

NRC MEDICAL RADIATION SAFETY PROGRAM UPDATES

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Medical Radiation Safety Team
August 13, 2025

Outline

01

Guidance Updates

02

Emerging Medical
Technologies

Guidance Updates

Training and Experience Guidance

- Interim Staff Guidance consolidates current guidance.
- Evaluating licensing practices for efficiency.
 - Modernizing Forms.
 - Enabling Training Curriculum.
 - Authorized User Database.



Training and Experience Look Up Tables

Training & Experience “Alternate Pathway” for Authorized Users (AU)

Purpose	Uptake, Dilution & Excretion Studies	Imaging & Localization Studies	Use of Unsealed Material Requiring a Written Directive	Oral Administration of ≤33 mCi NaI I-131 Requiring a Written Directive	Oral Administration of >33 mCi NaI I-131 Requiring a Written Directive	Parenteral Administration of Unsealed Material Requiring a Written Directive	Use of Manual Brachytherapy Sources	Ophthalmic Use of Sr-90	Use of Sealed Sources and Medical Devices for Diagnosis	Use of Remote Afterloader, Teletherapy, and GSR Units
Regulation (10 CFR)	35.190	35.290	35.390	35.392	35.394	35.396	35.490	35.491	35.590	35.690
Total Training and Work Experience	60 hours 35.190(c)(1)	700 hours 35.290(c)(1)	700 hours 35.390(b)(1)	-	-	-	-	-	-	-
Classroom & Laboratory Training (Minimum Number of Hours)	8 hours in topics listed in 35.190(c)(1)(i)	80 hours in topics listed in 35.290(c)(1)(i)	200 hours in topics listed in 35.390(b)(1)(i)	80 hours in topics listed in 35.392(c)(1)	80 hours in topics listed in 35.394(c)(1)	80 hours in topics listed in 35.396(b)(1)	200 hours in topics listed in 35.490(b)(1)(i)	24 hours in topics listed in 35.491(b)(1)	8 hours in topics listed in 35.590(c)	200 hours in topics listed in 35.690(b)(1)(i)
Supervised Work Experience	Topics listed in 35.190(c)(1)(ii)	Topics listed in 35.290(c)(1)(ii)	Topics listed in 35.390(b)(1)(ii)	Topics listed in 35.392(c)(2)	Topics listed in 35.394(c)(2)	Topics listed in 35.396(b)(2)	500 hours in topics listed in 35.490(b)(1)(ii) and 3 years of clinical experience in radiation oncology 35.490(b)(2)	Clinical training in topics listed in 35.491(b)(2)	No	500 hours in topics listed in 35.690(b)(1)(ii) and 3 years of clinical experience in radiation therapy 35.690(b)(2)
Supervised Patient Case Experience	No	No	3 patient cases in each of the categories listed under 35.390(b)(1)(ii)(G)¹	3 patient cases involving the oral administration of 33 mCi or less of NaI I-131 35.392(c)(2)(vi)	3 patient cases involving the oral administration of >33mCi of NaI I-131 35.394(c)(2)(vi)	3 patient cases involving parenteral administrations as specified in 35.390(b)(1)(ii)(G)(3)	No	5 patient cases involving use of Sr-90 for ophthalmic treatment	No	No

NRC Follow-up to a Medical Event

- Assess the NRC's response to medical events using the Risk Triplet.
 - What can go wrong?
 - How likely is it?
 - What are the consequences?
- Area of Focus
 - Timing
 - Scope



Inspection Procedure Update

Microspheres

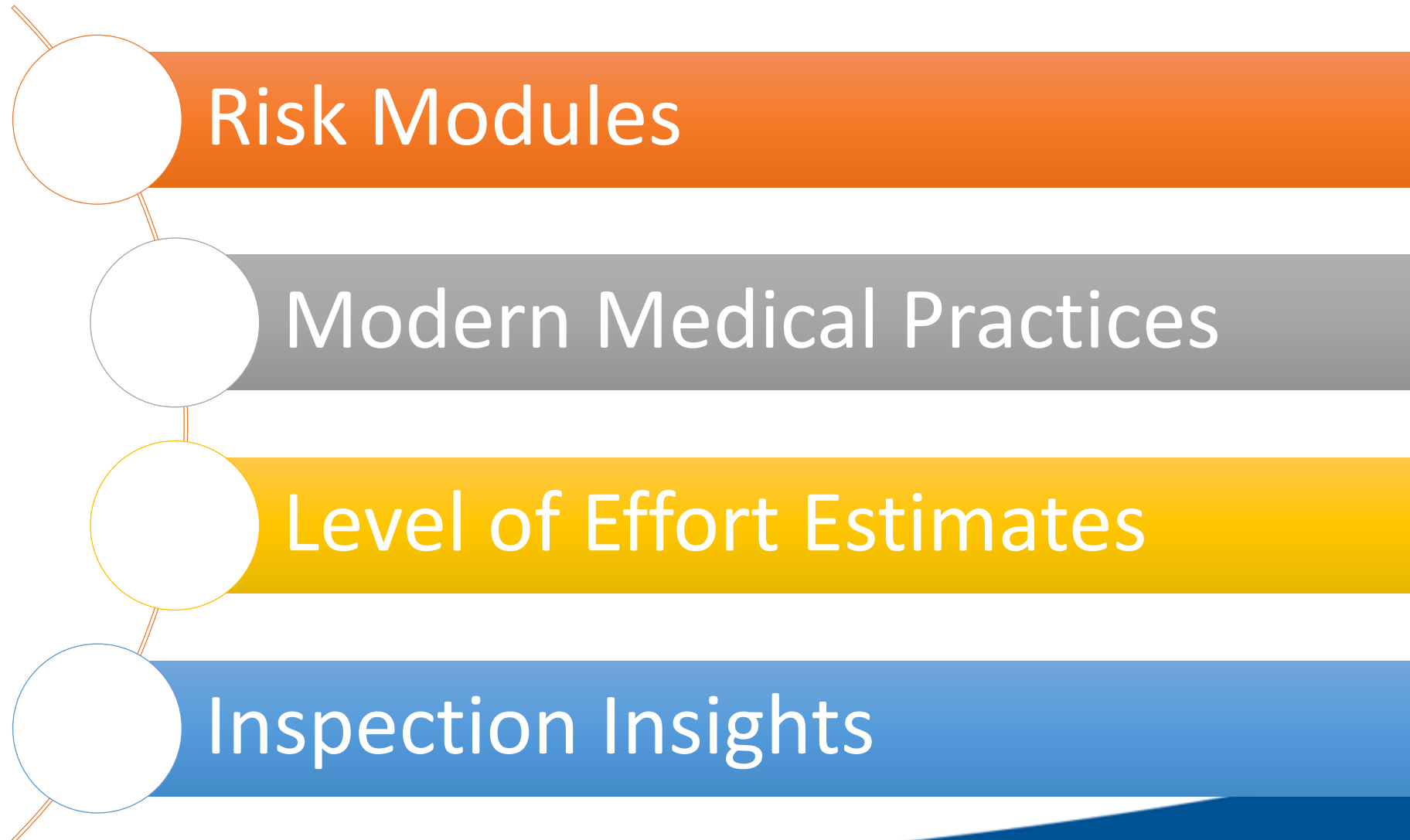
Brachytherapy

Gamma Stereotactic Radiosurgery Units

Medical Broadscope

Radiopharmacies

Inspection Procedure Update



Emerging Medical Technologies

EMT STANDING COMMITTEE

- Katie Tapp – NRC Co-Chair (NMSS)
- Meghan Cromie– Organization of Agreement State Co-Chair (Co)
- John Pavlica – Agreement State Representative (TX)
- Magdalena Gryglak – Regional Representative (RIII)
- Dan Shaw, Standing Committee Coordinator
- NRC OGC

EMERGING MEDICAL TECHNOLOGIES

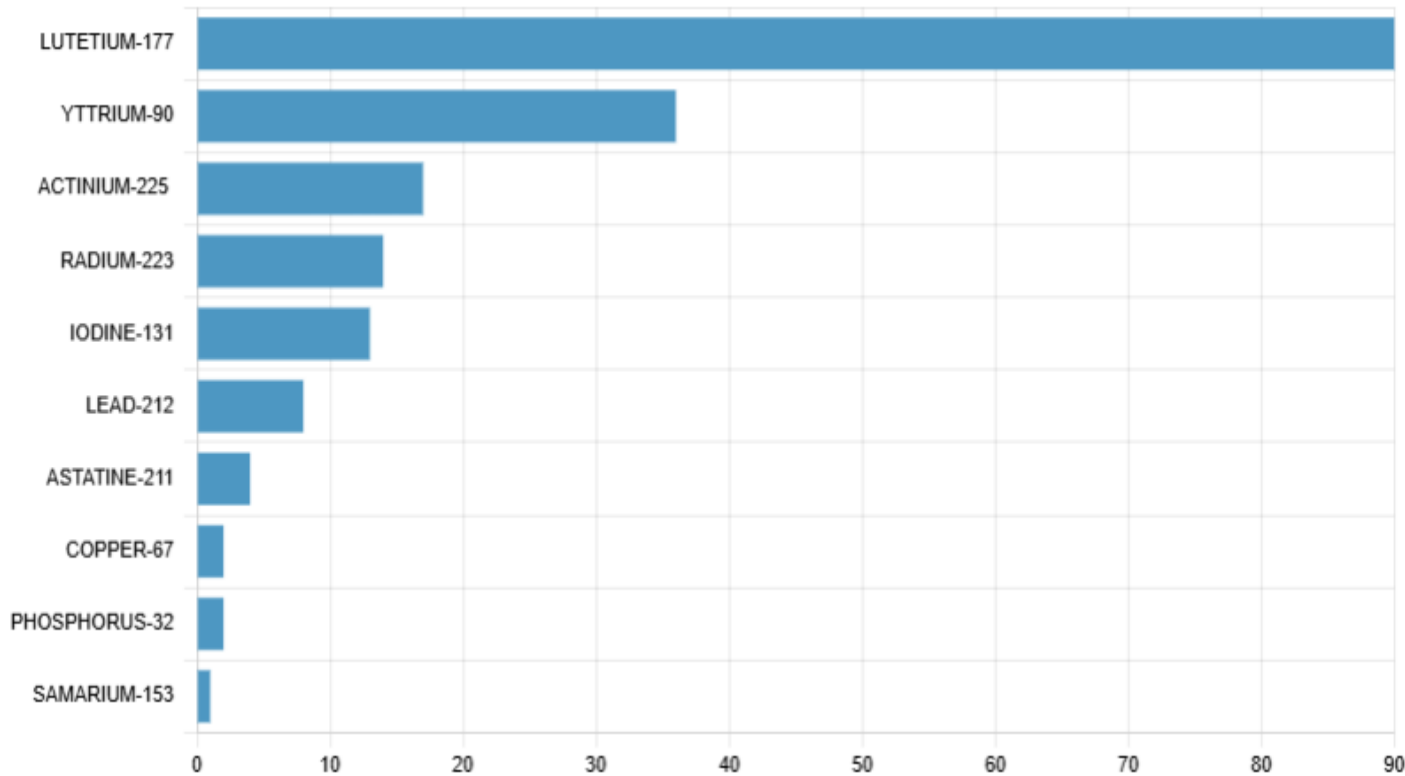
FREQUENTLY ASKED QUESTIONS FOR

LICENSING OF EMERGING MEDICAL TECHNOLOGIES



<https://www.nrc.gov/materials/miau/med-use-toolkit/emerg-licensed-med-tech.html>

INCREASED USE OF RADIOPHARMACEUTICALS



<https://www.theranostictrials.org/>

- Expansive growth involving radiopharmaceuticals.
- Subparts D and E are flexible and currently address emerging radiopharmaceuticals.
- Increased licensing actions and questions are expected.

LICENSING OF THORIUM GENERATORS

- Thorium generators use thorium (Th)-229, Th-228, and Th-227 to produce alpha/beta emitting progeny for targeted alpha therapy (TAT).
- Licensing memo was issued in April 2025.
 - Thorium can be licensed as either byproduct or source material depending on how the thorium was originally produced or generated.
 - Memo lists known pathways for how thorium is produced for generators at this time and explains that all current pathways point to byproduct material.

EYE90 MICROSPHERES®

- Eye90 Microspheres® are glass yttrium-90 microspheres used for radioembolism to treat diseases in the liver, similar to other yttrium-90 microspheres.
- Eye90 Microspheres® are radiopaque which allows direct fluoroscopic imaging during administration.
- Licensing guidance containing one set of approved regulations and conditions issued September 2024.

EYE90 MICROSPHERES®

TRAINING AND EXPERIENCE

- Similar to other yttrium-90 microspheres with pathways for radiation oncology, nuclear medicine, and interventional radiologist
- Specific training in the operation of the delivery system, safety procedures, and clinical use specific to Eye90 microspheres.
- If already approved for another yttrium-90 microsphere, should have training in the differences.

EYE90 MICROSPHERES®

MEDICAL EVENT REPORTING

- Similar to other yttrium-90 microspheres
 - AUs can modify the written directive if administration is terminated for stasis or emergent patient conditions.
- AU can make an oral revision to written directive during administration if they observe undesired microsphere deposition.

AKESIS® GALAXY RTI

- Akesis Galaxy® RTi is a gamma stereotactic radiosurgery (GSR) unit that contains thirty Cobalt-60 sources with approximately 6000 curies (Ci) total initial source activity.
- Integrated Image Guidance System moves the treatment couch to target position.
- Source and collimators rotate to deliver the desired prescribed dose.
- Licensing guidance containing one set of approved regulations and conditions was issued August 2024.

AKESIS® GALAXY RTI

TRAINING AND EXPERIENCE

- Training and experience criteria for radiation oncologist (AU), authorized medical physicist, and radiation safety officer similar to other GSR units licensed under 10 CFR 35.1000.
- Specific training in the hands-on operation of the delivery system, safety procedures, and clinical use specific to the Akesis.
- If already approved for another GSR, should have training in the differences.

AKESIS® GALAXY RTI

RADIATION SAFETY PRECAUTIONS AND INSTRUCTIONS

- Similar to other GSR units with specific radiation safety precautions such as unique spot and full calibration tests specific to the design and function to ensure safe use.
- Physical Presence recommendations similar to other 10 CFR 35.1000 GSR units.
 - AU/AMP should be physically present at initiation
 - AMP and AU or trained physician under supervision of the AU should be physically present during continuation of patient treatments
 - AU will return to the console if there is an interruption of treatment prior to re-initiation

LIBERTY VISION YTTRIUM-90 OPHTHALMIC SYSTEM

- LV Liberty Vision yttrium-90 disc is a manual brachytherapy source intended to be used within the Liberty Vision iWand[®] Ophthalmic System.
- The LV Y-90 Disc is temporarily positioned at the surface or at depth beyond the surface of the eye.
- Licensing guidance containing one set of approved regulations and conditions was issued June 2025.
- Surface placement can be licensed similar to other strontium-90 ophthalmic brachytherapy while at depth placement should be licensed similar to manual brachytherapy.

ALPHA DART™ REVISION

- Licensing guidance revision was issued in February 2025.
- Purpose was to provide additional survey recommendation based on operational experience that Rn-220 can escape through the glycerin encapsulation causing contamination of the inside of the packaging is possible.
- Recommended commitment to survey:
 - AU and supporting staff hands and
 - Packaging (sterile bag) of the applicator.

REFLEXION MEDICAL RADIOTHERAPY

- RefleXion is a linear accelerator therapy unit which uses PET for biological guidance.
- Licensing memo was issued in April 2025.
- Purpose of the memo is to specify that while the use of the PET isotopes is to be licensed under 10 CFR 35 Subpart D, “Unsealed Byproduct Material, Written Directive Not Required”.
- Reminder that an AU for 10 CFR 35.200 would therefore be required.
- The linear accelerator does not require an NRC license.



Contact Us!



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