Nuclear Pharmacist's Potential Role in Radiopharmaceutical Therapy (RPT)

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SPEAKER DISCLOSURE

I do not have (nor does any immediate family member have):

- a vested interest in or affiliation with any corporate organization offering financial support or grant monies for this continuing education activity
- any affiliation with an organization whose philosophy could potentially bias my presentation

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CPE INFORMATION

iCARE Pharmacy Services, Inc. is accredited by the Accreditation Council for Pharmacy Education (ACPE) as a provider for continuing pharmacy education.

This activity offers 1.5 contact hours (0.15 CEU).

- Target Audience: Pharmacists and Technicians
- ACPE #: 0675-0000-23-023-L04
- Activity Type:
  Knowledge based

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LEARNING OBJECTIVES

1. Describe logistical, technical, and radiation safety considerations for implementing a radiopharmaceutical therapy program
2. List major operating procedures for the RPT example Lu-177-PSMA
3. Develop a plan for implementing a radiopharmaceutical therapy program

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LEARNING ASSESSMENTS

Question 1:

Which of the following factors, beside patient safety, should be considered to determine the best method to prepare patient doses of radiopharmaceuticals?

a. Convenience
b. Cost
c. Radiation dose to workers
d. Workflow
e. All of above

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LEARNING ASSESSMENTS

Question 2:

Which of the following statements regarding Pluvicto administration is correct?

a. When using the syringe method for Pluvicto administration, a syringe pump must be used to precisely control the administration rate.
b. Pluvicto can only be administered using the gravity method or the syringe method with a syringe pump.
c. Pluvicto can only be administered using the gravity method, syringe method (with or without a syringe pump), or vial method with an infusion pump.

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LEARNING ASSESSMENTS

Question 3:

What are the recommended dosage guidelines for Pluvicto?

a. 3.7 GBq (100 mCi) intravenously every 4 weeks for up to 8 doses, or until disease progression or unacceptable toxicity
b. 7.4 GBq (200 mCi) intravenously every 6 weeks for up to 6 doses, or until disease progression or unacceptable toxicity
c. 7.4 GBq (200 mCi) every 8 weeks (± 1 week) for a total of 4 doses, or until disease progression or unacceptable toxicity
d. 3.7 GBq (100 mCi) every 4 weeks (± 1 week) for a total of 8 doses, or until disease progression or unacceptable toxicity

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LEARNING ASSESSMENTS

Question 3:

What BUD should be assigned to a radiopharmaceutical that was dispensed in ISO Class 5 PEC (Primary Engineering Control) located in ISO Class 8 or better buffer area with ISO Class 8 or better ante-room?

a. 1 hour
b. 12 hours
c. 24 hours
d. 96 hours

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Overview

- FDA approved therapeutic radiopharmaceuticals (RPs)
- Nuclear pharmacist responsibilities
- Regulatory compliance
- WU nuclear pharmacy's involvement in therapeutic RPs
- Radiopharmaceutical Therapy (RPT) Workflow

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SNMMI targeted cancer treatment infographic

https://www.snmmi.org/Patients/About

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FDA Approved Therapeutic Radiopharmaceuticals (RPs)

Generic Name	Trade Name	Half-Life	Dosage Form	Indication	FDA Approval Year
Radium Ra-223 dichloride	Xofigo	11.4 days	Injection	CRPC	2013
Sm-153 lexidronam	Quadramet	1.9 days	Injection	relief of bone pain (palliative treatment)	1997
Chromic phosphate 32	Phosphocol P32	14.3 days	Intraperitoneal, intrapleural, interstitial injection	treatment of malignant effusion, treatment of ovarian or prostatic carcinoma, palliative treatment of bone metastases.	1974
Strontium-89 chloride	Metastron, available in generic form	50.5 days	Injection	relief of bone pain	2003
Yttrium-90 ibritumomab tiuxetan	Zevalin	64.2 hr	Injection	non-Hodgkin's lymphoma (NHL)	2002

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FDA Approved Therapeutic Radiopharmaceuticals (RPs)

Generic Name	Trade Name	Half-Life	Dosage Form	Indication	FDA Approval Year
Iodine I-131 Sodium iodide		8 days	oral solution, capsules	hyperthyroidism carcinoma of the thyroid	1971
Iodine I-131 tositumomab	Bexxar	8 days	Injection	non-Hodgkin's lymphoma (NHL) (discontinued 2014)	2003
Iodine I-131 iobenguane	Azedra	8 days	Injection	pheochromocytoma or paraganglioma	2018
Lutetium Lu-177 dotatate	Lutathera	6.6 days	Injection	somatostatin receptor-positive gastroenteropancreatic neuroendocrine tumors (GEP-NETs)	2018
Lutetium Lu-177 vipivotide tetraxetan	Pluvicto	6.6 days	Injection	prostate-specific membrane antigen (PSMA)-positive metastatic castration-resistant prostate cancer (mCRPC)	2022

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Nuclear Pharmacist responsibilities

- Ordering/purchasing, preparing, compounding, dispensing, and distribution of radiopharmaceuticals (RPs), as well as the regulatory aspects governing these processes
  - ✓ Approved drug
  - ✓ Investigational drug
- Radiation Safety Officer Role
- Quality Control and Quality Assurance
- Training
- Logistic coordination
- Cleaning and surveying the area
- Supporting translational work (diagnostic and therapeutic)

Some responsibilities are depending on the size of operations

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Nuclear Pharmacist Responsibilities

- Clinical (compounding& dispensing)
  - ✓ Compounding Tc-99m RPs
  - ✓ I-131 sodium idodide solution or capsule: ordering, receiving, and dispensing (nowadays patient doses are in capsule)
  - ✓ I-131 MIBG: Performing QC for the shipped drug (QC no longer needed at the receiving site)
  - ✓ Preparing (dispensing) Y-90 Microspheres patient dose (note: Y-90 Microspheres are a medical device)
  - ✓ Dispensing Pluvico patient doses
  - ✓ Quality Assurance (QA)
- Clinical Research
  - ✓ Preparation, review and release of RP used under approved IND
  - ✓ QA

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Dispensing Unit Doses

- Administration method

  Oral, IV Infusion (bolus, over 30 min)?
- Does the patient dose need to be dispensed by nuclear pharmacy?

  Yes

  No because;
  - ✓ Nuclear Medicine technologists draw the patient dose from the shipped vial under immediate use procedure
  - ✓ Drug in its shipped vial from mfg. can be used for infusion

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Dispensing: Regulatory Compliance

- State Board of Pharmacy Requirements
- USP Chapter <825> Radiopharmaceuticals-Preparation, Compounding, Dispensing, and Repackaging
  - ✓ Becomes compendially applicable on 01-Nov-2023
  - ✓ Replacing chapter <797> Pharmaceutical Compounding-Sterile Preparations
  - ✓ Applies to all individuals who prepare, compound, dispense, or repackage radiopharmaceuticals
    - Authorized nuclear pharmacists (ANPs)
    - Authorized User (AU) physicians
    - Individuals working under the supervision of ANP or AU (e.g. nuclear pharmacy technicians, student pharmacists, nuclear medicine technologists and students, and physician residents and trainees)

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USP Chapter <825>Radiopharmaceuticals-Preparation, Compounding, Dispensing, and Repackaging

1. Introduction
2. Radiation Safety Considerations
3. Immediate Use of Sterile radiopharmaceuticals
4. Personnel Qualification, Training, and Hygiene
5. Facilities and Engineering Controls
6. Microbiological Air and Surface Monitoring
7. Cleaning and Disinfecting
8. Assigning BUD
9. Documentation
10. Preparation
11. Compounding
12. Dispensing
13. Repackaging
14. Quality Assurance and Quality Control

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USP Chapter <825>

4. Personnel Qualification, Training, and Hygiene

Aseptic Qualification

- Aseptic technique training with a documented assessment
- Garbing and hand hygiene
- Primary Engineering Control (PEC) cleaning and disinfecting
- Gloved fingertip and thumb sampling
- Media-fill testing

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Aseptic Training

Combination of;

- Didactic Training
  - ✓ Lead by experienced and qualified trainer
  - ✓ Learn fundamental concept of sterile preparation
    - Building & Facilities, Equipment, Raw Materials, Sterilization method, Environmental Control, Quality Control testing
  - ✓ Learn hand washing, garbing, and cleaning procedure (in class)
  - ✓ Pass written assessment
- Hands-on Training
  - ✓ Learn & perform hand washing and gowning
  - ✓ Learn & perform proper use of equipment
  - ✓ Learn & perform cleaning procedure
  - ✓ Perform media fill testing

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Initial Aseptic Training: Equipment

WUSTL example

ISO Classification	Number of particles generated

Dispensing Hot cell | Isolator | Laminar Airflow Workbench | ISO class 5 Certification

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Initial Aseptic Training: Materials and How to Work in ISO class 5 PEC, Microbiology

WUSTL example

Where We Should Not Touch | Examples

Endospore Structure

Red = do not touch
Green = can touch

How to work in ISO class 5 PEC

First Air ↓ First Air

Clean → Waste

Organize items to make one way flow

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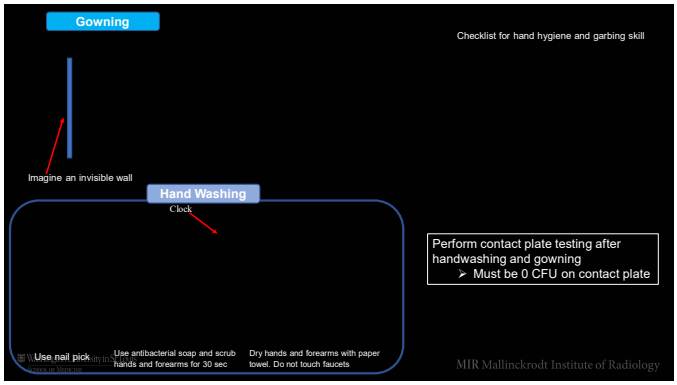
Gowning
Checklist for hand hygiene and garbing skill
Imagine an invisible wall
Hand Washing
Clock
Perform contact plate testing after handwashing and gowning
Must be 0 CFU on contact plate
Use nail pick
Use antibacterial soap and scrub hands and forearms for 30 sec
Dry hands and forearms with paper towel. Do not touch faucets
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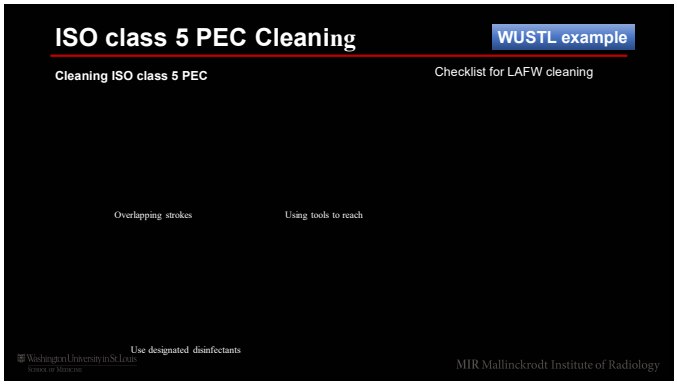
ISO class 5 PEC Cleaning
WUSTL example
Cleaning ISO class 5 PEC
Checklist for LAFW cleaning
Overlapping strokes
Using tools to reach
Use designated disinfectants
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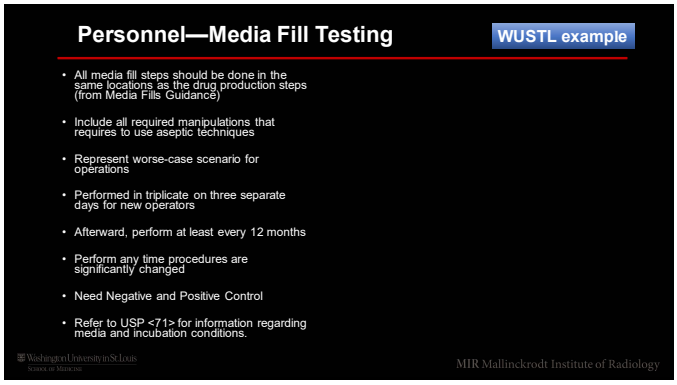
Personnel—Media Fill Testing
WUSTL example
All media fill steps should be done in the same locations as the drug production steps (from Media Fills Guidance)
Include all required manipulations that requires to use aseptic techniques
Represent worse-case scenario for operations
Performed in triplicate on three separate days for new operators
Afterward, perform at least every 12 months
Perform any time procedures are significantly changed
Need Negative and Positive Control
Refer to USP <71> for information regarding media and incubation conditions.
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5. Facilities and Engineering Controls
   - Primary Engineering Controls (PECs)
     - ✓ Laminar Airflow Workbench (LAFW)
     - ✓ Biological Safety Cabinet (BSC)
     - ✓ Compounding Aseptic Isolator (CAI)
   - Secondary Engineering Controls (SECs)
     - ✓ ISO-classified buffer room with ante-room
     - ✓ Unclassified area (Segregated Radiopharmaceutical Processing Area (SRPA))

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5. Facilities and Engineering Controls
   - Air-Exchange Requirement
     - ✓Measured in terms of the number of HEPA-filtered air changes per hour (ACPH)

Processing Area	ACPH Requirement
Unclassified SPRA	No requirement
ISO Class 7 area	≥30 ACPH
ISO Class 8 area	≥20 ACPH

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6. Microbiological Air and Surface Monitoring

Viable Air and Surface Sampling		
ISO Class	Air Sampling Action Levels (cfu/m^3 of air per plate)	Surface Sampling Action Levels (cfu/device or swab)
5	>1	>3
7	>10	>5
8	>100	>50

7. Cleaning and Disinfecting

Site	Cleaning	Disinfecting	Applying Sporicidal
PEC	Prior to performing sterile processing of RP	Following cleaning each day	Monthly
Hot-cells	Daily	Daily	Monthly
Work surface outside of PEC	Daily	Daily	Monthly
Ceiling	Monthly	Monthly	Monthly
Wall	Monthly	Monthly	Monthly
Floor	Daily	Daily	Monthly
Storage shelving and storage bins	Monthly	Monthly	Monthly

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6. Microbiological Air and Surface Monitoring

Viable Air and Surface Sampling

ISO Class	Air Sampling Action Levels (cfu/m^3 of air per plate)	Surface Sampling Action Levels (cfu/device or swab)
5	>1	>3
7	>10	>5
8	>100	>50

7. Cleaning and Disinfecting

8. Assigning BUD

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Assigning BUD

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WU Nuclear Pharmacy Background

- Part of WU MIR Cyclotron Facility and Nuclear Pharmacy
- Cyclotron Facility has been operational since 1960's
- Nuclear Pharmacy was established in 2001

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WU Nuclear Pharmacy's involvement in therapeutic RPs

Approached by the Radiation Oncology group regarding the possibility of WU Nuclear Pharmacy dispensing Y-90 Microshperes in 2021

- Concerns regarding the regulatory compliance (USP chapter <825>)
- WU Nuclear Pharmacy started providing the service (Y-90 Microshperes)
- WU Nuclear Pharmacy expanded the range of service (Lu-177 RPs)

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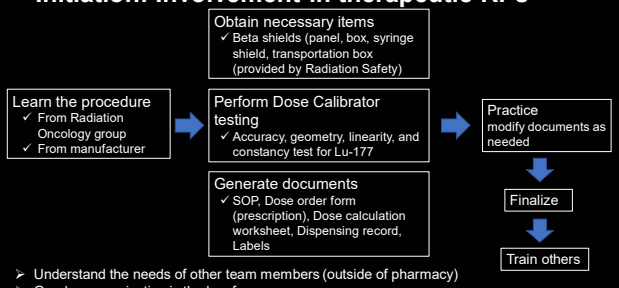
Initiation: Involvement in therapeutic RPs



- Understand the needs of other team members (outside of pharmacy)
- Good communication is the key for success

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Tools

- Use appropriate tools

Beta-gamma syringe shield

Beta shield

Benchtop Beta radiation shield

Forceps

Shielded Syringe Carriers

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Dose Calibrator (DC) Testing

Accuracy

Annual Constancy

Geometry

Linearity

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Documents

Labels

Change Control document is needed to initiate any change (per WU Nuclear Pharmacy SOP)

SOP

Dose Order Form

Dose Calculation Worksheet

Dispensing Record

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Dry Run at WU

- Workflow
  - ✓ Transportation
  - ✓ Personnel, imaging scanner, lab
- DC calibration
- Gamma counter and SPECT calibration if needed
- Document review
  - ✓ Protocol
  - ✓ SOP
  - ✓ Consent form
  - ✓ Dose order form (prescription)
  - ✓ Dose calculation worksheet
  - ✓ Labels

Nuclear pharmacy: Change Control (CC) needed

Communication between all team members is essential

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Dry Run

- Dose Calibrator calibration

Step 1

i. Perform daily check (BKG and constancy)
ii. Obtain information for the reference vial (activity at calibration time (date &time), volume, batch ID, vial size)
iii. Calculate the activity at the date& time of measurement
iv. Multiple (3-5) Measurement of the vial activity, DC cal factor, or correction factor date and time, document
v. % difference NMT 1%? 3%?

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Dry Run

- Dose Calibrator calibration

Step 2

i. Transfer the activity into a syringe
ii. Multiple measurement of the activity in syringe
iii. Multiple measurement of the remaining activity in vial (NS added to the vial after activity transferred into syringe?)
iv. Multiple (3-5) Measurement of the activity, DC cal factor, or correction factor date and time, document
v. % difference NMT 1%? 3%?

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Dry Run: DC calibration

Step 1

Obtain reference vial

Calculate the activity at measurement on-site

DC in Nuc Pharmacy

Multiple (3-5) Measurement of the vial activity, Determine DC cal factor, or correction factor, Document data

DC in Rad Onc

Multiple (3-5) Measurement of the vial activity, Determine DC cal factor, or correction factor, Document data

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Dry Run: DC calibration

Step 2

Transfer activity into syringe

DC in Nuc Pharmacy

Multiple (3-5) Measurement of the syringe activity, Determine DC cal factor, or correction factor, Document data

DC in Rad Onc

Multiple (3-5) Measurement of the syringe activity, Determine DC cal factor, or correction factor, Document data

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Lu-177 Facts

Half-Life	6.647 days
B^- (beta minus)	Max. 498 keV (79%)
gamma	208 keV (11%)
gamma	113 keV (6.4%)
2 methods of Lu-177 production	Carrier added: Lu-176 (n, gamma) Lu-177 + Lu-177m No carrier added (n.c.a.) : Yb-176 (n, gamma) ytterbium Yb-177, Yb-177 beta minus decays to Lu-177 Lu-177m: half-life 160.4 days, more difficult in terms of radiation protection and waste management

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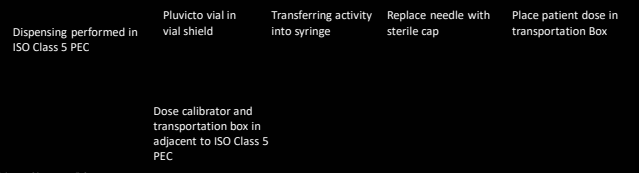
Pluvicto Dose Dispensing



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How to handle patient dose preparation: ALARA

Dose Monitor Measurements during Pluvicto 7.4 GBq dispensing

Process Step	Dose rate (mRem/hr)
Vial in dose calibrator	0.07
Shielded vial in LAFW, lid on, through β shield	0.05
Shielded vial in LAFW, lid on, around β shield at forearm position	0.07
Shielded vial in LAFW, lid off, through β shield	0.15
Shielded vial in LAFW, lid off, around β shield at forearm position	0.5
Dose syringe in shield, in transfer tray	18
Dose syringe in transport box (surface)	9

Measured by gamma survey meter (Pancake probe)

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Dose Preparation: Documentation

- Verify the dose order request (prescription)
- Generate dose dispensing worksheet
- Dispensing record
- Labels for syringe and syringe shield (transportation box)

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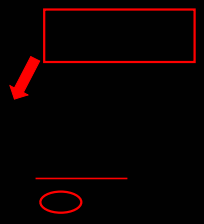
Dose Preparation: Dose measurement

- Measure the starting activity in vial
- Transfer the calculated volume into syringe
- Measure the activity in syringe
- Measure the residual activity in shipped vial
- Patient dose in syringe = initial activity in vial – residual activity in vial



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Contamination Control

- Using absorbing pads
- Wipe testing of work areas
- Beta-gamma survey meter

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Radiopharmaceutical Therapy (RPT) Program: Team effort

- Nuclear Medicine
- Radiation Oncology
- Brachytherapy group
- Medical Physicists
- Nurses
- Technologists
- Coordinators
- Radiation Safety
- Nuclear Pharmacy

Define Responsibilities of Each Group

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Establish the procedure

1. Learn about the therapy
2. Allocate resources
   - Personnel, equipment, space, etc.
3. Satisfy radioactive material use regulations
4. Generate the written procedures and accompanying forms
   - SOPs, dose order form, dose calculation worksheet, dose, labels, etc.
5. Conduct training
6. Initiate and maintain therapy

Dry run (test drug shipment) can be very useful to validate the procedure and forms

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How to handle patient dose preparation

- Shipped product vial for patient dose is used as it is
- Dispensed by nuclear pharmacy
  - By on-site nuclear pharmacy
  - By off-site nuclear pharmacy
- Drawn under immediate procedure by the technologist
- What administration method is used ?
  - Factors to consider: Convenience, Cost, Occupational dose to workers, facility resources, etc.

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How to handle patient dose preparation: ALARA

- Use appropriate tools

Vial shield*

Beta-gamma syringe shield*

Bricks*

*https://radiuminc.com

Lucite + tungsten shield

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Pluvicto Administration Methods

- Syringe method (with or without a syringe pump)
- Gravity method (with or without an infusion pump)
- Vial (with a peristaltic infusion pump)
- Refer to Pluvicto Prescribing Information (PI)

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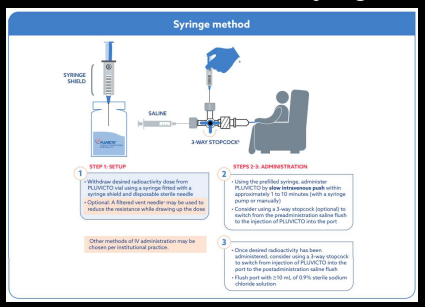
Pluvicto Administration Methods: Syringe Method



https://www.hcp.novartis.com/siteassets/vilupsa/dosing/184981-pluvicto-branded-hcp-dosing-guide-digital_3.29.22.pdf

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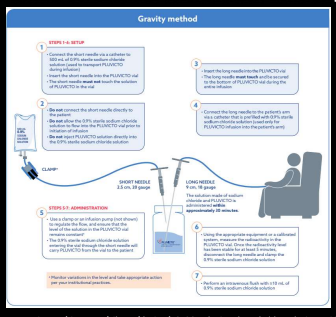
Pluvicto Administration Methods: Gravity Method



https://www.hcp.novartis.com/siteassets/vilupsa/dosing/184981-pluvicto-branded-hcp-dosing-guide-digital_3.29.22.pdf

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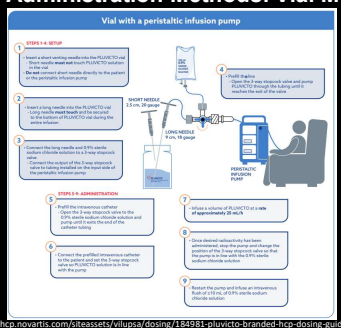
Pluvicto Administration Methods: Vial Method



https://www.hcp.novartis.com/siteassets/vilupsa/dosing/184981-pluvicto-branded-hcp-dosing-guide-digital_3.29.22.pdf

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Pluvicto Dose Dispensing by Nuclear Pharmacy

ISO Class 5 PEC

Pluvicto vial in vial shield

Transferring activity into syringe

Replace needle with sterile cap

Place patient dose in transportation Box

Dose calibrator and transportation box in adjacent to ISO Class 5 PEC

Dispensing performed in ISO Class 5 PEC in classified area

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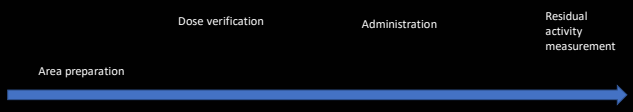
Pluvicto Administration at Radiation Oncology



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Pluvicto Dose Preparation: Immediate Use Procedure at Nuclear Medicine Department

- Dose not require a segregated radiopharmaceutical processing area (SRPA), classified area, or PEC
- Dose not require personnel to complete the aseptic qualification
- Intended for a single patient dose
- Perform hand hygiene
- Immediately after hand hygiene, don a clean gown that has not been exposed to a patient or patient care area

Must be administered within 1 hour of the fist container puncture

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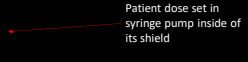
Treatment Area at Nuclear Medicine Department



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Pluvicto Facts

Indication	Treatment if adult patients with PSMA-positive mCRPC who have been treated with androgen receptor (AR) pathway inhibition and taxane-based chemotherapy
Patient Selection	Use Ga-68 gozetotide (Locametz) or another approved PSMA-11 imaging agent (F-18 piflufolastat (Pylarify))
Recommended Dosage	7.4 GBq (200 mCi) intravenously every 6 weeks for up to 6 doses, or until disease progression, or unacceptable toxicity
Dosage Modification	Temporary dose interruption (extending the dosing interval) Dose reduction by 20% once: do not re-escalate dose Permanent discontinuation
Dosage Forms and Strengths	Injection: 1000 MBq/mL. Clear and colorless to slightly yellow solution in a single-dose vial
Solution Volume	7.5 - 12.5 mL
Elimination	Primarily renal elimination
Shelf life	120 hours (5 days)
Storage	Below 30 °C (86 °F)

PSMA: prostate-specific membrane antigen
mCRPC: metastatic castration-resistant prostate cancer

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Pluvicto Facts

Radiation exposure (to self)	Ensure patient increase oral fluid intake and advise patients to void as often as possible
Radiation exposure (to others)	Limit close contact (<3 feet) with household contacts for 2 days, children and pregnant women for 7 days Refrain sexual activity for 7 days Sleep in a separate bedroom from household contacts for 3 days, from children for 7 days, or from pregnant women for 15 days
Myelosuppression	Perform complete blood counts. Withhold, reduce dose, or permanently discontinue PLUVICTO and clinically treat based on severity.
Renal Toxicity	Advise patients to remain well hydrated and to urinate frequently. Perform kidney function laboratory tests. Withhold, reduce dose, or permanently discontinue PLUVICTO based on severity
Embryo-Fetal Toxicity	Can cause fetal harm. Advise male patients with female partners of reproductive potential to use effective contraception.
Infertility	PLUVICTO may cause temporary or permanent infertility.

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Pluvicto Workflow for Routine Operation: WU example

- Identify therapy candidates
- Image therapy candidates using Ga-68 PSMA-11 (Locametz) or another approved PSMA-11 imaging agent (F-18 DCFPyL (Pylarify))
- Determination of whether Pluvicto treatment is appropriate
- Schedule treatment dates
- Order Pluvicto (6 doses)
- 1st dose receiving
- Follow up

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RAM Receiving, Transportation, and RAM Waste Management

Provided by WU Radiation Safety Office

RAM receiving transportation Waste management

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Hiccups

1. Moving dispensing area
   - ✓ DC re-calibration, etc.
   - ✓ DC different setting for same Lu-177 for different clinical trial
   - ✓ Communication
   - ✓ Air exchange-BUD change
2. LAFW contamination
   - ✓ LAFW contamination
     - Decontamination process

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Moving forward…

- Pharmacy dispensing software program
- Dose ordering process
- Dispensing other therapeutic RPs

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Clinical Trial: Producing Therapeutic Radiopharmaceuticals for investigational use

- Beta or Alpha emitting radiopharmaceuticals
- Product release following review of production batch record and QC test results
- Collaboration with industrial partners

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Potential Roles for Nuclear Pharmacist Beyond Dispensing

- Patient and family member counseling
- Assurance of drug supply for continuation of therapy
- Close interaction with other team members
- Expanded responsibilities: dose monitoring?
- Greater involvement with patient response/tolerance assessment

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References

- Pluvicto Prescribing Information
- USP Chapter <825> Radiopharmaceuticals-Preparation, Compounding, Dispensing, and Repackaging
- Advanced Accelerator Applications Dosing and Administration Guide—Pluvicto®. Available online: https://www.hcp.novartis.com/siteassets/vilupsa/dosing/184981-pluvicto-branded-hcp-dosing-guide-digital_3.29.22.pdf (accessed on October 1, 2023)
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- Jacqueline DZ, Garcia-Ramirez J, Luechtefeld D, Maughan NM, Amurao M, **Oyama R**, Baumann BC, Gay HA, and Michalski JM, Logistical, technical, and radiation safety aspects of establishing a radiopharmaceutical therapy program: A case in Lutetium-177 prostate-specific membrane antigen (PSMA) therapy, *Journal of Applied Clinical Medical Physics*, 2023 Jan 13

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LEARNING ASSESSMENTS

Question 1:

Which of the following factors, beside patient safety, should be considered to determine the best method to prepare patient doses of radiopharmaceuticals?

a. Convenience
b. Cost
c. Radiation dose to workers
d. Workflow
e. All of above

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LEARNING ASSESSMENTS

Question 2:

Which of the following statements regarding Pluvicto administration is correct?

a. When using the syringe method for Pluvicto administration, a syringe pump must be used to precisely control the administration rate.
b. Pluvicto can only be administered using the gravity method or the syringe method with a syringe pump.
c. Pluvicto can only be administered using the gravity method, syringe method (with or without a syringe pump), or vial method with an infusion pump.

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LEARNING ASSESSMENTS

Question 3:

What are the recommended dosage guidelines for Pluvicto?

a. 3.7 GBq (100 mCi) intravenously every 4 weeks for up to 8 doses, or until disease progression or unacceptable toxicity
b. 7.4 GBq (200 mCi) intravenously every 6 weeks for up to 6 doses, or until disease progression or unacceptable toxicity
c. 7.4 GBq (200 mCi) every 8 weeks (± 1 week) for a total of 4 doses, or until disease progression or unacceptable toxicity
d. 3.7 GBq (100 mCi) every 4 weeks (± 1 week) for a total of 8 doses, or until disease progression or unacceptable toxicity

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LEARNING ASSESSMENTS

Question 3:

What BUD should be assigned to a radiopharmaceutical that was dispensed in ISO Class 5 PEC (Primary Engineering Control) located in ISO Class 8 or better buffer area with ISO Class 8 or better ante-room?

a. 1 hour
b. 12 hours
c. 24 hours
d. 96 hours

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Thank you!

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