



Bracco Research USA Inc.

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Princeton, New Jersey 08540
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REGION I

2001 JAN 18 AM 11: 28

030-34011

January 15, 2001

Licensing Assistant Section
Nuclear Materials Safety Branch
U.S. Nuclear Regulatory Commission, Region I
475 Allendale Road
King of Prussia, PA 19406-1415

Subject: **Renewal of NRC License #29-30262-01**
Control # 129016

Dear Sir/Madam,

Enclosed is the renewal application for the above referenced license. Thank you in advance for your time and effort.

Best Regards,

Micheal Tweedle, Ph.D.
President

ASL
NMSS/RGN MATERIALS-002

(8-2000)
10 CFR 30, 32, 33,
34, 35, 36, 38, and 40

APPLICATION FOR MATERIAL LICENSE

Estimated burden per response to comply with this mandatory collection request: 7.4 hours. Submittal of the application is necessary to determine that the applicant is qualified and that adequate procedures exist to protect the public health and safety. Send comments regarding burden estimate to the Records Management Branch (T-6 E6), U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, or by internet e-mail to bjs1@nrc.gov, and to the Desk Officer, Office of Information and Regulatory Affairs, NEOB-10202, (3150-0000), Office of Management and Budget, Washington, DC 20503. If a means used to impose an information collection does not display a currently valid OMB control number, the NRC may not conduct or sponsor, and a person is not required to respond to, the information collection.

INSTRUCTIONS: SEE THE APPROPRIATE LICENSE APPLICATION GUIDE FOR DETAILED INSTRUCTIONS FOR COMPLETING APPLICATION. SEND TWO COPIES OF THE ENTIRE COMPLETED APPLICATION TO THE NRC OFFICE SPECIFIED BELOW. 030-34011

APPLICATION FOR DISTRIBUTION OF EXEMPT PRODUCTS FILE APPLICATIONS WITH:

DIVISION OF INDUSTRIAL AND MEDICAL NUCLEAR SAFETY
OFFICE OF NUCLEAR MATERIALS SAFETY AND SAFEGUARDS
U.S. NUCLEAR REGULATORY COMMISSION
WASHINGTON, DC 20555-0001

ALL OTHER PERSONS FILE APPLICATIONS AS FOLLOWS:

IF YOU ARE LOCATED IN:

CONNECTICUT, DELAWARE, DISTRICT OF COLUMBIA, MAINE, MARYLAND,
MASSACHUSETTS, NEW HAMPSHIRE, NEW JERSEY, NEW YORK, PENNSYLVANIA,
RHODE ISLAND, OR VERMONT, SEND APPLICATIONS TO:

LICENSING ASSISTANT SECTION
NUCLEAR MATERIALS SAFETY BRANCH
U.S. NUCLEAR REGULATORY COMMISSION, REGION I
475 ALLENDALE ROAD
KING OF PRUSSIA, PA 19406-1415

ALABAMA, FLORIDA, GEORGIA, KENTUCKY, MISSISSIPPI, NORTH CAROLINA, PUERTO
RICO, SOUTH CAROLINA, TENNESSEE, VIRGINIA, VIRGIN ISLANDS, OR WEST VIRGINIA,
SEND APPLICATIONS TO:

SAM MUNN ATLANTA FEDERAL CENTER
U. S. NUCLEAR REGULATORY COMMISSION, REGION II
61 FORSYTH STREET, S.W., SUITE 23785
ATLANTA, GEORGIA 30303-8831

IF YOU ARE LOCATED IN:

ILLINOIS, INDIANA, IOWA, MICHIGAN, MINNESOTA, MISSOURI, OHIO, OR WISCONSIN, SEND
APPLICATIONS TO:

MATERIALS LICENSING BRANCH
U.S. NUCLEAR REGULATORY COMMISSION, REGION III
801 WARRENVILLE RD.
LISLE, IL 60532-4351

ALASKA, ARIZONA, ARKANSAS, CALIFORNIA, COLORADO, HAWAII, IDAHO, KANSAS,
LOUISIANA, MONTANA, NEBRASKA, NEVADA, NEW MEXICO, NORTH DAKOTA, OKLAHOMA,
OREGON, PACIFIC TRUST TERRITORIES, SOUTH DAKOTA, TEXAS, UTAH, WASHINGTON, OR
WYOMING, SEND APPLICATIONS TO:

NUCLEAR MATERIALS LICENSING SECTION
U.S. NUCLEAR REGULATORY COMMISSION, REGION IV
611 RYAN PLAZA DRIVE, SUITE 400
ARLINGTON, TX 76011-8084

PERSONS LOCATED IN AGREEMENT STATES SEND APPLICATIONS TO THE U.S. NUCLEAR REGULATORY COMMISSION ONLY IF THEY WISH TO POSSESS AND USE LICENSED MATERIAL IN STATES SUBJECT TO U.S. NUCLEAR REGULATORY COMMISSION JURISDICTIONS.

1. THIS IS AN APPLICATION FOR (Check appropriate item)

- ☐ A. NEW LICENSE
☐ B. AMENDMENT TO LICENSE NUMBER
☒ C. RENEWAL OF LICENSE NUMBER 29-30262-01

2. NAME AND MAILING ADDRESS OF APPLICANT (include ZIP code)

Bracco Research USA
305 College Rd East
Princeton, New Jersey 08540

3. ADDRESS WHERE LICENSED MATERIAL WILL BE USED OR POSSESSED

305 College Rd East
Princeton, New Jersey

4. NAME OF PERSON TO BE CONTACTED ABOUT THIS APPLICATION

Scott Dennerlein

TELEPHONE NUMBER

(609) 597-1721

SUBMIT ITEMS 5 THROUGH 11 ON 8-1/2 X 11" PAPER. THE TYPE AND SCOPE OF INFORMATION TO BE PROVIDED IS DESCRIBED IN THE LICENSE APPLICATION GUIDE.

5. RADIOACTIVE MATERIAL

a. Element and mass number; b. chemical and/or physical form; and c. maximum amount
which will be possessed at any one time.

6. PURPOSE(S) FOR WHICH LICENSED MATERIAL WILL BE USED.

7. INDIVIDUAL(S) RESPONSIBLE FOR RADIATION SAFETY PROGRAM AND THEIR
TRAINING EXPERIENCE.

8. TRAINING FOR INDIVIDUALS WORKING IN OR FREQUENTING RESTRICTED AREAS.

9. FACILITIES AND EQUIPMENT.

10. RADIATION SAFETY PROGRAM.

11. WASTE MANAGEMENT.

12. LICENSE FEES (See 10 CFR 170 and Section 170.31)

FEE CATEGORY 3M AMOUNT \$
ENCLOSED

13. CERTIFICATION. (Must be completed by applicant) THE APPLICANT UNDERSTANDS THAT ALL STATEMENTS AND REPRESENTATIONS MADE IN THIS APPLICATION ARE BINDING UPON

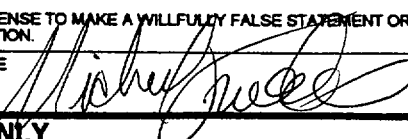
THE APPLICANT AND ANY OFFICIAL EXECUTING THIS CERTIFICATION ON BEHALF OF THE APPLICANT, NAMED IN ITEM 2, CERTIFY THAT THIS APPLICATION IS PREPARED IN CONFORMITY WITH TITLE 10, CODE OF FEDERAL REGULATIONS, PARTS 30, 32, 33, 34, 35, 36, 38, AND 40, AND THAT ALL INFORMATION CONTAINED HEREIN IS TRUE AND CORRECT TO THE BEST OF THEIR KNOWLEDGE AND BELIEF.

WARNING: 18 U.S.C. SECTION 1001 ACT OF JUNE 25, 1948 62 STAT. 749 MAKES IT A CRIMINAL OFFENSE TO MAKE A WILLFULLY FALSE STATEMENT OR REPRESENTATION TO ANY DEPARTMENT OR AGENCY OF THE UNITED STATES AS TO ANY MATTER WITHIN ITS JURISDICTION.

CERTIFYING OFFICER - TYPED/PRINTED NAME AND TITLE

Dr. Michael Tweedle, President

SIGNATURE



DATE

1/16/01

FOR NRC USE ONLY

TYPE OF FEE	FEE LOG	FEE CATEGORY	AMOUNT RECEIVED	CHECK NUMBER	COMMENTS
			\$		
APPROVED BY				DATE	

129016

**NRC License #29-30262-02
Renewal Application**

5. In addition to the current radioactive isotopes and quantity authorizations we wish to;

Increase the limit for Sulfur-35 to 25 millicuries.
Increase the limit for Technetium-99m to 4 curies

Add the following isotopes;

Molybdenum-99	4 curies
Yttrium-90	25 millicuries
Holmium-166	25 millicuries
Lutetium-177	25 millicuries
Rhenium-186	25 millicuries
Rhenium-188	1 curie
Tungsten-188	1.3 curies

The Moly-99 and Tungsten-188 will be in the form of commercially available generators. The Mo-99 to generate Tc-99m, and the W-188 to generate Re-188.

**NRC License #29-30262-01
Renewal Application**

6. A. through I. Research and development as defined in 10 CFR 30.4;
 animal studies.
 J. Calibration reference standards.

**NRC License #29-30262-02
Renewal Application**

7. Scott Dennerlein will continue to be the RSO for this license. This renewal application proposes Karen Linder as Assistant RSO. Dr. Linder is currently an Authorized User, and member of the Radiation Safety Committee.

In addition to the current Authorized Users, Steve Eaton, Ernie Shramm, and Adrian Nunn, please add John Johnstone as an Authorized User. Please remove Ruth Wager as an Authorized user.

Bracco Research USA
Authorized User Radioactive Material Experience Record

Name: John Johnstone

Title: Senior Research Scientist

Room # 50

Telephone Ext. 609-514-2413

Formal Radiation Training:

College/University Courses:
 none

Short Courses: (indicate duration)
 none

In-house Training:
 Annual training for over 20 years

Specific isotope usage:

Nuclide	Chemical form	Physical form	Maximum Quantity	
			per experiment	total possession
^{99m} Tc	NaTcO ₄	solution	typically 20 mCi	100 mCi
³ H	tritiated peptides	lyophilized, or solution	several uCi	app 250 uCi
¹⁴ C	¹⁴ C labeled peptides	lyophilized, or solution	several uCi	app 100 uCi
¹⁵³ Gd	GdCl ₃	solution	typically 100 uCi	app 1000 uCi
¹²⁵ I	¹²⁵ I-antibody	lyophilized, or solution	typically 1 uCi	app 10 uCi
At previous employers (nuclear medicine manufacture and quality control)				
¹³¹ I	NaI	solution	100 uCi	150 mCi
⁵¹ Cr	NaCrO ₄	solution	30 uCi	30 uCi
¹³³ Xe	¹³³ Xe	gas	10 mCi	10 mCi
⁵⁷ Co	cyanocobalamine	solution	0.5 uCi	50 uCi
¹³⁷ Cs	CsCl ₃	solution	15 uCi	500 uCi

Radiation detection equipment experience: (circle all that apply)

Beta survey meter

low energy gamma detector

well crystal detector

Dose rate meter

high energy gamma detector

liquid scintillation counter

**NRC License #29-30262-01
Renewal Application**

8,9,10,11. These items are described in the Radiation Safety Manual, which was submitted as part of the original license application. A revised manual is included with this application. The changes to the manual are indicated by strikethroughs for deletions, and underlines for additions.

Bracco Research USA

Radiation Safety Manual

Management's' Radiation Protection Philosophy

The management of Bracco Research USA encourages the appropriate use of radioactive material in our research, with the proper controls. Any questions or concerns about the use, storage or disposal of radioactive material should be freely expressed. While the safe limits for radiation exposure to workers have been established by international and national agencies, Bracco will strive to limit exposure to workers and potential exposures to members of the public to 10% of those limits. We support the ALARA philosophy, that is, to keep radiation risks "as low as reasonably achievable". A Radiation Safety Committee has been established, with my full support to oversee the safe handling of radioactive material in our facility and implement the policies contained in this manual.

Michael F. Tweedle
President, Bracco Research USA

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1.0 Introduction

The use of radioactive material is licensed by the Nuclear Regulatory Commission for by-product material and by the State of New Jersey, Radiation Protection Programs, for accelerator produced material. The program described in this document is incorporated into these licenses by reference, and therefore is legally binding. This radiation safety manual is intended to provide guidance for the safe use of radioactive material for research, in compliance with all applicable regulations and Bracco Research USA's radioactive material licenses. If there are any questions or doubts in the application of these guidelines to your work, contact the Radiation Safety Officer before proceeding.

2.0 Program Organization & Responsibilities

The President of Bracco Research USA has the ultimate responsibility to provide the resources to safely manage licensed radioactive material. The ongoing program management is under the control of the Radiation Safety Committee. The routine operational compliance with license conditions and technical support is the responsibility of the Radiation Safety Officer. An organizational chart showing the lines of authority and responsibility for radioactive material use is on the last page of this manual.

2.1 Radiation Safety Committee

All aspects of the use of radioactive materials onsite are under the control of the Radiation Safety Committee (RSC). The membership is composed of all authorized users, the Radiation Safety Officer, and assistant Radiation Safety Officer. The RSC will meet ~~once each calendar quarter~~ twice each year to conduct business. Any course of action wherein dissenting opinions are expressed will be decided by a simple majority of the full membership. Absent members may be contacted by the chairman and their votes counted before any action is final. Minutes of all regular and special meetings will be maintained onsite for the duration of the license.

The RSC will prescribe special conditions and requirements related to training of users, approve procedures, regulation of quantities and types of radioactivity to be used in specific areas, methods of disposal, etc. as may be necessary. The RSC will investigate and judge the adequacy of radiation safety measures and protection from radiation

hazards for all employees and contractors of Bracco Research USA. The RSC has the authority to prohibit the use of radioactive material by any employee, if, in its judgment, an undue health, safety, or environmental hazard is involved. The RSC will ensure annual audits of radioactive material labs are conducted to ensure compliance with this manual and the requirements of 10 CFR 20.

2.2 Radiation Safety Officer

The Radiation Safety Officer is Scott W. Dennerlein, ~~a contract employee.~~ He will work under the provisions of Bracco Research USAs' NRC license. The RSO shall arrange for Instrument calibration and maintain all radiation safety equipment. The RSO is responsible for conducting monthly surveys in the affected areas and maintaining detailed records of such monitoring, and will report his findings at the next regularly scheduled meeting of the RSC. The RSO is responsible for training researchers in health physics, assisting authorized users in experiment planning, and overall technical accuracy of the program. The RSO will oversee and coordinate waste handling and disposal for all radioactive materials. Annual dosimetry or waste profile reports will be generated by the RSO.

2.3 Assistant RSO

The assistant RSO is Dr. ~~Adrian D. Nunn~~ Karen Linder, a Bracco Research USA employee. ~~He~~ She will provide a day to day presence with the authority to direct authorized users or other employees in the event of an emergency. The assistant RSO shall enforce the personnel monitoring program, including dosimetry and bioassay. He She will ensure timely and accurate filing of forms by the authorized users. ~~He will oversee the health physics program budget.~~

2.4 Authorized Users (AU)

Authorized users are responsible for all individuals in their lab, with regards to radiation safety. This includes all permitted users and all contractors or maintenance personnel. The AU should approve any renovation or maintenance in a lab. The AU must contact the RSO for a contamination survey prior to any work on systems or equipment suspected of being contaminated. In addition each AU is responsible for tracking the radioactive material, (until accepted as waste by the health physics staff), he or she has procured.

2.5 Permitted Users

Permitted users are approved by the RSC to work under the supervision of authorized users after receiving radiation safety training. Permitted users cannot order or receive radioactive material, and are not responsible for inventories.

3.0 Training Requirements

There are three levels of radiation safety training provided at Bracco Research USA. The first level is a brief session between the RSO and the secretarial or maintenance staff. These individuals will be made aware of the presence of radioactive material onsite, how to recognize the radiation symbol, and instructions to avoid coming into contact with same. Both permitted users and authorized users will receive the initial and refresher training discussed in the next section. ~~In addition, the authorized users will receive training in emergency decontamination techniques, record keeping, and any specialized counting equipment (i.e. thyroid scanner).~~

3.1 Initial and Refresher Training

Training will be provided to all individuals who will use, or may come in contact with, radioactive material. Initial training will follow the outline enclosed. Retraining on selected topics, identified during lab audits, will be provided annually. Changes in regulations or waste disposal options will also be discussed. Procedure specific training will be provided to individuals as necessary. Both classroom and "hands-on" training will be employed. In particular, meter selection and survey techniques will be hands-on, as well as donning and doffing protective equipment, and handling liquid or unconfined volatile radioactive material. Classroom instruction will include directions when operations should be confined to a hood or glove box. A listing of general rules

for handling radioactive materials will be posted in each affected lab. A copy of those rules is provided on the next page.

General Rules for Working with Radioactive Materials

1. Eating, drinking, smoking, or using cosmetics is not permitted in affected areas.
2. Wash hands after handling any radioactive material, even if gloves are worn.
3. Never pipette anything by mouth.
4. Always use rubber or plastic gloves when handling radioisotopes. Lab coats should be worn in the laboratory and left in the laboratory.
5. Notify the RSO of all major spills.
6. Label radioactive material with your name, date, isotope and quantity.
7. Clean and monitor your area after working with radioactive materials.
8. Follow all procedures for proper handling and disposal of waste.
9. Material which could become airborne must be used in a hood. If uncertain contact health physics.
10. Never store food or beverages in refrigerators or freezers with radioisotopes.

This ~~should~~ shall remain posted in all radioactive materials laboratories. |

4.0 Radioactive Material Control

The licensed radioactive material used at Bracco research USA is controlled through administrative procedures as well as physical controls. Every level of management is responsible for a part of the control. The RSC will approve procedures and determine the need for new procedures based on requests from users, audit findings, or other sources of information. The RSC will also recommend changes in facility design or purchase of equipment to support the radiation safety program. The RSO will ensure the technical accuracy of the control mechanisms, and compliance with the regulations. Each authorized user is responsible for the material under their control as well as those researchers working in their labs. ANY person using radioisotopes at Bracco Research USA must first obtain RSC authorization, documented on an application for authorization to use radioisotopes.

4.1 General

4.1.1 Labeling containers

Containers with quantities of radioactive material greater than 10CFR20 Appendix C values will be labeled "Caution-Radioactive Materials". In addition the isotope, radioactivity and date should be written on the label.

4.1.2 Posting of rooms

Rooms with greater than ten times 10CFR20 Appendix C values must be placarded "Caution- Radioactive Material". These values for many of the radio nuclides used in this facility are presented in Table 2, at the end of this manual.

4.1.3 Radioactive Material Procurement & Receipt

Only authorized users can order radioactive material. When the purchase order (PO) is prepared, the AU must contact the RSO or Assisstant RSO to discuss the current site inventory, including radioactive waste. The RSO will verbally approve the purchase, allowing the order to proceed. Radioactive material should only be received at the loading dock. The outside phone will ring at the receptionists desk, who will contact the AU. Only ~~an AU~~ a permitted user will receive and survey incoming packages. Surveys will be performed only on packages with greater than Appendix C quantities in liquid or solid form. The package will be surveyed on the loading dock,

according to written procedure which satisfy the conditions in 10CFR20.1906, and documented on a radioactive package receipt form. The RSO or Asst. RSO shall be notified if wipe tests indicate contamination levels of 200 dpm above background. Packages with contamination levels greater than 1,000 dpm/100 cm² will be locked in the radioactive waste storage area on the loading dock until further instructions from the RSO.

~~A special provision is made for delivery of short lived nuclear medicine. If the nuclear medicine company (presently Syncor) arrives before eight am, and no authorized user is present, the driver may place the package in a lock box on Bracco's loading dock, adjacent to the waste storage cage. The AU will survey the package upon arrival, or make provisions with another authorized user if delayed. Weekends deliveries will not be scheduled.~~

4.1.4 Inventory

Authorized users will maintain an inventory of radioactive material under their control. The RSO will maintain the total inventory of radioactive material both in use and in the waste stream. A current inventory will be presented to the RSC at the quarterly meetings.

4.1.5 Sealed Sources

Sealed sources containing more than 100 micro curies of a beta or gamma emitter will be leak tested at six month intervals. A written procedure which satisfies the conditions in 10CFR35.59 will be followed by the RSO or his staff.

4.1.6 Securing radioactive material

Authorized users will ensure that radioactive material under their control is secured at the end of each day through storage in a locked refrigerator, cabinet, or other enclosure. Affected labs should be locked as well. Radioactive material in process systems in hoods need not be secured but must be clearly labeled, "Caution - Radioactive Material". Animals administered radio tracers will have their cage clearly labeled, and all bedding, waste, and the cage itself will be treated as contaminated, ~~until proven otherwise.~~ Only authorized users or their designate can handle animals, bedding, and cages of radio tracer labeled animals.

4.1.7 Transporting radioactive material onsite.

Transporting material between labs should be minimized. Avoid transporting unpackaged dry material, never transport uncapped liquid containers. Dose rates on packages of nuclear medicine should be well established prior to transport. Use a cart when possible, and shielding when appropriate. Place container of radioactive liquid in larger containers during transport surrounded by absorbent. Do not transport material through the reception area or lunch room. Radioactive waste should be stored in the labs and transported to the waste room only by personnel trained in radioactive waste procedures. Do not transport delivered radioactive material packages until the survey has been completed on the loading dock, and the wipe survey results have been reviewed by the Authorized or permitted-User receiving the package.

4.2 Specific

4.2.1 Nuclear Medicine

Only an ~~AUa~~ permitted or authorized user can survey and transport nuclear medicine delivered to Bracco. Specific written procedures concerning shielding, surveys, and personal protection are provided for handling this material onsite. All individuals utilizing nuclear medicine must survey their hands, feet, and the general area after use.

4.2.2 Iodination

Iodination will be performed in a glove box with two charcoal filters, placed on a bench top in the iodination laboratory. The glove box does not discharge through a stack, so there will be no effluent monitoring. An air sample will be obtained within a few feet of the exhaust and considered a worst case, breathing zone air sample. A particulate and charcoal filtered air sample will be collected during iodination's, and counted onsite in a calibrated well crystal, with a minimum detectable activity below 10% of the derived air concentration. A specific written procedure is to be followed for iodinations, incorporating health physics monitoring.

5.0 Radiation Monitoring

As a condition of our licenses, Bracco Research USA is required to monitor or evaluate contamination in laboratories, releases of radioactive material to air and water, and personal intakes of radioactive materials. This is accomplished via contamination surveys, both "after use" for ~~some~~ all procedures and monthly, dose rate surveys and air sampling during iodinations.

Personnel monitoring to evaluate total effective dose equivalent is achieved through dosimetry such as film and/or TLD's (whole body and/or ring) and bioassays such as urine samples and thyroid scans. Individuals in the bioassay program will submit baseline samples or measurements prior to initial handling of radioactive material. Bracco has set administrative limits at 10% of the allowable federal regulations in 10 CFR 20. When these levels are exceeded, the RSO will investigate, conduct additional measurements to evaluate dose, and report to the RSC.

5.1 Personnel

5.1.1 Urinalysis

Urine samples will be submitted for analysis within 24 hours but at least two hours after individuals utilize more than 100 millicuries of tritium or carbon-14 within one month.

5.1.2 Thyroid scans

Thyroid scans will be conducted according to written procedures within 72 hours, but no sooner than 6 hours after exceeding the levels specified in Table 1. The thyroid scan will be performed with a sodium iodide type detector connected to a single channel analyzer/scalar, and calibrated using a neck phantom and NIST traceable standard. The quantities listed apply to the cumulative amount in process handled by a worker during a three month period. At a minimum a baseline and termination thyroid scan will be conducted for individuals handling radio iodine.

Table 1. Activity Levels above which Bioassay for I-125 or I-131 is Necessary*

Location of Process	Volatile or dispersible	Bound to nonvolatile agent
open bench	0.1 mCi	1 mCi
fume hood	1 mCi	10 mci
glovebox	10 mCi	100 mci

*Applications of Bioassay for I-125 and I-131, NRC Reg. Guide 8.20

5.2 Environmental

5.2.1 Area surveys

Surveys will be performed monthly in the affected laboratories and the radioactive waste storage cage by members of the health physics staff. These surveys will assess fixed and removable contamination and dose rates, in representative areas of each lab and documented. ~~AU's~~ All radioactive material users are expected to conduct surveys after use of radioactive material above Appendix C values, ~~although they do not have to be documented and record the surveys on the Area/Personnel Survey Form posted at the exits from the laboratories.~~ At a minimum, personnel should survey their hands and feet after handling radioactive material.

5.2.2 Water sampling

At this time, licensed material will not be directly discharged into the air or sanitary sewer as a disposal method.

5.2.3 Air sampling

Present operations call for air sampling at the exhaust of the iodination glove box. Both particulate and charcoal samples will be obtained following a written procedure. The need for air sampling other areas or hoods will be determined by the RSC in consultation with the RSO.

6.0 Radioactive Waste Management

Bracco's system for maintaining accurate records of radioactive waste to assure accountability shall include labeling waste containers with appropriate information and

a documented waste tracking system. Waste is segregated in the laboratory by half-life, greater than or less than 65 days, and placed in five gallon pails for dry waste or screw top plastic containers for liquids. Each container is labeled with isotope, activity in mCi and assay date. When bags are placed into 55 gallon drums in the waste room, this information is transferred to a drum log sheet. When the drum is full, it is sealed, wipe tested, labeled and monitored for external radiation. The activities recorded on the log are totaled at that time. The RSO will schedule and supervise all radioactive waste shipments. Bracco anticipates generating only ~~ten to fifteen~~four to five drums of Class A waste each year. There will be monthly container inspections and area surveys for contamination and dose rate. The storage area is a fenced portion of an enclosed loading dock. Access will be granted to -authorized and permitted users and radiation safety office staff, controlled via a locked gate.

6.1 Laboratory Storage

Radioactive waste can be stored in an affected laboratory for up to one month. The waste should be kept in one location, clearly labeled "Caution-Radioactive Material", and separated by half-life category, as defined above. Liquids should be kept in closed plastic containers, labeled as above. An inventory log should be attached to each container.

6.2 Decay in Storage

All radioactive material with half lives less than sixty-five days will be held for ten half lives, surveyed, and if indistinguishable from background, disposed as non-radioactive waste. The waste will be segregated in each laboratory at the time of disposal, into separate waste containers for long and short lived isotopes. All references to radiation should be obliterated on items placed into the short lived isotopes container. A written procedure for the final disposal survey will be followed, the surveyor, date, equipment and survey results documented. Routine inspection of the containers will ensure containment of the waste and integrity of the containers. Waste will be packaged in DOT 17H drums, fiberboard containers, or equivalent. Radioactive waste streams not specifically described below will be disposed at a licensed disposal facility.

6.3 Biological Waste

Biological waste will be stored onsite in a freezer in the radioactive waste storage area on the loading dock. Biological waste is subject to the same decay in storage procedures outlined above, when applicable. Decayed biological waste will be disposed through a licensed hazardous waste broker.

6.4 Sanitary sewer disposal

There will be no sanitary sewer disposal of liquid waste onsite. Liquid waste will be stored in screw top plastic containers in a designated area at the point of generation, then in the radioactive waste storage cage. Offsite disposal through incineration, or adsorption and burial, may be performed using a licensed radioactive waste broker.

7.0 Radiation Emergencies

Authorized users will be trained in emergency response procedures appropriate for the material handled at Bracco Research USA. Permitted users and other staff will be instructed to follow AU instructions in an emergency. In addition Radiation emergency Emergency procedures will be posted in each radioactive materials laboratory. A copy is provided on the next page.

RADIATION EMERGENCY PROCEDURES

Major Spills, Involving Radiation Hazards to Personnel

1. Notify all persons not involved in the spill to vacate the room at once. Limit the movement of displaced persons to confine the spread of contamination until they are monitored.
2. If the spill is liquid and the hands are protected, right the container, otherwise use long tongs.
3. If the spill is on the skin, immediately flush thoroughly and monitor.
4. If the spill is on clothing, discard outer or protective clothing at once, monitor and decontaminate.
5. Turn off fans, try to avoid creation of airborne contamination.
6. Vacate the room but take care not to track or spread contamination.
7. Notify the **RSO** as soon as possible, if he is not onsite
call 609 290-4643
8. Take immediate steps to decontaminate personnel involved as necessary.
9. The RSO will direct the decontamination.

Example: Rupture of a vial of Technecium.

RADIATION EMERGENCY PROCEDURES

Minor spills, Involving No radiation Hazard to Personnel

1. Notify all persons in the room and area at once.
2. Survey people which were in the immediate area of the spill.
3. Permit only the minimum number of persons necessary to deal with the spill into the area.
4. Confine the spill immediately.
 - A. Liquid spills
 - a. Don protective gloves
 - b. Drop absorbent on spill.
 - B. Dry spills
 - a. Don protective gloves
 - b. Dampen thoroughly, taking care not to spread contamination. Water may generally be used, except where chemical reaction with the water would generate an air contaminant: oil should be used instead.
5. Decontaminate: make a plan first.
6. A complete history of the accident and subsequent remedial or protective measures should be submitted to the RSO.

Example: TLC plate breakage.

Injuries to Personnel, Involving Radiation Hazard

1. Wash minor wounds immediately under running water, spreading the edges of the gash. If at all practical collect and retain cotton sponges, fluids, etc. for analysis.
2. Report all radiation accidents involving personnel wounds, overexposure, ingestion, or inhalation to the RSO as soon as possible.
3. No person involved in a radiation injury should return to work without the approval of the attendant physician and the RSO.
4. Prepare a complete history of the accident and subsequent activity for the RSC.

Example: Finger cut by TLC plate or HPLC needle

RADIATION EMERGENCY PROCEDURES

Accidents Involving Radioactive Dusts, Mists, and Gases

1. Notify all other persons to vacate the room immediately.
2. Hold breath and close air vents.

3. Vacate the room. Seal off area, if possible.
4. Notify the RSO at once.
5. Ascertain that all doors giving access to the room are closed. Post conspicuous warnings or guards to prevent accidental opening of doors.
6. Monitor all persons suspected of contamination. Proceed with decontamination of personnel.
7. Report at once to the RSO all known or suspected ingestions or inhalations of radioactive materials.
8. Collect bioassay samples as directed by the RSO.
9. Decontaminate the area only upon the advice of the RSO. Air sampling should be conducted prior to resuming work in the area.

Example: Loss of glovebox containment during iodinations.

Table 2. Properties of Some Isotopes used @ Bracco Research USA

Isotope	App. C* value	ALI# (inhalat)	Principle Emissions	Half-life
H-3	1,000 μ Ci	80,000 μ Ci	18 keV β	12 yrs.
C-14	100 μ Ci	2,000 μ Ci	156 keV β	5730 yrs.
I-125	1 μ Ci	60 μ Ci	35 keV γ	60 dys.
Tc-99	100 μ Ci	500 μ Ci	294 keV β	2×10^5 yrs.
Tc-99m	1,000 μ Ci	700 μ Ci	140 keV γ	6 hrs.
Mn-54	100 μ Ci	800 μ Ci	835 keV γ	312 dys.
Gd-153	10 μ Ci	100 μ Ci	100 keV γ	242 dys.
Tl-201	1,000 μ Ci	20,000 μ Ci	167 keV γ	73 hrs.
In-111	100 μ Ci	6,000 μ Ci	245 keV γ	3dys.
Mo-99	100 μ Ci	3,000 μ Ci		
Yt-90	10 μ Ci	700 μ Ci	2 MeV β	
Ho-166	100 μ Ci	2,000 μ Ci	1.8 Mev β	<u>27 hours</u>
Lu-177	100 μ Ci	2,000 μ Ci	1.4 Mev β	<u>6.7 days</u>
Re-186	100 μ Ci	2,000 μ Ci	1 Mev β	<u>3.8 days</u>
Re-188	100 μ Ci	3,000 μ Ci	764 keV β	<u>17 hours</u>
W-188	10 μ Ci	1,000 μ Ci	7.7 MeV β	<u>69 days</u>

* Containers with greater than this quantity must be labeled "Caution-Radioactive Materials". Rooms with greater than ten times these values must be placarded "Caution-Radioactive Material".

The Annual Limit on Intake (ALI) will deliver 5 Rem Total Effective Dose Equivalent (TEDE). Bioassays indicating uptakes of 10% of these values will initiate an investigation and increased monitoring.