U.S.NRC
United States Nuclear Regulatory Commission
Protecting People and the Environment

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

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

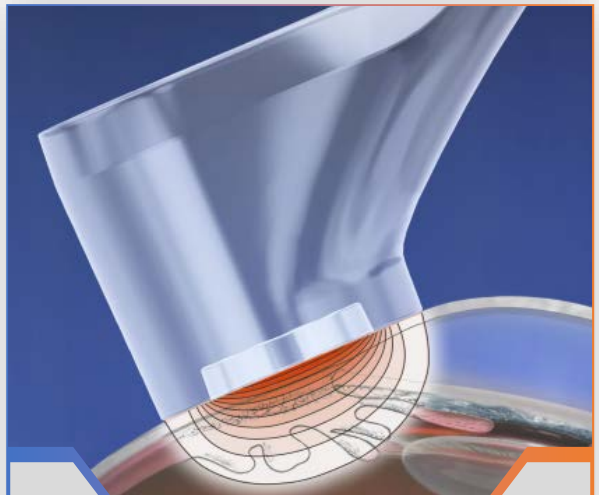
Brachytherapy

Y-90 Microspheres

Hepatocellular carcinoma and other cancers

Alpha DaRT

Solid tumors



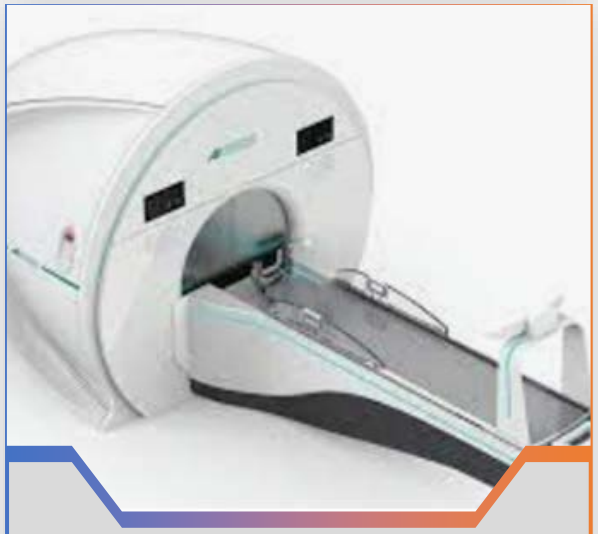
Liberty Vision Y-90 Disc Sources

Episcleral ocular diseases, tumors, and benign growths

Gamma Stereotactic Radiosurgery

Icon, Perfexion, Esprit

Tumors, vascular and neurological disorders



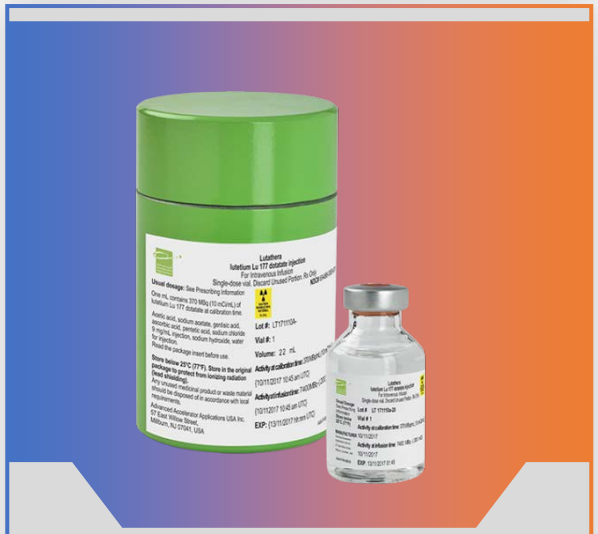
Akesis Galaxy RTi

Cancer and intracranial diseases

Xcision GammaPod

Breast cancer

Radiopharmaceuticals (§35.300)



LUTATHERA
(Lu-177 dotatate)

GEP-NETs

PLUVICTO
(Lu-177 PSMA)

PSMA-positive mCRPC

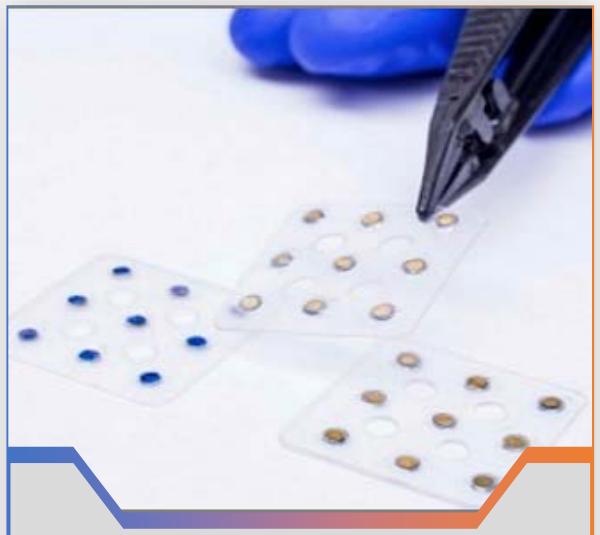
Xofigo
(Ra-223 dichloride)

MCRPC
(bone metastasis)

Brachytherapy (§35.400)

GammaTile

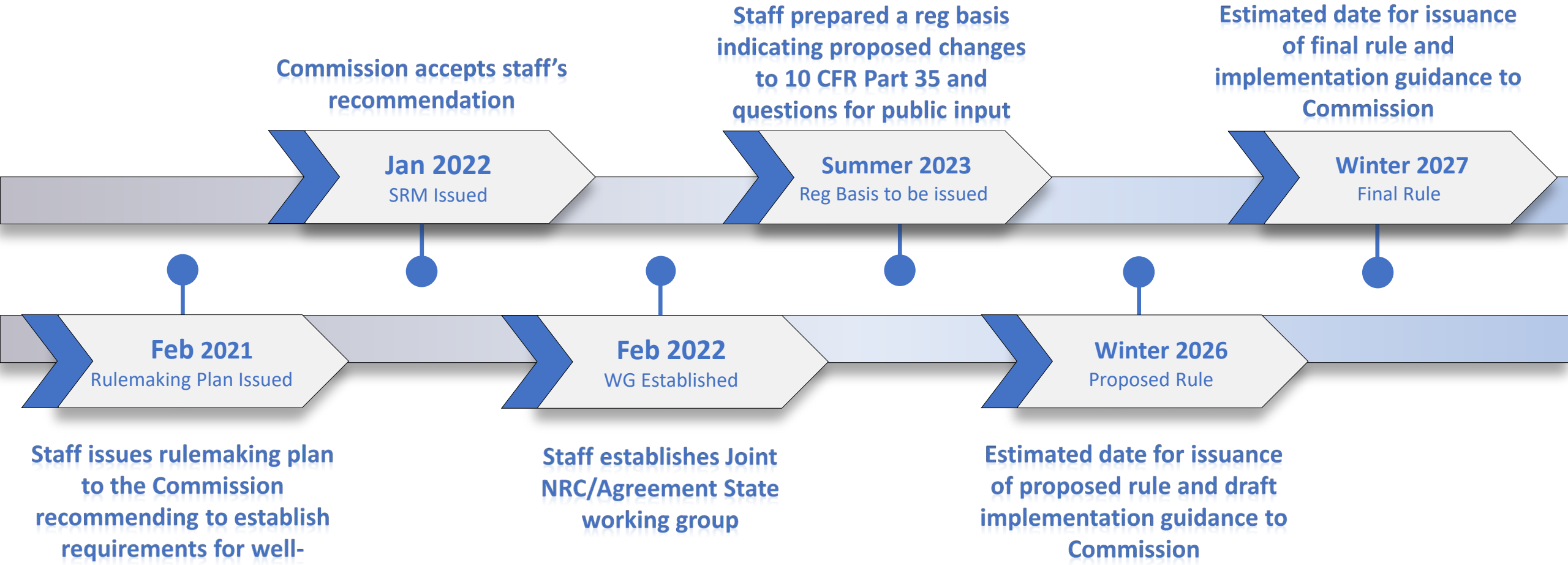
Brain tumors



CivaDerm

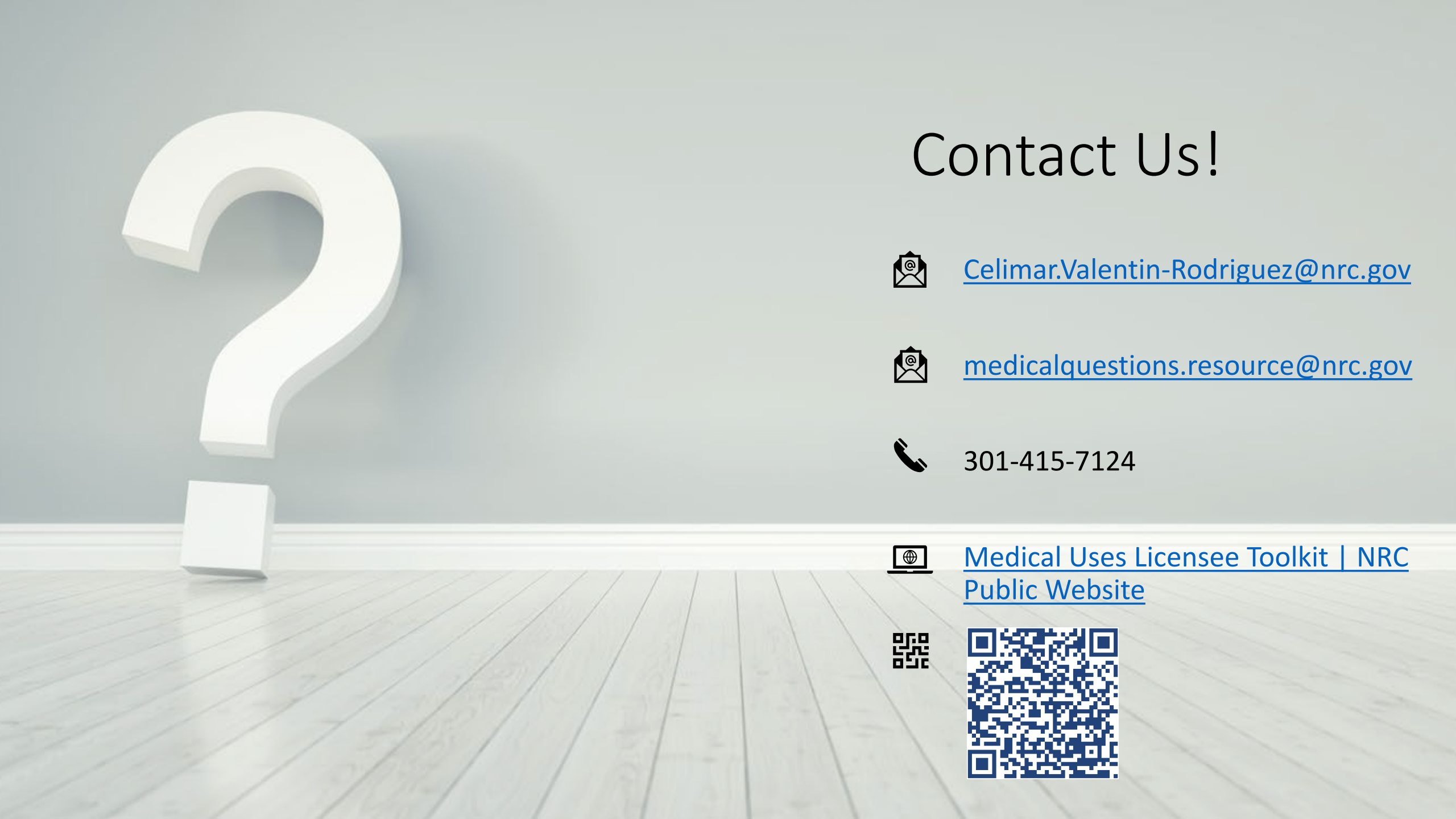
Skin cancer and other lesions

EMT/Rb-82 Generator Rulemaking



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