FORM NRC-313M (8-78) 10 CFR 35	U.S. NUCLEAR REGULATORY COMMISSION APPLICATION FOR MATERIALS LICENSE – MEDICAL	Approved: GAO R0557

INSTRUCTIONS – *Complete Items 1 through 26 if this is an initial application or an application for renewal of a license. Use supplemental sheets where necessary. Item 26 must be completed on all applications and signed. Retain one copy. Submit original and one copy of entire application to : Director, Office of Nuclear Materials Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555. Upon approval of this application, the applicant will receive a Materials License. An NRC Materials License is issued in accordance with the general requirements contained in Title 10, Code of Federal Regulations, Part 30, and the Licensee is subject to Title 10, Code of Federal Regulations, Parts 19, 20 and 35 and the license fee provision of Title 10, Code of Federal Regulations, Part 170. The license fee category should be stated in Item 26 and the appropriate fee enclosed.*

1.a. NAME AND MAILING ADDRESS OF APPLICANT *(Institution, firm, clinic, physician, etc.)* INCLUDE ZIP CODE

Pharmaco Nuclear, Inc.
100 North Euclid Avenue, Suite 900
St. Louis, MO 63108

TELEPHONE NO.: AREA CODE (314) 367 9300

1.b. STREET ADDRESS(ES) AT WHICH RADIOACTIVE MATERIAL WILL BE USED *(If different from 1.a.)* INCLUDE ZIP CODE

Same as 1. (a)

30-11488
02/06
L+L 19360

2. PERSON TO CONTACT REGARDING THIS APPLICATION

Frank M. Comer

TELEPHONE NO.: AREA CODE (816) 523 4014

3. THIS IS AN APPLICATION FOR: *(Check appropriate item)*

a. [X] NEW LICENSE
b. [ ] AMENDMENT TO LICENSE NO. _____
c. [ ] RENEWAL OF LICENSE NO. _____

4. INDIVIDUAL USERS *(Name individuals who will use or directly supervise use of radioactive material. Complete Supplements A and B for each individual.)*

Gary Redmore, Radiopharmaicst
David Hurwitz, Ph.D Radiopharmacist
Terry O'Hara, B.S. "
Richard E. Keesee "
William H. McHugh, Ph.D "

5. RADIATION SAFETY OFFICER (RSO) *(Name of person designated as radiation safety officer. If other than individual user, complete resume of training and experience as in Supplement A.)*

Administrative: Frank M. Comer, B.S.
Day to Day Manager: William H. McHugh, PHD

6.a. RADIOACTIVE MATERIAL FOR MEDICAL USE

See Attachment #1 RADIOACTIVE MATERIAL LISTED IN:	ITEMS DESIRED "X"	MAXIMUM POSSESSION LIMITS *(In millicuries)*
10 CFR 31.11 FOR IN VITRO STUDIES		
10 CFR 35.100, SCHEDULE A, GROUP I		AS NEEDED
10 CFR 35.100, SCHEDULE A, GROUP II		AS NEEDED
10 CFR 35.100, SCHEDULE A, GROUP III		
10 CFR 35.100, SCHEDULE A, GROUP IV		AS NEEDED
10 CFR 35.100, SCHEDULE A, GROUP V		AS NEEDED
10 CFR 35.100, SCHEDULE A, GROUP VI		

ADDITIONAL ITEMS:	MARK ITEMS DESIRED "X"	MAXIMUM POSSESSION LIMITS *(In millicuries)*
IODINE-131 AS IODIDE FOR TREATMENT OF HYPERTHYROIDISM		
PHOSPHORUS-32 AS SOLUBLE PHOSPHATE FOR TREATMENT OF POLYCYTHEMIA VERA, LEUKEMIA AND BONE METASTASES		
PHOSPHORUS-32 AS COLLOIDAL CHROMIC PHOSPHATE FOR INTRACAVITARY TREATMENT OF MALIGNANT EFFUSIONS.		
GOLD-198 AS COLLOID FOR INTRACAVITARY TREATMENT OF MALIGNANT EFFUSIONS.		
IODINE-131 AS IODIDE FOR TREATMENT OF THYROID CARCINOMA		
XENON-133 AS GAS OR GAS IN SALINE FOR BLOOD FLOW STUDIES AND PULMONARY FUNCTION STUDIES.		

6.b. RADIOACTIVE MATERIAL FOR USES NOT LISTED IN ITEM 6.a. *(Sealed sources up to 3 mCi used for calibration and reference standards are authorized under Section 35.14(d), 10 CFR Part 35 , and NEED NOT BE LISTED.)*

ELEMENT AND MASS NUMBER	CHEMICAL AND/OR PHYSICAL FORM	MAXIMUM NUMBER OF MILLICURIES OF EACH FORM	DESCRIBE PURPOSE OF USE
See Attachment #1			See Attachment #2

03407

8005060122

INFORMATION REQUIRED FOR ITEMS 7 THROUGH 23

For Items 7 through 23, check the appropriate box(es) and submit a detailed description of all the requested information. Begin each item on a separate sheet. Identify the item number and the date of the application in the lower right corner of each page. If you indicate that an appendix to the medical licensing guide will be followed, do not submit the pages, but specify the revision number and date of the referenced guide: Regulatory Guide 10.8 , Rev. _____ Date: _____

7. MEDICAL ISOTOPES COMMITTEE	**15. GENERAL RULES FOR THE SAFE USE OF RADIOACTIVE MATERIAL** *(Check One)*
☐ Names and Specialties Attached; and	☒ Appendix G Rules Followed; or See Attachment #8
☐ Duties as in Appendix B; or *(Check One)*	☐ Equivalent Rules Attached
☐ Equivalent Duties Attached	**16. EMERGENCY PROCEDURES** *(Check One)*
8. TRAINING AND EXPERIENCE	☒ Appendix H Procedures Followed; or Attachment #8
☐ Supplements A & B Attached for Each Individual User; and See Attachment #3	☐ Equivalent Procedures Attached
☐ Supplement A Attached for RSO.	**17. AREA SURVEY PROCEDURES** *(Check One)*
9. INSTRUMENTATION *(Check One)*	☐ Appendix I Procedures Followed; or
☐ Appendix C Form Attached; or	☐ Equivalent Procedures Attached See Attachment #8
☐ List by Name and Model Number See Attachment #4	**18. WASTE DISPOSAL** *(Check One)*
10. CALIBRATION OF INSTRUMENTS	☒ Appendix J Form Attached; or See Attachment 9
☐ Appendix D Procedures Followed for Survey Instruments; or See Attachment #5 *(Check One)*	☐ Equivalent Information Attached
☐ Equivalent Procedures Attached; and	**19. THERAPEUTIC USE OF RADIOPHARMACEUTICALS** *(Check One)*
☒ Appendix D Procedures Followed for Dose Calibrator; or *(Check One)*	☐ Appendix K Procedures Followed; or
☐ Equivalent Procedures Attached	☐ Equivalent Procedures Attached
11. FACILITIES AND EQUIPMENT	**20. THERAPEUTIC USE OF SEALED SOURCES**
☐ Description and Diagram Attached See Attachment #7	☐ Detailed Information Attached; and
12. PERSONNEL TRAINING PROGRAM	☐ Appendix L Procedures Followed; or *(Check One)*
☒ Description of Training Attached	☐ Equivalent Procedures Attached
13. PROCEDURES FOR ORDERING AND RECEIVING RADIOACTIVE MATERIAL	**21. PROCEDURES AND PRECAUTIONS FOR USE OF RADIOACTIVE GASES (e.g., Xenon – 133)**
☒ Detailed Information Attached	☐ Detailed Information Attached
14. PROCEDURES FOR SAFELY OPENING PACKAGES CONTAINING RADIOACTIVE MATERIALS *(Check One)*	**22. PROCEDURES AND PRECAUTIONS FOR USE OF RADIOACTIVE MATERIAL IN ANIMALS**
	☐ Detailed Information Attached
☐ Appendix F Procedures Followed; or	**23. PROCEDURES AND PRECAUTIONS FOR USE OF RADIOACTIVE MATERIAL SPECIFIED IN ITEM 6.b**
☒ Equivalent Procedures Attached	☒ Detailed Information Attached Attachment #2

24. PERSONNEL MONITORING DEVICES

TYPE (Check appropriate box)			SUPPLIER	EXCHANGE FREQUENCY
a. WHOLE BODY	X	FILM	R.S. Landauer	Monthly
		TLD		
		OTHER (Specify)		
b. FINGER		FILM		
	X	TLD	R.S. Landauer	Monthly
		OTHER (Specify)		
c. WRIST		FILM		
		TLD		
		OTHER (Specify)		

d. OTHER (Specify)

25. FOR PRIVATE PRACTICE APPLICANTS ONLY

a. HOSPITAL AGREEING TO ACCEPT PATIENTS CONTAINING RADIOACTIVE MATERIAL

NAME OF HOSPITAL

MAILING ADDRESS

CITY | STATE | ZIP CODE

b. ATTACH A COPY OF THE AGREEMENT LETTER SIGNED BY THE HOSPITAL ADMINISTRATOR.

c. WHEN REQUESTING THERAPY PROCEDURES, ATTACH A COPY OF RADIATION SAFETY PRECAUTIONS TO BE TAKEN AND LIST AVAILABLE RADIATION DETECTION INSTRUMENTS.

26. CERTIFICATE

(This item must be completed by applicant)

The applicant and any official executing this certificate on behalf of the applicant named in Item 1a certify that this application is prepared in conformity with Title 10, Code of Federal Regulations, Parts 30 and 35, and that all information contained herein, including any supplements attached hereto, is true and correct to the best of our knowledge and belief.

a. LICENSE FEE REQUIRED
(See Section 170.31, 10 CFR 170)

(1) LICENSE FEE CATEGORY: 3B

(2) LICENSE FEE ENCLOSED: $ $190.00

b. APPLICANT OR CERTIFYING OFFICIAL *(Signature)*

Richard E Keese

(1) NAME *(Type of Print)*
Richard E. Keesee

(2) TITLE
President

c. DATE
April 7, 1980

FORM NRC-313M (8-78)

PRIVACY ACT STATEMENT

Pursuant to 5 U.S.C. 552a(e)(3), enacted into law by section 3 of the Privacy Act of 1974 (Public Law 93-579), the following statement is furnished to individuals who supply information to the Nuclear Regulatory Commission on Form NRC-313M. This information is maintained in a system of records designated as NRC-3 and described at 40 Federal Register 45334 (October 1, 1975).

1. **AUTHORITY** Sections 81 and 161(b) of the Atomic Energy Act of 1954, as amended (42 U.S.C. 2111 and 2201(b)).

2. **PRINCIPAL PURPOSE(S)** The information is evaluated by the NRC staff pursuant to the criteria set forth in 10 CFR Parts 30-36 to determine whether the application meets the requirements of the Atomic Energy Act of 1954, as amended, and the Commission's regulations, for the issuance of a radioactive material license or amendment thereof.

3. **ROUTINE USES** The information may be used: (a) to provide records to State health departments for their information and use; and (b) to provide information to Federal, State, and local health officials and other persons in the event of incident or exposure, for their information, investigation, and protection of the public health and safety. The information may also be disclosed to appropriate Federal, State, and local agencies in the event that the information indicates violation or potential violation of law and in the course of an administrative or judicial proceeding. In addition, this information may be transferred to an appropriate Federal, State, or local agency to the extent relevant and necessary for a NRC decision or to an appropriate Federal agency to the extent relevant and necessary for that agency's decision a you. A copy of the license issued will routinely be placed in the NRC's Public Document Room, 1717 H Street, Washington, D.C.

4. **WHETHER DISCLOSURE IS MANDATORY OR VOLUNTARY AND EFFECT ON INDIVIDUAL OF NOT PRO INFORMATION** Disclosure of the requested information is voluntary. If the requested information is not however, the application for radioactive material license, or amendment thereof, will not be processed.

5. **SYSTEM MANAGER(S) AND ADDRESS** Director, Division of Fuel Cycle and Material Safety, Office of N rial Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555.

Attachment #1

BYPRODUCT SOURCE AND/OR SPECIAL NUCLEAR MATERIAL	CHEMICAL/PHYSICAL FORM	POSSESSION LIMIT (MAXIMUM AMOUNT)
A. Molybdenum 99	A. Molybdenum 99/Technetium 99 Generators	A. 20 curies
B. Tin 113	B. Tin 113/Indium 113 Generators	B. 60 millicuries
~~C. Indium 113m~~ G-I	~~C. Chloride~~	~~C. 50 millicuries~~
D. Any byproduct material listed in Group I of Schedule A, Section 35.100 of 10 CFR Part 35	D. Any form listed in A, Group I of Schedule A, Section 35.100 of 10 CFR 35	D. 1 Curie Total possession limit
E. Any byproduct material listed in Group II of Schedule A, Section 35.100 of 10 CFR 35	E. Any form listed in Group II of Schedule A, Section 35.100 of 10 CFR 35	E. 20 ~~3~~ Curies Total possession limit
F. Any byproduct material listed in Group IV of Schedule A, Section 35.100 of 10 CFR 35	F. Any form listed in Group IV of Schedule A, Section 35.100 of 10 CFR 35	F. 500 millicuries Total possession limit
G. Any byproduct material listed in Group V of Schedule A, Section 35.100 of 10 CFR 35	G. Any form listed in Group V of Schedule A, Section 35.100 of 10 CFR 35	G. 1 Curie Total possession limit
H. Any byproduct material listed in 10 CFR 31.11	H. Any form listed in 10 CFR 31.11 for in-vitro studies	H. 50 millicuries Total possession limit

I Xenon 133 Materials listed in 35.31

? list to specific and gen'l licenses

NOTES

1. Byproduct material under (A) will be used to produce Technetium 99m Pertechnetate.

2. Byproduct material under (B) will be used to produce Indium 113m Chloride.

3. Byproduct material under (C), (D), (E), (F), and (G) will be used for processing, mixing or compounding, and distribution of prepared radiopharmaceuticals to authorized recipients.

4. Byproduct material listed under (H) will be redistributed in accordance with the statement in Section 170.31 (3G) of 10 CFR, Part 170. See supplement to Attachment #2.

Attachment #2

Item6b-NRC-313M

1. General Requirements of 30.33

   a. Authorized Purpose of Act:

   The intention of Pharmaco Nuclear, Inc. is to act as a compounding and dispensing Radiopharmacy. Criteria for this purpose has been published by the NRC and is contained in the NRC outline "Supplemental Information Required for Licensure of Compounding and Dispensing Radiopharmacy". It is the further intention of Pharmaco Nuclear, Inc. to work with drugs approved by the FDA and contained in Groups I, II, IV, and V.

   Radiopharmaceuticals distributed for human use shall be:

   1. Repackaged from radiopharmaceuticals that are the subject of an FDA - Approved NDA or for which an IND has been accepted by the FDA.

   2. Prepared from generators and reagent kits that are the subject of an FDA-approved NDA or for which an IND has been accepted by the FDA.

   If IND radiopharmaceuticals and radiopharmaceuticals prepared from generators or reagent kits that are under IND status, these drugs will be dispensed:

   1. In accordance with directions provided by the sponsors of the IND, and

   2. Only to physicians who have been accepted by the sponsors of the IND to participate in clinical evaluations of the drug, and

   3. With the understanding that the physician is responsible to the sponsors of the IND for use of the drug in accordance with protocols established by the sponsors, and for reporting the clinical information obtained through the use of the drug.

2. The Applicant Submits Evidence That:

   a. The radiopharmaceutical containing byproduct materials will be compounded, labeled, and packaged in accordance with the Federal Food, Drug, and Cosmetic Act.

   Pharmaco Nuclear, Inc. does not at this time propose to manufacture reagent kits to other radiopharmaceuticals starting with raw materials. It is our intention to prepare radiopharmaceuticals which have been manufactured by manufacturer's such as Squibb, Abbott, CIS, Cambridge Nuclear, Mallinckrodt, Diagnostic Isotopes, New England Nuclear, Medi-Physics, Amersham, and to distribute these products in unit dose form to nuclear physicians and nuclear medicine departments licensed to use them. We are a licensed pharmacy and the unit dose will be treated as prescription. The labeling and dispensing of such prescriptions meet FDA requirements as specified in Federal Food, Drug, and Cosmetic Act, Section 503.

Attachment #2 Continued

b. Licensed Pharmacy

Enclosed is photostatic copy of our pharmacy license from the state of Missouri (Appendix 1).

c. Each package will contain the statement, "This radiopharmaceutical is licensed by the U.S. Nuclear Regulatory Commission for distribution to persons licensed pursuant to 35.100 Group I, or Group II, or Group IV, or Group V of 10 CFR, Part 35."

d. Pharmaco Nuclear, Inc. does not intend to dispense radiopharmaceuticals that cannot be assayed by use of a dose calibrator, i.e. Carbon 14.

e. A photostatic copy of the FDA approved package insert utilizing the manufacturer's package insert will be forwarded to each user.

3. The applicant submits information on the radionuclide, chemical and physical form, packaging including maximum activity per package and shielding provided by the packaging of the byproduct material that is appropriate for safe handling and storage of radiopharmaceuticals of group licensees:

Byproduct Material	Chemical/Physical Form	Max. mCi Per pkg.
Group I		
Iodine 125	Sodium Iodide Solution/capsule	0.5 mCi
Iodine 131	Sodium Iodide Solution/capsule	1.0 mCi
Iodine 125	Human Serum Albumin Solution	0.5 mCi
Iodine 131	Rose Bengal Solution	0.5 mCi
Iodine 125	Triolein Solution/capsule	0.5 mCi
Iodine 131	Triolein Solution/capsule	0.5 mCi
Iodine 131	O-Iodohippurate Solution	0.5 mCi
Chromium 51	Sodium Chromate Solution	0.5 mCi
Technetium 99m	Sodium Pertechnetate Solution	70.0 mCi
Mercury 197	Chlormerodrin Solution	0.5 mCi
Iodine 125	Sodium Iothalmate	0.5 mCi
Group II		
Iodine 125	Sodium Iodide Solution/capsule	0.5 mCi
Iodine 131	Sodium Iodide Solution/capsule	2.0 mCi
Iodine 131	Human Serum Albumin Solution	0.5 mCi
Iodine 131	Macroaggregated Albumin Suspension	1.0 mCi
Iodine 131	Rose Bengal Solution	1.0 mCi
Iodine 131	O-Iodohippurate Solution	2.0 mCi

Byproduct material	Chemical/Physical Form	Max. mCi Per pkg.
Chromium 51	Sodium Chromate Solution	0.5 mCi
Gold 198	Elemental Gold Colloidal Suspension	1.0 mCi
Mercury 197	Chlormerodrin Solution	1.0 mCi
Selenium 75	Selenomethionine Solution	2.0 mCi
Strontium 85	Nitrate or Chloride Solution	0.1 mCi
Technetium 99m	Sodium Pertechnetate Solution	70.0 mCi
Technetium 99m	Sulfur Colloid	10.0 mCi
Technetium 99m	Macroaggregated Albumin Suspension	8.0 mCi
Technetium 99m	Polyphosphate, Stannous/Solution	30.0 mCi
Technetium 99m	Diphosphonate, Stannous/Solution	30.0 mCi
Technetium 99m	Pyrophosphate, Stannous/Solution	30.0 mCi
Technetium 99m	Iron-Ascorbate-Diethylenetriamine pentaaceitc acid/solution	30.0 mCi
Technetium 99m	Diethylenetriamine pentaacetic acid Stannous/Solution	30.0 mCi
Technetium 99m	Human Serum Albumin Microspheres	8.0 mCi
Ytterbium 69	Pentetate Trisodium Calcium	6.0 mCi
Technetium 99m	Human Serum Albumin Solution	30.0 mCi
Technetium 99m	Methylene Diphosphonate/Solution	30.0 mCi
Technetium 99m	Gluceptate, Stannous/Solution	30.0 mCi
Group IV		
Iodine 131	Sodium Iodide/Solution or Capsule	*30.0 mCi
Group V		
Iodine 131	Sodium Iodide/Solution or Capsule	*200.0 mCi

*These therapy doses will remain in their original containers and shielding devices as supplied by the commercial manufacturer.

Therapeutic quantities of gold - 198 and phosphorous - 32 will be ordered for the hospitals on a demand basis. For this reason, they will be dispensed in their original containers. Both diagnostic quantities of oral Iodine Solution and diagnostic I-131 Capsules will also be dispensed in the original containers as supplied by the original manufacturer.

Personnel dispensing therapeutic quantities of liquid I-131 Iodine will be instructed to wear gloves and to perform this operation in the fume hood. There will be an L-Block drawing station in the fume hood with 2" leaded glass and 2" lead. The Iodine will be drawn behind it.

The lead unit dose container in which the radiopharmaceutical will be placed provides an effective thickness of 0.92 cm, for medium or high energy pharmaceuticals.

4. The label affixed to each package of the radiopharmaceutical will contain information as to the radionuclide, its chemical form, the quantity and the date of assay. The label affixed to each package or the leaflet or brochure which accompanies each package will contain a statement that the radiopharmaceutical is licensed by the U.S. Nuclear Regulatory Commission for distribution to persons licensed pursuant to 35.14 and 35.100 Group I, or Group II, or Group IV, or Group V of 10 CFR, Part 35. See Appendix 3 for labels.

5. Pharmaco Nuclear, Inc. at this time does not intend to manufacture generators or reagent kits. Should Pharmaco Nuclear, Inc. anticipate the manufacture of generators or reagent kits, we would meet all FDA and NRC requirments. (e.g. we would apply to the FDA for an IND and to the NRC for the appropriate license amendment.)

6. Packaging of radioactive material for transport and transportation of radioactive material:

Pharmaco Nuclear, Inc. will comply with applicable regulations for packaging and transportation of radioactive materials as specified in Title 10 Part 71, Department of Transportation 49 CFR, Parts 170 - 189, and 14 CFR, Part 103.

All of the radionuclides which the nuclear pharmacy will work with are under transport groups III and IV. All quantities are under the Type A specification.

Vehicle:

a. Vehicles will be placarded in accordance with Department of Transportation regulations.

b. The number of packages of radioactive material in the vehicle will never approach a transportation index of 10.

c. Packages of radioactive material bearing "radioactive yellow II" or "radioactive yellow III" will not be placed closer to passengers than is specified in 40 CFR 117, para. 177.842.

7. Packaging of radioactive material for transport by a common carrier:

   a. The radioactive material will be placed in packages (unit dose containers) described in Appendix 2.

   b. Absorbent material will be placed in the unit dose containers.

   c. The dose container will be put into a fiberboard box with packing to prevent movement. The fiberboard box will be sealed with fiber tape. The dimensions of the box will be not less than 4 inches on a side and will conform to the requirements set forth in 49 CFR, Parts 170-189.

   d. The appropriate radioactive label will be applied to the outside of the box. Determination of the transport index is accomplished by placing the package 1 meter distant from a calibrated GM tube and reading the transportation index on the scale in mr/hr.

   e. A shippers certification for radioactive material will be effected and attached to the package.

8. Packaging of radioactive material for transport to immediate area hospitals:

   a. The radioactive materials will be placed in packages described in Appendix 2.

   b. Transportation boxes made of hard wood ½ inch thick which have been tested to withstand a force of 1000 G's. These boxes will be positively sealed when used to transport radioactive material.

   c. All labeling requirements set forth by DOT will be met.

9. Sealed Sources

   a. The sealed calibration sources will be tested for leakage every six months by the radiation safety officer.

10. Description of procedure for ordering radioactive materials for receipt of materials during off-duty hours and for notification of responsible persons upon receipt of radioactive material:

   a. Ordering of Radioactive Materials

      1. Orders for radioactive material will be initiated by the radiopharmacist.

      2. Orders will be placed only after determination that the additional activity will not cause the maximum possession limits to be exceeded; taking into account precalibration of the radiopharmaceutical.

   b. Receipt of Radioactive Materials

      1. All incoming shipments of radioactive material will be monitored by a radiopharmacist. Disposable gloves will be worn when performing this procedure. The package inspection procedure will:

a. Include a survey of the package surface to determine that radiation levels do not exceed 200 mR per hour, and

b. Include a wipe sample of the outside of the container and a wipe of the final source container. These wipes will be counted for one minute in the well counter and contamination above 100 DPM will be reported to the radiation safety officer. The results of these wipe tests will be recorded in the Radionuclide Log Book.

c. The packing material will be monitored for contamination prior to disposal by nonradioactive methods. (If any contamination is found, the packing material will be placed in the radioactive waste storage area.)

2. All shipments of radioactive material will be unboxed and placed behind the proper shielding. The Radionuclide Log Book will be utilized to record the following"

Wipe test (Negative or Positive), radionuclide, manufacturer, nuclear pharmacy control number assigned to the item, assay, assay date, volume, lot or control number of manufacturer, date received, expiration date, disposal method, and date.

After the appropriate entries have been made in the log book, the manufacturer's duplicate label will be attached to the radiopharmaceutical lot control sheet.

c. Receipt of Materials During Off-duty Hours:

In the St. Louis area the bulk of the radioactive drugs delivered to our pharmacy will be delivered by Purolator or Gelco. These couriers do have night delivery service.

The delivery services mentioned will be given a key that will open the building into the reception area of the radiopharmacy. They will be instructed in writing to leave the radioactive drugs in the reception room and lock the door upon departure. The key given to them will not open the radiopharmacy lab and/or the isotope storage area.

All procedures for picking up, receiving, and opening of packages as stated in part 20 - 205 will be followed.

11. Records

a. Radiopharmaceutical Product Worksheet

A radiopharmaceutical product worksheet will be prepared for each radiopharmaceutical prepared in-house (from manufacturer's kits). In-house preparation is defined as any process other than drawing a dose from a vial purchased from a commercial pharmaceutical house and the definition of an in-house preparation shall include the elution of a commercially available generator system. The radiopharmaceutical worksheet shall include:

Date of prepartion, time of preparation, calculations for determining concentration, volume, and the radiopharmaceutical control number prefixed by the letters PR (these are doled out consecutively).

The final product will be shielded by a lead container and will be labeled to include:

Name of radionuclide, chemical form, time of preparation, assay (total millicuries or microcuries), volume, concentration (mCi/ml or uCi/ml), control number, and expiration date if applicable.

b. Radiopharmaceutical Lot Control Sheet

Each time a dose is drawn from a lot, the appropriate entries will be made. The entries on the radiopharmaceutical lot control sheet will include:

Date, hospital, prescription number, activity dispensed, volume dispensed, volume remaining, calibration time, initials of the radiopharmacist dispensing the drug.

c. Radionuclide Log Book

All radionuclides received from outside sources shall be entered on the Radionuclide Log Book. The following will be entered:

Wipe test (negative or positive), radionuclide, manufacturer, nuclear pharmacy control number assigned to the item, assay, volume, assay date, lot or control number of manufacturer, date received, expiration date, disposal method and date.

After the appropriate entries have been made in the log book, the manufacturer's duplicate label will be attached to the radiopharmaceutical lot control sheet.

d. Generator Log Book

The extra manufacturer's generator label will be attached in this book, along with the day of receipt, wipe test results, sequential in-house lot number and disposal method and date. The lot number assigned will be prefixed G-.

e. Prescription Form

All radiopharmaceuticals dispensed from the radiopharmacy shall bear a prescription number and the proper label. The prescription shall include:

Name of patient or hospital, procedure (e.g. brain scan), radiopharmaceutical lot or control number, assay and date, time of assay, present strength, activity requested, amount dispensed, dose calibrator reading, initial of radiopharmacist dispensing the drug, name of physician, and the date.

Each prescription will be given the next consecutive prescription number from a Bates numbering machine. The machine will stamp the number in triplicate and then automatically advance. The prescription will contain one number, the label for the prescription will contain the duplicate number, and the prescription record book will contain the triplicate number.

f. Labels

The prescription label will include:

Name of radionuclide, chemical form, time, date, total activity, volume, prescription number, and name of requesting physician (see Appendix 3).

12. Quality Control

a. Radiochemical Purity

Radiochemical purity for products prepared in-house will be determined by using paper partition chromatography with the appropriate solvent system. The radiochromatogram will be developed and the results will be recorded on the radiopharmaceutical work sheet for the product.

b. Microscopic Examination

For preparations of colloids or particles, a microscopic examination routinely will be performed. Products which show an abnormal appearance will not be dispensed or utilized for human use.

c. Radionuclides

1. 99 Mo/99m Tc Generator

a. Source-Reactor and/or fission Molybdenum 99/Technetium 99m generators will be purchased from manufacturers possessing an approved NDA for their generator.

b. Molybdenum breakthrough - the sodium pertechnetate elutions will be checked routinely for molybdenum breakthrough. This test will be performed by enclosing the pertechnetate vial in a shield thick enough to prevent penetration of the 142 kev gamma of Tc-99m, but not the much higher energy gamma of Mo-99. This product will then be counted in a dose calibrator and no eluant will be used that does not meet or exceed the NRC requirements (not more than 1 uCi of 99-Mo per 1 mCi of 99m-Tc or not more than 5 uCi of 99-Mo per dose).

c. Alumina breakthrough - the sodium pertechnetate elutions will be checked routinely for alumina breakthrough using the Aluminum Ion Indicator Kit by New England Nuclear, Cat. No. NRP-122. If the Intensity of the center spot of the sample is less than that for the center spot of the standard solution, the eluate contains less than 15 ug/ml of Aluminum. If the center spot of the sample is greater than that of the standard, we will use the colormetric reaction developed by using aurin tricarboxylic acid. No eluate will be used if it exceeds 15 micrograms of alumina per milliliter of eluate.

d. Assay - Radioassay procedures for the sodium pertechnetate will be performed on each eluate utilizing a dose calibrator.

e. If anything other than a clear solution is ever eluated from the generator, it will not be used.

f. Manufacturer's directions for eluting the generator will be strictly followed.

2. All other radionuclides in Groups I, II, IV, V,

a. All radiopharmaceuticals prepared in-house will be prepared exclusively from radiopharmaceuticals which are the subject of an FDA-approved NDA ("New Drug Application") or for which an IND (Notice of Claimed Investigational Exemption for a New Drug") has been accepted by the FDA; or

b. Prepared from generators and reagent kits that are the subject of an FDA approved NDA or for which an IND has been accepted by the FDA.

c. If the radionuclide contains particles, appropriate microscopic examination will be done to determine the product's usability.

d. Radioassay procedures will be done using a dose calibrator and each individual dose will be assayed and recorded prior to patient use.

e. Radiochemical purity will be verified using paper chromatography.

f. In all cases the manufacturer s directions for preparation, storage, and use will be followed.

g. Radionuclides which are not pharmaceutically refined:

1. As stated previously, we do not plan on using any radionuclides which are not pharmaceutically refined.

2. If, at a later date, we decide to use such radionuclides, this will be the procedure we will follow:

a. We will notify the NRC for a license amendment.

b. We will apply to the FDA for an IND.

c. For new radiopharmaceuticals, toxicological and pharmaceutical test will be run by David A. Hurwitz, Ph.D.

Supplement, Attachment #2

For authorization to redistribute in-vitro test kits as described in Section 31.11 (9) (1) - (b) and prepackaged individual doses to physicians licensed pursuant to Section 35.31 of 10 CFR, Part 35 the following information is submitted:

1. We confirm that:

   a. We plan to obtain prepackaged in-vitro test kits as described in Section 31.11 (9) (1) - (b) for redistribution to specific licensees.

   b. We will insure that labels or brochures associated with the kits do not reference general licenses or exempt quantites or those sections of NRC regulations that authorize a general license.

   c. We will insure that the labeling will conform to the requirements in Section 20.203 of 10 CFR Part 20.

2. We confirm that the "Warning" statement will not be used on products distributed to specific licensees.

   We do wish authorization to redistribute to general licensees. The following information is submitted in support of this request.

3. We confirm that:

   a. In-vitro test kits to be redistributed to persons generally licensed pursuant to Section 31.11 of 10 CFR Part 31 will be obtained only from manufacturers/distributors licensed pursuant to Section 32.71 of 10 CFR Part 32.

   b. We will not alter the labeling or packaging of these kits.

   c. We will insure that manufacturer/distributor supplied leaflets or brochures with radiation safety instructions accompany all kits to our customers.

4. We Confirm that:

   a. Prepackaged individual doses to be redistributed to physicians generally licensed pursuant to Section 35.31 of 10 CFR Part 35 will be obtained only from manufacturers/distributors licensed pursuant to Section 32.70 of 10 CFR Part 32, and

   b. We will not alter the labeling or packaging of these individual doses.

Attachment #3

Training & Experience

Item 8-NRC-313M

NAME	PREVIOUS LICENSE NUMBER
Gary R. Redmore, B.S., R.Ph.	24-16617-01 MD
David A. Hurwitz, Ph.D., R.Ph.	34-16405-01 MD
Terry O'Hara, B.S., R.Ph.	24-16617-01 MD 12-17190-01 MD 34-16405-01 MD
Richard E. Keesee, Pharm. D., R.Ph.	24-16617-01 MD 12-17190-01 MD 34-16405-01 MD
Frank M. Comer, B.S., Physicist	24-16617-01 MD 12-17190-01 MD 34-16405-01 MD
William H. McHugh, Ph.D., R.Ph.	12-17190-01 MD 37-18467-01 MD

Attachment #4

Item 9-NRC-313M (Use supplemental sheets if necessary)

TYPE OF INSTRUMENTS (Include make and model number of each)	NUMBER AVAILABLE	RADIATION DETECTED	SENSITIVITY RANGE (mr/hr)	WINDOW THICKNESS (mg/cm²)	USE (Monitoring, surveying, measuring)
Dose Calibrators Picker - 632-507	1 - 4	Beta Gamma	uCi - Ci	Ion-Chamber & Electro-meter	Measuring
Picker Spectroscaler IV Model 023436 & Shielded Well Counter	1	Gamma	N/A	2" x 2" NAI (TL) Crystal	Measuring
Victoreen "Cutie Pie" 740-F	1	Alpha Beta Gamma	1 - 2500	0.00025 Mylar	Surveying & Monitoring
Victoreen 491 Low Level Survey Meter	1	Beta Gamma	1 - 100	30 mgm/cm^2	Survey & Monitoring
Victoreen 495 Frisker Laboratory Monitor	1	Beta Gamma	$0-5x10^5$ CPM	30 mgm/cm^2	Monitoring

ATTACHMENT #5

1. Well Counter (Scintillation Detector)

   The well counter will be calibrated before use by utilizing the manufacturer's stated procedure.

2. Calibration of Dose Calibrator

   See Page 15

3. Survey Meters and Radiation Monitors

   See Page 16

CALIBRATION OF DOSE CALIBRATOR

A. Sources Used for Linearity Test:

Check as appropriate

_____ First elution from new Mo-99/Tc99m Generator

OR

__X__ Other* (specify) 400 mCi

B. Sources Used for Instrument Accuracy and Constancy Tests

Radionuclide	Activity (mCi)	Accuracy
57 Co	5.0	5%
133 Ba	.250	5%
137 Cs	.200	5%
Other		

C. __X__ The procedures described in Section 2 of Appendix D, NRC Regulatory Guide 10.8, will be used for calibration of the dose calibrator.

OR

_____ Equivalent procedures are attached.

* Must be equivalent to the highest activity used.

CALIBRATION OF SURVEY INSTRUMENTS

Check Appropriate Items

X 1. Survey instruments will be calibrated at least annually and following repair.

X 2. Calibration will be performed at two points on each scale. The two points will be approximately 1/3 and 2/3 of full scale. A survey instrument may be considered properly calibrated when the instrument readings are within ± 10% of the calculated or known values for each point checked. Readings within ± 20% are considered acceptable if a calibration chart or graph is prepared and attached to the instrument.

X 3. By a consultant or outside firm

(i) Name Pharmaco Nuclear, Inc.

(ii) Location 1734 East 63rd Street, Kansas City, MO 64110

(iii) Procedures and sources

X have been approved by NRC and are on file in License #24-16617-01 MD

____ are attached

Pharmaco Nuclear, Inc. of Kansas City has purchased an extra Victoreen "Cutie Pie" 740-F and an extra Victoreen 491 low level survey meter to be used as loaners. These calibrated loaner survey meters will be sent to St. Louis, MO, before theirs are returned to Kansas City for calibration.

Attachment #6

1. Personnel Monitoring Devices

Type	Supplier	Exchange Frequency
A. Whole body, film	R.S. Landauer, Jr. & Co.	Monthly
B. Finger, TLD	R.S. Landauer, Jr. & Co.	Monthly

2. Bioassay

For our bioassay programs, action levels, frequency of bioassay, and actions to be taken if those levels are exceeded will be in accordance with U.S. NRC Regulatory Guide 8.20, Application of Bioassay for I-125 and I-131.

Bioassays for thyroid uptake will be obtained with a Picker Nuclear Magnascanner 500. Measurements of the thyroid will be taken using a flat field collimator and spacer bar, and will be compared to a thyroid capsule housed in an appropriate thyroid phantom to take into account tissue attenuation from the employees neck.

3. A record of bioassay results on the above test will be maintained. Records will contain the name of the individual, results of testing, and date.

All positive bioassay results will be investigated. Corrective actions taken to prevent further uptake will be documented in accordance with Section 20.103, 10 CFR, Part 20.

ATTACHMENT #7

Item 11 NRC 313M Facilities and Equipment

Pharmaco Nuclear has leased approximately 1300 square feet for use as a pharmacy on the ninth floor of a free standing building located:

100 North Euclid Avenue, Suite 900
St. Louis, Missouri 63108

A sketch of the floor plan and equipment placement is attached to this written description. The entire area is located on the ninth floor of a free standing commercial building. Three sides of the pharmacy are located on outside walls. The fourth side is adjacent to corridors in the most part with the pharmacists' office and a portion of the drivers room adjacent to office space leased by other tennants. The floor and ceiling are reinforced concrete slab with a minimum thickness of four inches.

The rooms are:

A. Pharmacist Office - 162 ft^2 use by the pharmacists to conduct day to day business.

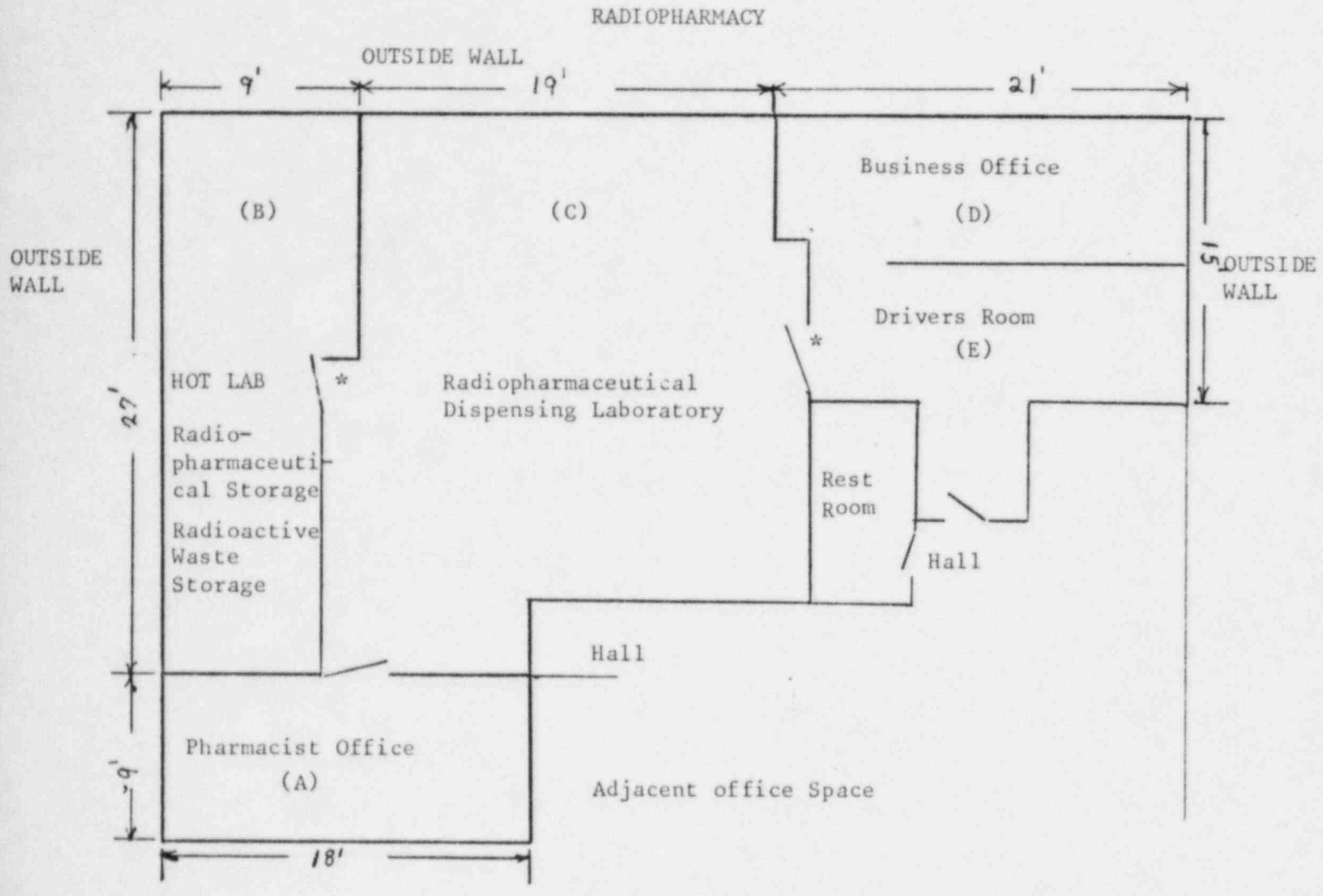
B. Hot Lab - Approximately 240 ft^2. This area will be used for storage of all radioactive material including radioactive waste storage. Benches are provided on the outside wall for generator storage and elution. All actively used generators will be housed in auxilary shielding provided by the manufacturer. Five 1/2" thick lead barrels 16" in diameter and 24" high are provided for storage of radioactive waste. The barrels have 1/2" bottoms and lids and will be located along the outside wall as shown on the attached sketch. A fume hood will also be located along the outside wall which will be utilized for storage of 133-Xenon and I-131. A 2 inch thick lead L-block with 2 inch thick leaded glass drawing station will also be located in this fume hood. This fume hood will be ducted independently of other ventilation in the building. Twelve 2" x 4" x 8" lead bricks as well as approximately 20 pieces of lead 1/2" thick of various dimensions (12"x12", 4"x8", etc) are provided for auxilary shielding as needed. The door to this area has a dead bolt lock with keys made available only to authorized pharmacists.

C. Radiopharmaceutical Dispensing Laboratory - Approximately 500 ft^2. This area will be utilized for the preparation and dispensing of radiopharmaceuticals. Two drawing stations will be located as shown on the attached sketch. Each drawing station will consist of: Leaded glass L-Block shield consisting of 1" thick lead with 2 sheets of x-ray lead glass, a dose calibrator, 1/2" thick lead bin 10" x 18" and one set of 12" ring forceps.

Technetium and Technetium products will be eluted, prepared, and stored in elution vial shields supplied by Mallinckrodt, New England Nuclear, and Squibb, all of which have a minimum of 1/4" thick lead. The refrigerator will be utilized for storage of both radiopharmaceuticals (in appropriate shielding) and cold kits needing refrigerated storage. Quality Control as well as shipping and packaging will be done in this area.

D. Business office - Approximately 160 ft^2.

E. Drivers Room - Approximately 160 ft^2. Holding area for delivery personnel with a dead bolt lock on the door into the dispensing area.

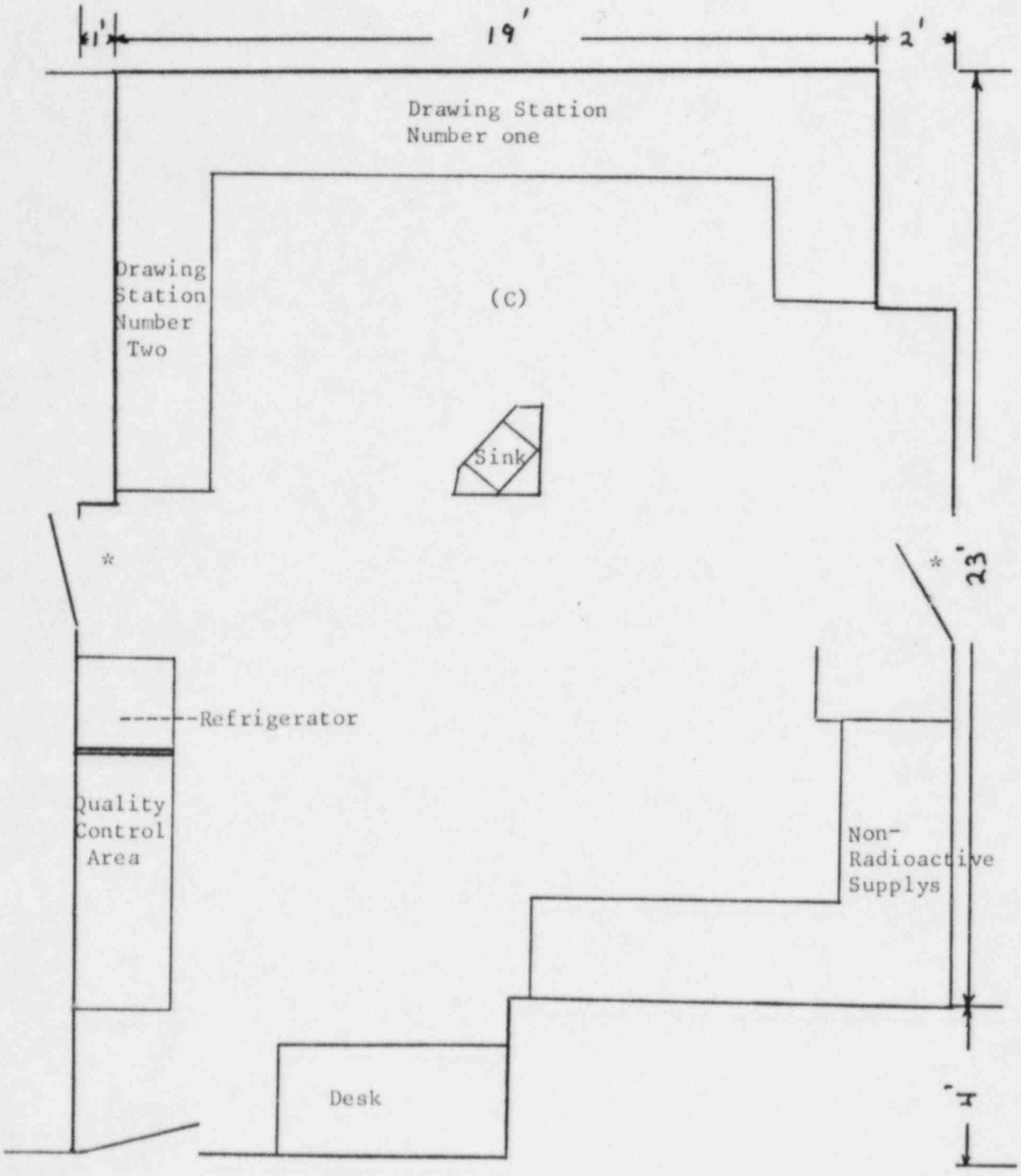


* Dead Bolt Locks

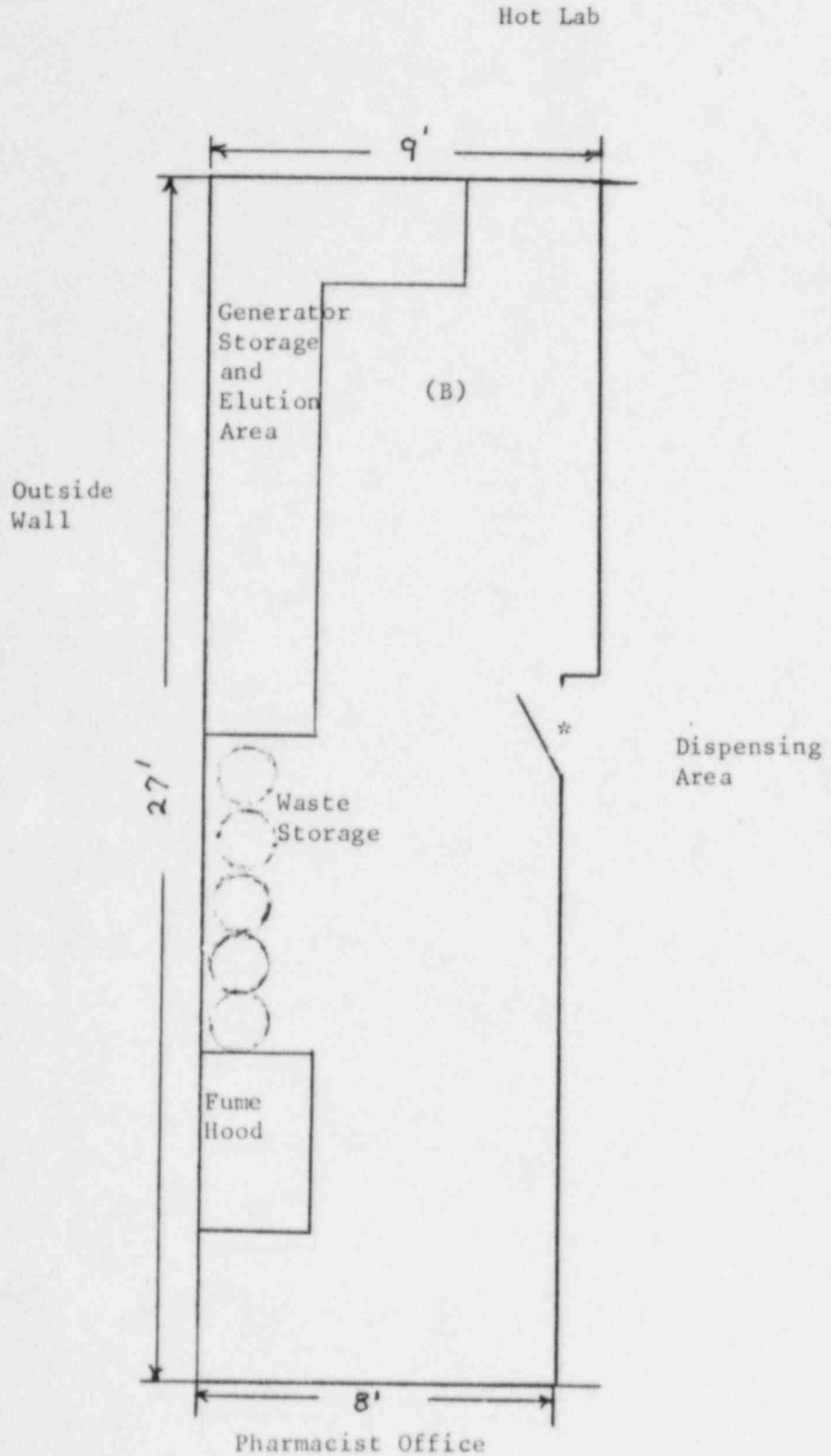
Total area approximately 1300 square feet
Located on the ninth floor of a free standing building

Scale 1/8"= 1'

Radiopharmaceutical Dispensing Laboratory



* Dead Bolt Locks



* Dead Bolt Locks

Attachment #8

1. Training program required for personnel who are involved or associated with the use of radioactive materials.

   a. Training of the pharmaceutical staff working with radioactive material in the nuclear pharmacy will consist of formal courses in (1) principles and practices of radiological safety, (2) radioactivity measurement, standardization and monitoring techniques and instruments, (3) mathematics and calculations basic to the use and measurement of radioactivity, (4) radionuclide identification, and (5) biological effects of radiation. A minimum of thirty hours study will be required which relates to recent NRC requirements; in the absence of formal course training a minimum of three (3) months on-the-job training under a licensed or approved program.

   b. The only other personnel working in the nuclear pharmacy will be delivery personnel. They will not be working with any dispensing act. These personnel will receive on-the-job training and in-house lectures on the principles and practices of radiological-biological effects of radiation. See additional information on Request for Authorization to Collect Radioactive Waste.

   c. All workers will receive complete indoctrination as to the specifics mentioned in Section 19.12 of 10 CFR Part 19.

   d. All personnel will receive training before beginning work and annually thereafter or whenever there is a significant change in personnel duties, regulations, or terms and conditions of the license change.

2. Routine Area Survey Program

   a. An area monitor will be in continuous operation in the dispensing area of the nuclear pharmacy. It is equipped with an audible and visual alarm system. The level of radiation which acts as a trip for the alarm may be varied from 0.1 mR/hr to 100 mR/hr.

   b. Portable survey meters are on hand to check packages, suspected spills, small area contamination, etc. These will be utilized on an as need basis. The meters are (1) Victoreen Model 491 meter with 491-30 GM Probe (or equivalents) and (2) Victoreen Cutie Pie Model 740-F - suitable for detection of alpha, beta, and gamma radiation. Acceptable levels of contamination in unrestricted areas when monitored with portable survey instruments shall be 0.1 mR/hr.

   c. The entire nuclear pharmacy, including uncontrolled areas, will undergo a weekly procedure by pharmacy personnel which provides for wipes or smears to be taken from floors, work tables, walls, work instruments, etc. These samples will then be counted in the well type scintillation detector for one (1) minute each sample. For smears the acceptable level per 100 cm^2 for beta-gamma emitters will be 100 dpm. Alpha emitters will not be used in the nuclear pharmacy. A record of each survey will be maintained which will show via a floor plan diagram where the smear was taken, the date, the level of contamination, type of radionuclide contamination as determined by the use of the single channel analyzer.

d. Radioactive contamination levels greater than those mentioned above shall be cleansed or controlled as soon as excessive levels are known. The area will be posted and barricaded immediately to maintain good radiological control and to prevent unnecessary access by personnel. Adequate protective apparel will be utilized by persons in areas designated as contaminated until such areas are cleaned.

e. Our dispensing area and hot lab will be monitored daily using a suitable portable survey instrument. In addition, all laboratory areas will be surveyed weekly using the same survey meter.

3. Sealed Sources

a. It will be the responsibility of Frank Comer, B.S., to check our sealed sources for possible leakage every six months. Mr. Comer is licensed to perform leak and wipe tests under license #12-17190-01 MD.

4. Description for ordering and receipt of radioactive materials during both open and off-duty hours is described under Attachment 2, Item 10.

5. Packaging of radioactive materials is described under Attachment 2, Items 6, 7, and 8.

6. All persons working in the nuclear pharmacy will be required to wear a body badge and a TLD finger badge.

7. All the radioactive doses must be drawn up in one of the dispensing areas.

8. Laboratory Rules for Use of Radioactive Material

a. We will follow the laboratory rules described in Regulatory Guide 10.8, Appendix G, Guide for Preparation of Applications for Medical Programs, with the following modifications:

1. The use of syringe shields for the preparation and dispensing of radiopharmaceuticals

2. Assay each vial and/or syringe containing radiopharmaceutical preparations prior to distribution.

9. Emergency Procedures

a. Emergency Procedures will be posted in all laboratory areas where radioactive materials are used. The Emergency Procedures in Regulatory Guide 10.8, Appendix H, will be used for this purpose.

10. Liaison — Phone Numbers

Radiation Safety Officer — Home: ( )
Office: ( )

St. Louis Police ( )

St. Louis Fire ( )

USNRC Region III Compliance ( )

11. Posting

Posting of radiations at the nuclear pharmacy shall be in accordance with applicable regulations. Radiation signs shall bear the radiation symbol of authorized color and background and wording consistent with regulations. Additional wording to describe the situation or to provide additional information is authorized on the sign but not on the radiation symbol.

NRC form 3 will be posted in a sufficient number of places to permit workers to observe a copy on the way to and/or from work. We will post other signs, wording, or other instructions as deemed advisable by the Radiation Safety Officer.

12. A perpetual monitoring of inventories of radioactive materials utilized by the nuclear pharmacy will be performed by nuclear pharmacy personnel to assure that the pharmacy does not exceed possession limits. The pharmacy may also be inventoried periodically by the Radiation Safety Officer to insure compliance with limits of possession.

13. See Appendix #5 for the safety and procedural manual. The manual will be given to each employee (a personal copy) and a copy will be kept in the nuclear pharmacy at all times.

Attachment #9

1. Liquid Waste Will Be Disposed of

Check as appropriate

_____ By commercial waste disposal service (See also No. 4 below)

__X__ In the sanitary sewer system in accordance with Section 20.303 of 10 CFR Part 20.

_____ Other (specify): _____

2. Mo-99/Tc-99m generators will be

Check as appropriate

_____ Returned to the manufacturer for disposal

__X__ Held for decay until radiation levels as measured with a low-level survey meter and with all shielding removed, have reached background levels. All radiation labels will be removed or obliterated and the generators disposed of as normal trash. (Note: this method of disposal may not be practical for generators containing long-lived radioactive contaminants).

_____ Disposed of by commercial waste disposal service (See also No. 4 below)

_____ Other (specify): _____

_____

3. Other Solid Waste Will Be

Check as appropriate

__X__ Held for decay until radiation levels as measured with a low-level survey meter and with all shielding removed, have reached background levels. All radiation labels will be removed or obliterated and the waste will be disposed of in normal trash.

X Disposed of by commercial waste disposal service (See also No. 4 below)

_____ Other (specify): _____

4. The commercial waste disposal service used will be: _____

RAD-Services, Inc.	Laurel, Maryland	20810
Name	City & State	Zip

NRC/Agreement State License No.: NRC 37-1710-01
Maryland - MD-27-012-01

REQUEST FOR AUTHORIZATION TO COLLECT RADIOACTIVE WASTE

The following information is submitted in support of this request.

1. Packaging and Pick Up From Customers

   a. Type of Radioactive Waste

      Radioactive waste picked up will be comprised of plastic syringes, needles, needle covers, and vials which have been used in Medical Nuclear Medicine Programs. These items will represent solid waste, which has contained radiopharmaceutical substances, which are listed in Groups I, II, III, IV of 10 CFR, Part 35.100.

   b. Pharmaco Nuclear uses a unique unit dose shield to transport dispensed radiopharmaceuticals to Nuclear Medicine Programs (see enclosed letter describing this shield). All multi-dose materials are transported in their original shipping containers from licensed suppliers. These shields and shipping containers are placed in ½" thick hard wood cases which have polystyrene foam inserts that accommodate the exact size of the shield or container, and have been tested to withstand a force of 1,000 G's. These boxes are positively sealed when used to transport radioactive materials.

      A complete description of our method for transporting material to immediate area hospitals can be found in application for Byproduct Material License No. 24-17716-01MD, Appendix 2, dated 6/12/76. We will transport radioactive waste in precisely the same manner that the original radiopharmaceuticals are transported to the customer. Only waste syringes, needles, needle covers, and vials will be accepted for pickup, if they have been returned to their original containers after use, and placed in the wooden containers for return to the radiopharmacy. Enclosed please find the step-by-step procedures for handling of radioactive waste. One procedure will be used at the radiopharmacy, by the licensed user, and one procedure will be supplied to the Nuclear Medicine Technologist in charge of the program being supplied by our firm.

   c. The individual handling the radioactive waste will be a registered or equivalently trained Nuclear Medicine Technologist at the hospital. The individual handling the radioactive waste at the radiopharmacy will meet that criteria for training established in our application for Byproduct Material License No. 24-16617-01MD, Attachment 9, dated 6/12/76. The individual transporting the above material will at no time handle radioactive waste except to transport the material back to the radiopharmacy.

2. Storage Facilities

   Please see enclosed sketch of storage area. Bins for the storage of waste syringes, needles, needle covers, and vials will be located along the outside wall of the storage area. Since this building is free standing and waste will be stored above ground level, external exposure to the outside is not a problem. We are located on the ninth floor and the nearest structure is over 100 feet away. Five bins will be used:

Bin 1 and 2 For 99m-Tc waste (very short lived materials), ½" lead on all sides.

Bin 3 and 4 For I-131, 133-Xe (shortlived materials), ½" lead on all sides.

Bin 5 For 59-Fe, 169-Yb, 75-Se, 51-Cr, (intermediate lived materials), ½" lead on all sides.

Bins will be double compartment bins so that the material being stored can be saved for a predetermined time for decay before disposal procedures are initiated. Since 95% of the waste material returned will be 99m-Tc syringes, needles, needle covers, adequate storage will be available through the use of these bins.

3. Method of Ultimate Disposal

a. Short lived and very short lived materials will be disposed of by storage until the material has reached background levels as determined by the use of a low level survey meter.

Very short lived materials, i.e., 99m-Tc waste.

Procedure:

1. A ½" lead two compartment bin is provided. Each compartment of the bin is lined with a sturdy plastic bag. The volume of each compartment will accommodate well over the number of waste units returned in any one week.

2. Waste syringes, needles, and needle covers will be collected in one section of the bin for one week (7 days). The beginning of the second week, the second section of the bin will be used for collection of waste units. The third week, the material in the first section of the bin will be removed in its plastic bag, surveyed to confirm that it has reached background levels with a low level survey meter, and disposed of in the normal trash. Survey meter readings for background and for measurements on the decayed material will be recorded. This weekly rotational method will insure that the material will have decayed for a minimum of 28 half lives.

Short lived materials, i.e., 133-Xenon, 131-I

The same procedure will be followed for these materials with the exception that the thickness of lead in the bin will be ½" and the storage interval will be 6 months. For the 8 day half life 131-Iodine this will represent storage for 22.8 half lives.

Intermediate lived materials, i.e., 169-Yb, etc.

A ½" lead bin is provided for storage. Material will be collected until this bin is full and the material will be shipped to a commercial waste material vendor.

b. Name of Commercial Vendor

Rad-Services, Inc.
9381 C - Davis Avenue
Laurel, Maryland 20810

NRC License No. 37-17010-01
Maryland License No. MD-27-012-01

c. Step-by step procedure for the safe handling of radioactive waste material.

It must be emphasized that used unit dose material represents very low level radioactive waste. With the exception of vials, which have contained radiopharmaceuticals, the syringes will have been flushed out with patient blood in the process of injecting the patient. Also, because of the routine of a radiopharmacy, these materials will be retrieved 24 hours after use; therefore, the 99m Tc products will have decayed at the user sight for three half-lives. Those vials retrieved as waste represent a very small portion of the waste in this system. Examples of vial waste would be 131-I oral therapy vials, 169-Yb DTPA vials, 51-Cr vials, 133-Xenon vials, and 131-I IHSA vials. This represents 5% of the waste retrieved from the customer.

It must also be pointed our that each unit dose syringe or vial is identified by prescription number and radiopharmaceutical. This is required by state pharmacy regulations. Therefore, returned, used materials are easily identifiable.

The following procedure for handling waste or used syringes is supplied to our customers:

Procedure For Returning Used Unit
Dose Containers To Pharmaco Nuclear

Pharmaco Nuclear has been licensed by the Nuclear Regulatory Commission to pick up those materials which after use, represent radioactive waste. Only those materials supplied to you by Pharmaco Nuclear may be returned to the pharmacy as waste.

A. Syringes, Needles, and Needle Covers

1. After injection, return the needle cover to the needle, remove the syringe from the syringe shield and return the syringe to the unit dose shield provided. Make sure that the needle cover is firmly seated on the needle.

2. Place the unit dose shield in the wooden case provided for return to the pharmacy.

B. Unit Dose Vials

1. After use return the vial to its original shipping container and place in the wooden case provided.

2. In those situations (usually 131-I therapy doses) that material has been delivered to you in appropriate D.O.T. packaging, return the vial to its container, replace in packaging, and seal.

PROCEDURE FOR RECEIVING WASTE AT PHARMACO NUCLEAR

Returned unit dose shields may contain used syringes and/or vials; therefore, it is necessary for the individual checking in this material to wear disposable rubber gloves.

1. Open unit dose shield, identify material (by Rx label).

2. Dump used unit dose container directly from shield into bin provided. Touch only the outside of the unit dose shield.

3. Survey unit dose container for contamination with a low level survey meter. If a unit dose shield demonstrates activity levels greater than background, remove from service, and place in storage area for decay to background levels. Prior to reuse of the unit dose shield, survey meter to assure that it has attained background levels. Survey of returned unit dose shields is and has been a routine practice in our pharmacies since their inception.

TRAINING PROGRAM FOR DELIVERY PERSONNEL

Individuals who deliver radiopharmaceuticals and who collect radioactive waste from our customers and transport it to our facility will be required to attend lectures before assuming their duties with or in the vicinity of radioactive materials, annually for refresher training, and whenever there is a significant change in duties, regulations, or terms of the license. The training program will be of sufficient scope to insure that all personnel will receive proper instruction in the items specified in Section 19:12 of 10 CFR, Part 19 and will include:

A. Areas where radioactive material is used or stored
B. Potential hazards associated with radioactive materials
C. Radiological safety procedures appropriate to their respective duties
D. Pertinent NRC Regulations
E. The rules and regulations of the license
F. The pertinent terms of the license
G. Their obligation to report unsafe conditions
H. Appropriate response to emergencies and unsafe conditions
I. Their right to be informed of their radiation exposure and bioassay results

Individuals hired as delivery personnel will have little or no experience; however, they will be trained with respect to delivery, by an experienced radiopharmacist. All initial deliveries and retrieval of used material will be by the pharmacist who will train the delivery personnel on the job. As delivery personnel gain experience, they in turn will be used to train new drivers at established accounts.

All new drivers will accompany an experienced driver to each hospital we service. A list of hospitals will be given to each new driver, and when he has made a delivery with an experienced driver, he must check that hospital off of the list. THIS LIST MUST BE KEPT IN THE PHARMACY AND MUST BE RETURNED TO THE PHARMACIST IN CHARGE WHEN IT IS COMPLETED.

In addition to verbal instructions, each driver must be given written instructions. These instructions shall include:

1. The sequence of hospital delivery i.e. this will be the order that the hospitals appear on the shipping certificate.

2. The number of doses to be delivered to each hospital. This number should appear on the tape placed on the case. Check the names on the doses if necessary.

3. Retrieve and bring back all cases and used dose containers. If the dose container still has the prescription on it, make sure that it is not a dose with that day's date. Check with the Nuclear Medicine technician to make sure that the dose with the day of delivery date may be returned to the pharmacy.

4. Make sure when you leave your vehicle that all windows are closed and that all doors are locked.

5. Deliver all doses to the Nuclear Medicine Department unless directed otherwise. In consideration of the above, each driver is to be furnished with written instructions for proper delivery to each institution which we supply. These instructions shall include:

   a. Where to park upon arrival at the hospital.
   b. What entrance to enter the hospital by.
   c. Whether to check in with security or not.
   d. Route to take from entry into the hospital to Nuclear Medicine.
   e. Area where doses may be left during off-duty hours, if not Nuclear Medicine.
   f. Any special instructions such as checking in at desk, special area in Nuclear Medicine to leave doses, having security personnel unlock doors, etc.

6. Each driver must have in his vehicle the instructions which we supply in case of an accident.

7. Each driver must carry on his person, a company card, with the pharmacy's address and phone number.

In addition to the above, these individuals will be given the following written instructions. They will be required to read them and document that they under-

stand them and will follow them.

Instructions for individuals collecting radioactive waste from our customers:

1. You may not pick up any radioactive waste from our customer which is not comprised of material delivered by Pharmaco Nuclear, Inc., to this customer.

2. All material must have been returned to its original shipping container, and packaging before you are authorized to collect it. No loose material, syringes, needles, vials, etc. shall be accepted by you for transport.

3. You shall not open any unit dose syringe shield, manufacturers shipping container, or packaging containing the above during collection or transport to the pharmacy.

4. Upon arrival to the pharmacy, check in with the pharmacist on duty and indicate that you have returned containers which may contain radioactive waste materials.

It is our company policy that all new accounts are set up by an experienced radiopharmacist, and that from time to time deliveries are made by the pharmacist. This is to establish a working rapport with the accounts, Nuclear Medicine personnel, and to stay abreast of any changes in procedure, etc. which may effect delivery, unit dose levels, licensing or change of established procedures.

APPENDIX # 1

APPENDIX # 3

NU MEDICO
Associates
Biomedical Consultants

F. Eugene Hall, [redacted]

I. Stephen Graham, Ph.D.
[redacted]

2 November 1974

Quality Assurance
Teaching
Diagnostic Radiology
Health Physics
Instrumentation
Medical Physics
Nuclear Medicine
Radiation Dosimetry
Radiation Physics
Radiation Therapy
Radiologic Calibration

General Design/Development
4526 Brookwood N.E.
Albuquerque, NM 87109

RE: ATTENUATION TESTING OF MODEL 1C-004 SYRINGE SHIPPING CONTAINER

Method of Testing

The attenuation of 131-I and 51-Cr gamma rays by the sample syringe container was measured in a low level scintillation counter. The effective thickness and the dose rates/mCi were calculated using standard techniques. Both film and active dosimetry were employed to measure the dose-rates at 6", 1' and one meter from the holder loaded with a 5 mCi of 131-Iodine.

Results:

1. The average effective thickness of the sample was 0.02 cm. of lead. Less than 3% variation was noted in rotation through 90, 180, and 270 degrees.

2. The permissable levels for such items, in most Agreement States are:

a. 2 mrem in any one hour
b. 100 mrem in any seven days, or
c. 0.5 rem in any one year.

Since it appears unlikely that these items would remain in any uncontrolled area for more than one (1) hour during routine transit, loading calculations were based upon the 2 mrem/hr. The results for three common isotopes are as follows:

[illegible] ([illegible])
([illegible] Loadings [illegible])
([illegible]rem/hr at [illegible])

[illegible]	[illegible] Inches	1 [illegible]	1 meter
13[illegible]-[illegible]	1.2	5	50
123-I	250**	--	---
67-Ga	150	--	---

*Total loading--whether 1 unit or several

**Presence of high-energy contaminants are not considered

---------- END OF FACSIMILE LETTER ----------

APPENDIX #3

FACSIMILE LABEL

PHARMACO NUCLEAR, INC.
100 N. Euclid, Suite 900
St. Louis, Missouri 63108

Hospital _____
Doctor _____ Date _____
Radionuclide _____
Pharmaceutical _____
Procedure _____
Lot Number _____
Assay _____ As of _____
Present Strength _____
Activity Needed _____
Volume Dispensed _____
Activity Dispensed _____
Dispensed by _____ Rx
Patient Name _____
Use as directed by physician.

Label for outer container of unit dose. Extra copy supplied for hospital records.

CAUTION RADIOACTIVE MATERIAL Rx. Dr.

This label is placed on the syringe.

Pharmaco nuclear inc. CAUTION RADIOACTIVE MATERIAL

Warning: This radiopharmaceutical is licensed by the U.S. Nuclear Regulatory Commission for distribution to persons licensed pursuant to 35.14 and 35.100 Group I of 10 CFR part 35. Syringe containing drug should be kept in this container or within heavier shield.

Pharmaco nuclear inc. CAUTION RADIOACTIVE MATERIAL

Warning: This radiopharmaceutical is licensed by the U.S. Nuclear Regulatory Commission for distribution to persons licensed pursuant to 35.14 and 35.100 Group II, of 10 CFR part 35. Syringe containing drug should be kept in this container or within heavier shield.

Pharmaco nuclear inc. CAUTION RADIOACTIVE MATERIAL

Warning: This radiopharmaceutical is licensed by the U.S. Nuclear Regulatory Commission for distribution to persons licensed pursuant to 35.14 and 35.100 Group IV of 10 CFR part 35. Syringe containing drug should be kept in this container or within heavier shield.

These labels are placed on the container.

Group V materials will be shipped in their original shipping containers.

03407

APPENDIX # 4

RADIOACTIVE MATERIALS TRANSFER RECORD

TYPE OR PRINT: COMPLETE APPLICABLE PARTS

SENDER
License No.:_____
Permit No.:_____
Name:_____
Bldg.:_____ Room:_____
Signature:_____
P.O. No.:_____ P.R. No.:_____

RSO LAB
License No.:
Permit No.:
Signature _____
Transported Via:_____

RECEIVER
License No.: _____
Permit No.: _____
Name _____
Bldg.:_____ Room:___
Signature _____

Isotope	Formula or Name	No. of units	Activity per unit mCi	Total Activity mCi			Date, Time			Comments
				sender	RSO	rec.	sender	RSO	rec.	

RADIATION SURVEY
A. Surface:_____mR/hr; at 1 meter:_____mR/hr
B. Smearable contamination:_____
C. Surveyed by:_____ ICC Labeling:_____

	Incoming Shipment		Waste Transfer
Permit Inventory			Permit Inventory
University Inventory			
Log Book			Log Book
RSO Lab Inventory	In	Out	RSO Lab Inventory

APPENDIX #5

PHARMACO NUCLEAR, INC.

SAFETY AND PROCEDURAL MANUAL

This manual will be utilized as the guide to safety procedures relating to the control and use of radionuclides in this nuclear pharmacy.

It is the responsibility of each person who works for the nuclear pharmacy to:

1. be fully acquainted with the safety regulations and emergency procedures listed in this manual.
2. so conduct his work that he does not create a hazard to the safety of himself/herself, coworkers, and members of the public.
3. report immediately any unsafe working conditions to the radiopharmacist in charge and/or to the radiation safety officer.

Under normal operating conditions, it is expected that some of the procedures contained in this manual will seldom if ever be invoked.

The procedures and conditions of use of radioactive material may change with time. When such changes occur they will be added or deleted from this manual as required.

PHARMACO NUCLEAR, INC.

St. Louis, Missouri

Radiopharmacist Manager	
William H. McHugh, PHD	Work:
	Home:
Health Physicist	
Frank M. Comer	Work: 816-523-4014
	Home: [redacted]
St. Louis Fire Department	
St. Louis Police Department	
USNRC Region III Compliance	312-932-2500

Radiation Survey Procedures

In order to ensure that radiation levels do not exceed tolerance levels, frequent radiation surveys must be made using the appropriate monitoring instruments.

1. An area monitor will be in continuous operation in the dispensing area of the nuclear pharmacy. It is equiped with an audible and visual alarm system. The level of radiation which acts as a trip for the alarm may be varied from 0.1mr/hr to 100 mr/hr.

2. Portable survey meters are on hand to check packages, suspected spills, small area contaminations, routine monitoring, etc. These will be utilized on an as need basis.

   Acceptable levels of contamination in unrestricted areas when monitored with portable survey instruments shall be 0.1 mr/hr.

3. The entire nuclear pharmacy will undergo a weekly procedure by pharmacy personnel which provides for wipes or smears to be taken from floors, work tables, walls, work instruments, etc. These samples will then be counted in the well type scintillation detector for 1 minute, each sample. For smears the acceptable level per 100 cm^2 for beta-gamma emitters will be 100 dpm. A record of each survey will be maintained which will show via a floor plan diagram where the smear was taken, the date, the level of contamination, type of radionuclide contamination as determined by use of the single channel analyzer.

4. Radioactive contamination levels greater than those mentioned above shall be cleansed or controlled as soon as excessive levels are known.

5. All personnel involved with dispensing, kit preparation, or generator eluation shall monitor their hands and clothing prior to leaving the pharmacy at the completion of their shift.

Pharmaco Nuclear Film Badge Policy

Film badges and TLD ring badges shall be issued to all employees of the company, and shall be worn at all times during the normal work day. The film badge shall be worn on the trunk portion of your body, and the ring badge shall be worn on the appropriate hand depending on whether you are right or left handed.

These radiation monitoring devices are valuable in checking the adequacy of our radiation safety program, and also as a means of documenting your occupational exposure to ionizing radiation.

It is the policy of the company that these radiation monitor shall remain in the pharmacy when not being worn. When you complete your shift, leave the badge in the pharmacy. When you begin work, be sure to pick up your badges and put them on. An area in the pharmacy will be designated for badge storage.

Since radiation cannot be seen and affects none of the senses, it is necessary to use special means of recording exposures to individuals. This is accomplished by film badges or TLD badges. The sole purpose of the film badge is to record the exposure to the individual. It does not, in itself, protect against radiation.

Radiation, at the maximum permissible level has no known effect on the fertility of male or female. Nor has this level any special hazard for the embryo during pregnancy because of the protection of the mother's body. However, in the interest of keeping the genetic effects in the population to a minimum, it is considered desirable that personnel who become pregnant should be transferred from a position where personnel are normally required to wear film badges. Also a minimum age limit has been set. Persons below this age should not handle radioactive materials. This age limit has been set at 18 years of age.

1. Film badges, TLD rings, and/or wrist badges will be changed every month.
2. Each person shall wear only the badges, etc. assigned to him/her.
3. Do not interfere with the film badge.
4. Film badges shall be worn at all times when working in the nuclear pharmacy.
5. Any inadvertent exposure of the badge to radiation while not being worn should be reported.
6. Records of radiation exposure will be kept on file. This information is available to personnel on demand. Unless notified, personnel may assume that exposure levels are below the maximum permissible.
7. Film badges, etc. are obtained (and analyzed monthly) from:
   R. S. Landauer, Jr. & Co.
   Glenwood, Illinois 60425

PERSONNEL RADIATION CONTROL

1. Smoking, eating, and drinking will not take place in the dispensing area or hot storage area.

2. Fingernails should be kept short and clean.

3. Rubber gloves will be worn whenever radioactive materials are handled.

4. Pipetting by mouth is not permitted. Rubber gloves, syringes, or other devices shall be used.

5. The nuclear pharmacy should be kept neat and clean.. Equipment or material not in use should be stored away.

6. Use an underpad lined with plastic whenever radioactive material is being handled on the bench top.

Records

1. Prescriptions
2. Radionuclide Log Book (contain disposal info.)
3. Generator Elution Form
4. Bioassay Records
5. Radioactive Materials Transfer Record
6. Prepared Radiopharmaceutical Lot Control Sheet (contain disposal info.)
7. Radiopharmaceutical Lot Control Sheet (contain disposal info.)
8. Quality Control Records
9. Prescription Record Book
10. Survey Records
11. Exposure Records

Logging Radiopharmaceutical Shipments

1. Inspect package for external damage.
2. Open package--remove packing slip and verify contents of package against packing slip.
3. Perform a wipe or smear test.
4. Mark the assigned control number onto the radiopharmaceutical container and place behind lead shielding in the hot storage area.
5. Record in the Radionuclide Log Book: Assigned Control Number, results of wipe test, name of radionuclide, assay, assay date, volume or amount, manufacturer's lot number, date received, expiration date.
6. Attach manufacturer's second label to the radiopharmaceutical lot control sheet. Also enter: assigned control number, date received, name of supplier, volume or amount, initials of person placing in inventory.
7. On packing slip record: Date received, assigned control number, initials of person placing in inventory.
8. Immediately notify the Radiation Safety Officer of damage or breakage in the shipping container or of any discrepancies.

Note: Disposable gloves will be worn while processing the packages.

Fire Procedure

1. Alert all persons in the nuclear pharmacy and if the fire is likely to be hazardous instruct personnel to leave the pharmacy.
2. Alert the building manager as to condition so that he may evacuate other offices in the building if necessary.
3. Alert fire department if necessary.
4. Arrange for a member of the nuclear pharmacy to be at the entrance door to guide the Fire Marshall and/or firemen.
5. Arrange for someone to turn off all electrical power except lighting.
6. Close all windows and doors in the fire area.
7. Use fire extinguisher only if it is safe for you to remain in the room while attempting to put out fire.

Spillage of Radioactive Material

In the event of a major spill of radioactive materials or dispersion of radioactive dusts or gases, the following actions will be taken immediately:

1. Obtain the aid of the Radiation Safety Officer.
2. Prevent the activity from spreading beyond the room or work area if possible, i.e.,
   a. use absorbent material for liquid spills.
   b. close doors and windows and shut off air conditioning systems as necessary.
   c. keep traffic out of the area by use of ropes, signs, etc.
3. Evacuate the area.
4. Post the affected area with radiation warning signs to advise others of the condition and not to enter the area without following proper re-entry procedures.
5. Utilize appropriate protective apparel in preparation for re-entry.
6. Restrict involved personnel from leaving a designated controlled area until they are surveyed for contamination and are provided with other instructions of conduct.
7. Radiation Safety will assist contaminated personnel.
8. Radiation Safety will assist in re-entry, evaluation of conditions, and follow-up surveys as necessary.

The Nuclear Regulatory Commission will be notified as per 10 CFR 20, Part 20.403.

EMERGENCY PROCEDURES

A. Minor Spills Involving No Radiation Hazard to Personnel

1. Notify all other persons in the room at once.
2. Permit only the minimum number of persons necessary to deal with the spill into the area.
3. Confine the spill immediately.
   Liquid Spills: Don protective gloves and drop absorbent paper on spill.
4. Notify the radiological safety officer (health physicist) as soon as possible.
5. Decontaminate.
6. Monitor all personnel involved in the spill and cleaning.
7. Permit no person to resume work in the area until a survey is made and approval of the radiological safety officer is secured.
8. Prepare a complete history of the accident and subsequent activity related thereto for the laboratory records.

B. Major Spills Involving Radiation Hazard to Personnel

1. Notify all persons not involved in the spill to vacate the room at once.
2. If the spill is liquid and the hands are protected, right the container.
3. If the spill is on the skin, flush thoroughly.
4. If the spill is on clothing, discard outer or protective clothing at once.
5. Switch off all fans.
6. Vacate the room.
7. Notify the radiological safety officer (health physicist) as soon as possible.
8. Take immediate steps to decontaminate personnel involved, as necessary.
9. Decontaminate the area. (Personnel involved in decontamination must be adequately protected.)
10. Monitor all persons involved in the spill and cleaning to determine adequacy of decontamination.
11. Permit no person to resume work in the area until a survey is made and approval of the radiological safety officer is secured.
12. Prepare a complete history of the accident and subsequent activity related thereto for the laboratory records.
13. If necessary, NRC is to be notified as per 10 CFR 20, Part 20.403.

NOTIFY IMMEDIATELY
William H. McHugh, Ph.D.

Medicial Emergency or Injury

1. Notify the radiopharmacist in charge.
2. Notify an emergency room and arrange for the necessary medical assistance.
3. Arrange for transportation to the hospital emergency room.

All injuries incurred within the nuclear pharmacy must be reported to the radiopharmacist in charge.

PHARMACO NUCLEAR INC.

Instructions For Delivery Personnel

A. Non-injury Accident

1. No radioactivity in car:
   a. Notify the pharmacy as soon as possible where you are and an estimate of the length of time you will be tied up. Telephone 367-9300.

2. Radioactivity in car:
   a. Notify the pharmacy where you are as soon as possible. If necessary have the patrolman notify the pharmacy where you are. Tell the police officer you are delivering emergency medicine and that it is radioactive. When you call or contact the pharmacy tell us whether you are delivering material or returning to the lab and whether the material you are delivering has been damaged. This will give us the opportunity to send out another driver to deliver the drugs if necessary.

B. Injury Accident:

1. If you are injuried and can still communicate, ask the officer to read the instructions located in the packet on the dash. If possible tell the officer whether you have radioactive drugs in the car.

IN CASE OF AN ACCIDENT PROCEED AS FOLLOWS:

1. Call Pharmaco Nuclear, Inc. immediately. Telephone Number 314-367-9300.

   Pharmaco Nuclear, Inc. will immediately send trained personnel and the appropriate radiation detection equipment to ascertain:
   1. Whether the vehicle contains radioactive materials.
   2. If the vehicle contains radioactivity, whether there has been contamination or whether the materials are still in tact and represent no hazard.

2. Isolate the area of the accident from the public, and remain at least 10 feet from the vehicle until Pharmaco Nuclear personnel arrive to certify the vehicle is safe for removal or use.

Frank M. Comer
Health Physicist
Pharmaco Nuclear

r material licensed by the Nuclear
tory Commission pursuant to the
ions in Parts 30 through 35, 40,
this chapter, including persons li-
to operate a production or utili-
facility pursuant to Part 50 of
apter.

783, Mar. 3, 1975]

Definitions.

ed in this part:
"Act" means the Atomic Energy
954, (68 Stat. 919) including any
ments thereto;
Commission" means the United
Nuclear Regulatory Commission;
Worker" means an individual
in activities licensed by the Com-
and controlled by a licensee,
not include the licensee.
License" means a license issued
e regulations in Parts 30 through
or 70 of this chapter, including
to operate a production or utili-
acility pursuant to Part 50 of this
"Licensee" means the holder of
icense.
Restricted area" means any area
which is controlled by the li-
or purposes of protection of in-
from exposure to radiation and
ve materials. "Restricted area"
include any areas used as resi-
quarters, although a separate
rooms in a residential building
et apart as a restricted area.

217, Aug. 17, 1973, as amended at
3, Mar. 3, 1975]

Interpretations.

as specifically authorized by the
on in writing, no interpretation
eaning of the regulations in this
any officer or employee of the
on other than a written in-
on by the General Counsel will
ized to be binding upon the
on.

Communications.

where otherwise specified in
all communications and reports
s the regulations in this part
addressed to the Director, Of-
ection and Enforcement, U.S.
Regulatory Commission, Wash-
C. 20555. Communications re-
applications may be delivered
at the Commission's offices at
reet, NW., Washington, D.C.;
9 Norfolk Avenue, Bethesda,

Mar. 3, 1975]

§ 19.11 Posting of notices to workers.

(a) Each licensee shall post current copies of the following documents: (1) The regulations in this part and in Part 20 of this chapter, (2) the license, license conditions, or documents incorporated into a license by reference and amendments thereto, (3) the operating procedures applicable to licensed activities, (4) any notice of violation involving radiological working conditions, proposed imposition of civil penalty, or order issued pursuant to Subpart B of Part 2 of this chapter, and any response from the licensee.

(b) If posting of a document specified in paragraph (a)(1), (2), or (3) of this section is not practicable, the licensee may post a notice which describes the document and states where it may be examined.

(c) Form NRC 3, "Notice to Employees", shall be posted by each licensee wherever individuals work in or frequent any portion of a restricted area.

Note: Copies of Form NRC 3 may be obtained by writing to the Director of the appropriate U.S. Nuclear Regulatory Commission Inspection and Enforcement Regional Office listed in Appendix D, Part 20 of this chapter or the Director, Office of Inspection and Enforcement, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555.

(d) Documents, notices, or forms posted pursuant to this section shall appear in a sufficient number of places to permit individual engaged in licensed activities to observe them on the way to or from any particular licensed activity location to which the document applies, shall be conspicuous, and shall be replaced if defaced or altered.

(e) Commission documents posted pursuant to paragraph (a)(4) of this section shall be posted within 2 working days after receipt of the document from the Commission; the licensee's response, if any, shall be posted within 2 working days after dispatch by the licensee. Such documents shall remain posted for a minimum of 5 working days or until action correcting the violation has been completed, whichever is later.

[40 FR 22997, May 30, 1975, as amended at 40 FR 26391, June 4, 1975]

§ 19.12 Instructions to workers.

All individuals working in or frequenting any portion of a restricted area shall be kept informed of the storage, transfer, or use of radioactive materials or of radiation in such portions of their

stricted area, shall be instructed in the health protection problems associated with exposure to such radioactive materials or radiation, in precautions or procedures to minimize exposure, and in the purposes and functions of protective devices employed; shall be instructed in, and instructed to observe, to the extent within the worker's control, the applicable provisions of Commission regulations and licenses for the protection of personnel from exposures to radiation or radioactive materials occurring in such areas; shall be instructed of their responsibility to report promptly to the licensee any condition which may lead to or cause a violation of Commission regulations and licenses or unnecessary exposure to radiation or to radioactive material; shall be instructed in the appropriate response to warnings made in the event of any unusual occurrence or malfunction that may involve exposure to radiation or radioactive material; and shall be advised as to the radiation exposure reports which workers may request pursuant to § 19.13. The extent of these instructions shall be commensurate with potential radiological health protection problems in the restricted area.

§ 19.13 Notifications and reports to individuals.

(a) Radiation exposure data for an individual, and the results of any measurements, analyses, and calculations of radioactive material deposited or retained in the body of an individual, shall be reported to the individual as specified in this section. The information reported shall include data and results obtained pursuant to Commission regulations, orders or license conditions, as shown in records maintained by the licensee pursuant to Commission regulations. Each notification and report shall: be in writing; include appropriate identifying data such as the name of the licensee, the name of the individual, the individual's social security number; include the individual's exposure information; and contain the following statement:

> This report is furnished to you under the provisions of the Nuclear Regulatory Commission regulation 10 CFR Part 19. You should preserve this report for further reference.

(b) At the request of any worker, each licensee shall advise such worker annually of the worker's exposure to radiation or radioactive material as shown in records maintained by the licensee pursuant to § 20.401(a) and (c).

(c) At the request of a worker formerly engaged in licensed activities controlled by the licensee, each licensee shall furnish to the worker a report of the worker's exposure to radiation or radioactive material. Such report shall be furnished within 30 days from the time the request is made, or within 30 days after the exposure of the individual has been determined by the licensee, whichever is later; shall cover, within the period of time specified in the request, each calendar quarter in which the worker's activities involved exposure to radiation from radioactive materials licensed by the Commission; and shall include the dates and locations of licensed activities in which the worker participated during this period.

(d) When a licensee is required pursuant to § 20.405 or § 20.408 of this chapter to report to the Commission any exposure of an individual to radiation or radioactive material the licensee shall also provide the individual a report on his exposure data included therein. Such report shall be transmitted at a time not later than the transmittal to the Commission.

[38 FR 22217, Aug. 17, 1973, as amended at 40 FR 8780, Mar. 3, 1975]

§ 19.14 Presence of representatives of licensees and workers during inspections.

(a) Each licensee shall afford to the Commission at all reasonable times opportunity to inspect materials, activities, facilities, premises, and records pursuant to the regulations in this chapter.

(b) During an inspection, Commission inspectors may consult privately with workers as specified in § 19.15. The licensee or licensee's representative may accompany Commission inspectors during other phases of an inspection.

(c) If, at the time of inspection, an individual has been authorized by the workers to represent them during Commission inspections, the licensee shall notify the inspectors of such authorization and shall give the workers' representative an opportunity to accompany the inspectors during the inspection of physical working conditions.

(d) Each workers' representative shall be routinely engaged in licensed activities under control of the licensee and shall have received instructions as specified in § 19.12.

(e) Different representatives of licensees and workers may accompany the inspectors during different phases of an inspection if there is no resulting interference with the conduct of the inspection. However, only one workers' representative at a time may accompany the inspectors.

(f) With the approval of the licensee and the workers' representative an individual who is not routinely engaged in licensed activities under control of the licensee, for example, a consultant to the licensee or to the workers' representative, shall be afforded the opportunity to accompany Commission inspectors during the inspection of physical working conditions.

(g) Notwithstanding the other provisions of this section, Commission inspectors are authorized to refuse to permit accompaniment by any individual who deliberately interferes with a fair and orderly inspection. With regard to areas containing information classified by an agency of the U.S. Government in the interest of national security, an individual who accompanies an inspector may have access to such information only if authorized to do so. With regard to any area containing proprietary information, the workers' representative for that area shall be an individual previously authorized by the licensee to enter that area.

§ 19.15 Consultation with workers during inspections.

(a) Commission inspectors may consult privately with workers concerning matters of occupational radiation protection and other matters related to applicable provisions of Commission regulations and licenses to the extent the inspectors deem necessary for the conduct of an effective and thorough inspection.

(b) During the course of an inspection any worker may bring privately to the attention of the inspector, either orally or in writing, any past or present condition which he has reason to believe may have contributed to or caused any violation of the act, the regulations in this chapter, or license condition, or any unnecessary exposure of an individual to radiation from licensed radioactive material under the licensee's control. Any such notice in writing shall comply with the requirements of § 19.16(a).

(c) The provisions of paragraph (b) of this section shall not be interpreted as authorization to disregard instructions pursuant to § 19.12.

§ 19.16 Requests by workers for inspections.

(a) Any worker or representative of workers who believes that a violation of the Act, the regulations in this chapter, or license conditions exists or has occurred in license activities with regard to radiological working conditions in which the worker is engaged, may request an inspection by giving notice of the alleged violation to the Director of Inspection and Enforcement, to the Director of the appropriate Commission Regional Office, or to Commission inspectors. Any such notice shall be in writing, shall set forth the specific grounds for the notice, and shall be signed by the worker or representative of workers. A copy shall be provided the licensee by the Director of Inspection and Enforcement, Regional Office Director, or the inspector no later than at the time of inspection except that, upon the request of the worker giving such notice, his name and the name of individuals referred to therein shall not appear in such copy or on any record published, released or made available by the Commission, except for good cause shown.

(b) If, upon receipt of such notice, the Director of Inspection and Enforcement or Regional Office Director determines that the complaint meets the requirements set forth in paragraph (a) of this section, and that there are reasonable grounds to believe that the alleged violation exists or has occurred, he shall cause an inspection to be made as soon as practicable, to determine if such alleged violation exists or has occurred. Inspections pursuant to this section need not be limited to matters referred to in the complaint.

(c) No licensee shall discharge or in any manner discriminate against any worker because such worker has filed any complaint or instituted or caused to be instituted any proceeding under the regulations in this chapter or has testified or is about to testify in any such proceeding or because of the exercise by such worker on behalf of himself or others of any option afforded by this part.

[38 FR 22217, Aug. 17, 1973, as amended at 40 FR 8783, Mar. 3, 1975]

§ 19.17 Inspections not warranted; informal review.

(a) If the Director of Inspection and Enforcement or of the appropriate Regional Office determines, with respect to a complaint under § 19.16, that an inspection is not warranted because there are no reasonable grounds to believe that a violation exists or has occurred, he shall notify the complainant in writing of such determination. The complainant may obtain review of such determination by submitting a written statement of position with the Executive Director for Operation, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555, who will provide the licensee with a copy of such statement by certified mail, excluding, at the request of the complainant, the name of the complainant. The licensee may submit an opposing written statement of position with the Executive Director for Operations who will provide the complainant with a copy of such statement by certified mail. Upon the request of the complainant, the Executive Director for Operations or his designee may hold an informal conference in which the complainant and the licensee may orally present their views. An informal conference may also be held at the request of the licensee, but disclosure of the identity of the complainant will be made only following receipt of written authorization from the complainant. After considering all written and oral views presented, the Executive Director for Operations shall affirm, modify, or reverse the determination of the Director of Inspection and Enforcement or of the appropriate Regional Office and furnish the complainant and the licensee a written notification of his decision and the reason therefor.

(b) If the Director of Inspection and Enforcement or of the appropriate Regional Office determines that an inspection is not warranted because the requirements of § 19.16(a) have not been met, he shall notify the complainant in writing of such determination. Such determination shall be without prejudice to the filing of a new complaint meeting the requirements of § 19.16(a).

[38 FR 22217, Aug. 17, 1973, as amended at 40 FR 8783, Mar. 3, 1975]

§ 19.30 Violations.

An injunction or other court order may be obtained prohibiting any violation of any provision of the Act or Title II of the Energy Reorganization Act of 1974, or any regulation or order issued thereunder. A court order may be obtained for the payment of a civil penalty imposed pursuant to section 234 of the Act for violation of section 53, 63, 81, 82, 161, 181, 182, 183, 184, 185, 186, 187, or 189 of the Act or any rule, regulation, or order issued thereunder, or any term, condition or limitation of any license issued thereunder, or for any violation for which a license may be revoked under section 186 of the Act. Any person who willfully violates any provision of the Act or any regulation or order issued thereunder may be guilty of a crime and, upon conviction, may be punished by fine or imprisonment or both, as provided by law.

[38 FR 22217, Aug. 17, 1973, as amended at 40 FR 8783, Mar. 3, 1975]

§ 19.31 Application for exemptions.

The Commission may, upon application by any licensee or upon its own initiative, grant such exemptions from the requirements of the regulations in this part as it determines are authorized by law and will not result in undue hazard to life or property.

§ 19.32 Discrimination prohibited.

No person shall on the ground of sex be excluded from participation in, be denied the benefits of, or be subjected to discrimination under any program or activity licensed by the Nuclear Regulatory Commission. This provision will be enforced through agency procedures and rules similar to those already established with respect to racial and other discrimination, under title VI of the Civil Rights Act of 1964. This remedy is not exclusive, however, and will not prejudice or cut off any other legal remedies available to a discriminatee.

[40 FR 8783, Mar. 3, 1975]

March 1975

REGULATORY GUIDE

OFFICE OF STANDARDS DEVELOPMENT

REGULATORY GUIDE 8.13

INSTRUCTION CONCERNING PRENATAL RADIATION EXPOSURE

A. INTRODUCTION

Section 19.12 of 10 CFR Part 19 states that all individuals working in or frequenting any portion of a restricted area must be instructed in the health protection problems associated with exposure to radioactive materials or radiation. This guide describes the instruction that should be provided concerning biological risks to embryos or fetuses resulting from prenatal exposure.

B. DISCUSSION

Since the Law of Bergonie and Tribondeau was published in 1906[1] it has been known that the sensitivity of cells to radiation damage is related to their reproductive activity and inversely related to their degree of differentiation. It follows that children could be expected to be more radiosensitive than adults, fetuses more radiosensitive than children, and embryos even more radiosensitive.

This principle has long been a factor in the development of radiation exposure standards. Section 20.104 of 10 CFR Part 20 places different limits on minors than on adult workers. Specifically, it limits anyone under the age of 18 to exposures not exceeding 10% of the limits for adult workers.

A special situation arises when an occupationally exposed woman is pregnant. Exposure of the abdomen of such a worker to penetrating radiation from either external or internal sources would also involve exposure of the embryo or fetus. Because a number of studies have indicated that the embryo or fetus is more sensitive than an adult, particularly during the first three months after conception, when a woman may not be aware that she is pregnant, the National Council on Radiation Protection and Measurements (NCRP) recommended in its Report No. 39 that special precautions be taken to limit exposure when an occupationally exposed woman could be pregnant.

C. REGULATORY POSITION

Instruction to workers performed under §19.12 should be given prior to assignment to work in a restricted area. In providing instruction about health protection problems associated with radiation exposure, female workers and those who may supervise or work with them should be given specific instruction about prenatal exposure risks to the developing embryo and fetus.

The instruction should ensure that the employees understand:

1. That the NCRP has recommended holding prenatal occupational exposure to 0.5 rem or less during the entire period of gestation; and

2. The reasons for this recommendation.

The instruction should include the information provided in the Appendix to this guide. It should be presented to the employee, her supervisors, and her co-workers both orally and in written form. Each person should be given an opportunity to ask questions, and each person should be asked to acknowledge in writing that the instruction has been received.

D. IMPLEMENTATION

The purpose of this section is to provide information to licensees regarding the use of this guide.

[1] *Comptes Rendus des Seances de l'Academie des Sciences*, Vol. 143, pp. 983-985, 1906.

to propose an alternative method for com[illegible]ing with the [illegible]tion of the Commission's regulations previously specified, the methods described herein should be used after September 1, 1975, to instruct female employees [illegible]working in or frequenting any portion of a restricted area, and those who may [illegible]pervise or work with such employees, concerning the health protection problems associated with prenatal radiation exposure.

APPENDIX TO REGULATORY GUIDE 8.13

POSSIBLE HEALTH RISKS TO CHILDREN OF WOMEN WHO ARE EXPOSED TO RADIATION DURING PREGNANCY

Some recent studies have shown that the risk of leukemia and other cancers in children increases if the mother is exposed to a significant amount of radiation during pregnancy. According to a report by the National Academy of Sciences, the incidence of leukemia among children under 10 years of age in the United States could rise from 3.7 cases in 10,000 children to 5.6 cases in 10,000 children if the children were exposed to 1 rem of radiation before birth (a "rem" is a measure of radiation). The Academy has also estimated that an equal number of other types of cancers could result from this level of radiation. Although other scientific studies have shown a much smaller effect from radiation, the Nuclear Regulatory Commission wants women employees of its licensees to be aware of any possible risk so that the women can take steps they think appropriate to protect their offspring.

As an employee of a Nuclear Regulatory Commission licensee, you may be exposed to more radiation than the general public. However, the Nuclear Regulatory Commission has established a basic exposure limit for all occupationally exposed adults of 1.25 rems per calendar quarter, or 5 rems per year. No clinical evidence of harm would be expected in an adult working within these levels for a lifetime. Because the risks of undesirable effects may be greater for young people, persons under 18 years of age are permitted to be exposed to only 10 percent of the adult occupational limits. (This lower limit is also applied to members of the general public.)

The scientific organization called the National Council on Radiation Protection and Measurements has recommended that because unborn babies may be more sensitive to radiation than adults, their radiation dose as a result of occupational exposure of the mother should not exceed 0.5 rem. Other scientific groups, including the International Commission on Radiation Protection, have also stressed the need to keep radiation doses to unborn children as low as practicable.

All Nuclear Regulatory Commission licensees are now required* to inform all individuals who work in a restricted area of the health protection problems associated with radiation exposure. This instruction would in many cases include information on the possible risks to unborn babies. The regulations also state** that licensees should keep radiation exposures as low as practicable. According to the National Council on Radiation Protection and Measurements, particular efforts should be made to keep the radiation exposure of an embryo or fetus at the very lowest practicable level during the entire period of pregnancy.

Thus it is the responsibility of your employer to take all practicable steps to reduce your radiation exposure. Then it is your responsibility to decide whether the exposure you are receiving is sufficiently low to protect your unborn child. The advice of your employer's health physicist or radiation protection officer should be obtained to determine whether radiation levels in your working areas are high enough that a baby could receive 0.5 rem or more before birth. If so, the alternatives that you might want to consider are:

(a) If you are now pregnant or expect to be soon, you could decide not to accept or continue assignments in these areas.

(b) You could reduce your exposure, where possible, by decreasing the amount of time you spend in the radiation area, increasing your distance from the radiation source, and using shielding.

(c) If you do become pregnant, you could ask your employer to reassign you to areas involving less exposure to radiation. If this is not possible, you might consider leaving your job. If you decide to take such steps, do so without delay. The unborn child is most sensitive to radiation during the first three months of your pregnancy.

(d) You could delay having children until you are no longer working in an area where the radiation dose to your unborn baby could exceed 0.5 rem.

*By Title 10, Part 19 of the Code of Federal Regulations.

**In Title 10, Part 20.

You may also, of course, choose to:

(e) Continue working in the higher radiation areas, but with full awareness that you are doing so at some small increased risk for your unborn child.

The following facts should be noted to help you make a decision:

1. The first three months of pregnancy are the most important, so you should make your decision quickly.

2. At the present occupational exposure limit, the actual risk to the unborn baby is small, but experts disagree on the exact amount of risk.

3. There is no need to be concerned about sterility or loss of your ability to bear children. The radiation dose required to produce such effects is more than 100 times larger than the Nuclear Regulatory Commission's dose limits for adults.

4. Even if you work in an area where you receive only 0.5 rem per three-month period, in nine months you could receive 1.5 rems, which exceeds the full-term limit suggested by the NCRP. Therefore, if you decide to restrict your unborn baby's exposure as recommended by the NCRP, be aware that the 0.5 rem limit applies to the full nine-month pregnancy.

The remainder of this document contains a brief explanation of radiation and its effects on humans. As you will see, some radiation is present everywhere and the levels of radiation most employees of Nuclear Regulatory Commission licensees receive are not much larger than these natural levels. Because the radiation levels in the facility where you will be working are required by law to be kept quite low, there is not considered to be a significant health risk to individual adult employees.

Discussion of Radiation

The amount of radiation a person receives is called the "dose" and is measured in "rems." The average person in the United States gets a dose of one rem from natural sources every 12 years. The dose from natural radiation is higher in some states, such as Colorado, Wyoming, and South Dakota, primarily because of cosmic radiation. There the average person gets one rem every 8 years.

Natural background radiation levels are also much higher in certain local areas. A dose of one rem may be received in some areas on the beach at Guarapari, Brazil, in only about 9 days, and some people in Kerala, India, get a dose of one rem every 5 months.

Many people receive additional radiation for medical reasons. The annual radiation dose averaged over the United States population from diagnostic X-rays is 0.072 rem per year. The average dose from one chest X-ray is 0.045 rem.

Radiation can also be received from natural sources such as rock or brick structures, from consumer products such as television and glow-in-the-dark watches, and from air travel. The possible annual dose from working 8 hours a day near a granite wall at the Redcap Stand in Grand Central Station, New York City, is 0.2 rem, and the average annual dose in the United States from TV, consumer products, and air travel is 0.0026 rem.

Radiation, like many things, can be harmful. A large dose to the whole body (such as 600 rems in one day) would probably cause death in about 30 days, but such large doses result only from rare accidents. Control of exposure to radiation is based on the assumption that any exposure, no matter how small, involves some risk. The occupational exposure limits are set so low, however, that medical evidence gathered over the past 50 years indicates no clinically observable injuries to individuals due to radiation exposures when the established radiation limits are not exceeded. This was true even for exposures received under the early occupational exposure limits, which were many times higher than the present limits. Thus the risk to individuals at the occupational exposure levels is considered to be very low. However, it is impossible to say that the risk is zero. To decrease the risk still further, licensees are expected to keep actual exposures as far below the limits as practicable.

The current exposure limits for people working with radiation have been developed and carefully reviewed by nationally and internationally recognized groups of scientists. It must be remembered, however, that these limits are for adults. Special consideration is appropriate when the person being exposed is, or may be, an expectant mother, because the exposure of an unborn child may also be involved.

Prenatal Irradiation

The prediction that an unborn child would be more sensitive to radiation than an adult is supported by observations for relatively large doses. Large doses delivered before birth alter both physical development and behavior in experimentally exposed animals. A report of the National Academy of Sciences states that short-term doses in the range of 10 to 20 rems cause subtle changes in the nerve cells of unborn and infant rats. The report also states, however, that no radiation-induced changes in development have been demonstrated to result in experimental animals from doses up to about 1 rem per day extended over a large part of the period before birth.

The National Academy of Sciences also noted that doses of 25 to 50 rems to a pregnant human may cause

growth disturbances in her offspring. Such doses substantially exceed, of course, the maximum permissible occupational exposure limits.

Concern about prenatal exposure (i.e., exposure of a child while in its mother's uterus) at the permissible occupational levels is primarily based on the possibility that cancer (especially leukemia) may develop during the first 10 years of the child's life. Several studies have been performed to evaluate this risk. One study involved the followup of 77,000 children exposed to radiation before birth (because of diagnostic abdominal X-rays made for medical purposes during their mother's pregnancy). Another study involved the followup of 20,000 such children. In addition, 1292 children who received prenatal exposure during the bombing of Hiroshima and Nagasaki were studied. Although contradictory results have been obtained, most of the evidence suggests a relationship between prenatal exposure and an increased risk of childhood cancer.

Summary

Occupational exposures to radiation are being kept low. However, qualified scientists have recommended that the radiation dose to a pregnant woman should not exceed 0.5 rem because of possible risks to her unborn child. Since this 0.5 rem is lower than the dose generally permitted to adult workers, women may want to take special actions to avoid receiving higher exposures, just as they might stop smoking during pregnancy or might climb stairs more carefully to reduce possible risks to their unborn children.

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   A. PART 19, NOTICES, INSTRUCTIONS AND REPORTS TO WORKERS: INSPECTIONS.

   B. PART 20, STANDARDS FOR PROTECTION AGAINST RADIATION.

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