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NRLSD BULLETIN 92-07: **LISTING OF RADIOACTIVE MATERIALS APPROVED FOR LICENSING BY PNRI FOR MEDICAL USE**

A. ADDRESSEES

All holders of radioactive material licenses for use in nuclear medicine and brachytherapy.

B. PURPOSE

This bulletin is issued to provide all licensees with a listing of radioactive materials that the PNRI has approved for licensing for medical use. This listing will help facilitate the processing of license applications and form the basis for developing safety standards and procedures in the medical use of radioactive materials.

C. DESCRIPTION OF CIRCUMSTANCES

The medical use of radioactive material is generally guided by the availability of the radioisotope and the advances in technology in the medical field, particularly in nuclear medicine and brachytherapy.

As a general observation, the application of new technology in the medical use of radioactive material may encounter some difficulties in its immediate use because of regulatory and licensing requirements. A recently developed radiopharmaceutical cannot be administered or used without complying with PNRI requirements on the safe handling of radioactive materials. Non-adherence to regulatory requirements is a violation and could result to more difficulties and problems for the user.

Any additional radioactive material to be introduced by any licensee requires the modification of the license.

D. DISCUSSION

Section 3 of CPR Part 2 provides that "No person shall produce, acquire, receive, possess, use, transfer, import or export radioactive material except in accordance with a license issued by the Institute".

The use of any radioactive material, particularly those that are not in the PNRI-approved list, prior to the issuance of a PNRI license authorizing the use of such material is not allowed by this provision.

Section 35(c) of CPR Part 2 requires that "A licensee shall apply for and must receive a license amendment before he can use radioactive materials other than those specified in the license.

In complying with these requirements, the licensee may be guided by this PNRI approved list of radioactive materials (Appendix A).

E. REQUIRED LICENSEE ACTION

Licensees especially the physicians in the practice of nuclear medicine and radiotherapy are requested to comment on the listings attached herewith. If there are questions about this bulletin, please contact the person listed below.

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APPENDIX A

GROUPS OF MEDICAL USES OF RADIOACTIVE MATERIAL

Group I. Use of prepared radiopharmaceuticals for certain diagnostic studies involving measurements of uptake, dilution and excretion. This group does not include imaging or localization studies:

1) Iodine-131 as sodium iodide, iodinated human serum albumin, labeled rose bengal, triolein, or sodium iodohippurate;

2) Iodine-125 as sodium iodide, iodinated human serum albumin, oleic acid or sodium iodothalamate;

3) Cobalt-58 as labeled cyanocobalamin;

4) Cobalt-60 as labeled cyanocobalamin;

5) Chromium-51 as sodium chromate or labeled human serum albumin;

6) Iron-59 as citrate;

7) Technetium-99m as pertechnetate; and

8) Any radioactive material in a radiopharmaceutical and for a diagnostic use involving measurements of uptake, dilution or excretion studies which has been accepted by the Bureau of Food and Drug (BFAD).

Group II. Use of prepared radiopharmaceuticals for diagnostic imaging and localization studies:

1) Iodine-131 as sodium iodide, iodinated human serum albumin, macroaggregated iodinated human serum albumin, colloidal (microaggregated) iodinated human serum albumin, rose bengal or sodium iodohippurate;

2) Iodine-125 as sodium iodide or fibrinogen;

3) Chromium-51 as human serum albumin;

4) Gallium-67 as Gallium Citrate;

5) Gold-198 in colloidal form;

6) Mercury-197 as chlormerodrin;

7) Mercury-203 as chlormerodrin;

8) Selenium-75 as selenomethionine;

9) Strontium-85 as nitrate;

10) Technetium-99m as pertechnetate, sulfur colloid or macroaggregated human serum albumin;

11) Thallium-201 as Thallous Chloride;

12) Ytterbium-169 as pentatate sodium;

13) Indium-111 as calcium DTPA and oxine solution;

14) Indium-113m as Chloride;

15) Any radioactive material in a radiopharmaceutical prepared from a reagent kit listed in Group III(4);

16) Any radioactive material in a radiopharmaceutical and for diagnostic use involving imaging or localizing studies which has been accepted by the Bureau of Food and Drug (BFAD).

Group III. Use of generators and reagent kits for the preparation and use of radiopharmaceuticals containing radioactive material for certain diagnostic studies:

1) Molybdenum-99m/technetium-99m generators for the elution of technetium-99m as pertechnetate;

2) Technetium-99m as pertechnetate for use with reagent kits for preparation and use of radiopharmaceuticals containing technetium-99m;

3) Tin-113/indium-113m generators for the elution of the indium-113m as chloride;

4) Reagent kits for preparation of technetium-99m labeled;

a. Sulfur colloid;
b. Pentatate sodium;
c. Human serum albumin microspheres;
d. Polyphosphates;
e. Macroaggregated human serum albumin;
f. Etidronate sodium;
g. Stannous pyrophospate;
h. Human serum albumin;
i. Medronate sodium;
j. Gluceptate sodium;
k. Oxidronate sodium;
l. Disofenin;
m. Succimer;
n. Diethylenetriaminepenta-acetic acid (DTPA)
o. Glucoheptonate (GHA);
p. Tin Colloid (Hepatate);
q. Diethylphenyl-carbamaz methyl-iminoacetic acid;
r. Stannous Medronate;
s. Methyoxy isobutyl isonitrite;
t. Hexamethylpropylene amino oxime;

5) Any generator or reagent kit for preparation and diagnostic use of a radiopharmaceutical containing radioactive material for which generator or reagent kit has been accepted by the Bureau of Food and Drug (BFAD).

Group IV. Use of prepared radiopharmaceuticals for certain therapeutic uses that do not normally require hospitalization for purposes of radiation safety:

1) Iodine-131 as iodide for treatment of hyperthyroidism and cardiac dysfunction;

2) Phosphorus-32 as soluble phosphate for treatment of polycythemia vera, leukemia and bone metastases;

3) Phosphorus-ND32 as colloidal chromic phosphate for intracavitary treatment of malignant effusions;

4) Any radioactive material in a radiopharmaceutical and for a therapeutic use not normally requiring hospitalization for purposes of radiation safety and has been accepted by the Bureau of Food and Drug (BFAD).

Group V. Use of prepared radiopharmaceuticals for certain therapeutic uses that normally require hospitalization for purposes of radiation safety:

1) Gold-198 as colloid for intracavitary treatment of malignant effusions;

2) Iodine-131 as iodide for treatment of thyroid carcinoma;

3) Any radioactive material in a radiopharmaceutical and a therapeutic use normally require hospitalization for radiation safety reasons and has been accepted by the Bureau of Food and Drug (BFAD).

Group VI. Use of sources and devices containing radioactive material for certain medical uses:

1) Americium-241 as a sealed source in a device for bone mineral analysis;

2) Cesium-137 encased in needles and applicator cells for topical, interstitial, and intracavitary treatment of cancer;

3) Cobalt-60 encased in needles and applicator cells for topical, interstitial, and intracavitary treatment of cancer;

4) Gold-198 as seeds for interstitial treatment of cancer;

5) Iodine-125 as sealed source in a device for bone mineral analysis;

6) Iridium-192 as seeds encased in nylon ribbon for interstitial treatment of cancer;

7) Strontium-90 sealed in an applicator for treatment of superficial eye conditions;

8) Iodine-125 as seeds for interstitial treatment of cancer;

9) Palladium-103 as a sealed source in seeds for interstitial treatment of cancer.