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United States Nuclear Regulatory Commission
Protecting People and the Environment

Discussion of Medical Uses of Radioactive Materials

Commission Meeting

January 28, 2020

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United States Nuclear Regulatory Commission
Protecting People and the Environment

Overview of the NRC's Program for Medical Use

Steven West
Deputy Executive Director for Materials, Waste, Research, State, Tribal, Compliance, Administration and Human Capital Programs

NRC Panel will Address the Following Topics

- Status of NRC Staff Activities
- Innovation Opportunities and Initiatives
- Efforts to Prepare for the Review of Emerging Medical Technologies
- Regional Perspective on Licensing and Inspecting Medical Uses

Meeting the Medical Uses Policy Statement Objectives

Regulate to provide for radiation safety of workers and the general public.

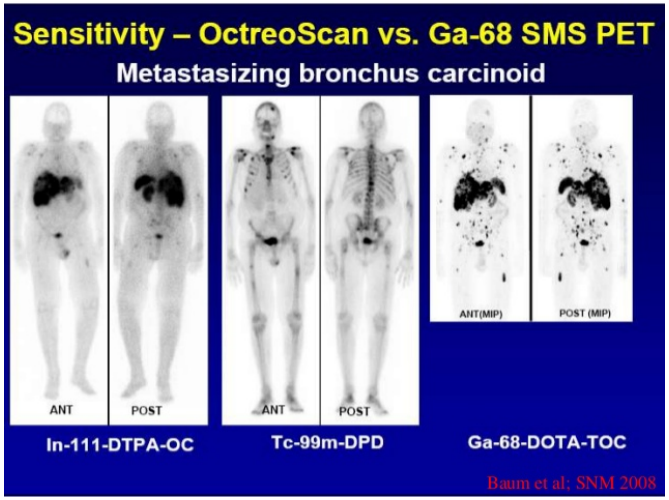
Not intrude into medical judgements, except as necessary to protect radiation safety of workers and the general public.

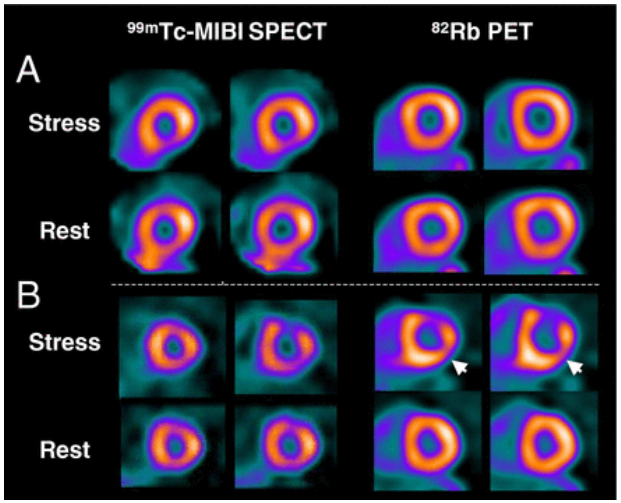
When justified by the risk to patients, regulate radiation safety of patients primarily to assure medical use is in accordance with the physician's directions.

In developing a specific regulatory approach, consider industry and professional standards that define acceptable approaches of achieving radiation safety.

Two Categories of Medical Use

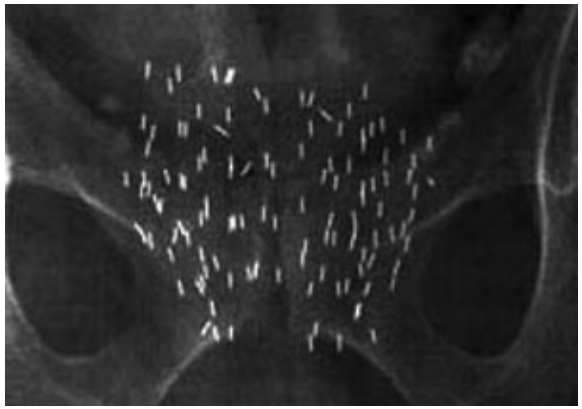
- Diagnostic
  - Imaging organs, systems, and functions
  - Gamma camera, PET, PET/CT, or SPECT
  - Nuclear medicine, nuclear cardiology, endocrinology, diagnostic radiology





Two Categories of Medical Use

- Therapeutic
  - Radiopharmaceutical therapy, teletherapy, brachytherapy, gamma stereotactic radiosurgery
  - Nuclear medicine, endocrinology, radiation oncology, interventional radiology



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Status of NRC Staff Activities

Kevin Williams, Deputy Director
Division of Materials Safety, Security, State, and Tribal Programs
NMSS

Ensuring an Effective Medical Program through Coordination

- Training and experience
- Patient release
- Prevention of medical events
- Medical AO thresholds
- Extravasations

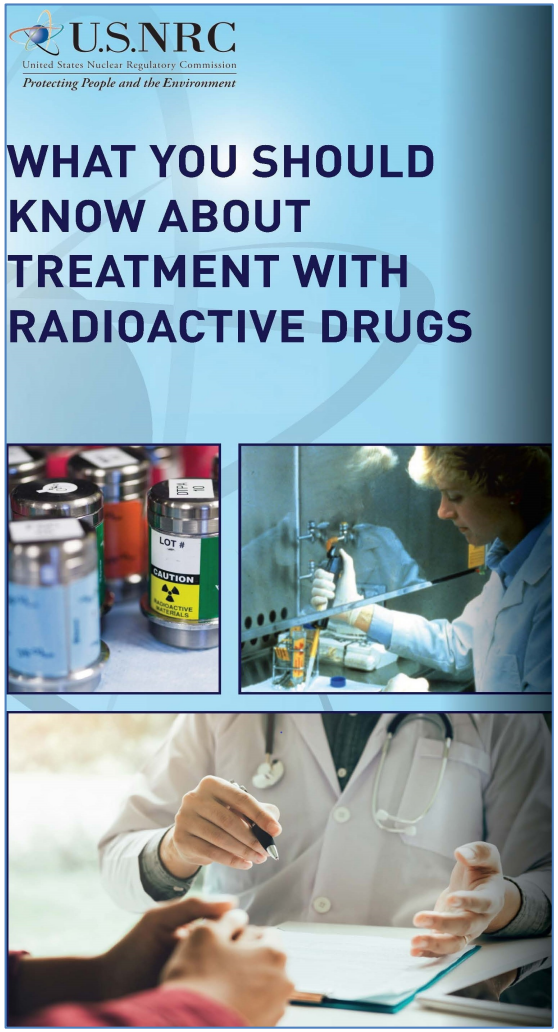
Gathering Stakeholder Input on Training and Experience

Outreach for the staff's evaluation of T&E for radiopharmaceuticals under 10 CFR 35.300 included

- Three *Federal Register* notices
- Two public comment periods
- Six public meetings
- Five online newsletter articles published
- Four conferences attended
- Three medical list server announcements
- 200+ letters to solicit input

Informing the Public About Treatment with Radioactive Drugs

- Phase 1 revision to RG 8.39, "Release of Patients Administered Radioactive Material" expected April 2020
- Phase 2 update to RG 8.39 began in October 2019



Preventing Medical Events

IN-2019-06
Patient Skin Contamination Events with I-131 MIBG

IN-2019-07
Methods to Prevent Medical Events

IN-2019-11
Sr-82/Rb-82 Generator Elution Events

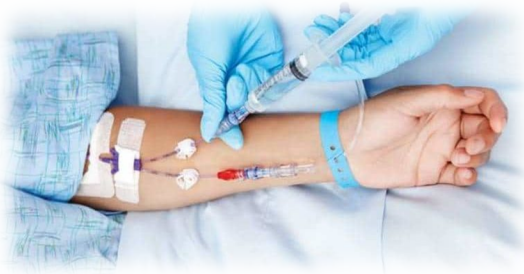
IN-2019-12
Y-90 Medical Events

Evaluating Medical Abnormal Occurrence Thresholds

- Staff reviewed medical event AOs
- Concluded that medical event AO criteria may capture events that are not significant from the standpoint of public health and safety
- Recommended in SECY-19-0088 that AO criteria be revised

Evaluating Extravasations

- ACMUI subcommittee recommendations on extravasations and infiltrations in April 2019
  - Extravasation is a practice of medicine issue, not an item that needs to be regulated by the NRC
  - Extravasation should not be considered a medical event unless there is unintended permanent functional damage
- NRC staff is conducting an independent evaluation



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Innovation Opportunities and Initiatives

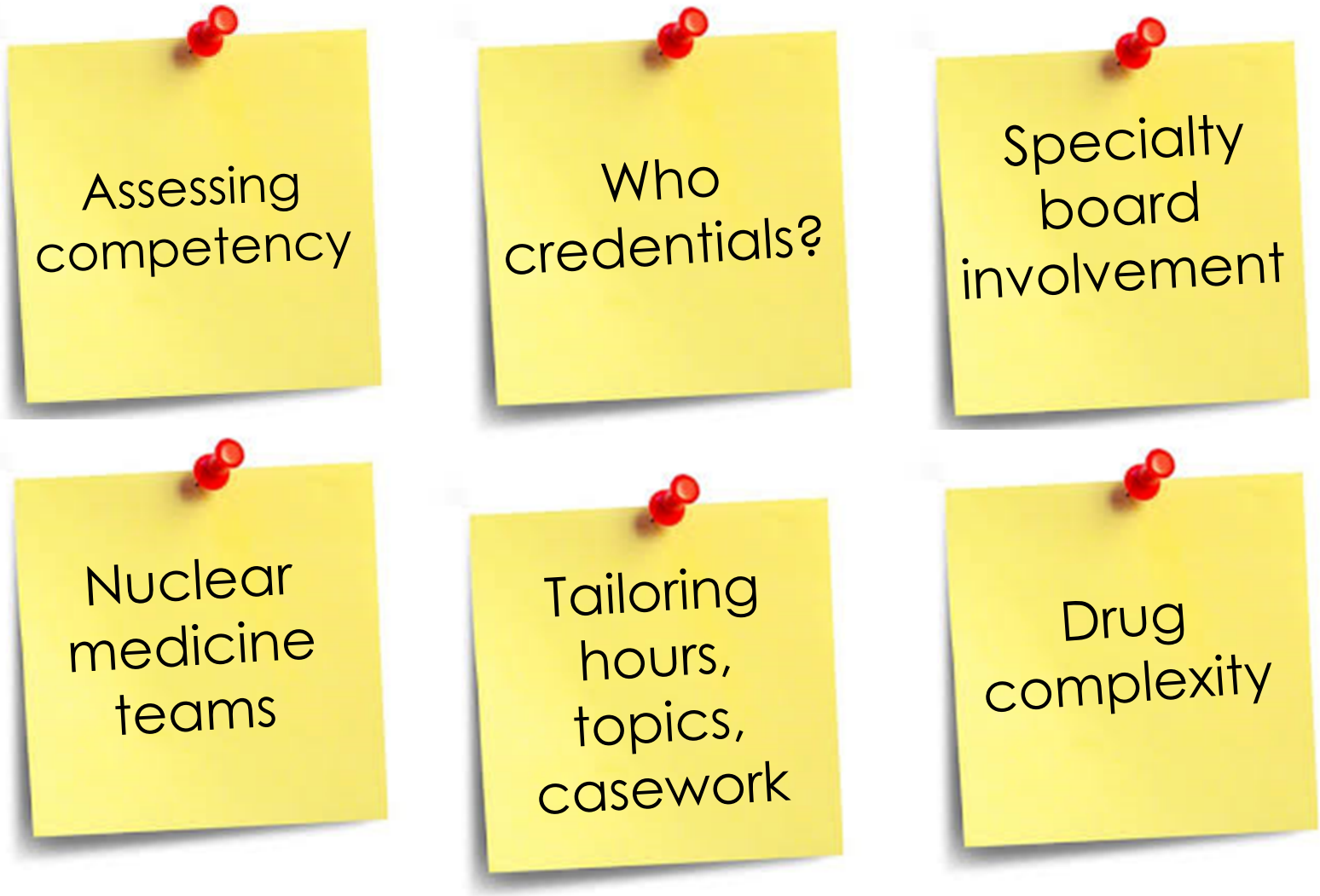
Lisa Dimmick, Team Leader
Medical Radiation Safety Team

Reconsidering the Training and Experience Requirements

- TASK: Determine whether and how to tailor the T&E requirements for different categories of radiopharmaceuticals
- CHALLENGES: Current regulatory framework is prescriptive; NRC and Agreement States must review and approve T&E for AUs

What if we changed the framework?

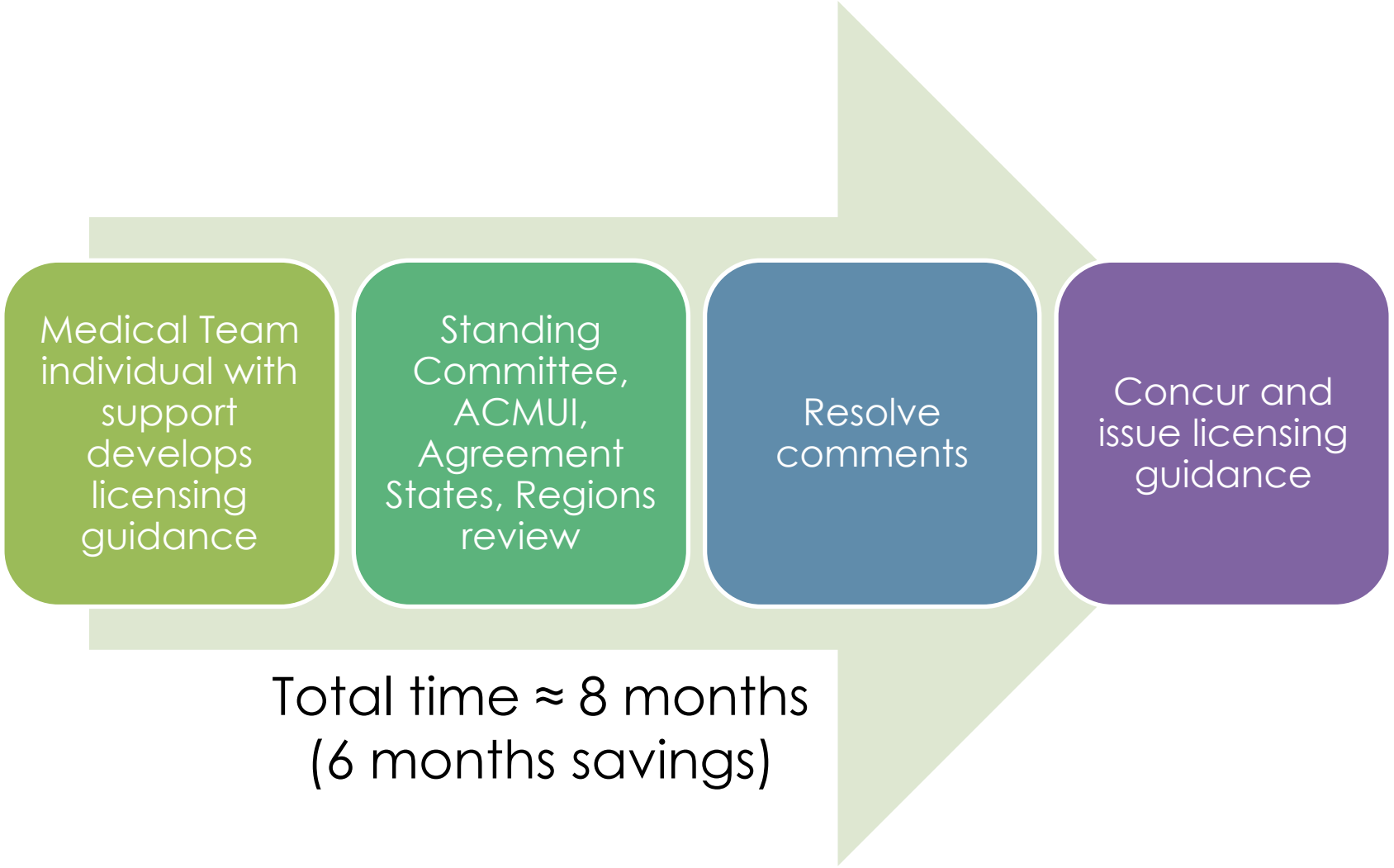
Thinking About Transformation



Proposing to Change the Regulatory Framework

- Removal of prescriptive T&E for AUs of unsealed byproduct material
- NRC and Agreement States no longer review and approve T&E
- AUs must be credentialed by a recognized medical specialty board
- Maintain high-level board recognition criteria

Streamlining our Process for Reviewing Emerging Technologies



Total time ≈ 8 months
(6 months savings)

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Efforts to Prepare for the Review of Emerging Medical Technologies

Katie Tapp, Ph.D., Medical Physicist
Medical Safety and Events Assessment Branch

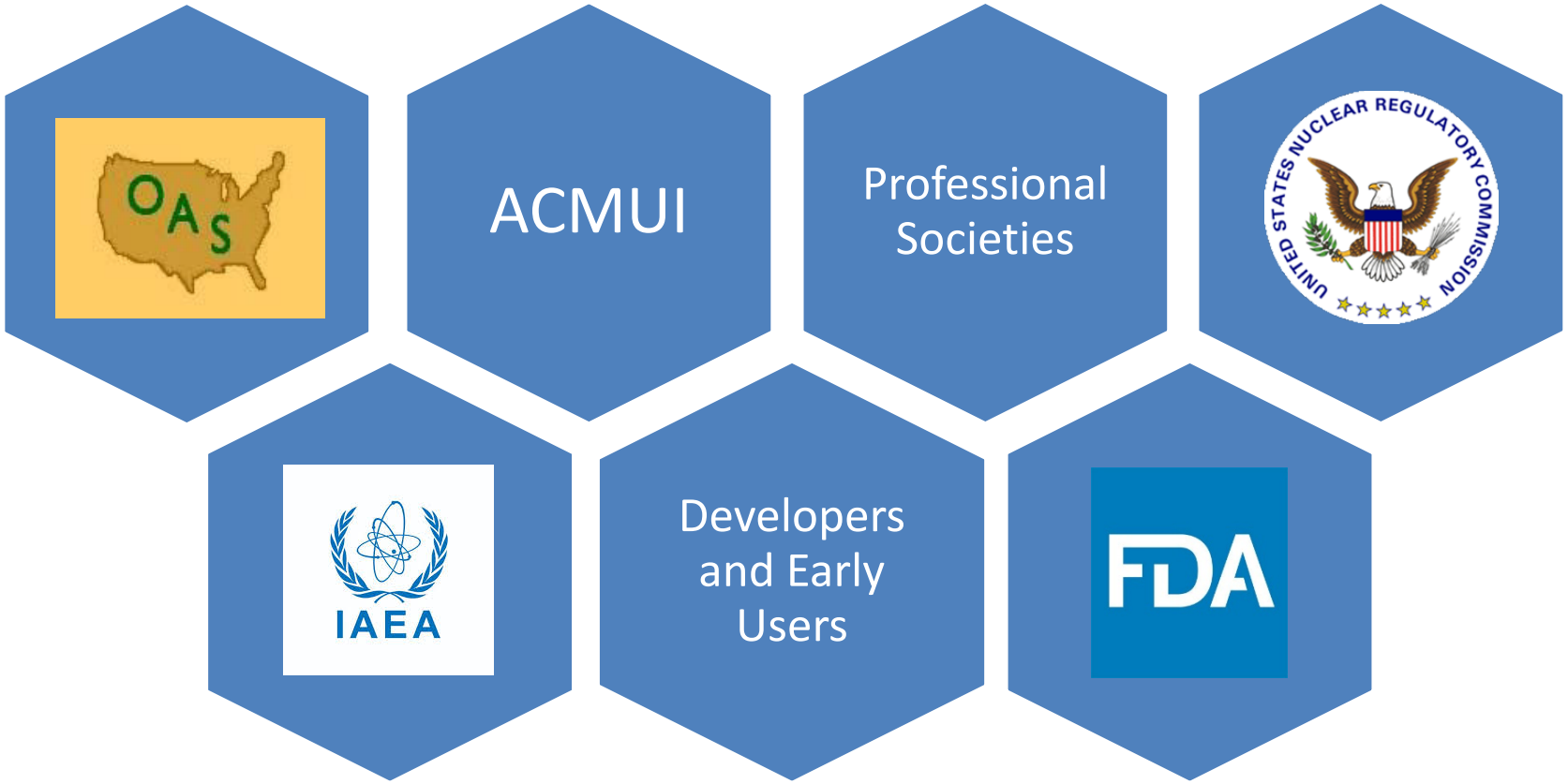
Flexible Regulatory Framework for Emerging Medical Technologies

- 10 CFR Part 35, Subpart K – Other Medical Uses of Byproduct Material or Radiation from Byproduct Material (10 CFR 35.1000)
- Supports efficient licensing of emerging technologies

Evaluation Process of Emerging Medical Technologies

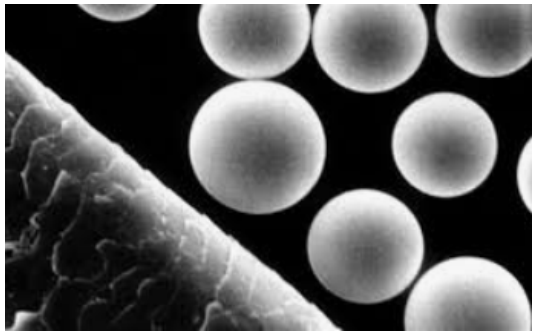
- Evaluate if medical use is addressed in 10 CFR 35 Subparts D through H
  - If no, staff develops recommended conditions of use and 10 CFR 35.1000 licensing guidance
  - If yes, staff may still provide licensing and inspection guidance on specific radiation safety aspects

Effective Stakeholder Engagement on Emerging Technologies



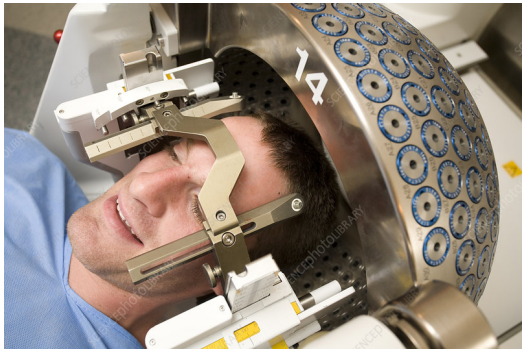
Yttrium-90 Microsphere Brachytherapy

- Permanent implant brachytherapy for treatment of liver lesions
- Several new manufacturers developing microsphere and micro-particle devices



Gamma Stereotactic Radiosurgery Units

- Original regulations developed for Gamma Knife, which treated the brain using stationary sources, helmet collimators, and a frame
- Newer units – Perfexion, Icon, GammaPod, Infini, Galaxy, Orbiter, Vertex

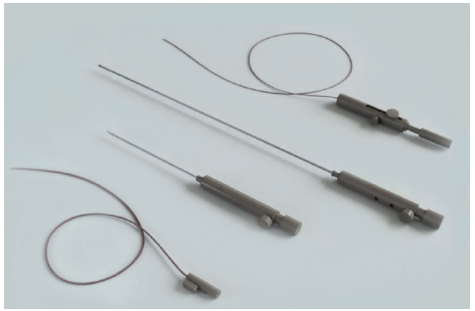


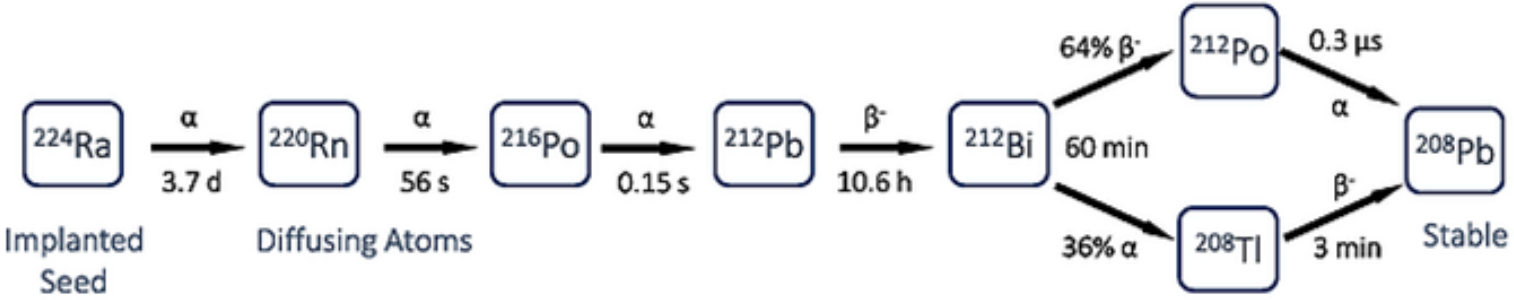
Response to Evolving Medical Landscape

- Updates for Emerging Medical Technologies Rulemaking would incorporate medical uses approved under 10 CFR 35.1000 into relevant subparts of 10 CFR Part 35
- Joint NRC/OAS WG working to complete the rulemaking plan by Summer 2020

Alpha DaRT (Diffuse Alpha Radiation Therapy)

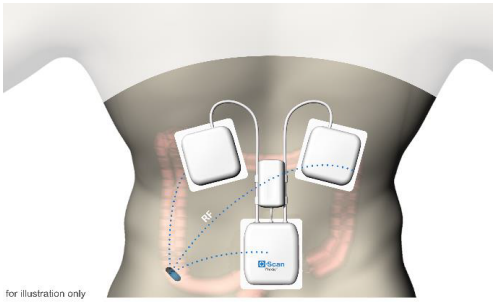
- Brachytherapy utilizing alpha-emitting daughters of Ra-224
- Device evaluation performed by Massachusetts





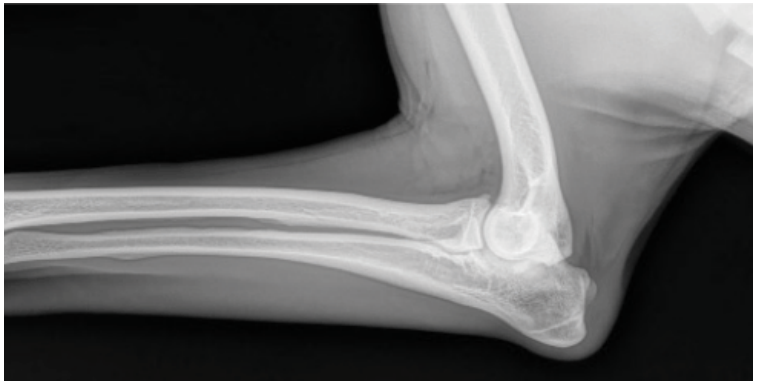
Check-Cap

- Colorectal cancer screening
- Sealed source for diagnosis (35.500 vs. 35.1000)
- Authorized user T&E
- Waste disposal



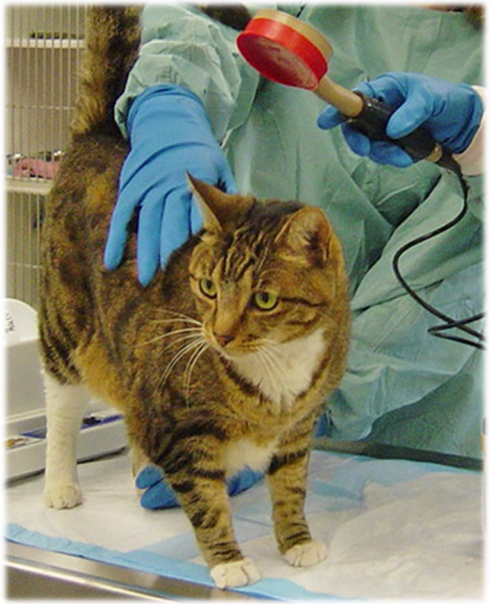
Increase in Veterinary Uses of Byproduct Material

- Sn-117m colloid for treatment of osteoarthritis of canine elbow
- Y-90 particles for treatment of pet sarcomas



Different Public Dose Limits for Animal Release

- Higher public dose limits for the release of human patients
- Release of animals must comply with 10 CFR Part 20 public dose limits



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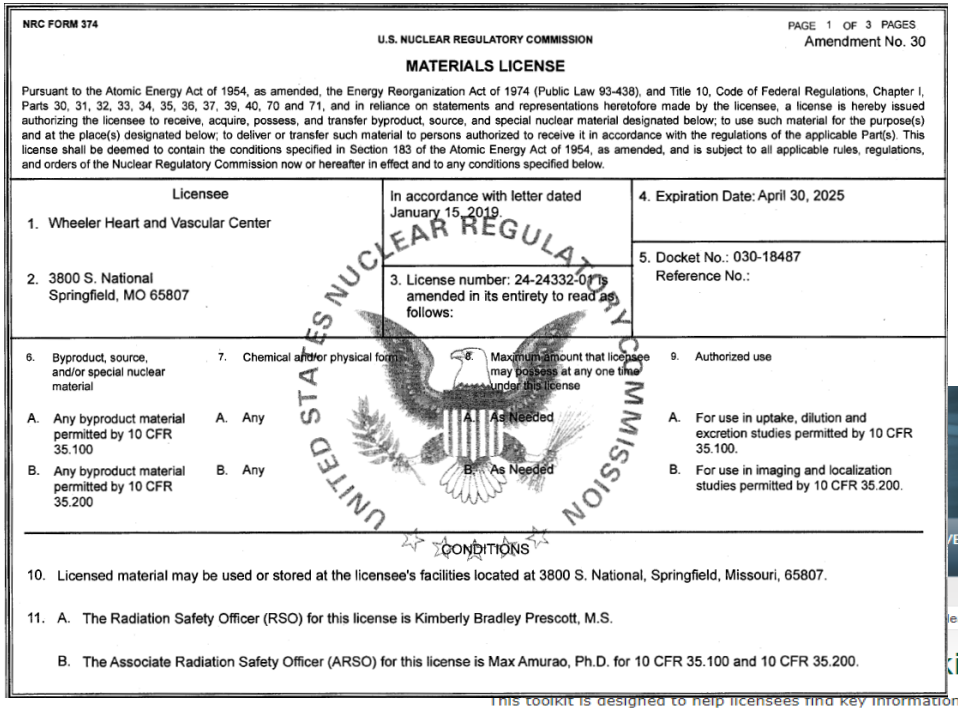
Regional Perspective on Licensing and Inspecting Medical Uses

Donna Janda, Branch Chief
Medical Licensing Assistance Branch
Division of Nuclear Materials Safety, Region I

Regional Experiences with the Part 35 Changes



NRC FORM 374 — U.S. NUCLEAR REGULATORY COMMISSION — PAGE 1 OF 3 PAGES

Amendment No. 30

MATERIALS LICENSE

Pursuant to the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974 (Public Law 93-438), and Title 10, Code of Federal Regulations, Chapter I, Parts 30, 31, 32, 33, 34, 35, 36, 37, 39, 40, 70 and 71, and in reliance on statements and representations heretofore made by the licensee, a license is hereby issued authorizing the licensee to receive, acquire, possess, and transfer byproduct, source, and special nuclear material designated below; to use such material for the purpose(s) and at the place(s) designated below; to deliver or transfer such material to persons authorized to receive it in accordance with the regulations of the applicable Part(s). This license shall be deemed to contain the conditions specified in Section 183 of the Atomic Energy Act of 1954, as amended, and is subject to all applicable rules, regulations, and orders of the Nuclear Regulatory Commission now or hereafter in effect and to any conditions specified below.

Licensee	In accordance with letter dated January 15, 2019.	4. Expiration Date: April 30, 2025
1. Wheeler Heart and Vascular Center		5. Docket No.: 030-18487 Reference No.:
2. 3800 S. National Springfield, MO 65807	3. License number: 24-24332-01 is amended in its entirety to read as follows:	

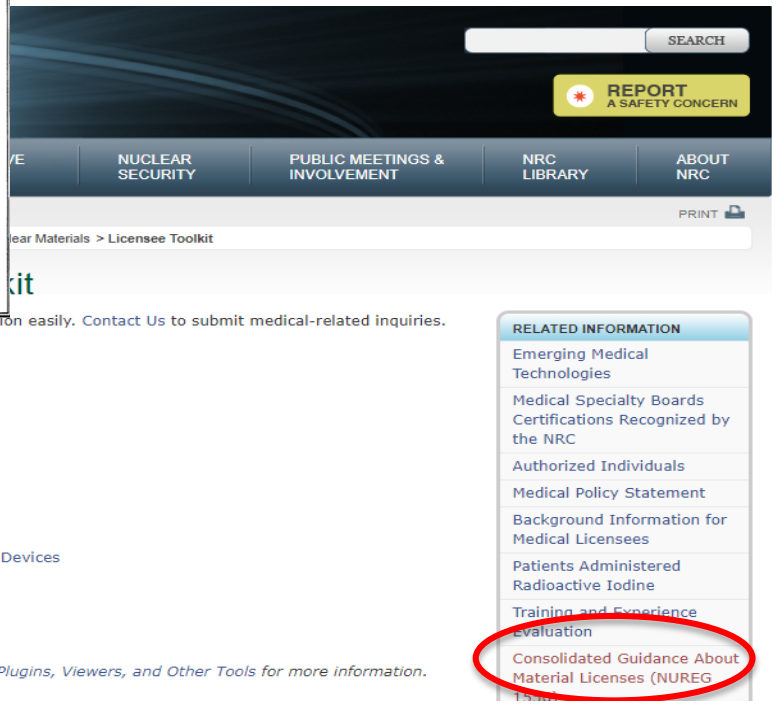
6. Byproduct, source, and/or special nuclear material	7. Chemical and/or physical form	8. Maximum amount that licensee may possess at any one time under this license	9. Authorized use
A. Any byproduct material permitted by 10 CFR 35.100	A. Any	A. As Needed	A. For use in uptake, dilution and excretion studies permitted by 10 CFR 35.100.
B. Any byproduct material permitted by 10 CFR 35.200	B. Any	B. As Needed	B. For use in imaging and localization studies permitted by 10 CFR 35.200.

CONDITIONS

10. Licensed material may be used or stored at the licensee's facilities located at 3800 S. National, Springfield, Missouri, 65807.

11. A. The Radiation Safety Officer (RSO) for this license is Kimberly Bradley Prescott, M.S.

B. The Associate Radiation Safety Officer (ARSO) for this license is Max Amurao, Ph.D. for 10 CFR 35.100 and 10 CFR 35.200.



SEARCH

REPORT A SAFETY CONCERN

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PRINT

...lear Materials > Licensee Toolkit

...kit

This toolkit is designed to help licensees find key information easily. Contact Us to submit medical-related inquiries.

On this page:

- Announcements
- Medical List Server
- Evaluation of Training and Experience
- Regulations
- Guidance
- Generic Communications
- Inspection
- Medical Events
- High Dose-Rate Remote Afterloader Brachytherapy Devices
- Licensing
- Fees
- Forms

This page includes links to files in non-HTML format. See Plugins, Viewers, and Other Tools for more information.

RELATED INFORMATION

- Emerging Medical Technologies
- Medical Specialty Boards Certifications Recognized by the NRC
- Authorized Individuals
- Medical Policy Statement
- Background Information for Medical Licensees
- Patients Administered Radioactive Iodine
- Training and Experience Evaluation
- Consolidated Guidance About Material Licenses (NUREG ...

Inspection of Patient Release

$$D(t) = \frac{34.6\ \Gamma\ Q_0\ T_p\ (1 - e^{-0.693t/T_p})}{r^2}$$

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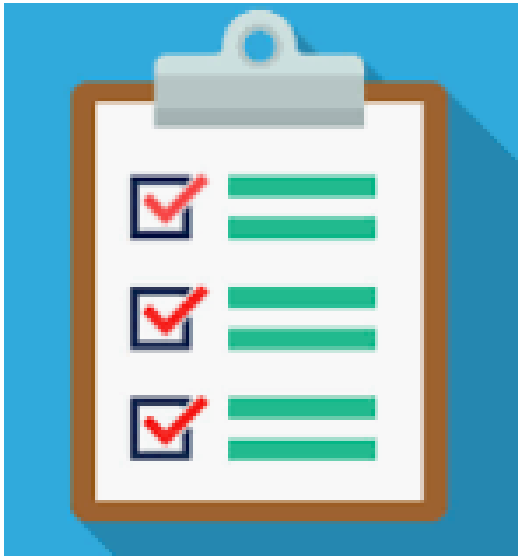
NUREG-1556
Volume 9, Rev. 3

Consolidated Guidance About Materials Licenses

Program-Specific Guidance About Medical Use Licenses

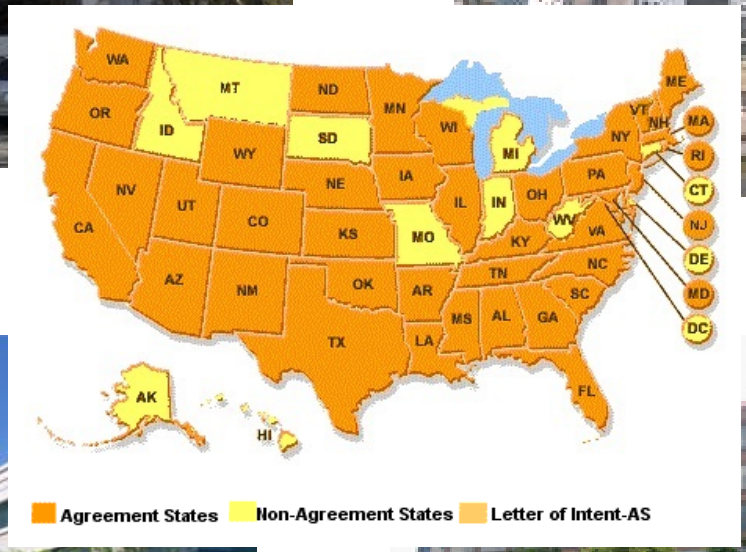
Final Report

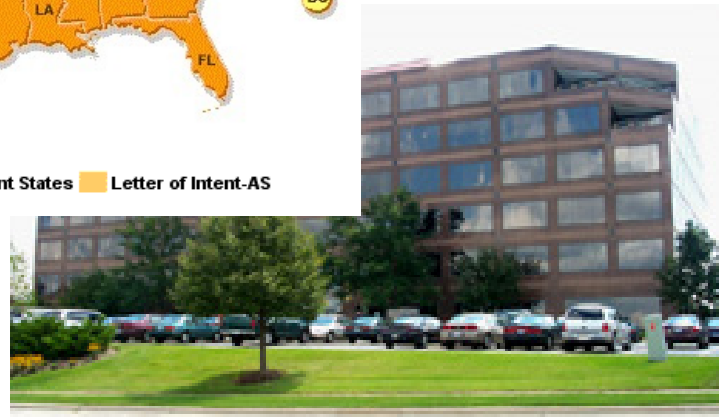
Review of Medical Events



Samples from two manufacturers of yttrium-90 (Y-90), SIR-Spheres® (left) and TheraSphere® (right); these vials contain millions of Y-90 microspheres used to treat liver cancers.

Coordination with Agreement States and Headquarters





Acronyms

ACMUI – Advisory Committee on the Medical Uses of Isotopes

AO – Abnormal Occurrence

AU – Authorized User

CFR – Code of Federal Regulations

CRCPD – Conference of Radiation Control Program Directors

CT – Computed Tomography

DaRT – Diffuse Alpha Radiation Therapy

FDA – U.S. Food and Drug Administration

Acronyms

GSR – Gamma stereotactic radiosurgery
I-131 MIBG – Iodine-131 Metaiodobenzylguanidine
IAEA – International Atomic Energy Agency
IN – Information Notice
NRC – U.S. Nuclear Regulatory Commission
OAS – Organization of Agreement States
PET – Positron-emission tomography
Ra-224 – Radium-224

Acronyms

Rb-82 – Rubidium-82

RG – Regulatory Guide

Sn-117m – Tin-117m

SPECT – Single-Photon Emission Computerized Tomography

Sr-82 – Strontium-82

T&E – Training and Experience

WG – Working Group

Y-90 – Yttrium-90