1. **Purpose:** The purpose of this SOP is to provide guidance for developing, maintaining, and implementing procedures for administrations that require written directives (WDs).

2. **Scope:** Authorized Users (AUs) should use this SOP as a guide for developing, maintaining, and implementing procedures for administrations that require WDs: any administration of iodine-131 sodium iodide greater than 30 microcuries, any therapeutic dosage of a radiopharmaceutical, and any therapeutic dose of radiation from byproduct material.

3. **Definitions:**

   **3.1** Authorized Medical Physicist (AMP) – a medical physicist who meets the requirements in 10 CFR 35.51(a) and 35.59 or is identified on an NRC license.

   **3.2** Authorized User (AU) – a physician who is identified on an NRC license that authorizes the medical use of byproduct material.

   **3.3** Brachytherapy – a method of radiation therapy in which sources are used to deliver a radiation dose at a distance of up to a few centimeters by surface, intracavitary, intraluminal, or interstitial application.

   **3.4** High Dose-Rate Remote Afterloader – a brachytherapy device that remotely delivers a dose rate in excess of 12 gray (1200 rads) per hour at the point or surface where the dose is prescribed.

   **3.5** Medical Event – an event that meets the criteria in 10 CFR 35.3045 (a) or (b).

   **3.6** Sealed Source – any byproduct material that is encased in a capsule designed to prevent leakage or escape of the byproduct material.

   **3.7** Therapeutic Dose/Dosage – a radiation dose/dosage delivered from a source containing byproduct material to a patient or human research subject for palliative or curative treatment.

   **3.8** Written Directive – an AU's written order for the administration of byproduct material or radiation from byproduct material to a specific patient or human research subject, as specified in 10 CFR 35.40.

4. **Procedure Details:**

   **4.1** Procedures for any therapeutic dose or dosage of a radionuclide or any dosage of quantities greater than 30 microcuries of I-131 Sodium Iodide:

      4.1.1 A WD must contain the patient or human research subject's name, the radiopharmaceutical administered, the dosage, and the route of administration [10 CFR 35.40].

4.1.2 An AU must sign and date a WD prior to the administration of any dose or dosage [10 CFR 35.40].

4.1.2.1 If, because of the emergent nature of the patient's condition, a delay in order to provide a written directive would jeopardize the patient's health, an oral directive is acceptable. The information contained in the oral directive must be documented as soon as possible in writing in the patient's record. A written directive must be prepared within 48 hours of the oral directive.

4.1.3 A written revision to an existing WD may be made if the revision is dated and signed by an AU before the administration. [10 CFR 35.40(c)(1)].

4.1.4 WDs must be retained for three years and must be available for inspection [10 CFR 35.2040].

4.1.5 Prior to the administration of any dose or dosage, the identity of the patient or human research subject must be positively verified as the individual named in the WD. Examples of positive patient identity verification include examining the patient’s ID bracelet, hospital ID card, driver’s license, or other forms of identification [10 CFR 35.41].

4.1.6 Prior to the administration of any dose or dosage, the specific details of the administration must be verified to be in accordance with the WD. All components of the WD (radionuclide, total dose, etc) must be confirmed by the person administering the dose or dosage to verify with the WD [10 CFR 35.41]. Appropriate verification methods include:

4.1.6.1 Measuring the activity in a dose calibrator.

4.1.6.2 Checking the serial number of the sealed sources behind an appropriate shield.

4.1.6.3 Using color-coded sealed sources.

4.1.6.4 Using clearly marked storage locations.

**4.2** Procedures for sealed therapeutic sources and devices containing sealed therapeutic sources:

4.2.1 A WD must contain:

4.2.1.1 For high dose-rate remote afterloading brachytherapy: The radionuclide, treatment site, dose per fraction, number of fractions, and total dose [10 CFR 35.40(b)(5)].

4.2.1.2 For temporary implants, before implantation: record the treatment site, radionuclide, and dose [10 CFR 35.40(b)(7)(i)]. For temporary implants after

implantation but before completion of the procedure: record the radionuclide, treatment site, number of sources, total source strength and exposure time (or the total dose), and date [10 CFR 35.40(b)(7)(ii)].

4.2.1.3 For permanent implants, before implantation: record the treatment site, radionuclide, and total source strength [10 CFR 35.40(b)(6)(i)]. For permanent implants after implantation but before the patient leaves the post-treatment recovery area: record the treatment site, the number of sources implanted, the total source strength implanted, and the date [10 CFR 35.40(b)(6)(ii)].

4.2.2 An AU must sign and date a WD prior to the administration of any dose or dosage [10 CFR 35.40].

4.2.2.1 If, because of the emergent nature of the patient's condition, a delay in order to provide a written directive would jeopardize the patient's health, an oral directive is acceptable. The information contained in the oral directive must be documented as soon as possible in writing in the patient's record. A written directive must be prepared within 48 hours of the oral directive.

4.2.3 A written revision to an existing written directive may be made if the revision is dated and signed by an authorized user before the administration of the brachytherapy dose or the next fractional dose [10 CFR 35.40(c)(1)].

4.2.4 WDs must be retained for three years and must be available for inspection [10 CFR 35.2040].

4.2.5 Prior to the administration of any brachytherapy dose, the identity of the patient or human research subject must be positively verified as the individual named in the WD. Examples of positive patient identity verification include examining the patient’s ID bracelet, hospital ID card, driver’s license, or other forms of identification [10 CFR 35.41].

4.2.6 To ensure that the dose is delivered in accordance with the WD, the AU must sign and date the treatment plan, indicating approval. The treatment plan should provide sufficient information and direction to meet the objectives of the WD.

4.2.7 For sealed sources inserted into the patient’s body, radiographs or other comparable images will be used as the basis for verifying the position of the nonradioactive dummy sources and calculating the administered dose before administration. Immediately after implanting sources in the patient, a survey of the patient and the surrounding area will be performed to confirm that no sources are unintentionally located outside of the patient.

4.2.7.1 For some brachytherapy procedures, the use of various fixed geometry applicators (e.g., appliances or templates) may be required to establish the location of the temporary sources and to calculate the exposure time (or, equivalently, the total dose) required to administer the prescribed brachytherapy treatment. In these cases, radiographs or other comparable images may not be necessary, provided the position of the sources is known prior to insertion of the radioactive sources and calculation of the exposure time (or, equivalently, the total dose).

4.2.8 Dose calculations will be checked before administering the prescribed therapy dose. An AU or a qualified person under the supervision of an AU (e.g., an AMP, oncology physician, dosimetrist, or radiation therapist), preferably an individual who did not make the original calculations, will check the dose calculations. Methods for checking the calculations include the following:

4.2.8.1 For computer-generated dose calculations, examining the computer printout to verify that correct input data for the patient was used in the calculations (e.g., source strength and positions).

4.2.8.2 For computer-generated dose calculations entered into the therapy console, verifying correct transfer of data from the computer (e.g., channel numbers, source positions, and treatment times).

4.2.8.3 For manually generated dose calculations, verifying:

4.2.8.3.1 No arithmetical errors.
4.2.8.3.2 Appropriate transfer of data from the WD, treatment plan, etc.
4.2.8.3.3 Appropriate use on nomograms (when applicable).
4.2.8.3.4 Appropriate use of all pertinent data in the calculations.

4.2.8.4 If an AU determines that delaying brachytherapy treatment in order to perform the checks of dose calculations would jeopardize the patient's health because of the emergent nature of the patient's medical condition, the checks of the calculations will be performed within two working days of completion of the brachytherapy treatment.

4.2.9 Before the first use of treatment planning or dose calculating computer programs for brachytherapy dose calculations, acceptance testing of the programs will be performed by a qualified person. Each treatment-planning or dose-calculating computer program will be assessed, based on specific needs and applications. A check of the acceptance testing will also be performed after each source replacement or when spot-check measurements indicate that the source output

differs by more than 5 percent from the output obtained at the last full calibration corrected mathematically for radioactive decay.

4.2.10 For HDR patients, a weekly chart check will be performed by a qualified person under the supervision of an AU (e.g., an AMP, dosimetrist, oncology physician, or radiation therapist) to detect mistakes (e.g., arithmetical errors, miscalculations, or incorrect transfer of data) that may have occurred in the daily and cumulative dose administrations from all treatment fields or in connection with any changes in the WD or treatment plan.

4.2.11 For HDR units, independent checks on full calibration measurements will be performed. The independent check will be performed by either:

4.2.11.1 An individual who did not perform the full calibration (who meets the requirements specified in 10 CFR 35.51) using a dosimetry system other than the one that was used during the full calibration (the dosimetry system will meet the requirements specified in 10 CFR 35.630).

4.2.11.2 An AMP (or an oncology physician, dosimetrist, or radiation therapist who has been properly instructed) using a thermoluminescence dosimetry service available by mail that is designed for confirming therapy doses and that is accurate within 5 percent.

**4.3** Review of administrations requiring a written directive:

4.3.1 The Radiation Safety Staff (RSS) will perform routine reviews of administrations in each applicable program area (radiopharmaceutical therapy, HDR, implant brachytherapy, etc) to determine whether the administered radiopharmaceutical dosage or radiation dose was in accordance with the WD or treatment plan, as applicable, and whether a medical event has occurred [10 CFR 35.41]. When deviations from the WD are found, the cause of each deviation and the action required to prevent recurrence will be identified.

4.3.2 For permanent implant brachytherapy, within 60 calendar days from the date the implant was performed, a determination will be made of the total source strength administered outside of the treatment site compared to the total source strength documented in the post-implant portion of the WD, to evaluate whether a medical event has occurred.

**4.4** Reports of medical events:

4.4.1 In the event of a medical event the RSS will notify the U.S. Nuclear Regulatory Commission (NRC) Operations Center at 301-816-5100 no later than the next calendar day after discovery of the medical event. A written report will be

submitted to the Region III office within 15 days after the discovery of the medical event [10 CFR 35.3045]. The referring physician and the patient should also be notified.

**5. References:**

**5.1** NUREG 1556 Volume 9, Revision 3, Appendix S

**6. Revisions**

**6.1** Rev 01 – 2024-1-1 – New SOP.