Launching a New Radiopharmaceutical Therapy Program: A Review of Program Blueprints and Necessary Tools

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University of Vermont Health

Disclosures

M3D, Inc. Advisory Board Member

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Please consult your local regulations, which may be defined at the state, county, or city level

Outline


Planning, permits
Review FDA-approved RPTs
Engage stakeholders, establish scope, roles and responsibilities
Conduct initial education
Write SOP
Site prep
Update RML, request provider privileges, add RPT to EMR
Determine treatment location
Procure supplies and equipment
Construction
Establish release criteria and patient instructions
Design patient consult
Special considerations during the consultation
Finishing
Conduct a dry run
Go live
Final inspection
Specialized accreditation

Planning, permits

Nomenclature

- Theranostics
- Theragnostics
- Targeted radionuclide therapy
- Radiotheranostics
- Radiopharmaceutical therapy
- Radionuclide therapy
- Radioligand therapy
- Radioimmunotherapy
- Precision medicine
- Personalized medicine
- Peptide receptor radiation therapy
- Molecular radiotherapy
- Molecular radiation therapy
- Internal radiation therapy

Radioiodine

- Diagnostic agent: I-131 or I-123
- Therapy agent: I-131
- The radioisotope I-131 or I-123 can be directly mediated by the sodium-iodide symporter in the thyroid cells.
- Indicated for the treatment of hyperthyroidism and thyroid carcinomas that take up iodine. Palliative effects may be observed in patients with advanced thyroid malignancy if the metastatic lesions take up iodine.

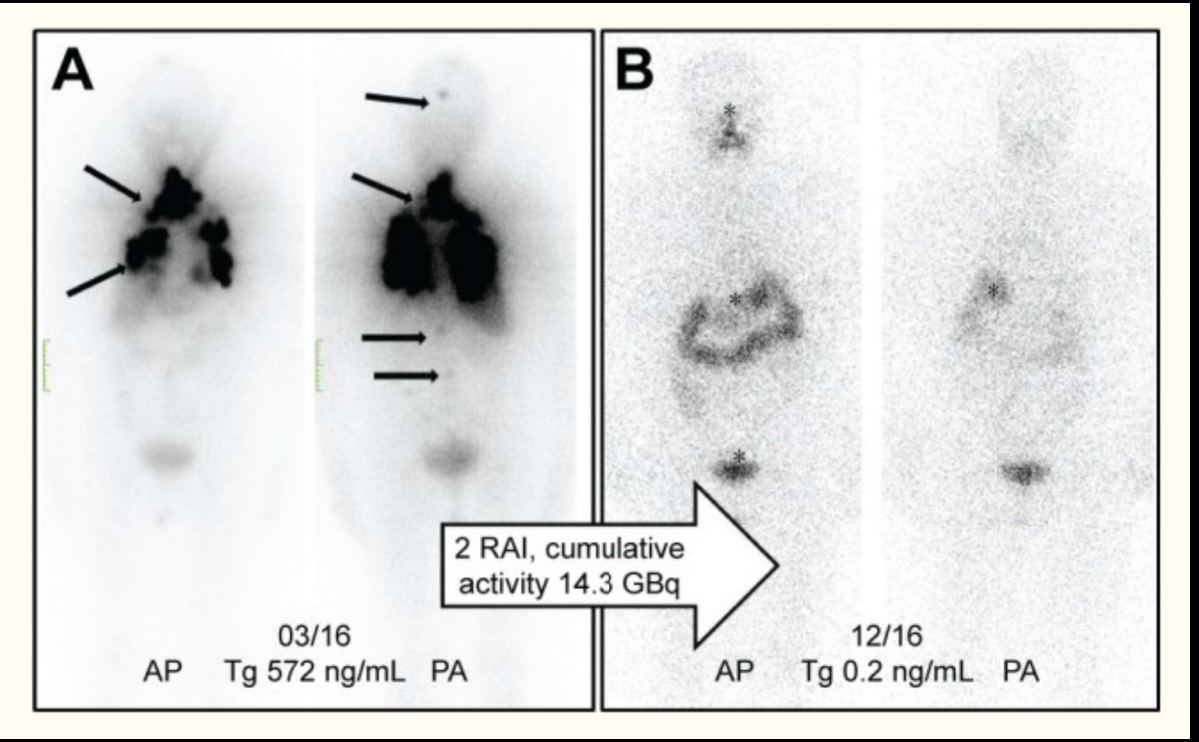


Image: Initial I-131 planar images of a patient with metastatic thyroid cancer. After two administrations of RAI, pt is in complete remission.
Reference: Theranostics in nuclear medicine practice, Onco Targets Ther. 2017; 10: 4821-4828

1940s 1950s 1960s 1970s 1980s 1990s 2000s 2010s 2020s

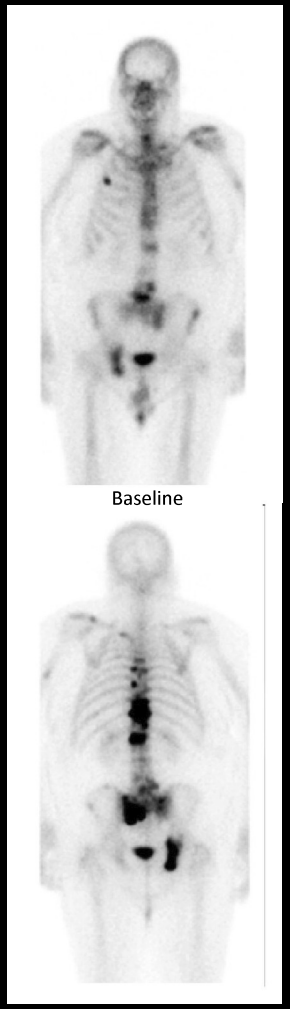
SIR-Spheres

- Diagnostic agent: Tc-99m MAA
- Therapy agent: Y-90 Microspheres
- Uses: the treatment of unresectable metastatic liver tumors from primary colorectal cancer with adjuvant intrahepatic artery chemotherapy (IHAC) of FUDR (Floxuridine).

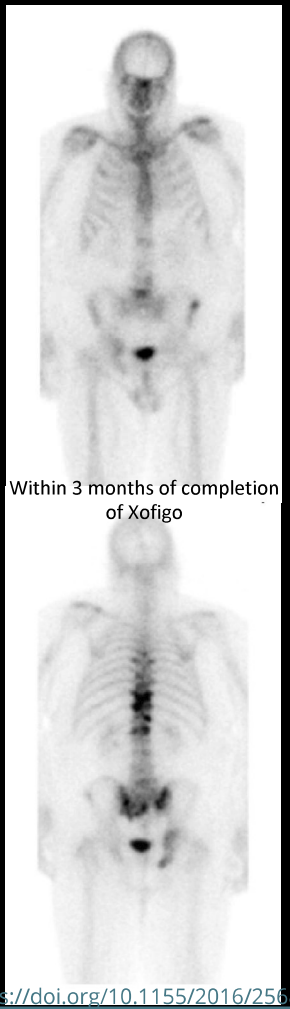
1940s 1950s 1960s 1970s 1980s 1990s 2000s 2010s 2020s

Xofigo

- Diagnostic agent: Ga-68 PSMA and Tc-99m MDP
- Therapy agent: Ra-223
- Uses: Treatment of patients with castration-resistant prostate cancer, specifically those with symptomatic bone metastases
- Administration: 55 kBq/kg for 6 cycles at 4



Baseline



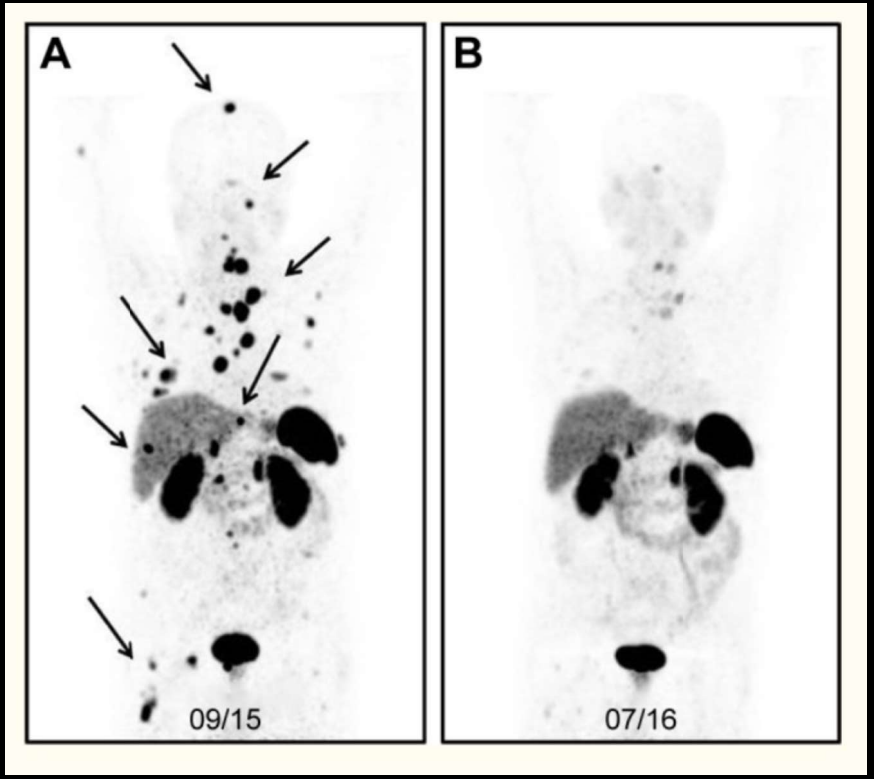
Within 3 months of completion of Xofigo

https://doi.org/10.1155/2016/2568031

1940s 1950s 1960s 1970s 1980s 1990s 2000s 2010s 2020s

Lutathera

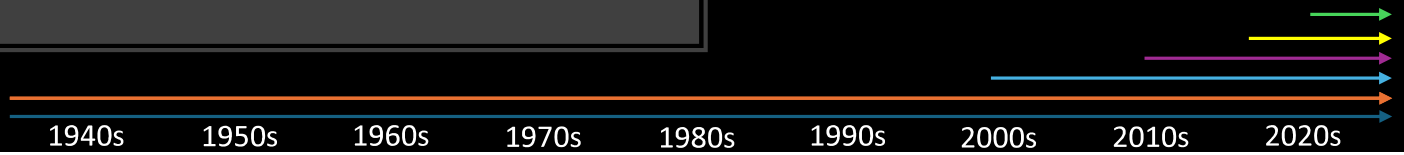
- Diagnostic agent: DOTA-TATE, DOTA-TOC, and DOTA-NOC, all labelled with Ga-68
- Therapy agent: DOTA-TATE and DOTA-TOC labeled with either Lu-177
- Neuroendocrine tumors often originated from the pancreas, jejunum, ileum, cecum, rectum, appendix and colon express somatostatin receptors



Left, Ga-DOTA-TOC image of neuroendocrine tumors, right, after course of three cycles of treatment.

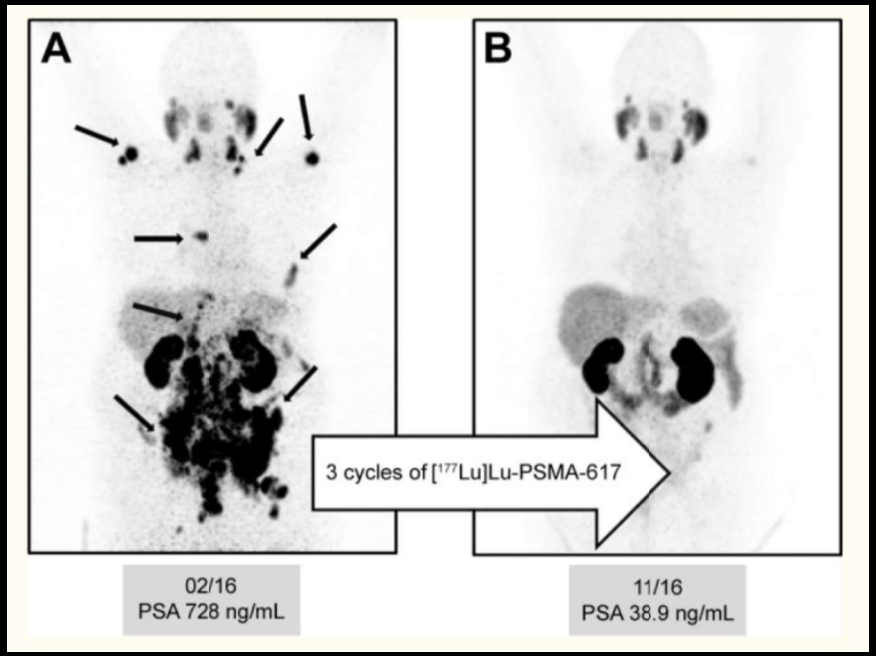
TheraSphere

- Diagnostic agent: Tc-99m MAA
- Therapy agent: Y-90 Microspheres
- Uses: Selective Internal Radiation Therapy (SIRT) for local tumor control of solitary tumors (1-8 cm in diameter), in patients with unresectable hepatocellular carcinoma (HCC), Child-Pugh Score A cirrhosis, well-compensated liver function, no macrovascular invasion, and good performance status.

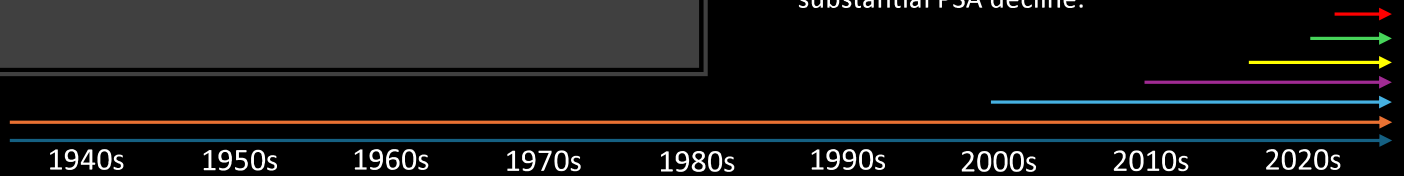


Pluvicto

- Diagnostic agent: Ga-PSMA-617 and Ga-PSMA-11 PET-tracers
- Therapy agent: Lu-PSMA-617
- Prostate cancer cells overexpress prostate-specific membrane antigen (PSMA) on the cell surface.



Left image before 3 cycles of Lu-PSM-617. Very good response with substantial PSA decline.




3B Pharmaceuticals
Blue Earth Therapeutics
MODULATION Therapeutics
QSAM Biosciences
Soricimed
SOFIE
From start to clinic
Abdera Therapeutics
CLARITY PHARMACEUTICALS
ImaginAb
opM Oncodesign Precision Medicine
PRECIRIX®
Telix
spago NANOMEDICAL
Actinium Pharmaceuticals, Inc.
CellBion
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Indi Molecular
oranomed
TRANSCODE THERAPEUTICS
AKTIS ONCOLOGY
Cancer Targeted Technology
CTT
EVERGREEN THERAGNOSTICS
MERCK
PRECISION MOLECULAR
RAD
RADIOPHARM THERANOSTICS
alpha 9 THERANOSTICS
CELLECTAR BIOSCIENCES
FULL-LIFE TECHNOLOGIES
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ANDARIX
Targeted Therapies for Personalized Medicine
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PROVIDING ANSWERS FOR CANCER PATIENTS
Fusion
JUBILANT THERAPEUTICS
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RadioMedix
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TREVARX BIOMEDICAL
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Bicycle
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WE DEVELOP FOR PATIENTS
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NUVIEW LIFE SCIENCES
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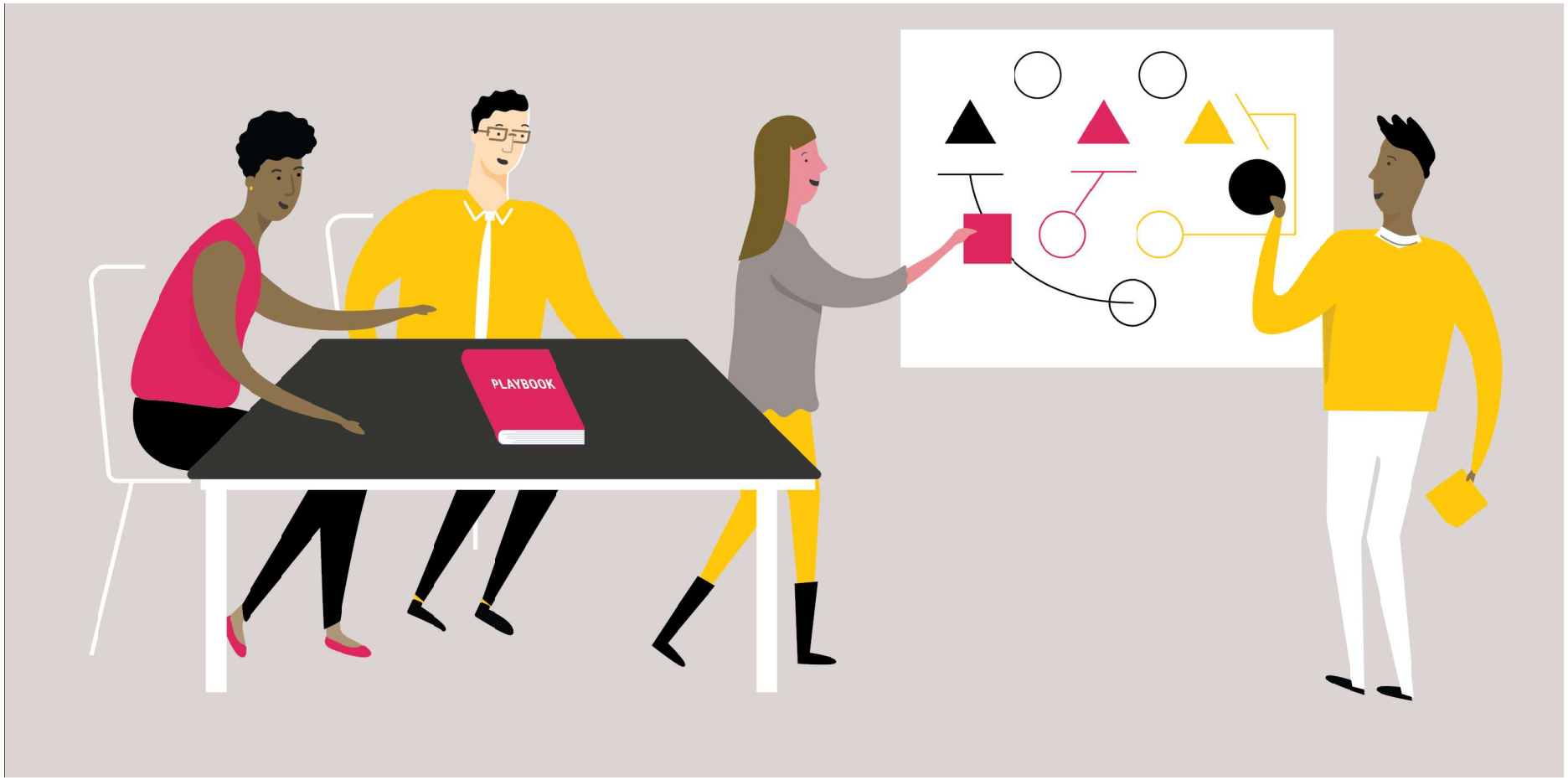
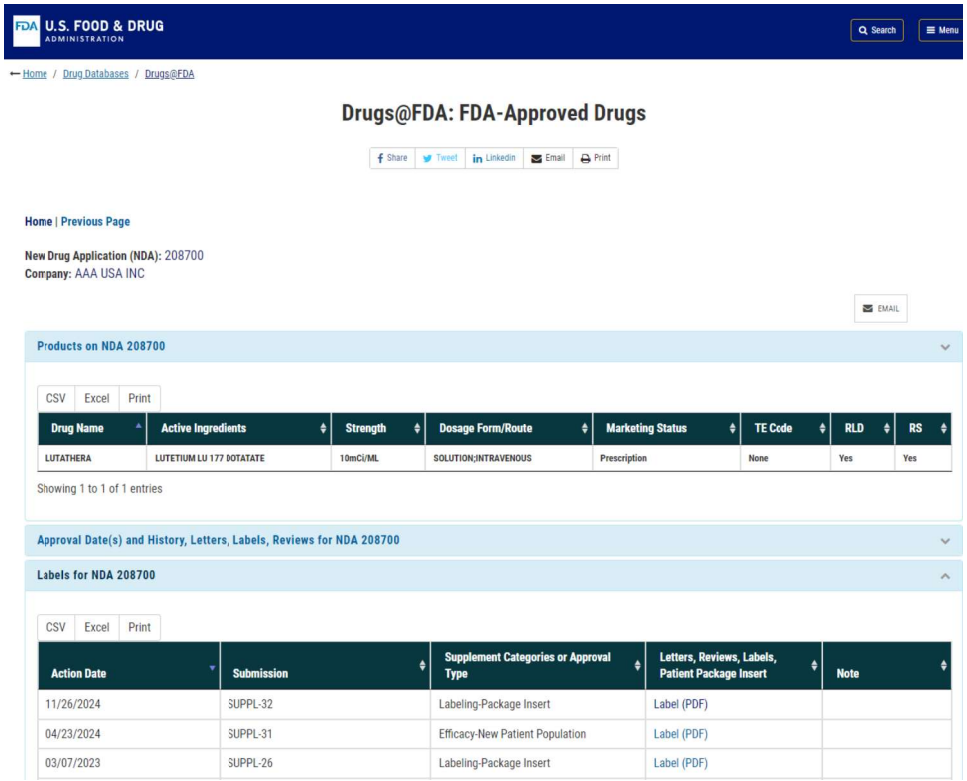
-mAbs Therapeutics, Inc.


PLAYBOOK

Conduct Initial Education

- Review:
  - Manufacturer's prescribing information and recommended procedures
    - Current package inserts: https://www.accessdata.fda.gov/
  - Practice Guidelines
  - Published Best Practices
  - Established facility practices – visit a colleague, phone a friend!
- Determine if additional credentialing is required at the facility
- Perform general radiation safety training for the treatment team
- Conduct procedure-specific training for each member of the treatment team
  - May be provided by the manufacturer



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Drugs@FDA: FDA-Approved Drugs

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New Drug Application (NDA): 208700
Company: AAA USA INC

EMAIL

Products on NDA 208700

CSV | Excel | Print

Drug Name	Active Ingredients	Strength	Dosage Form/Route	Marketing Status	TE Code	RLD	RS
LUTATHERA	LUTETIUM LU 177 DOTATATE	10mCi/ML	SOLUTION;INTRAVENOUS	Prescription	None	Yes	Yes

Showing 1 to 1 of 1 entries

Approval Date(s) and History, Letters, Labels, Reviews for NDA 208700

Labels for NDA 208700

CSV | Excel | Print

Action Date	Submission	Supplement Categories or Approval Type	Letters, Reviews, Labels, Patient Package Insert	Note
11/26/2024	SUPPL-32	Labeling-Package Insert	Label (PDF)	
04/23/2024	SUPPL-31	Efficacy-New Patient Population	Label (PDF)	
03/07/2023	SUPPL-26	Labeling-Package Insert	Label (PDF)	

HIGHLIGHTS OF PRESCRIBING INFORMATION

These highlights do not include all the information needed to use LUTATHERA safely and effectively. See full prescribing information for LUTATHERA.

LUTATHERA® (lutetium Lu 177 dotatate) injection, for intravenous use
Initial U.S. Approval: 2018

----------RECENT MAJOR CHANGES----------

Indications and Usage (1)	4/2024
Dosage and Administration (2.2, 2.5, 2.6)	4/2024
Warnings and Precautions (5.1)	4/2024

----------INDICATIONS AND USAGE----------

LUTATHERA is a radiolabeled somatostatin analog indicated for the treatment of adult and pediatric patients 12 years and older with somatostatin receptor-positive gastroenteropancreatic neuroendocrine tumors (GEP-NETs), including foregut, midgut, and hindgut neuroendocrine tumors. (0)

----------DOSAGE AND ADMINISTRATION----------

- Verify pregnancy status of females of reproductive potential prior to initiating LUTATHERA. (0)
- Administer 7.4 GBq (200 mCi) every 8 weeks (± 1 week) for a total of 4 doses. (2.2)
- Administer long-acting octreotide 30 mg intramuscularly 4 to 24 hours after each LUTATHERA dose and short-acting octreotide for symptomatic management. (0)
- Continue long-acting octreotide 30 mg intramuscularly every 4 weeks after completing LUTATHERA until disease progression or for 18 months following treatment initiation. (0)
- Administer antiemetics before recommended amino acid solution. (0)
- Initiate recommended intravenous amino acid solution 30 minutes before LUTATHERA infusion; continue during and for at least 3 hours after LUTATHERA infusion. Do not decrease dose of amino acid solution if LUTATHERA dose is reduced. (0)

----------DOSAGE FORMS AND STRENGTHS----------

Injection: 370 MBq/mL (10 mCi/mL) in single-dose vial. (3)

----------CONTRAINDICATIONS----------

None. (0)

----------WARNINGS AND PRECAUTIONS----------

- Risk From Radiation Exposure: Minimize radiation exposure during and after treatment with LUTATHERA consistent with institutional good radiation safety practices and patient management procedures. (0, 0)
- Myelosuppression: Monitor blood cell counts. Withhold dose, reduce dose, or permanently discontinue based on the severity. (2.4, 0)
- Secondary Myelodysplastic Syndrome (MDS) and Leukemia: Median time to onset: MDS is 29 months; acute leukemia is 55 months. (0)
- Renal Toxicity: Advise patients to hydrate and to urinate frequently before, on the day of and the day after administration of LUTATHERA. Monitor serum creatinine and calculated creatinine clearance. Withhold dose, reduce dose, or permanently discontinue based on the severity. (2.3, 2.4, 0)
- Hepatotoxicity: Monitor transaminases, bilirubin, serum albumin and INR. (2.4, 5.5)
- Hypersensitivity Reactions: Monitor patients closely for signs and symptoms of hypersensitivity reactions, including anaphylaxis. Permanently discontinue LUTATHERA based on severity. (2.3, 2.4, 5.6)
- Neuroendocrine Hormonal Crisis: Monitor for flushing, diarrhea, hypotension, bronchoconstriction or other signs and symptoms. (5.7)
- Embryo-Fetal Toxicity: Can cause fetal harm. Advise females and males of reproductive potential of the potential risk to a fetus and to use effective contraception. (5.8, 0, 0)
- Risk of Infertility: LUTATHERA may cause infertility. (5.9, 0)

----------ADVERSE REACTIONS----------

Most common Grade 3-4 adverse reactions (≥ 4% with a higher incidence in LUTATHERA arm) are lymphopenia, increased GGT, vomiting, nausea, increased AST, increased ALT, hyperglycemia and hypokalemia. (0)

To report SUSPECTED ADVERSE REACTIONS, contact Novartis Pharmaceuticals Corporation at 1-888-669-6682 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

----------DRUG INTERACTIONS----------

Somatostatin Analogs: Discontinue long-acting analogs at least 4 weeks and short-acting octreotide at least 24 hours prior to each LUTATHERA dose. (0, 0)

----------USE IN SPECIFIC POPULATIONS----------

Lactation: Advise not to breastfeed. (0)

See 0 for PATIENT COUNSELING INFORMATION.

Revised: 11/2024

Written Protocol Development

Treatment Planning	RPT Administration	Emergency Procedures	Patient Release
• Team Training • Determination of whether treatment is indicated • Scheduling • Screening/ Contraindications • Patient Education • Pre-treatment Steps • Written Directive	• Administration Area Prep • Patient Prep • Required Supplies and Equipment • Administration • Patient Monitoring	• Radiation Safety Surveys • Spills • Adverse Events • Patient Death • Waste Management	• Radiation Safety Surveys • Patient Release Criteria • Patient Instructions

ASTRO Quality and Safety Considerations for Radiopharmaceutical Therapy in the Radiation Oncology Environment: An ASTRO Safety White Paper

https://doi.org/10.1016/j.prro.2025.03.006

Table 1 Roles and responsibilities in the RPT workflow

RPT Responsibilities	RPT Roles						
	AU	QMP	NMT or RTT	RPT Nurse	RadioPharmacist (NP/ANP)	RSO (RS/HP)	Coordinator/ Navigator
Patient selection	X						
Ongoing patient management including laboratory values and symptom management	X						
Scheduling			X				X
Supervision and prescription	X						
Agent ordering†		X	X		X		X
Equipment QA/QC		X	X		X	X	
Agent preparation (requiring access to drug contents)		X*	X*		X*		
Agent QA checks and assay†		X	X		X	X	
Patient preparation and monitoring	X		X	X			
Administration†	X		X	X			
Determination of administered activity†		X	X		X		
Exposure/contamination control and waste management†		X	X			X	
Patient release with precautions†	X	X	X			X	
Imaging and patient-specific dosimetry	X	X	X (NMT)				

Abbreviations: ANP = authorized nuclear pharmacist; AU = authorized user; NMT = nuclear medicine technologist; NP = nuclear pharmacist; QA = quality assurance; QC = quality control; QMP = qualified medical physicist; RS/HP = radiation safety/health physics staff; RSO = radiation safety officer; RPT = radiopharmaceutical therapy; RTT = radiation therapy technologist.

*Performed under AU/ANP supervision with adherence to the United States Pharmacopeia 825.[7]

†Performed under AU supervision per Nuclear Regulatory Commission 10 CFR 35.27 Subpart B.[3]

Administration Approaches in use in the U.S.

Fixed Activity

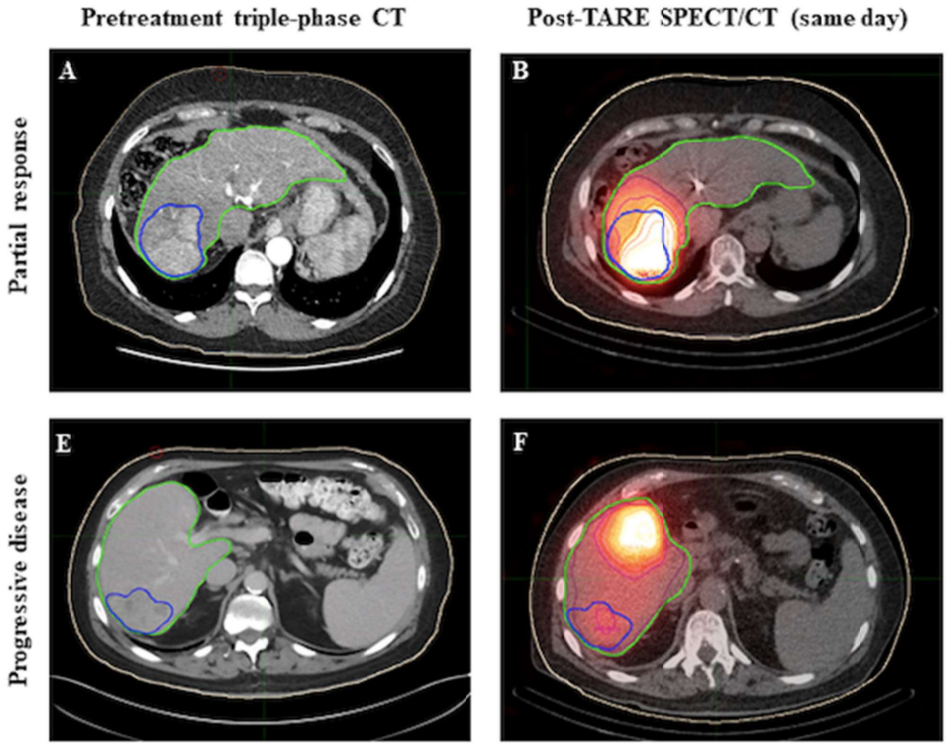
Standard administered activity for most patients with some opportunities to empirically adjust for patient factors

Patient-specific

Based on patient anatomy and pharmacokinetics to estimate an accurate prediction of toxicity and efficacy of the treatment.

Why is dosimetry performed?

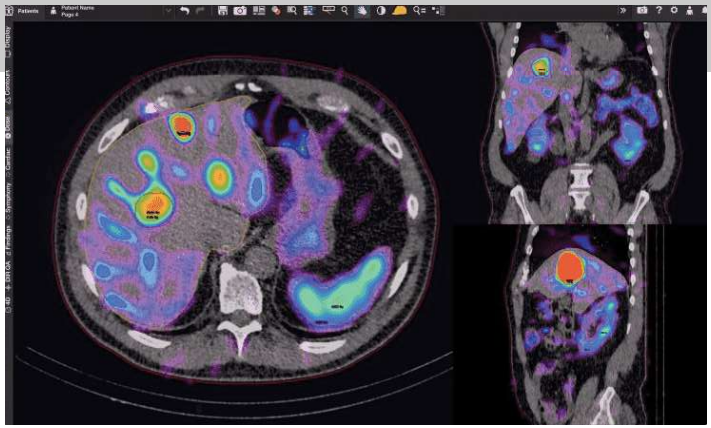
- Goals:
  - Delivering a specific dose to target tissues – effective treatment
  - Keeping dose to healthy tissues below thresholds – tissue sparing / safety
  - Post-therapy, this can be used to verify the activity delivered



https://www.mdpi.com/2072-6694/15/3/645

Differences between RPT and External Beam Radiation Therapy

RPT	EBRT
- Source is an unencapsulated radionuclide that distributes and is subjected to a physical and biological half-life	- Source is a machine-produced external beam turned on for set amounts of time
- The source is heterogeneously distributed in cells	- Delivers the same absorbed dose per cell regardless of the number of cells
- Longer exposure times, lower absorbed dose rates	- Short exposure times at higher dose rates



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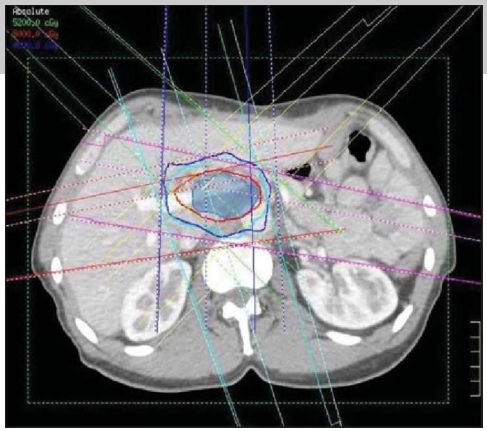
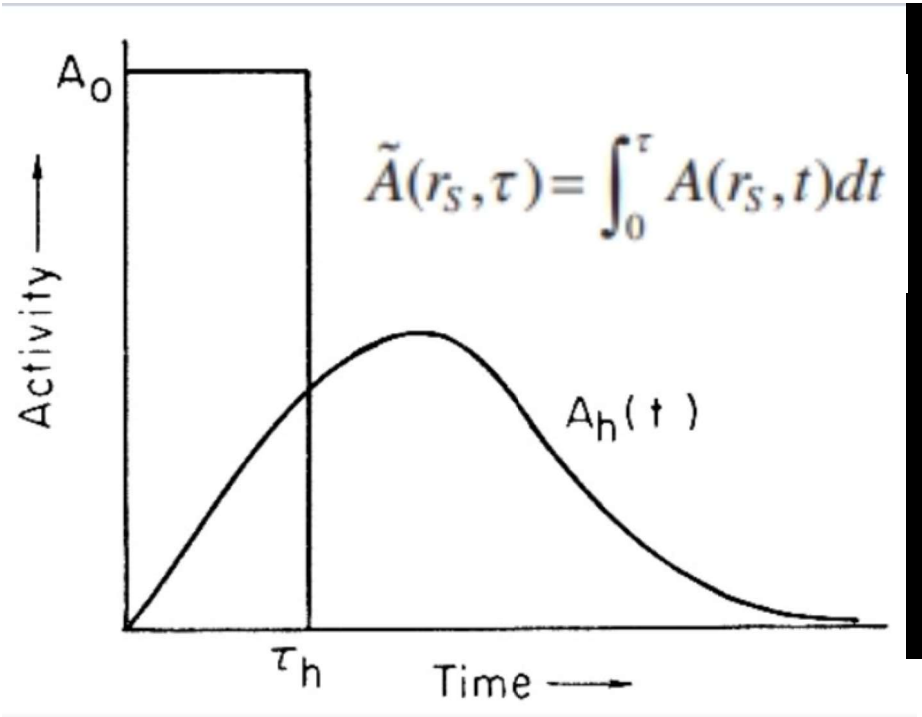
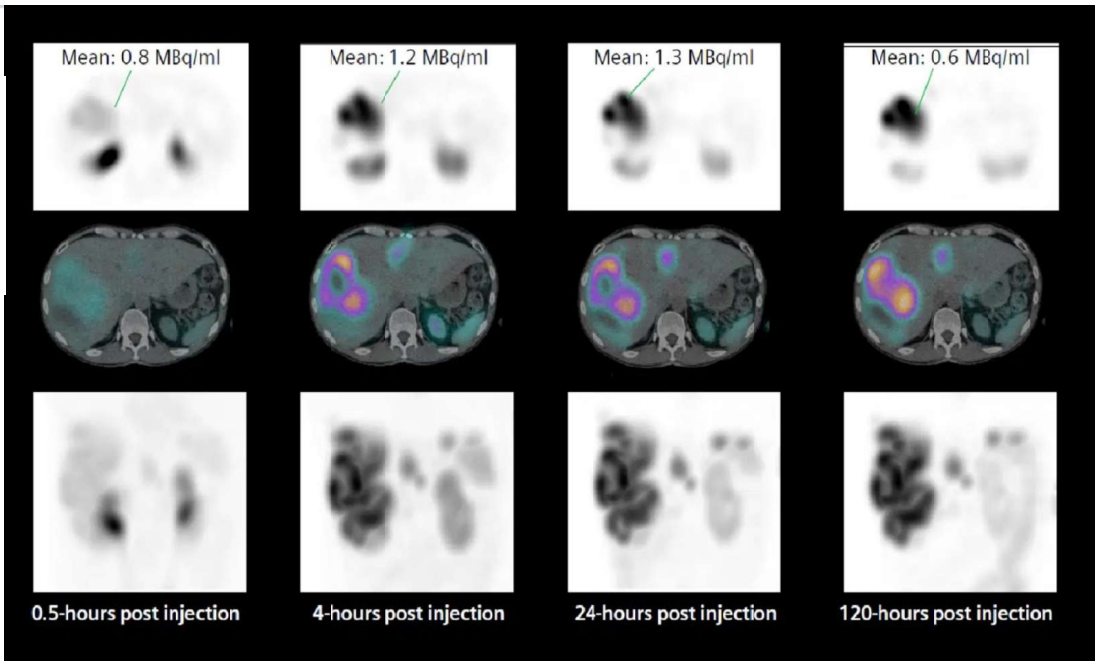


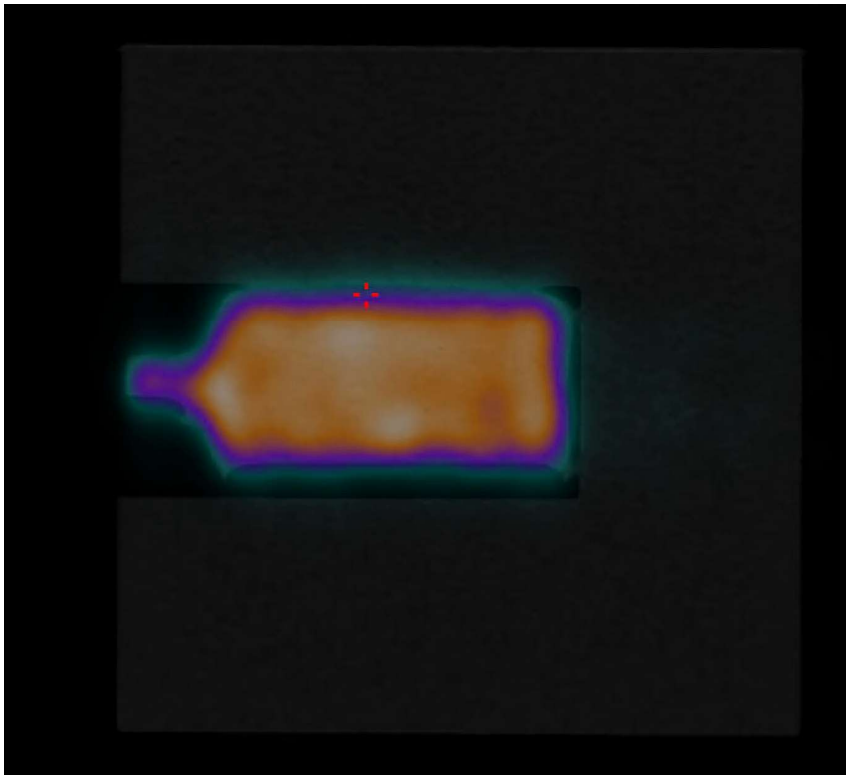
https://doi.org/10.1177/107327481001700205

Time-Integrated Activity

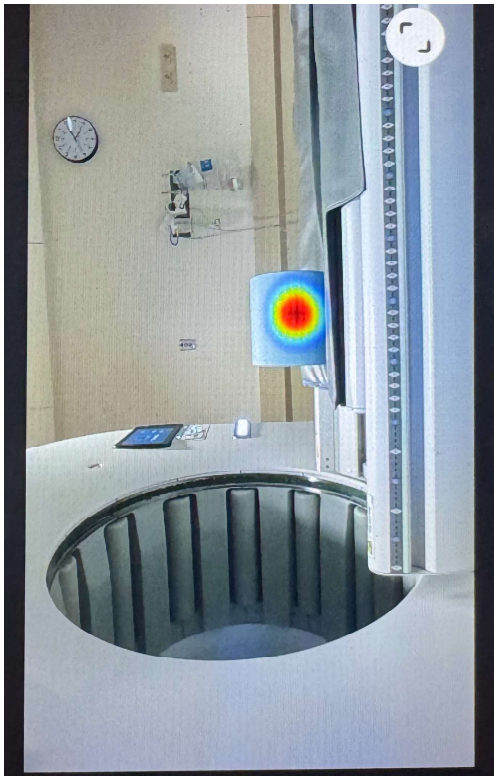




https://www.siemens-healthineers.com/en-us/molecular-imaging/mi-clinical-corner/clinical-case-studies/spectct-lu177dotatate.html




StarGuide



Planning, permits

RML Review

2026

January

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October

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November

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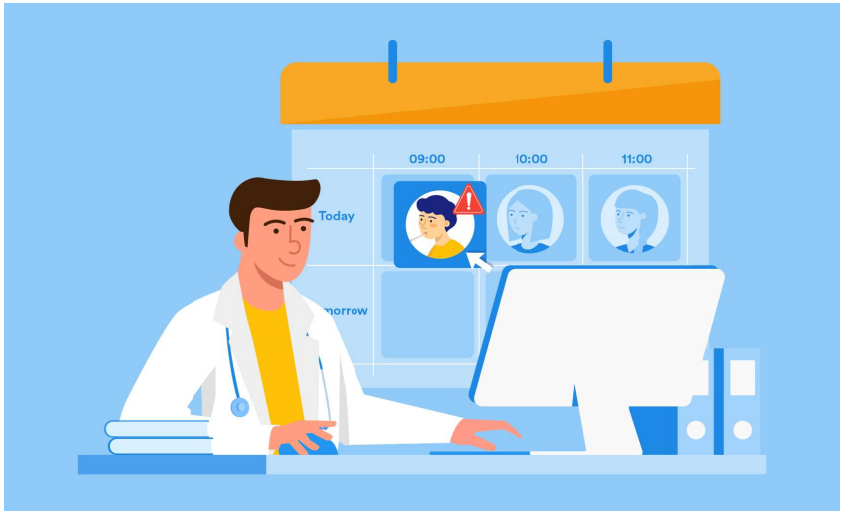
PROGRAM PREPARATION: POSSESSION LIMIT



Authorized Users

- Combination of training and education required to be named as an AU
- Responsibilities defined in 10 CFR 35.2:
  - Radiation safety commensurate with use of byproduct material
  - Administration of a radiation dose or dosage and how it is prescribed
  - Direction of individuals under the AUs supervision in the preparation of byproduct material for medical use and in the medical use of byproduct material
  - Preparation of the written directive, if required

Authorized Users

- Must be approved at each location (RML)
- Training and education 10 CFR 35 Subparts D – K
- Specific Guidance for 35.1000 categories in NRC licensing guides
- NRC List of certifications by type
- AMP is defined for HDR and Gamma Knife RAM only

**Facility privileges

- AU status is just one part of the process
- Providers should be aware of facility requirements for continuing experience to maintain privileges
- This process can be slow!

Emergency Procedures

- Spill/Contamination
- Leaking or damaged source
- Theft or loss of material
- Medical event reporting
- Emergency surgery
- Death of a patient

Français

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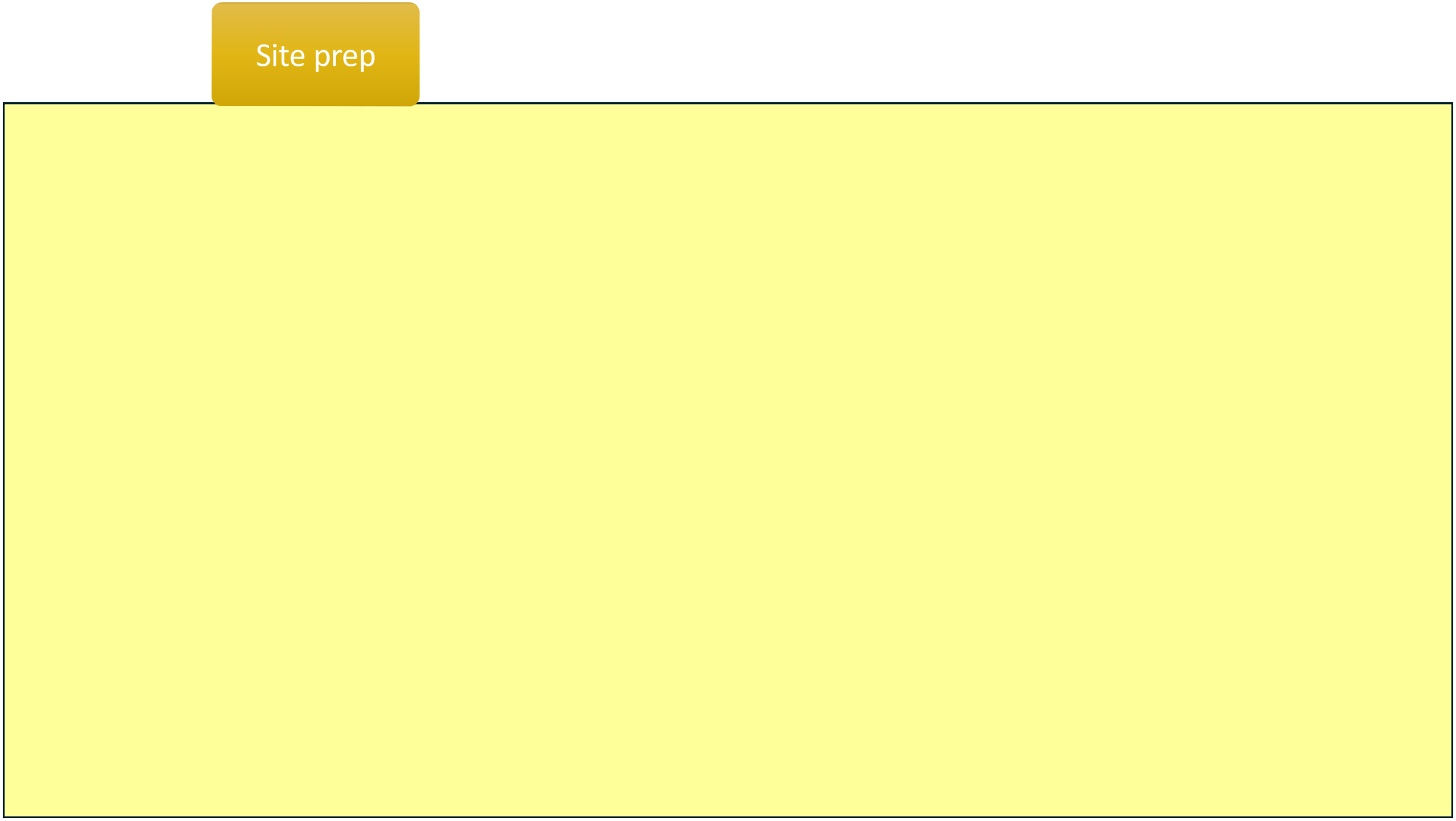
REGDOC-2.7.3, Radiation Protection Guidelines for Safe Handling of Decedents

View or download as a PDF [31 pages, 282 KB]

Preface

This regulatory document is part of the CNSC's radiation protection series of regulatory documents. The full list of regulatory document series is included at the end of this document and can also be found on the CNSC's website.


Site prep

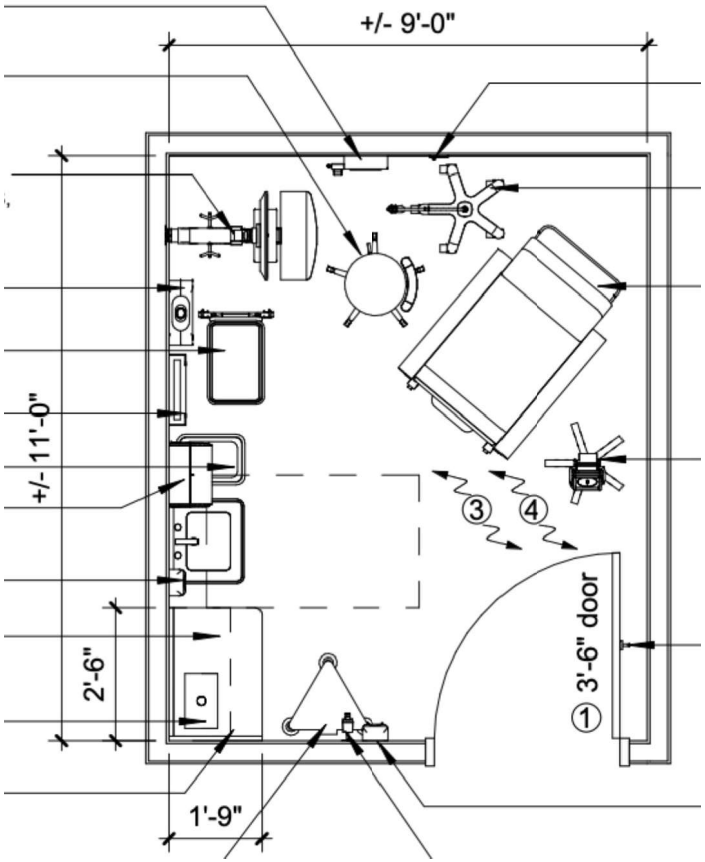
Treatment Location

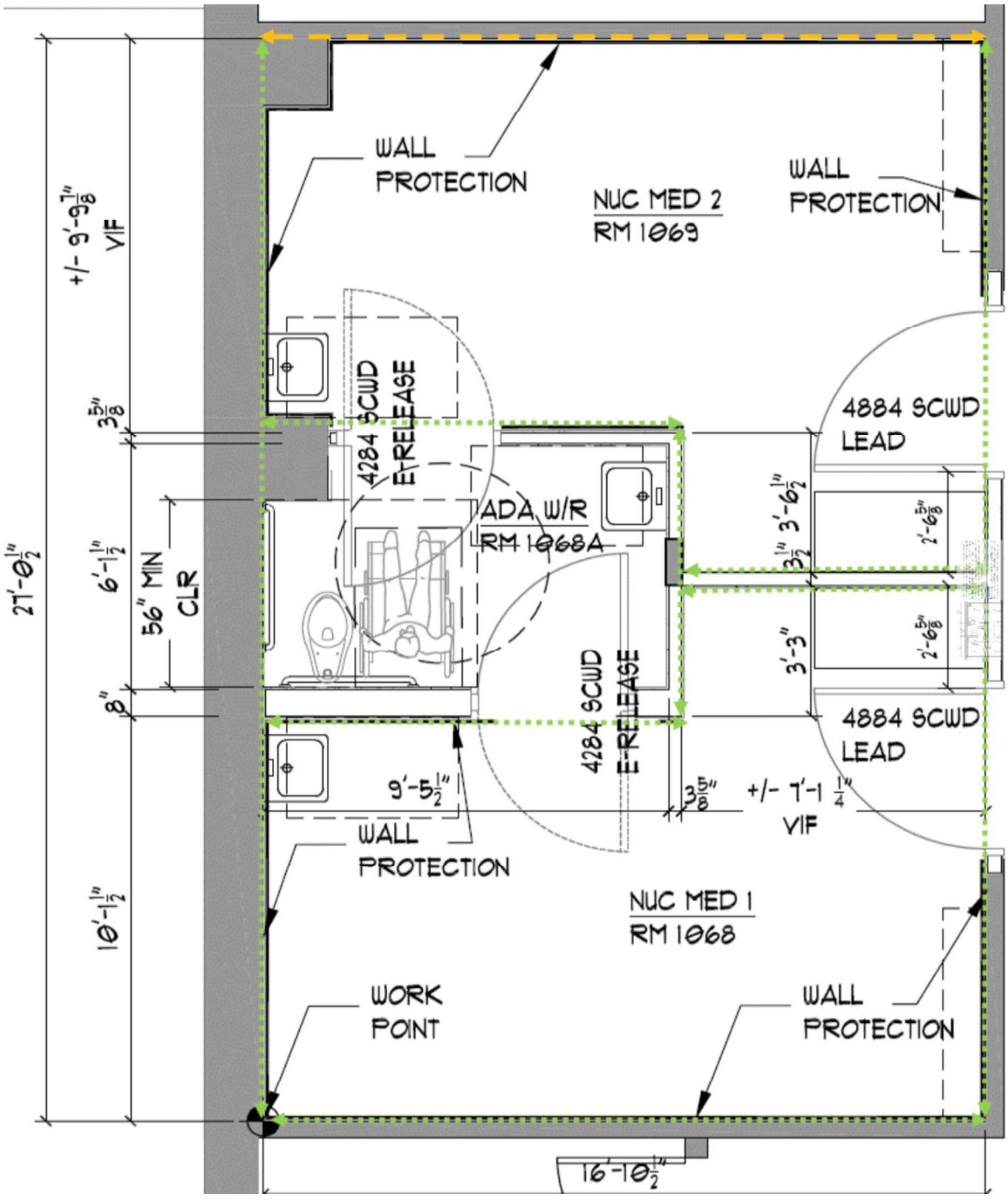
Must be authorized for RAM use

Location should have:

- Enough room for an uptake chair and staff
- Nearby patient bathroom
- Preferably enclosed with controlled access
- Doses to members of the public and personnel within limits

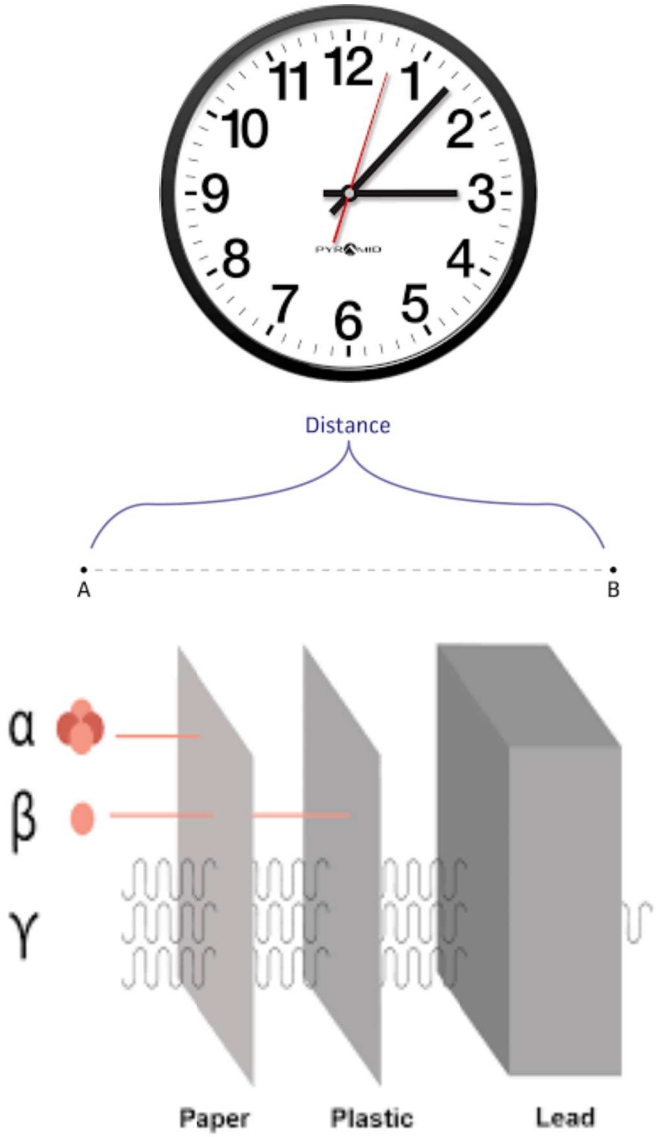
Is shielding required?




WALL PROTECTION
NUC MED 2
RM 1069
WALL PROTECTION
+/- 9'-9 7/8" VIF
3 5/8"
4284 SCWD E-RELEASE
4884 SCWD LEAD
ADA W/R
RM 1068A
3 1/2" 3'-6 1/2"
2'-6 5/8"
27'-0 1/2"
6'-1 1/2"
56" MIN CLR
3'-3"
2'-6 5/8"
8"
4284 SCWD E-RELEASE
4884 SCWD LEAD
9'-5 1/2"
3 5/8"
+/- 7'-1 1/4" VIF
WALL PROTECTION
NUC MED 1
RM 1068
10'-1 1/2"
WORK POINT
WALL PROTECTION
16'-10 1/2"

Radio-pharmaceutical	Radio-isotope	Emission Type	Exposure Rate Constant (R cm^2 / mCi h)	Half-Life (days)	HVL (mm Pb)	Administration Guidance from Package Inserts
Sodium iodide	I-131	Beta Gamma	2.2[1]	8.04[2]	2.74[1]	Hyperthyroidism: 148–370 MBq (4–10 mCi) Thyroid carcinoma: 3700–5550 MBq (100–150 mCi)
Azedra	I-131	Beta Gamma	2.2[1]	8.04[2]	2.74[1]	<62.5 kg 296 MBq/kg (8 mCi/kg) >62.5 kg 18,500 MBq (500 mCi) for up to 2 cycles
Xofigo	Ra-223	Alpha Beta Gamma	0.77[1]	11.43[3]	0.69[1]	50 kBq/kg body weight (1.35 µCi/kg) at 4-week intervals for 6 administrations
Lutathera	Lu-177	Beta Gamma	0.181[1]	6.7[4]	0.542[1]	7.4 GBq (200 mCi) at 8- week intervals for 4 administrations
Pluvicto	Lu-177	Beta Gamma	0.181[1]	6.7[4]	0.542[1]	7.4 GBq (200 mCi) at 6-week intervals for 6 administrations
Quadramet	Sm-153	Beta Gamma	0.481[1] 0.46[5]	1.946[2] 1.93[5]	0.0876 [1] 0.1[5]	37 MBq/kg (1 mCi/kg)
Zevalin	Y-90	Beta	N/A[2]	2.67[2]		14.8 MBq/kg (0.4 mCi/kg) with a maximum of 1184 MBq (32 mCi)

[1]Smith et al. 2012; [2]NRC 2020; [3]ACMUI 2012; [4]NRC 2022; [5]FDA 2017



Canada's Nuclear Regulator

Radionuclide Information Booklet

Janary 2026

Canadian Nuclear Safety Commission | Commission canadienne de sûreté nucléaire

Canada

Lu-177

Part 1 – RADIONUCLIDE IDENTIFICATION

Chemical symbol: Lu	Common name: Lutetium	Atomic weight: 177	Atomic number: 71

Part 2 – RADIATION CHARACTERISTICS

Physical half-life: 6.65 days
Decay scheme: Lu-177 (6.65 d, β(-) 100%) → Hf-177 (stable)

Radiation type	Most abundant emissions (>10 keV, >0.01%)	Most energetic emissions (>10 keV, >0.01%)	Shielding information (mm)					
Gamma & X-ray	208.37 keV (10.4%) 112.95 keV (6.2%) 55.79 keV (2.79%)	321.32 keV (0.22%) 249.67 keV (0.20%) 208.37 keV (10.4%)	Lead		Steel		Concrete	
			1st H/TVL	2nd H/TVL	1st H/TVL	2nd H/TVL	1st H/TVL	2nd H/TVL
			0.53	0.65	8.95	8.74	70.8	37.5
			2.13	2.64	28.7	25.9	152.7	101.6
Beta(-), Beta(+), electrons	498.30 keV (79.3%) 176.98 keV (11.6%) 385.35 keV (9.10%)	498.30 keV (79.3%) 385.35 keV (9.1%) 255.97 keV (0.01%)	Continuous Slowing Down Approximation (CSDA) range					
			Aluminium		PMMA (Plexiglass)		Water	Air
			0.8062		1.450		1.607	1630
Alpha	None	None	Not applicable					

Part 3 – DOSE RATE CONSTANTS AND COEFFICIENTS

External dose

Dose rate (mGy/h or mSv/h) @ 1 m per MBq				Equivalent dose rate to skin from direct contamination (mSv/h per kBq/cm² at 70 µm)	Equivalent dose rate to skin from direct contamination (mSv/h per kBq/cm² at 400 µm)
Air kerma	Effective	H*10	Hp10		
4.078E-06	4.935E-06	5.996E-06	6.420E-06	1.22E+00	1.43E-01

Internal dose

	Ingestion	Inhalation
Worker dose coefficient (Sv/Bq)	3.5E-11	2.9E-10

Part 4 – CLEARANCE AND EXEMPTION

EQ:	1 kBq/g or 10 MBq	**CNSC dassification:**	Class C
UCL:	100 Bq/g	**Release of surface**	30 or 10 Bq/cm²
CCL (landfill | atmosphere | sewer):	1 kBq/g | 1 GBq/y | 10 MBq/y	**contaminated objects:**	(fixed + removable)

Part 5 – DETECTION AND MEASUREMENT

Method of detection (gamma dose rate):

1. Plastic scintillator, ion chamber, ion chamber with window, energy compensated NaI, energy compensated Geiger-Mueller

Method of detection (contamination):

1. Hand-held: gas-flow proportional, sealed-gas proportional, NaI scintillator, plastic scintillator, halogen quenched thin window Geiger-Mueller
1. Non-portable: liquid scintillation counter, gas-flow proportional counter, NaI well counter

Dosimetry

External: Gamma/beta
Internal: In-vivo, in-vitro

Part 6 – SAFETY PRECAUTIONS

For emergency procedures, please refer to appendix B.

For general safety precautions, please refer to appendix C.

Shielding resources for four common radiopharmaceuticals utilized for imaging and therapy: Tc-99m, F-18, I-131, and Lu-177

Michael Oumano, Richard Wendt, James Botti, Nathan Busse, David Hintenlang, Stephanie Leon, Kevin Little, Melissa Martin, Richard Massoth, Kenneth Matthews, Rameshwar Prasad, Sharon White, Jessica Clements

Authors and Affiliations >

Journal of Applied Clinical Medical Physics - Open Access Publish Ahead of Print, March 26, 2025. | *DOI:* 10.1002/acm2.70084

TABLE 2 Archer equation parameters (for thicknesses in mm) based upon the simulations using GATE.

Radionuclide	Barrier	α	β	γ
Tc-99m	Lead	2.558	1.010	4.344
Tc-99m	Gypsum	0.009549	−0.005312	1.430
Tc-99m	LW concrete	0.02047	−0.01122	0.4389
Tc-99m	NW concrete	0.03102	−0.01729	0.3622
Tc-99m	514 Steel	0.1581	−0.04346	0.2602
Tc-99m	Glass	0.03419	−0.02009	0.3076
Lu-177	Lead	0.3855	1.071	0.2822
Lu-177	Gypsum	0.009594	−0.003783	0.3739
Lu-177	LW concrete	0.01615	−0.007056	0.5194
Lu-177	NW concrete	0.02477	−0.01173	0.4404
Lu-177	514 Steel	0.0797	2.243	28.74
Lu-177	Glass	0.02456	−0.01197	0.6480
I-131	Lead	0.1082	0.2072	0.5385
I-131	LW concrete	0.01363	−0.007896	0.4847
I-131	NW concrete	0.02062	−0.01220	0.4179
I-131	514 Steel	0.05786	−0.02574	0.8742
I-131	Glass	0.02191	−0.01319	0.4497
F-18	Lead	0.166	−0.02184	0.2436
F-18 TG-108	Lead	0.1543	−0.04406	2.133
F-18	LW concrete	0.01126	−0.006463	0.7475
F-18	NW concrete	0.01558	−0.008775	0.8600
F-18 TG-108	NW concrete	0.01539	−0.01161	2.076
F-18	514 Steel	0.05032	−0.02632	1.223
F-18 TG-108	Iron	0.05705	−0.03063	0.6319

Abbreviations:NW, noraml-weight; LW, light-weight.

Review Equip

- Appropriate instru
  - Activity measurem
  - Identifying contan
  - Patient exposure r
  - Personnel monito
- Treatment Area Pr
  - Chux, floor coveri
  - Waste containers
  - Cleaning agents
  - Staff PPE

aceutical

or the
naceutical (syringe
for delivery
:)
ecial needles
air or stretcher

dosimetry

ging systems
planning software


Construction

Identify post-treatment location

- Outpatient Release
  - If TEDE to any member of the public is < 500 mrem
  - Determination may be made by the:
    - administered activity
    - exposure rate measurements
    - patient-specific calculations
    - Check out reg guide 8.39 – but note: a draft revision is coming….soon!
- Inpatient Admission
  - May be required if the:
    - patient can't meet outpatient requirements
    - activity administered exceeds regulatory release guidance
    - patient has a unique medical condition that requires medical observation

Release Criteria

- 10 CFR 35.75 permits the licensee to authorize the release of any individual from its control who has been administered unsealed byproduct material or implants containing byproduct material if the total effective dose equivalent to any other individual from exposure to the released individual is not likely to exceed 5 millisieverts (mSv) (0.5 rem).
- Current Regulatory Guide 8.39 Rev. 1 (4/2020) - Regulatory Guide 8.39, Revision 1, Release of Patients Administered Radioactive Material (nrc.gov)
- Proposed Revision 2 (4/2023) - DG 8061 (RG 8.39 Rev 2) Release of Patients Administered Radioactive Material (nrc.gov)

Release Criteria

- Current Regulatory Guide 8.39 Rev. 1 (4/2020)

Table 4. Summary of Release Criteria, Required Instructions to Patients, and Records To Be Maintained

PATIENT GROUP	BASIS FOR RELEASE	CRITERIA FOR RELEASE	INSTRUCTIONS NEEDED?	RELEASE RECORDS REQUIRED?
All patients, including patients who are breast-feeding an infant or child	Administered activity	Administered activity ≤ Column 1 of Table 1	Yes, if administered activity > Column 1 of Table 2	No
	Retained activity	Retained activity ≤ Column 1 of Table 1	Yes, if retained activity > Column 1 of Table 2	Yes
	Measured dose rate	Measured dose rate ≤ Column 2 of Table 1	Yes, if dose rate > Column 2 of Table 2	Yes
	Patient-specific calculations	Calculated dose ≤ 5 mSv (0.5 rem)	Yes, if calculated dose > 1 mSv (0.1 rem)	Yes
Patients who are breast-feeding an infant or child	All the above bases for release	All of the above bases for release	Additional instructions required if administered dosage > Column 1 of Table 3 or licensee-calculated dose from breastfeeding > 1 mSv (0.1 rem) to the infant or child	Records that instructions were provided if administered dosage > Column 2 of Table 3 or licensee-calculated dose from continued breastfeeding > 5 mSv (0.5 rem) to the infant or child

Release Criteria

- Current Regulatory Guide 8.39 Rev. 1 (4/2020)

Table 1. Activities and Dose Rates for Authorizing Patient Release[a]

	COLUMN 1 ACTIVITY AT OR BELOW WHICH PATIENTS MAY BE RELEASED		COLUMN 2 DOSE RATE AT 1 METER, AT OR BELOW WHICH PATIENTS MAY BE RELEASED[b]	
RADIONUCLIDE	**(GBq)**	**(mCi)**	**(mSv/h)**	**(mrem/h)**
Ag-111	19	520	0.08	8
Au-198	3.5	93	0.21	21
Cr-51	4.8	130	0.02	2
Cu-64	8.4	230	0.27	27
Cu-67	14	390	0.22	22
Ga-67	8.7	240	0.18	18
I-123	6.0	160	0.26	26
I-125	0.25	7	0.01	1
I-125 implant	0.33	9	0.01	1
I-131	1.2	33	0.07	7
In-111	2.4	64	0.2	20
Ir-192 implant	0.074	2	0.008	0.8
P-32[c]	c	c	c	c
Pd-103 implant	1.5	40	0.03	3
Re-186	28	770	0.15	15
Re-188	29	790	0.20	20
Sc-47	11	310	0.17	17
Se-75	0.089	2	0.005	0.5
Sm-153	26	700	0.3	30
Sn-117m	1.1	29	0.04	4
Sr-89[c]	c	c	c	c
Tc-99m	28	760	0.58	58
Tl-201	16	430	0.19	19
Yb-169	0.37	10	0.02	2

a. The activity values were computed based on a 5-mSv (0.5-rem) total effective dose equivalent.
b. If the release is based on the dose rate at 1 meter in Column 2, the licensee must maintain a record as required by 10 CFR 35.75(c) and 35.2075(a)(4) because the measurement includes shielding by tissue. See Staff Regulatory Guidance 3.1, "Records of Release," for information on records.
c. Activity and dose rate limits do not apply to these radionuclides because of the minimal exposures to members of the public resulting from dosages normally administered for diagnostic or therapeutic purposes.

Table 2. Activities and Dose Rates above Which Instructions Should Be Given When Authorizing Patient Release[a]

	COLUMN 1 ACTIVITYABOVE WHICH INSTRUCTIONS ARE REQUIRED		COLUMN 2 DOSE RATE AT 1 METER ABOVE WHICH INSTRUCTIONS ARE REQUIRED	
RADIONUCLIDE	**(GBq)**	**(mCi)**	**(mSv/h)**	**(mrem/h)**
Ag-111	3.8	100	0.02	2
Au-198	0.69	19	0.04	4
Cr-51	0.96	26	0.004	0.4
Cu-64	1.7	45	0.05	5
Cu-67	2.9	77	0.04	4
Ga-67	1.7	47	0.04	4
I-123	1.2	33	0.05	5
I-125	0.05	1	0.002	0.2
I-125 implant	0.074	2	0.002	0.2
I-131	0.24	7	0.02	2
In-111	0.47	13	0.04	4
Ir-192 implant	0.011	0.3	0.002	0.2
P-32[b]	b	b	b	b
Pd-103 implant	0.3	8	0.007	0.7
Re-186	5.7	150	0.03	3
Re-188	5.8	160	0.04	4
Sc-47	2.3	62	0.03	3
Se-75	0.018	0.5	0.001	0.1
Sm-153	5.2	140	0.06	6
Sn-117m	0.21	6	0.009	0.9
Sr-89[b]	b	b	b	b
Tc-99m	5.6	150	0.12	12
Tl-201	3.1	85	0.04	4
Yb-169	0.073	2	0.004	0.4

a. The activity values were computed based on a 1-mSv (0.1-rem) total effective dose equivalent.
b. Activity and dose rate limits are not applicable to these radionuclides because of the minimal exposures to members of the public resulting from dosages normally administered for diagnostic or therapeutic purposes.

NOTES: The mCi values in Table 2 were calculated using Equation 2 or 3 and the physical half-life. The GBq values were calculated based on mCi values and the conversion factor from mCi to gBq. The dose rate values were calculated based on mCi values and exposure rate constants. In general, values are rounded to two significant figures. However, values less than 0.37 GBq (10 mCi) or 0.1 mSv (10 mrem) per hour are rounded to one significant figure. NUREG-1492 describes the calculations in detail. Agreement State regulations may vary. Agreement State licensees should check their State regulations before using these values.

Release Criteria

- Current Regulatory Guide 8.39 Rev. 1 (4/2020)

Table 3. Activities of Radiopharmaceuticals That Require Instructions and Records When Administered to Patients Who Could Breastfeed an Infant or Child After Release

RADIOPHARMACEUTICAL	COLUMN 1 ACTIVITY ABOVE WHICH INSTRUCTIONS ARE REQUIRED (MBq)	(mCi)	COLUMN 2 ACTIVITY ABOVE WHICH A RECORD IS REQUIRED (MBq)	(mCi)	COLUMN 3 EXAMPLES OF RECOMMENDED DURATION OF INTERRUPTION OF BREASTFEEDING[a]
I-131 NaI	0.01	0.0004	0.07	0.002	Complete cessation (for this infant or child)
I-123 NaI	20	0.5	100	3	3 days[b]
I-123 OIH	100	4	700	20	
I-123 MIBG	70	2	400	10	24 hours for 370 MBq (10 mCi)
I-125 OIH	3	0.08	15	0.4	
I-131 OIH	10	0.30	60	1.5	
Tc-99m DTPA	1,000	30	6,000	150	24 hours[b]
Tc-99m MAA	50	1.3	200	6	24 hours[b]
Tc-99m Pertechnetate	100	3	600	15	24 hours[b]
Tc-99m DISIDA	1,000	30	6,000	150	24 hours[b]
Tc-99m Glucoheptonate	1,000	30	6,000	150	24 hours[b]
Tc-99m HAM	400	10	2,000	50	24 hours[b]
Tc-99m MIBI	1,000	30	6,000	150	24 hours[b]
Tc-99m MDP	1,000	30	6,000	150	24 hours[b]
Tc-99m PYP	900	25	4,000	120	24 hours[b]
Tc-99m Red Blood Cell In Vivo Labeling	400	10	2,000	50	24 hours[b]
Tc-99m Red Blood Cell In Vitro Labeling	1,000	30	6,000	150	24 hours[b]
Tc-99m Sulphur Colloid	300	7	1,000	30	24 hours[b]
Tc-99m DTPA	1,000	30	6,000	150	24 hours[b]
Tc-99m DTPA Aerosol	1,000	30	6,000	150	24 hours[b]
Tc-99m MAG3	1,000	30	6,000	150	24 hours[b]
Tc-99m White Blood Cells	100	3	600	15	24 hours[b]
Ga-67	1	0.04	7	0.2	28 days[b]
Cr-51 EDTA	60	1.6	300	8	
In-111 White Blood Cells	10	0.2	40	1	6 days[b]
Tl-201 Chloride	40	1	200	5	4 days[b]
C-11, N-13, O-15, Rb-82	The activity to the infant or child can be calculated by using the dose conversion factors given by M. Stabin, "Internal Dosimetry in Pediatric Nuclear Medicine" (Ref. 6).				No interruption[b]
F-18 FDG					4 hours[b]
Lu-177 Octreotate , diagnostic or therapeutic					Complete cessation (for this infant or child)[b]
Ra-223 and all alpha emitters					Complete cessation (for this infant or child)[b]
Zr-89					28 days[b]
Ga-68 Octreotate					4 hours[b]
In-111 Octreotate					6 days[b]
I-124 NaI					Complete cessation (for this infant or child)[b]

a. The duration of interruption of breastfeeding is selected to reduce the maximum dose to a newborn infant to less than 1 mSv (0.1 rem), although the regulatory limit is 5 mSv (0.5 rem). The actual doses that most infants would receive would be far below 1 mSv (0.1 rem). The physician may use discretion to recommend increasing or decreasing the duration of interruption as long as his or her instructions would ensure that the dose to the child is less than the regulatory limit of 5 mSv (0.5 rem).

b. These recommendations on the interruption or discontinuation of breastfeeding are from the ACMUI Subcommittee on "Nursing Mother Guidelines for the Medical Administration of Radioactive Materials" (Ref. 7). If there is no recommendation in Column 3 of this Table, the maximum activity normally administered is below the activities that require instructions on interruption or discontinuation of breast-feeding. (For Tc-99m labeled radiopharmaceuticals, rather than a radiopharmaceutical-specific interruption period, a single 24-hour interruption period is recommended. Although this time interval may be longer than necessary for some Tc-99m labeled radiopharmaceuticals, it is compliant with the 0.1-rad dose threshold and simplifies the guidance, thereby avoiding confusion and reducing the likelihood of error.)

NOTES: Activities are rounded to one significant figure, except when the use of two significant figures was considered appropriate. NUREG-1492 describes the calculations in detail Agreement State licensees should check with their State regulations before using the values on the Table.

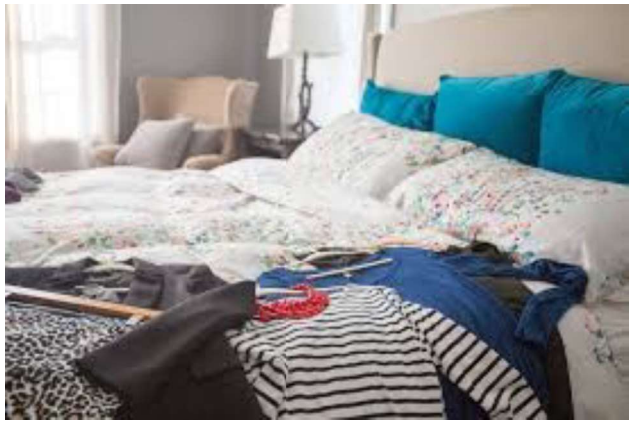
Release Criteria

- Proposed Revision 2 (4/2023)
- Includes thresholds for several new radionuclides
- Several organizations provided public comments, which are available in the public domain: https://www.regulations.gov/docket/NRC-2023-0086/comments

Initial consult and radiation safety education

- Can the patient manage time, distance and contamination at home?





Special situations: Single Bathroom

- New study shows what happens when we flush a lidless toilet | CNN

Special situations: No personal vehicle

- Alternatives to public transportation:
  - Informed relative or friend
  - Off duty ambulance, hospital security
  - Informed medical transport company
  - Very conservative: admit the patient

Special situations

- Upcoming travel, border crossings

Special situations

- Small children at home or desire to stay in a hotel

Special situations - Incontinence

Table 1. Urinary disorder grade and urinary collection strategy for renal-filtered radiopharmaceutical administration.

	Grade 1	Grade 2	Grade 3
Urinary incontinence[a]	Occasional (e.g., with sneezing or coughing); pads not indicated	Spontaneous; pads indicated; limiting instrumental activities of daily living	Intervention indicated (e.g., clamp or catheter); operative intervention indicated; limiting self-care
Therapy collection strategy	Pads or briefs	External catheter	Indwelling catheter
Going home guidance	Check or change pad/briefs every couple of hours for the first two days. Change pad/briefs at least one time during the first evening	For patients with catheter: Empty Foley frequently into toilet slowly to avoid splashing. Wash hands well. Do not attach catheter to leg for extended periods of time. At home, instruct family members to keep distance from Foley as well as patient in concurrence with going home instructions. For patients without catheter: Check or change pad/briefs every couple of hours for the first 2 days Change pad/briefs at least one time during the first evening	For patients with catheter: Empty Foley frequently into toilet slowly to avoid splashing. Wash hands well. Do not attach catheter to leg for extended periods of time. At home, instruct family members to keep distance from Foley as well as patient in concurrence with going home instructions. For patients without catheter: Check or change pad/briefs every hour for 2 days after treatment. Check or change pad/briefs every 2 hours for the following 5 days. Pad/Briefs changes continue overnight. An extra ½ to 1 hour can be added for patients who typically see less wetness during sleep.

[a] Common Terminology Criteria for Adverse Events, version 5, 2017. https://ctep.cancer.gov/protocoldevelopment/electronic_applications/docs/ctcae_v5_quick_reference_5x7.pdf. Accessed 4 May 2023.

Kunos CA, Lemieux BP, Recca K, Oates ME, El Khouli RH. Leveraging Radiopharmaceutical Programmatic Collaboration for Management of Pretherapy and On-treatment Urinary Incontinence. Health Phys. 2023 Oct 1;125(4):316-319. doi: 10.1097/HP.0000000000001721. Epub 2023 Aug 8. PMID: 37548565.

Special situations

Radiation Safety Considerations of Household Waste Disposal After Release of Patients Who Have Received [^{177}Lu]Lu-PSMA-617

Stephen A. Graves

Journal of Nuclear Medicine Jul 2023, jnumed.123.265750; **DOI:** 10.2967/jnumed.123.265750

- Waste Management/Incontinence
  - Option A: patient retains waste in plastic trash bags in the home until radioactive decay is complete and the waste can be disposed of normally
  - Option B: patient contains the waste in sanitary trash bags and immediately disposes of it in the normal household waste stream
  - *Option C: patient retains the waste in plastic trash bags at home and contacts the licensee to arrange waste pickup

    *may be logistically intractable for many medical providers

Special situations

Radiation Safety Considerations of Household Waste Disposal After Release of Patients Who Have Received [^{177}Lu]Lu-PSMA-617

Stephen A. Graves

Journal of Nuclear Medicine Jul 2023, jnumed.123.265750; **DOI:** 10.2967/jnumed.123.265750

- "…the expected excess effective dose to a member of the household is expected to be approximately 330 µSv (33 mrem) per 7.4 GBq (200 mCi) of treatment if waste is retained for decay within the household. By comparison, if the waste is disposed of in the normal household waste stream, the maximally exposed sanitation worker is expected to receive approximately 10.3 µSv (1.03 mrem) per 7.4 GBq (200 mCi) of treatment, and the household member exposure is reduced to 36 µSv (3.6 mrem). Therefore, disposal of solid contaminated waste in the normal waste stream results in approximately a 10-fold reduction in estimated household member exposure, with respect to the waste, with only a marginal increase in sanitation worker exposure relative to natural background radiation (~8 µSv/d [~0.8 mrem/d])."

Special situations – household waste

WM Residential Commercial Sustainability & Recycling About Us Support

Support Home / Legal / Terms and Conditions – Residential Subscription Services

Terms and Conditions – Residential Subscription Services

Notice About Dispute Resolution

These Terms & Conditions contain provisions on jury trial waiver and binding arbitration of disputes on an individual which will be binding on you (the "Customer"), unless Customer opts out as described in Section 10(l) below. Unless Customer opts-out of arbitration: (a) Customer will only be permitted to pursue claims against us on an individual basis, not as part of any class or representative action or proceeding and (b) Customer will only be permitted to seek relief (including monetary, injunctive, and declaratory relief) on an individual basis.

1. **SERVICES RENDERED; WASTE MATERIALS.** Customer grants to WM the exclusive right, and WM through itself and its affiliates shall furnish equipment and services, to collect and dispose of and/or recycle (collectively, the "Services") all of Customer's Waste Materials at Customer's service address. Customer agrees that the Waste Materials collected under these terms and conditions shall not include any Excluded Materials. "Waste Materials" means all non-hazardous solid waste, organic waste, and if applicable, recyclables, generated by Customer or at Customer's service address. Waste Materials shall not include any Excluded Materials. "Excluded Materials" means (a) any waste tires, (b) radioactive, volatile, corrosive, flammable, explosive, biomedical, infectious, bio-hazardous, toxic, regulated medical or hazardous waste, substance or material, as defined by, characterized or listed under applicable federal, state, or local laws or regulations; (c) any materials containing information protected by federal, state or local privacy and security

State/City Guidance: PA, NY, AK

WM

ALLIANCE LANDFILL

- Facility Information
- Controls and Monitoring
  - Radiation
  - Groundwater
  - Air Quality
  - Stormwater
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Radiation Monitoring

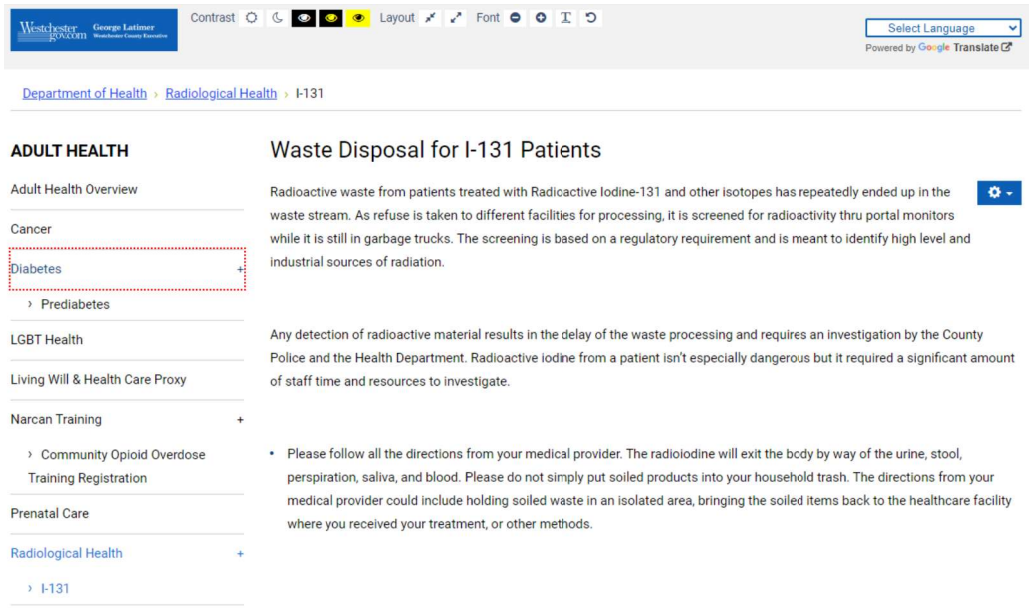
All vehicles that carry waste to Alliance's working area pass across the landfill's scales where they are weighed and subjected to our radiation monitoring system. This system tells us if a load of waste contains any radioactive material. It provides an extra measure of safety for our employees and the environment.

What our monitors routinely detect are items discarded by people receiving radiological medical treatment, including adult diapers, tissues, papers and paper cups. We've also found kitty litter used by pets receiving this type of veterinary treatment. Alliance, in accord with state guidelines, is allowed to accept these wastes. Our monitors are so sensitive they have detected visitors who've recently received these types of medical treatments, including a site tour visitor who had recently undergone a CT Scan.

On occasion other types of radiation have been detected, including a radioactive medical needle that dated to the 1950s and a World War II-era aircraft gauge that was painted with glow-in-the-dark paint that was radioactive (something that wasn't uncommon years ago). When items like these are detected, they are either returned to their place or origin or placed in special packaging and shipped to an appropriate disposal site.

In 2000, the state Department of Environmental Protection (DEP) adopted new regulations requiring landfills to monitor all incoming wastes for radioactivity, even residential trash from the curb. Pennsylvania was first in the nation to introduce these regulations as a precautionary principle, taking advantage of improvements in technology to detect sources of radiation. Alliance's radiation monitoring system was in place and operating several months before this regulation went into effect.

The system we use to prevent the disposal of radioactive material integrates a rigorous training program with advanced monitoring technology. It provides an additional measure of safety to ensure that only proper types of waste are accepted at Alliance Landfill.



Westchester County George Latimer

Contrast Layout Font Select Language

Powered by Google Translate

Department of Health › Radiological Health › I-131

ADULT HEALTH

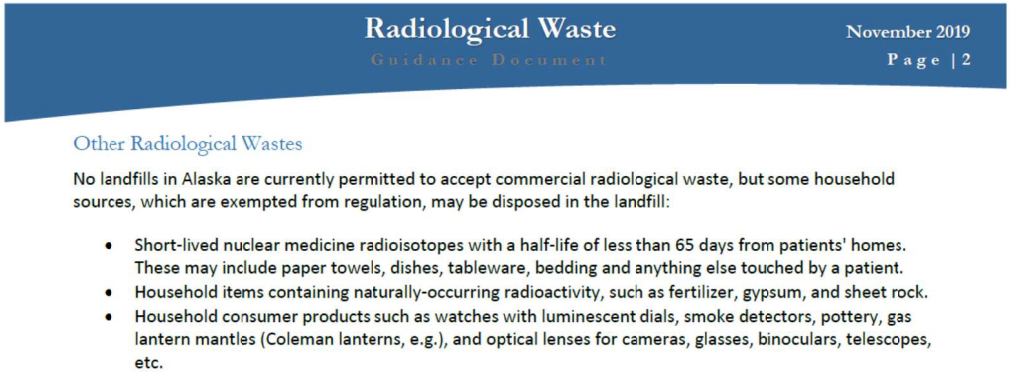
- Adult Health Overview
- Cancer
- Diabetes +
  - Prediabetes
- LGBT Health
- Living Will & Health Care Proxy
- Narcan Training +
  - Community Opioid Overdose Training Registration
- Prenatal Care
- Radiological Health +
  - I-131

Waste Disposal for I-131 Patients

Radioactive waste from patients treated with Radicactive Iodine-131 and other isotopes has repeatedly ended up in the waste stream. As refuse is taken to different facilities for processing, it is screened for radioactivity thru portal monitors while it is still in garbage trucks. The screening is based on a regulatory requirement and is meant to identify high level and industrial sources of radiation.

Any detection of radioactive material results in the delay of the waste processing and requires an investigation by the County Police and the Health Department. Radioactive iodine from a patient isn't especially dangerous but it required a significant amount of staff time and resources to investigate.

- Please follow all the directions from your medical provider. The radioiodine will exit the body by way of the urine, stool, perspiration, saliva, and blood. Please do not simply put soiled products into your household trash. The directions from your medical provider could include holding soiled waste in an isolated area, bringing the soiled items back to the healthcare facility where you received your treatment, or other methods.



Radiological Waste
Guidance Document
November 2019
Page | 2

Other Radiological Wastes

No landfills in Alaska are currently permitted to accept commercial radiological waste, but some household sources, which are exempted from regulation, may be disposed in the landfill:

- Short-lived nuclear medicine radioisotopes with a half-life of less than 65 days from patients' homes. These may include paper towels, dishes, tableware, bedding and anything else touched by a patient.
- Household items containing naturally-occurring radioactivity, such as fertilizer, gypsum, and sheet rock.
- Household consumer products such as watches with luminescent dials, smoke detectors, pottery, gas lantern mantles (Coleman lanterns, e.g.), and optical lenses for cameras, glasses, binoculars, telescopes, etc.

Patient instructions

- 10 CFR 35.75(b) – written instructions are required if the dose to a member of the public could exceed 100 mrem
- Explain how time, distance, and contamination impact radiation exposure to those around the patient
- Describe ways to incorporate these concepts into everyday living
- # of nights to sleep alone, live in a separate part of the home, use a separate bathroom, eating utensils, laundry, what do to in an emergency situation

Patient instructions – our approach

- Our documents state the number of days or nights for restricted activities
- To help the patient keep track, we also include the date when they may resume normal activities and organize activities by the number of days they are restricted.
- Example: For 7 days or until 2/6/2026
- Use your own bathroom
- Sit to use the toilet
- Close the lid and flush twice
- Wipe regularly touched surfaces with a cleaning wipe, thoroughly wash hands
- For 3 nights or until 2/2/2026
- Sleep alone or a distance of 6 feet from other adults

Finishing

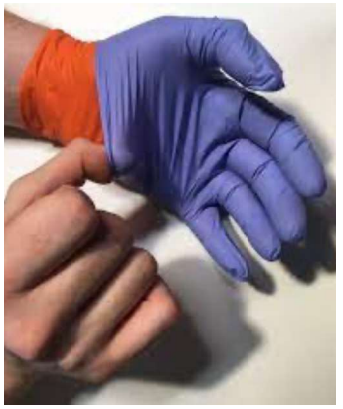
Minimizing Contamination: Treatment Area Preparation

- Prepare surfaces with absorbent pads or paper to protect them from contamination
- Patient chair/stretcher
- Floor in administration area
- Surfaces in the bathroom

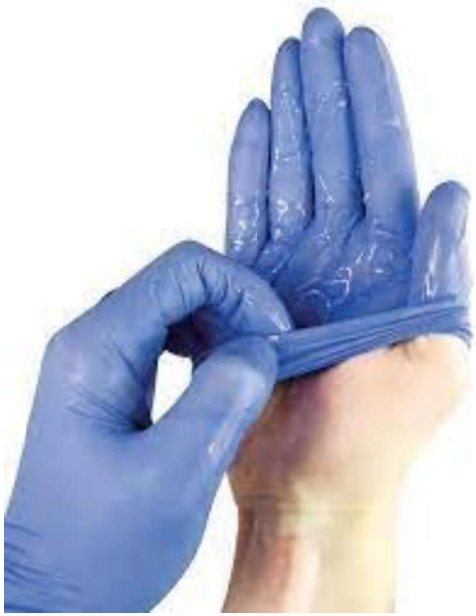
Photo credit: Guidance on ^{177}Lu-DOTATATE Peptide Receptor Radionuclide Therapy from the Experience of a Single Nuclear Medicine Division
Amanda Abbott, Christopher
G. Sakellis, Eric Andersen, Yuji Kuzuhara, Lauren Gilbert, Kelly Boyle, Matthew
H. Kulke, Jennifer A. Chan, Heather A. Jacene, Annick D. Van den Abbeele
Journal of Nuclear Medicine Technology Sep 2018, 46 (3) 237-
244; **DOI:** 10.2967/jnmt.118.209148

Minimizing Contamination: Treatment Area Preparation

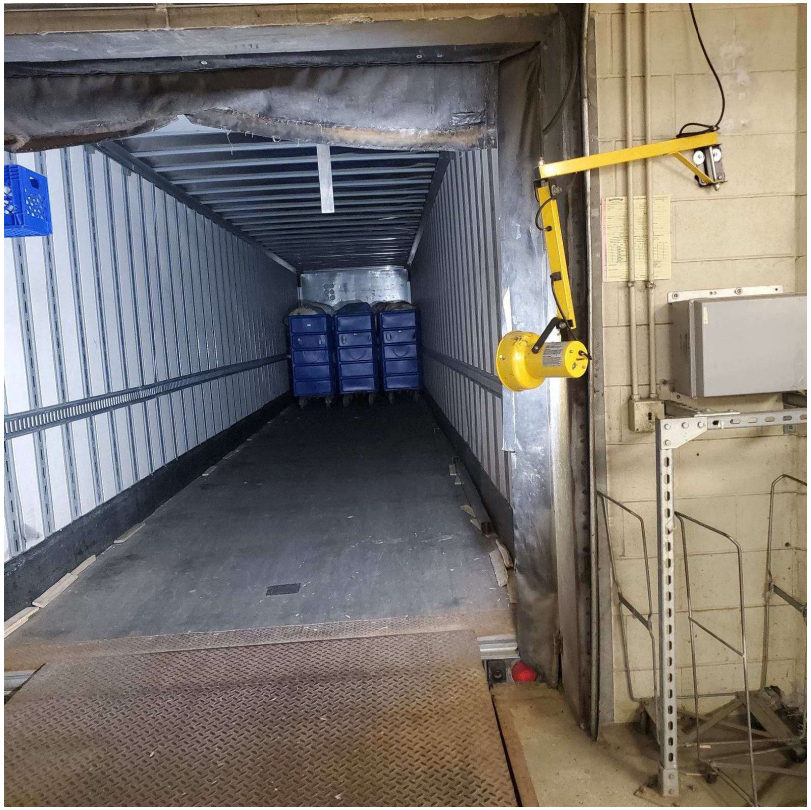
Minimizing Contamination: PPE



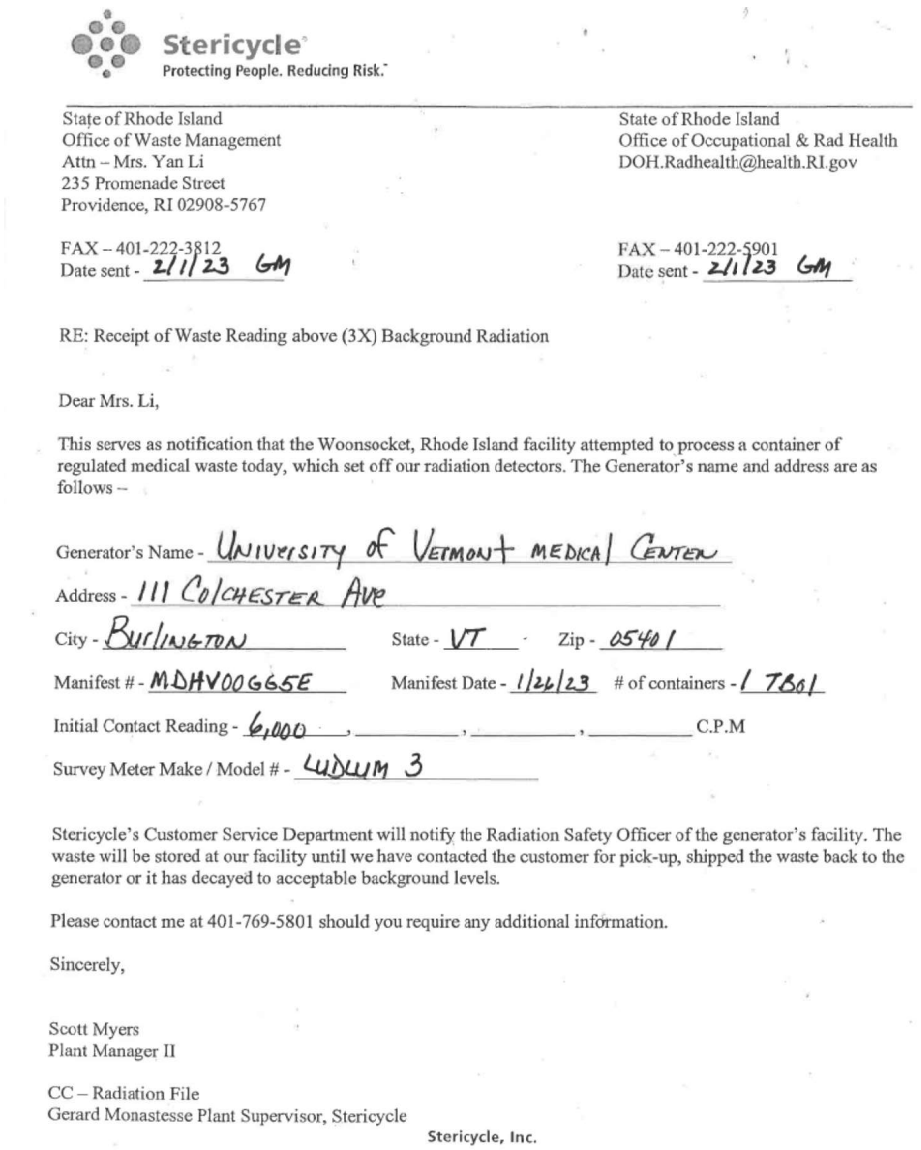
How do you decontaminate skin?



Monitoring Waste



More than just landfills



Stericycle
Protecting People. Reducing Risk.

State of Rhode Island
Office of Waste Management
Attn – Mrs. Yan Li
235 Promenade Street
Providence, RI 02908-5767

FAX – 401-222-3812
Date sent - 2/1/23 GM

State of Rhode Island
Office of Occupational & Rad Health
DOH.Radhealth@health.RI.gov

FAX – 401-222-5901
Date sent - 2/1/23 GM

RE: Receipt of Waste Reading above (3X) Background Radiation

Dear Mrs. Li,

This serves as notification that the Woonsocket, Rhode Island facility attempted to process a container of regulated medical waste today, which set off our radiation detectors. The Generator's name and address are as follows –

Generator's Name - University of Vermont Medical Center
Address - 111 Colchester Ave
City - Burlington State - VT Zip - 05401
Manifest # - MDHV00G65E Manifest Date - 1/26/23 # of containers - 1 Tbl
Initial Contact Reading - 6,000 , _____ , _____ , _____ C.P.M
Survey Meter Make / Model # - Ludlum 3

Stericycle's Customer Service Department will notify the Radiation Safety Officer of the generator's facility. The waste will be stored at our facility until we have contacted the customer for pick-up, shipped the waste back to the generator or it has decayed to acceptable background levels.

Please contact me at 401-769-5801 should you require any additional information.

Sincerely,

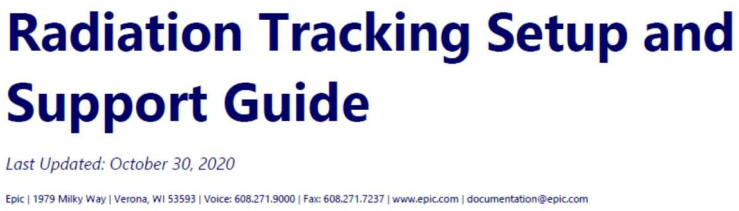
Scott Myers
Plant Manager II

CC – Radiation File
Gerard Monastesse Plant Supervisor, Stericycle

Stericycle, Inc.

Return visits for urgent/emergent care

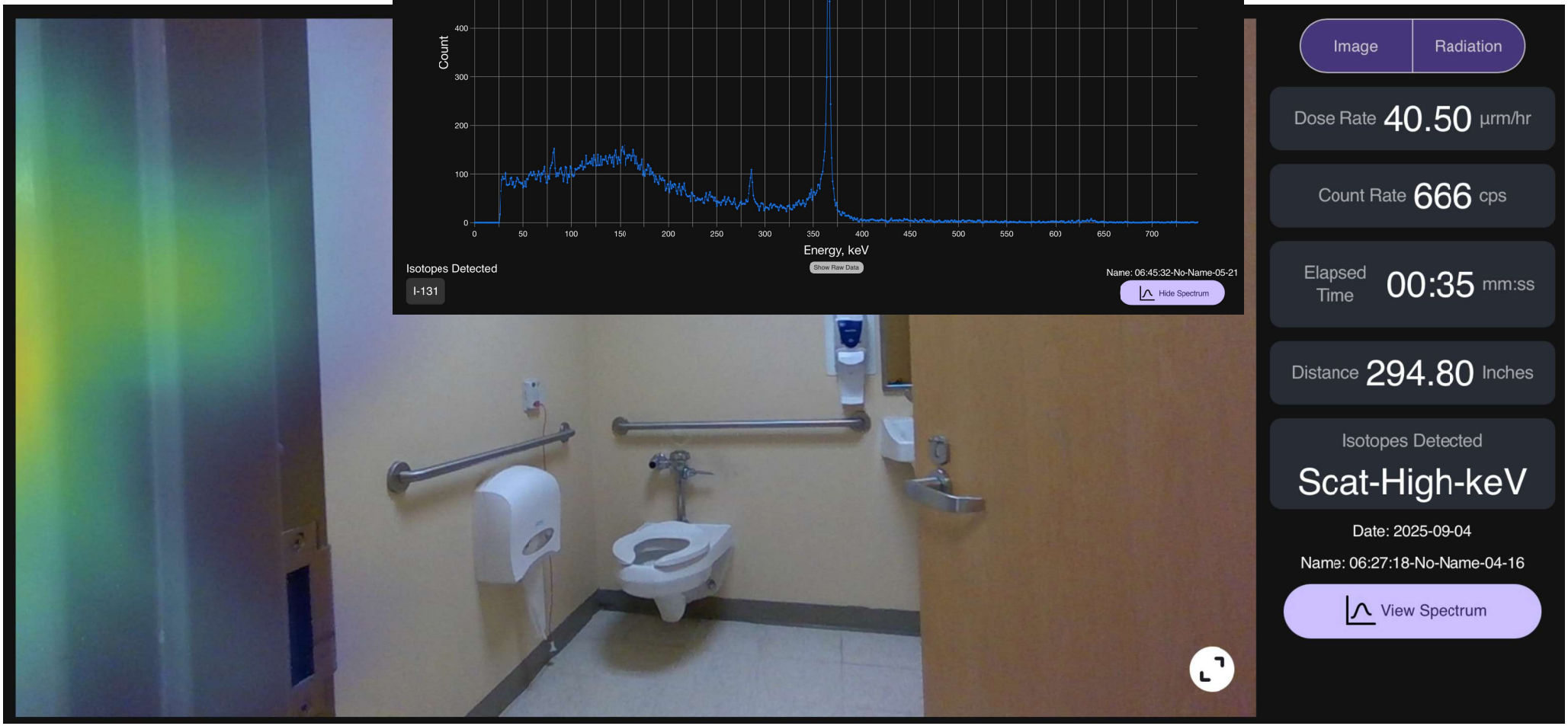
- Patient FYI – special radioactive banner with note containing instructions about using universal precautions and PPE, holding waste for radiation safety, etc.
- Best Practice Alert (BPA) – pop up or notification to specific teams when a patient meeting certain criteria is on site



Radiation Tracking Setup and Support Guide

Last Updated: October 30, 2020

Epic | 1979 Milky Way | Verona, WI 53593 | Voice: 608.271.9000 | Fax: 608.271.7237 | www.epic.com | documentation@epic.com


Spectrum of the detected isotopes - RECORDED MEASUREMENT
Count
Energy, keV
Show Raw Data
Isotopes Detected
I-131
Name: 06:45:32-No-Name-05-21
Hide Spectrum
Image
Radiation
Dose Rate 40.50 µrm/hr
Count Rate 666 cps
Elapsed Time 00:35 mm:ss
Distance 294.80 Inches
Isotopes Detected
Scat-High-keV
Date: 2025-09-04
Name: 06:27:18-No-Name-04-16
View Spectrum

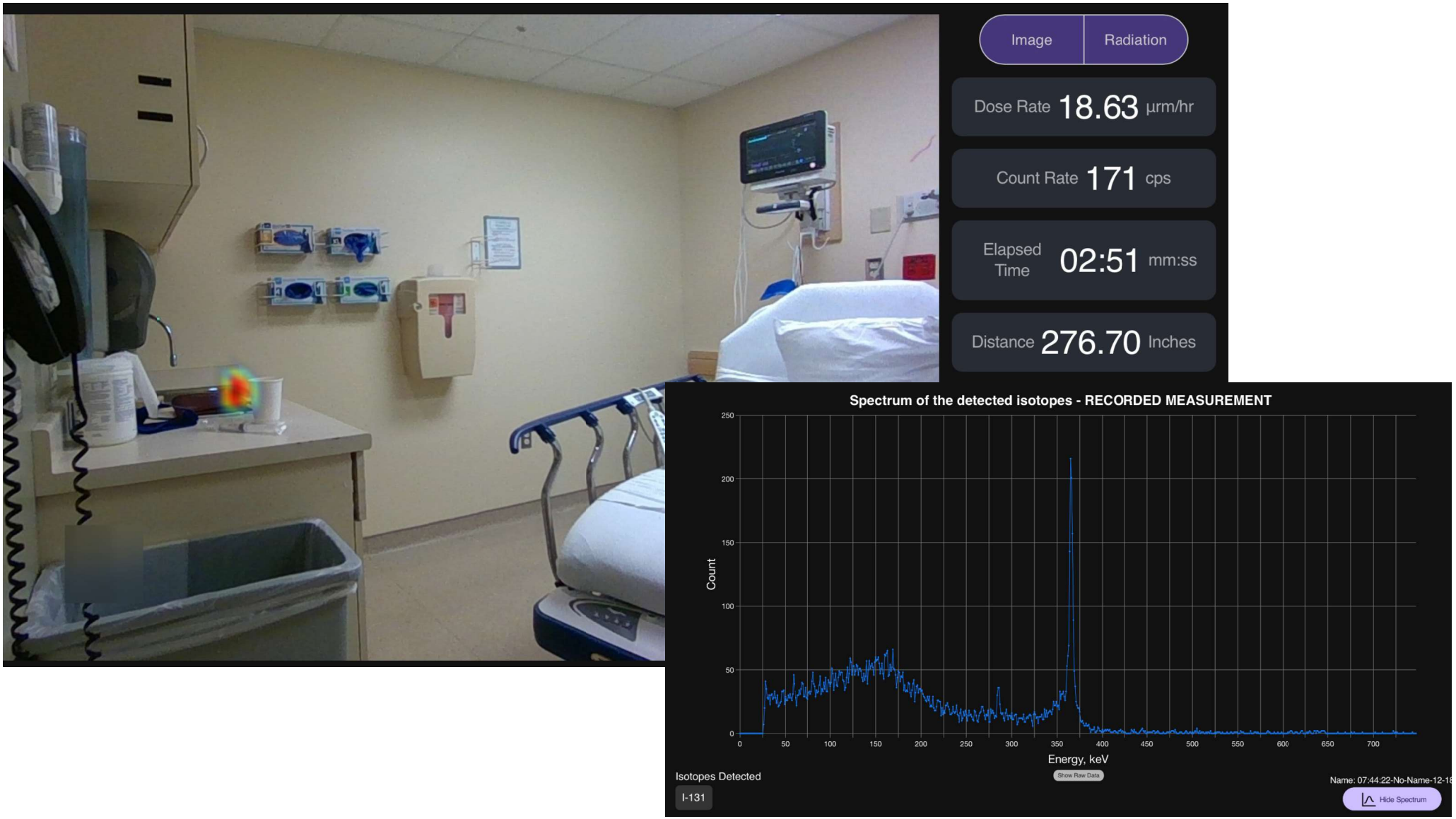
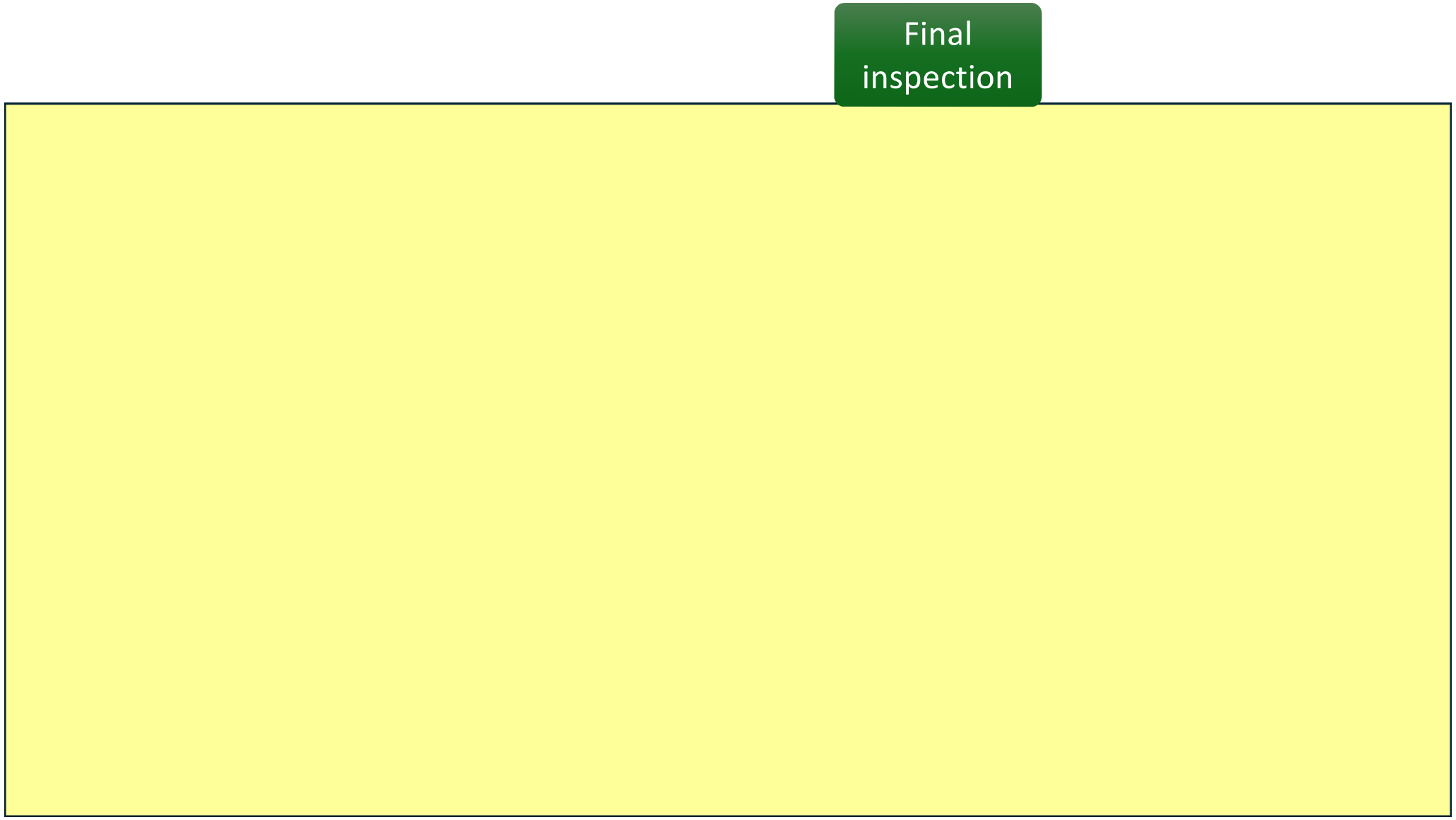


Image
Radiation
Dose Rate 18.63 µrm/hr
Count Rate 171 cps
Elapsed Time 02:51 mm:ss
Distance 276.70 Inches
Spectrum of the detected isotopes - RECORDED MEASUREMENT
Count
Energy, keV
Show Raw Data
Isotopes Detected
I-131
Hide Spectrum

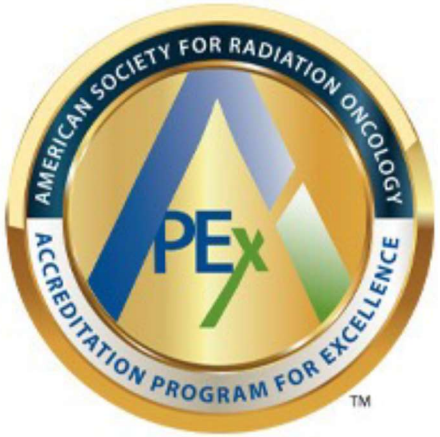
A tale of two patients…


Final inspection

Existing accreditation programs

- SNMMI and IAC Radiopharmaceutical Therapy Accreditation Program

- ASTRO APEx RPT Designation



Future accreditation programs

- ACR

- Resolution 113: The ACR is authorized to develop a new theranostics accreditation program. This program and plan will be developed through collaboration with relevant stakeholders. The ACR Commission on Quality and Safety/Accreditation Committee will report back to the Council regarding the status of the program's development at the 2026 ACR annual meeting.

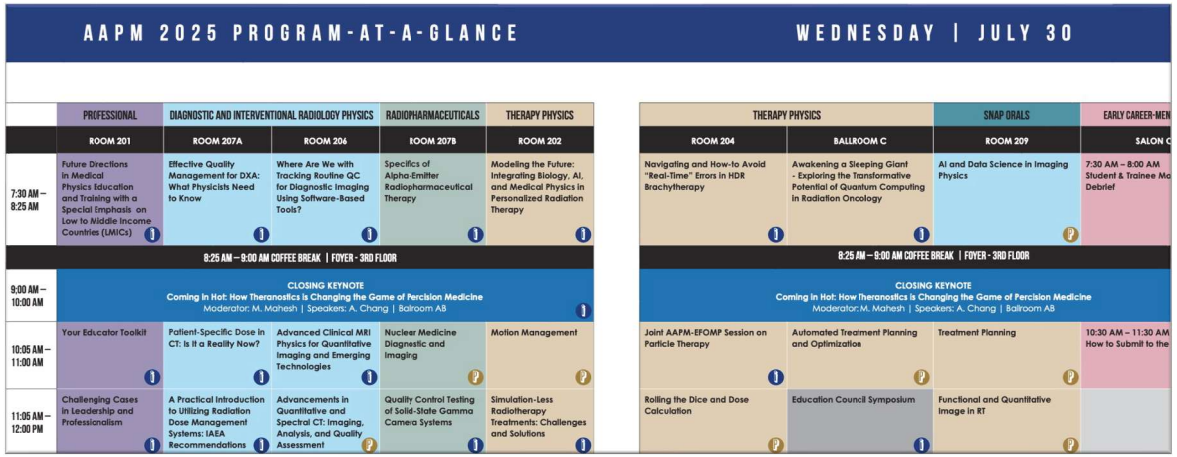
- ACRO?

American College of Radiology™

ACRO ACCREDITED PRACTICE The Standard of Excellence

References – additional training

- AAPM Annual meeting radiopharmaceutical track
- 2023 AAPM Summer School RPT Dosimetry
- SNMMI Dosimetry Certificate Program (in development) by the Dosimetry Task Force



AAPM 2025 PROGRAM-AT-A-GLANCE — WEDNESDAY | JULY 30

	PROFESSIONAL	DIAGNOSTIC AND INTERVENTIONAL RADIOLOGY PHYSICS		RADIOPHARMACEUTICALS	THERAPY PHYSICS
	ROOM 201	ROOM 207A	ROOM 206	ROOM 207B	ROOM 202
7:30 AM – 8:25 AM	Future Directions in Medical Physics Education and Training with a Special Emphasis on Low to Middle Income Countries (LMICs)	Effective Quality Management for DXA: What Physicists Need to Know	Where Are We with Tracking Routine QC for Diagnostic Imaging Using Software-Based Tools?	Specifics of Alpha-Emitter Radiopharmaceutical Therapy	Modeling the Future: Integrating Biology, AI, and Medical Physics in Personalized Radiation Therapy
	8:25 AM – 9:00 AM COFFEE BREAK | FOYER - 3RD FLOOR				
9:00 AM – 10:00 AM	CLOSING KEYNOTE Coming in Hot: How Theranostics is Changing the Game of Precision Medicine Moderator: M. Mahesh | Speakers: A. Chang | Ballroom AB				
10:05 AM – 11:00 AM	Your Educator Toolkit	Patient-Specific Dose in CT: Is it a Reality Now?	Advanced Clinical MRI Physics for Quantitative Imaging and Emerging Technologies	Nuclear Medicine Diagnostic and Imaging	Motion Management
11:05 AM – 12:00 PM	Challenging Cases in Leadership and Professionalism	A Practical Introduction to Utilizing Radiation Dose Management Systems: IAEA Recommendations	Advancements in Quantitative and Spectral CT: Imaging, Analysis, and Quality Assessment	Quality Control Testing of Solid-State Gamma Camera Systems	Simulation-Less Radiotherapy Treatments: Challenges and Solutions

	THERAPY PHYSICS		SNAP ORALS	EARLY CAREER-MEN
	ROOM 204	BALLROOM C	ROOM 209	SALON C
7:30 AM – 8:25 AM	Navigating and How-to Avoid "Real-Time" Errors in HDR Brachytherapy	Awakening a Sleeping Giant - Exploring the Transformative Potential of Quantum Computing in Radiation Oncology	AI and Data Science in Imaging Physics	7:30 AM – 8:00 AM Student & Trainee Mo Debrief
	8:25 AM – 9:00 AM COFFEE BREAK | FOYER - 3RD FLOOR			
9:00 AM – 10:00 AM	CLOSING KEYNOTE Coming in Hot: How Theranostics is Changing the Game of Precision Medicine Moderator: M. Mahesh | Speakers: A. Chang | Ballroom AB			
10:05 AM – 11:00 AM	Joint AAPM-EFOMP Session on Particle Therapy	Automated Treatment Planning and Optimization	Treatment Planning	10:30 AM – 11:30 AM How to Submit to the
11:05 AM – 12:00 PM	Rolling the Dice and Dose Calculation	Education Council Symposium	Functional and Quantitative Image in RT	

References – program start up

- Quality and Safety Considerations for Radiopharmaceutical Therapy in the Radiation Oncology Environment: An ASTRO Safety White Paper Practical Radiation Oncology 2025; 15(5) https://doi.org/10.1016/j.prro.2025.03.006
- Essentials of Theranostics: A Guide for Physicians and Medical Physicists RadioGraphics 2024; 44(1):e230097 https://doi.org/10.1148/rg.230097
- A Review of Theranostics: Perspectives on Emerging Approaches and Clinical Advancements Radiol Imaging Cancer 2023; 5(4):e220157 https://doi.org/10.1148/rycan.220157

References – Emergency Procedures

- Handling Patient Emergencies During Radiopharmaceutical Therapy Practical Radiation Oncology 2024; 14 https://doi.org/10.1016/j.prro.2023.12.014
- Unplanned Emergency Department or Inpatient Acute Care Within 1 Week After Administration of Peptide Receptor Radionuclide Therapy: Frequency of Occurrence and Standard Operating Procedures for Radioprotection in These Situations Practical Radiation Oncology 2024; https://doi.org/10.1016/j.prro.2024.07.002
- Canadian Nuclear Safety Commission (CNSC) REGDOC-2.7.3 Radiation Protection Guidelines for Safe Handling of Decedents https://www.cnsc-ccsn.gc.ca/eng/acts-and-regulations/regulatory-documents/published/html/regdoc2-7-3/

References - Shielding

- Shielding resources for four common radiopharmaceuticals utilized for imaging and therapy: Tc-99m, F-18, I-131, and Lu-177 Journal of Applied Clinical Medical Physics https://doi.org/10.1002/acm2.70084
- Canadian Nuclear Safety Commission (CNSC) Radionuclide Information Booklet https://open.canada.ca/data/en/info/ac988c2a-ce33-4e8e-bf64-2c052c50892f

References - Accreditation

- https://snmmi.org/Web/Clinical-Practice/Radiopharmaceutical-Therapy-Centers-of-Excellence/Become-a-Comprehensive-Radiopharmaceutical-Therapy-Center-of-Excellence.aspx
- https://www.astro.org/practice-support/accreditation/apex-rpt-designation



Thank you! Jessica.Clements@uvmhealth.org