

# Emerging Medical Technologies

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# Outline



Regulatory Background



Guidance Development Process



Emerging Medical Technologies



Rulemaking

# EMT Regulatory Background

- In 2002, the Commission added 10 CFR 35.1000 to add *generic requirements* for new medical uses of byproduct material or radiation from byproduct material (**EMTs**)
- 10 CFR 35.1000 allows the NRC and Agreement States to regulate medical uses that are not otherwise addressed in 10 CFR Part 35 on a case-by-case basis



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# Standing Committee on Reviewing Emerging Medical Technologies

- Established in 2020
- Assist NRC staff in evaluating the licensing of EMTs and provide early feedback on draft documents
- Includes members from
  - MRST
  - NRC Regions
  - OGC
  - Agreement States



# Evaluation & Guidance Development Process

## STAKEHOLDER Outreach

Receive input from NRC Regions, Agreement States, and the ACMUI on draft documents

## GUIDANCE Development

Develop licensing guidance or licensing memorandum depending on licensing determination



## EMT Evaluation

Evaluate radiation safety aspects of the EMT; T&E; methodology for measurement of doses and dosage; calibration & maintenance; etc.

## 35.1000 Licensing Determination

Review use and unique characteristics to determine if EMT can be licensed under other Part 35 Subparts or Subpart K

## SCREMT Engagement

Engage with SCREMT to get early feedback on licensing determination and draft documents

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# EMT Evaluations

- Since 2002
  - reviewed more than 16 EMTs
  - issued 12 licensing guidance documents
  - issued 3 licensing memoranda
- Licensing guidance is revised as needed, as we gain operating experience with EMTs

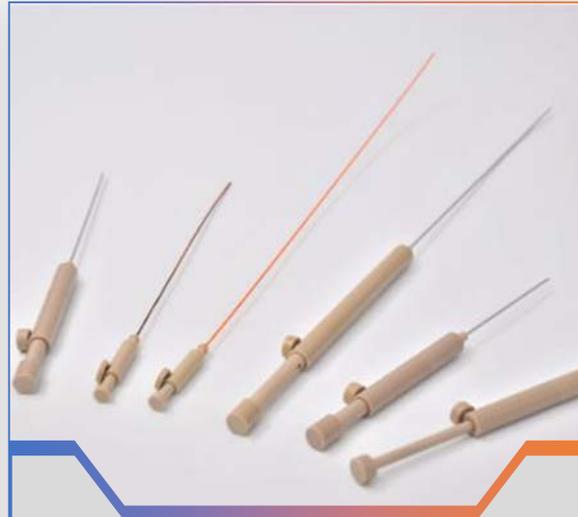


# Brachytherapy



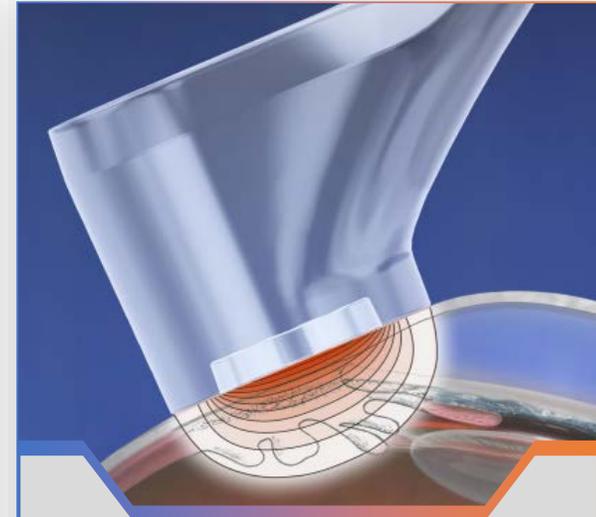
## Y-90 Microspheres

Hepatocellular carcinoma  
and other cancers



## Alpha DaRT

Solid tumors



## Liberty Vision Y-90 Disc Sources

Episcleral ocular diseases,  
tumors, and benign growths

# Gamma Stereotactic Radiosurgery



**Icon, Perfexion, Esprit**

Tumors, vascular and neurological disorders



**Akesis Galaxy RTi**

Cancer and intracranial diseases



**Xcision GammaPod**

Breast cancer

# Radiopharmaceuticals (§35.300)



**LUTATHERA**  
(Lu-177 dotatate)  
GEP-NETs

The image shows a green vial and a glass syringe. The vial label includes the following text: Lutathera Lutetium Lu 177 dotatate injection For intravenous use. Single-dose vial. One mL contains 22 MBq (600 µCi) of Lutetium Lu 177. Volume: 22 mL. Storage: Store below 20°C (68°F). Do not freeze. The syringe label includes: Lutetium Lu 177 dotatate injection. Volume: 22 mL. Storage: Store below 20°C (68°F). Do not freeze.



**PLUVICTO**  
(Lu-177 PSMA)  
PSMA-positive mCRPC

The image shows a green vial and a glass syringe. The vial label includes the following text: PLUVICTO Lutetium Lu 177 vipivotide tetraxetan injection Intravenous use Single-dose vial. One mL contains 1,000 MBq of lutetium Lu 177 vipivotide tetraxetan at calibration time. Contents: Acetic acid, sodium acetate, pantoic acid, sodium ascorbate, pantoic acid, water for injection. Store below 30°C (86°F). Do not freeze. The syringe label includes: PLUVICTO Lutetium Lu 177 vipivotide tetraxetan injection. Volume: 1 mL. Storage: Store below 30°C (86°F). Do not freeze.



**Xofigo**  
(Ra-223 dichloride)  
MCRPC  
(bone metastasis)

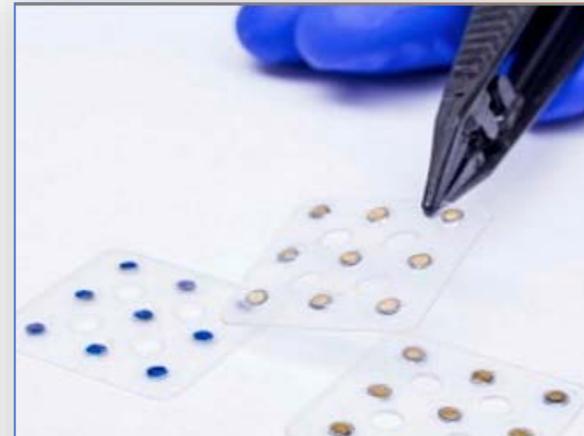
The image shows a grey vial and a white syringe. The vial label includes the following text: NIST 2015. Xofigo Radium Ra 223 dichloride For intravenous use. 6 mL. 1100 kBq/mL at 12 h (CET) ref. date. 6.6 MBq/vial at 12 h (CET) ref. date. The syringe label includes: Xofigo Radium Ra 223 dichloride For intravenous use. 6.6 MBq/vial at 12 h (CET) ref. date. Lot: F.

# Brachytherapy (§35.400)



**GammaTile**

Brain tumors



**CivaDerm**

Skin cancer and other lesions

# EMT/Rb-82 Generator Rulemaking



Commission accepts staff's recommendation

Jan 2022  
SRM Issued

Staff prepared a reg basis indicating proposed changes to 10 CFR Part 35 and questions for public input

Summer 2023  
Reg Basis to be issued

Estimated date for issuance of final rule and implementation guidance to Commission

Winter 2027  
Final Rule

Feb 2021  
Rulemaking Plan Issued

Feb 2022  
WG Established

Winter 2026  
Proposed Rule

Staff issues rulemaking plan to the Commission recommending to establish requirements for well-established EMTs and Rb-82 generators and provide flexibility for future EMTs

Staff establishes Joint NRC/Agreement State working group

Estimated date for issuance of proposed rule and draft implementation guidance to Commission

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# Acronyms

- CFR – Code of Federal Regulations
- EMT – emerging medical technology(ies)
- GEP-NETs – gastroenteropancreatic neuroendocrine tumors
- Lu-177 – lutetium-177
- MRST – Medical Radiation Safety Team
- mCRPC – metastatic castration-resistant prostate cancer
- PSMA – prostate-specific membrane antigen
- Ra-223 – radium-223
- Rb-82 – rubidium-82
- OGC – Office of the General Counsel
- SRM – staff requirements memorandum
- WG – working group
- Y-90 – yttrium-90



# Contact Us!



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[Medical Uses Licensee Toolkit | NRC Public Website](#)

