can be tested on known data with known values. The final test needs to be performed on many studies; normal, abnormal and intermediate (if possible) to establish the limits of performance of the complete system.

PART VI: DISCLAIMER

The Society of Nuclear Medicine has written and approved guidelines to promote the cost-effective use of high quality nuclear medicine procedures. These generic recommendations cannot be applied to all patients in all practice settings. The guidelines should not be deemed inclusive of all proper procedures or exclusive of other procedures reasonably directed to obtaining the same results. The spectrum of patients seen in a specialized practice setting may be quite different than the spectrum of patients seen in a more general practice setting. The appropriateness of a procedure will depend in part on the prevalence of disease in the patient population. In addition, the resources available to care for patients may vary greatly from one medical facility to another. For these reasons, guidelines cannot be rigidly applied.

Advances in medicine occur at a rapid rate. The date of a guideline should always be considered in determining its current applicability.

PART VII: ISSUES REQUIRING FURTHER CLARIFICATION

A guideline for general PET imaging needs to be developed.

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Procedure Guideline for Imaging with Radiopharmaceuticals: 1.0

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Key Words: radiopharmaceuticals; practice guidelines; scintigraphic studies

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PART I: PURPOSE

This guideline was developed by the Society of Nuclear Medicine to describe important factors common to most scintigraphic studies. It is intended to guide nuclear medicine practitioners in establishing policies and procedures for the use of radiopharmaceuticals in clinical practice. This guideline is intended to be concordant with the regulations of the Nuclear Regulatory Commission (NRC) and other state and federal government agencies.

PART II: BACKGROUND INFORMATION AND DEFINITIONS

A. Diagnostic radiopharmaceuticals (also known as radioactive drugs) are substances that contain radionuclides that emit penetrating radiation(s). The distribution of the radiopharmaceutical within the body is determined by the physiochemical properties of the drug, the stability of the label, the purity of the radiopharmaceutical preparation, the pathophysiological state of the patient and the presence or absence of interfering drugs. Dynamic and static images of the distribution of the radiopharmaceutical within the body

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Note: All 26 SNM-approved procedure guidelines are available on the SNM home page. We encourage you to download these documents via the Internet at www.snm.org. If you would like information on the development process of this guideline or require additional copies of this or other SNM-approved guidelines, please contact Joanna Wilson, Society of Nuclear Medicine, 703-708-9000 or via email at jwilson@snm.org.

can be obtained using a gamma camera or other suitable instrument appropriate for the radiopharmaceutical being imaged, e.g. positron-emitting radiopharmaceuticals.

B. Physiologic and pharmacologic interventions are procedures which increase the sensitivity and/or specificity of a diagnostic procedure by affecting the distribution and pharmacokinetics of the administered agents through an alteration in organ physiology.

PART III: COMMON INDICATIONS

Any procedure that uses a radiopharmaceutical (see specific procedure guideline).

PART IV: PROCEDURES

A. Clinical Use of Radiopharmaceuticals

1. A physician-derived order (e.g., prescription, requisition) is required for the conduct of all procedures. The order should specify the procedure desired, the drug(s) to be used, the amount(s) to be administered and the route of administration. Alternately, the order may specify a standard procedure with the other required information addressed in a routinely updated procedure manual located within the nuclear medicine laboratory.
2. The prescribing physician is ultimately responsible for the safety and quality of all radiopharmaceuticals prepared and dispensed for administration under his (her) direction.
3. The nuclear pharmacist is ultimately responsible for the quality and correctness of radiopharmaceuticals prepared and dispensed under his (her) supervision.
4. The compounding, quality control, dispensing and patient administration of radiopharmaceuticals and adjunctive drugs may be delegated to qualified personnel, in accordance with applicable state and local laws.
5. There must be a signed and dated written directive for each patient for ^{125}I- or ^{131}I-sodium iodide in quantities $\geq$1.1 MBq (30 μCi) and for all therapeutic radiopharmaceuticals such as ^{89}Sr.
6. The identity of the radiopharmaceutical, patient and route of administration shall be verified prior to administration. Female patients who are postmenarche and premenopause should be asked about pregnancy, lactation and breastfeeding prior to administration.
7. The quantity of each radiopharmaceutical dosage must be determined prior to patient administration and must be consistent with that ordered by the physician or addressed in the procedure manual of the nuclear medicine laboratory. The quantity of radioactivity dispensed should be within 10% of the prescribed dose, and the actual quantity administered must be recorded in the patient's nuclear medicine file.
8. Radiopharmaceuticals should not be used beyond the manufacturer's recommended expiration date/time unless specific quality control testing demonstrates that the product still meets applicable USP specifications at the time of use.
9. Any discrepancies shall be resolved prior to administration.

B. Elution of Generators and On-Site Preparation of Kits

1. Each time a generator is to be eluted, the generator to be eluted and the volume of eluent to be used should be selected based on the calibration and elution history of the generator. The quantity of radioactivity eluted and the concentration of parent nuclide breakthrough must be measured and recorded. The extent of breakthrough must be verified to be below the appropriate regulatory limit. The final volume of the eluate, the identity of the person performing the elution and the date and time of elution shall be recorded. Proper radiation safety procedures must be employed throughout the elution process.
2. Radiopharmaceuticals should be prepared according to manufacturer's instructions. Deviations from the package insert instructions may be made by the prescribing physician or authorized nuclear pharmacist.
3. Aseptic procedures must be followed whenever handling parenteral or ophthalmic radiopharmaceutical preparations or their components.
4. A comprehensive radiopharmaceutical quality control program should be developed and implemented. The scope of the program should be compatible with the type of practice and the availability of equipment and personnel. The parameters to monitor in a radiopharmaceutical quality control program include: (a) chemical purity; (b) radiochemical purity; (c) radionuclide purity; (d) biological purity (sterility and apyrogenicity); and (e) pharmaceutical purity (e.g., pH, particle size, absence of foreign particulate matter).

C. Positron-Emitting Radiopharmaceuticals

Radiopharmaceuticals used in PET require specialized personnel, facilities and equipment due primarily to the relatively short physical half-lives of the radionuclides used (2 min to 1.8 hr), their energetic photon emissions and the chemical syntheses necessary for their preparation. Nuclear medicine practitioners involved in positron emission tomography should consult with qualified chemists, pharmacists, physicists and technologists in establishing and operating a PET program.

D. Record Keeping

1. Records of receipt, usage, administration and disposal of all radiopharmaceuticals shall be kept in compliance with license conditions and applicable medical records and radiation control regulations.
2. Records concerning the receipt of packages containing radioactive material should include proper identification of contents, inspection for physical damage and testing for external contamination, as required by the appropriate regulatory agency. Appropriate records of the receipt of radioactive material shall be maintained and stored in accordance with applicable local state and federal regulations. Such records shall address the identity of the radiopharmaceutical, its source, the amount of activity received and the results of radiation surveys and contamination testing. Any discrepancies must be reported to the manufacturer and/or proper regulatory agency.
3. For all radiopharmaceuticals prepared on-site, records should include the date and time of preparation, quantity, volume and concentration of radioactivity used, reagent lot numbers, quality control data, expiration time and waste disposal information.
4. For all radiopharmaceuticals, the identity of the radiopharmaceutical, the amount of radioactivity administered, patient identity, identity of individual

performing the administration, route of administration and date and time of use must be recorded.

5. Appropriate records of radionuclide dose calibrator testing for constancy, accuracy, linearity and geometric variation shall be maintained.
6. Disposal of all radioactive material must be accomplished in accordance with institutional, state and federal regulations. Policy and procedures should be developed to assure that radioactive material does not enter the normal waste stream of the institution except in exempt quantities or in exempt forms (e.g., patient excreta).

E. Adverse Reactions

Adverse reactions associated with administration of radiopharmaceuticals should be investigated and documented. Reports should be made to the manufacturer and to the Society of Nuclear Medicine/USP Drug Problem Reporting Program.

F. Misadministration of Radiopharmaceuticals

Policies and procedures should be developed which assure that the right patient receives the right drug, at the right time, at the right dose and by the right route of administration. Misadministrations and recordable events have been defined by federal and state regulatory agencies and include a timely reporting requirement. When required, such events should be reported to the appropriate agency within the time frame specified.

G. Special Considerations for Labeled Blood Products

While the misadministration of any radiopharmaceutical is serious, special precautions must be implemented to prevent the misadministration of radiopharmaceuticals containing blood products, i.e., ^{99m}Tc-red blood cells and ^{111}In- and ^{99m}Tc-leukocytes. Procedures involving the removal of blood for radiolabeling and subsequent reinjection have potential for misadministration to the wrong patient. The handling and administration of blood products must be subject to special safeguards and procedures, the goal of which is to eliminate any possibility of administration to the wrong patient and contamination of workers.

H. Drug Interactions and Altered Distribution Patterns

1. The in vivo distribution of radiopharmaceuticals can be altered by concurrent medications and prior diagnostic tests (including contrast dye and previous radiopharmaceuticals). The nuclear medicine practitioner should be familiar with documented drug interactions and consider this information when planning the nuclear medicine procedure to be performed, and when altered distribution patterns are identified on patient studies.
2. Problems in the formulation of radiopharmaceuticals can result in altered distribution patterns. Appropriate quality control programs should identify such problems prior to patient administration. The possibility of a formulation-related cause of an altered distribution pattern should be considered in evaluation of any unexplained image findings.

PART V: DISCLAIMER

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PART VI: ISSUES REQUIRING FURTHER CLARIFICATION

None

PART VII: CONCISE BIBLIOGRAPHY

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