The Cleveland Clinic Foundation

Quality Management Program

Radiopharmaceutical Uses for Therapies other than I-125 or I-131 as NaI
(Revised December 1997)

1. A written directive will be prepared which will contain the name and identification number of the patient, chemical form and prescribed dosage of the radiopharmaceutical, the route of administration. The authorized user will sign and date the written directive prior to the dose administration.

   Written revisions to the written directive may be made prior to administration of the treatment. The authorized user physician must sign and date the revision to the written directive. Oral revisions are acceptable if the delay to provide for the written revision would jeopardize the patient's health due to the emergent nature of the patient's medical condition. In such situations, the oral revision will be documented immediately in the patient's record and a revised written directive shall be signed and dated by the authorized user within 48 hours of the oral revision.

2. The patient's identity will be verified by more than one method prior to administration. The patient's name will be asked and confirmed by the authorized user or technologist. In addition, confirmation of one of the following will be performed: confirming with the patient record, the birth date, or address, or social security number, or signature; checking the patient's name on the patient's ID bracelet, hospital ID card or patient's medical insurance card. The two methods used will be documented on the checklist and initialed by the individual performing the verification.

3. Before administering the treatment, the authorized user or the technologist performing the procedure shall confirm the specific details of the administration as indicated in the written directive. Prior to administration, the radiopharmaceutical, dosage and route of administration will be verified. For a photon emitting radionuclide, dosage will be confirmed by assay in a dose calibrator. For a beta or alpha emitting radionuclide, dosage will be determined by direct measurement or by combination of measurements and calculations, except for a unit dosage obtained from a manufacturer or preparer licensed pursuant to 10CFR32.72 or equivalent Agreement State requirements. The technologist performing this verification shall note compliance on the checklist and this shall include the dose calibrator assay and initials.

4. All individuals will be instructed to seek guidance from the authorized user for clarification if they do not understand a written directive. That is, workers will

ask if they have any questions about what or how it should be done in a given situation rather than proceeding with the treatment when there is any doubt.

5. Each administration shall be reviewed to ensure treatment was in accordance with the written directive. Following administration, the administered radiopharmaceutical and dosage will be recorded on the checklist and the percent difference between the administered versus prescribed dosages will be calculated. The authorized user or a qualified person under the supervision of an authorized user (e.g. nuclear medicine physician, nuclear medicine fellow, radiology resident, or nuclear medicine technologist) shall sign and date the patient's appropriate records indicating that the administered dosage is in accordance with the prescribed dosage. Any unintended deviations will be noted on the checklist. Any deviations greater than +/- 10%, will be immediately reported to the Radiation Safety Officer (Ext. 46645) to permit proper investigation, reporting, documentation and follow-up.