Part B: Process

Section 1B: Radiopharmaceutical Therapy Procedures and Protocols

STANDARD – Radiopharmaceutical Therapy Administration Volumes

1.1B The facility must have performed at least five cases (courses of therapy) per year in therapies in which they are applying for accreditation.

1.1.1B For radiopharmaceutical therapy accreditation, a facility must be able to submit the minimum number of cases required in the application process. The cases must be performed within one year from the date of submission.

STANDARD – General Protocol Guidelines

1.2B To ensure standardized operation the facility must have and follow site-specific written protocols that accurately describe the details for all procedures performed within the facility.

1.2.1B Complete procedure manuals must be present in the facility and include corresponding references.

1.2.2B Protocols must be organized for easy use (such as in notebook or electronic form) with a table of contents with sections/headings such as: clinical imaging protocols, therapeutic protocols, equipment quality control, radiation safety and radioactive materials handling, administrative policies and facility quality assessment and improvement.

1.2.2.1B The protocol manual must be readily accessible to appropriate staff members during operational hours.

1.2.2.2B Where appropriate, records must be maintained to document compliance with protocols (e.g., radiopharmaceutical receipt/disposal records, spill records, etc.).

1.2.3B Radiopharmaceutical therapy protocols must be reviewed and updated at least annually by the Medical Director or qualified designee. For areas in which the Medical Director does not have education, training and experience, a designee must be appointed to review those protocols.

Comment: A qualified designee can be a physician, physicist or other radiation safety staff.

1.2.3.1B All protocols and/or revisions must be dated and initialed/signed by the Medical Director or the designated person.

Comments: It is acceptable for the Medical Director to sign a summary page to indicate he/she has approved the entire protocol manual.

The Radiation Safety Program must also be reviewed annually (see Standard 3.2.1A).

1.2.4B Personnel must have read, be appropriately trained in and have current competence documented to perform/comply with relevant protocols. Documentation is typically found as initial training/orientation and annual training records.

1.2.5B The protocols and the facility's performance must be in compliance with:

1.2.5.1B All applicable federal, state, provincial, and local requirements, including Nuclear Regulatory Commission (NRC) regulations or, in Agreement States, with state regulations for medical use of radioisotopes.

1.2.5.2B Accepted practices such as those in published guidelines.[1-16]

STANDARD – Radiopharmaceutical Therapy Clinical Protocols

1.3B Radiopharmaceutical therapy protocols must describe in detail:

1.3.1B Requirement that the treating physician must be an authorized user for and are on site and immediately available for the administration of the therapeutic radiopharmaceutical. The treating physician or physician designee must be available until patient discharge.

Comment: Virtual oversight is not acceptable for therapeutic administrations

1.3.2B clinical indications and contraindications;

1.3.3B patient preparation and education/instruction such as food/diet restrictions, if any, withholding or non-withholding of medications or other relevant information;

Comment: If there are no patient preparations or restrictions, it must be specifically stated in the protocol.

1.3.4B radiopharmaceutical therapy identity, dosage range or method of calculation and route of administration;

1.3.5B Requirement for a written directive prior to radiopharmaceutical administration which includes:

1.3.5.1B patient's name;

1.3.5.2B radiopharmaceutical identity;

1.3.5.3B radiopharmaceutical dosage for the specific patient;

1.3.5.4B route of administration; and

1.3.5.5B manual signature and printed name or electronic signature of an authorized user, as defined by the Nuclear Regulatory Commission in 10 CFR §35.217, for that specific agent and date.

1.3.6B non-radioactive drugs used in the procedure including identity, dosage, timing of administration, route of administration and any precautions or restrictions;

1.3.7B treatment procedure including:

1.3.7.1B review of relevant clinical history, laboratory/pathology results and imaging data;

1.3.7.2B informed consent with risks, benefits, alternatives and likelihood of success;

1.3.7.3B pregnancy and/or lactation status check;

1.3.7.4B immediately prior to dosing, verification of the patient's identity with two identifiers by two members of the medical and/or technical staff;

1.3.7.5B immediately prior to dosing, verification of the radiopharmaceutical therapy identity, amount and route of administration by two members of the medical and/ or technical staff (refer to Standards 1.1A-1.4A); and

1.3.7.6B immediately prior to dosing, verify patency of access (if applicable).

1.3.8B Radiation precautions following treatment, as appropriate:

Comment: Guidance concerning breast feeding cessation (if relevant) must also be included in radiation precautions following treatment.

1.3.8.1B outpatient instructions, to include, as appropriate:

i. maintaining distance from others, especially children and pregnant women (including during sleep and time in public);
ii. travel (including public transportation and border crossings);
iii. control of body fluids;
iv. handling of potentially radioactive household trash;
v. the duration of these restrictions; and
vi. response to medical emergencies or patient death.

1.3.8.2B in-patient instructions, to include, as appropriate:

i. radiation safety instruction to direct care (e.g., nursing) and housekeeping staff;
ii. hospital room/signage requirements;
iii. radiation monitoring requirements;
iv. visitation policy;
v. handling of materials used by the patient;
vi. release criteria (including travel instructions); and
vii. response to medical emergencies or patient death.

1.3.9B Description of any imaging required in conjunction with the radiopharmaceutical therapy (e.g., I131 post-radiopharmaceutical therapy whole body imaging).