

The University of Texas
Southwestern Medical Center at Dallas

1. Department or Group:	
2. Address:	3. Mail Code:
	4. Phone:
5. Name of person with primary responsibility for this sublicense:	6. Social Security Number:

7. List room numbers of all rooms inwhich RAM will be used or stored: _____

8. For each room listed in item 7, the applicant shall submit with this application a completed RSF-005a.

9. Physicians to be authorized to order radioactive material (RAM) under this sublicense:

Full Name	Degree(s)	Faculty Title	Phone Number	Mail Code

10. In order for the persons listed in item 9 to be approved for the application use of RAM under this sublicense, each individual must submit one of the following:
- 1) Completed preceptor statements (TRC Form 42-2a, available from the Radiation Safety Office) from each preceptor from whom they have received relevant training in the handling of RAM for medical use.
 - 2) A copy of an institutional, state, or NRC license authorizing that person for the medical use of RAM.
 - 3) Certification from the American Board of Nuclear Medicine.
 - 4) Certification from the American Board of Radiology in Diagnostic Radiology with special competence in Nuclear Radiology.
 - 5) Certification from the American Board of Radiology in Therapeutic Radiology.
 - 6) Documentation of training in specific diagnostic procedures (i.e., nuclear cardiology, bone densitometry) as outlined in the Texas Bureau of Radiation Control Regulatory Guide 3.1.

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11. Applications for departmental sublicenses may be approved for the following categories of radioactive materials: Group I, Group II, Group III, Xe-133, DTPA Aerosols Therapeutic Radiopharmaceuticals, Implant Sources, and Sealed Sources for diagnosis. Please check each box that applies.

Group I		Group II		Group III (without generators)		Xe-133	
DTPA Aerosols		Therapeutic Radiopharmaceuticals		Brachytherapy Sources		Sealed Sources for Diagnosis	

Group I comprises those uptake, dilution, and excretion studies for which the Food and Drug Administration (FDA) has accepted a New Drug Application (NDA).

Group II comprises all routine NDA imaging and tumor localization studies.

Group III comprises all routine NDA reagent kits used to prepare radiopharmaceuticals. Although included in Group III, radioisotope generators must be applied for separately.

Group I, Group II, and Group III RAM are listed in attachemtn I, II, and III respectively.

If Xe-133 is requested under this sublicense, a RSF-003 must be completed and submitted with this application.

If DTPA aerosols are requested under this sublicense, a RSF-004 must be completed and submitted with this application

12. Radioactive Material not listed in Item 11. (investigational drugs, generators)

Isotope	Form	Manufacturer	Maximum Activity

13. List all non-exempt sealed sources to be authorized under this sublicense:

Isotope	Manufacturer	Serial Number	Date of Assay	Activity on Date of Assay

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14. Special Radiation Safety Concerns:

a. Describe the type of procedures in which RAM will be used.

b. Describe any particular radiation safety hazards that these procedures may produce and the methods to be used to minimize those hazards (i.e., protective shielding, surveys, storage methods).

c. List the form and type of radioactive waste expected to be produced from these procedures and how it will be disposed of.

Department Chairman's Signature: _____

Applicant's Signature: _____

Date: _____

Radiation Safety Officer's Signature: _____

Date: _____

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Attachment I

Group I

Use of prepared radiopharmaceuticals for certain diagnostic studies involving measurements of uptake, dilution, and excretion. This group does not include uses involving imaging and tumor localizations:

- Iodine-123, iodine-125, and iodine-131, as sodium iodide (NaI) for measurement of thyroid uptake.
- Iodine-125 and iodine-131 as iodinated human serum albumin (IHSA) for determinations of blood and blood plasma volume and for studies of cardiovascular function and protein turnover.
- Iodine-131 as labeled rose bengal for liver function studies.
- Iodine-125 and iodine-131 as labeled fats or fatty acids for fat absorption studies.
- Iodine-125 as labeled sodium isothalamate for kidney function studies.
- Iodine-123 and iodine-131 as labeled sodium iodohippurate for kidney function studies.
- Cobalt-57, cobalt-58, and cobalt-60 as labeled cyanocobalamin for intestinal absorption studies.
- Chromium-51 as sodium chromate for determination of red blood cell volume and studies of red blood cell survival time and gastrointestinal blood loss.
- Chromium-51 as labeled human serum albumin for gastrointestinal protein loss studies.
- Iron-59 as citrate for iron turnover studies.
- Potassium-42 as chloride for potassium space determinations.
- Technetium-99m as pertechnetate for blood flow studies.

Any radioactive material contained in a radiopharmaceutical used for diagnostic purposes involving the measurement of uptake, dilution, or excretion for which a New Drug Application (NDA) or Product License Application (PLA) has been approved by the U.S. Food and Drug Administration (FDA) when the product is used in accordance with the manufacturer's product package insert for the purposes specified therein.

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Attachment I

Group II

Use of prepared radiopharmaceuticals for diagnostic studies involving imaging and tumor localizations:

- Fluorine-18 in solution for bone imaging.
- Indium-111 as disodium pentetate for cisternography.
- Indium-111 as oxyquinoline (oxine) for preparation of labeled autologous leukocytes for focal inflammatory lesion imaging.
- Indium-113m as indium chloride for placenta localization and blood pool imaging.
- I-123, I-125, I-131 as sodium iodide (NaI) for thyroid imaging.
- Iodine-125 as labeled fibrinogen (human) for use as an aid in the diagnosis of deep-vein thrombosis of the legs.
- Iodine-131 as iodinated human serum albumin (IHSA) for brain tumor localizations, cardiac imaging, and placenta localization.
- Iodine-131 as colloidal (microaggregated) iodinated human serum albumin for liver imaging.
- Iodine-131 as labeled rose bengal for liver imaging.
- Iodine-131 as sodium iodohippurate for kidney imaging.
- Chromium-51 as labeled human serum albumin for placenta localization.
- Gallium-67 as citrate for tumor imaging and diagnosis of acute inflammatory lesions.
- Gold-198 in colloidal form for liver imaging.
- Mercury-197 as labeled chlormerodrin for kidney and brain imaging.
- Selenium-75 as labeled selenomethionine for pancreas imaging.
- Strontium-85 as nitrate for bone imaging.
- Technetium-99m as pertechnetate for brain, thyroid, salivary gland, blood pool, placenta localization, cystography, and dacryocystography.
- Technetium-99m as labeled sulfur colloid for liver, spleen, esophageal, and bone marrow imaging.
- Technetium-99m as labeled macroaggregate human serum albumin for lung imaging.
- Ytterbium-169 as pentetate calcium trisodium for cisternography.
- Thallium-201 as chloride for myocardial and myocardial perfusion imaging.

Any radioactive material in a radiopharmaceutical prepared from a reagent kit listed in item (c) of Group III.

Any radioactive material contained in a radiopharmaceutical used for diagnostic purposes involving imaging for which a New Drug Application (NDA) or Product License Application (PLA) has been approved by the U.S. Food and Drug Administration (FDA) when the product is used in accordance with the manufacturer's product package insert for the purposes specified therein.

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Attachment I

Group III

Use of generators and reagent kits for the preparation and use of radiopharmaceuticals containing radioactive material for certain diagnostic uses:

- (a) Molybdenum-99/technetium-99m generators for the elution of technetium-99m as pertechnetate for:
- (1) brain imaging
 - (2) thyroid imaging;
 - (3) salivary gland imaging;
 - (4) blood pool imaging including placenta localization;
 - (5) blood flow studies;
 - (6) cystography;
 - (7) dacryocystography; or
 - (8) use with reagent kits for preparation and use of radiopharmaceuticals containing technetium-99m as provided in Items (c) and (d) of this Group.
- (b) Tin-113m/indium-113m generators for the elution of indium-113m as chloride for:
- (1) blood pool imaging;
 - (2) placenta localization; or
 - (3) use with reagent kits for preparation and use of radiopharmaceuticals containing indium-113m as provided in Item (d) of this Group.
- (c) Reagent kits for preparation of technetium-99m labeled:
- (1) sulfur colloid for liver, spleen, gastroesophageal, and bone marrow imaging;
 - (2) pentetate sodium for brain and kidney imaging and kidney function studies;
 - (3) human serum albumin microspheres for lung imaging and diagnosis of deep vein thrombosis of the legs;
 - (4) polyphosphates for bone imaging;
 - (5) macroaggregated human serum albumin for lung imaging;
 - (6) etidronate sodium for bone imaging;
 - (7) stannous pyrophosphate for bone and cardiac imaging;
 - (8) human serum albumin for heart blood pool and pericardial imaging;
 - (9) medronate sodium for bone imaging;
 - (10) gluceptate sodium for brain and renal perfusion imaging;
 - (11) oxidronate sodium for bone imaging;
 - (12) disofenin for hepatobiliary imaging;
 - (13) succimer for renal imaging; or
 - (14) albumin colloid for liver, spleen, and bone marrow imaging.
- (d) Any generator or reagent kit used for the preparation of radiopharmaceuticals for which the U.S. Food and Drug Administration has approved a New Drug Application (NDA) or Product License Application (PLA) when used in accordance with the manufacturer's product package insert for the purposes specified therein.