a national register, 3) work underway before 9/11/2001, and 4) Energy Policy Act of 2005 codified requirement for rule and placed requirements on system.

The NSTS will have two phases: 1) interim inventory now provides database on sources – short term solution; gathered valuable data to locate sources, permit implementation of security measures and provide baseline data for NSTS, and 2) introduction of the NSTS.

The speaker added that an interim inventory will be performed annually until NSTS is in place. Requirements for design were guided by a working group consisted of NRC, DOE, and Agreement State representatives. The design was approved by a Screening Committee, with NRC, DOE, and Agreement State membership, and an interagency Committee comprised of representatives from NRC, DOE, Agreement States, and ten other Federal agencies.

The speaker also explained to the Committee that the NSTS will include sealed sources from NRC and Agreement States licensees; and DOE facilities. Special nuclear materials will not be included except Pu-239/Be and Pu-238 sources. Toward the end, the presenter provided the schedule to the Committee.

STATUS OF MEDICAL EVENTS

Dr. Howe, PhD, NRC, provided a list of medical events to the ACMUI to seek insights on the occurrence of these events and how they may be prevented or reduced. Dr. Howe presented the summary of 33 recent medical events for 2006 listed according to the type of use. Dr. Howe then provided an overview of the specific medical events.

Mr. Lieto, ACMUI, made his presentation to inform the Committee of the other medical events involving or related to medical uses of radioactive materials. Mr. Lieto provided an overview of 42 other medical events from October 2005 to October 2006.

The Committee suggested the following action item:

> **ACTION: The NRC should send a strong message to the licensees on the air kerma source strength versus activity.**

PATIENT RELEASE

Ms. Cindy Flannery, NRC, summarized a collaborative effort with Agency Healthcare Research and Quality (AHRQ) on information collection related to patient release. The driver behind this initiative was an AHRQ *Federal Register* Notice issued by AHRQ expressing its intent to perform this study (71 FR 2550). Several NRC stakeholders responded to this FRN. Comments focused on the fact that NRC should be engaged and that this topic falls under NRC jurisdiction. Consequently, AHRQ and NRC began a dialogue concerning the study, and NRC agreed to collaborate.

Patients who have been administrated or have implants are released in accordance with 10 CFR 35.75, and medical facilities are not required to provide patients with information that could be presented to law enforcement personnel. Many patients who are stopped at security checkpoints are not aware that they have received a procedure involving radioactive materials and, therefore, sometimes can not adequately communicate with the law enforcement or personnel at these security checkpoints.

In 2003, NRC issued an Information Notice (IN) to urge medical facilities to provide the patients with information or documentation to present to law enforcement or security personnel at these security checkpoints. NRC has recently issued a temporary instruction (TI). This TI is intended to give direction to the inspectors of the medical facilities on gathering information in addition to what is collected during the inspections. Ultimately, the data will be used and evaluated by AHRQ or CDC and an article will be published in a peer review journal.

ADMINISTRATIVE CLOSING

Mohammad Saba, NRC, reviewed the motions and action items arising from the meeting and discussed proposal dates for the Spring 2007 meeting. The ACMUI and the staff agreed on April 24-25 for the Spring meeting. In addition, the Committee has also requested to meet with the Commission in the Spring of 2007 at the same time. Therefore, the date of the next ACMUI meeting is considered tentative, until such time as the date for Commission Meeting is set by the Office of the Secretary. The meeting was adjourned at 5:24 p.m.

February 21, 2007

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

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

SUBJECT: RESPONSE TO RECOMMENDATIONS FROM THE OCTOBER 24, 2006 MEETING OF THE ADVISORY COMMITTEE ON THE MEDICAL USES OF ISOTOPES

Below are recommendations and action items from the October 24, 2006, meeting of the Advisory Committee on the Medical Uses of Isotopes (ACMUI). Following each recommendation is the U.S. Nuclear Regulatory Commission (NRC) staff's response and/or position.

MOTION: ACMUI approve proposed changes to the ACMUI bylaws.

RESPONSE: The ACMUI bylaws were revised to incorporate all of the changes proposed at October 24, 2006 meeting. The revised bylaws went into effect on that same day.

MOTION: NRC staff follow-up with ACMUI regarding proposed rewording of statements in NUREG 1556, Volume 21.

RESPONSE: Draft NUREG 1556 Volumes 9, 13, and 21 were sent to ACMUI members via Federal Express on November 7, 2006. ACMUI comments were taken into consideration when finalizing the draft for NUREG 1556, Volume 21. Comments from the October 24, 2006, meeting were also considered. For example, the term "Authorized User" will not be used in Vol. 21 because the term is confusing to medical facilities that also had a production facility. At medical facilities the term, "authorized user," refers specifically to a physician, podiatrist, or dentist.

MOTION: ACMUI opposed the petition as submitted by Dr. William Stein.

RESPONSE: NRC staff forwarded ACMUI's recommendation to the Petition for Rulemaking working group.

MOTION: NRC should remove the preceptor attestation requirements in 10 CFR 35.50 for individuals seeking approval as RSO.

RESPONSE: NRC staff is considering the ACMUI's recommendation to remove the attestation requirement for the various RSO pathways in 10 CFR 35.50.

MOTION: **NRC staff should establish a system for evaluating proposed agenda items and provide a response to the Committee member as to why a proposed topic was denied.**

RESPONSE: As an advisory body to the NRC on the medical uses of byproduct material, agenda items proposed by ACMUI members have always been given high priority. If a clearly identified proposed agenda item is not accepted, NRC staff will provide a response to ACMUI stating the reason for denial. If a committee member does not see a proposed item on the agenda or receive a response indicating it was denied, the member should contact NRC staff for further clarification.

MOTION: **NRC staff should verify whether ACMUI members can access Informs on-line or whether an editable PDF Financial Disclosure form can be obtained for the Committee member use.**

RESPONSE: Form OGE 450 'Financial Disclosure' is available as an editable PDF file on the following website: http://www.usoge.gov/pages/forms_pubs_otherdocs/fpo_files/forms/oge450_2006/oge450_automated_06.pdf

MOTION: **NRC staff should provide a copy of the Nuclear Material Safety and Safeguards (NMSS) reorganization slides to the ACMUI.**

RESPONSE: NRC staff provided reorganization charts to ACMUI members at the October 24, 2006 meeting.

MOTION: **NRC should consider listing ACMUI on the main NRC web page and adding ACMUI to the Federal and State Materials and Environmental Management Programs (FSME) organization chart.**

RESPONSE: NRC staff agrees and is in the process of adding ACMUI to the FSME organization chart. ACMUI is currently listed on the main NRC web page under 'Committees and Boards' at http://www.nrc.gov/who-we-are/organization.html.

MOTION: **NRC should amend future ACMUI agendas by adding a standing agenda item that allows the ACMUI a period of time to discuss emerging medical issues.**

RESPONSE: NRC staff agrees. Discussion of emerging medical issues will be added as a standing agenda item for future ACMUI meetings

MOTION: **NRC staff should send the draft final NARM rule to ACMUI for review at the same time that the rule is sent to Agreement States.**

RESPONSE: NRC staff agrees. It is standard practice to forward draft proposed and final rules regarding the medical use of byproduct material to ACMUI for review and comment at the same time that the rules are sent to Agreement States. This practice will also apply to the draft final NARM rule, which is expected to be provided to Agreement States and ACMUI in February 2007.

MOTION: NRC staff should consider workshops regarding NARM implementation for licensees.

RESPONSE: NRC staff is considering NARM workshops for licensees after the final rule is published in the Federal Register.

MOTION: NRC staff should provide NUREG 1556 Volumes 9, 13, and 21 to ACMUI for review and comments.

RESPONSE: NUREG 1556 Volumes 9, 13, and 21 were sent to ACMUI members via Fed-Ex on November 7, 2006. Comments from ACMUI members were solicited for NUREG 1556 Vol. 21. NRC staff took ACMUI comments into consideration when making revisions to this volume. With regard to NUREG 1556, Volumes 9 and 13, ACMUI members will be able to provide comments during the public comment period. The public comment period has been delayed as it pending publication of the final NARM rule.

MOTION: NRC should allow the Regions some flexibility in meeting metrics requirements when reviewing NARM-related amendment requests.

RESPONSE: NRC will discuss flexibility in meeting metrics requirements for NARM-related amendment requests with management.

MOTION: NRC staff should provide ACMUI a copy of the pre-decisional paper to the Commission regarding a summary on the results of staff actions to identify problems in authorizing medical physicists under 10 CFR Part 35.

RESPONSE: NRC staff provided ACMUI a copy of the pre-decisional paper on November 6, 2006.

MOTION: NRC should send a strong message to the licensees on air kerma source strength versus activity.

RESPONSE: This subject will be discussed in further detail at the spring ACMUI meeting.

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MOTION: NRC should send a strong message to the licensees on air kerma source strength versus activity.

RESPONSE: This subject will be discussed in further detail at the spring ACMUI meeting.

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OFFICE	FSME/DMSSA	FSME/DMSSA	FSME/DMSSA		
NAME	A.Tull:td	C.Flannery	S.Wastler		
DATE	02/20/07	02/20/07	02/21/07		

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ADVISORY COMMITTEE ON THE MEDICAL USES OF ISOTOPES

Position	Name	Phone	Email	Title	Address	Fax	Assistant	Comments
Nuclear Medicine Physician	**Douglas F. Eggli, M.D.**	(717) 531-8940	deggli@psu.edu	Dept of Radiology, H066, Penn State Univ Hospital, The Milton S. Hershey Med Center	Room HG300B, PO Box 850, 500 University Dr., Hershey, PA 17033	(717) 531-5596	Debra Pavone (717) 531-5341 dpavone@psu.edu	
Patient Advocate	**Darrell R. Fisher, Ph.D.**	(509) 373-2000 *Restricted PII* cell	dr.fisher@pnl.gov	Sr Scientist, Radioisotopes Program, Pacific Northwest National Lab	*Home: Restricted PII* 902 Battelle Blvd., P7-27, Richland, WA 99354	(509) 373-2001		
Medical Physicist Nuclear Medicine	**Ralph P. Lieto**	(734) 712-8746	lietor@trinity-health.org	RSO, St Joseph Mercy Hospital	Radiation Safety Office, Dept. of Radiation Oncology, 5301 E. Huron River Dr., Ann Arbor, MI 48106-0995 *Home (binder): Restricted PII*	(734) 712-5344		
Health Care Administrator	**Leon S. Malmud, M.D.** CHAIRMAN	(215) 707-7074 (215) 885-0756	malmudls@tuhs.temple.edu	Dean Emeritus, Temple Univ School of Med, Temple Univ Health System	3401 N. Broad St., Philadelphia, PA, 19140	(215) 707-3261	Pat Martin (215) 707-7078 martinp@tuhs.temple.edu	
Radiation Oncologist	**Subir Nag, M.D.**	(408) 851-8085 (408) 851-8000 *Restricted PII* cell	subir.nag@kp.org	Kaiser Permanente Radiation Oncology	3800 Homestead Rd., Santa Clara, CA 95051	(408) 851-8010		
Nuclear Pharmacist	**Sally W. Schwarz, R.Ph.**	(314) 362-8426	schwarzs@mir.wustl.edu	Div of Nuc Med, Mallinckrodt Institute of Radiology, WA Univ School of Med	510 S. Kingshighway Blvd., 4424C Clinical Sciences Research Building Campus Box 8225, St. Louis, MO 63310	(314) 362-9940		
FDA*	**Orhan H. Suleiman, Ph.D.**	(301) 796-1471 *(301) 443-5368	orhan.suleiman@fda.hhs.gov	Senior Science Policy Advisor, Office of Oncology Drug Products, Office of New Drugs, Center for Drug Evaluation and Research (CDER), FDA	USFDA, White Oak Building 22, Room 2206, 1093 New Hampshire Ave., Silver Spring, MD 20993 *Rockwall II Building, 5515 Security Ln., Rockville, MD 20852	(301) 796-9909	*Vikki Kinsey (301) 443-5368 vikki.kinsey@fda.hhs.gov	*Vikki Kinsey, alternate contact for FDA
Medical Physicist Therapy	**Bruce R. Thomadsen, Ph.D**	(608) 263-8500 (608) 263-4183	thomadsen@humonc.wisc.edu	University of Wisconsin-Madison, University of Wisconsin Medical School, Associate Professor	1530 Medical Science Center, 1300 University Avenue, Madison, WI 53706	(608) 262-2413		
Nuclear Cardiologist	**William A. Van Decker, M.D.**	(215) 707-3347 (215) 707-9857	vandecwa@tuhs.temple.edu	Dir of Nuc Card and Assoc Prof of Med, Temple Univ School of Med	1051 Montgomery Ave., Narberth, PA 10972 3401 N. Broad St., 9PP, Philadelphia, PA, 19140	(215) 707-3946	Tanya Santiago 215-707-9587 tanya.santiago@tuhs.temple.edu	
Radiation Safety Officer	**Richard J. Vetter, Ph.D.** VICE CHAIRMAN	(507) 284-4408	rvetter@mayo.edu	Prof of Biophysics, Mayo Clinic College of Med	Medical Sciences B28, 200 1st Street SW, Rochester, MN 55905	(507) 284-0150	Tammy (507) 284-9463	
Radiation Oncologist	**James S. Welsh, M.D.**	(715) 421-7442 *Restricted PII* cell	welsh@humonc.wisc.edu	Med Dir, UW Cancer Center, Riverview	410 Dewey St., P.O. Box 8080, Wisconsin Rapids, WI 54495-8080	(715) 421-7408	Barbara Schmalz (715) 422-9208 schmba@rhahealthcare.org	
Medical Physicist Therapy	**Jeffrey F. Williamson, Ph.D.**	(804) 628-1047	JWilliamson@mcvh-vcu.edu	Prof & Dir, Med Phys Dept of Rad Onc, Med College of VA Hospitals, VA Commonwealth Univ	Department of Radiation Oncology, Virginia Commonwealth University, 401 College Street, B-129, PO Box 980058, Richmond, VA 23298	(804) 827-1670	Sahira Muhammed smuhammad@mcvh-vcu.edu	