Health
AUGUSTA UNIVERSITY

Written Directives Program

September 2016

Approved:

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Radiation Oncology

Written Directives Program

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Written Directives Program

1. Purpose

To establish procedures that provide high confidence that each administration of radioactive material (or associated radiation) is administered as directed by the authorized user physician.

2. Requirement

Georgia Rule 391-3-17-.05, *Use of Radionuclides in the Healing Arts* (hereafter Rule .05)

3. Definitions

Authorized medical physicist (AMP) means a physicist who meets the requirements in Rule .05 (23); is approved as an authorized medical physicist by the institution Radiation Safety Committee, and is designated by name on a GRHS radioactive material sublicense.

Authorized Nuclear Pharmacist (ANP) means a pharmacist who meets the requirements in Rule .05 (24 and 27); is approved as an authorized nuclear pharmacist by the institution Radiation Safety Committee, and is designated by name on a GRHS radioactive material sublicense.

Authorized user (AU) means a physician, dentist, or podiatrist who: meets the requirements in Rule .05 (27) and .05(43)(a), .05(47)(a), .05(52)(a), .05(53)(a), .05(54)(a), .05(63)(a), .05(66)(a), or .05(84)(a); is approved as an authorized user by the institution Radiation Safety Committee; and is designated by name on a GRHS radioactive material sublicense.

Brachytherapy means a method of radiation therapy in which plated, embedded, activated, or sealed sources are utilized to deliver a radiation dose at a distance of up to a few centimeters, by surface, intracavitary, intraluminal or interstitial application.

High dose-rate remote afterloader (HDR) means a device that remotely delivers a dose rate in excess of 12 gray (1200 rad) per hour at the treatment site.

Manual brachytherapy means a type of therapy in which brachytherapy sources are manually applied or inserted.

Medical Event means any event, except for an event that results from patient intervention, in which the administration of byproduct material or radiation from byproduct material results in—

(1) A dose that differs from the prescribed dose or dose that would have resulted from the prescribed dosage by more than 0.05 Sv (5 rem) effective dose equivalent, 0.5 Sv (50 rem) to an organ or tissue, or 0.5 Sv (50 rem) shallow dose equivalent to the skin; and

(i) The total dose delivered differs from the prescribed dose by 20 percent or more;

(ii) The total dosage delivered differs from the prescribed dosage by 20 percent or more or falls outside the prescribed dosage range; or

(iii) The fractionated dose delivered differs from the prescribed dose, for a single fraction, by 50 percent or more.

(2) A dose that exceeds 0.05 Sv (5 rem) effective dose equivalent, 0.5 Sv (50 rem) to an organ or tissue, or 0.5 Sv (50 rem) shallow dose equivalent to the skin from any of the following—

(i) An administration of a wrong radioactive drug containing byproduct material;

(ii) An administration of a radioactive drug containing byproduct material by the wrong route of administration;

(iii) An administration of a dose or dosage to the wrong individual or human research subject;

(iv) An administration of a dose or dosage delivered by the wrong mode of treatment; or

(v) A leaking sealed source.

(3) A dose to the skin or an organ or tissue other than the treatment site that exceeds by 0.5 Sv (50 rem) to an organ or tissue and 50 percent or more of the dose expected from the administration defined in the written directive (excluding, for permanent implants, seeds that were implanted in the correct site but migrated outside the treatment site).

(4) Any event resulting from intervention of a patient or human research subject in which the administration of radioactive material or radiation from radioactive material results or will result in unintended permanent functional damage to an organ or a physiological system, as determined by a physician.

Nuclear medicine technologist (NMT) means an individual who meets the requirements of Rule .05(25)(a) and is under the supervision of an authorized user, to prepare or administers radioactive drugs to patients or human research subjects, or perform in vivo or in vitro measurements for medical purposes.

Prescribed dosage means the specified activity or range of activity of radioactive drug as documented:

(1) In a written directive; or

(2) In accordance with the directions of the authorized user for procedures performed pursuant to Rule .05(41), (44) and (48).

Prescribed dose means:

(1) For gamma stereotactic radiosurgery, the total dose as documented in the written directive;

(2) For brachytherapy, either the total source strength and exposure time or the total dose, as documented in the written directive; or

(4) For remote brachytherapy afterloaders, the total dose and dose per fraction as documented in the written directive.

Principal Authorized User (PAU) means the AU who holds the radioactive material sublicense, supervises the AUs named on the sublicense, and is responsible for the safe use of radioactive material listed on the sublicense.

Radiation Safety Officer (RSO) means an individual who meets the requirements in Rule .05(22)(a) or .05(22)(c)1. and .05(27); and is identified as a Radiation Safety Officer on the GRHS Georgia Radioactive Materials License.

Radioactive drug means any chemical compound containing radioactive material that may be used on or administered to patients or human research subjects as an aid in the diagnosis, treatment, or prevention of disease or other abnormal condition.

Radiation Therapist means an individual who meets the requirements of Rule .05(25)(b) and is under the supervision of an authorized user to perform procedures and apply radiation emitted from sealed radioactive sources to human beings for therapeutic purposes.

Sealed source means any radioactive material that is encased in a capsule designed to prevent leakage or escape of the radioactive material.

Stereotactic radiosurgery (SR) means the use of external radiation in conjunction with a stereotactic guidance device to very precisely deliver a dose to a treatment site.

Therapeutic dosage means a dosage of unsealed radioactive material that is intended to deliver a radiation dose to a patient or human research subject for palliative or curative treatment.

Therapeutic dose means a radiation dose delivered from a sealed source containing radioactive material to a patient or human research subject for palliative or curative treatment.

Treatment site means the anatomical description of the tissue intended to receive a radiation dose, as described in a written directive.

Written directive (WD) means an authorized user's written order for the administration of radioactive material or radiation from radioactive material to a specific patient or human research subject, as specified in Rule .05(19).

4. Applicability

A written directive must be dated and signed by an authorized user before the administration of ^{131}I sodium iodide greater than 1.11 megabecquerels (MBq), any therapeutic dosage of unsealed byproduct material, or any therapeutic dose of radiation from byproduct material, except:

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.

5. Written Directive Content

The written directive must contain the patient or human research subject's name and the following information--

(1) For any administration of quantities greater than 1.11 MBq (30 microCi) of ^{131}I sodium iodide: the dosage;

(2) For an administration of a therapeutic dosage of unsealed byproduct material other than ^{131}I sodium iodide: the radioactive drug, dosage, and route of administration;

(3) For gamma stereotactic radiosurgery: the total dose, treatment site, and values for the target coordinate settings per treatment for each anatomically distinct treatment site;

(4) For high dose-rate remote afterloading brachytherapy: the radionuclide, treatment site, dose per fraction, number of fractions, and total dose; or

(5) For all other brachytherapy, including low, medium, and pulsed dose rate remote afterloaders:

(i) Before implantation: treatment site, the radionuclide, and dose; and

(ii) After implantation but before completion of the procedure: the radionuclide, treatment site, number of sources, and total source strength and exposure time (or the total dose).

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 dosage of unsealed byproduct material, the brachytherapy dose, the gamma stereotactic radiosurgery dose, the teletherapy dose, or the next fractional dose.

6. General Requirements for Administration of Radioactive Material or Associated Radiation

The following requirements apply for any administration requiring a written directive:

(1) The patient's or human research subject's identity is verified before each administration; and

(2) Each administration is in accordance with the written directive.

At a minimum, for each procedure requiring a written directive, requirements include:

(1) Verifying the identity of the patient or human research subject;

(2) Verifying that the administration is in accordance with the treatment plan, if applicable, and the written directive;

(3) Checking both manual and computer-generated dose calculations; and

(4) Verifying that any computer-generated dose calculations are correctly transferred into the consoles of therapeutic medical units.

7. Specific Procedures for Any Therapeutic Dose or Dosage of a Radionuclide, Including Doses or Dosages of Accelerator-Produced Radioactive Materials and Discrete Sources of Radium-226, or Any Dosage of Quantities Greater than 1.11 MBq (30 microCi) of 131I Sodium Iodide

(1) An AU must date and sign a WD prior to the administration of any dose or dosage. Written directives may be maintained in patients' charts.

(2) Prior to administering a dose or dosage, the identity of a patient or human research subject will 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 Social Security card. Asking or calling the patient's name does not constitute positive patient identity verification.

(3) The specific details of the administration will be verified, including the dose or dosage, in accordance with the WD or treatment plan. All components of the WD (radionuclide, total dose or dosage, etc.) will be confirmed by the person administering the dose or dosage to verify agreement with the WD. Appropriate verification methods include: measuring the activity in the dose calibrator, checking the serial number of the sealed sources behind an appropriate shield, using color-coded sealed sources, or using clearly marked storage locations.

8. Additional procedures for Sealed Therapeutic Sources and Devices Containing Sealed Therapeutic Sources

(1) To ensure that the dose is delivered in accordance with the WD, the AU (and the neurosurgeon for SR therapy) must date and sign (indicating approval of) the treatment plan that provides sufficient information and direction to meet the objectives of the WD.

(2) For sealed sources inserted into the patient's body, radiographs or other comparable images (e.g., computerized tomography) will be used as the basis for verifying the position of the nonradioactive dummy sources and calculating the administered dose before administration. 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).

(3) 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 one who did not make the original calculations, will check the dose calculations. Methods for checking the calculations include the following:

(i) 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).

(ii) 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).

(iii) For manually-generated dose calculations, verifying:
- a. No arithmetical errors;
- b. Appropriate transfer of data from the WD, treatment plan, tables, and graphs;
- c. Appropriate use of nomograms (when applicable); and
- d. Appropriate use of all pertinent data in the calculations.

(4) After implantation but before completion of the procedure: record in the WD the radionuclide, treatment site, number of sources, and total source strength and exposure time (or

the total dose). For example, after insertion of permanent implant brachytherapy sources, an AU should promptly record the actual number of radioactive sources implanted and the total source strength. The WD may be maintained in the patient's chart.

(5) Acceptance testing will be performed by a qualified person (e.g., an AMP) on each treatment planning or dose calculating computer program that could be used for dose calculations. Acceptance testing will be performed before the first use of a treatment planning or dose calculating computer program for therapy dose calculations. 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% from the output obtained at the last full calibration corrected mathematically for radioactive decay.

(6) Independent checks on full calibration measurements will be performed by an AMP. The independent check will include an output measurement for a single specified set of exposure conditions and will be performed within 30 days following the full calibration measurements. The independent check will be performed by either:

> (i) An individual who did not perform the full calibration using a dosimetry system other than the one that was used during the full calibration; or
>
> (ii) 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%.

(6) For SR, particular emphasis will be directed on verifying that the stereoscopic frame coordinates on the patient's skull match those of the treatment plan.

(7) 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.

(8) Treatment planning computer systems using removable media to store each patient's treatment parameters for direct transfer to the treatment system will have each card labeled with the corresponding patient's name and identification number. Such media may be reused (and must be relabeled) in accordance with the manufacturer's instructions.

9. Written Directives Program Review

(1) The RSO/designee shall conduct periodic reviews of the WDs for each applicable program area (e.g., radiopharmaceutical therapy, high-dose-rate brachytherapy, implant brachytherapy, gamma stereotactic radiosurgery) no less frequently than each calendar quarter.

(2) The RSO shall report deviations from the WD to the Principal Authorized User, who shall determine the cause of each deviation and the action required to prevent recurrence.

(2) The RSO shall report the review findings to the Radiation Safety Committee during regularly scheduled meetings.

10. Reporting a Medical Event

Medical events are reported to the state Radioactive Materials Program by the RSO. The PAU shall notify the RSO as soon as possible following the detection of a medical event. The RSO will report medical events to the Radioactive Materials Program no later than the next calendar day after discovery. The RSO will follow-up with a written report based on input from the PAU, including:

(1) The name of the prescribing physician;

(2) A brief description of the event;

(3) Why the event occurred;

(4) The effect, if any, on the individual(s) who received the administration;

(5) What actions, if any, have been taken or are planned to prevent recurrence; and

(6) Certification that the licensee notified the individual (or the individual's responsible relative or guardian), and if not, why not.

(7) The report may not contain the individual's name or any other information that could lead to identification of the individual.

Additionally, the authorized user shall provide notification of the event to the referring physician and also notify the individual who is the subject of the medical event no later than 24 hours after its discovery, unless the referring physician personally informs the licensee either that he or she will inform the individual or that, based on medical judgment, telling the individual would be harmful. The authorized user is not required to notify the individual without first consulting the referring physician. If the referring physician or the affected individual cannot be reached within 24 hours, the authorized user shall notify the individual as soon as possible thereafter. The authorized user may not delay any appropriate medical care for the individual, including any necessary remedial care as a result of the medical event, because of any delay in notification. The notification of the individual who is the subject of the medical event may be made instead to that individual's responsible relative or guardian. If a verbal notification is made, the authorized user shall inform the individual or appropriate responsible relative or guardian that a written description of the event can be obtained upon request.

11. Forms

Example templates for written directives are provided at appendices A-C. Principal Authorized Users are not limited to the example templates, and may adopt any written directive format (including digital) that best meets clinical needs. The elements of the written directive may be incorporated in the patient record. In all cases the written directive must contain the elements of paragraph 5, above, and be readily retrievable for review.

Appendix A – Example Template for Written Directive Nuclear Medicine

GEORGIA CANCER CENTER
AUGUSTA UNIVERSITY

Radiation Therapy Center

Written Directive for Radiopharmaceutical Therapy

1. Authorized User's Prescription

Patient name: _____ Treatment Date: _____

Hospital ID number: _____ Prescribed Dose: _____

Treatment site: _____ Radiopharmaceutical: _____

Diagnosis: _____ Route of administration: _____

This patient may be released following radiopharmaceutical administration on the basis of quantity administered, in accordance with Georgia Rule 391-3-17-.05 (37) (a), and the guidance of NUREG 1556, Volume 9, Appendix U and column 1 of Table U.1.

2. Pregnancy/Breast Feeding Status (Female Patients)

Hysterectomy ☐ Tubal Ligation ☐ Age 55 or older ☐

β hCG ☐ Positive ☐ Negative Date pregnancy test performed: _____

Breast Feeding ☐ Yes ☐ No

3. Verification of Patient Identification

Verbal confirmation of patient name: yes ☐ no ☐

Additional confirmation of patient identification by: (check one)

☐ date of birth ☐ SSN ☐ ID bracelet ☐ insurance card

☐ address ☐ signature ☐ other _____

4. Verification of Administration with Prescription

Radiopharmaceutical agrees with that ordered in prescription: YES ☐ NO ☐

Dosage agrees with that ordered in prescription: YES ☐ NO ☐

Route of administration agrees with that ordered in prescription: YES ☐ NO ☐

5. Documentation of Radiopharmaceutical Administration

A record of the following has been made in the patient chart:

- Radioisotope and total dose YES ☐ NO ☐
- Authorized user or authorized person under the supervision of the authorized user has signed or initialed this information in the patient's chart.

YES ☐ NO ☐

Authorized User Approval (1 thru 5 above)

Printed Name	Signature	Date

OHST Pre-Administration Verification of Suppliers Assay

Dose on label: _____(mCi)(uCi) @ _____/_____(date/time)

Assayed dose: _____(mCi)(uCi) @ _____/_____(date/time)

Administration: _____/_____(date/time)

Printed Name	Signature	Date
_____	_____	_____

Shipping Label Here

Appendix B – Example Template for Written Directive Radiation Therapy

Augusta University
Department of Radiation Oncology

Written Directive
High Dose-rate Remote Afterloading Brachytherapy

Physician section — Pre-administration

Authorized User Physician (AUP) Prescription

Patient Name: _____ ID Number: _____ Treatment Date: _____

Radionuclide: Iridium-192 Treatment site: _____ Treatment fraction: _____of_____

Dose per fraction: _____cGy Total HDR dose: _____cGy Applicator size:_____mm

Prescription Point_____ Total EBRT Dose_____ cGy

I have checked the prescribed dose and treatment plan and they are correct.

Physician name (print): _____Physician signature: _____

Therapist or Nurse section — Pre-administration

Patient Identification Verification

Verbal confirmation of patient name: _____Yes _____No

Additional confirmation of patient identity by:

____ Date of birth ____ SSN ____ID bracelet _____Photo ID ____ Other (_____)

Patient identification verified by (print) _____ Signature_____

Physicist section — Pre-administration

Verification Checks that Administration Corresponds to Prescription

_____I have checked the primary and secondary treatment plans and they are correct.

_____The intended dwell time and dose per fraction agrees with the prescription.

Physicist name (print): _____ Signature: _____

Radiation Safety section — Post-administration

Radiation Survey

Survey instrument type/serial number/calibration due date: _____/_____/_____

Patient survey initial: _____mR/h HDR unit initial: _____mR/h

Patient survey final: _____mR/h HDR unit final: _____mR/h

Technician name (print): _____Signature: _____

GEORGIA CANCER CENTER
AUGUSTA UNIVERSITY

Department of Radiation Oncology

Written Directive
Intravascular Brachytherapy with Beta-Cath™

Authorized User Physician Section — *Pre-administration*

Authorized User Physician (AUP) Prescription

Patient Name: _____ ID Number: _____ Treatment Date: _____

Interventional Cardiologist administering treatment: _____

Radionuclide: $^{90}Sr/^{90}Y$ Treatment site: _____-_____

Dose: _____Gy Dwell Time: _____ seconds

I have checked the dwell time calculation and it is correct.

AUP name (print): _____ AUP signature: _____

Physicist Section — *Pre-administration*

Medical Physics Verification Checks

Source Train Selection: _____ Transfer Device Serial Number:_____

_____ The intended dwell time and dose agrees with the AUP's prescription.

_____ The appropriate source train and transfer device have been selected for this treatment..

Physicist name (print): _____ Signature: _____

Catheterization Laboratory Nurse or Technician Section — *Pre-administration*

Patient Identification Verification

Verbal confirmation of patient name: _____Yes _____No

Additional confirmation of patient identity by:

____ Date of birth ____ SSN ____ID bracelet _____Photo ID ____ Other (_____)

Patient identification verified by (print) _____ Signature_____

Radiation Safety Section — *Post-administration*

Radiation Survey

Survey instrument type/serial number/calibration due date: _____/_____/_____

Patient survey initial: _____mR/h Transfer device initial: _____mR/h

Patient survey final: _____mR/h Transfer device final: _____mR/h

Technician name (print): _____Signature:_____

Appendix C – Example Template for Written Directive
Gamma Knife

GAMMA STEREOTACTIC RADIOSURGERY (Gamma Knife)
QUALITY MANAGEMENT PROGRAM

1. Prescription (Written Directive) — **PRE-ADMINISTRATION**

Patient name: _____ Treatment Date: _____

Sources: Cobalt-60

Target coordinates attached: yes ☐, no ☐ Treatment site(s) attached: yes ☐, no ☐

Sector settings attached: yes ☐, no ☐ Prescribed Total Dose: _____(Gy)@____% isodose

Signature: _____ Date: _____

Authorized User

2. Verification of Patient Identification — **PRE-ADMINISTRATION**

Verbal confirmation of patient name: yes ☐, no ☐

Additional confirmation of patient identification by: (check one)

☐ date of birth ☐ SSN ☐ ID bracelet ☐ insurance card

☐ address ☐ signature ☐ ask family ☐ other _____

Signature: _____

Authorized User or Authorized Medical Physicist

3. Verification of Administration with Prescription — **PRE-ADMINISTRATION**

Target coordinates agree with those ordered in prescription: yes ☐, no ☐

Sector settings agrees with that ordered in prescription: yes ☐, no ☐

Total dose agrees with that ordered in prescription: yes ☐, no ☐

Signature: _____

Authorized User or Authorized Medical Physicist

4. Verification of Dose Calculations — **PRE-ADMINISTRATION**

The original dose plan was calculated by the treatment planning computer. I have independently checked the treatment plan and dose calculations and they are in accordance with the written directive.

Signature: _____

Authorized User or Authorized Medical Physicist

5. Documentation of Teletherapy Administration — **POST-ADMINISTRATION**

A record of the following has been made in the patient record:

- total dose: yes ☐, no ☐ Room Survey _____ mR/hr
- target coordinates: yes ☐, no ☐ Meter _____ SN _____
- sector settings: yes ☐, no ☐ Calibration Due _____
- treatment site(s): yes ☐, no ☐ Date _____ Time _____
- physician signature: yes ☐, no ☐ By _____

Signature: _____

Authorized User or Authorized Medical Physicist