Dear Miss Phillips,

Please Excuse me for payment of $580.00, I was told by my Physics Consultant group that it would be $580.00 Please could you inform me the next step to receiving the Licensing Control No. 378733

Thank you

Steven Sands
President I.D.S.

NRC FORM 313
(1-84)
10 CFR 30, 32, 33, 34, 35 and 40

U.S. NUCLEAR REGULATORY COMMISSION
APPROVED BY OMB
3150-0120
Expires: 5-31-87

APPLICATION FOR MATERIAL LICENSE

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

FEDERAL AGENCIES FILE APPLICATIONS WITH:

U.S. NUCLEAR REGULATORY COMMISSION
DIVISION OF FUEL CYCLE AND MATERIAL SAFETY, NMSS
WASHINGTON, DC 20555

ALL OTHER PERSONS FILE APPLICATIONS AS FOLLOWS, IF YOU ARE LOCATED IN:

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

U.S. NUCLEAR REGULATORY COMMISSION, REGION I
NUCLEAR MATERIAL SECTION B
631 PARK AVENUE
KING OF PRUSSIA, PA 19406

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

U.S. NUCLEAR REGULATORY COMMISSION, REGION II
MATERIAL RADIATION PROTECTION SECTION
101 MARIETTA STREET, SUITE 2900
ATLANTA, GA 30323

IF YOU ARE LOCATED IN:

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

U.S. NUCLEAR REGULATORY COMMISSION, REGION III
MATERIALS LICENSING SECTION
799 ROOSEVELT ROAD
GLEN ELLYN, IL 60137

ARKANSAS, COLORADO, IDAHO, KANSAS, LOUISIANA, MONTANA, NEBRASKA, NEW MEXICO, NORTH DAKOTA, OKLAHOMA, SOUTH DAKOTA, TEXAS, UTAH, OR WYOMING, SEND APPLICATIONS TO:

U.S. NUCLEAR REGULATORY COMMISSION, REGION IV
MATERIAL RADIATION PROTECTION SECTION
611 RYAN PLAZA DRIVE, SUITE 1000
ARLINGTON, TX 76011

ALASKA, ARIZONA, CALIFORNIA, HAWAII, NEVADA, OREGON, WASHINGTON, AND U.S. TERRITORIES AND POSSESSIONS IN THE PACIFIC, SEND APPLICATIONS TO:

U.S. NUCLEAR REGULATORY COMMISSION, REGION V
MATERIAL RADIATION PROTECTION SECTION
1450 MARIA LANE, SUITE 210
WALNUT CREEK, CA 94596

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

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

- [X] A. NEW LICENSE
- [ ] B. AMENDMENT TO LICENSE NUMBER _____
- [ ] C. RENEWAL OF LICENSE NUMBER _____

2. NAME AND MAILING ADDRESS OF APPLICANT *(Include Zip Code)*

Iso-Diagnostic Services of Michigan
575 Robbins Drive
Troy, Michigan 48083

3. ADDRESS(ES) WHERE LICENSED MATERIAL WILL BE USED OR POSSESSED.

SAME AS ABOVE

4. NAME OF PERSON TO BE CONTACTED ABOUT THIS APPLICATION

Steven Sands, M.S.

TELEPHONE NUMBER: 313-879-9330

SUBMIT ITEMS 5 THROUGH 11 ON 8½ x 11" PAPER. THE TYPE AND SCOPE OF INFORMATION TO BE PROVIDED IS DESCRIBED IN THE LICENSE APPLICATION GUIDE. (attached)

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

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

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

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

9. FACILITIES AND EQUIPMENT.

10. RADIATION SAFETY PROGRAM.

11. WASTE MANAGEMENT.

12. LICENSEE FEES *(See 10 CFR 170 and Section 170.31)*
FEE CATEGORY: 7C
AMOUNT ENCLOSED: $580.00

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

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

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

SIGNATURE–CERTIFYING OFFICER	TYPED/PRINTED NAME	TITLE	DATE
Steven Sands	Steven Sands	President	4/12/85

14. VOLUNTARY ECONOMIC DATA

a. ANNUAL RECEIPTS
- [ ] <$250K
- [ ] $250K–500K
- [ ] $500K–750K
- [ ] $750K–1M
- [ ] $1M–3.5M
- [ ] $3.5M–7M
- [ ] $7M–10M
- [ ] >$10

b. NUMBER OF EMPLOYEES *(Total for entire facility excluding outside contractors)*

c. NUMBER OF BEDS

d. WOULD YOU BE WILLING TO FURNISH COST INFORMATION *(dollar and/or staff hours)* ON THE ECONOMIC IMPACT OF CURRENT NRC REGULATIONS OR ANY FUTURE PROPOSED NRC REGULATIONS THAT MAY AFFECT YOU? *(NRC regulations permit it to protect confidential commercial or financial–proprietary–information furnished to the agency in confidence)*
- [X] YES
- [ ] NO

RECEIVED
APR 15 1985

FOR NRC USE ONLY

TYPE OF FEE	FEE LOG	FEE CATEGORY	COMMENTS	APPROVED BY
MP2C	apr 29	3C	REGION III	
AMOUNT RECEIVED	**CHECK NUMBER**			**DATE**
521394 522764	$580	CONTROL NO. 78733	APR 15 1985	5/13/85

PRIVACY ACT STATEMENT ON THE REVERSE

8507200551 47pp.

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 NRC Form 313. 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, 32, 33, 34, 35 and 40 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 (a) provided to State health departments for their information and use; and (b) provided 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 a 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 an NRC decision or to an appropriate Federal agency to the extent relevant and necessary for that agency's decision about you.

4. **WHETHER DISCLOSURE IS MANDATORY OR VOLUNTARY AND EFFECT ON INDIVIDUAL OF NOT PROVIDING INFORMATION**: Disclosure of the requested information is voluntary. If the requested information is not furnished, however, the application for radioactive material license, or amendment thereof, will not be processed. A request that information be held from public inspection must be in accordance with the provisions of 10 CFR 2.790. Withholding from public inspection shall not affect the right, if any, of persons properly and directly concerned need to inspect the document.

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

Supplement to form NRC-313 10 CFR 35

5 & 6 Radioactive Material For Medical Use

Byproduct Material	Chemical and/or Physical Form	Maximum amount license may possess at any one time	
A. Molybdenum	Molybdenum 99/ technetium 99m generators	25 curies	
B. Any byproduct material listed in Section 31.11(a) of 10 CFR 31	Prepackaged in vitro diagnostic test kits	50 millicuries total possession limit	
C. Any byproduct material authorized under Section 35.14 (d)(4) of 10 CFR 35	Any sealed source	25 millicuries total possession limit	✓
D. Xenon 133	Gas or gas in solution - prepackaged unit doses.	1.5 curies	✓
E. Iodine 131	Capsular form for use in Groups, I, II, IV, V of Schedule A Section 35.100 of 10 CFR 35	250 millicuries	✓
F. Technetium 99m	Any	25 curies	✓
G. Any byproduct material except I-131 listed in Group .I of Schedule A, Section 35.100 of 10 CFR 35	Any form listed in Group I of schedule A Section 35.100 of 10 CFR 35	25 millicuries total possession limit	
H. Any byproduct material except I-131 listed in Group II of Schedule A, Section 35.100 of 10 CFR 35	Any	75 millicuries total possession limit.	

I.	Any byproduct material except I-131 listed in Group IV of Schedule A, Section 35.100 of 10 CFR 35	Any	50 millicuries total possession limit

Radiation Safety Officers

(1) Michael Grawburg R.Ph
Listed as a practicing nuclear pharmacist on NRC License #34-16654-01MD for the past 7 1/2 years.

(2) Steven Sands, M.S.
371-56-2137
1373 Prosper Dr.
Troy, Michigan 48098
B.S. Western Michigan University 1973
M.S. Radiobiology - Wayne State University 1980
NMTCB 1979 Harper-Grace Hospital

Training Location - Harper-Grace Hospital
Date of Attendance June 1977 - June 1979

Course Content is Hrs. Classwork

Radiation Physics & Instrumentation	120 Hrs. Jan 78/Mar 78
Radiation Protection	90 Hrs. Nov 77/Dec 77
Math Pertaining to Radioactivity	100 Hrs. Mar 78/Jun 78
Radiation Biology/Instrumentation	Seminar in work study program at Wayne State University. One semester Sept-Dec 1979 Radiation Biology at Harper-Grace Sept--Nov 1978. 50 Hrs Radiopharmaceutical Chemistry Harper-Grace Hospital. 75 Hrs Aug-Dec 1977.

Total Hours : 435 at Harper-Grace Hospital

EXPERIENCE WITH RADIATION (Steven Sands)

Isotope	Maximum Amount Used	Hours	Types of Use (See key below)
Tc-99m	102 Ci	4,000	1,2,3,4,6
Thallium - 201	2.5 Ci	1,000	1-5
Xenon-133	2.5 Ci	1,000	1-5
Gallium GA 67	1.6 Ci	1,000	1-5
Ytterbium - 169	1.0 Ci	500	1-5
Indium In 111	1.0 Ci	500	1-5
Cobalt 57	2.0 Ci	200	1,3,4,5
Chromium 51	2.0 Ci	500	1,3,4,5
Iodine 123	2.8 Ci	1,000	1-5
Iodine 125	3.5 Ci	10,000	1,4,5
Iodine 131	12.7 Ci	1,000	1-5

Key for "Type of Use"

The number or numbers entered under "Type of Use" correspond to experience in the following activities:

1. Ordering, receiving, and unpacking radioactive materials safely, including performance of related radiation surveys.

2. Calibration of dose calibrators, scintillation detectors, and survey meters.

3. Calculation, dispensing, and calibration of patient doses, including proper use of radiation shields.

4. Appropriate internal control procedures to prevent mislabeling errors.

5. Emergency procedures to handle and contain spilled materials safely, including related decontamination procedures, surveys, and wipe tests.

6. Elution of Tc-99m generator systems, assay and testing of the eluate for Mo-99 and alumina contamination, and processing the eluate with reagent kits to prepare Tc-99m labeled radiopharmaceuticals.

TRAINING RECEIVED IN RADIOISOTOPE HANDLING

Steven Sands, M.S.:

Location of Training	Attendance	Course Title	Hours of Course	Radiation Physics & Instrumentation	Radiation Protection	Math Pertaining to Radioactivity	Radiation Biology	Radiopharmaceutical Chemistry
Harper - Grace Hos.	6-77 thru 6-79	Nuclear Medicine Technical School	800	160 Hours	120 Hours & 3 Seminars in protection	80 Hours	40 Hours	120 Hours
			On the job training. 2yr/40hrs per week	Instrumentation Course at W.S.U. (For Masters)			Radicbiology Course at W.S.U. (For Masters)	

AUTHORIZED USERS

Michael Grawburg, R.Ph
Michael Klug, R.Ph. (previously authorized under license #34-16654-01 MD)

Steven Sands, M.S.

NOTE:

The State of Michigan Board of Pharmacy License application has been submitted and IDS is awaiting its arrival.

PERSONNEL TRAINING PROGRAM

I. Individuals who work in or frequent restricted areas will be instructed in the items specified in 10 CFR 19.12 at the time of initial employment and at least annually thereafter.

This instruction will include:

a. All terms of the license pertinent to radiation safety.

b. Areas where radioactive material is used or stored.

c. Potential hazards associated with radioactive material.

d. Radiological safety procedures appropriate to their respective duties.

e. Pertinent NRC regulations.

f. Rules and regulations of the license.

g. Obligation to report unsafe conditions to the Radiation Safety Officer.

h. Appropriate response to emergencies or unsafe conditions.

i. Right to be informed of their radiation exposure and bioassy results.

j. Locations where the license has been posted or make available notices, copies of pertinent regulations, and copies or pertinent licenses and license conditions (including applications and applicable correspondence,) as required by 10 CFR Part 19.

II. Individuals whose duties may require them to work in the vicinity of licensed material will be informed about radiation hazards and appropriate precautions at the time of initial employment and at least annually thereafter. This information will be provided initially at employee orientation sessions and annually thereafter at in-service meetings.

FACILITIES & EQUIPMENT

1. Site Description:

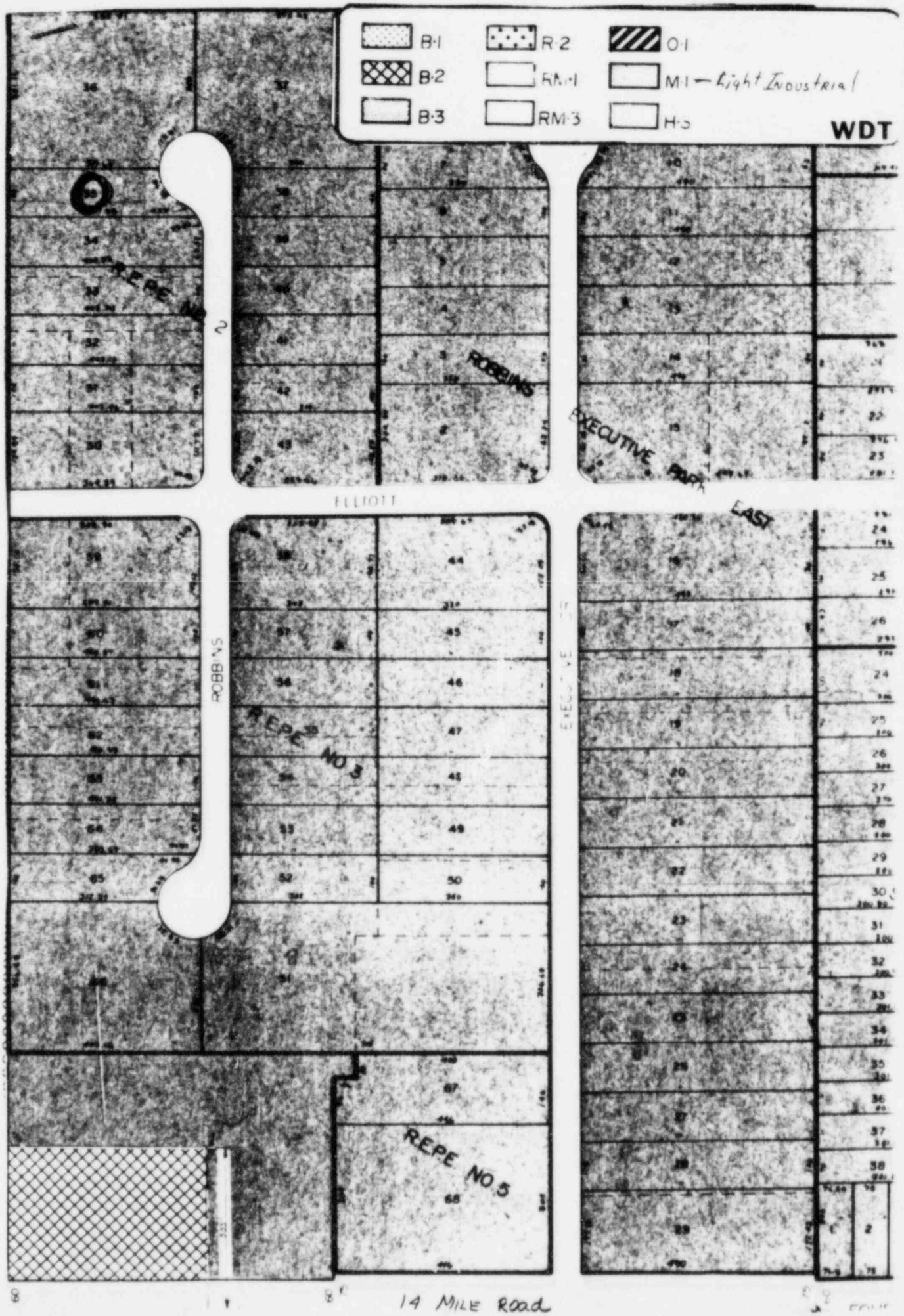
As shown on the attached diagrams, the facility is located in an area designated by the City of Troy as a light industrial zone. All buildings surrounding the building of interest are either warehouses or manufacturing firms.

The building of interest is multi-tenant structure containing four other areas outside the restricted area lie within the limits specified in 10 CFR 20.105(b)(2). Note that an existing NRC licensee #21-14-161-02 commercially labels I-125 to radioimmuno assay kits on the premisis.

Iso-Diagnostic Services of Michigan is located on the 2nd floor of the structure. It is completely isolated from the other businesses located there. The only accessible door leads to the exterior of the building, whereby deliveries can be made. The only persons having access to this door are the delivery people and the IDS personne. This door is not alarmed.

The entrance to the pharmacy (restricted area) is at the top of the stairs leading from the delivery area. This door is alarmed and has a different lock than that which is downstairs. Only authorized personnel will have access to this restricted area. There are no windows in this area.

With regard to the fume hood and exhaust stack, a minimum of 800 CFM will be vented from the hood and remaining pharmacy circulation directly to the environment. No recirculation of air from the pharmacy will take place. The exhaust vent will be located on the roof of the building away from all air intake ducts. Negative pressure will be maintained with respect to the rest of the building at all times. Verification of proper air flow will be made on a semi-annual basis. Note that only iodine in capsular form and xenon in unit dose form will be posessed by IDS.


B-1
B-2
B-3
R-2
RM-1
RM-3
O-1
M-1 — Light Industrial
H-3
WDT
REPE NO 2
ROBBINS
EXECUTIVE PARK
ELLIOTT
LAST
ROBB N.S
REPE NO 3
REPE NO 5
14 MILE Road

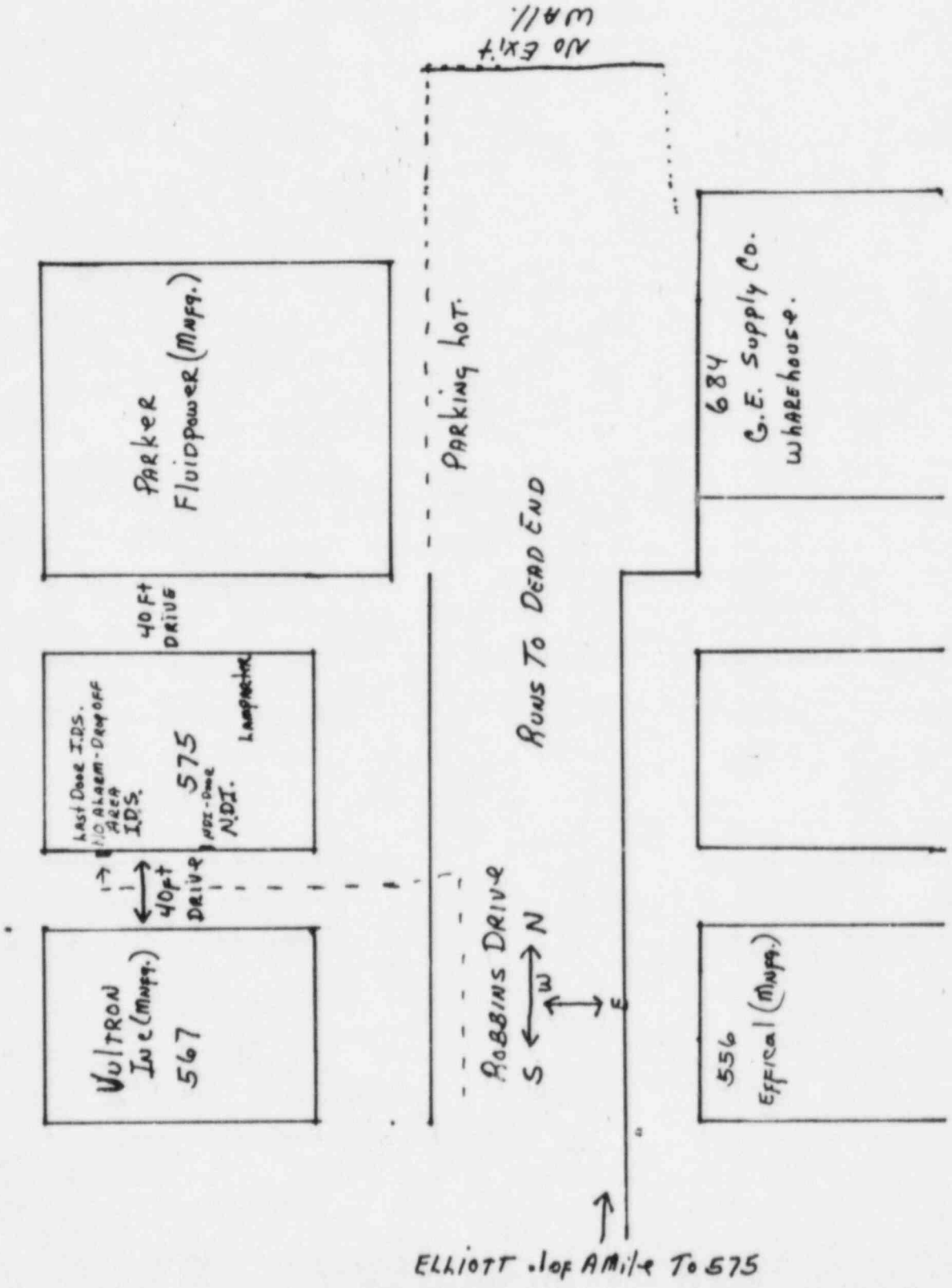
ITEM 9
April 1985

X=20Ft./1sq.

Neighborhood AREA
Zoned Commercial (All Neighboring Bussinesses Are MANUFACTURING Corp.)

ITEM 9
April 1985

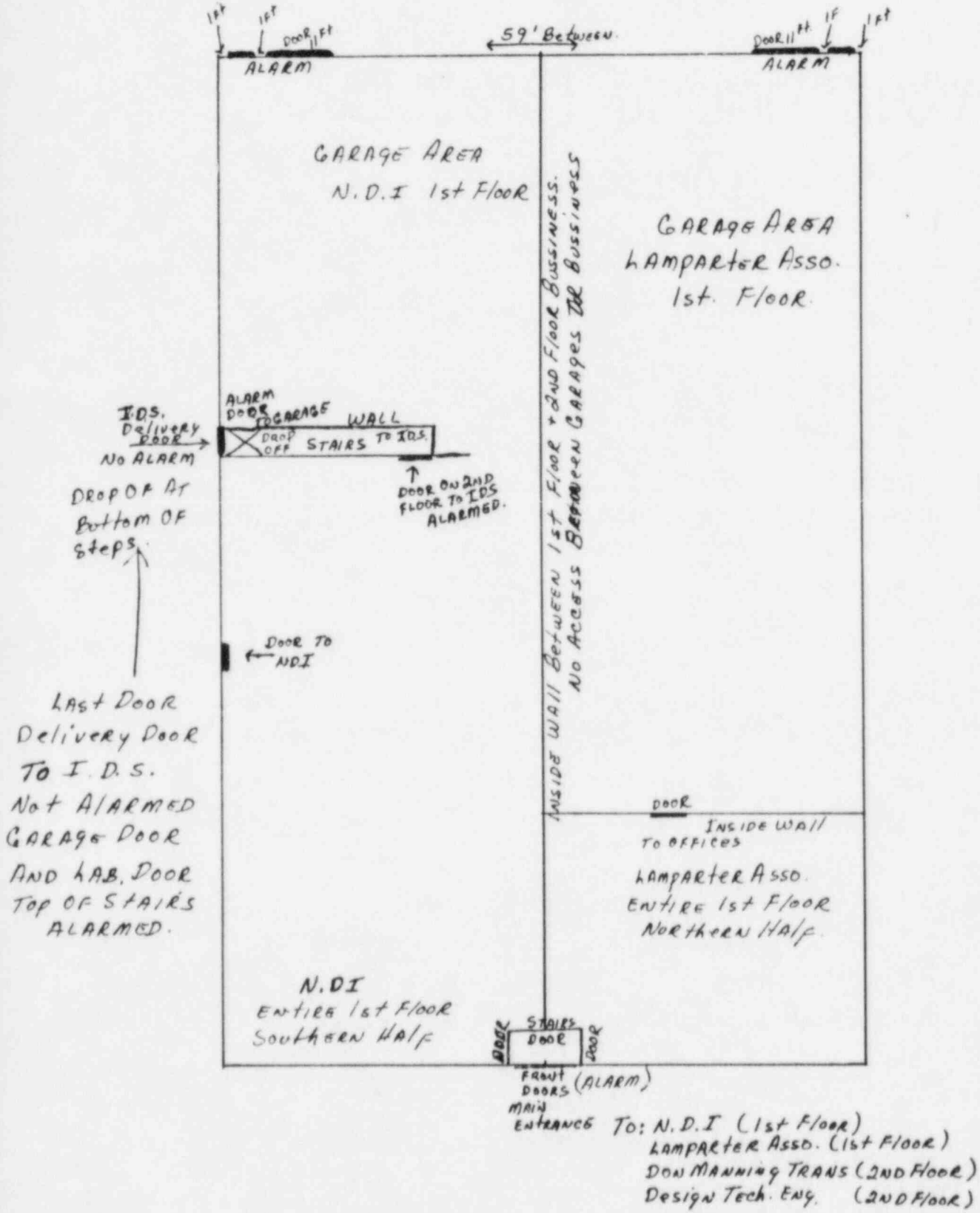
Delivery Drop OFF



X=5Ft

OUTSIDE OF BLDG. + ALARMED DOORS + Delivery AREA.

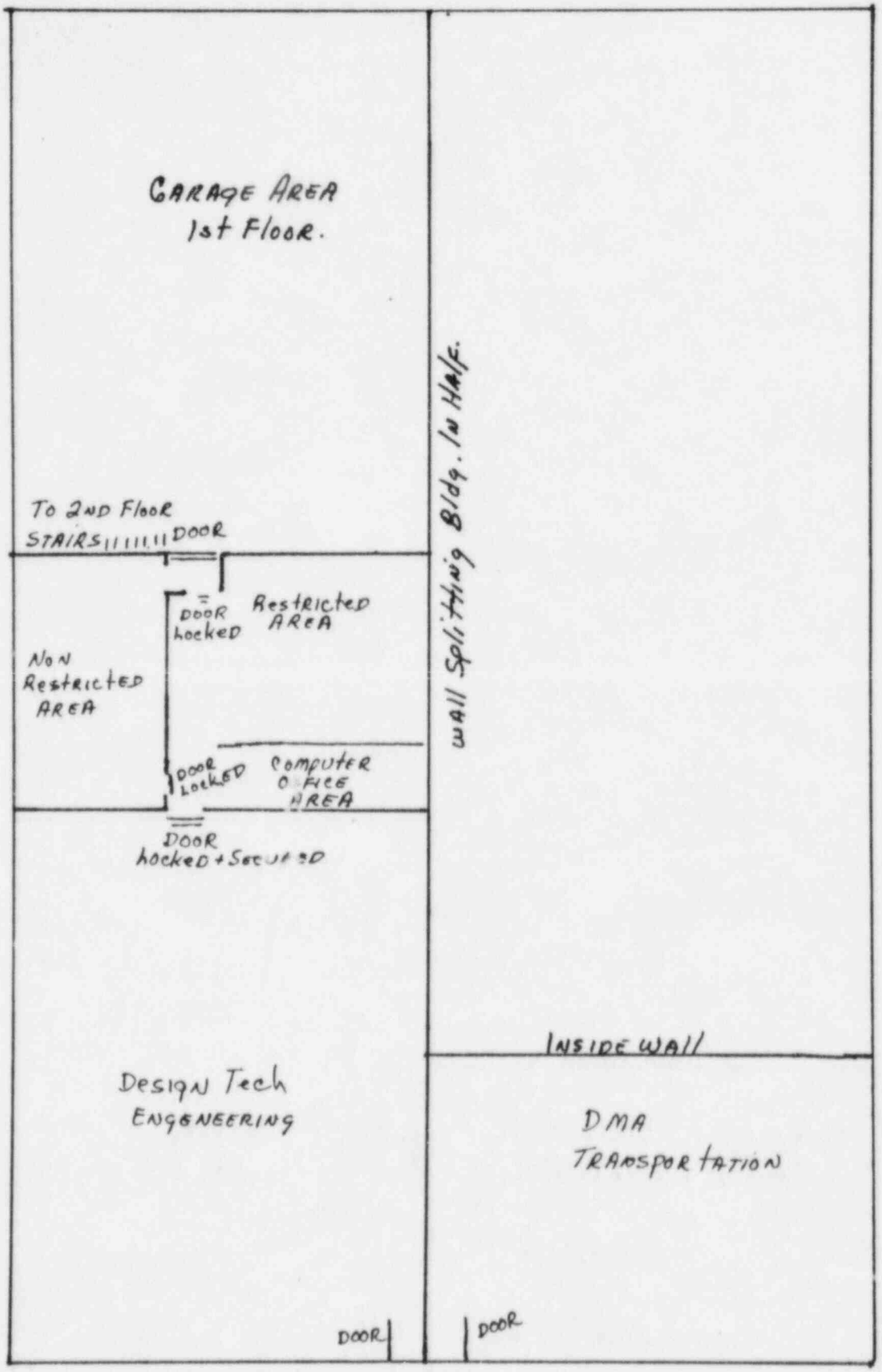
ITEM 9
April 1985



To: N.D.I (1st Floor)
LAMPARTER ASSO. (1st Floor)
DON MANNING TRANS (2ND Floor)
Design Tech. ENG. (2ND Floor)

2ND FLOOR DIAGRAM
NO WINDOWS IN I.D.S. AREA

ITEM 9
April 1985

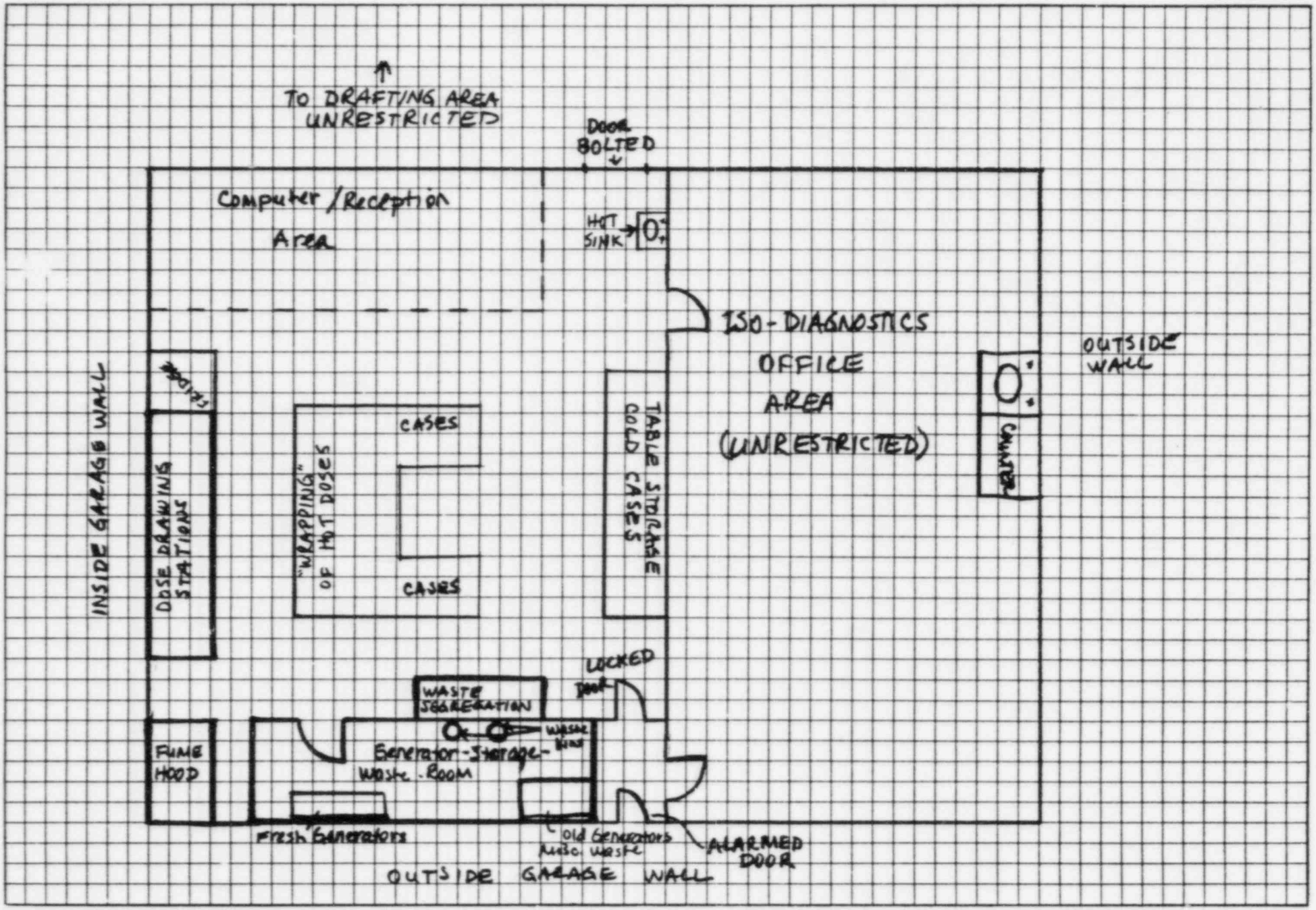


CONTROL NO. 78733

2. Facility Description

All storage of generators, pharmaceuticals, and radioactive waste will be situated in a "hot locker" shielded by at least 1/8" lead. Generators which have been calibrated within the previous two weeks will be shielded secondarily with additional lead housing. After being removed from the secondary shielding, the generators will be placed in a 1/8" leaded "bunker" for decay. All waste will be segregated as "Tc-99m waste" or "other waste". The waste dumping barrels will be of 1/4" lead thickness, and will also be situated in the already shielded "hot locker". The "hot locker" will have 2-50 CFM fans with no air intake. Therefore, the locker will be ventilated at all times and will remain under negative pressure. The fume hood will be shielded with a lead thickness of 1/4". The dose preparation and drawing area will contain 1/4" lead shielding on the respective counters, and at least 1/8" lead extending 12 inches up on the adjacent wall. 1" and 2" lead bricks will be available for additional shielding when necessry.

IDS - FACILITY DIAGRAM.



▬ Denotes shielding

3. Instrumentation

Iso-Diagnostic services of Michigan will have in its possession and available for use at the time operation begins the following items:

a. At least one low-level thin-window survey meter, capable of detecting 0.1 milliroentgens per hour to perform contamination surveys.

b. A high-level survey meter such as an ionization chamber capable of reading up to one roentgen per hour to measure radiation exposure rates that may exist in the vicinity of Mo-99/Tc99m generators.

c. At least one dose calibrator which assays radiopharmaceuticals to 2.0 curies.

d. Sodium iodide well counter and gamma spectrometer to analyze wipe tests and perform quality control procedures.

e. A minimum of two (2) G-M room/contamination monitors with thin-window pancake probes.

f. Syringe holders of both 1/4" and 1/8" lead thicknesses will be available to contain unit doses for delivery.

Item 10 - Attached

a. Personnel Monitoring

b. Calibration of survey meters

c. Calibration of Dose Calibrators

d. Receipt of Shipments Containing Radioactive Materials

e. Safe Opening of Packages Containing Raioactive Materials

f. General Procedures for Safe Use of Radioactive Materials

g. Emergency Instructions

h. Area Survey Procedures

i. Retrieval of Waste from Customers

j. Precautions for Handling of Radioiodine

k. Information Required for Use of Xenon-133

l. Distribution Procedures

m. Product Labels

n. Product Shielding

o. Packaging & Trasnporting Radiopharmaceuticals

p. Independent Audit Program

PERSONNEL MONITORING PROGRAM

Badge Location	Type	Supplier	Frequency
a. Whole Body	Film	R.S. Landauer, Jr. & Co.	monthly
b. Finger	TLD	R.S. Landauer, Jr. & Co.	monthly

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 used for radiation protection purposes, i.e., at least up to 1 R/hr.

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 percent of the calculated or known values for each point checked. Readings within ± 20 percent are considered acceptable if a calibration chart, graph, or response factor is prepared, attached to the instrument, and used to interpret readings to within ± 10 percent. Also, when higher scales are not checked or calibrated, an appropriate precautionary note will be posted on the instrument.

3. Survey instruments will be calibrated

X a. By the manufacturer

_____ b. At the licensee's facility

(1) Calibration source

Manufacturer's name _____
Model no. _____
Activity in millicuries _____
or
Exposure rate at a specified distance _____
Accuracy _____
Traceability to primary standard _____

_____ (2) The calibration procedures in Section I of Appendix D will be used
or
_____ (3) The step-by-step procedures, including radiation safety procedures, are attached.

X c. By a consultant or outside firm

(1) Name Medical Physics Consultants, Inc.

(2) Location 3200 W. Liberty, Suite F1, Ann Arbor, MI 48103

(3) Procedures and sources

X have been approved by NRC and are on file in License No. 21-20153-01

_____ have been approved by an Agreement State; a copy of the Agreement State license, the procedures, and a description of the sources are attached, and the consultant's report will contain the information on

_____ the attached "Certificate of Instrument Calibration."
_____ the consultant's reporting form as attached.

_____ are described in the attachment, and the consultant's report will contain the information on

_____ the attached "Certificate of Instrument Calibration."
_____ the consultant's reporting form as attached.

Medical Physics Consultants, Inc.

3200 West Liberty, Suite F1
Ann Arbor, Michigan 48103
(313) 662-3197

CERTIFICATE OF INSTRUMENT CALIBRATION

For:

Instrument:

Manufacturer-
Type-
Model Number-
Serial Number-

	Nuclide	Exposure Rate at Specified Distance	Calibration Accuracy
Calibration Source:	Cs-137	26.0 mR/h at 1 m	+/- 3% NBS

Calibration Data:

Scale	Exposure rate (mR/h)	Instrument reading (mR/h)	Exposure rate (mR/h)	Instrument reading (mR/h)

Comments:

Calibrated by: _____ Date: _____

APPENDIX D (Continued)

Section 2

METHODS FOR CALIBRATION OF DOSE CALIBRATOR*

All radiopharmaceuticals must be assayed for activity to an accuracy of 10 percent. The most common instrument for accomplishing this is an ionization-type dose calibrator. The instrument must be checked for accurate operation at the time of installation and periodically thereafter.

A. Test for the following:

1. Instrument constancy (daily)
2. Instrument accuracy (at installation and annually thereafter)
3. Instrument linearity (at installation and quarterly thereafter)
4. Geometrical variation (at installation)

B. After repair or adjustment of the dose calibrator, repeat all the appropriate tests listed above (dependent upon the nature of the repairs).

C. Test for Instrument Constancy

Instrument constancy means that there is reproducibility, within a stated acceptable degree of precision, in measuring a constant activity over time. Assay at least one relatively long-lived reference source such as Cs-137, Co-57,** or Ra-226** using a reproducible geometry before each day's use of the instrument. Preferably, at least two reference sources (for example, 3-5 mCi of Co-57 and 100-200 μCi of Cs-137 or 1-2 mg Ra-226 (with appropriate decay corrections) will be alternated each day of use to test the instrument's performance over a range of photon energies and source activities.

1. Assay each reference source using the appropriate instrument setting (i.e., Cs-137 setting for Cs-137).
2. Measure background level at same instrument setting, or check that automatic background subtraction is operating properly when blanks are inserted in the calibrator.
3. Calculate net activity of each source subtracting out background level.
4. For each source, plot net activity versus the day of the year on semilog graph paper.
5. Log the background levels.
6. Indicate the predicted activity of each source based on decay calculations and the $\pm$5 percent limits on the graph.
7. Repeat the procedure used for the Cs-137 source for all the commonly used radionuclide settings.
8. Variations greater than $\pm$5 percent from the predicted activity indicate the need for instrument repair or adjustment.
9. Investigate higher than normal background levels to determine their origin and to eliminate them if possible by decontamination, relocation, etc.

D. Inspect the instrument on a quarterly basis to ascertain that the measurement chamber liner is in place and that instrument zero is properly set (see manufacturer's instructions).

E. Test of Instrument Linearity

The linearity of a dose calibrator should be ascertained over the entire range of activities employed. This test will use a vial of Tc-99m whose activity is equivalent to the maximum anticipated activity to be assayed (e.g., the first elution from a new generator).

1. Assay the Tc-99m vial in the dose calibrator, and subtract background level to obtain net activity in millicuries.
2. Repeat step 1 at time intervals of 6, 24, 30, and 48 hours after the initial assay.
3. Using the 30-hour activity measurement as a starting point, calculate the predicted activities at 0, 6, 24, and 48 hours using the following table:

---

* See ANSI N42.13-1978, "Calibration and Usage of Dose Calibrator Ionization Chambers for the Assay of Radionuclides" (American National Standards Institute, Inc., 1430 Broadway, New York, N.Y. 10018).

** Co-57 and Ra-226 are not subject to NRC licensing; the respective State agency should be consulted to determine its requirements for possessing this material.

Assay Time (hr)*	*Correction Factor*
0	31.633
6	15.853
24	1.995
30	1
48	0.126

Example: If the net activity measured at 30 hours was 15.625 mCi, the calculated activities for 6 and 48 hours would be 15.625 mCi x 15.853 = 247.7 mCi and 15.625 mCi x 0.126 = 1.97 mCi, respectively.

4. On log-log coordinate paper, plot the measured net activity (for each time interval) versus the calculated activity (for the same time interval).

5. The activities plotted should be within ±5 percent of the calculated activity if the instrument is linear and functioning properly. Errors greater than ±5 percent indicate the need for repair or adjustment of the instrument.

6. If instrument linearity cannot be corrected, it will be necessary in routine assays to use either (a) an aliquot of the eluate that can be accurately measured or (b) the graph constructed in step 4 to relate measured activities to calculated activities.

F. Test for Geometrical Variation

There may be significant geometrical variation in activity measured as a function of sample volume or configuration, depending on the volume and size of the ionization chamber used in the dose calibrator. The extent of geometrical variation should be ascertained for commonly used radionuclides and appropriate correction factors computed if variations are significant, i.e., greater than ±2 percent. (Even though correction factors may be provided by the manufacturer, the accuracy of these should be checked.) When available from the manufacturer, certified data on geometrical variations may be used in lieu of these measurements.

To measure variation with volume of liquid, a 30-cc vial containing 2 mCi of Co-57 or other appropriate radionuclide in a volume of 1 ml will be used.

1. Assay vial at the appropriate instrument setting, and subtract background level to obtain net activity.

2. Increase the volume of liquid in the vial in steps to 2, 4, 8, 10, 20, and 25 ml by adding the appropriate amount of water or saline. After each addition, gently shake vial to mix contents and assay as in step 1. (Follow good radiation safety practices to avoid contamination and to minimize radiation exposure.)

3. Select one volume as a standard (such as the volume of reference standard used in performing the test for instrument accuracy), and calculate the ratio of measured activities for each volume to the reference volume activity. This represents the volume correction factor (CF).

Example: If activities of 2.04, 2.02, and 2.00 mCi are measured for 4, 8, and 10 ml volumes and 10 ml is the reference volume selected.

$$4 \text{ ml Volume CF} = \frac{2.00}{2.04} = 0.98$$

4. Plot the correction factors against the volume on linear graph paper. Use this graph to select the proper volume correction factors for routine assay of that radionuclide.

5. The true activity of a sample is calculated as follows:

True Activity = Measured Activity x Correction Factor

where the correction factor used is for the same volume and geometrical configuration as the sample measured.

6. Similarly, the same activity of Co-57 in a syringe may be compared with that of 10 ml in a 30-cc vial, and a correction factor may be calculated.

7. It should be noted that differences of 200 percent in dose calibrator readings between glass and plastic syringes have been observed for lower-energy radionuclides such as I-125, which should be assayed in a dose calibrator only if the reliability of such an assay can be established. Glass tubes and syringes may also vary enough in thickness to cause significant errors in assaying I-125. Hence, adequate correction factors must be established.

An alternative to providing syringe calibration factors is to simply assay the stock vial before and after filling the syringe. The activity in the syringe is then the difference in the two readings (with a volume correction if significant).

G. Test for Instrument Accuracy

Check the accuracy of the dose calibrator for several radionuclides, including Cs-137, Co-57, and Ba-133, using appropriate reference standards whose activities have been calibrated by comparisons with standard sources that have been assayed by NBS and documented.

* Assay times should be measured in whole hours and correction factors should be used to the third decimal place as indicated. The more recent half-life of $T_{1/2}$ = 6.02 hours has been used in calculating these correction factors.

The activity levels of the reference sources used should approximate those levels normally encountered in clinical use (e.g., Co-57, 3-5 millicuries) giving adequate attention to source configuration. Identify in your application the three sources that you will use. State nuclide, activity, and calibration accuracy. The lower-energy reference standards (Tc-99m, Xe-133, I-125) must be in vials with the same thickness of glass as the actual samples to be measured for best accuracy.

1. Assay the reference standard in the dose calibrator at the appropriate setting, and subtract the background level to obtain the net activity.

2. Repeat step 1 for a total of 3 determinations, and average results.

3. The average activity determined in step 2 should agree with the certified activity of the reference source within ±5 percent after decay corrections.

4. Repeat the above steps for other commonly used radionuclides for which adequate reference standards are available.

5. Keep a log of these calibration checks.

6. Calibration checks that do not agree within ±5 percent indicate that the instrument should be repaired or adjusted. If this is not possible, a calibration factor should be calculated for use during routine assays of radionuclides.

7. At the same time the instrument is being initially calibrated at the licensee's facility with the reference standards, place a long-lived source in the calibrator, set the instrument, in turn, at the various radionuclide settings used (Cs-137, I-131, Tc-99m, I-125, etc.), and record the readings. These values may later be used to check instrument calibration at each setting (after correcting for decay of the long-lived source) without requiring more reference standards. Keep a log of these initial and subsequent readings.

CALIBRATION OF DOSE CALIBRATOR

A. Sources Used for Linearity Test

(Check as appropriate)

__X__ First elution from new Mo-99/Tc-99m generator

or

_____ Other* (specify) _____

B. Sources Used for Instrument Accuracy and Constancy Tests

Radionuclide	Suggested Activity (mCi)	Activity (mCi)	Accuracy
Co-57	3-5	One milicurie or more	+ - 5%
Ba-133	0.1-0.5	100 microcuries or more	+ - 5%
Cs-137	0.1-0.2	100 microcuries or more	+ - 5%
Ra-226	1-2	_____	_____
_____		_____	_____

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

or

_____ Equivalent procedures are attached.

*For licensees who are not authorized for Mo-99/Tc-99m generators, activity must be equivalent to the highest activity used.

* In addition, to the test procedures outlined in Appendix D-Section 2 for instrument linearity, we would like to add, as an option, the test procedure for instrument linearity using a device called Calicheck from Calcorp. Inc. The manufacturer's instructions for use as revised on March 2, 1982, will be followed. Test results will be recorded and retained for inspection. Corrective action as stated in our License application will be followed if unacceptable linearity is demonstrated.

PROCEDURES FOR ORDERING AND RECEIVING RADIOACTIVE MATERIAL

1. A nuclear pharmacist will place all orders for radioactive material and will ensure that the requested materials and quantities are authorized by the license and that possession limits are not exceeded.

2. During normal working hours, carriers will be instructed to deliver radioactive packages directly to the receiving area of the nuclear pharmacy.

3. During off-duty hours, delivery firms will have written instructions to place packages in the receiving area of the nuclear pharmacy. If the carrier notices that the package is wet or appears to be damaged, he will be instruced to immediately contact the nuclear pharmacist on call (by calling the answering service) who then comes to the nuclear pharmacy to inspect the package. The carrier will be asked to remain at the nuclear pharmacy until it can be determined that neither he nor the delivery vehicle is contaminated. The following letter will be posted in the receiving area and will be given to each carrier service:

   TO: Any courier service delivering radioactive materials to* _____

   (name of nuclear pharmacy)

   FROM: *_____

   (name of radiation safety officer)

   RE: Delivery of packages containing radioactive materials

   Any packages containing radioactive materials that are to be delivered to our nuclear pharmacy after normal hours of operation are to be placed in the receiving area. Be sure to lock the door upon leaving.

   If the package is wet or appears damaged, immediately contact the nuclear pharmacist on call by calling our answering service at _____.

4. The receiving area must be located such that radiation levels in the unrestricted areas do not exceed the limits specified in 20.105 of CFR, Part 20.

*This information to be filled in and updated as necessary

APPENDIX F

PROCEDURES FOR SAFELY OPENING PACKAGES CONTAINING RADIOACTIVE MATERIAL

1. Special requirements will be followed for packages containing quantities of radioactive material in excess of the Type A quantity limits as specified in paragraphs 20.205(a)(1) and (c)(1) of 10 CFR Part 20 (more than 20 Ci for Mo-99 and Tc-99m). They will be monitored for surface contamination and external radiation levels within 3 hours after receipt if received during working hours or within 18 hours if received after working hours, in accordance with the requirements of paragraphs 20.205(a) through (c). All shipments of liquids greater than exempt quantities will be tested for leakage. The NRC Regional Office will be notified in accordance with the regulations if removable contamination exceeds 0.01 μCi/100 cm^2 or if external radiation levels exceed 200 mR/hr at the package surface or 10 mR/hr at 3 feet (or 1 m).

2. For all packages, the following additional procedures for opening packages will be carried out:

   a. Put on gloves to prevent hand contamination.

   b. Visually inspect package for any sign of damage (e.g., wetness, crushed). If damage is noted, stop procedure and notify Radiation Safety Officer.

   c. Measure exposure rate at 3 feet (or 1 m) from package surface and record. If >10 mR/hr, stop procedure and notify Radiation Safety Officer

   d. Measure surface exposure rate and record. If >200 mR/hr, stop procedure and notify Radiation Safety Officer.

   e. Open the package with the following precautionary steps:

      (1) Open the outer package (following manufacturer's directions, if supplied) and remove packing slip.

      (2) Open inner package and verify that contents agree with those on packing slip. Compare requisition,* packing slip, and label on bottle.

      (3) Check integrity of final source container (i.e., inspect for breakage of seals or vials, loss of liquid, and discoloration of packaging material).

      (4) Check also that shipment does not exceed possession limits.

   f. Wipe external surface of final source container and remove wipe to low background area. Assay the wipe and record amount of removable radioactivity (e.g., μCi/100 cm^2, etc.). Check wipes with a thin-end-window G-M survey meter, and take precautions against the spread of contamination as necessary.

   g. Monitor the packing material and packages for contamination before discarding.

      (1) If contaminated, treat as radioactive waste.

      (2) If not contaminated, obliterate radiation labels before discarding in regular trash.

3. Maintain records of the results of checking each package, using "Radioactive Shipment Receipt Record" (see next page) or a form containing the same information.

---

*In the case of special orders (e.g., therapy doses), also compare with physician's written request.

APPENDIX G

GENERAL RULES FOR SAFE USE OF RADIOACTIVE MATERIAL

1. Wear laboratory coats or other protective clothing at all times in areas where radioactive materials are used.

2. Wear disposable gloves at all times while handling radioactive materials.

3. Monitor hands and clothing for contamination after each procedure or before leaving the area.

4. Always use syringe shields for routine preparation of patient doses and administration to patients, except in circumstances such as pediatric cases when their use would compromise the patient's well-being. In these exceptional cases, use other protective methods such as remote delivery of the dose (e.g., through use of a butterfly valve).

5. a. Do not eat, drink, smoke, or apply cosmetics in any area where radioactive material is stored or used.

   b. Do not store food, drink, or personal effects with radioactive material.

6. a. Assay each patient dose in the dose calibrator prior to administration. Do not use any doses that differ from the prescribed dose by more than 10 percent.

   b. For therapeutic doses, also check the patient's name, the radionuclide, the chemical form, and the activity vs. the order written by the physician who will perform the procedure.

7. Wear personnel monitoring devices (film badge or TLD) at all times while in areas where radioactive materials are used or stored. These devices should be worn at chest or waist level. Personnel monitoring devices when not being worn to monitor occupational exposures should be stored in a designated low background area.

8. Wear TLD finger badges during elution of generator and preparation, assay, and injection of radiopharmaceuticals.

9. Dispose of radioactive waste only in specially designated and properly shielded receptacles.

10. Never pipette by mouth.

11. Survey generator, kit preparation, and injection areas for contamination after each procedure or at the end of the day. Decontaminate if necessary.

12. Confine radioactive solutions in covered containers plainly identified and labeled with name of compound, radionuclide, date, activity, and radiation level, if applicable.

13. Always transport radioactive material in shielded containers

APPENDIX H

EMERGENCY PROCEDURES

Minor Spills

1. NOTIFY: Notify persons in the area that a spill has occurred.

2. PREVENT THE SPREAD: Cover the spill with absorbent paper.

3. CLEAN UP: Use disposable gloves and remote handling tongs. Carefully fold the absorbent paper and pad. Insert into a plastic bag and dispose of in the radioactive waste container. Also insert into the plastic bag all other contaminated materials such as disposable gloves.

4. SURVEY: With a low-range, thin-window G-M survey meter, check the area around the spill, hands, and clothing for contamination.

5. REPORT: Report incident to the Radiation Safety Officer.

Major Spills

1. CLEAR THE AREA: Notify all persons not involved in the spill to vacate the room.

2. PREVENT THE SPREAD: Cover the spill with absorbent pads, but do not attempt to clean it up. Confine the movement of all personnel potentially contaminated to prevent the spread.

3. SHIELD THE SOURCE: If possible, the spill should be shielded, but only if it can be done without further contamination or without significantly increasing your radiation exposure.

4. CLOSE THE ROOM: Leave the room and lock the door(s) to prevent entry.

5. CALL FOR HELP: Notify the Radiation Safety Officer immediately.

6. PERSONNEL DECONTAMINATION: Contaminated clothing should be removed and stored for further evaluation by the Radiation Safety Officer. If the spill is on the skin, flush thoroughly and then wash with mild soap and lukewarm water.

RADIATION SAFETY OFFICER: _____*
OFFICE PHONE: _____
HOME PHONE: _____

ALTERNATE NAMES AND TELEPHONE NUMBERS DESIGNATED BY RADIATION SAFETY OFFICER:

_____
_____
_____

*The appropriate information for your facility should be supplied in these blanks when posting these procedures or submitting them with the application.

APPENDIX I

AREA SURVEY PROCEDURES

1. All elution, preparation, and injection areas will be surveyed daily with an appropriately low-range survey meter and decontaminated if necessary.*

2. Laboratory areas where only small quantities of radioactive material are used (less than 200 μCi) will be surveyed monthly.

3. Waste storage areas and all other laboratory areas will be surveyed weekly.

4. The weekly and monthly surveys will consist of:

   a. A measurement of radiation levels with a survey meter sufficiently sensitive to detect 0.1 mR/hr.

   b. A series of wipe tests to measure contamination levels. The method for performing wipe tests will be sufficiently sensitive to detect 200 dpm per 100 cm^2 for the contaminant involved. Wipes of elution and preparation areas or other "high background" areas will be removed to a low background area for measurement.

5. A permanent record will be kept of all survey results, including negative results. The record will include: one year

   a. Location, date, and identification of equipment used, including the serial number and pertinent counting efficiencies.

   b. Name of person conducting the survey.

   c. Drawing of area surveyed, identifying relevant features such as active storage areas, active waste areas, etc.

   d. Measured exposure rates, keyed to location on the drawing (point out rates that require corrective action).

   e. Detected contamination levels, keyed to locations on drawing.

   f. Corrective action taken in the case of contamination or excessive exposure rates, reduced contamination levels or exposure rates after corrective action, and any appropriate comments.

6. Area will be cleaned if the contamination level exceeds 200 dpm/100 cm^2.

* For daily surveys where no abnormal exposures are found, only the date, the identification of the person performing the survey, and the survey results will be recorded.

Modification: "Any areas indicating removable contamination upon wipe testing, will be cleaned."

Wipe tests will be read on the NaI(Tl) well counter. The spectrometer "window" will be set to encompass the photon energies of interest.

PROCEDURE FOR THE RETRIEVAL OF RADIOACTIVE WASTE MATERIAL FROM CUSTOMER

Dear Customer:

One of the services offered by Iso-Diagnostics Inc. involves pick up of radioactive waste material from your department. In order for us to do this without the need of shipping papers, there are two tasks we ask you to perform:

1. Insure that the activity in the case does not exceed the specified amounts for limited shipment quantites.

2. Use a low level survey meter to insure that surface radiation level does not exceed 0.5 mR/hr.

Our personnel will place a cover over the case which will ensure that the surface of the case is free of removable contamination. This cover will have the labeling which will identify the case as a "limited shipment quantity" package.

Limited Shipment Quantities
For Each Commonly Used Radiopharmaceutical

Radionuclide	Limited Shipment Quantity (mCi)
57-Co	9
58-Co	2
51-Cr	60
67-Ga	10
123-I	5
125-I	7
131-I	1
111-I	2.5
99-Mo	2
32-P	3
75-Se	4
99m-Tc	10
201-T1	20
133-Xe (Uncompressed)	100
169-Yb	8

When shipping more than one type of waste in the same package, the limit on the total activity is determined by the lowest mCi quantity assigned for the items being shipped.

It may be necessary to hold unused doses for 48 hours to insure that the total quantity of activity being returned not exceed the specified amount.

If you have any question regarding the returning of waste for disposal, please call our office for further clarification.

PRECAUTIONS FOR HANDLING OF RADIOIODINE

All radioiodine will be received and dispensed in capsular form only. The capsules will be stored in the fume hood. Neither a bioassay program nor a charcoal filtration system is therefore necessary

PROCEDURES FOR USE WITH XENON-133

A. Emergency Procedures

The worst occurrence possible will be the accidental release of the contents of a Xe-133 unit dose vial. This could happen through breakage or a cracked vial.

In that event, the room in which the fume hood is located is approximately 25 X 32 X 10 feet, or 800 cubic feet. The fume hood has a flow rate of at least 800 CFM and is the only source of exhaust in the room other than the two 50 CFM fans which exist in the "hot locker". A simplified calculation yields about 10 minutes for one air change. In the event of a spill, personnel in the room will attempt to withhold inspiration and leave the room, ensuring against room access until the room has been appropriately ventilated (approximately 30 minutes.) After this time, the room monitor will be observed for an indication of higher than normal background. If levels have returned to normal, the room may be re-entered and operations resumed.

B. Air concentrations of Xe-133 in Restriced and Unrestricted Areas.

The maximum amount of activity to be received per week is estimated to be about 500 mCi. However, the following calculations assume that 1500 mCi (possession limit) exists at all times.

New England Nuclear Corporation has provided a letter (attached) stating that their Xe-133 unit dose vials average less than 0.5% leakage per day. (Xenon gas ordered from other manufacturers will be used only in special cases and will not be routinely stored in the pharmacy.)

(1) Restricted Area Calculations

$$\frac{A\ F}{V} = MPC$$

$A = 1.5$ Ci

$$F = \frac{0.005}{day} \times \frac{7\ day}{week} = 3.5 \times 10^{-2}/week$$

MPC (restricted area) $= 1 \times 10^{-5}$ uCi/ml

$\therefore$ V must be at least;

$$\frac{1.5 \times 10^{6}\ uCi \times 3.5 \times 10^{-2}/week}{1 \times 10^{-5}\ uCi/ml} = \frac{5.25 \times 10^{9}\ ml}{week}$$

$$5.25 \times 10^{9}\ \frac{ml}{wk} \times \frac{1\ in^3}{16.39 ml} \times \frac{1\ ft^3}{1728\ in^3} \times \frac{1\ wk}{7\ d} \times \frac{1\ d}{24h} \times \frac{1\ h}{60m} = 18.4\ CFM$$

(2) Unrestricted Area Calculations

$A = 1.5$ Ci
$F = 3.5 \times 10^{-2}$/wk
MPC (unrestricted area) = 3×10^{-7} uCi/ml

$\therefore$ V must be at least;

$$\frac{1.5 \times 10^{6} \text{ uCi} \times 3.5 \times 10^{-2}/\text{wk}}{3 \times 10^{-7} \text{ uCi/ml}} = 1.75 \times 10^{\text{"}} \frac{\text{ml}}{\text{wk}}$$

$$1.75 \times 10^{\text{"}} \frac{\text{ml}}{\text{wk}} \times \frac{1 \text{ in}^3}{16.39\text{ml}} \times \frac{1 \text{ ft}^3}{1728\text{in}^3} \times \frac{1 \text{ wk}}{7 \text{ d}} \times \frac{1 \text{ d}}{24\text{h}} \times \frac{1 \text{ h}}{60\text{m}} = 613.0 \text{ CFM}$$

Thus, the ventilation from the fume hood alone is sufficient to dilute the Xe-133 concentration to well within permissible levels.

E.I. DU PONT DE NEMOURS & CO. (INC.).
BIOMEDICAL PRODUCTS DEPARTMENT

28 February 1985

Kathy O'Deare
Dept. of Medical Physics
William Beaumont Hospital
3601 W. 13 Mile Road
Royal Oak, MI 48072

REF: RA/MDR/PM/11/85

Dear Ms. O'Deare:

As per our discussion concerning leakage rates of Xenon-133 gas, our regulations stipulate that leakage rates be less than 0.5% per vial per day.

I hope this information satisfies your needs for calculating your potential discharge levels of Xe-133 during storage. If we can be of any further assistance please call.

Best regards,

Pete Mansbeaker
Supervisor
Clinical Monitoring
Regulatory Affairs

PM/jc

cc:
S. Brodsky
R. Marterella

NEN MEDICAL PRODUCTS
331 Treble Cove Road, No. Billerica, MA 01862 Telephone 617-667-9531 Telex 94-0996

DISTRIBUTION PROCEDURES

1. Iso-Diagnostics of Michigan, Inc. has submitted an application to the state of Michigan Board of Pharmacy. Upon approval, the NRC will be immediately notified.

2. The activity of the above-named pharmacy is limited to the preparation of radiopharmaceuticals for delivery on a prescription basis to physicians within a specified geographical area. A current copy of each client's NRC license will be obtained prior to making any initial delivery.

3. The activity of the nuclear pharmacy is limited to repackaging IND/NDA radiopharmaceuticals and/or preparing radiopharmaceuticals by tagging IND/NDA reagent kits with a radionuclide eluted from an IND/NDA generator by following the procedures in the labeling of the reagent kit and the generator. The activity of Mo-99 contained in the Tc-99m eluant will be assayed prior to the release of any Tc-99m containing radiopharmaceutical from the nuclear pharmacy. The levels of Mo-99 will not exceed the limits specified in 10 CFR, Section 35.

REQUIRED CONTAINER LABELING

1. Vials
   Vials will be labeled with the manufacturer's original label or with label 1, and/or label 2b.

2. Vial Shields
   Vial shields will be labeled with the manufacturer's original label and/or label 1 and/or label 2a, and/or label 3.

3. Unit Dose Container Shields
   These will be labeled with label 2a and label 4.

4. Syringes
   Syringes will be labeled with label 2b and 4.

Label 1

I.D.S.
of Michigan

Warning!

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

RETURN CONTAINER TO

I.D.S.

Warning!

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

Please return this container to

Label 2a

Rx

Radionuclide _____

Pharmaceutical _____

Lot Number _____

Assay _____ as of _____

Quantity Ordered ____ Dispensed _____

Volume Dispensed _____

Label 2b

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 or Group II of 10 CFR part 35 or under equivalent licenses of Agreement States. Syringe containing drug should be kept in this container or within heavier shield.

Label 3

I.D.S.
of Michigan

CAUTION
RADIOACTIVE MATERIAL

Rx

Radionuclide _____

Pharmaceutical _____

Lot Number _____

Assay _____ as of _____

Quantity Ordered ____ Dispensed _____

Volume Dispensed _____

Label 4

I.D.S. of Michigan

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 or Group II of 10 CFR part 35 or under equivalent licenses of Agreement States. Syringe containing drug should be kept in this container or within heavier shield.

CONTROL NO. 78733

EXPLAINATION OF 4 PART PRESCRIPTION

1. Original:
   This part will remain in the pharmacy for records and receipt of isotope dispensed

   The remaining 3 parts of the perscription will be attached to the lead pig when it is received by the Licensee.

2. Rec/Used/Returned to I.D.S. for disposal.
   This part will be used by the Licensee for its permanent records; rec/used will remain intact on the label and the patient's name will be written in on the line provided for Patient Name. If the isotope is not given to a patient, therefore not used, the section "/used/" will be crossed off by the Licensee. e.g. rec/disposal to I.D.S. This will show that the isotope was received in the Nuc. Med. Dept, not given to a patient, and returned to I.D.S. for disposal.

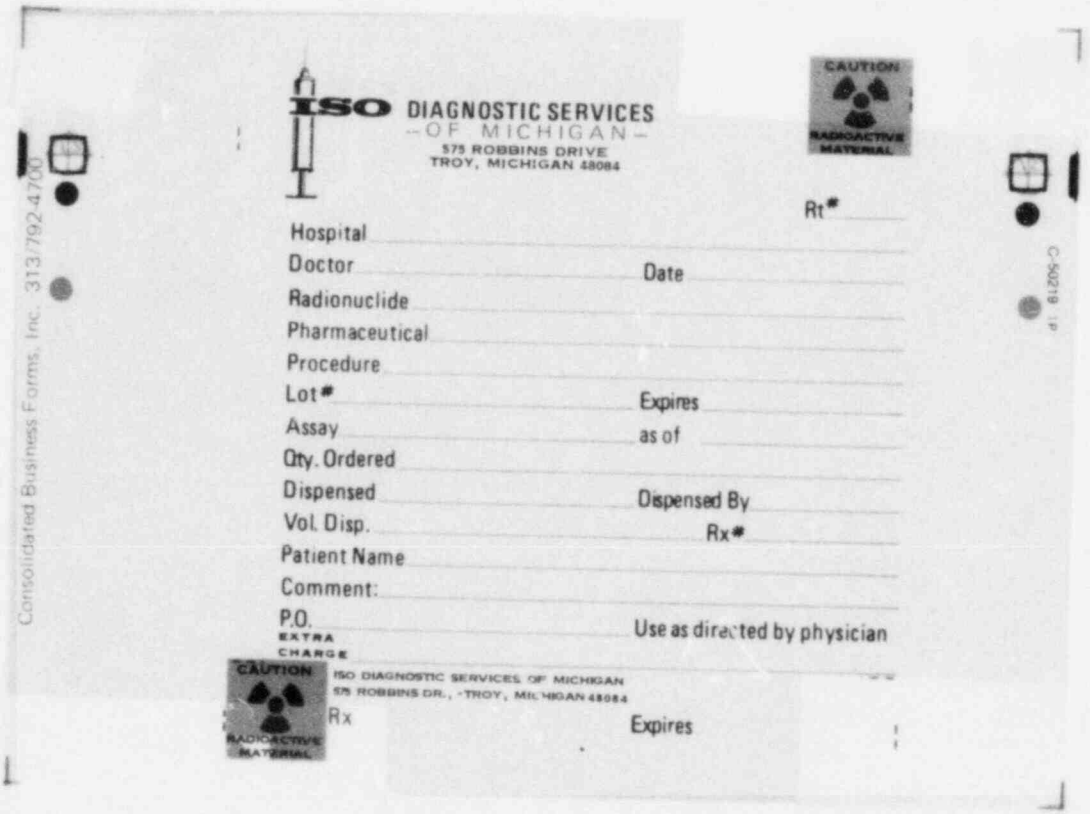
3. Disposal to I.D.S./PT. rec/.
   If the Licensee does not administer the isotope to a patient, this label will remain on the lead pig and returned by the pharmacy for its records of disposal. If the isotope is administered to a patient, the Licensee may also keep this part, crossing off disposal to I.D.S. and using this for a Patient receipt or for its other records.

4. Container Label
   This is for I.D.S. pharmacy records. It will remain on the lead pig at all times, whether the dose is used by the Licensee or not. It is a record for I.D.S. to know what isotopes are being returned to I.D.S. for disposal.

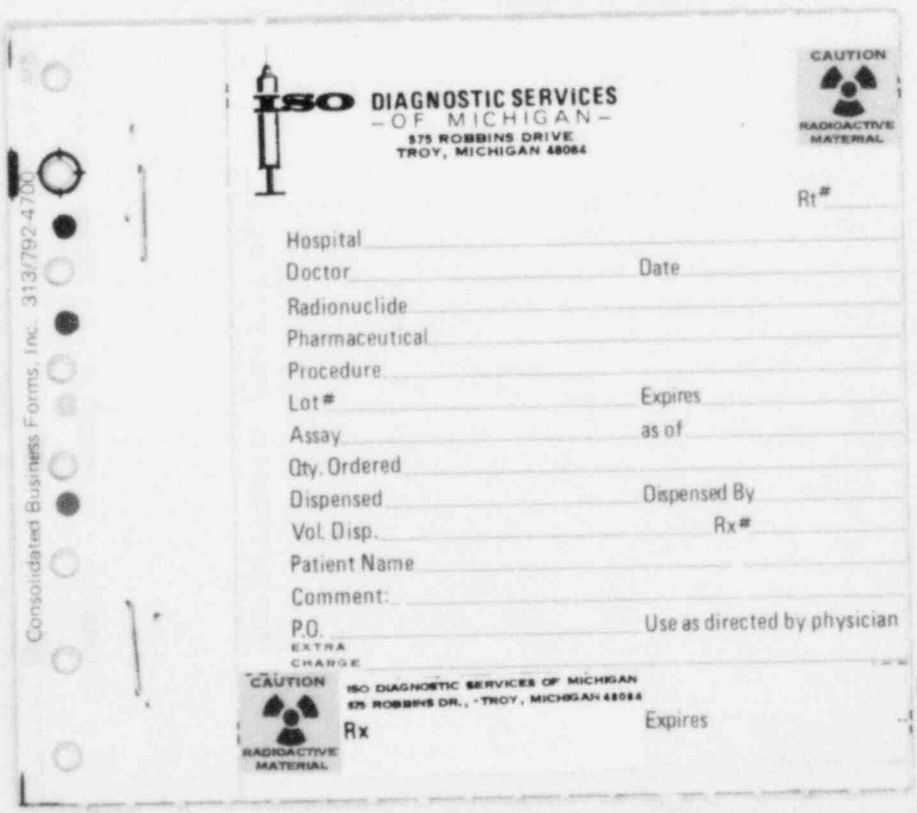
5. The small portion on the bottom will have the pharmacy phone number, the perscription number and expiration date. This portion from the original part of the prescription will be attached to the syringe inside the lead pig, the other 3 parts will remain attached to the outside of the lead pig for verification of the isotope inside.

4 PART PRESCRIPTION FORM

MASTER FORM



4 PART EXAMPLE



CONTROL NO. 78733

PRODUCT SHIELDING

The following approximates the maximum external radiation associated with radiopharmaceuticals which would be distributed to customer under this license.

Radionuclide	Amount	Shielding	mR/ at Shield Surface
Tc-99m	150 mCi	8mm Pb Syringe Shield	0.0
Tc-99m	1000 mCi	9mm NEN Pb Vial Shield	0.1
Se-75	0.35 mCi	9mm NEN Pb Vial Shield	0.5
I-131	0.90 mCi	9mm NEN Pb Vial Shield	2.3
I-131	200 mCi	Original Manuf. Container	59.0
Xe-133	200 mCi	Original NEN Tube Shield	1.2
Yb-169	1.5 mCi	Original Manuf. Shield (Medi-Physics 8mm)	12.4

EMERGENCIES INVOLVING MOTOR VEHICLES

ACTING AS CARRIERS OF RADIOACTIVE MATERIALS

Because of the nature of these kinds of emergencies, the following is a completely self-contained set of instructions which will be carried in every vehicle used while transporting radioactive substances. These instructions are to be read and followed by all personnel in the event of an emergency.

a. Driver is to take the following immediate action:
   1. Do not touch any open or broken containers.
   2. Call the pharmacy immediately, using the two-way radio if at all possible. If you must use a telephone to notify the pharmacy, have someone maintain security over the vehicle and radioactive material and keep by-standers away while calls are being made.
   3. Keep all people away from the radioactive material.
   4. Stay at the scene until a Pharmatopes representative arrives.

b. Pharmacist is to take the following immediate action:
   1. Notify Pharmacy manager of the accident.
   2. Dispatch car with qualified person to assist the driver. Take emergency kit including monitor, use car with mobile radio if at all possible.
   3. Notify State Police Operations to have police on the scene for traffic and crowd control.
   4. Notify Michigan Department of Public Health, Division of Radiological Health between 0830-1700 Mon. thru Fri. at number below. All other times, they can be reached through State Police number.
   5. If the spill meets the criteria in CFR Title 10 Section 20.403, notify the NRC, Region III at (312)932-2500 anytime.

Phone Numbers:

State Police Operations:	(517)373-0800	anytime
Mich. Dept. Pub. Hlth, Dept. Radiol.	(517)373-1578	0830-1700 M-F
Nuclear Pharmacist(Radiation Protection Officer)	(313)	anytime
Region III NRC	(312)932-2500	anytime

* To be updated as necessary

c. All traffic should be detoured around the scene of the accident. If this is not possible, vehicles should be moved the shortest distance necessary to clear the right-of-way. If radioactive material is spilled, passage through areas should be prevented unless absolutely necessary. If the right-of-way must be cleared before assistance has arrived, the spill should be washed to shoulders of right-of-way with minimum dispersal of wash water, or covered with at least four inches of earth or sand.

d. The nearest Nuclear Regulatory Commission office should be notified as soon as possible. See phone numbers above.

e. If the accident involves wreckage and a person is believed to be alive and entrapped, every possible effort should be made to rescue him/her.

f. The area of the accident should be restricted. The public should be kept as far from the scene as is practical. Local authorities should make only necessary entries and investigations into the accident area. No attempt should be made to open or examine contained material. No attempt should be made to clean up any debris or material involved in the accident prior to the arrival of experienced help.

g. Any persons who have had possible contact with the radioactive material should be segregated and confined until they can be examined further. The names and addresses of those involved should be obtained.

h. The injured should be removed from the area of the accident with as little contact as possible and held at a transfer point. All life-saving measures should be performed promptly, but elective first aid and surgical procedures should be delayed until advice or help can be obtained from a physician familiar with radiation medicine. Except in extreme emergency, patients should not be moved to local hospital or doctor's office before a radiological survey has been made.

i. If the accident involves fire, attempt to extinguish it should be made from as great a distance as possible. The fire should be treated as one involving toxic chemicals. Suspected material should not be handled until it has been monitored and released by monitoring personnel. Clothing and tools used at the fire should be segregated until they can be checked by the monitoring teams.

j. Eating, drinking, or smoking in the area of the accident should be prohibited. Food or drinking water which may have been in contact with material from the accident should not be used.

k. Careful attention and consideration should be given in matters of public relations to:
   1. Transmission of information to the public by press, radio, and television, and
   2. Tactful handling of volunteers and crowds of curious onlookers.

INDEPENDENT AUDIT PROGRAM

IDS of Michigan will be audited for State and NRC compliance at least four times per year. The auditing company used will be:

Medical Physics Consultants, Inc.
3200 West Liberty, Suite F-1
Ann Arbor, Michigan 48103

The consulting group will make recommendations regarding compliance/non-compliance, as well as safe practicing methods.

APPENDIX J

WASTE DISPOSAL

Note: In view of the recent problems with shallow-land burial sites used by commercial waste disposal firms, NRC is encouraging its licensees to reduce the volume of wastes sent to these facilities. Important steps in volume reduction are to segregate radioactive from nonradioactive waste, to hold short-lived radioactive waste for decay in storage, and to release certain materials in the sanitary sewer in accordance with §20.303 of 10 CFR Part 20.

1. Liquid waste will be disposed of (check as appropriate)

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

_____ By commercial waste disposal service (see also Item 4 below).

__X__ Other (specify): Held for decay as in part 3: Solid Waste

2. Mo-99/Tc-99m generators will be (check as appropriate)

__X__ Returned to the manufacturer for disposal.

__X__ Held for decay* until radiation levels, as measured in a low background area 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 will be disposed of as normal trash.**

_____ Disposed of by commercial waste disposal service (see also Item 4 below).

_____ Other (specify): _____

_____

3. Other solid waste will be (check as appropriate)

__X__ Held for decay* until radiation levels, as measured in a low background area 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.

_____ Disposed of by commercial waste disposal service (see also Item 4 below).

_____ Other (specify): _____

_____

4. The commercial waste disposal service used will be

_____
(Name) (City, State)

NRC/Agreement State License No. _____

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* Be sure that waste storage areas were described in Item 11 and that they are surveyed periodically (Item 17).

** These generators may contain long-lived radioisotopic contaminants. Therefore, the generator columns will be segregated so that they may be monitored separately to ensure decay to background levels prior to disposal.

The Troy Fire Department has been notified of the nuclear pharmacy operation. The information provided to consist of the following:

Phone number to call in an emergency
Isotopes used
Isotope physical properties
Quantities used & stored
Floor plan of the pharmacy
Areas of high activity and/or risk
Potential isotopes released in the environment in an accident.
Shielding present
What to do in case of fire.