USE OF RADIONUCLIDE AGENTS IN THERAPEUTIC TREATMENT OF PATIENTS PROCEDURE

Purpose:

The purpose of this oversight outline is to define the roles, responsibilities and processes used in the ordering, preparation, administration, and documentation of radionuclide therapies for patients at the University of Wisconsin Hospital and Clinics. These procedures are intended to ensure the safe use of these therapies through detailed standardized procedures and provide an oversight infrastructure to review and approve radionuclide agent/protocol-specific procedures, maintain updated policies and protocols, and implement quality improvement initiatives in concordance with applicable institutional policies and regulatory agencies.

Policy:

All therapeutic radionuclide regimens will be reviewed and approved by the Human Radiation Use Committee and result in the development of an agent/protocol-specific, comprehensive and multidisciplinary procedural document. Such documents will be developed for any human use therapy, either non-research and research, and will detail the flow from the prescribing of the radiopharmaceutical to filing the paperwork at the completion of administration. This policy covers multiple departments including Nuclear Pharmacy, Nuclear Medicine, Radiation Oncology, and Inverventional Radiology. The Human Radiation Use Committee process will ensure all the elements of this procedure are embodied in the regimen specific worksheet. Review by the Radiation Human Use Committee does not obviate additional review by other committees, as required by institutional or regulatory policy.

Definitions:

- Authorized User = Medical Physician licensed by the State of Wisconsin and approved by the UW Radiation Safety Committee to prescribe radiopharmaceuticals
- Authorized Nuclear Pharmacist = Pharmacist licensed by the State of Wisconsin and approved by the UW Radiation Safety Committee to handle, compound, and dispense radioactive material
- Authorized Medical Physicist = Medical Physicist added to the UW license to handle radioactive material
- Administering Clinician = Authorized User, Medical Physicist, Nuclear Medicine Technologist, Physician, Registered Nurse
- Contracted Nuclear Pharmacy = Licensed facility external to UWHC approved for the compounding and dispensing of radiopharmaceuticals
- Nuclear Pharmacy, Nuclear Pharmacist or Nuclear Pharmacy Technician= UWHC Nuclear Pharmacy facility or UWHC personnel of the Nuclear Pharmacy

- Patient = Individuals receiving the therapeutic radionuclide agent regardless of non-research or research ("subjects") status
- Radionuclide Therapy Dose Documentation Form (Appendix B) – an agent and protocol specific written directive that is designed to incorporate all elements outlined in this policy related to the ordering, preparation, administration and documentation of the radionuclide including the written directive.

Procedure:

1. The appropriate radionuclide therapy agent/protocol-specific procedural document will detail the procedures to be followed and will capture the general procedures outlined below. See Appendix A for template
2. All therapeutic radionuclide agents shall be ordered using HRUC approved preprinted physician orders, the department standard requisition process, or providing a completed written directive to the Authorized Nuclear Pharmacist, Authorized Medical Physicist or Senior Nuclear Medicine Technologist. For inventory verification and patient convenience, the Nuclear Pharmacist may order therapeutic inventory via telephone or email order to ensure that product will be available. A written directive will be forwarded to the Nuclear Pharmacist or Medical Physicist, who will forward to the Authorized User.
   2.1. Research protocols will utilize preprinted physician orders or written directives processed and approved by multidisciplinary review in accordance applicable hospital policies and approved by the Human Radiation Use Committee as part of the agent/protocol-specific development process
3. Upon receipt of the order/requisition, the Authorized User will:
   3.1. Determine appropriateness of the order and calculate or confirm the requested dose based on appropriate clinical determinations, commercial agent dosing parameters and/or protocol stipulations
   3.2. Sign the written directive utilizing the Radionuclide Therapy Dose Documentation form specific to that radionuclide and protocol.
4. Other Patient Information/Education Verifications: Prior to administration of the radionuclide, the Authorized User will complete and document the following on the Radionuclide Therapy Dose Documentation Form:
   - Confirmation that the prescribing physician has explained the dose and treatment to the Administering Clinician
   - Confirmation (reasonable assurance) of negative pregnancy test or excluding clinical condition
   - Confirmation that the patient is not currently breast feeding
   - The identity of the patient according to hospital procedures using two (2) methods of identification
   - Verify (or obtain) informed consent
   - Written radiation safety instructions provided to the patient
   - If applicable, provision of the applicable Health Facts for You to the patient
   - Other elements as prompted on the Radionuclide Therapy Dose Documentation form

   For therapy doses that will be administered at a future appointment, the written directive is forwarded to the Nuclear Pharmacy before the completion of the Patient Information/Education Verifications. These verifications will be done, however, when the patient arrives at the clinic and meets with the physician.

5. The written directive is forwarded to the Nuclear Pharmacy or Radiation Oncology
6. Upon receipt of the written directive within the Nuclear Pharmacy or Radiation Oncology

6.1. **Written Directive Verification:** The Nuclear Pharmacist or Medical Physicist will verify the completeness and accuracy of the written directive and document his/her verification on the Radionuclide Therapy Dose Documentation form (section A)

6.1.1. The written directive verification process will ensure the therapy is appropriate and properly completed. The written directive shall contain the following::

- Dose in mCI
- Indication
- Clinical versus Research Status
- Pertinent Lab Values, if applicable
- Signed, dated and timed by Authorized User

6.2. Radionuclide Computer Order Entry:

6.2.1. Once the written directive has been verified, it will be entered into the Nuclear Pharmacy computer system by the Nuclear Pharmacy

6.3. Radionuclide Preparation:

6.3.1. The radiopharmaceutical can be prepared by nuclear pharmacy personnel following standard safe handling procedures and labeled, with the dose preparation documented (including dose assay) on the Radionuclide Therapy Dose Documentation Form

6.3.2. A prescription label will be produced from the Nuclear Pharmacy computer system and attached to the radiopharmaceutical

6.4. **Radionuclide Computer Order Entry and Preparation Verification:**

6.4.1. In order to ensure the correct patient, correct therapy, correct dose and correct time, the administering nuclear medicine technologist or med physicist will double check the completeness of the documentation..

6.4.2. The verification process will include comparison of the written directive against the pharmacy computer entry and activity confirmation using a dose calibrator.

6.4.2.1.The administering technologist or med physicist will confirm the following:

- Patient Name
- MR Number
- Radionuclide therapy
- Dose in mCi, and correct isotope selection on the dose calibrator
- Date of administration (Calibration Date)
- Time of administration

6.4.3. Products prepared by Contracted Pharmacy: The pharmacy product verification process will involve the placement of the dose into the dose calibrator, and comparison of the assay to the Contracted Pharmacy's radionuclide therapy label, the product label generated at the completion of dose assay, and the written directive. Any further verification steps required will be detailed in the **Radionuclide Therapy: Agent/Protocol Specific Procedure** document.

6.4.4. The Nuclear Pharmacy order entry label will be attached to the product received from the Contracted Pharmacy after verification has been completed. Upon completion of the radionuclide therapy agent preparation and its verification, an Administering Clinician will obtain the final product from the Nuclear Pharmacy

7. The Administering Clinician will perform the final patient identification checks before administration
8. The Administering Clinician will administer the radionuclide therapy agent and will provide appropriate patient monitoring during the administration
9. The Authorized User will be responsible for the appropriateness of the patient's release from administration area and will provide the patient with the appropriate discharge instructions, documenting the completion of this step on the Radionuclide Therapy Dose Documentation form
10. The Authorized User or designate will determine any exposure calculations required and document them in the appropriate sections of the Radionuclide Therapy Dose Documentation form
11. The completed, original Written Directive/Radionuclide Therapy Dose Documentation form will be retained in the department the therapy is administered. .

Responsibilities

Human Radiation Use Committee (HRUC)

1. Charge – this committee functions to provide an infrastructure for
   - The establishment and maintenance of all radionuclide therapy standard operating procedures
   - The assessment of new radiopharmaceuticals and protocols involving radiation exposure to humans proposed for utilization within the UWHC
   - The assessment of the clinical appropriateness, scientific integrity, logistical practicability and safe delivery of research protocols utilizing therapeutic radionuclides
   - The development, review and approval of radionuclide therapy agent/protocol-specific procedure documents
   - The identification and implementation of quality improvement initiatives to enhance the safe delivery of radiopharmaceuticals
   - The establishment and maintenance of core training and competency requirements
   - The creation of other best practice or re-engineering strategies as deemed necessary
   - Approval of UWHC Authorized Users, Authorized Nuclear Pharmacists, and Authorized Medical Physicists
   - Oversight of brachytherapy
   - Investigation of diagnostic radionuclide misadministrations

2. Composition – this committee will be multidisciplinary in nature and consist of representation from the following stakeholders
    - Nuclear Medicine Physician (Chair of Nuclear Medicine)
    - UWHC Administration
    - Nuclear Pharmacy
    - Nuclear Medicine
    - Radiation Oncology
3. Frequency – this committee will meet quarterly and on an ad hoc basis if additional meetings are necessary.
4. Radionuclide therapy Agent/Protocol-Specific Procedure Document will
    - Detail procedural steps beginning from the identification of the patient targeted for radionuclide therapy to the completion of therapy
    - Detail the ordering procedures to be utilized (preparation location; use of preprinted physician order or standard requisition process; etc) and in the case of preprinted physician orders will
        - Establish the elements to be stipulated in the preprinted physician order including required dosing parameters and their corresponding time limits, if applicable (example: platelet count to be within X days of radionuclide therapy dosing)
        - Obtain the institutional requirement for multidisciplinary review and approval of preprinted physician orders
    - Be appropriately disseminated to involved individuals/departments
    - Be retained by the Radionuclide Therapy Coordinating Committee and Nuclear Pharmacy, the Nuclear Pharmacy, the Principal Investigator's of therapeutic radionuclide therapy research protocols (if applicable) and other individuals/departments as necessary
    - Be formally reviewed every three years by the Radionuclide Therapy Coordinating Committee

Forms

Appendix A: Therapeutic Radionuclide therapy Agent/Protocol Specific Procedure Document

Appendix B: Radionuclide Therapy Dose Documentation form (UW Nuclear Medicine Division; incorporates the Written Directive and associated verification procedures within this form)

Related Policies

Nuclear Medicine Procedure Manual

Applicable state and federal regulatory policies

Coordination

Human Radiation Use Committee

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Version Date:	March2016
Expiration Date:	March2019
Original Approval Date:	September 2005
File/Path Name location:	\\r-RadNAS\PCUsers\NuclearGroup\Protocols\Radiopharm Therapy Policy 06.08.doc