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October 11, 2021

Mountain View Hospital

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Mountain View Hospital
Credible Evidence of Correction of Violations

October 6, 2021

ATTN: Document Control Desk,
Washington, DC 20555-0001

RE: Mountain View Hospital, NRC Inspection Report 030-38701/2020-0; EA-21-034

Dear Dr. Lizette Rolan-Otero,

We have received and acted upon the Statement of Deficiencies/Violations based off the remote inspection on November 9, 2020 and onsite inspection performed between November 16 and 19, 2020 sent to our facility (NRC Inspection Report 030-38701/2020-0; EA-21-034). We appreciate the surveyors who visited us and the helpful information they shared with us while here. It is our sincere intent to come into and remain in compliance with all the Nuclear Regulatory Commission standards.

Attached you will find the corrections for the six identified deficiencies/violations:

- **Apparent violation of 10 CFR 35.41(a)(2)** - Failure to develop, implement, and maintain written procedures to provide high confidence that each administration of Lu-177 is in accordance with the written directive
- **Apparent violation of 10 CFR 35.75(a)** - Release of individuals who had been administered Lu-177 and had radiation dose rates that exceeded the licensee's release criteria.
- **Apparent violation of 10 CFR 35.310(b)** - Failure to document the instructions or training provided to individuals caring for patients administered Lu-177.
- **Apparent violation of 10 CFR 20.2103(a)** - Failure to document radiation surveys to demonstrate that rooms used for Lu-177 patients could be released for unrestricted use.
- **Apparent violation of 10 CFR 20.2003(a) (1)** - Discharge to the sanitary sewer of Lu-177 contaminated materials that were not readily soluble in water or biological materials.
- **Apparent violation of 10 CFR 20.1904(a)** - Failure to label a Lu-177 radioactive waste storage container and its contents to indicate that they contained radioactive materials.

Please note that we have recreated the Statement of Deficiencies/Plan of Correction document in an abbreviated format so we could respond clearly in the Evidence of Correction column.

After review of the enclosed information, if you have questions, please contact Ned Hillyard, CCO, at 208-557-2711.

Respectfully,

Ned Hillyard, Ph.D., CCEP, CHC, CPHRM
Chief Clinical Operations/Compliance Officer
Mountain View Hospital

Prepared By:

Jasmine Stockwell
Risk Management/Compliance
Mountain View Hospital

MOUNTAIN VIEW HOSPITAL, IDAHO FALLS ID

Nuclear Regulatory Commission

Response to Apparent Violations in NRC Inspection Report 030-38701/2020-001; EA-21-034

Remote inspection commenced on November 9, 2020; onsite inspection occurred during November 16-19, 2020; continued in-office review conducted through September 2, 2021

Deficiency / Tag #: Apparent violation of 10 CFR 35.41(a)(2)	
Deficiency Brief Description: Failure to develop, implement, and maintain written procedures to provide high confidence that each administration of Lu-177 is in accordance with the written directive	
Title of Person Responsible for Implementing action	David Theel, Radiation Safety Officer
Date Action Plan was or will be Implemented	10/2021
Is a Monitoring Plan required (Yes or No)	Yes
What will be monitored	Nursing interview form, scheduling process, pre-administration checklist items and post-administration checklist.
What is the sample size	100%
What is the threshold of Compliance	100%
How frequently will monitoring occur	Quarterly
How long will monitoring last	Indefinite
Who will oversee the monitoring	Radiation Safety Committee
What committee will receive the reports on the results	Radiation Safety Committee/ Annual Review
Attachments/Evidence of Action Plan: A. Lutathera Radiation Procedure policy	
Action Plan: • Policy updated to reflect process of nursing interview form, scheduling process, pre-administration checklist items and post-administration checklist bulletized. • No hospital transportation of radioisotope doses between MVH main campus and TCI Radiation Oncology. • Policy lists radiation safety in regards to necessary placement of long and short needles within the Lu-177 vial, the order in which they are inserted, the depths to which they are inserted, the various connections that are associated with each, the management of the vial, the marking of the fluid level in the vial and cautions regarding possible variances in the needle placement. • The bulletized list for Lu-177 administration that was being used by the licensee contained no troubleshooting guidance to address Lu-177 administration problems." In the new policy, specific reference to the procedure of troubleshooting the Lu-177 set up is detailed in "Administration" (G)(1) (a) through (e).	

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Mountain View Hospital

Origination:	*12/2020*
Last Approved:	*10/2021*
Last Revised:	*10/2021*
Next Review:	*10/2022*
Owner:	*David Theel: Radiation Safety Officer*
Policy Area:	*Clinical Services: Oncology*
References:	

Lutathera Radiation Procedure

Lutathera (Lu-177 Dotatate)

Indications:

Treatment of somatostatin receptor positive gastroenteropancreatic neuroendocrine tumors (GEP-NETs), including foregut, midgut and hindgut neuroendocrine tumors in adults.

Principle:

Lu-177 Lutetium Dotatate binds to somatostatin receptors with the highest affinity for subtype 2 receptors (SSRT2). Upon binding to the somatostatin receptor expressed cells, including malignant somatostatin receptor positive tumors, the compound is internalized. The beta emission from Lu-177 induces cellular damage by formation of free radicals in somatostatin receptor positive cells and in neighboring cells.

Radiopharmaceutical:

Name of Pharmaceutical: Lutathera

Name of Isotope: Lutetium-177 Dotatate

Radiation Emission: Betas:490 keV

Gammas and X-rays:113 keV (6%)

208 keV (11%)

Half-Life: Physical:6.78 days

Biological (GI):24 hrs.

Effective (GI):21.6 hrs.

Gamma Ray Constant: (Γ): 0.1810 R cm^2 / mCi h

Excretion Pathways: Urine, Stool, Vomit, Saliva

Warnings: Lutetium-177m contaminate has a half-life of 161 days requiring special considerations for low-level radioactive waste.

Survey Meter Efficiency:Ludlum 14C + Pancake Probe:48 %

Safety Labs:

A. (CBC, CMP, PTT/Pregnancy if required) should be performed ≤ 72 hours pre Treatment

B. Peripheral blood cell counts should be followed every other week to document degree of platelet count and WBC count suppression.

Dosage/Standard Procedure:

A. Lutathera is prescribed by standard patient unit dose. Administer 7.4 GBq (200 mCi) every 8 weeks for a total of 4 doses. (Lutathera Pkg Insert 2.2) (Prepared dose to be no more than +/- 5%)

B. Continue long-acting octreotide 30 mg intramuscularly every 4 weeks after completing Lutathera until disease progression or for up to 18 months following treatment initiation. (2.3)

C. Administration may be dose reduced or delayed for up to 16 weeks based on reactions. See package insert for Table 2. Recommended Dose Modifications for Lutathera for Adverse Reactions. (2.4)

D. Do not reduce dose of amino acid solution even if Lutathera dose is reduced. (2.3)

E. 10 – 20% of patients will experience a brief increase in pain (flare pain) for 2 – 3 days following the injection. Usually self-limiting (managed by increasing pain meds), or may be per physician discretion.

Drug Interactions:

A. Somatostatin Analogs: Discontinue long-acting analogs for at least 4 weeks and short-acting octreotide at least 24 hours prior to each Lutathera dose. (2.3, 7.1)

Warnings:

A. Myelosuppression: Monitor blood cell counts. Withhold, reduce dose, or permanently discontinue based on severity. (2.4, 5.2)

B. Secondary Myelodysplastic Syndrome (MDS) and Leukemia: Median time to development: MDS is 28 months; acute leukemia is 55 months. (5.3)

C. Renal Toxicity: Advise patients to urinate frequently during and after administration of Lutathera. Monitor serum creatinine and calculated creatinine clearance. Withhold, reduce dose, or permanently discontinue based on severity. (2.3, 2.4, 5.4)

D. Hepatotoxicity: Monitor transaminases, bilirubin and albumin. Withhold, reduce dose, or permanently discontinue based on severity. (2.4, 5.5)

E. Neuroendocrine Hormonal Crisis: Monitor for flushing, diarrhea, hypotension, bronchoconstriction or other signs and symptoms. (5.6)

F. Embryo-Fetal Toxicity: Lutathera can cause fetal harm. Advise females and males of reproductive potential of the potential risk to a fetus and to use effective contraception (5.7, 8.1, 8.3)

G. Risk of Infertility: Lutathera may cause infertility. (8.3)

To report SUSPECTED ADVERSE REACTIONS, contact Advanced Accelerator Applications USA, Inc. at 1-844-863-1930 or *us-pharmacovigilance@adacap.com*, or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

Consult:

A. Following referral from Medical Oncologist, the patient will consult with the Radiation Oncologist and determine whether to proceed with Lutathera evaluation and treatment.

B. The Radiation Oncology Nurse/Medical Assistant will give the patient the Lutathera procedure and educational materials:

1. Lutathera vendor "What you can expect before, during, and after treatment with Lutathera"
2. TCIRO Lutathera Patient Education Handouts
3. The Radiation Oncology Nurse/Medical Assistant will document the giving of educational materials to the patient in ARIA/EMR.

C. The Oncologists will evaluate the patient to see if Lutathera is appropriate. Mark any item with an 'X' that would cause the patient to FAIL TO MEET INCLUSION/EXCLUSION.

1. **Inclusion Criteria**
   - ___Presence of metastasized or locally advanced abdominal neuroendocrine tumor, inoperable at enrollment time (curative intent), or patient refuses surgery.
   - ___Ki67 index ≤ 20%. (Path report that shows lower grade of tumor. "The Power Against Progression" Pg 6.)
   - ___Patients progressive during or after SSA (any dose) at the time of enrollment.
   - ___Patient's ≥18 years of age.
   - ___Target lesions over-expressing somatostatin receptors according to an appropriate imaging method (e.g. 111In-pentetreotide (Octreoscan) imaging or 68Ga-DOTA0-Tyr3-Octreotate (or 68Ga-edotreotide) imaging)
2. **Exclusion Criteria**
   - ___Either serum creatinine >150 µmol/L (>1.7 mg/dL), or creatinine clearance <50 mL/min calculated by the Cockroft Gault method, eventually confirmed by measured creatinine clearance (or measured glomerular filtration rate (GFR) using plasma clearance methods, not gamma camera-based) <50 mL/min (the measured creatinine clearance / GFR is required only as confirmatory exam).
   - ___Hb concentration <5.0 mmol/L (<8.0 g/dL); WBC <2x109/L (2000/mm3); platelets <75x109/L (75x103/mm3).
   - ___Total bilirubin >3 x ULN.
   - ___Serum albumin <3.0 g/dL unless prothrombin time is within the normal range.
   - ___Patient is Pregnant or Lactating (Breast Feeding).
   - ___Patients who are not using an effective, non-hormonal means of contraception in conjunction with spermicidal gel. [Female patients of childbearing potential (defined as < 2 years after last menstruation and not surgically sterile) / Male patients, who are not surgically sterile or with female partners of childbearing potential].
   - ___Any surgery, radioembolization, chemoembolization, chemotherapy and radiofrequency ablation within 12 weeks prior to enrollment.
   - ___Interferons, Everolimus (mTOR-inhibitors) or other systemic therapies within 4 weeks prior

to enrollment.

- ___Known brain metastases, unless these metastases have been treated and stabilized.
- ___Uncontrolled congestive heart failure (NYHA II, III, IV).
- ___Uncontrolled diabetes mellitus as defined by a fasting blood glucose >2 ULN.
- ___Any patient receiving treatment with short-acting Octreotide, which cannot be interrupted for 24 h before and 24 h after the administration of 177Lu-DOTA0-Tyr3-Octreotate, OR any patient receiving treatment with Octreotide LAR, which cannot be interrupted for at least 4 weeks before the administration of 177Lu-DOTA0-Tyr3-Octreotate.
- ___Patients with any other significant medical, psychiatric, or surgical condition, currently uncontrolled by treatment, which may pose a risk to the patient safety
- ___External beam radiation therapy to more than 25% of the bone marrow within the last 10 years.
- ___Current spontaneous urinary incontinence making impossible the safe administration of the radioactive IMP.
- ___Other known co-existing malignancies except non-melanoma skin cancer and carcinoma in situ of the uterine cervix, unless definitively treated and with no evidence of recurrence.

D. Nurse Patient Interview evaluation criteria

1. Criteria for the evaluation via the Patient Interview
    a. Review of comorbidities (chronic kidney disease, chronic liver disease)
    b. Assess urination, urgency, use of attends, incontinence or self-catheterization
    c. Assess diarrhea
    d. Review patient's lab results (Creatinine, Bilirubin, CBC, CMP, Pregnancy test)
    e. Assess the patient's ability to ambulate to the bathroom
    f. Assess IV access if the patient can't have a PICC line
    g. Clearance during previous Lutathera administration based on 1 m measurement
    h. Assess side effects from previous doses/comorbidities for possible dose reduction as outlined in the package insert for Table 2. Recommended Dose Modifications for Lutathera for Adverse Reactions. (2.4).

E. Nurse/Radiation Oncology staff Patient Interview discoveries that require Authorized User/Radiation Oncologist approval to proceed to scheduling may include but are not limited to:

1. Incontinence
2. Requires full assistance to ambulate to the bathroom
3. Chronic kidney disease
4. Chronic liver disease
5. Creatinine > 1.3
6. Bilirubin > 1.2

Authorization and Financial Aid:

A. Radiation Oncology Medical Assistant will notify Prior Authorization and Financial Counselors.
   1. Prior Authorization specialist will work with Lutathera Authorization specialists for commercial insurance, no assistance is offered for Medicare or Medicare supplements.
   2. For patients with Medicare only or Medicare supplements, Financial Counselor will meet with patient to inform them of their cost, and to work on financial agreement.

B. Once prior authorization is obtained, and financial agreements are in place, Prior Authorization Specialist will notify Radiation Oncology MA that we are okay to order.

C. Radiation Oncology Medical Assistant or Technologist will print the Written Directive for the patient and have the Authorized User fill in the order section.

D. Radiation Oncology Medical Assistant or Technologist will begin the ordering process for Lutathera through Advanced Accelerators Applications. E-mails will be sent to Nurse, Oncology Pharmacy and the appropriate Schedulers with the anticipated date of infusion.

Scheduling:

A. Considerations for scheduling:
   IMPORTANT: There is a 2 week lead time on Lutathera orders
   1. At this time Lutathera will only be given on Thursdays to conform to the PET/CT schedule.
   2. Radiation Oncology medical assistant will send an e-mail to Nursing staff, Oncology Pharmacy and appropriate Schedulers with anticipated date of infusion.
      a. Nursing staff will make sure that a nurse is scheduled for Radiation Oncology on the date of procedure.
      b. Schedulers will get patient scheduled for PICC line for the day prior to the Lutathera infusion.
      c. Pharmacy staff will get amino acids, antiemetics and Lasix, if necessary, ordered to be delivered to Radiation Oncology on the date of infusion.
   3. RSO will be notified of date and time of infusion.
   4. Radiation Oncology Medical Assistant or Technologist will verify if the infusion will be done in Radiation Oncology or at Mountain View Hospital. If at the hospital, refer to policy "Radiation Inpatient Radioisotope Admission." Radioisotope administrations will only be done at Mountain View Hospital when the patient as additional medical conditions that require it.

B. Radiation Oncology Medical Assistant or Technologist will contact the patient to verify date and time of procedure.

C. Radiation Oncology Medical Assistant or Technologist will notify the MVH medical floor manager of procedure date for administration and on all patients in case there is a need for an emergency admission.

Pre-Administration:

A. Documents:
   1. Partially completed Written Directive containing the prescription information
   2. Pre-Administration Radiation Safety Instructions and Acknowledgement

3. Sign for Radiopharmaceutical Bathroom
4. Printed Consent Form from Aria prior to 1st administration.
5. Copy of Nurses Patient Interview regarding pre-existing comorbidities to include side effects from previous doses and consideration of dose reduction and discussions with the patient's Medical Oncologist, when necessary.
6. Print the Lutathera Checklists
    a. Pre-Administration Checklist
    b. Administration Checklist
    c. Post Administration Checklist

B. Preparation of Tech Equipment:
1. Run daily QA on Hot Lab equipment as per the "Hot Lab" policy.
2. Check the Survey Meter calibration value and battery charge.

C. Preparation of **Lutathera Dose:**
1. Receive the dose from the courier as per the "Radiation Package Receipt" policy.
2. Ensure that the dose is appropriately labeled with
    a. Correct Patient Name
    b. Correct Drug
    c. Correct Isotope
    d. Correct Treatment Site
    e. Correct Route of Administration
    f. Correct Dosage/Activity (+/- 5%) [5% of a 200 mCi unit dose = 10 mCi]
    g. Correct Calibration Date
    h. Fill in the appropriate information on the Written Directive and the Nuclear Medicine software. Bioassay for Lutathera is not applicable (NA).
    i. Place/keep dose in lead container, ready to move to the Administration room when the Authorized User is ready to begin the administration.

D. Preparation of **Isolated Bathroom:**
1. Tape absorbent paper around toilet.
2. Cling wrap on door handles, faucet handles and toilet handle.
3. Absorbent paper ready for covering toilet during flushing.
4. See Reference Photos Floor and Sink, Floor and Toilet, Toilet Handle, Paper Towels and Wipes, Door Handle, Sink.

E. Preparation of **Selected Administraion Room:**
1. Absorbent Chux pad on infusion chair.
2. Absorbent paper on side table of chair.
3. Absorbent paper under patient's arm on side that PICC line is placed.

4. See Reference Photo Infusion Chair and Side Table.

F. Infusion and Nursing Preparation:

1. Saline solution 0.9 mg/ml NaCl, 500 mL
2. Saline for priming the lines
3. Amino Acid (lysine and arginine) solution bag (which amino acids)
4. Anti-emetics for IV infusion

G. Complete the "RO Consent for Lutathera" from Aria and scan into Aria/EMR prior to the first administration.

H. Complete the "Patient Acknowledgment of Instructions" form:

1. Review the Patient Instructions with the patient, ensure they understand the instructions, ensure they agree to comply with the instructions, have the patient sign the Acknowledgement form, sign the form as the staff member presenting the instructions, scan the document and upload it to Aria/EMR.

Administration Set Up (Pre-Administration):

A. The Nurse/Radiation Oncology staff will evaluate venous access (either PICC Line or peripheral) first for the amino acids, and a second separate line for the Lutathera. (e.g. other arm, second lumen)

1. Ensure that the PICC line has good blood return and is appropriate for administration.
2. Identify secondary venous access route in case the primary access for Lutathera is compromised.

B. The Nurse will deliver anti-emetics as prescribed.

C. The Nurse will spike the amino acids and prime the tubing set.

D. The Nurse will set the flow rate to 250 cc/hr, open patient line, and begin amino acid administration.

1. If the patient can tolerate 250 cc/hr, continue for 30 minutes.
2. If the patient becomes nauseous, titrate the flow rate down, not going below 200 cc/hr.

E. The Nurse will prepare the Lutathera line and will open 500 cc saline bag, prime IV pump and tubing set, and program for 50 cc/hr.

IMPORTANT: The Nurse/Radiation Oncology staff will have the patient use the bathroom prior to beginning the Lutathera administration.

F. The Nurse staff will prime the m/m patient line with sterile saline in syringe-use 2 way stopcock to attach saline to line.

G. The Nurse/Radiation Oncology staff will lay out the 18 gx 1" needle and the 18 gx 3.5" needle.

H. The Nurse/Radiation Oncology staff will lay out the Authorized Users gloves.

I. The Radiation Oncology staff will ensure that the staff and Authorized User are wearing their personnel radiation badges.

J. The Radiation Oncology staff will bring the Lutathera dose from the Hot Lab to the Uptake Room in the lead container, and radiation monitoring will be done on anyone/anything leaving the room from this point until the Lutathera container has been returned to the Hot Lab, and the pads, needles and tubing used for the Lutathera administration have been collected and removed.

K. The Radiation Oncology staff will place a few 2x2 pads under the Lutathera vial inside the lead container

to improve visibility of the air gap at the top of the Lutathera vial.

L. The Nurse/Radiation Oncology will draw a line marking the fluid level in the Lutathera vial.

M. The Nurse will flush the patient's access catheter.

N. The Authorized User will review the Written Directive and procedure for correctness (Right Patient, Right Drug, Right Isotope, Right Activity, Right Route) and verbally confirm with the staff in the room.

O. The Authorized User will connect the short needle to the saline tubing.

P. The Authorized User will place the short needle into the vial septum, ensuring the needle is inserted only so far as to safely pass the bevel fully into the vial.

WARNING: the short needle cannot touch the solution in the vial.

Q. The Authorized User will connect the patient line to the patient catheter and ensure the patient line is closed.

R. The Authorized User will connect the m/m tubing to the Long 18 gx needle.

S. The Authorized User will place the long needle into the vial at an angle and through the outside edge of the septum and advance the needle to the bottom of the vial; pulling back very slightly to ensure the needle isn't jammed against the vial wall.

Administration:

A. The Radiation Oncology staff will use a survey meter to survey the top of the Lutathera vial (close to but not touching) to obtain a baseline measurement of exposure rate.

B. The Nurse/Radiation Oncology staff will obtain baseline vitals.

C. The Nurse will open the Saline line.

D. The Authorized User will open the Patient line.

E. The Authorized User will confirm the IV Pump is set to 50 cc/hr, verbally declare to start, and the Nurse will start the pump.

F. After 5 minutes of administration the Radiation Oncology staff will survey the patient catheter to confirm flow of Lutathera into the patient.

G. IMPORTANT: The Authorized User/Radiation Oncology staff will ensure that the air gap at the top of the Lutathera vial remains unchanged.

1. If the air gap at the top of the Lutathera vial is lost or getting smaller:
    a. Pause the IV Pump
    b. Determine if tubing system has high pressure or blockage
    c. Use a 10 cc syringe to introduce air into the vial via the port on the saline tubing.

H. If the air gap at the top of the Lutathera vial is lost or getting smaller, refer to G above. The Nurse may slowly increase the flow rate of the IV Pump up to the value slower than the one that compromised the air gap.

I. If after 2 to 3 minutes, the patient catheter is confirmed to contain Lutathera and the air gap at the top of the Lutathera vial remains unchanged, and if the patient is comfortable, the Nurse may increase the flow rate to 100 cc/hr.

J. The Authorized User/Radiation Oncology staff will continue to monitor the air gap at the top of the Lutathera vial for 2 to 3 minutes, and if the air gap remains unchanged and if the patient is comfortable, the Nurse may increase the flow rate to 300 cc/hr over approximately 30 minutes.

K. Once the Authorized User has verified normal infusion **without** concerns, he may turn the infusion over to the Radiation Oncology Staff Member. The Authorized User must remain readily available within the department should any concerns arise. The Radiation Oncology staff will document the administration until the Authorized User returns or the administration is concluded.

L. After 35 minutes, the Radiation Oncology staff will survey the top of the Lutathera vial (close to but not touching) and compare it to the baseline value obtained prior to the patient administration and confirm that the vial is nearly empty of Lutathera.

M. After 40 minutes, and every 5 minutes thereafter, the Radiation Oncology staff will survey the top of the Lutathera vial. A reading will be declared stable when the value changes no more than 5%. (table included on attached Aria Document Administration Checklist)

N. The Authorized User will declare a Stop to the Administration and complete the administration section of the Written Directive.

O. The Nurse/Radiation Oncology staff will **disconnect** the Lutathera infusion from the patient:

1. Clamp the patient line
2. Disconnect the tubing from PICC line and cap the line and the patient catheter.

P. The Radiation Oncology staff will take the Lutathera vial to the Hot Lab to measure the residual activity of the Lutathera vial in the dose calibrator and record the activity on the Written Directive.

Q. The Radiation Oncology staff will transport all materials to the Hot Lab to be disassembled including absorbent pad under the patient's arm, Lutathera Vial, lead container, all IV tubing and saline bag, or any other materials that may have become contaminated.

1. The Radiation Oncology staff will disconnect the saline tubing from the saline bag.
2. Carefully remove the long needle with the tubing remaining attached from the Lutathera vial.
3. Carefully remove the short needle from the Lutathera vial.
4. After disassembly, the materials will be surveyed and placed in proper storage containers for decay and/or storage.

R. Once the Lutathera vial, IV tubing, and contaminated items have been removed from the administration room, the personnel and items will be surveyed a final time before the radiation monitoring of personnel/ items may be discontinued.

Post Administration:

A. The Nurse/Radiation Oncology staff will have the patient use the bathroom every 45 minutes and will inquire whether a stream of urine and average output was achieved by the patient. If there is any concern with the ability of the patient to appropriately clear the Lutathera activity through urination, the Nurse may:

1. Provide the patient with increased hydration support in order to increase urine output.
2. Provide the patient with a urinal to measure the output in order to keep up with post administration hydration and clearance and to prevent abnormal tissue retention.
3. Provide the patient with Lasix by physician order in order to assist with fluid clearance.

B. The Nurse will continue the amino acid infusion at 200 cc/hr for the remainder of the bag.

C. After the 4 hour infusion of amino acids with the possible addition of hydration, the Nurse will administer the long acting Sandostatin.

D. The Nurse will remove the PICC line and the Radiation Oncology staff will add it to the radioactive waste that was previously collected for decay and/or storage.

E. The Radiation Oncology staff will take a final exposure rate at 1 m from the umbilicus and note it on the Written Directive. The exposure rate readings are for understanding patient clearance and completeness of documentation only.

F. The patient may be released according to NRC 10 CFR 35.75 as calculated according to NRC Regulatory Guide 8.39 based on **ADMINISTERED DOSE/ACTIVITY** of less than 240 mCi of Lutathera per patient dose.

G. In the 96 hours (time required to excrete all but 30% of the activity and 99% of all non-sequestered activity) following the administration of Lutathera, if a patient requires hospitalization, consideration for ALARA protection of staff and the public will be made as described in "Precautions for Post Chemo and Radiation Therapy Patients." If admitted to another community healthcare provider, forward a copy of the "Community Colleague" letter.

Post Procedure Decontamination and Clean-Up at TCI:

A. Radiation Oncology staff will use a GM survey meter to check for contamination on the cart, lead pot, equipment, and the areas under the cart and bathroom.

B. Radiation Oncology staff will decontaminate and/or dispose/store of items as appropriate using the radiologic cleaner and paper towels. Paper towels used in patient areas for decontamination may be stored for decay with other patient excreta, and paper towels used to clean up Lutathera liquid/blood spills need to be stored for decay with the medical waste and sent to long term decay.

C. Radiation Oncology staff will check the surface contamination to ensure that Area Surveys < 2 mR/hour in all controlled areas. If the survey is greater than the trigger level, clean the area with the radiologic cleaner and paper towels, then repeat the measurement.

D. Radiation Oncology staff will check the surface contamination to ensure that Wipe Tests of 100 cm^2 < 2000 dpm in all areas where Lutathera was used, stored, or transported. If the wipe test is greater than the trigger level, clean the area with the radiologic cleaner and paper towels, then repeat the measurement.

E. The Radiation Oncology staff will complete the Written Directive for Discharge of Patients and other documentation for the entire procedure as was required, and will scan these documents into the patient's chart.

    1. For Radioisotope spill clean up refer to "Radioisotope Spill and Decontamination (RSO)."

Post Procedure Decontamination and Clean-Up at MVH:

A. Radiation Oncology staff will use a GM survey meter to check for contamination on the cart, lead pot, equipment, and the areas under the cart and bathroom.

B. Radiation Oncology staff will decontaminate and/or dispose/store of items as appropriate using the

radiologic cleaner and paper towels. Paper towels used in patient areas for decontamination may be stored for decay with other patient excreta, and paper towels used to clean up Lutathera/blood spills need to be stored for decay with the medical waste and sent to long term decay.

C. Radiation Oncology staff will check the surface contamination to ensure that Area Surveys < 2 mR/hour in all controlled areas. If the survey is greater than the trigger level, clean the area with the radiologic cleaner and paper towels, then repeat the measurement.

D. Radiation Oncology staff will check the surface contamination to ensure that Wipe Tests of 100 cm^2 < 2000 dpm in all areas where Lutathera was used, stored, or transported. If the wipe test is greater than the trigger level, clean the area with the radiologic cleaner and paper towels, then repeat the measurement.

E. The Radiation Oncology staff will complete the Written Directive for Discharge of Patients and other documentation for the entire procedure as was required, and will scan these documents into the patient's chart.

F. The Patient's room will be marked with the appropriate signs listing things such asa warnings, limits on visitation and prohibition of trash removal that may be necessary as defined by "Radiation In-Patient Safety."

   1. For Radioisotope spill clean up refer to "Radioisotope Spill and Decontamination (RSO)."

Misadministration/Medical Event/Reporting:

A. A Medical Event for RadioIsotope Administration results when:

   1. Administration to the Wrong Person or via the Wrong Route.
   2. Administration of the Wrong Drug or the Wrong Radionuclide.
   3. The Dose Delivered differs from the Prescribed Dose by more than 5 rem.
   4. The Fractional Dose Delivered differs from the Prescribed Dose by 50%.
   5. The Dose Delivered differs from the Prescribed Dose by 20% or more.

B. The Medical Event will be reported to the NRC no later than the next calendar day.

C. Method of Contact and details: **see Mis-administration of a Radiopharmaceutical policy or NRC 10 CFR 35.3045.**

All revision dates: 10/2021, 03/2021, 12/2020

Attachments

RN Interview and MD Criteria.pdf
Lutathera Administration Checklist.pdf
Lutathera Patient Documents.pdf
Lutathera Radiation Protective Barrier Photos.pdf

Approval Signatures

Step Description	Approver	Date
Compliance	Ned Hillyard: CHIEF COMPLIANCE OFFICER [JS]	10/2021
Policy Coordinator	Wendy Bateman: POLICY COORDINATOR [JS]	10/2021
RSO	David Theel: Radiation Safety Officer	10/2021
Radiation Oncology	Lisa Anderson: MANAGER	10/2021
Radiation Oncology	Debra Fuelling: SUPERVISOR	10/2021

TETON CANCER INSTITUTE

PATIENT NAME: <Full Name>

MRN: <Patient Id 1> **DATE OF BIRTH**: <Date of Birth>

LUTATHERA Pre-Administration Form

Items Required for Lu-177 Dotatate Administration:

- ❑ Patient prescription for Lu-177 Dotatate (signed Written Directive)
- ❑ Lutathera Patient Discharge Instructions
- ❑ Signed Informed consent
- ❑ Geiger-Mueller (GM) contamination meter
- ❑ Spill kit/Rescue kit
- ❑ Contamination protection applied in the patient bathroom and side table

Have the following items available:

Pharmaceuticals	***Equipment***
❑ 1 100 ml 0.9% sterile sodium chloride solution. ❑ 1 500 ml 0.9% sterile sodium chloride solution. ❑ 3 1000 ml 0.9% sterile sodium chloride solution. ❑ 10 mL NS filled syringes, approx. 10 ❑ Amino Acid solution bag ❑ Anti-emetics for premedication ❑ Sandostatin injection ❑ Lu-177 Dotatate in lead container	❑ Tongs/forceps to handle the vial ❑ Long needle; 90-100 mm long; 18 G ❑ Short needle; 3cm,18 G ❑ 10 cc syringe ❑ Sterile gloves ❑ Gauze ❑ Waste container for contaminated items ❑ 2 Infusion pumps on a pole ❑ Dinamap ❑ Alcohol swabs ❑ 6 sterile tubing sets ❑ 1 0.2 micron filter ❑ Pack of 4x4's ❑ Coban ❑ Bandaid ❑ Computer for documentation ❑ Gloves

Teton Cancer Institute - Radiation Oncology 1550 Hoopes Ave Idaho Falls, ID 83404
208-542-7220

PATIENT NAME: <Full Name>

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LUTATHERA Pre-Administration Form (cont.)

- ❑ Review Patient Interview form for infusion considerations
- ❑ Lay down the appropriate absorbent items and wrap the appropriate handles as described in Lu-177 Dotatate Policy and Procdure under "Pre-Administration D and E and Photo D.4 and E.4.
- ❑ Typical patient will have a double lumen PICC line in place prior to arrival for Lu-177 Dotatate. Assess each lumen for blood return and flush with one (1) 10 ml normal saline syringe in each lumen. If no blood return is noted from either PICC line lumen, access peripherally to replace each compromised line per protocol.
- ❑ Open one (1) sterile tubing set and spike 100 ml 0.9% sterile sodium chloride solution; prime tubing set. Prepare anti-emetics as prescribed in the primed 100 ml 0.9% sterile sodium chloride bag. Administer anti-emetics over thirty (30) minutes (one (1) hour prior to Lu-177 Dotatate infusion).
- ❑ Open one (1) sterile tubing set and 0.2 micron filter tubing. Attach filter tubing to end of sterile tubing set. Spike the bag containing amino acids; prime tubing set.
- ❑ After anti-emetics have infused for thirty (30) minutes, start amino acid infusion at the rate of 250 ml/hour for thirty (30) minutes. Amino acids are to be infused thirty (30) minutes prior to Lu-177 Dotatate infusion. Notify Technologist the amino acids have begun.
- ❑ Prepare for Lu-177 Dotatate infusion line set with 500 ml 0.9% sterile sodium chloride solution. Open one (1) sterile tubing set and spike 500 ml 0.9% sterile sodium chloride bag; prime tubing set.
- ❑ **IMPORTANT**: Assist patient to the restroom ten (10) minutes prior to infusion.
- ❑ **Once the Lutathera dose is brought to the infusion area** the room will be considered an area of use and all personnel and items leaving the room will be checked for radiation contamination.
- ❑ Prior to beginning the Lutathera administration, the Technologist will survey the top of the Lutathera vial and document the baseline exposure measurement.
- ❑ Attach blood pressure cuff and pulse oximeter to the patient. Take a baseline set of vitals just prior to Lu-177 Dotatate infusion start time.
- ❑ The Technologist will verify that all staff present are wearing their assigned radiation badges.
- ❑ The Technologist will inform the physician of the assayed activity of the Lutathera dose that was received, will ensure the prepared dose is +/- 5% of the prescribed dose, and the Authorized User will determine how to proceed.

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LUTATHERA Pre-Administration Form (cont.)

- ❑ The Authorized User will review the Written Directive and verbally confirm
  - Right Patient
  - Right Drug / Right Isotope / Right Activity
  - Right Route
- ❑ Nurse will assist physician with the NS 500 ml line for attachment to short needle.
- ❑ Physician will connect the patient line to patient catheter and ensure patient line is closed.
- ❑ Physician will place the short needle into the septum, barely passing through the septum.
- ❑ Physician will connect the m/m tubing to the long, 18 G needle.
- ❑ Physician with place the long needle into the vial at an angle and through outside edge of septum and advance to bottom of vial; pulling back very slightly to ensure needle isn't jammed against the vial.
  WARNING: the short needle cannot touch the solution in the vial.

Nurse/Radiation Oncology Tech	Date	Time

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208-542-7220

TETON CANCER INSTITUTE

PATIENT NAME: <Full Name>

MRN: <Patient Id 1> **DATE OF BIRTH**: <Date of Birth>

LUTATHERA Administration Form

- ❑ Authorized User declares Start to Administration
- ❑ Assist physician with confirming the IV Pump is set at 50 cc/hour, opening the saline line, opening the patient line, and starting the IV Pump.
- ❑ **IMPORTANT: Maintain the air pocket**
- ❑ Once the Lu-177 Dotatate IV infusion has begun:
- ❑ Throughout entire Lu-177 Dotatate infusion, monitor the air gap at the top of the Lutathera vial. If the air gap diminishes/changes, stop the IV Pump, use a 10 cc syringe to introduce air into the vial via the saline tubing, then carefully continue the infusion. If the air gap diminishes again, repeat.
- ❑ After two (2) minutes, the Nurse/Technologist will survey the Lutathera line and verify the radiopharmaceutical is being delivered to the patient.
- ❑ Once the Lutathera flow is confirmed, increase IV pump rate to 100 ml/hour for two (2) minutes per physician command.
- ❑ After two (2) minutes of infusion time, increase IV pump rate to max of 300 ml/hour per physician command for remaining infusion time. (about forty (40) minutes).
- ❑ Throughout entire Lu-177 Dotatate infusion, monitor the patient for any infusion related symptoms and treat per physician order.
- ❑ Monitor the patient's vitals every 3-5 minutes during the ramp up stages of Lu-177 Dotatate infusion. Once at the max ramp stage of 300 ml/hour, monitor the patient's vitals every 5-10 minutes.
- ❑ After 25 minutes of Lutathera administration, the Technologist will survey the top of the Lutathera vial, compare the survey to the baseline, and confirm the administration is nearly complete.
- ❑ After 30 minutes survey the top of the Lutathera vial every 5 minutes. When survey is stable (+/- 5%), the infusion is completed.
- ❑ Disconnect Lutathera line from patient and flush PICC line with 10 cc NS Flush.
- ❑ The Authorized User will declare Stop to Administration and document on the Written Directive that the administration is complete.

Survey Meter Reading Equivalency		
Meter Read	- 5%	+ 5%
45.0	42.8	47.3
44.5	42.3	46.7
44.0	41.8	46.2
43.5	41.3	45.7
43.0	40.9	45.2
42.5	40.4	44.6
42.0	39.9	44.1
41.5	39.4	43.6
41.0	39.0	43.1
40.5	38.5	42.5
40.0	38.0	42.0
39.5	37.5	41.5
39.0	37.1	41.0
38.5	36.6	40.4
38.0	36.1	39.9
37.5	35.6	39.4
37.0	35.2	38.9
36.5	34.7	38.3
36.0	34.2	37.8
35.5	33.7	37.3
35.0	33.3	36.8
34.5	32.8	36.2
34.0	32.3	35.7
33.5	31.8	35.2
33.0	31.4	34.7

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PATIENT NAME: <Full Name>

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LUTATHERA Administration Form (cont.)

- ❑ Remove all items contaminated with Lu-177 Dotatate to the Hot Lab for disassembly, sorting, and appropriate disposal.
- ❑ The Technologist will measure the Lu-177 Dotatate vial for residual activity and document this value on the Written Directive.
- ❑ Confirm that the residual is less than 5% of the original assayed value and/or evaluate the need for continued infusion.
- ❑ The Technologist will complete the Administration section of the Written Directive.
- ❑ **Once the Lutathera vial and contamination are removed** and the personnel have been checked for contamination, additional routine surveys upon entry/exit for radiation contamination may be discontinued.

_____	_____	_____
Nurse/Radiation Oncology Tech	Date	Time

Teton Cancer Institute - Radiation Oncology 1550 Hoopes Ave Idaho Falls, ID 83404
208-542-7220

PATIENT NAME: <Full Name>

MRN: <Patient Id 1> **DATE OF BIRTH**: <Date of Birth>

LUTATHERA Post-Administration Form

- ❑ At completion of Lu-177 Dotatate infusion, decrease the amino acid infusion rate to 200 ml/hour for the remaining volume of the bag, this will complete in approximately 3-4 hours.
- ❑ Open one (1) sterile tubing set and spike one (1) 1000 ml 0.9% sterile sodium chloride solution bag; prime tubing set. Administer saline bag over one (1) hour. May repeat this step times two (2) as needed to assist in flushing out the Lu-177 Dotatate through patient urination.
- ❑ If patient is requiring Lasix to aid in elimination of Lu-177 Dotatate, give at this time. Administer Lasix dose per medical oncologist order.
- ❑ Assist patient to the restroom at least every hour, preferably every 30-45 minutes.
- ❑ Four (4) hours after the completion of Lu-177 Dotatate the Nurse will:
  - ❑ Administer Sandostatin 30 mg intramuscular (or dose prescribed by medical oncologist).
  - ❑ Flush each lumen on PICC line with one (1) 10 ml normal saline syringe. Remove PICC line per protocol and give it to the Technologist to discard appropriately.
  - ❑ Survey the patient at 1 m from umbilicus and document for clearance assistance and completeness of documentation **ONLY**. This measurement has **NO** bearing on the patient release criteria per 10CFR35.75.
- ❑ Nurse will document the 1 m measurement and will include this information in the next pre-administration Patient Interview for assessment of LOW/MEDIUM/HIGH Risk.
- ❑ Assist patient with belongings for discharge.

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PATIENT NAME: <Full Name>

MRN: <Patient Id 1> **DATE OF BIRTH**: <Date of Birth>

LUTATHERA Post-Administration Form

2. Patient Release

- ❑ Lutathera patients are released based on administered activity of less than 240 mCi patient unit dose and the patient release calculations are available for review from the Radiation Safety Officer.

3. Cleanup and Waste Disposal

- ❑ The Technologist will use GM contamination meter to check for contamination on the cart, lead container, equipment, and the areas under the cart and bathroom.
- ❑ The Technologist will decontaminate and/or dispose/store of items as appropriate.
- ❑ The Technologists will complete Written Directive for Discharge of Patients and other documentation for entire procedure as needed, and scan these documents into the patient's chart.

Nurse/Radiation Oncology Tech	Date	Time

Teton Cancer Institute - Radiation Oncology 1550 Hoopes Ave Idaho Falls, ID 83404
208-542-7220

TETON CANCER INSTITUTE

PATIENT NAME: <Full Name>

MRN: <Patient Id 1> **DATE OF BIRTH**: <Date of Birth>

To Whom It May Concern:

This letter is to certify that <Full Name> has received a radioactive isotope for a medical treatment procedure at Teton Cancer Institute. Radiation detectors may reveal traces of the isotope following the procedure, however, the patient has been provided with discharge instructions that are meant to keep the dose to the public below the guidelines stipulated by the Nuclear Regulatory Commission.

Isotope:	177 Lutetium
Medication:	^{177}Lu-DOTA0-Tyr3-Octreotate
Half-Life:	6.7 days
Dose:	7.4 GBq or 200 mCi

Please direct all questions regarding the medical procedure, the radioactive isotope, or radiation safety to:

Teton Cancer Institute
1550 Hoopes Avenue
Idaho Falls, Idaho, 83404
208-542-7220

Radiation Safety Officer
David Theel, DABR
208-221-8322

TETON CANCER INSTITUTE

PATIENT NAME: <Full Name>

MRN: <Patient Id 1> **DATE OF BIRTH**: <Date of Birth>

Lutathera Patient Discharge Instructions

Thank you for choosing Mountain View Hospital as you care provider for your Lutathera (Lu-177) infusion therapy. In choosing this therapy, you have also agreed to comply with the following discharge instructions that provide for the safety of your loved ones, care providers, and the public that you may come into contact with in the weeks following your infusion.

For the next **48 hours:**

1. **Maintain a distance of 6 feet** – between yourself and any visitors when the duration of the visit exceeds 5 minutes. At a distance of 6 feet, any duration of visit is permitted.
2. **Only use the designated restroom -** within the home that is not used by anyone else.
3. **Urinate hourly** – make sure to drink enough water to avoid possible damage to the urinary tract. Men must sit when urinating, and tissue paper must be used to absorb any remaining urine. Hands must be washed immediately following urination in order to avoid contaminating other surfaces. Do not allow leaked urine to sit next to skin.
4. **Move your bowels daily -** using a gentle laxative if necessary, to avoid possible damage to the lower bowel and rectum. Hands must be washed immediately.
5. **Shower or bathe daily -** being sure to thoroughly rinse the genitals and anus.
6. **Use flushable wipes and disposable gloves -** to clean up any spilled body fluids such as urine, feces, and vomit with water and mild soap. If a non-flushable absorber is used, it should be immediately machine washed.
7. **Sleep alone** – in a room separate from other family or care providers by at least 6 feet.
8. **Do not use mass transit** – as you will expose others who sit closer than 6 feet, and you may trigger radiation detection equipment in public transportation terminals.
9. **Do not take <u>non-essential</u> long trips** – by automobile this could put family and care providers at risk for health problems. This excludes trips seeking medical care, etc.
10. **Use dedicated or disposable utensils** – when eating and do not share utensils, food or drinks with anyone else.

PATIENT NAME: <Full Name>

MRN: <Patient Id 1> **DATE OF BIRTH**: <Date of Birth>

Lutathera Patient Discharge Instructions

For the next **4 days:**
If you require inpatient care, precautions should be taken to ensure that exposure to caregivers and other patients is kept As Low As Reasonably Achievable. After 4 days, 99% of the unattached Lu-177 will have typically been excreted.

For the next **7 days:**
1. **Limit your contact with Pregnant Women and Children (<18 years) –** to visits that maintain a distance of 6 feet or more and for durations of less than two hours.

For the next **45 days:**
1. **Do not Breastfeed.**

For the next **70 days:**
1. **Wash your underwear, pajamas, sheets, and any clothes that contain urine or feces –** separately from the rest of the house laundry and run them through a second wash cycle using a standard washing machine.
2. **Keep trash that contains urine or feces that cannot be flushed down a toilet –** (such as sanitary pads and bandages) in a separate plastic trash bag, away from people and pets. Once the 70 days has elapsed, the trash may be disposed of as usual.
3. **In the unlikely event that the patient passes away within 3 months of treatment** – contact the Radiation Safety Officer prior to final arrangements.

For the next **6 months:**
1. **Do not become Pregnant.**
2. **Use Highly Efficient Birth Control.**
3. **Carry your Discharge Card and Letter** – that describes your procedure and contact numbers for your radiation providers should questions or concerns arise.

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TETON CANCER INSTITUTE

PATIENT NAME: <Full Name>

MRN: <Patient Id 1> **DATE OF BIRTH**: <Date of Birth>

Clinical Procedure Document

LUTATHERA Lu^{177} (Lu-DOTATE)

Name of Isotope:	Lutetium-177	
Radiation Emission:	Betas:	490 keV
	Gammas and X-rays:	113 keV (6%)
		208 keV (11%)
Half-Life	Physical:	6.78 days
	Biological (GI):	24 hrs.
	Effective (GI):	21.6 hrs.
Gamma Ray Constant	(Γ):	0.1810 R cm^2 / mCi h

Medical Use: Radionuclide Therapy for treatment of somatostatin receptor-positive gastroenteropancreatic neuroendocrine tumors (GEP-NETs) in adults.

Administration Procedure:

- Administered by IV custom compounded amino acids and antiemetics.
- Administered by IV 200 mCi unit dose of Lutathera (Lu-DOTATE).
- The Patient will be discharged when the infusion is completed.
- The patient must receive enough fluids to urinate at least once per hour (flush twice) for the first 48 hours.
- Lutathera is excreted in stool, urine, and vomit. Use standard precautions, and quarantine any contaminated material for a minimum of 70 days or until indistinguishable from background.

Radiation Safety Considerations:

- The predominant mode of decay is through Beta decay.
- The Patient has been discharged by NRC Regulatory Guide 8.39 rev1 Equation 2 criteria for amount administered and maximum exposure to public from administration being less than 5 mSv.
- The discharge of outpatients receiving Lutathera has been studied and compared to the discharge of patients who have received Iodine-131 thyroid therapy. It has been determined that the external dose rate and total effective dose equivalent is less for Lutathera than it is for I-131.

Medical Considerations:

- **In the event of a low blood pressure episode within 24 hours of receiving Lutathera**: Communicate clearly with all medical professionals that you have received a radionuclide and that the therapy has the remote potential to cause low blood pressure events. This can be treated with the administration of Sandostatin until the blood pressure stabilizes.
- **In the event of a condition requiring medical attention:** Be prepared to present this clinical procedure document, the patient discharge instructions, and the patient wallet card.
- **If a patient passes away after having received Lutathera in the previous 3 month:** contact the Radiation Safety Officer for guidance regarding final arrangements, as cremation and viewings may be restricted.

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TETON CANCER INSTITUTE

PATIENT NAME: <Full Name>

MRN: <Patient Id 1> **DATE OF BIRTH**: <Date of Birth>

Lutathera Patient Discharge Instructions
Patient Acknowledgment of Instructions

☐ I have received written discharge instruction, a letter "To Whom It May Concern" regarding my therapy and the possibility of external radiation exposure and detection, and a clinical description of my medical procedure should I need to see a doctor or seek additional medical care.

I have discussed with my healthcare provider:

☐ Whether I take water pills or other diuretic medications.

☐ The treatment process before my treatment was started.

☐ The radiation safety instructions, especially regarding children and pregnant women, and I have been informed how long to exercise special care.

☐ My plans for transportation home and my arrangements for protecting others once I am home.

☐ My plans for protection others when I leave my home.

☐ The need to separate my biological waste from the rest of the trash, and what should finally be done with the biological waste.

☐ What I should do in the event that I need to see a doctor or seek emergency care.

☐ The relevant contact information for the office in which I received my radiation care and for the radiation safety officer.

☐ The potential issues that may arise regarding radiation isotopes and final arrangements, in the unlikely event that I should pass away within 3 months of my treatment.

_____ _____

Patient Signature Date

_____ _____

Technologist Signature Date

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Lu-177 Dotatate Procedure

Oncologists Criteria for Lutathera Appropriateness

Mark any item with an 'X' that would cause this patient to FAIL TO MEET INCLUSION/EXCLUSION.

1. **Inclusion Criteria**

___ Presence of metastasized or locally advanced abdominal neuroendocrine tumor, inoperable at enrollment time (curative intent), or patient refuses surgery.

___ Ki67 index ≤ 20%. (Path report that shows lower grade of tumor. "The Power Against Progression" Pg 6.)

___ Patients progressive during or after SSA (any dose) at the time of enrolment.

___ Patient's ≥18 years of age.

___ Target lesions overexpressing somatostatin receptors according to an appropriate imaging method (e.g. 111In-pentetreotide (Octreoscan) imaging or 68Ga-DOTA0-Tyr3-Octreotate (or 68Ga-edotreotide) imaging)

2. **Exclusion Criteria**

___ Either serum creatinine >150 μmol/L (>1.7 mg/dL), or creatinine clearance <50 mL/min calculated by the Cockroft Gault method, eventually confirmed by measured creatinine clearance (or measured glomerular filtration rate (GFR) using plasma clearance methods, not gamma camera-based) <50 mL/min (the measured creatinine clearance / GFR is required only as confirmatory exam).

___ Before 1st Administration Hb concentration <5.0 mmol/L (<8.0 g/dL); WBC <2x109/L (2000/mm3); platelets <75x109/L (75x103/mm3).

___ Total bilirubin >3 x ULN.

___ Serum albumin <3.0 g/dL unless prothrombin time is within the normal range.

___ Patient is Pregnant or Lactating (Breast Feeding).

___ Patients who are not using an effective, non-hormonal means of contraception in conjunction with spermicidal gel. [Female patients of childbearing potential (defined as < 2 years after last menstruation and not surgically sterile) / Male patients, who are not surgically sterile or with female partners of childbearing potential].

___ Any surgery, radioembolization, chemoembolization, chemotherapy and radiofrequency ablation within 12 weeks prior to enrolment.

___ Interferons, Everolimus (mTOR-inhibitors) or other systemic therapies within 4 weeks prior to enrolment.

___ Known brain metastases, unless these metastases have been treated and stabilized.

___ Uncontrolled congestive heart failure (NYHA II, III, IV).

___ Uncontrolled diabetes mellitus as defined by a fasting blood glucose >2 ULN.

Lu-177 Dotatate Procedure

Oncologists Criteria for Lutathera Appropriateness (cont.)

___ Any patient receiving treatment with short-acting Octreotide, which cannot be interrupted for 24 h before and 24 h after the administration of 177Lu-DOTA0-Tyr3-Octreotate, or any patient receiving treatment with Octreotide LAR, which cannot be interrupted for at least 4 weeks before the administration of 177Lu-DOTA0-Tyr3-Octreotate, unless the tumor uptake on target lesions is at least as high as normal liver uptake.

___ Patients with any other significant medical, psychiatric, or surgical condition, currently uncontrolled by treatment, which may pose a risk to the patient safety

___ External beam radiation therapy to more than 25% of the bone marrow within the last 10 years.

___ Current spontaneous urinary incontinence making impossible the safe administration of the radioactive IMP.

___ Other known co-existing malignancies except non-melanoma skin cancer and carcinoma in situ of the uterine cervix, unless definitively treated and with no evidence of recurrence.

Oncologist Comments: _____

_____

_____

_____

_____

_____

_____

Oncology Staff:_____ Time:_____ Date:_____

Lu-177 Dotatate Procedure

Nursing Criteria for Lutathera Risk Assessment

Considerations should include: Review of inclusion / exclusion criteria

- Review of comorbidities (chronic kidney disease, chronic liver disease)
- Assess urination, urgency, use of attends, incontinence or self-catheterization
- Assess diarrhea
- Lab results (Creatinine, Bilirubin, CBC, CMP, Pregnancy test)
- Assess the patient's ability to ambulate to the bathroom
- Assess IV access if the patient can't have a PICC line
- Clearance during previous Lutathera administration based on 1 m measurement
- Assess side effects from previous doses/comorbidities for possible dose reduction

Nursing Comments: _____

_____

_____

_____

_____

_____

_____

_____

_____

_____

Evaluated Risk For Post-Infusion Clearance: LOW MEDIUM HIGH

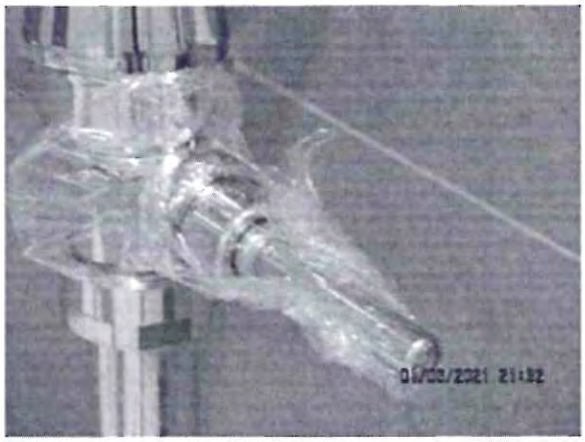
Nursing Staff:_____ Time:_____ Date:_____

Lutathera Radiation Procedure
Layout of Protective Barriers

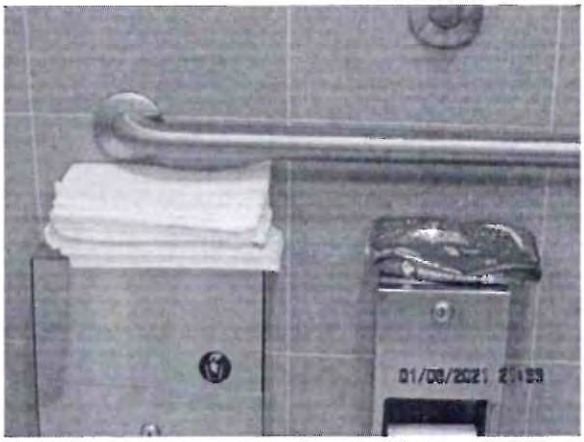
Bathroom

Floor and Sink

Floor and Toilet



Toilet Handle



Paper Towels and Wipes

Door Handle

Sink

Lutathera Radiation Procedure
Layout of Protective Barriers

Infusion Room

Infusion Chair and Side Table

MOUNTAIN VIEW HOSPITAL, IDAHO FALLS ID

Nuclear Regulatory Commission

Response to Apparent Violations in NRC Inspection Report 030-38701/2020-001; EA-21-034

Remote inspection commenced on November 9, 2020; onsite inspection occurred during November 16-19, 2020; continued in-office review conducted through September 2, 2021

Deficiency / Tag #: Apparent violation of 10 CFR 35.75(a)	
Deficiency Brief Description: Release of individuals who had been administered Lu-177 and had radiation dose rates that exceeded the licensee's release criteria.	
Title of Person Responsible for Implementing action	David Theel, Radiation Safety Officer
Date Action Plan was or will be Implemented	10/2021
Is a Monitoring Plan required (Yes or No)	Yes
What will be monitored	Patient discharge radiation dose rates
What is the sample size	100%
What is the threshold of Compliance	100%
How frequently will monitoring occur	Quarterly
How long will monitoring last	Indefinite
Who will oversee the monitoring	Radiation Safety Committee
What committee will receive the reports on the results	Radiation Safety Committee
Attachments/Evidence of Action Plan: A. Attached release criteria/calculated external gamma exposure worksheet B. Attached are the letters sent out to neighboring hospitals regarding radioisotopes.	
Action Plan: • Discontinuation of observation of patients in outpatient setting at Mountain View hospital. • Granted an amendment to our Radioactive Materials License that grants us the use of our inpatient facility for Lu-177 patient if necessary for further observation of the patient. • Provide oral Lasix for assistance in urinary excretion. • Development of release criteria specific to the Lu-177 administration procedure. • Continued monitoring of the patient 4 hours post infusion of Lu-177 with infusion of amino acids and urination. • Patient may be immediately released based on the administered activity of 240mCi patient dose. • Letter sent out to neighboring hospitals stating the intention to administer radioisotopes to our patients and contact information for the RSO.	

2325 Coronado Street, Idaho Falls, ID 83404 • 208.557.2700 • FAX 208.557.2701• www.mountainviewhosptial.org

TEDE Calculations for **Lutathera** **Lu -177**

Thus, for radionuclides with a physical half-life that is greater than 1 day, the following equation applies:

$$D(\infty) = \frac{34.6\,\Gamma\,Q_0 T_p (0.25)}{(100\text{ cm})^2} \qquad \text{(Equation 2)}$$

D(t)= Accumulated exposure at time t, in roentgens
34.6= Conversion factor of 24 hrs/day times the total integration of decay (1.44)
Γ = Specific gamma ray constant for a point source, R/mCi-hr at 1 cm
Q_0 = Initial activity of the point source in millicuries, at the time of the release
T_p = Physical half-life in days
r = Distance from the point source to the point of interest, in centimeters
t = Exposure time in days.

Decay Characteristics of			Lutathera			Lu -177		
%alpha =	0.0%	E_{range} =	0.000 MeV	to	0.000 MeV	Range =	100 µm	
%beta =	78.6%	E_{range} =	0.498 MeV	to	0.498 MeV	Range =	0.164 cm	
%gamma =	11.0%	E_{range} =	0.113 MeV	to	0.208 MeV			
$T_{phys\ 1/2}$ =	6.70 days			$T_{biol\ 1/2}$ =	2.00 days	(due to excretion)		
T_{EFF} =	1.54 days			Time not expressed in days requires a formula change.				
Excretion Rates:								
4 hours		56% of Isotope Remained in Blood						
24 hours		42% of Isotope Remained in Blood						
336 hours		1% of Isotope Remained in Blood						
		Beta Range < 2.5		approx tiss ρ				
Beta Range in tissue:		0.163 g/cm^2	/	0.9922 g/cm^3	=	0.1641 cm		
Rx Information:	200 mCi	unit D	for a maximum RX of	240 mCi		(pkg insert)		
			and an average RX of	200 mCi		(80 kg pt)		

TEDE Calculation	Max at Q_0				Max D=5 mSv	
(R/mCi h at 1 cm)	Γ =	0.1810	Rcm^2/mCih	Rcm^2/m(	Γ =	0.1810
Initial \gamma Activity	Q_0 =	240 mCi			Q_0 =	240 mCi
Half-life	$T_{phys\ 1/2}$ =	6.70 days			$T_{phys\ 1/2}$ =	6.70 days
Occupancy factor	E =	0.25			E =	0.25
(Typically 100 cm)	r =	100 cm			r =	100 cm
	t =				D_∞=	5 mSv
	D_1 =	0.252 R		$\dot{D}$ ((Γ*Q_0)/(100*100))=		8.63 mR/h
TEDE based on Q_0	D_1 =	2.52 mSv		TEDE based on meter reading at 1-meter.		

When calculating for maximum dose rate reading on discharge: rate = Γ x Q_0 / 10,000 cm^2

Γ = 0.1810 Dose rate maximum at 1m for Q_{max} to meet TEDE D_{max} < 5.0 mSv

Q_{max} = 240.0 mCi

dist = 100.0 cm Maximum exposure rate on Q_{max} and D_{max} < 5 mSv: 8.63 mR/h

COMMENTS:
Using NRC Regulatory Guide 8.39 rev 1, and the discharge criteria for administered unit dose of < 240 mCi, the TEDE to public will be less than 5 mSv. Considering 44% excretion after 4 hours, it will be much less.

David Theel, DABR
Medical Physics

Patients may be immediately released with administration of < 240 mCi unit dose.

10 CFR 35.75 TEDE < 5.0 mSv

Mountain View Hospital

Getting you back to what you Love
A Physician Owned Hospital

October 6, 2021

ATTN: Radiation Safety Officer
Eastern Idaho Regional Medical Center
3100 Channing Way
Idaho Falls, ID 83404

To Whom It May Concern,

Mountain View Hospital has a radioactive materials licensed from the Nuclear Regulatory Commission that allows the use for radioisotope therapies. The therapies we currently offer are Lutathera (Lutetium Lu-177 Dotatate), Radium-223 (Xofigo), Iodine-125, Cesium-131 (CS-131), Palladium 103.

We are informing you of this information in the event a patient who has been administered radioactive materials presents to your facility. If you have any further questions please direct them to our Radiation Safety Officer at 208-542-7220.

Respectfully,

David J Theel

David Theel, DABR
Radiation Safety Officer
Teton Cancer Institute/Radiation Oncology an affiliate of Mountain View Hospital

Mountain View Hospital

Getting you back to what you Love
A Physician Owned Hospital

October 6, 2021

ATTN: Radiation Safety Officer
Bingham Memorial Hospital
98 Poplar St.
Blackfoot, ID 83221

To Whom It May Concern,

Mountain View Hospital has a radioactive materials licensed from the Nuclear Regulatory Commission that allows the use for radioisotope therapies. The therapies we currently offer are Lutathera (Lutetium Lu-177 Dotatate), Radium-223 (Xofigo), Iodine-125, Cesium-131 (CS-131), Palladium 103.

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Respectfully,

David Theel, DABR
Radiation Safety Officer
Teton Cancer Institute/Radiation Oncology an affiliate of Mountain View Hospital

Mountain View Hospital

Getting you back to what you Love
A Physician Owned Hospital

October 6, 2021

ATTN: Radiation Safety Officer
Madison Memorial Hospital
450 E Main St.
Rexburg, ID 83440

To Whom It May Concern,

Mountain View Hospital has a radioactive materials licensed from the Nuclear Regulatory Commission that allows the use for radioisotope therapies. The therapies we currently offer are Lutathera (Lutetium Lu-177 Dotatate), Radium-223 (Xofigo), Iodine-125, Cesium-131 (CS-131), Palladium 103.

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Respectfully,

David Theel, DABR
Radiation Safety Officer
Teton Cancer Institute/Radiation Oncology an affiliate of Mountain View Hospital

Mountain View Hospital

Getting you back to what you Love
A Physician Owned Hospital

October 6, 2021

ATTN: Radiation Safety Officer
Portneuf Medical Center
777 Hospital Way,
Pocatello, ID 83201

To Whom It May Concern,

Mountain View Hospital has a radioactive materials licensed from the Nuclear Regulatory Commission that allows the use for radioisotope therapies. The therapies we currently offer are Lutathera (Lutetium Lu-177 Dotatate), Radium-223 (Xofigo), Iodine-125, Cesium-131 (CS-131), Palladium 103.

We are informing you of this information in the event a patient who has been administered radioactive materials presents to your facility. If you have any further questions please direct them to our Radiation Safety Officer at 208-542-7220.

Respectfully,

David Theel, DABR
Radiation Safety Officer
Teton Cancer Institute/Radiation Oncology an affiliate of Mountain View Hospital

Deficiency / Tag #: Apparent violation of 10 CFR 35.310(b)	
Deficiency Brief Description: Failure to document the instructions or training provided to individuals caring for patients administered Lu-177.	
Title of Person Responsible for Implementing action	David Theel, Radiation Safety Officer
Date Action Plan was or will be Implemented	12/2020
Is a Monitoring Plan required (Yes or No)	Yes
What will be monitored	Educational training for use and administration of Lu-177
What is the sample size	100%
What is the threshold of Compliance	100%
How frequently will monitoring occur	Yearly and upon hire
How long will monitoring last	Indefinite
Who will oversee the monitoring	Radiation Safety Officer and Lisa Anderson RN, Teton Cancer Manager
What committee will receive the reports on the results	Radiation Safety Committee
Attachments/Evidence of Action Plan: A. Competency Attached B. Attached training packet/video information- Lutathera Test Vial Training.	
Action Plan: • Completed video conference training for safe handling of Lu-177 for all TCI/Rad Onc staff. Advanced Accelerator Applications and all TCI staff and authorized users describing the proper procedure and protocols: *Hosted by Nancy Bensinger on 12/16/2020* • Competencies for nursing on Lu-177 procedure set up, post procedure clean up and patient education. • MVH Medical Surgical floor completed Lutathera Administration training 03/2021 held by the RSO. • Lutathera refresher course with TCI staff held 07/2021. • We additionally plan to further update the authorized users, staff at TCI, and staff at MVH following the completion of the NRC findings. • Checklists have been created that support the cross-specialty knowledge and procedure for the technologist, the nurse and authorized user. • Policy has been updated to reflect the bullet point detail of the duties for those involved in the procedure. • Specialty silos have been dismantled that previously existed through vendor training and staff meetings so that the technologist, the nurse and the authorized user can now understand the duties of all that are involved in the administration.	

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TETON CANCER INSTITUTE

LUTATHERA TEST VIAL TRAINING

Advanced Accelerators has provided training and test vials to review the insertion of the long and short needles.

Objectives:

- Review the Lutathera administration policy.
- Review the equipment needed for starting the infusion.
- Practice insertion of the long and short needles.
- Sign the completion sheet below.

Completion:

Signature	Date and Time
Steven J Todd MD	12/28/2020
[illegible] MD	12/28/2020

AN AFFILIATE OF MOUNTAIN VIEW HOSPITAL

STEVEN J. TODD, MD • CALVIN J. MCALLISTER, MD • MICHAEL T. CALLAGHAN, MD

RADIATION ONCOLOGY 1550 HOOPES AVE. IDAHO FALLS, ID 83404
TETONCANCER.COM
INFO@TETONCANCER.CO
M 208.542.7220

TETON CANCER INSTITUTE

TCIRO Staff Training
For
Lutathera Administration (Refresher)

Account Manager: Nancy Bensinger DATE: 12/16/2020
Radiotherapy Specialist: Beth TIME: 15:00

1. Clinical Necessity – Neuroendocrine Tumors
2. Patient Selection
    a. Journal of Nuclear Medicine, "NANETS/SNMMI Consensus Statement on Patient Selection and Appropriate Use of Lu-177 Dotatate Peptide Receptor Radionuclide Therapy," Thomas Hope et al
3. Ordering
    a. Authorized User / RAM License
    b. 10 days lead / 1 week with rush
    c. Arrives day before procedure
    d. Batch Release sent day before / morning of
4. Procedure
    a. Batch Release
    b. Room / Bathroom prep
    c. Antiemetics
    d. Amino acids (Lysine and Arginine)
    e. Acrylic Box – from Pine Stars for needle and tubing support
    f. Review of clinical procedure completed with physicians, nurse and technologist (noted that TCIRO performs procedure according to package insert)
5. PICC Line
    a. Dual lumen
6. Pretreatment Education
    a. Prevent dehydration – water and Gatorade
7. RN Patient Interview
    a. How many times a day do you pee?
    b. Chronic Renal issues may be the delineator for High Risk.
8. Practice kits are on the way (vial and long and short needles)
9. Training concluded. (attendance sheet attached)

AN AFFILIATE OF MOUNTAIN VIEW HOSPITAL

STEVEN J. TODD, MD · CALVIN J. MCALLISTER, MD · MICHAEL T. CALLAGHAN, MD

RADIATION
ONCOLOGY 1550
HOOPES AVE. IDAHO
FALLS, ID 83404
TETONCANCER.COM
INFO@TETONCANCER.CO
M 208.542.7220

Lutathera Training Attendance Sheet 12/16/2020

Name	Signature
David Theel – Medical physicist	
Candice Beck – RN	
Gail Kurpinski – PET CT Tech	
Steven Todd, M.D	
Calvin McAllister, M.D.	
Eric Malcom – Radiation Therapist	
Nate Esplin – Radiation Therapist	

TETON CANCER INSTITUTE

TCIRO Staff Training
For
Lutathera Administration
Mar 2021

Presented by David Theel and Julie Snyder to the Nurses of Med Surg

1. Clinical Necessity – Neuroendocrine Tumors
2. Patient Selection
    a. Journal of Nuclear Medicine, "NANETS/SNMMI Consensus Statement on Patient Selection and Appropriate Use of Lu-177 Dotatate Peptide Receptor Radionuclide Therapy," Thomas Hope et al
3. Ordering
    a. Authorized User / RAM License
    b. 10 days lead / 1 week with rush
    c. Arrives day before procedure
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    a. Batch Release
    b. Room / Bathroom prep
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    d. Amino acids (Lysine and Arginine)
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    a. Dual lumen
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8. Practice kits are on the way (vial and long and short needles)
9. Training concluded. (attendance sheet attached)

AN AFFILIATE OF MOUNTAIN VIEW HOSPITAL

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INFO@TETONCANCER.CO
M 208.542.7220

Attendance

Lu-177 Admin / Safety

03/2021 – Training

Medical Staff RN's

Bryce Jones

Craig Funke

Leah Young

Amy Siler

Amber Stephens

Jayce Malloy

Jake Schoence

James Steel

Teresa Johnson

Edy Clarke

Leslie Wilson

LUTATHERA REFRESHER MEETING
July 2021

Review revised Policy and Procedure

- On Policy Stat
- Attachments
- Aria Docs
- Questionnaire

Review Patient Interview documents

- Review of Conditions
- Use many words to describe a condition to minimize the impact of patient's misunderstanding
- Stratify the patients into Low/Medium/High Risk for unusual retention
- 1st dose should be stratified conservatively, and following doses more based on 1st dose performance

Scheduling

- Following Consult TCIRO medical assistant will notify
  - PET/CT as to when the isotope is to be ordered
  - Patient for appointment
  - TCIMO infusion nurse to conduct patient interview
  - MVH medical floor of isotope date
- Following patient interview and patient stratification by TCIMO they will notify TCIRO medical assistant of the location for patient scheduling
- TCIRO medical assistant will finalize scheduling with PET/CT, patient, and MVH medical floor
  - MVH medical floor will need to reserve a room that provides radiation safety to the other patients and staff

Procedure

- At TCIRO
  - TCIMO will secure meds, premeds, and emergency meds
  - Follow the Pre-Administration Checklist
  - Follow the Administration Checklist
  - Follow the Post-Administration Checklist
- At MVH
  - Radiation Safety staff will attend (either PET/CT Tech or Radiation Safety Staff)
  - Authorized User
  - MVH Medical Floor RN will assist with IV pump settings
  - Following the administration a Radiation Survey will be performed at all 4 walls, floor and ceiling as is possible

Distinction between Release Criteria and Patient Safety Observation explained in detail

- Do NOT use the words "Release" or "Criteria" when documenting the procedure or talking with the patient unless you mean the NRC definition based on release for public safety
- Patients may be kept for observation in order to provide medical intervention when they exhibit an inability to maintain excretions at a normal rate. These interventions may include Lasix, etc.

Staff @ Lutheran Refresher meeting
- Renewed policy + Procedure
- Candice Beck, RN
- Daniel Theel Physics
- Brandi Lish, RN
Julie Schneider RN
Dan Kwapinski PET/CT tech
Mulu Ghebrekidan PET/CT Tech
NATE ESPLIN RADIATION THERAPIST
Debra Fuelling RTRT

Teton Cancer Institute-Registered Nurse Lutathera Competency

Employee Name: _____

Lutathera Procedure Competency	Date Task Completed	Evaluator's Initials	Comments
1. Complete **MVH Radiation Safety Module June 2020** on HealthStream			
2. Review PolicyStat - **Lutathera Radiation Procedure**			
Prior To The Ordering of Lutathera Dose: 1. Complete Nurse/Patient interview evaluation criteria by phone or in person. This needs completed prior to the ordering of the Lutathera dose (at least 2 weeks prior to scheduled appointment) A. Review of comorbidities (chronic kidney disease, chronic liver disease) B. Assess urination, urgency, use of attends, incontinence or self-catheterization C. Assess diarrhea D. Review patient's lab results (Creatinine, Bilirubin, CBC, CMP, Pregnancy test) E. Assess the patient's ability to ambulate to the bathroom F. Assess IV access if the patient can't have a PICC line G. Clearance during previous Lutathera administration H. Assess side effects from previous doses/comorbidities for possible dose reduction as outlined in the package insert for Table 2. Recommended Dose Modifications for Lutathera for Adverse Reactions. (2.4)			
2. Determine "risk category" patient falls into based on nurse/patient interview questions see PolicyStat "Lutathera Radiation Procedure")			
3. Confirm prior authorization for Lutathera, Sandostatin, pre-medication has been obtained			
4. Notify Radiation team of the determining risk category patient falls into and plan to move forward with ordering Lutathera			

Pre Administration of Lutathera: 1. Obtain radiation badge from RSO's office and place on yourself at chest level			
2. Identify the correct patient, patient to state name and DOB			
3. Obtain patient vitals			
4. Evaluate PICC line for adequate blood return and ability to flush. If unable to get blood return or flush, place two peripheral IV lines			
5. Prepare and administer anti-emetics over 30 minutes, as prescribed			
6. Prepare amino acids by priming tubing set and a 0.2 micron filter 7. Prepare line for Lutathera infusion using NS 500 ml IV bag and prime with tubing set			
8. After anti-emetics are complete, administer amino acids at a rate of 250 ml/hr (this is to run at this rate for 30 minutes prior to Lutathera infusion and throughout entire Lutathera infusion)			
9. Assist patient to the restroom 10 minutes prior to the start of the Lutathera infusion			
10. Flush second lumen to PICC line or peripheral IV access with 10 cc NS syringe (this is done prior to Authorized User connecting saline line to patient)			
11. Program IV pump with NS 500 ml bag to 50 ml/hr. DO NOT start at this point			
Administration of Lutathera: 1. Attach blood pressure cuff and pulse oximeter to patient and obtain baseline set of vitals			
2. Open clamp to saline line per Authorized Users command			
3. Start IV pump with Lutathera/NS 500 ml at 50 ml/hr (rate on IV pump set at 50 and volume set at 1.5 ml)			
4. Monitor patients vital signs every 3-5 minutes			
5. If Lutathera is infusing without difficulty and patient is stable after 2-3 minutes, increase IV pump rate to 100 ml/hr (rate on IV pump set at 100 and volume set at 3 ml)			
6. If Lutathera is infusing without difficulty and patient is stable after 2-3 minutes, increase IV pump rate to 300 ml/hr (rate on IV pump set at 300 and volume set at 200 ml) for the remaining approximate time of 35-40 minutes			
7. Titrate Lutathera infusion rate down per Authorized User and patient status as needed			
8. If patient is stable, monitor patients vital signs every 5-10 minutes			
9. After the survey reading is determined stable and per Authorized User, increase IV pump to 500 ml/hr for 2-4 minutes			
10. At the completion of the Lutathera, stop IV pump, clamp saline line. Authorized User will disconnect saline line from patients PICC line. Flush PICC line with 10 cc NS syringe			

Post Administration of Lutathera: 1. Turn down the rate of infusion on the amino acids to 200 ml/hr for remaining bag volume			
2. Assist patient to the restroom approximately every 45 minutes and inquire on success of urination for elimination of Lutathera			
3. Administer Lasix (per MO MD order) to assist with fluid clearance, as needed with consideration of Risk Level			
4. Administer NS 1000 ml IV over 1 hour to assist with fluid clearance. May repeat x2 as needed			
5. After 4 hours post administration of Lutathera, administer Sandostatin IM per protocol, as prescribed			
6. When radiation oncology and nursing staff agree, the patient can be prepared for discharge and the PICC line removed per protocol. PICC line to be given to radiation oncology staff for proper disposal			
7. Complete all necessary documentation			
IV Access Competency	**Date Task Completed**	**Evaluator's Initials**	**Comments**
1. Review PolicyStat - **IV Therapy-Peripheral IV Line** a. Demonstrates or reviews with mentor the ability to maintain and care for IV site			
2. Review PolicyStat - **PICC Line Maintenance and Removal of Peripherally inserted central cath (PICC)** a. Reviews with mentor sterile dressing technique on PICC lines b. Demonstrates the ability to maintain PICC c. Demonstrates how to discontinue PICC line			
Intramuscular Injections Competency	**Date Task Completed**	**Evaluator's Initials**	**Comments**
1. Demonstrates the ability to give Z-track and Intramuscular Injections (IM)			
2. Understands Hormonal Agents and How to administer IM • Sandostatin			

Employee Signature: _____ Printed Name:_____

Date:_____ Time:_____

Evaluator Signature: _____ Printed Name:_____

Date:_____ Time:_____

Room Entry Reminder Sheet

Visitor - Before Entry to the Room (checked items):

- ❑ Check-In with the patient's nurse
- ❑ Leave all bags and personal items with the nurse or in your car (No Food)
- ❑ Put on protective paper gown
- ❑ Put on protective paper shoe protectors
- ❑ Review and Discuss with the nurse where to sit as described on the "Inpatient Radiation Safety Precaution Worksheet"
- ❑ Print your name and entry time on the log sheet (Remember to log out upon exiting.)
- ❑ Immediately before **Exiting** the room, remove all paper protective items and place them in the container near the door.

Nurse - Before Entry to the Room (checked items):

- ❑ Only take essential items pertaining to patient care into the room
- ❑ Put on protective paper gown
- ❑ Put on protective paper shoe protectors
- ❑ Review nurse bedside time as described on the "Inpatient Radiation Safety Precaution Worksheet." When possible, provide care from beyond the 2 mR/h line marked with red tape.
- ❑ Print your name and entry time on the log sheet (Remember to log out upon exiting.)
- ❑ Items used for patient care must remain in the room for the duration of the patient admission until they are checked for contamination by the radiation safety officer.
- ❑ Immediately before **Exiting** the room, remove all paper protective items and place them in the container near the door.

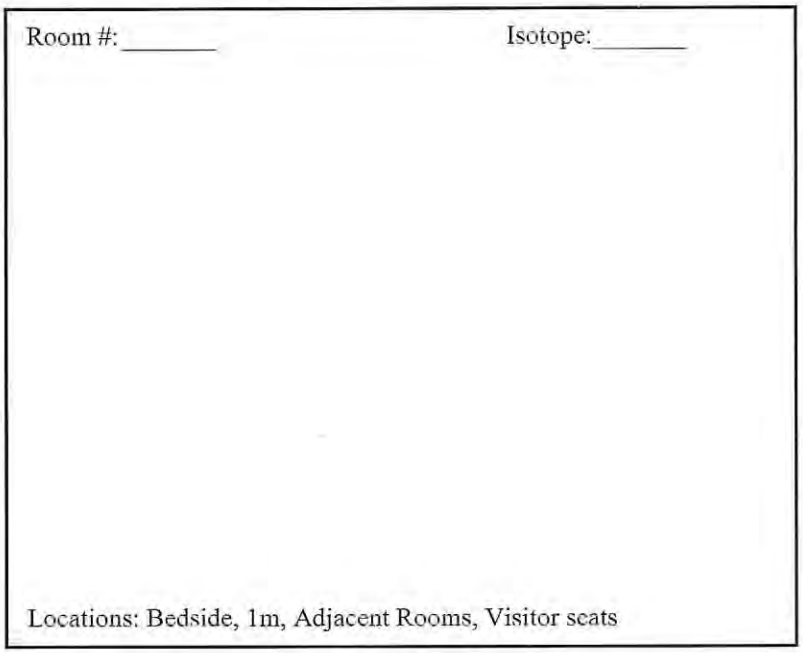
Patient Discharge:

- ❑ Patient received radioisotope procedure at MVH
  - ❑ Patient was Released based on Administered Activity as documented on Written Directive
  - ❑ Patient was Released based on 1 meter exposure reading: _____mR/h

  Name:_____ Date:_____ Time:_____
- ❑ Patient received radiosope procedure outside of MVH, patient Release documents were reviewed, patient is released from MVH utilizing same provided documentation.

Inpatient Radiation Safety Precaution Worksheet

Room Diagram, Labeling and Exposure Rate



A. _____

_____ mR/h

B. _____

_____ mR/h

C. _____

_____ mR/h

D. _____

_____ mR/h

E. 2 mR/h line (____ft)

Adjacency Considerations:_____

_____

Excretion Considerations:_____

Reason for Admission:_____

Expected Duration of Admission: _____(Conservative Overestimate)

ALL VISITORS must check in with the patient's nurse prior to entering room. No personal items are to be taken into the room, and should be left in the car or with the nurse.

- Pregnant Women and visitors under 18 years

  May visit at location _____ for a duration not to exceed _____ hr/day and _____ visits.
- Other Visitors
- May visit at location _____ for a duration not to exceed _____ hr/day and _____ visits.

NURSING GUIDELINES

- Attend Bedside for duration of _____ hr/day not to exceed _____ days

For any questions or irregularities, do not hesitate to contact the radiation safety officer as these may constitute a violation of federal guidelines.

David Theel
Mountain View Hospital
Radiation Safety Officer

Radiation Safety and Patient Care Reminders Training for Medical Staff

1. All staff who care for radiation patients should be assigned the appropriate HealthStream class.
2. Review of Time – Distance – Shielding as a means of reducing exposure for purposes of ALARA. (Differentiate between ALARA and providing necessary medical care.)
3. Comparison of Radiation Contamination to Sterile Technique
4. You don't have to know it all – you just have to know how to find it. (RSO contact info)
5. Nursing badges and log sheet. Primary caregivers only. No staff who are pregnant or are under 18.
6. Visitation rules and log sheet.
7. Need for PPE regarding specific isotope in use.
8. Contact information for radiation safety officer.

Deficiency / Tag #: Apparent violation of 10 CFR 20.2103(a)	
Deficiency Brief Description: Failure to document radiation surveys to demonstrate that rooms used for Lu-177 patients could be released for unrestricted use.	
Title of Person Responsible for Implementing action	David Theel, Radiation Safety Officer
Date Action Plan was or will be Implemented	10/2021
Is a Monitoring Plan required (Yes or No)	Yes
What will be monitored	Survey of the Inpatient and Outpatient rooms.
What is the sample size	100%
What is the threshold of Compliance	100%
How frequently will monitoring occur	Continuous
How long will monitoring last	Indefinite
Who will oversee the monitoring	David Theel Radiation Safety Officer
What committee will receive the reports on the results	Radiation Safety Committee
Attachments/Evidence of Action Plan: A. Policy created for Radiation Inpatient Radioisotope Admission- including survey information. B. Attached Radiation Hot Lab Policy	
Action Plan: • MVH main campus policy has been re-written to allow for the administration, allocated the beds necessary and commenced the training of the hospital staff. • The "Lutathera Radiation Procedure" was also modified to include the possibility of an inpatient administration, though the needle prep and radioisotope delivery by the authorized user remains unchanged. • The new policy includes forms and door postings that clearly remind the staff about the requirements for room entry and visitations. The documents provide clear areas for documentation of the room surveys and wipe tests in such a way as to preserve this information with signatures, date, and time to be scanned into the medical record upon discharge. • Added decontamination producer to align with regulator guidelines. (Cleaning of Inpatient room)	

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Mountain View Hospital

Origination:	*10/2021*
Last Approved:	*10/2021*
Last Revised:	*10/2021*
Next Review:	*10/2022*
Owner:	*David Theel: Radiation Safety Officer*
Policy Area:	*Targeted Patient Quality & Safety Practices (QS)*
References:	

Radiation Inpatient Radioisotope Admission

POLICY:

Patients with acute conditions or refractory symptoms may need to be admitted as inpatients. Precautions are needed for appropriate and safe management of patients who are currently receiving radiation radioisotope treatment in order to ensure safety for the public, other patients and staff.

GUIDELINES:

A. Some radiation radioisotope therapies allowed under Mountain View Hospital's Radioactive Materials License may be administered to inpatients. This process requires a great amount of coordination of care by authorized user, radiation safety officer, education department and trained hospital staff. To that end,
   1. Staff responsible for the administration of the radioisotope will receive annual refresher courses.
   2. Staff responsible for care of the radioactive patient will receive annual refresher courses.
   3. Staff responsible for dietary services, facility cleanliness, and building maintenance will receive annual refresher courses.

B. Upon Scheduling of the Admission:
   1. When an Inpatient Radioisotope Procedure or a Radioactive Patient Admission is scheduled, the radiation safety officer and the manager of the involved nursing unit will be notified and an appropriate room selection based on the isotope to be used will be made.
      a. Must be single occupancy with no carpets.
      b. Should have two external walls or vacancies in the adjacent rooms.
      c. Should be removed from high traffic areas and high occupancy areas such as offices and nursing stations.
   2. The radiation safety officer will discuss with the nursing manager the available nursing schedule, the recentness of HealthStream training, and the need and scheduling of "Radiation Safety and Patient Care Reminders Training for Medical Staff."
   3. The facilities department will be contacted and all non-essential items that can be removed from the room, should be removed prior to admission.

C. Pre-Admission of the Inpatient Radioisotope Procedure or Radioactive Patient Admission
   1. Verify the correct room has been assigned, that all nonessential items have been removed from the

room, and has been appropriately prepared for the patient admission.

2. Verify the staffing schedule as planned with nursing manager.
3. Schedule and Verify that dietary services has been notified to use disposable services.
4. Schedule and Verify that facilities, maintenance, and environmental services have been alerted not to enter room.
5. Room items such as door knobs, sink knobs, telephone, and tv remote, should be covered with cellophane.
6. Patient sitting surfaces should be covered with leak-proof absorbent paper. Patients will not use the same chairs/sitting surfaces as visitors.
7. Ensure the room is stocked with plenty of gloves and shoe covers.
8. Ensure the room has extra trash and linen receptacles, one placed inside the room at the door.
9. The radiation safety officer will mark the floor with a red stripe of reminder tape.
10. The radiation safety officer will post to the door the sign stating "Radiation Procedure in Progress."
11. The radiation safety officer will set up the container of nursing radiation badges and the badge log sheet in an appropriate area near the patient's room.

D. After admission of the Radioactive Patient or After the Administration of the Radioisotope Procedure

1. The radiation safety officer will begin the "Inpatient Radioisotope Checklist."
    a. Complete the room diagram to include information such as:
        i. Room number
        ii. Isotope
        iii. Exposure Rate Readings at various points
            a. Bedside
            b. 1 meter from Bedside
            c. 1 foot from the walls in the adjacent rooms
            d. 3 feet above the floor on the floor above (if applicable)
            e. 6 feet above the floor on floor below (if applicable)
            f. Visitor sitting areas
            g. 2 mR/h line to be measured in feet from bedside
    b. Adjacency Considerations that might impact occupancy and exposure rate calculations.
    c. Excretion Considerations relative to the radiopharmaceutical used and the side effects that can be expected, such as urine, stool, vomit, etc.
    d. Reason for Admission would include whatever comorbidities or conditions necessitated the admission and the expected duration of the admission with an appropriately conservative overestimate for radiation safety.
    e. For Pregnant Women and those under the age of 18 the exposure rate for the designated visitor sitting areas will be used to calculate an exposure that is not to exceed 10 mRem over the course of the designated number of visitations, never to exceed 2 mR/h or 3 mR/day.

f. For all other visitors the exposure rate for the designated visitor sitting areas will be used to calculate an exposure that is not to exceed 50 mRem over the course of the designated number of visitations, never to exceed 2 mR/h or 6 mR/day.

g. For all the medical staff the exposure rate for the bedside care will be used to calculate an exposure that is not to exceed 100 mRem over the course of the designated number of visitations.

i. If an unexpectedly lengthening of the inpatient admission occurs, it may become necessary to designate different staff to badge and care for the patient.

2. The radiation safety officer will check the appropriate boxes for the isotope and the exposure rates of the inpatient admission on the "Room Entry Reminder Sheet."

3. The radiation safety officer will post to the door the completed "Inpatient Radiation Safety Precaution Worksheet" with Room Diagram and the "Room Entry Reminder Sheet."

E. Medical care provided while an inpatient should be performed in such a way as to generate as little contamination as possible.

1. Laboratory specimens should only be collected when absolutely necessary.

a. Any specimens collected, must be returned to the patient room immediately after analysis for appropriate collection, decay storage, and waste.

2. To the extent that it is possible, diagnostics should be performed in the patient room.

a. When it is necessary to transport the patient outside of the room for diagnostic procedures, the radiation safety officer must be contacted first.

F. Patient Discharge

1. When the inpatient has been medically declared ready to discharge, the nursing staff will contact the radiation safety officer.

2. The radiation safety officer will validate the Patient Release based on the radiation isotope procedure.

a. The radiation safety officer will document on the "Patient Discharge and Decontamination" sheet the bases for Patient Release.

b. The radiation safety officer will advise the nursing staff whether the patient may be discharged.

G. Decontamination

1. If available, refer to the decontamination section of the relevant radioisotope administration procedure for specific cleaning guidance.

2. Also refer to policy "Radiation Spill and Decontamination."

3. Use appropriate radiologic detergent and paper towels that are to be collected and stored in decay until safe to dispose of "Radiation Waste Policy."

4. For inpatient rooms, areas of concern would include, but may not be limited to:

a. the patient bed

b. the floor leading to the bathroom

c. the bathroom sink and toilet

d. the patient sitting area

e. the room counter top

f. trash bags(sort out any items that are not contaminated to minimize the number of items in storage)

g. linen bags (sort out any items that are not contaminated to minimize the number of items in storage)

5. Areas that are surveyed with the Ludlum and 44-9 Pancake probe and show more than background radioactivity should be cleaned with the radiologic detergent and paper towels.
6. All areas of concern should then be wipe tested and evaluated for remaining contamination.
   a. Any area where the wipe test exceeds the removable contamination limit by radioisotope as listed in the attached "NRC Contamination Limit" document will be re-cleaned and retested.
7. Document the final wipe test values achieved in the areas of concern on the "Patient Discharge and Decontamination" sheet.
8. Document on the Patient Discharge and Decontamination sheet any items collected for decay storage and waste disposal such as linens, trash, and laboratory samples.

All revision dates: 10/2021

Attachments

Inpatient Radiation Safety Precaution Worksheet.pdf
Inpatient Radioisotope Checklist.pdf
Room Entry Reminder Sheet.pdf
NRC Contamination Limit.pdf
Patient Discharge and Decontamination.pdf

Approval Signatures

Step Description	Approver	Date
Compliance	Ned Hillyard: CHIEF COMPLIANCE OFFICER [JS]	10/2021
Policy Coordinator	Wendy Bateman: POLICY COORDINATOR [JS]	10/2021
Nursing Director	Marian Walker: DIRECTOR of NURSING [JS]	10/2021
Nursing	Marie Rolfe: MANAGER [KR]	10/2021
Nursing	Edythe Clark: MANAGER	10/2021
Nursing	Treana Jones: MANAGER	10/2021
RSO	David Theel: Radiation Safety Officer	10/2021
	Kellee Robinette: ASSISTANT RISK MANAGER	10/2021
	Marie Rolfe: MANAGER	10/2021

Inpatient Radiation Safety Precaution Worksheet

Room Diagram, Labeling and Exposure Rate

Room #:_____ Isotope:_____

Locations: Bedside, 1m, Adjacent Rooms, Visitor seats

A. _____

_____ mR/h

B. _____

_____ mR/h

C. _____

_____ mR/h

D. _____

_____ mR/h

E. 2 mR/h line (____ft)

Adjacency Considerations:_____

_____

Excretion Considerations:_____

Reason for Admission:_____

Expected Duration of Admission: _____(Conservative Overestimate)

ALL VISITORS must check in with the patient's nurse prior to entering room. No personal items are to be taken into the room, and should be left in the car or with the nurse.

- Pregnant Women and visitors under 18 years

  May visit at location _____ for a duration not to exceed _____ hr/day and _____ visits.
- Other Visitors
- May visit at location _____ for a duration not to exceed _____ hr/day and _____ visits.

NURSING GUIDELINES

- Attend Bedside for duration of _____ hr/day not to exceed _____ days

For any questions or irregularities, do not hesitate to contact the radiation safety officer as these may constitute a violation of federal guidelines.

David Theel
Mountain View Hospital
Radiation Safety Officer

Inpatient Radiation Safety Precaution Worksheet

Scheduling

- ❑ Discuss with nurse manager appropriate room (single occup, no carpets, low traffic)
- ❑ Discuss with nurse manager recentness of HealthStream radiation safety refresher
- ❑ Discuss with nurse manager available nurses to provide care
- ❑ Schedule with facilities to remove non-essential items from room

Pre-Admission

- ❑ Verify correct room for admission
- ❑ Verify staffing and recentness of training (provide refresher if necessary)
- ❑ Verify dietary has been notified to provide services with disposable items
- ❑ Verify that facilities, maintenance, and EVS have been told not to enter room
- ❑ Cover items such as door knobs, sink knobs, telephone, and tv remote, should be covered with cellophane
- ❑ Cover patient sitting surfaces with leak-proof absorbent paper
- ❑ Verify room stocked with extra gloves, shoe covers, and gowns (if needed)
- ❑ Verify room has extra linen and trash containers (1 next to door)
- ❑ Place red tape at door and post "Radiation Procedure in Progress"
- ❑ Place nursing badges and log sheet near patient room

Admission

- ❑ Begin "Inpatient Radiation Safety Precaution Worksheet"
- ❑ Document exposure readings from bedside, 1 meter, and find 2 mR/h line
- ❑ Document exposure 1 ft from adjacent room walls
- ❑ Document exposure readings from 3 feet above floor above
- ❑ Document exposure readings from 6 feet above floor below
- ❑ Complete exposure calculations for visitors and staff
- ❑ Complete the "Room Entry Reminder" sheet and post on door

Discharge and Decontamination

- ❑ Complete the Discharge and Decontamination sheet

Name:_____ Date:_____ Time:_____

APPENDIX U – NRC Acceptable Surface Contamination Levels

Nuclide[a]	Removable[b,e,f] (dpm/100 cm^2)
U_{Nat}, U-235, U-238, and associated decay products	1000 α
Transuranics, Ra-226, Ra-228, Th-230, Th-228, Pa-231, Ac-227, I-125, and I-129	20
Th-nat, Th-232, Sr-90, Ra-223, Ra-224, U-232, I-126, I-133, and I-131	200
Beta-gamma emitters (nuclides with decay modes other than alpha emission or spontaneous fission) except Sr-90 and others noted above	1000 $\beta\gamma$

Patient Discharge and Decontamination

Patient Discharge:

- ❑ Patient received radioisotope procedure at MVH
  - ❑ Patient was Released based on Administered Activity as documented on Written Directive
  - ❑ Patient was Released based on 1 meter exposure reading: _____mR/h

    Meter used:_____

    Name:_____ Date:_____ Time:_____
- ❑ Patient received radioisotope procedure outside of MVH, patient Release documents were reviewed, and patient is released from MVH utilizing same provided documentation.

Room Decontamination:

Radioisotope:_____ NRC Limit Removal Limit:_____

Meter used:_____

100 cm^2 wipe areas

Patient Bed:_____ Bathroom Toilet:_____

Floor to Bathroom:_____ Patient Sitting:_____

Bathroom Sink:_____ Room Counter Top:_____

Items collected for decay storage:_____

_____

_____

Name:_____ Date:_____ Time:_____

Room Entry Reminder Sheet

Visitor - Before Entry to the Room (checked items):

- ❑ Check-In with the patient's nurse
- ❑ Leave all bags and personal items with the nurse or in your car (No Food)
- ❑ Put on protective paper gown
- ❑ Put on protective paper shoe protectors
- ❑ Review and Discuss with the nurse where to sit as described on the "Inpatient Radiation Safety Precaution Worksheet"
- ❑ Print your name and entry time on the log sheet (Remember to log out upon exiting.)
- ❑ Immediately before **Exiting** the room, remove all paper protective items and place them in the container near the door.

Nurse - Before Entry to the Room (checked items):

- ❑ Only take essential items pertaining to patient care into the room
- ❑ Put on protective paper gown
- ❑ Put on protective paper shoe protectors
- ❑ Review nurse bedside time as described on the "Inpatient Radiation Safety Precaution Worksheet." When possible, provide care from beyond the 2 mR/h line marked with red tape.
- ❑ Print your name and entry time on the log sheet (Remember to log out upon exiting.)
- ❑ Items used for patient care must remain in the room for the duration of the patient admission until they are checked for contamination by the radiation safety officer.
- ❑ Immediately before **Exiting** the room, remove all paper protective items and place them in the container near the door.

Laboratory and diagnostic studies should be avoided if at all possible. If any need to be ordered, the radiation safety officer needs to be contacted prior.

Mountain View Hospital

Origination:	*09/2019*
Last Approved:	*07/2021*
Last Revised:	*09/2019*
Next Review:	*07/2023*
Owner:	*David Theel: Radiation Safety Officer*
Policy Area:	*Governance & Leadership (GL)*
References:	

Radiation Hot Labs

POLICY:

A. To outline the processes and safety procedures performed in Hot Labs of Mountain View Hospital (NUREG 1556 App T).

B. Mountain View Hospital wants to create a safe working environment for all staff members and all staff members are expected to comply with all safety procedures.

PROCEDURE:

A. Hot Labs are specified per department and no radioactive materials may be used in any area that is not specified:
   1. TCIRO:
      a. Hot Lab
   2. Mountain View Hospital
      a. Hot Lab (Short Stay)

B. Appropriate PPE and Personal Monitoring Devices will be worn:
   1. Laboratory Coats will be worn at all times in areas of radioisotope use.
   2. Personal Monitoring devices will be worn at all times in the manner described in the Radiation Safety Plan when staff is in areas of radioisotope use. If the staff is handling radioactive materials, this will include an appropriate extremity monitor.
   3. Gloves will be worn whenever handling any radioactive materials.

C. The Hot Labs at TCIRO and Mountain View Hospital Short Stay will
   1. Remain locked at all times and access will be limited to authorized personnel only.
   2. Will display the appropriate "**Hot Lab Reference Sheet**" for the materials handled.
   3. Personal items will not be stored in the Hot Lab.
   4. Cosmetics will not be applied in the Hot Lab.
   5. Food and beverages will not be consumed in the Hot Lab.
   6. The appropriate syringe shields will be used for patient doses.
   7. Pipetting will never be done by mouth.

8. No radioactive materials or known contaminated waste will be placed into the trash.

D. Use Area Specific Guidance:

1. Hot Lab at TCIRO:

a. Dose Calibrator Constancy tests will be performed daily using the Cs-137 source and the results documented and stored nearby. Results that are outside of +/- 5% of the expected value will be reported immediately to the RSO.

b. Wipe Tests

i. Wipe tests will be performed weekly for all diagnostic procedures.

ii. Wipe tests will be performed on any day of a therapeutic procedure.

iii. New Background settings will be obtained prior to the wipe test measurement if the daily background has changed since the daily calibration. (e.g. new isotope shipment delivered)

iv. Wipe tests will include 100 cm2 of the following surfaces for a total of 300 cm2:

a. L-Block

b. Counter

c. Floor

v. The Wipe Tests Trigger Level is 2000 dpm and the Minimum Detectable Activity of the AtomLab 500 is 475 dpm.

c. Area Surveys

i. Area Survey will be performed daily when radioactive materials are used:

a. Counter

b. Floors

ii. The Area Survey Trigger Level is > 2 mR/hr. in any controlled area and > 0.2 mR/hr. in any uncontrolled area.

d. Dose Calibrator Linearity tests will be performed quarterly using an FDG source for duration of no more than 8 hours on a day when the constancy of the hot lab background can be maintained throughout the testing period. The results are to be documented, and failed linearity tests will be reported to the RSO immediately. Documentation of the passed linearity tests will be provided to the RSO for review and storage in the Radiation Safety notebook.

e. All radioactive material waste will be disposed of appropriately:

i. Empty FDG syringes will be placed into the shielded sharps for FDG only.

ii. Empty F-18 syringes, IV tubing, and pads will be placed into the storage vault.

iii. Waste from other isotopes will be properly labeled and kept separately for decay storage.

iv. Lutathera waste will be decayed 10 half-lives, and then all medical waste from the procedure will be sent back to Advanced Accelerator Applications to decay the low-level long-lived Lu177m contaminant.

v. Fully decayed waste (10 half-lives and < background) will be surveyed prior to disposal. Once the disposal has taken place, the waste documentation will be completed.

f. Before Leaving the Hot Lab throughout the day, all staff will survey their hands, lab coat and

shoes with the GM survey meter to ensure that they are not contaminated and record the results in the personnel log.

g. At the end of the work day the trash will be surveyed to ensure that there is no contamination present and then will be placed in an area for emptying.

2. Mountain View Hospital Hot Lab:

a. Area Surveys

i. Area Survey will be performed daily to ensure that the level is less than equal to background on days when radioactive materials are used:

a. Counter

b. Floor

b. At the end of the work day the trash will be surveyed to ensure that there is no contamination present and then will be placed in an area for emptying.

E. Failed Quality and Safety Measures:

1. Failed Constancy:

a. Immediately notify the RSO.

b. Following a confirmation of variance, the Dose Calibrator will be sent for immediate repair and no patient procedures will be completed.

c. Following return from repair, and prior to reintroduction of the unit into service, an Accuracy test will be obtained to confirm operation.

d. Following the Passed Accuracy test, the RSO will approve the device for return to service.

2. Failed Linearity:

a. Immediately notify the RSO.

b. The Dose Calibrator will be removed from service, no patient procedures will be completed and a test dose of radioisotope will be ordered for immediate delivery.

c. Following a confirmation of variance, the Dose Calibrator will be sent for immediate repair.

d. Following return from repair, and prior to reintroduction of the unit into service, a test dose of radioisotope will be ordered for immediate delivery.

e. Following a Passed Linearity, an Accuracy test will be obtained.

f. Following the Passed Accuracy test, the RSO will approve the device for return to service.

3. Elevated Wipe Test:

a. When a wipe test is found to be elevated beyond the Trigger Levels indicated above, the area will be cleaned using the vendor specified methods for the particular isotope that is used in the area. The preferred methods for decontamination are to be available in the Hot Lab.

b. Following decontamination, the Wipe Test will be repeated.

c. If the Wipe Tests cannot be brought below the Trigger Level, close the area and immediately notify the RSO.

4. Elevated Area Survey:

a. When an Area Survey is found to be elevated beyond the Trigger Levels indicated above, the

area will be cleaned using the vendor specified methods for the particular isotope that is used in the area. The preferred methods for decontamination are to be available in the Hot Lab.

b. Following decontamination, the Area Survey will be repeated.

c. If the Area Survey cannot be brought below the Trigger Level, close the area and immediately notify the RSO.

All revision dates: 09/2019

Attachments

MVH Hot Lab Reference Sheet.pdf

Approval Signatures

Step Description	Approver	Date
Compliance	Ned Hillyard: Chief Compliance Officer [WB]	07/2021
Policy Coordinator	Wendy Bateman: Policy Coordinator	07/2021
RSO	David Theel: Radiation Safety Officer	07/2021

Mountain View Hospital

Hot Lab Reference Sheet

NRC NUREG1556 Appendix R

Table R.1 Ambient Dose Rate Trigger Levels		
Type of Survey	**Area Surveyed**	**Trigger Level**
Ambient Dose Rate	Unrestricted	0.1 mR/hr
Ambient Dose Rate	Restricted	5.0 mR/hr

NRC NUREG1556 Appendix R

Table R.2 Surface Contamination Levels in Restricted Areas (dpm/100 cm^2)			
Area, clothing	alpha emitters	P-32, Co-58, Fe-59, Co-60, Se-75, Sr-85, Y-90, In-111, I-123, I-125, I-131, Sm-153, Yb-169, Lu-177, Au-198	Cr-51, Co-57, Ga-67, Tc-99m, Hg-197, Tl-201
Restricted areas, protective clothing used only in restricted areas	200	2000	20000

NRC NUREG1556 Appendix R

Table R.3 Surface Contamination Levels in Unrestricted Areas (dpm/100 cm^2)			
Nuclide[1]	**Average[2, 3, 6]**	**Maximum[2, 4, 6]**	**Removable[2, 5, 6]**
I-125, I-126, I-131, I-133, Sr-90	1000	3000	200
Beta-gamma emitters (nuclides with decay modes other than alpha emission or spontaneous fission) except Sr-90 and others noted above.	5000	15000	1000
Ra-226	100	300	20

Survey following any day of use.

Wipe weekly and after each therapeutic procedure.

Recalibrate dose calibrator following any change in ambient exposure (e.g. after isotope delivery).

Emergency Contact Information

Supervisor: Deb 208-530-1396

Radiation Safety Officer

David Theel (office) 208-542-7228

(cell) 208-221-8322

Administrator On-Call call the operator from any hospital phone.

This box is 100 cm2 for purposes of wipe area example.

Minor Spills:

- Readily cleaned by worker without spreading.
- Notify others.
- Prevent spread (e.g. absorbent paper).
- Clean and place waste in appropriately labelled bag.
- Survey and wipe test to appropriate levels, otherwise continue to clean and repeat.
- Unable to clean completely, upgrade to Major Spill.
- Complete Incident Report and copy the RSO.

Major Spills:

- Large volume and/or spread beyond area of use.
- Clear area.
- Prevent spread (e.g. absorbent paper).
- Shield the source if feasible.
- Close room, lock if possible to prevent entry.
- Immediately notify the RSO.
- Decontaminate personnel with water, mild soap and scrubbing. May induce perspiration and repeat.
- Complete Incident Report and copy the RSO.

Deficiency / Tag #: Apparent violation of 10 CFR 20.2003(a)(1)	
Deficiency Brief Description: Discharge to the sanitary sewer of Lu-177 contaminated materials that were not readily soluble in water or biological materials.	
Title of Person Responsible for Implementing action	David Theel Radiation Safety Officer
Date Action Plan was or will be Implemented	December 2020
Is a Monitoring Plan required (Yes or No)	Yes
What will be monitored	In clinic waste of radiological substance
What is the sample size	100%
What is the threshold of Compliance	100%
How frequently will monitoring occur	Continuous
How long will monitoring last	Indefinite
Who will oversee the monitoring	Radiation Safety Officer
What committee will receive the reports on the results	Radiation Safety Committee
Attachments/Evidence of Action Plan: A. Lutathera Radiation Procedure policy (Policy section: Procedure Post Procedure Decontamination and Clean-Up at TCI and Post Procedure Decontamination and Clean-Up at MVH)	
Action Plan: • Addressed in policy proper storage for radiation products disposal. Stored in decay safe. • Discontinuing the use of flushable wipes and institutionalized the use of radiologic detergent and towels as described in the policy. • New policy for in-house care of radioactive patients at the MVH main campus calls for the sequestering of all materials contaminated with urine, and the use of radiological cleaner and paper towels that are to be stored on site and decayed.	

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Mountain View Hospital

Origination:	*12/2020*
Last Approved:	*10/2021*
Last Revised:	*10/2021*
Next Review:	*10/2022*
Owner:	*David Theel: Radiation Safety Officer*
Policy Area:	*Clinical Services: Oncology*
References:	

Lutathera Radiation Procedure

Lutathera (Lu-177 Dotatate)

Indications:

Treatment of somatostatin receptor positive gastroenteropancreatic neuroendocrine tumors (GEP-NETs), including foregut, midgut and hindgut neuroendocrine tumors in adults.

Principle:

Lu-177 Lutetium Dotatate binds to somatostatin receptors with the highest affinity for subtype 2 receptors (SSRT2). Upon binding to the somatostatin receptor expressed cells, including malignant somatostatin receptor positive tumors, the compound is internalized. The beta emission from Lu-177 induces cellular damage by formation of free radicals in somatostatin receptor positive cells and in neighboring cells.

Radiopharmaceutical:

Name of Pharmaceutical: Lutathera

Name of Isotope: Lutetium-177 Dotatate

Radiation Emission: Betas:490 keV

Gammas and X-rays:113 keV (6%)

208 keV (11%)

Half-Life: Physical:6.78 days

Biological (GI):24 hrs.

Effective (GI):21.6 hrs.

Gamma Ray Constant: (Γ): 0.1810 R cm^2 / mCi h

Excretion Pathways: Urine, Stool, Vomit, Saliva

Warnings: Lutetium-177m contaminate has a half-life of 161 days requiring special considerations for low-level radioactive waste.

Survey Meter Efficiency:Ludlum 14C + Pancake Probe:48 %

Safety Labs:

A. (CBC, CMP, PTT/Pregnancy if required) should be performed ≤ 72 hours pre Treatment

B. Peripheral blood cell counts should be followed every other week to document degree of platelet count and WBC count suppression.

Dosage/Standard Procedure:

A. Lutathera is prescribed by standard patient unit dose. Administer 7.4 GBq (200 mCi) every 8 weeks for a total of 4 doses. (Lutathera Pkg Insert 2.2) (Prepared dose to be no more than +/- 5%)

B. Continue long-acting octreotide 30 mg intramuscularly every 4 weeks after completing Lutathera until disease progression or for up to 18 months following treatment initiation. (2.3)

C. Administration may be dose reduced or delayed for up to 16 weeks based on reactions. See package insert for Table 2. Recommended Dose Modifications for Lutathera for Adverse Reactions. (2.4)

D. Do not reduce dose of amino acid solution even if Lutathera dose is reduced. (2.3)

E. 10 – 20% of patients will experience a brief increase in pain (flare pain) for 2 – 3 days following the injection. Usually self-limiting (managed by increasing pain meds), or may be per physician discretion.

Drug Interactions:

A. Somatostatin Analogs: Discontinue long-acting analogs for at least 4 weeks and short-acting octreotide at least 24 hours prior to each Lutathera dose. (2.3, 7.1)

Warnings:

A. Myelosuppression: Monitor blood cell counts. Withhold, reduce dose, or permanently discontinue based on severity. (2.4, 5.2)

B. Secondary Myelodysplastic Syndrome (MDS) and Leukemia: Median time to development: MDS is 28 months; acute leukemia is 55 months. (5.3)

C. Renal Toxicity: Advise patients to urinate frequently during and after administration of Lutathera. Monitor serum creatinine and calculated creatinine clearance. Withhold, reduce dose, or permanently discontinue based on severity. (2.3, 2.4, 5.4)

D. Hepatotoxicity: Monitor transaminases, bilirubin and albumin. Withhold, reduce dose, or permanently discontinue based on severity. (2.4, 5.5)

E. Neuroendocrine Hormonal Crisis: Monitor for flushing, diarrhea, hypotension, bronchoconstriction or other signs and symptoms. (5.6)

F. Embryo-Fetal Toxicity: Lutathera can cause fetal harm. Advise females and males of reproductive potential of the potential risk to a fetus and to use effective contraception (5.7, 8.1, 8.3)

G. Risk of Infertility: Lutathera may cause infertility. (8.3)

To report SUSPECTED ADVERSE REACTIONS, contact Advanced Accelerator Applications USA, Inc. at 1-844-863-1930 or *us-pharmacovigilance@adacap.com,* or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

Consult:

A. Following referral from Medical Oncologist, the patient will consult with the Radiation Oncologist and determine whether to proceed with Lutathera evaluation and treatment.

B. The Radiation Oncology Nurse/Medical Assistant will give the patient the Lutathera procedure and educational materials:

1. Lutathera vendor "What you can expect before, during, and after treatment with Lutathera"
2. TCIRO Lutathera Patient Education Handouts
3. The Radiation Oncology Nurse/Medical Assistant will document the giving of educational materials to the patient in ARIA/EMR.

C. The Oncologists will evaluate the patient to see if Lutathera is appropriate. Mark any item with an 'X' that would cause the patient to FAIL TO MEET INCLUSION/EXCLUSION.

1. **Inclusion Criteria**
   - ___Presence of metastasized or locally advanced abdominal neuroendocrine tumor, inoperable at enrollment time (curative intent), or patient refuses surgery.
   - ___Ki67 index ≤ 20%. (Path report that shows lower grade of tumor. "The Power Against Progression" Pg 6.)
   - ___Patients progressive during or after SSA (any dose) at the time of enrollment.
   - ___Patient's ≥18 years of age.
   - ___Target lesions over-expressing somatostatin receptors according to an appropriate imaging method (e.g. 111In-pentetreotide (Octreoscan) imaging or 68Ga-DOTA0-Tyr3-Octreotate (or 68Ga-edotreotide) imaging)
2. **Exclusion Criteria**
   - ___Either serum creatinine >150 µmol/L (>1.7 mg/dL), or creatinine clearance <50 mL/min calculated by the Cockroft Gault method, eventually confirmed by measured creatinine clearance (or measured glomerular filtration rate (GFR) using plasma clearance methods, not gamma camera-based) <50 mL/min (the measured creatinine clearance / GFR is required only as confirmatory exam).
   - ___Hb concentration <5.0 mmol/L (<8.0 g/dL); WBC <2x109/L (2000/mm3); platelets <75x109/L (75x103/mm3).
   - ___Total bilirubin >3 x ULN.
   - ___Serum albumin <3.0 g/dL unless prothrombin time is within the normal range.
   - ___Patient is Pregnant or Lactating (Breast Feeding).
   - ___Patients who are not using an effective, non-hormonal means of contraception in conjunction with spermicidal gel. [Female patients of childbearing potential (defined as < 2 years after last menstruation and not surgically sterile) / Male patients, who are not surgically sterile or with female partners of childbearing potential].
   - ___Any surgery, radioembolization, chemoembolization, chemotherapy and radiofrequency ablation within 12 weeks prior to enrollment.
   - ___Interferons, Everolimus (mTOR-inhibitors) or other systemic therapies within 4 weeks prior

to enrollment.

- ___Known brain metastases, unless these metastases have been treated and stabilized.
- ___Uncontrolled congestive heart failure (NYHA II, III, IV).
- ___Uncontrolled diabetes mellitus as defined by a fasting blood glucose >2 ULN.
- ___Any patient receiving treatment with short-acting Octreotide, which cannot be interrupted for 24 h before and 24 h after the administration of 177Lu-DOTA0-Tyr3-Octreotate, OR any patient receiving treatment with Octreotide LAR, which cannot be interrupted for at least 4 weeks before the administration of 177Lu-DOTA0-Tyr3-Octreotate.
- ___Patients with any other significant medical, psychiatric, or surgical condition, currently uncontrolled by treatment, which may pose a risk to the patient safety
- ___External beam radiation therapy to more than 25% of the bone marrow within the last 10 years.
- ___Current spontaneous urinary incontinence making impossible the safe administration of the radioactive IMP.
- ___Other known co-existing malignancies except non-melanoma skin cancer and carcinoma in situ of the uterine cervix, unless definitively treated and with no evidence of recurrence.

D. Nurse Patient Interview evaluation criteria

1. Criteria for the evaluation via the Patient Interview
    a. Review of comorbidities (chronic kidney disease, chronic liver disease)
    b. Assess urination, urgency, use of attends, incontinence or self-catheterization
    c. Assess diarrhea
    d. Review patient's lab results (Creatinine, Bilirubin, CBC, CMP, Pregnancy test)
    e. Assess the patient's ability to ambulate to the bathroom
    f. Assess IV access if the patient can't have a PICC line
    g. Clearance during previous Lutathera administration based on 1 m measurement
    h. Assess side effects from previous doses/comorbidities for possible dose reduction as outlined in the package insert for Table 2. Recommended Dose Modifications for Lutathera for Adverse Reactions. (2.4).

E. Nurse/Radiation Oncology staff Patient Interview discoveries that require Authorized User/Radiation Oncologist approval to proceed to scheduling may include but are not limited to:

1. Incontinence
2. Requires full assistance to ambulate to the bathroom
3. Chronic kidney disease
4. Chronic liver disease
5. Creatinine > 1.3
6. Bilirubin > 1.2

Authorization and Financial Aid:

A. Radiation Oncology Medical Assistant will notify Prior Authorization and Financial Counselors.

1. Prior Authorization specialist will work with Lutathera Authorization specialists for commercial insurance, no assistance is offered for Medicare or Medicare supplements.
2. For patients with Medicare only or Medicare supplements, Financial Counselor will meet with patient to inform them of their cost, and to work on financial agreement.

B. Once prior authorization is obtained, and financial agreements are in place, Prior Authorization Specialist will notify Radiation Oncology MA that we are okay to order.

C. Radiation Oncology Medical Assistant or Technologist will print the Written Directive for the patient and have the Authorized User fill in the order section.

D. Radiation Oncology Medical Assistant or Technologist will begin the ordering process for Lutathera through Advanced Accelerators Applications. E-mails will be sent to Nurse, Oncology Pharmacy and the appropriate Schedulers with the anticipated date of infusion.

Scheduling:

A. Considerations for scheduling:
IMPORTANT: There is a 2 week lead time on Lutathera orders

1. At this time Lutathera will only be given on Thursdays to conform to the PET/CT schedule.
2. Radiation Oncology medical assistant will send an e-mail to Nursing staff, Oncology Pharmacy and appropriate Schedulers with anticipated date of infusion.
    a. Nursing staff will make sure that a nurse is scheduled for Radiation Oncology on the date of procedure.
    b. Schedulers will get patient scheduled for PICC line for the day prior to the Lutathera infusion.
    c. Pharmacy staff will get amino acids, antiemetics and Lasix, if necessary, ordered to be delivered to Radiation Oncology on the date of infusion.
3. RSO will be notified of date and time of infusion.
4. Radiation Oncology Medical Assistant or Technologist will verify if the infusion will be done in Radiation Oncology or at Mountain View Hospital. If at the hospital, refer to policy "Radiation Inpatient Radioisotope Admission." Radioisotope administrations will only be done at Mountain View Hospital when the patient as additional medical conditions that require it.

B. Radiation Oncology Medical Assistant or Technologist will contact the patient to verify date and time of procedure.

C. Radiation Oncology Medical Assistant or Technologist will notify the MVH medical floor manager of procedure date for administration and on all patients in case there is a need for an emergency admission.

Pre-Administration:

A. Documents:

1. Partially completed Written Directive containing the prescription information
2. Pre-Administration Radiation Safety Instructions and Acknowledgement

3. Sign for Radiopharmaceutical Bathroom
4. Printed Consent Form from Aria prior to 1st administration.
5. Copy of Nurses Patient Interview regarding pre-existing comorbidities to include side effects from previous doses and consideration of dose reduction and discussions with the patient's Medical Oncologist, when necessary.
6. Print the Lutathera Checklists
    a. Pre-Administration Checklist
    b. Administration Checklist
    c. Post Administration Checklist

B. Preparation of Tech Equipment:
1. Run daily QA on Hot Lab equipment as per the "Hot Lab" policy.
2. Check the Survey Meter calibration value and battery charge.

C. Preparation of **Lutathera Dose:**
1. Receive the dose from the courier as per the "Radiation Package Receipt" policy.
2. Ensure that the dose is appropriately labeled with
    a. Correct Patient Name
    b. Correct Drug
    c. Correct Isotope
    d. Correct Treatment Site
    e. Correct Route of Administration
    f. Correct Dosage/Activity (+/- 5%) [5% of a 200 mCi unit dose = 10 mCi]
    g. Correct Calibration Date
    h. Fill in the appropriate information on the Written Directive and the Nuclear Medicine software. Bioassay for Lutathera is not applicable (NA).
    i. Place/keep dose in lead container, ready to move to the Administration room when the Authorized User is ready to begin the administration.

D. Preparation of **Isolated Bathroom:**
1. Tape absorbent paper around toilet.
2. Cling wrap on door handles, faucet handles and toilet handle.
3. Absorbent paper ready for covering toilet during flushing.
4. See Reference Photos Floor and Sink, Floor and Toilet, Toilet Handle, Paper Towels and Wipes, Door Handle, Sink.

E. Preparation of **Selected Administraion Room:**
1. Absorbent Chux pad on infusion chair.
2. Absorbent paper on side table of chair.
3. Absorbent paper under patient's arm on side that PICC line is placed.

4. See Reference Photo Infusion Chair and Side Table.

F. Infusion and Nursing Preparation:

1. Saline solution 0.9 mg/ml NaCl, 500 mL
2. Saline for priming the lines
3. Amino Acid (lysine and arginine) solution bag (which amino acids)
4. Anti-emetics for IV infusion

G. Complete the "RO Consent for Lutathera" from Aria and scan into Aria/EMR prior to the first administration.

H. Complete the "Patient Acknowledgment of Instructions" form:

1. Review the Patient Instructions with the patient, ensure they understand the instructions, ensure they agree to comply with the instructions, have the patient sign the Acknowledgement form, sign the form as the staff member presenting the instructions, scan the document and upload it to Aria/EMR.

Administration Set Up (Pre-Administration):

A. The Nurse/Radiation Oncology staff will evaluate venous access (either PICC Line or peripheral) first for the amino acids, and a second separate line for the Lutathera. (e.g. other arm, second lumen)

1. Ensure that the PICC line has good blood return and is appropriate for administration.
2. Identify secondary venous access route in case the primary access for Lutathera is compromised.

B. The Nurse will deliver anti-emetics as prescribed.

C. The Nurse will spike the amino acids and prime the tubing set.

D. The Nurse will set the flow rate to 250 cc/hr, open patient line, and begin amino acid administration.

1. If the patient can tolerate 250 cc/hr, continue for 30 minutes.
2. If the patient becomes nauseous, titrate the flow rate down, not going below 200 cc/hr.

E. The Nurse will prepare the Lutathera line and will open 500 cc saline bag, prime IV pump and tubing set, and program for 50 cc/hr.

IMPORTANT: The Nurse/Radiation Oncology staff will have the patient use the bathroom prior to beginning the Lutathera administration.

F. The Nurse staff will prime the m/m patient line with sterile saline in syringe-use 2 way stopcock to attach saline to line.

G. The Nurse/Radiation Oncology staff will lay out the 18 gx 1" needle and the 18 gx 3.5" needle.

H. The Nurse/Radiation Oncology staff will lay out the Authorized Users gloves.

I. The Radiation Oncology staff will ensure that the staff and Authorized User are wearing their personnel radiation badges.

J. The Radiation Oncology staff will bring the Lutathera dose from the Hot Lab to the Uptake Room in the lead container, and radiation monitoring will be done on anyone/anything leaving the room from this point until the Lutathera container has been returned to the Hot Lab, and the pads, needles and tubing used for the Lutathera administration have been collected and removed.

K. The Radiation Oncology staff will place a few 2x2 pads under the Lutathera vial inside the lead container

to improve visibility of the air gap at the top of the Lutathera vial.

L. The Nurse/Radiation Oncology will draw a line marking the fluid level in the Lutathera vial.

M. The Nurse will flush the patient's access catheter.

N. The Authorized User will review the Written Directive and procedure for correctness (Right Patient, Right Drug, Right Isotope, Right Activity, Right Route) and verbally confirm with the staff in the room.

O. The Authorized User will connect the short needle to the saline tubing.

P. The Authorized User will place the short needle into the vial septum, ensuring the needle is inserted only so far as to safely pass the bevel fully into the vial.

WARNING: the short needle cannot touch the solution in the vial.

Q. The Authorized User will connect the patient line to the patient catheter and ensure the patient line is closed.

R. The Authorized User will connect the m/m tubing to the Long 18 gx needle.

S. The Authorized User will place the long needle into the vial at an angle and through the outside edge of the septum and advance the needle to the bottom of the vial; pulling back very slightly to ensure the needle isn't jammed against the vial wall.

Administration:

A. The Radiation Oncology staff will use a survey meter to survey the top of the Lutathera vial (close to but not touching) to obtain a baseline measurement of exposure rate.

B. The Nurse/Radiation Oncology staff will obtain baseline vitals.

C. The Nurse will open the Saline line.

D. The Authorized User will open the Patient line.

E. The Authorized User will confirm the IV Pump is set to 50 cc/hr, verbally declare to start, and the Nurse will start the pump.

F. After 5 minutes of administration the Radiation Oncology staff will survey the patient catheter to confirm flow of Lutathera into the patient.

G. IMPORTANT: The Authorized User/Radiation Oncology staff will ensure that the air gap at the top of the Lutathera vial remains unchanged.

1. If the air gap at the top of the Lutathera vial is lost or getting smaller:
    a. Pause the IV Pump
    b. Determine if tubing system has high pressure or blockage
    c. Use a 10 cc syringe to introduce air into the vial via the port on the saline tubing.

H. If the air gap at the top of the Lutathera vial is lost or getting smaller, refer to G above. The Nurse may slowly increase the flow rate of the IV Pump up to the value slower than the one that compromised the air gap.

I. If after 2 to 3 minutes, the patient catheter is confirmed to contain Lutathera and the air gap at the top of the Lutathera vial remains unchanged, and if the patient is comfortable, the Nurse may increase the flow rate to 100 cc/hr.

J. The Authorized User/Radiation Oncology staff will continue to monitor the air gap at the top of the Lutathera vial for 2 to 3 minutes, and if the air gap remains unchanged and if the patient is comfortable, the Nurse may increase the flow rate to 300 cc/hr over approximately 30 minutes.

K. Once the Authorized User has verified normal infusion **without** concerns, he may turn the infusion over to the Radiation Oncology Staff Member. The Authorized User must remain readily available within the department should any concerns arise. The Radiation Oncology staff will document the administration until the Authorized User returns or the administration is concluded.

L. After 35 minutes, the Radiation Oncology staff will survey the top of the Lutathera vial (close to but not touching) and compare it to the baseline value obtained prior to the patient administration and confirm that the vial is nearly empty of Lutathera.

M. After 40 minutes, and every 5 minutes thereafter, the Radiation Oncology staff will survey the top of the Lutathera vial. A reading will be declared stable when the value changes no more than 5%. (table included on attached Aria Document Administration Checklist)

N. The Authorized User will declare a Stop to the Administration and complete the administration section of the Written Directive.

O. The Nurse/Radiation Oncology staff will **disconnect** the Lutathera infusion from the patient:

   1. Clamp the patient line
   2. Disconnect the tubing from PICC line and cap the line and the patient catheter.

P. The Radiation Oncology staff will take the Lutathera vial to the Hot Lab to measure the residual activity of the Lutathera vial in the dose calibrator and record the activity on the Written Directive.

Q. The Radiation Oncology staff will transport all materials to the Hot Lab to be disassembled including absorbent pad under the patient's arm, Lutathera Vial, lead container, all IV tubing and saline bag, or any other materials that may have become contaminated.

   1. The Radiation Oncology staff will disconnect the saline tubing from the saline bag.
   2. Carefully remove the long needle with the tubing remaining attached from the Lutathera vial.
   3. Carefully remove the short needle from the Lutathera vial.
   4. After disassembly, the materials will be surveyed and placed in proper storage containers for decay and/or storage.

R. Once the Lutathera vial, IV tubing, and contaminated items have been removed from the administration room, the personnel and items will be surveyed a final time before the radiation monitoring of personnel/ items may be discontinued.

Post Administration:

A. The Nurse/Radiation Oncology staff will have the patient use the bathroom every 45 minutes and will inquire whether a stream of urine and average output was achieved by the patient. If there is any concern with the ability of the patient to appropriately clear the Lutathera activity through urination, the Nurse may:

   1. Provide the patient with increased hydration support in order to increase urine output.
   2. Provide the patient with a urinal to measure the output in order to keep up with post administration hydration and clearance and to prevent abnormal tissue retention.
   3. Provide the patient with Lasix by physician order in order to assist with fluid clearance.

B. The Nurse will continue the amino acid infusion at 200 cc/hr for the remainder of the bag.

C. After the 4 hour infusion of amino acids with the possible addition of hydration, the Nurse will administer the long acting Sandostatin.

D. The Nurse will remove the PICC line and the Radiation Oncology staff will add it to the radioactive waste that was previously collected for decay and/or storage.

E. The Radiation Oncology staff will take a final exposure rate at 1 m from the umbilicus and note it on the Written Directive. The exposure rate readings are for understanding patient clearance and completeness of documentation only.

F. The patient may be released according to NRC 10 CFR 35.75 as calculated according to NRC Regulatory Guide 8.39 based on **ADMINISTERED DOSE/ACTIVITY** of less than 240 mCi of Lutathera per patient dose.

G. In the 96 hours (time required to excrete all but 30% of the activity and 99% of all non-sequestered activity) following the administration of Lutathera, if a patient requires hospitalization, consideration for ALARA protection of staff and the public will be made as described in "Precautions for Post Chemo and Radiation Therapy Patients." If admitted to another community healthcare provider, forward a copy of the "Community Colleague" letter.

Post Procedure Decontamination and Clean-Up at TCI:

A. Radiation Oncology staff will use a GM survey meter to check for contamination on the cart, lead pot, equipment, and the areas under the cart and bathroom.

B. Radiation Oncology staff will decontaminate and/or dispose/store of items as appropriate using the radiologic cleaner and paper towels. Paper towels used in patient areas for decontamination may be stored for decay with other patient excreta, and paper towels used to clean up Lutathera liquid/blood spills need to be stored for decay with the medical waste and sent to long term decay.

C. Radiation Oncology staff will check the surface contamination to ensure that Area Surveys < 2 mR/hour in all controlled areas. If the survey is greater than the trigger level, clean the area with the radiologic cleaner and paper towels, then repeat the measurement.

D. Radiation Oncology staff will check the surface contamination to ensure that Wipe Tests of 100 cm^2 < 2000 dpm in all areas where Lutathera was used, stored, or transported. If the wipe test is greater than the trigger level, clean the area with the radiologic cleaner and paper towels, then repeat the measurement.

E. The Radiation Oncology staff will complete the Written Directive for Discharge of Patients and other documentation for the entire procedure as was required, and will scan these documents into the patient's chart.

    1. For Radioisotope spill clean up refer to "Radioisotope Spill and Decontamination (RSO)."

Post Procedure Decontamination and Clean-Up at MVH:

A. Radiation Oncology staff will use a GM survey meter to check for contamination on the cart, lead pot, equipment, and the areas under the cart and bathroom.

B. Radiation Oncology staff will decontaminate and/or dispose/store of items as appropriate using the

radiologic cleaner and paper towels. Paper towels used in patient areas for decontamination may be stored for decay with other patient excreta, and paper towels used to clean up Lutathera/blood spills need to be stored for decay with the medical waste and sent to long term decay.

C. Radiation Oncology staff will check the surface contamination to ensure that Area Surveys < 2 mR/hour in all controlled areas. If the survey is greater than the trigger level, clean the area with the radiologic cleaner and paper towels, then repeat the measurement.

D. Radiation Oncology staff will check the surface contamination to ensure that Wipe Tests of 100 cm^2 < 2000 dpm in all areas where Lutathera was used, stored, or transported. If the wipe test is greater than the trigger level, clean the area with the radiologic cleaner and paper towels, then repeat the measurement.

E. The Radiation Oncology staff will complete the Written Directive for Discharge of Patients and other documentation for the entire procedure as was required, and will scan these documents into the patient's chart.

F. The Patient's room will be marked with the appropriate signs listing things such asa warnings, limits on visitation and prohibition of trash removal that may be necessary as defined by "Radiation In-Patient Safety."

   1. For Radioisotope spill clean up refer to "Radioisotope Spill and Decontamination (RSO)."

Misadministration/Medical Event/Reporting:

A. A Medical Event for Radiolsotope Administration results when:

   1. Administration to the Wrong Person or via the Wrong Route.
   2. Administration of the Wrong Drug or the Wrong Radionuclide.
   3. The Dose Delivered differs from the Prescribed Dose by more than 5 rem.
   4. The Fractional Dose Delivered differs from the Prescribed Dose by 50%.
   5. The Dose Delivered differs from the Prescribed Dose by 20% or more.

B. The Medical Event will be reported to the NRC no later than the next calendar day.

C. Method of Contact and details: **see Mis-administration of a Radiopharmaceutical policy or NRC 10 CFR 35.3045.**

All revision dates: 10/2021, 03/2021, 12/2020

Attachments

RN Interview and MD Criteria.pdf
Lutathera Administration Checklist.pdf
Lutathera Patient Documents.pdf
Lutathera Radiation Protective Barrier Photos.pdf

Approval Signatures

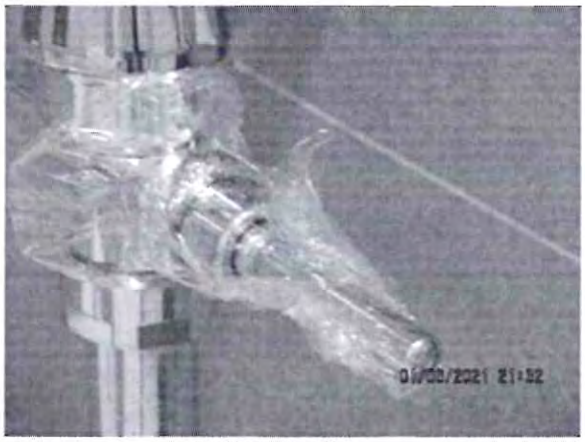
Step Description	Approver	Date
Compliance	Ned Hillyard: CHIEF COMPLIANCE OFFICER [JS]	10/2021
Policy Coordinator	Wendy Bateman: POLICY COORDINATOR [JS]	10/2021
RSO	David Theel: Radiation Safety Officer	10/2021
Radiation Oncology	Lisa Anderson: MANAGER	10/2021
Radiation Oncology	Debra Fuelling: SUPERVISOR	10/2021

Lutathera Radiation Procedure
Layout of Protective Barriers

Bathroom

Floor and Sink

Floor and Toilet



Toilet Handle

Paper Towels and Wipes

Door Handle

Sink

Lutathera Radiation Procedure
Layout of Protective Barriers

Infusion Room

Infusion Chair and Side Table

Deficiency / Tag #: Apparent violation of 10 CFR 20.1904(a)	
Deficiency Brief Description: Failure to label a Lu-177 radioactive waste storage container and its contents to indicate that they contained radioactive materials.	
Title of Person Responsible for Implementing action	David Theel, Radiation Safety Officer
Date Action Plan was or will be Implemented	December 2020
Is a Monitoring Plan required (Yes or No)	Yes
What will be monitored	Storage containers and use with radioactive materials
What is the sample size	100%
What is the threshold of Compliance	100%
How frequently will monitoring occur	Continuous
How long will monitoring last	Indefinite
Who will oversee the monitoring	Radiation Safety Officer
What committee will receive the reports on the results	Radiation Safety Committee
Attachments/Evidence of Action Plan: A. Pictures of labeled storage bin.	
Action Plan: • A sign has been affixed to the waste container. 	

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