



New Mexico Environment Department

New Policies and Challenges in Nuclear Medicine

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Emerging Medical Technologies (EMT) in Nuclear Medicine Therapy

- Elekta Esprit - Gamma stereotactic radiosurgery unit
- Akesis Galaxy[®] RTi - Gamma stereotactic radiosurgery unit
- Eye90 Microspheres - Glass microspheres with radioopacity
- CivaDerm[™] - Temporary radiation therapy to treat skin cancer and other lesions
- Liberty Vision Yttrium-90 (Y-90) Disc Source - High dose rate Y-90 disc source to treat ocular tumors and benign growths
- Technegas - Gas-like dispersion of Technetium-99m labeled carbon for functional lung imaging



NRC Major Proposed Changes to Nuclear Medicine Medical use regulations in 10 CFR 35

Major Proposed Changes

- New subpart for microspheres (i.e., “Microsource Manual Brachytherapy”)
- Requiring device-specific training for some generators and EMTs

Specific device components → Functional elements of the tech



Emerging Medical Technologies (EMT) in Nuclear Medicine NRC Medical Use Regulations

EMT/Rubidium-82 (Rb-82) Generator Rulemaking Background

- Issues under consideration:
 - Challenges associated with licensing Rb-82 generators under 10 CFR Part 35
 - Challenges associated with licensing existing and future EMTs under the current medical use regulations in 10 CFR Part 35

- Proposed changes to 10 CFR Part 35 regulations:
 - Address calibration and dose measurement for Rb-82 generators
 - Establish risk-informed, performance-based requirements for some existing and future EMTs within applicable subparts in Part 35, and outside of Subpart K



NRC Medical Rulemakings in Nuclear Medicine

Medical Rulemakings



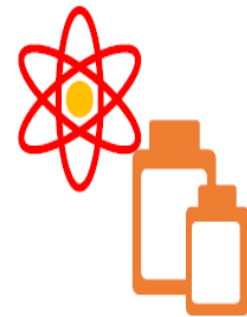
EXTRAVASATION

Ongoing rulemaking to amend 10 CFR Part 35 to require reporting of extravasations that require medical attention for suspected radiation injury.



VETERINARY RELEASE

Rulemaking plan to seek approval from the Commission to establish requirements for the release of animals containing byproduct material after veterinary procedures.



EMT/RB-82 GENERATORS

Ongoing rulemaking to establish requirements for Rb-82 generators and well-established EMTs currently regulated under 10 CFR 35.1000 and establish flexibility for future EMTs.



Nuclear Medicine Extravasations Current NRC Policy and ACMUI's Opposition

- Extravasation is the infiltration of injected fluid into the tissue surrounding a vein or artery.
- NRC recommended reporting of extravasation events that require medical attention for suspected radiation injury.
- The NRC's Advisory Committee on the Medical Uses of Isotopes Evaluation:
 - Reconsidered infiltration in light of NRC assumption of authority for accelerator-produced radioactive material.
 - Passed a motion that infiltrations not be reported as medical events at this time.



Recent Microsphere Therapy Medical Events Yttrium-90

- Three Y-90 Case Studies:
 - SIR-Spheres[®] administration involving a mathematical mistake
 - TheraSphere[™] administration involving "missing" microspheres
 - SIR-Spheres[®] administration involving stuck needle



Yttrium-90: SIR Spheres Math Mistake

The math mistake...

- A licensee reported a Y-90 SIR-Spheres[®] administration that was 135% of the prescribed activity.



~~0.7 GBq~~

0.77 GBq



~~1.6 GBq~~

2.34 GBq



3.11 GBq

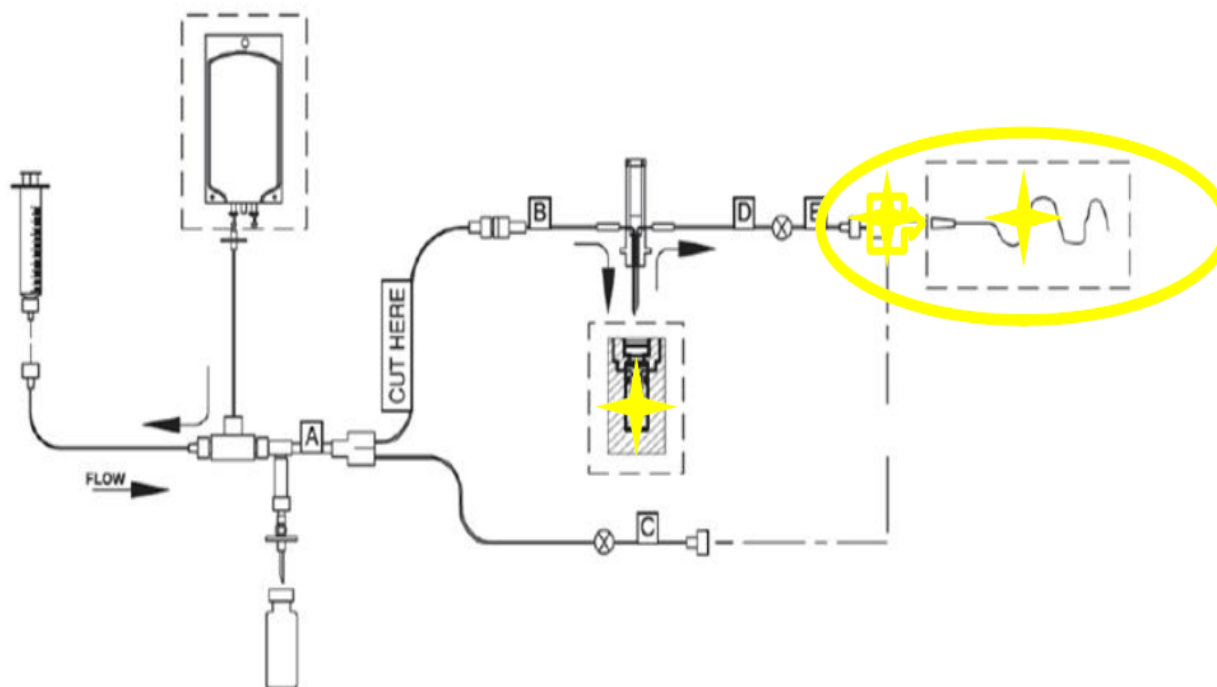
$$0.7 \text{ GBq} + 1.6 \text{ GBq} = 2.3 \text{ GBq}$$



Yttrium-90: "Missing" TheraSphere™

The "missing" microspheres...

- A Licensee reported a Y-90 TheraSphere™ administration that was 0% of the prescribed activity.

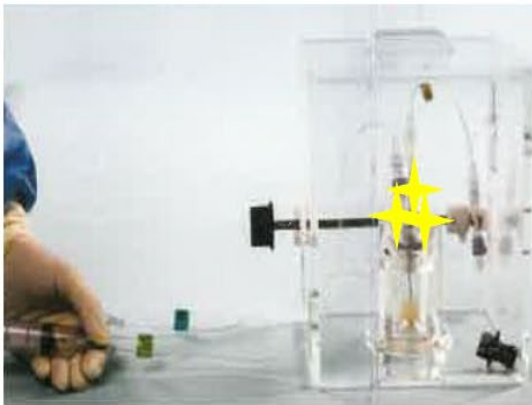




Yttrium-90: The Stuck Needle

The stuck needle...

- A licensee reported a Y-90 SIR-Spheres® administration that was 41% of the prescribed activity.





Summary - Nuclear Medicine Regulations

- ❑ Medical use rules are important to patient safety for all therapy and diagnostic nuclear medicine.
- ❑ Federal and state medical use regulations must be continuously updated to ensure patient safety errors on the side of the patient.
- ❑ Emerging technologies are advancing in nuclear medicine with new medical isotopes and procedures that require safe procedure evaluations before they are introduced for radiation therapy treatments.
- ❑ Federal regulations 10 CFR Part 35
- ❑ State regulations 20.3.7 NMAC