

## APPENDIX Y

### **Use of Diagnostic Radiopharmaceuticals**

#### 1. AUTHORIZED USERS SHALL HAVE THE FOLLOWING SPECIAL RESPONSIBILITIES.

- A. Prepare a written directive - **or** - assure that the procedure is in accordance with a diagnostic clinical procedures manual, by approving each clinical procedure in the manual including the radiopharmaceutical, dosage and route of administration. The authorized users will document approval of the diagnostic clinical procedures manual by signing and dating a statement of approval, to be maintained with the manual. Prior to administration, the authorized user must document deviations from the diagnostic clinical procedures manual for each patient. Written directives are required for diagnostic procedures involving more than 30 microcuries (1.11 MBq) of I-131 as sodium iodide.
- B. Review personally patients' cases - **or** - develop and implement written appropriateness procedures for use with a diagnostic clinical procedures manual, to assure those administering the radiopharmaceutical that the procedure requested by the referring physician is appropriate.
- C. Use radioactive material or direct nuclear medicine technologists in using radioactive material.
- D. At facilities authorized for physician training, direct physicians in training in the use of radioactive material with the prior approval of the radiation safety committee or the licensees' management.
- E. Interpret results of diagnostic procedures.

#### 2. PROCEDURES FOR ADMINISTERING DIAGNOSTIC RADIOPHARMACEUTICALS

- A. An authorized user will prepare a written directive for all diagnostic procedures involving more than 30 microcuries (1.11 MBq) of iodine 131 as sodium iodide.
- B. Administer the dose in accordance with the written directive.
- C. When an authorized user has not provided a written directive, ensure that the referring physician's request agrees with one or more of the appropriateness indicators for the requested procedure and ensure that the dose is administered in accordance with the diagnostic clinical procedures manual.
- D. Check the patient's name and identification number and the prescribed radionuclide, chemical form, and dosage before administering.
- E. Assay each patient dosage in the dose calibrator before administering it. Do not use a dosage if it varies by more than 20 percent from the prescribed dosage or if the dosage does not fall within the prescribed dosage range, except for prescribed dosages of less than 10 microcuries. (When measuring the dosage, you need not consider the radioactivity that adheres to the syringe wall or remains in the needle.)
- F. An authorized user or a nuclear medicine technologist shall determine by assay or by direct measurement within 30 minutes before each radiopharmaceutical dosage and record the activity of each dosage before medical use. A record of the assay shall be made and will include the information required by 64E-5.616(1), F.A.C.

#### 3. POSTING REQUIREMENTS

- A. A copy of our emergency (spill) procedures (Appendix K), general laboratory safety procedures for working with radioactive materials (Appendix J), our emergency notification notice, and a Notice to Employees document 3/01 will be conspicuously posted at our facility as required by 64E-5.901, F.A.C. Current copies of Part III and Part IX, the license, conditions or documents incorporated into the license by reference and amendments thereto, and operating procedures applicable to activities under the license are not required to be posted provided that a notice is posted which describes the documents and states where they may be examined.
- B. The radiation safety officer's name and phone number and our 24 hour emergency notification number are listed in our emergency procedures.
- C. The location of use for radioactive material will be posted with the proper signage as described in 64E-5.323, Florida Administrative Code.

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