**FINAL: 11/2/16**

**SCHEDULING NOTE**

**Title:** **MEETING WITH THE ADVISORY COMMITTEE ON THE MEDICAL USES OF ISOTOPES (Public Meeting)**

**Purpose:** Provide the Commission an opportunity to hear views from the Advisory Committee on the Medical Uses of Isotopes (ACMUI) on medical-related topics of regulatory interest.

**Scheduled:** **April 27, 2017**
**10:00 am**

**Duration:** Approx. 1.5 hours

**Location:** Commissioners' Conference Room, 1st fl OWFN

**Participants:** **Presentation**

**ACMUI Panel** **50 mins.***

**Philip Alderson, M.D.**, ACMUI Chair
Topic:
- Overview of ACMUI Activities

**Christopher Palestro, M.D.**, ACMUI Nuclear Medicine Physician
Topic:
- ACMUI's Comments on the Training and Experience Requirements for All Modalities

**Laura Weil**, ACMUI Patients' Rights Advocate
Topic:
- Patients' Rights Advocate's Comments on the Training and Experience Requirements

**Susan Langhorst, Ph.D.**, ACMUI Radiation Safety Officer
Topic:
- Source Tracking for Category 3 Sources and its Impact on Medical Use

**John Suh, M.D.**, ACMUI Radiation Oncologist
Topic:
- ACMUI's Comments on Medical Event Reporting for All Modalities Excluding Permanent Implant Brachytherapy

| | |
|---|---|
| **Commission Q & A** | **30 mins.** |
| **Discussion – Wrap-up** | **5 mins.** |

*For presentation only and does not include time for Commission Q & A's

**Documents:**
Staff background material distributed: 4/17/17
Slides distributed: 4/20/17

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# Overview of ACMUI Activities

Philip O. Alderson, M.D., ACMUI Chairman

ACMUI Commission Meeting

April 27, 2017

# Agenda

- Overview of ACMUI Activities
  - ACMUI Purpose
  - Membership
  - ACMUI Topics
  - Present and Future

# ACMUI Purpose

- The ACMUI exists to advise the NRC staff, and thus you, the Commission, on policy on medical uses of radionuclides.
- Also, to provide technical assistance and serve as consultants.

# Membership Positions

- Health Care Administrator
- Nuclear Medicine Physician
- 2 Radiation Oncologists
- Nuclear Cardiologist
- Diagnostic Radiologist
- 2 Medical Physicists*
- Nuclear Pharmacist*
- Radiation Safety Officer
- Patients' Right Advocate
- Agreement State Representative^
- U.S. FDA Representative

* Pending security clearance
^ Vacant

# ACMUI Topics Addressed in Last Year

- T & E requirements for alpha and beta emitters and for all modalities,
- Impact of medical event reporting on safety culture,

# ACMUI Topics (Continued)

- Clarification of patient intervention,
- Licensing for radioactive seed localization,
- Ge-68/Ga-68 generator licensing guidance,

# ACMUI Topics (Continued)

- Impact of Category 3 sources in medical practice,
- Progress in improving ACMUI internal and external communications.

# Current ACMUI Topics

- Continuing discussions:
  - T&E for AUs of all modalities,
  - Medical event reporting for all modalities,
  - Review of medical events,
  - Patient release,

# Current ACMUI Topics (Continued)

- Radioactive Seed Localization Licensing Guidance,
- Addressing the decommissioning funding plan requirements for the medical use of Ge-68/Ga-68 generators,
- Leksell Gamma Knife Icon Licensing Guidance,

# Current ACMUI Topics (Continued)

- Ways to enhance communications between the NRC staff, the ACMUI, and the medical community.

# Present and Future

The ACMUI currently has a number of issues under discussion. As new issues arise, including emerging technologies, we will address and provide advice on aspects relevant to safe handling of radioactive sources.

# Acronyms

- **ACMUI** – The Advisory Committee on Medical Uses of Isotopes
- **AUs** – Authorized Users
- **FDA** – The Food and Drug Administration
- **LNT** – Linear-No-Threshold
- **NRC** – U.S. Nuclear Regulatory Commission
- **T&E** – Training and Experience

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# Comments on Training and Experience Requirements for All Modalities

Christopher J. Palestro, M.D.
ACMUI Nuclear Medicine Physician
ACMUI Commission Meeting
April 27, 2017

# ACMUI Standing Subcommittee on Training & Experience (T&E)

- Established in 2016
- Charge
  - Periodically review T&E requirements currently in effect for all modalities
  - Make recommendations for changes as needed

# ACMUI Standing Subcommittee on Training & Experience

- Review T&E requirements currently in effect for uses of
  - Unsealed byproduct materials (10 CFR 35.100, 35.200, 35.300, & 35.1000)
  - Sealed byproduct materials (10 CFR 35.400, 35.500, 35.600, & 35.1000)

# Issues to be Addressed by the Subcommittee

- Periodic review
  - T & E requirements
  - Competency
  - Patient access

# Periodic Review

- What is a reasonable time interval between reviews?
  - 15 years: Too long
  - 1 year: Impractical
  - 5 years: Reasonable/practical
    - More frequently if needed
      New procedure
      Increase in ME's or RSE's
      Other

# Review Template for T&E Requirements

T & E Requirements for.....

- **Classification**
  - Appropriate
  - Inappropriate
  - Obsolete
- **Evaluation**
  - Medical Events
  - Radiation Safety Events
  - Patient access

# T & E Requirements Evaluation: Medical & Radiation Safety Events

- Number & Trends
  - Explanation
    - Procedure
    - Competency

# Competency

- General Definition:
  - Ability to do something, especially measured against a standard
- Medical Definition
  - Principle of professional practice, identifying the ability of a provider to consistently administer safe, reliable care

# Determining Competency

- Majority of individuals
  - Deemed status of various certifying boards (ABNM, ABR, etc.)
- Potential Alternative Pathways
  - Didactics (with examination) and "hands-on" experience with preceptor certification
  - Practical examination (independent examining committee)

# Patient Access

- Do current/proposed regulations limit patient access to procedures?
- Do current/proposed regulations provide adequate protection from unintended radiation exposure?
- Accessible/reasonable pathways for obtaining AU status

# Review Template Example

10 CFR 35.190 Training for uptake, dilution, and excretion studies.

**Evaluation**

ME's: None reported over 10 yrs.

RSE's: Not available

Patient access: No known issues

**Classification**

Appropriate

# Stakeholder Input

- Informal
  - Faster
  - Potential for bias
- Formal
  - Slower
  - Broader respondent base

# Acronyms

- ACMUI – Advisory Committee on the Medical Uses of Isotopes
- ABNM – American Board of Nuclear Medicine
- ABR – American Board of Radiology
- AU – Authorized User
- T&E – Training and Experience

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# Patients' Rights Advocate's Comments on the Training and Experience Requirements

Laura Weil

ACMUI Commission Meeting

April 27, 2017

# Ethical Framework for Evaluating Impact of T&E Regulations

- Beneficence
- Justice
- Autonomy

# The Safety Test

- Does existing or proposed T&E regulation adequately protect clinicians, patients, and the public from harm?
- Is existing or proposed T&E regulation unnecessarily restrictive such that it inhibits patients' access to necessary care?

# "700 Hours" Safety Test

- Effectively limits designation as authorized user to a narrow subset of clinical specialties. Physicians cover those 700 hours in residency training: comprehensive knowledge
- Is the depth of knowledge acquired in residency training for these clinical specialties necessary for safe use of all radiopharmaceuticals?

# Acronyms

- T&E – training and experience

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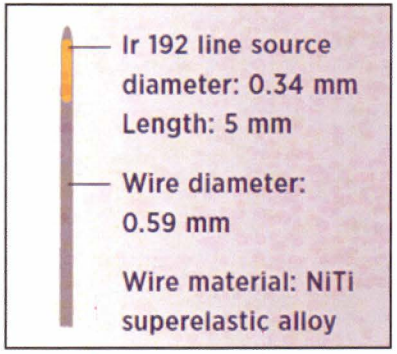
# Source Tracking for Category 3 Sources Impact on Medical Use

Susan M. Langhorst, Ph.D.
ACMUI Radiation Safety Officer
ACMUI Commission Meeting
April 27, 2017

# Category 3 Sources Used in Medicine

- Radiation therapy HDR (10 CFR 35.600)
- Ir-192; 74 day half-life; 10-11 Ci receipt



# HDR Medical Uses

- Internal radiation therapy
- Delivers radiation from HDR source placed close to, or inside, the tumor
- Types of cancer treatments include breast, esophagus, gynecologic, head and neck, lung, prostate, rectum, and skin (~33,000 in 2010)

# HDR Ir-192 Source Replacement

- 74 day half-life
- Source replacement due to:
  - Decay of source activity
  - Number of source cable runs
- Replacement about every 1 to 3 months

# HDR Ir-192 Shipments

- HDR vendor ships replacement source to their customer licensee
- HDR vendor arranges for service engineer to perform source exchange and return shipment of old source

# Impact of NSTS Tracking on HDR Ir-192 Use

- HDR licensee new reporting responsibilities
  - Estimated 1,100 HDR licensees
  - Estimated 75% of HDR licensees have no Category 1 or 2 sources
- Increased costs from HDR vendor to cover new reporting responsibilities

# Need to Track HDR Ir-192 Sources?

- HDR licensee will have only 1 to 2 sources per HDR unit at any given time
- HDR vendor maintains tracking information for all its customer licensees

# Questions about NSTS Tracking of HDR Ir-192 Sources

- Is the NSTS and staff capable of handling the significant increase in reporting?
- Would the HDR vendor need to verify their customer's license and vice versa for each source exchange?

# Questions about NSTS Tracking of HDR Ir-192 Sources [cont.]

- Are the LVS and WBL ready to support this effort?
- Are Agreement State programs ready to support this effort?

# Incorporating Category 3 Sources in 10 CFR 37 Security Requirements

- Existing control and reporting requirements in 10 CFR 20 provide robust security for Category 3 sources
- Would inclusion of Category 3 sources overwhelm the Part 37 security program and potentially diminish Category 1 and 2 source security?

# Acronyms

- ACMUI – Advisory Committee on Medical Uses of Isotopes
- CFR – Code of Federal Regulations
- Ci – curies
- HDR – high dose remote afterloader
- Ir-192 – iridium-192
- LVS – License Verification System

# Acronyms [cont.]

- NSTS – National Source Tracking System
- WBL – Web-Based Licensing System

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# Medical Event Reporting for All Modalities Except Permanent Implant Brachytherapy

John Suh, M.D., ACMUI Radiation Oncologist

ACMUI Commission Meeting

April 27, 2017

# Subcommittee Members

- Ronald Ennis, M.D.
- Vasken Dilsizian, M.D.
- Chris Palestro, M.D.
- John Suh, M.D. (chair)
- Frank Costello
- *Zoubir Ouhib, M.S.*

# Subcommittee Charge

- To propose the appropriate criteria for ME Reporting for events other than permanent implant brachytherapy.*

*Permanent implant brachytherapy MEs addressed previously by the ACMUI

# Rationale

- Medical event reporting has not changed significantly for many years.
- Given advances in technologies, in particular radiation oncology, the current definition may not be sufficient for AU and regulators.

# Number of Medical Events

- The annual number of reports is extremely low considering the estimated 15,000,000 diagnostic and 150,000 therapeutic procedures performed annually.

# Number of Medical Events

| | FY 2013 | FY 2014 | FY 2015 |
|---|---|---|---|
| 35.200 | | | 4 |
| 35.300 | | | 7 |
| 35.400 | 16 | 5 | 7 |
| 35.600 | 9 | 11 | 14 |
| 35.1000 | 15 | 26 | 14 |

ME Events Reporting FY 2015. Oct 6, 2016

# Number of Medical Events

- Does this accurately reflect the true number of cases if the current definition may be ambiguous?
- Does the current process, which is perceived as being punitive by some, lead to the desired goal of transparency, education, and adoption of best practices?

# Guiding Principles

- Medical events reporting should allow identification of an ME and provide a forum to discuss how to avoid/reduce the likelihood of such an event.
- The definitions of ME reporting need to be broad, simple, and consistent, so reports are easily applicable by AU, evaluable by regulators, and process-focused in order to eliminate any ambiguity.

# Guiding Principles

- The subcommittee believes that any proposed changes should not be overly prescriptive and must not encroach on the practice of medicine.
- Focus of ME reporting should be on education and improvement rather than punitive action whenever possible.

# ME criteria would need to cover a variety of treatment modalities

- HDR brachytherapy
- Gamma Knife™
- LDR temporary implants
- Intraoperative modalities
- 2D, 3D-CRT, IMRT, SRS, and SBRT
- SIRT

# Current Definition of 35.3045

- Clear ME: Wrong drug, route of administration, patient, and mode; or leaking sealed source
- Ambiguous ME:
  - Total dose delivered differs from prescribed dose by 20% or more;
  - Single fraction dose delivered differs from prescribed dose by 50% or more
  - Intervention of patient or human subject in which the administration of byproduct material or radiation from byproduct material results or will result in unintended permanent functional damage to an organ or a physiological system, as determined by a physician.

# 35.2 Definition

- "Treatment site means the anatomical definition of the tissue intended to receive a radiation dose, as described in the written directive."
- Since the written directive gives the AU a great deal of flexibility, this can be a potential source of ambiguity as treatment site can have different meanings among AU.

- Treatment site is often defined as a volume, which may be source of confusion.

# Recommendations

- Use new definitions for permanent implant brachytherapy.
- Continue to use the current 10 CFR part 35.3045 definition for medical event reporting for all modalities except permanent implant brachytherapy.
- ACMUI is discussing patient intervention at this time.

# Recommendations

- Encourage major societies to issue white paper(s) to develop consensus on what should be incorporated into a written directive for various diagnostic and therapeutic modalities.
- Benefits of white paper
  - Will help with inspections and regulations by promoting standardization for identifying ME.
  - Will assist licensees determine if ME has occurred.
  - Assist institutions to develop SOP to prevent future ME.

# Acronyms

- ACMUI – Advisory Committee on the Medical Uses of Isotopes
- AU – Authorized User
- CFR – Code of Federal Regulations
- FY – Fiscal Year
- GYN – Gynecological
- HDR – High Dose Rate
- IMRT – Intensity modulated radiation therapy
- LDR – Low Dose Rate

# Acronyms (Cont.)

- ME – Medical Event
- SBRT – Stereotactic body radiation therapy
- SOP – Standard Operating Procedures
- SRS – Stereotactic radiosurgery
- SIRT – Selective internal radiation therapy
- 2D – Two dimensional
- 3D-CRT – Three dimensional conformal radiation therapy