MATERIALS LICENSE

Pursuant to the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974 (Public Law 93-438), and Title 10, Code of Federal Regulations, Chapter I, Parts 30, 31, 32, 33, 34, 35, 40 and 70, and in reliance on statements and representations heretofore made by the licensee, a license is hereby issued authorizing the licensee to receive, acquire, possess, and transfer byproduct, source, and special nuclear material designated below; to use such material for the purpose(s) and at the place(s) designated below; to deliver or transfer such material to persons authorized to receive it in accordance with the regulations of the applicable Part(s). This license shall be deemed to contain the conditions specified in Section 183 of the Atomic Energy Act of 1954, as amended, and is subject to all applicable rules, regulations and orders of the Nuclear Regulatory Commission now or hereafter in effect and to any conditions specified below.

Licensee	
1. Iso-Diagnostic Service of Michigan	3. License number 21-24491-01MD
2. 575 Robbins Drive Troy, MI 48083	4. Expiration date July 31, 1990
	5. Docket or Reference No. 030-28636

6. Byproduct, source, and/or special nuclear material	7. Chemical and/or physical form	8. Maximum amount that licensee may possess at any one time under this license
A. Molybdenum-99	A. Any Molybdenum-99/ Technetium-99m generator manufactured, labeled, packaged and distributed in accordance with a specific license issued pursuant to Section 32.73 of 10 CFR Part 32 or a specific license issued to a manufacturer by an Agreement State pursuant to equivalent State regulations	A. 25 curies
B. Any byproduct material authorized under Section 35.14(d)(4) of 10 CFR Part 35	B. Any sealed source listed in Section 35.14(d)(4) of 10 CFR Part 35	B. 25 millicuries total for all sources authorized under Subitem 6.B.
C. Xenon-133	C. Unit dose containers of gas or gas in solution that is the subject of an active (i.e., not withdrawn or terminated) "New Drug Application" (NDA) approved by FDA or an active (i.e., not withdrawn, terminated or on "clinical hold") "Notice of Claimed Investigational Exemption for a New Drug" (IND) that has been accepted by FDA	C. 1.5 curies

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6. Byproduct, source, and/or special nuclear material	7. Chemical and/or physical form	8. Maximum amount that licensee may possess at any one time under this license
D. Iodine-131	D. Any form listed in Groups I through V of Schedule A, Section 35.100 of 10 CFR Part 35	D. 250 millicuries
E. Technetium-99m	E. Any form listed in Groups I and II of Schedule A, Section 35.100 of 10 CFR Part 35	E. 25 curies
F. Any byproduct material, except Iodine-131 and Technetium-99m listed in Group I of Schedule A, Section 35.100 of 10 CFR Part 35	F. Any form listed in Group I of Schedule A, Section 35.100 of 10 CFR Part 35	F. 25 millicuries total possession limit
G. Any byproduct material, exept Iodine-131 and Technetium-99m listed in Group II of Schedule A, Section 35.100 of 10 CFR Part 35	G. Any form listed in Group II of Schedule A, Section 35.100 of 10 CFR Part 35	G. 75 millicuries total possession limit
H. Any byproduct material, except Iodine-131, listed in Group IV of Schedule A, Section 35.100 of 10 CFR Part 35	H. Any form listed in Group IV of Schedule A, Section 35.100 of 10 CFR Part 35	H. 50 millicuries total possession limit
I. Any byproduct material listed in Section 31.11(a) of 10 CFR Part 31	I. Prepackaged in vitro diagnostic test kits	I. 50 millicuries total possession limit

9. Authorized Use

A. Production of technetium-99m pertechnetate.

B. Instrument calibration.

C. Distribution to authorized recipients.

D. Dispensing and/or distribution of prepared radiopharmaceuticals to authorized recipients.

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9. Authorized Use (cont'd)

E. Dispensing and/or distribution of prepared radiopharmaceuticals to authorized recipients. Use of technetium-99m pertechnetate for processing with reagent kits in the preparation of radiopharmaceuticals.

F. through H. Dispensing and/or distribution of prepared radiopharmaceuticals to authorized recipients.

I. Redistribution to general and specific licensess in accordance with statements, representations, and procedures contained in application dated April 12, 1985 and letter received July 10, 1985.

Pursuant to Section 32.72, 10 CFR Part 32, the licensee is authorized to distribute the byproduct material described in Items 6 and 7 of this license to persons licensed pursuant to Section 35.14 and Section 35.100, 10 CFR Part 35, or under equivalent licenses of Agreement States, for the Groups indicated below:

D. through H. Any form listed in each Group, Groups I, II, IV or V of Schedule A, Section 35.100 of 10 CFR Part 35, may be distributed to persons licensd pursuant to that Group.

CONDITIONS

10. Licensed material shall be used only at the licensee's facilities located at 575 Robbins Drive, Troy, Michigan.

11. The licensee shall comply with the provisions of Title 10, Chapter 1, Code of Federal Regulations, Part 19, "Notices, Instructions and Reports to Workers; Inspections" and Part 20, "Standards for Protection Against Radiation."

12. A. Licensed material shall be used by, or under the supervision of, Michael Grawburg or Steven Sands.

B. At least one individual named in Condition 12.A. shall be physically present at the authorized place or use whenever licensed material is being used.

C. The Radiation Protection Officer for the activities authorized by this license is Steven Sands.

13. Sealed sources containing licensed material shall not be opened.

14. A. (1) Each sealed source containing licensed material, other than Hydrogen 3, with a half-life greater than thirty days and in any form other than gas shall be tested for leakage and/or contamination at intervals not to exceed six months. In the absence of a certificate from a transferor indicating that a test has been made within six months prior to the transfer, a sealed source received from another person shall not be put into use until tested.

(2) Notwithstanding the periodic leak test required by this condition, any licensed sealed source is exempt from such leak tests when the source contains 100 microcuries or less of beta and/or gamma emitting material or 10 microcuries or less of alpha emitting material.

B. The test shall be capable of detecting the presence of 0.005 microcurie of radioactive material on the test sample. The test sample shall be taken from the sealed source or from the surfaces of the device in which the sealed source is permanently mounted or stored on which one might expect contamination to accumulate. Records of leak test results shall be kept in units of microcuries and maintained for inspection by the Commission.

C. If the test reveals the presence of 0.005 microcurie or more of removable contamination, the licensee shall immediately withdraw the sealed source from use and shall cause it to be decontaminated and repaired or to be disposed of in accordance with Commission regulations. A report shall be filed within five (5) days of the test with the U. S. Nuclear Regulatory Commission, Region III, 799 Roosevelt Road, Glen Ellyn, Illinois 60137, describing the equipment involved, the test results, and the corrective action taken.

D. Tests for leakage and/or contamination shall be performed by the licensee or by other persons specifically authorized by the Commission or an Agreement State to perform such services.

15. The licensee shall conduct a physical inventory every six (6) months to account for all sealed sources received and possessed under the license. The records of the inventories shall be maintained for two (2) years from the date of the inventory for inspection by the Commission, and shall include the quantities and kinds of byproduct material, manufacturer's name and model numbers, location of sealed sources and the date of the inventory.

16. The licensee may transport licensed material or deliver licensed material to a carrier for transport in accordance with the provisions of Title 10, Code of Federal Regulations, Part 71, "Packaging of Radioactive Material for Transport and Transportation of Radioactive Material Under Certain Conditions."

17. Radioactive waste may be picked up from the licensee's customers and disposed of in accordance with the procedures, statements and representations in application dated April 12, 1985 and letter received July 10, 1985 .

18. A. Radiopharmaceuticals dispensed and/or distributed for human use shall be either:

(i) Repackaged from prepared radiopharmaceuticals that are the subject of an FDA-approved "New Drug Application" (NDA) or for which FDA has accepted a "Notice of Claimed Investigational Exemption for a New Drug" (IND), or

(ii) Prepared from generators and reagent kits that are the subject of an FDA-approved NDA or for which FDA has accepted an IND.

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B. Prepared radiopharmaceuticals for which FDA has accepted an IND and radiopharmaceuticals prepared from generators or reagent kits for which FDA has accepted in IND shall be dispensed and/or distributed:

(i) In accordance with the directions provided by the sponsor of the IND, and

(ii) Only to physicians who have been accepted by the sponsor of the IND to participate in clinical evaluation of the drug.

The licensee shall inform in writing each physician who participates in an IND evaluation that the physician is responsible to the sponsor of the IND for use of the drug in accordance with protocols established by the sponsor and for reporting to the sponsor the clinical information obtained through use of the drug.

19. The licensee shall elute generators and process radioactive material with reagent kits in accordance with instructions furnished by the manufacturer on the label attached to or in the leaflet or brochure that accompanies the generator or reagent kit.

20. When using the Calicheck kit, the licensee shall follow the procedures contained in the manufacturer's instruction manual dated November 25, 1981, revised March 2, 1982.

21. Any proposed changes in packaging, shielding or labeling shall be submitted for review to the Material Licensing Branch, Division of Fuel Cycle and Material Safety, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555.

22. Except as specifically provided otherwise by this license, the licensee shall possess, use, package, label and distribute licensed material described in Items 6, 7, and 8 of this license in accordance with statements, representations, and procedures contained in application dated April 12, 1985; and letters received July 10, 1985 and July 19, 1985. The Nuclear Regulatory Commission's regulations shall govern the licensee's statements in applications or letters, unless the statements are more restrictive than the regulations.

For the U.S. Nuclear Regulatory Commission

Date July 23, 1985

Original Signed
By William J. Adam, Ph.D.
Materials Licensing Section, Region III

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