Steven Sands, M.S.
Iso-Diagnostic Services
of Michigan
575 Robbins Drive
Troy, Michigan 48083

William Adam, Ph.D.
Materials Licensing Section
United States Nuclear Regulatory Commission
Region III
799 Roosevelt Road
Glen Ellyn, Illinois 60137

Dear Dr. Adam:

In response to your letter dated June 17, 1985 (Control No. 78733), we are providing the additional information that you requested in order for the submitted nuclear pharmacy application to become approved.

1. a) The shielding available in the compounding and dose preparation areas consists of two lead L-blocks of 1 1/4" horizontal thickness and 2" vertically. Each L-block contains a leaded glass portion for convenient, yet protected, viewing of the work area. One L-block is placed at each of two work stations. Note that, in Item 9, page 16, of our license application, the counters upon which the L-blocks will be located are constructed of 1/4" lead. Also, the adjacent wall will contain at least 1/8" of lead extending 24 inches upward from the countertop level. See attached Figure 1.

   b) The "drop-off" area will contain a lead box of thickness 1/8" and dimensions 4.0' x 2.0' x 2.5'. The box, as shown in Figure 2, attached, will have four walls (i.e. three vertical sides and a horizontal top). The two walls which are left open are (1) the bottom, which rests on the concrete foundation of the building, and (2) the front face of the box, for insertion of packages. At all times, the box will be placed such that the open face is directed toward the staircase on the ground level. The area potentially exposed at the face of the box behind the staircase is a restricted area, currently used for storage of low-level waste by NRC licensee #21-14161-02.

2. In order to measure the exposure rates in facilities adjoining the hot lab, personnel monitoring badges will be placed either on the occupant side of the wall, or on the inside of the wall when the area is not easily accessible (e.g. second floor wall adjacent to stairway where no occupants exist). The latter case would yield a conservative estimation of the exposure rates on the other side of the wall. All walls of the hot lab will be routinely monitored in this fashion.

3. With regard to the radiation safety program, IDS will:

   a) Maintain a record of all survey instrument calibrations for a period of two years from the date of calibration.

   b) Include in its package opening procedures the assaying of final source container wipes for removable contamination.

   c) Post emergency procedures in each area of use or storage.

4. The waste storage area has the potential to hold eight 25-1/2-gallon drums of dry waste. It is anticipated that, on average, three to five gallons of waste will be collected daily. In a worst-case situation ten gallons of waste might be collected. There exists enough space, therefore, for 20 days worth of "worst-case" situations. In addition, when decay is taken into account there would be space for even more dry waste. It is felt that IDS has sufficient storage space to accommodate the anticipated amount of generated waste.

5. Please find attached a copy of the State of Michigan temporary pharmacy permit issued to IDS on June 11, 1985.

6. a) The Mo-99 content present in each Tc-99m dose will be handwritten in the "comment" section of the four-part prescription form. This form will accompany all doses delivered by IDS.

   b) The exposure rates expected at the surface of the shielded containers previously listed in item #10(n), page 43 of our license application should have been designated in the column entitled "mR/h at shield surface", not "mR/ at shield surface." This was previously typed incorrectly.

   c) Please find attached a copy of the procedures for radioactive shipments to be used by IDS. Note that all packages will meet the design criteria of 49 CFR 173.412. Contamination control criteria as printed in 49 CFR 173.443 will also be met at all times. **Documentation of DOT type 7A standards for delivery cases is being prepared and will be sent when available.**

   d) Attached are the routine safety and emergency instructions to be provided to delivery personnel. A copy of these procedures will be available within each vehicle for convenient referral when necessary.

7. With regard to the redistribution of material received from suppliers who have manufactured, packaged, and labeled the material in accordance with 10 CFR 32.71 through 10 CFR 32.74 we are specifying the following information:

a) In-Vitro Kits

(1) General licensees

Any prepackaged in vitro kits to be redistributed will have been obtained from a manufacturer authorized to distribute in vitro kits in accordance with a specific license issued pursuant to 10 CFR 32.71 or under equivalent licenses of an Agreement State. The manufacturer's packaging and labeling will not be altered in any way upon redistribution. Each redistributed in vitro kit will be accompanied by the manufacturer-supplied package insert, leaflet or brochure that provides radiation safety instructions for general licensees.

(2) Specific licensees

IDS of Michigan will obtain prepackaged in vitro kits (as described in 10 CFR 31.11(a) for redistribution to specific licensees. The labels, package insert, leaflet, brochure, or other documents accompanying the redistributed in vitro kits do NOT reference general licensees, exempt quantities, or NRC regulations that authorize a general license (e.g., 10 CFR 31.11). Labeling on redistributed in vitro kits will be checked to ensure conformance to 10 CFR 20.203.

b) Sealed Calibration or Reference Sources

These sources will be distributed by IDS to licensees operating under specific private practice, specific institutional, and specific broad scope licenses. The sources to be redistributed will have been obtained from a manufacturer authorized to distribute the sources in accordance with a specific license issued pursuant to 10 CFR 32.74 or under equivalent regulations of an Agreement State. The manufacturer's labeling and packaging will not be altered, and the redistributed sources will be accompanied by the manufacturer-supplied calibration certificate along with the leaflet brochure or other document that provides radiation safety instructions for handling and storing the sources.

c) Reagent Kits

All reagent kits to be redistributed will have been obtained from a manufacturer authorized to distribute reagent kits in accordance with a specific approval issued pursuant to 10 CFR 32.73 or under equivalent regulations of an Agreement State. These kits will be redistributed as received from the manufacturer in the "kit sleeve" and accompanied by the manufacturer-supplied package insert, leaflet, brochure or

other document that describes the procedures to be followed and the equipment and shielding to be used in processing radioactive material with the reagent kit.

We hope that we have provided you with the information you requested. Should you have any questions, please do not hesitate to call IDS of Michigan at (313) 589-1750 or (313) 879-9330. We would be eager to provide any additional information you may need.

Sincerely,

Steven Sands, M.S.

SS/mrs

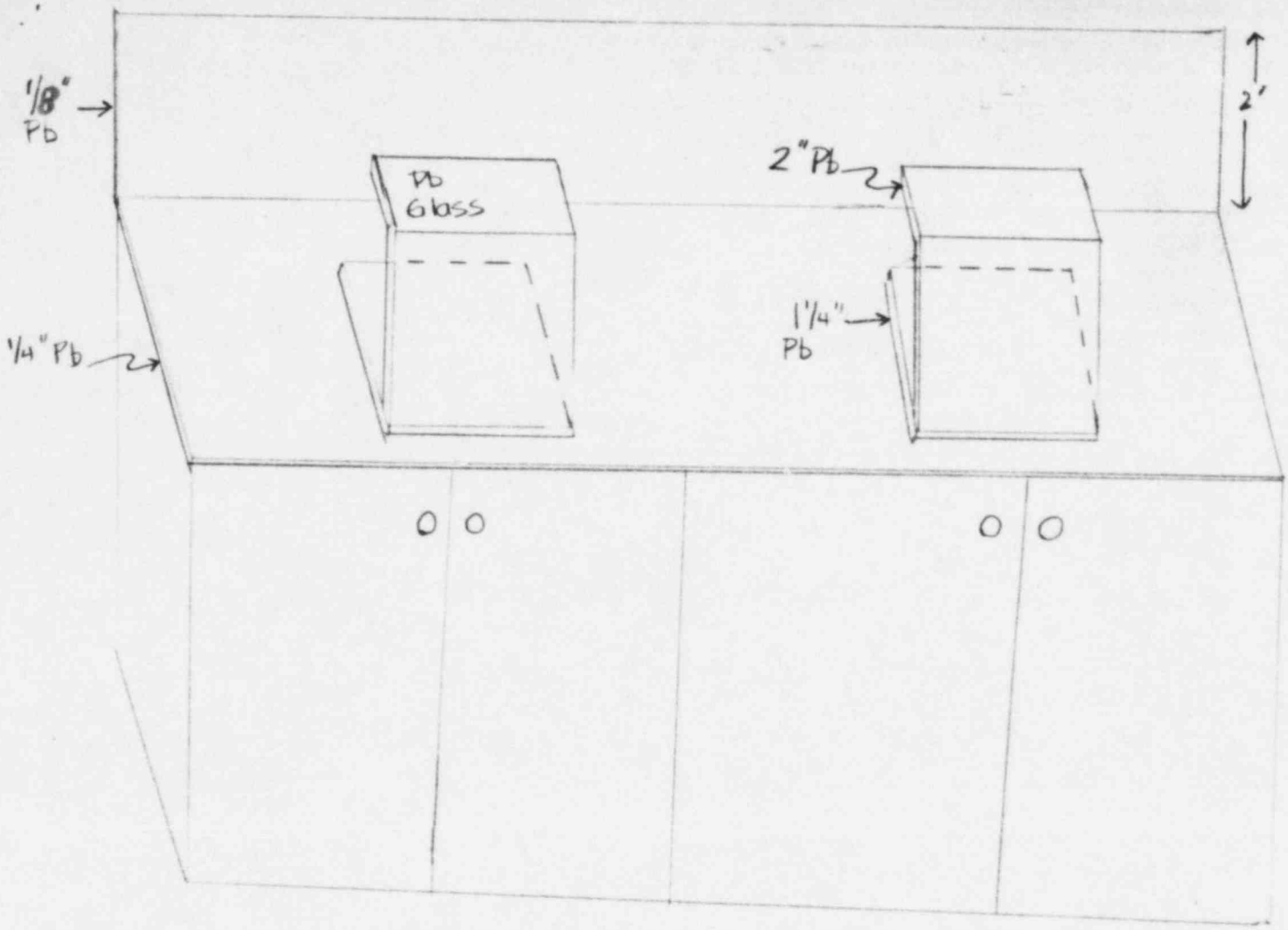

Figure 1. Dose preparation area, indicating shielding.

wall to restrict entry from other parts of building.
Only entry is through the door shown.

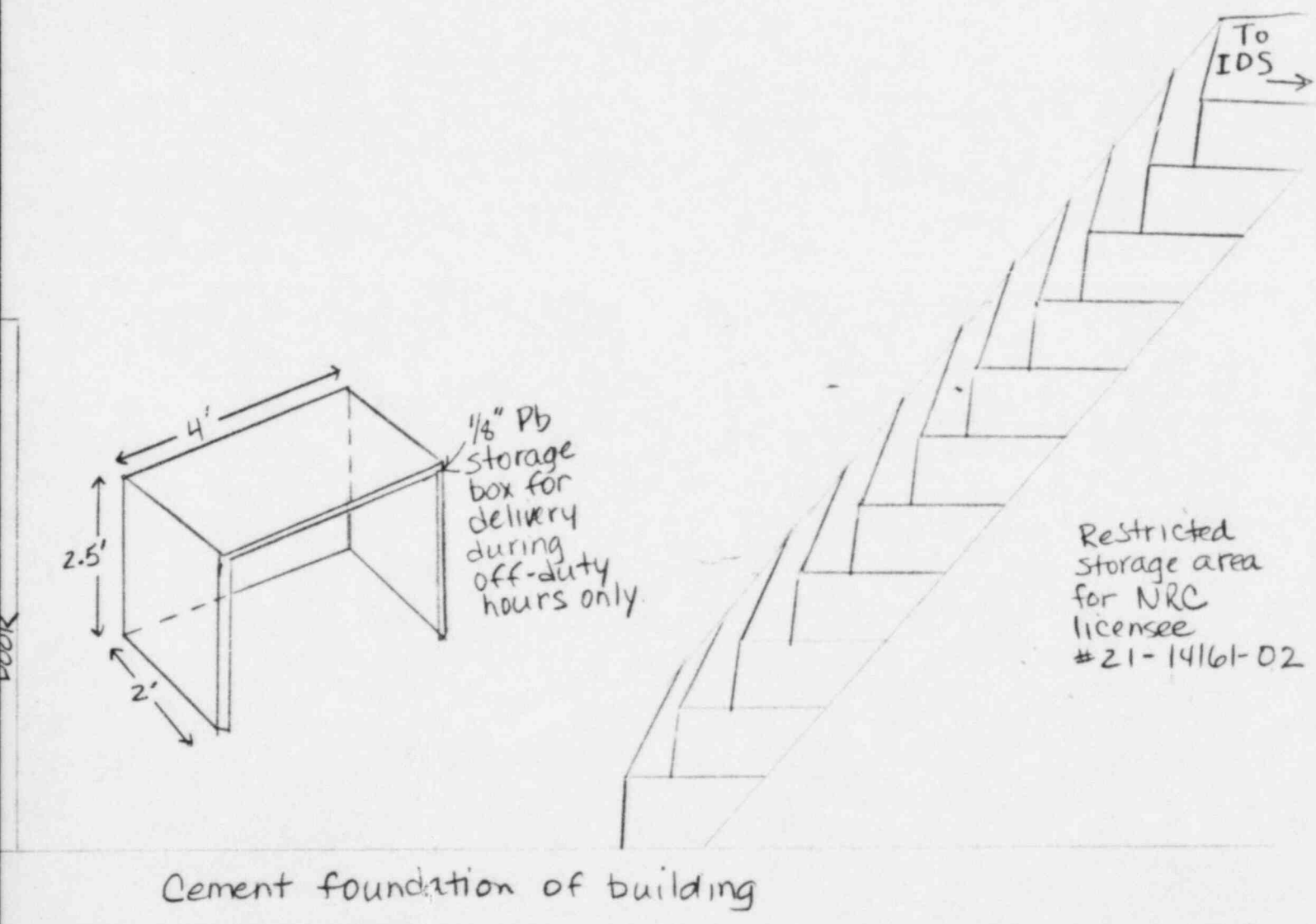

Figure 2. "Drop-off area" for deliveries during off-hours. The shielded lead box for placement of packages is shown.

STATE OF MICHIGAN

JAMES J. BLANCHARD, Governor

DEPARTMENT OF LICENSING AND REGULATION

Raymond W. Hood, Sr., Director

BOARD OF PHARMACY
P.O. Box 30018
Lansing, Michigan 48909
Telephone (517) 373-0620

Date June 11, 1985

TO: Michael Klug, R. Ph., Michael Grawburg, R. Ph. dba
Isodiagnostic Services of Michigan Inc
575 Robbins Drive
Troy, MI 48083

FROM: Michigan Board of Pharmacy

RE: TEMPORARY PERMIT TO OPERATE A PHARMACY

Your application for a new pharmacy license and/or transfer of pharmacy license together with appropriate fee has been received in this office.

In accordance with R 338.477(6) of the Administrative Rules of the board, the board may grant a permit, valid for 30 days, to allow a new pharmacy and/or transfer of pharmacy applicant to open while inspection of the premises by the department or board is pending.

Therefore, this office is assigning you permit number 4217. If you have a favorable inspection, the board office will authorize the issuance of appropriate licenses to you. If, however, your premises fail to achieve a satisfactory inspection, your temporary permit will be withdrawn until the discrepancies have been corrected.

PROCEDURES FOR RADIOACTIVE SHIPMENTS

Prior to use for radioactive shipments, all cases must meet the design criteria as stated in 49 CFR 173.412 as well as DOT type 7A standards.

Each time a package containing radioactive materials is prepared for shipment, the following procedures must be performed and documented. Disposable gloves shall be worn for the entire procedure.

1. The external surface of each package shall be wipe tested for the presence of non-fixed radioactive contamination. This will be performed by wiping an area of 300 cm^2 with an alcohol swab or other absorbent material and counting the wipe (using appropriate settings) in the well counter. The amount of radioactivity measured from a wipe across an area this size shall not exceed 6600 dpm, or 22 dpm/cm^2. If the level of non-fixed contamination exceeds this limit, the origin of the contamination will be determined. The external package will then be cleaned such that acceptable levels are obtained or stored for decay to background.

2. The maximum exposure rate of the package surface shall be measured. The appropriate shipping label will then be selected:

   a) White I
      $\leq$0.5 mR/h

   b) Yellow II
      >0.5 mR/h and $\leq$50 mR/h

   c) Yellow III
      >50 mR/h and $\leq$200 mR/h

3. The Transport Index will then be determined by measuring the maximum exposure rate at 3 feet from the surface using a survey meter which is appropriate for the radiation levels involved. This value shall be subsequently indicated on the associated shipping labels.

ISO-DIAGNOSTIC SERVICES OF MICHIGAN

INSTRUCTIONS TO DRIVERS CONCERNING RADIATION SAFETY AND DELIVERY PROCEDURES

1. NO DELIVERY CASES ARE TO BE REMOVED FROM THE NUCLEAR PHARMACY UNLESS THEY HAVE BEEN PLACED IN THE AREA DESIGNATED FOR PICK-UP.

2. ALL CASES PLACED IN THE PICK-UP AREA HAVE BEEN CHECKED BY THE NUCLEAR PHARMACY STAFF AND ARE SAFE TO HANDLE.

3. DO NOT ATTEMPT TO CARRY MORE THAN THREE CASES BY HAND AT ANY ONE TIME. EITHER MAKE ANOTHER TRIP OR USE A DOLLY.

4. ALL DELIVERY VEHICLES CONTAINING DELIVERY CASES WILL BE LOCKED WHEN UNATTENDED.

5. DELIVERY CASES ARE ONLY TO BE LEFT IN APPROVED AREAS WHICH HAVE BEEN DESIGNATED BY THE CUSTOMER. IF YOU CANNOT GAIN ACCESS TO THE DESIGNATED DELIVERY AREA, CALL THE NUCLEAR PHARMACY AT 589-1750.

   DO NOT LEAVE THE DELIVERY CASE UNATTENDED.

6. EXPOSURE RATES AT THE SURFACE OF THE DELIVERY CASE ARE MINIMAL, HOWEVER, IT IS GOOD PRACTICE NOT TO PLACE THE CASES ON THE FRONT SEAT OF YOUR VEHICLE, IMMEDIATELY NEXT TO YOU OR ANOTHER PERSON. YOU SHOULD PLACE THE CASES IN A STABLE LOCATION OF THE VEHICLE, NO CLOSER THAN 3 FEET TO ANY PERSON.

7. IN THE EVENT A DELIVERY CASE SUSTAINS DAMAGE, DO NOT ATTEMPT TO DELIVER THE CASE. CALL THE PHARMACY AT THE ABOVE NUMBER FOR INSTRUCTIONS.

8. YOU SHOULD READ THE NOTICE TO EMPLOYEES WHICH IS POSTED IN THE NUCLEAR PHARMACY. IF YOU HAVE ANY QUESTIONS REGARDING OUR NRC LICENSE WE WILL MAKE EVERY ATTEMPT TO PROVIDE YOU WITH AN UNDERSTANDABLE ANSWER.

9. IN THE EVENT OF A TRAFFIC ACCIDENT REFER TO EMERGENCY POLICY INSTRUCTIONS.

EMERGENCY POLICY: INSTRUCTIONS

PROCEDURE TO BE FOLLOWED IN THE EVENT OF A SERIOUS TRAFFIC ACCIDENT

1. GENERALLY, THE RADIOACTIVE MATERIAL CARRIED IN THIS VEHICLE CONSISTS OF DIAGNOSTIC NUCLEAR MEDICINE DOSES AND PRESENTS A MINIMAL RADIATION HAZARD.

2. A COMPLETE LIST OF MATERIALS CONTAINED IN THE DELIVERY CASES CAN BE FOUND **on the shipper certificate.**

3. THE FOLLOWING INDIVIDUALS SHOULD BE CONTACTED IMMEDIATELY FOR INSTRUCTIONS IF A TRAFFIC ACCIDENT HAS OCCURED INVOLVING THIS VEHICLE SUCH THAT THE VEHICLE IS DAMAGED AND/OR THE DRIVER IS INJURED TO THE EXTENT THAT THE CASES CANNOT BE DELIVERED:

IDS PHARMACY	589-1750
RAY ZAK	979-9332
MIKE GRAWBERG	296-0375
MIKE KLUG	329-4880
STEVE SANDS	879-9330

4. DELIVERY CASES ARE NOT TO BE REMOVED FROM THE VEHICLE.

5. IN THE EVENT A DELIVERY CASE HAS BEEN THROWN FROM THE VEHICLE IT SHOULD NOT BE MOVED UNTIL INSTRUCTIONS HAVE BEEN RECEIVED FROM ONE OF THE INDIVIDUALS ABOVE.