1. **Purpose:** The purpose of this SOP is to provide guidance for the release of human patients receiving brachytherapy or radiopharmaceuticals (diagnostic and/or therapeutic doses).

2. **Scope:** MUHC staff should apply this SOP to all clinical patients receiving brachytherapy or radiopharmaceuticals at MUHC facilities.

3. **Definitions:**

   3.1 Brachytherapy – a medical procedure during which sealed radioactive sources are implanted directly into a patient being treated for cancer either permanently or temporarily.

   3.2 Member of the Public – any individual who has not received formal radiation safety training, excluding patients undergoing brachytherapy and radiopharmaceutical procedures, whose annual dose limit is 100 mrem per 10 CFR 20.1301.

   3.3 Radiopharmaceutical – a pharmaceutical drug that emits radiation and is used in diagnostic or therapeutic medical procedures.

   3.4 Total Effective Dose Equivalent – the sum of the effective dose equivalent (for external exposures) and the committed effective dose equivalent (for internal exposures).

4. **Procedure Details:**

   4.1 A human patient or research subject cannot be released until a radiation worker ensures that the dose to members of the public from the patient for the procedure is within the limits of 10 CFR 35.75:

   4.1.1 The total effective dose equivalent (TEDE) to an individual member of the public from the licensed operation cannot exceed 500 mrem (1 mSv) in a year [10 CFR 35.75(a)].

   4.2 The Radiation Safety Manual (RSM) contains activities and dose rates for authorizing the release of patients based on an individual member of the public receiving 500 mrem or less from exposure to the patient. Values for when instructions must be given based on 100 mrem or less from exposure to the patient can also be found in the RSM. These values were developed using Regulatory Guide 8.39 “Release of Patients Administered Radioactive Materials.” Values for radionuclides that are not explicitly listed in RG 8.39 will have calculations documented to demonstrate how values are obtained.

   4.3 Patients can be released using three methods: administered activity, measured dose rate, or patient-specific dose calculations. The RSM lists values for activity administered and measured dose rate at 1 meter.

4.3.1 *Activity administered*: The values used to calculate the activity administered are based on a TEDE of 500 mrem using conservative assumptions. For example, the physical half-life is used rather than the effective half-life. An occupancy of 0.25 is used for a physical half-life greater than 1 day, and a value of 1 is used for a physical half-life of less than or equal to 1 day. The calculation also assumes that no shielding by tissue occurs. If using this method, the patient can be released when the activity administered is less than or equal to the values in the RSM. If a patient is an in-patient, this method can be used for release when the activity has decayed to the values listed in the RSM.

4.3.1.1 Records of release using this method are generally not required if the radiopharmaceutical usage falls under 10 CFR 35.100 or 35.200 uses (i.e. diagnostic administrations).

4.3.1.2 Records of release using this method are required if the administration falls under 10 CFR 35.300 uses for which a written directive is required.

4.3.1.3 Records of release are also required using this method if the patient's release is based on the retained activity rather than administered activity using the physical half-life.

4.3.2 *Measured Dose Rate:* To release a patient using this method, a dose rate will be taken at 1 meter from the patient making sure no other sources interfere with the reading. The measured dose rate should be taken using an ion chamber. If an ion chamber is unavailable, then a Geiger-Mueller (GM) detector may be used only if it has been exposure calibrated using an external source [10 CFR 20.1501(c)]. Release dose rate limits are calculated assuming the patient is a point source and using the activity determined from the "activity administered" release method. When using this method, the patient can be released if the measured dose rate is less than the values listed in the RSM, even if the activity administered is over the values listed in the RSM.

4.3.2.1 Because the release is based on considering shielding by tissue, a record of release is required per 10 CFR 35.75(c) and 10 CFR 35.2075(a).

4.3.3 *Patient-Specific Dose Calculations:* A patient may be released if patient-specific dose calculations confirm an individual exposed to the patient will not exceed 500 mrem. When using this method, the limits for activity administered or dose rate at 1 meter found in the RSM may be exceeded. At MU, this release method is typically only needed for I-131 administrations where an uptake study is performed with a smaller amount of radioiodine prior to I-131 administration.

4.3.3.1 Appendix A contains a template for performing patient-specific dose calculations for I-131 administrations.

4.3.3.2 Additional examples for performing patient-specific dose calculations can be found in Regulatory Guide 8.39.

4.4 Values for release criteria, specifically activity administered and measured dose rate, are subject to change depending on available literature that discusses effective half-lives and retention rates.

4.5 For pure beta emitters, the activity and dose rate limits are not applicable because of the minimal exposures to members of the public resulting from activities normally administered for diagnostic and therapeutic purposes [Regulatory Guide 8.39].

4.6 Upon release of the patient, the individual must be given written instructions on actions to maintain doses to other individuals as low as is reasonably achievable if the TEDE to any other individual is likely to exceed 100 mrem [10 CFR 35.75(b)].

4.6.1 Instructions should be specific to the type of treatment given and may include additional information for individual situations. Instructions should not interfere with or contradict the medical judgment of physicians.

4.6.2 For radiopharmaceuticals, instructions should generally cover topics such as maintaining distance from other persons, minimizing time in public places including posttreatment travel plans, precautions to reduce spreading contamination (including use of bathrooms, kitchen utensils, and laundry as well as frequent hand washing), how to clean up contaminated areas, abstention from forms of intimate contact, the length of time each precaution should be in effect, and appropriate medical and emergency contact information.

4.6.3 For patients receiving permanent implants, instructions should generally cover topics such as maintaining distance from other persons, minimizing time in public places including posttreatment travel plans, abstention from forms of intimate contact, a description or picture of the source implanted, what to do if a source is excreted or falls out, the length of time each precaution should be in effect, and appropriate medical and emergency contact information.

4.6.4 The patient should follow these instructions at home for a period determined by the physician. The time is typically based on the half-life of the radionuclide administered and can be altered depending on the individual patient.

4.6.5 If the TEDE to a nursing infant or child could exceed 100 mrem assuming there were no interruptions of breast-feeding, the instructions must also include guidance on the interruption or discontinuation of breast-feeding and information on the

potential consequences, if any, of failure to follow the guidance. The patient should notify the radiation worker if they are breast-feeding and discuss any questions.

4.7 It is recommended to discuss the release instructions and other requirements prior to administering the radioactive material. This will allow the physician to ensure that the patient can follow the release instructions and give the physician time to discuss with the Radiation Safety Staff if additional measures are needed. If the patient cannot comply with the release instructions, then they may need to be held as an inpatient following the treatment until the patient can be released without having to follow any specific instructions. If this occurs, refer to the radiation safety procedure on room preparation for inpatients.

4.8 While not a requirement, it is a good practice to have documentation that the patient acknowledges they have received and understand instructions for release.

4.9 Records of release must be documented when the TEDE is calculated by using retained activity rather than administered activity, using an occupancy factor less than 0.25 for 1 meter, using biological or effective half-life, or considering shielding by tissue [10 CFR 35.2075(a)].

4.9.1 When a patient is immediately released based on patient-specific dose calculations, the record must include the patient-specific factors (effective half-life, uptake fraction, time the physical half-life was assumed to apply to retention, and occupancy factor), the basis for selecting each factor, and the calculated dose.

4.9.2 When a patient is immediately released based on the measured dose rate, the record must include the measured dose rate, the specific survey instrument used, and the name of the individual performing the survey.

4.9.3 When a patient has a delayed release based on radioactive decay calculations, the record must include the time of the administration, the date and time of release, and the results of the decay calculation.

4.9.4 When a patient has a delayed release based on measured dose rate, the record must include the results of the survey meter measurement, the specific survey instrument used, and the name of the individual performing the survey.

4.9.5 In general, MU does not administer radiopharmaceuticals when individuals may be breast-feeding. However, if this were to occur, then a record of the instructions required must be retained if the radiation dose to the infant or child from continued breastfeeding could result in a TEDE exceeding 500 mrem [10 CFR 35.2075(b)].

4.9.6 All records shall be retained for three years after the date of the release of the individual [10 CFR 35.2075(c)].

5. References:

5.1 NUREG 1556 Volume 9, Revision 3

5.2 Regulatory Guide 8.39 Revision 1

5.3 10 CFR 35

5.4 10 CFR 20

6. Revisions

6.1 Rev 01 – 2023-11-1 – New SOP.

Appendix A – I-131 Therapy Patient Release Calculator

See attached worksheet.