CONVERSATION RECORD

TIME ~~8~~ 10.00A DATE 8/27/85

TYPE ☐ VISIT ☐ CONFERENCE ☑ TELEPHONE ☐ INCOMING ☑ OUTGOING

Location of Visit/Conference:

NAME OF PERSON(S) CONTACTED OR IN CONTACT WITH YOU	ORGANIZATION (Office, dept., bureau, etc.)	TELEPHONE NO
Steven Lefevre	Centra Pharm	(614) 475-0319

SUBJECT C/W 16016

ROUTING

NAME/SYMBOL	INT

SUMMARY Licensee wishes to withdraw application - was unable to procure sufficient financial backing for project.

ACTION REQUIRED Will void action 8/27

NAME OF PERSON DOCUMENTING CONVERSATION	SIGNATURE	DATE
	W. J. Adam	8/27/85

ACTION TAKEN

SIGNATURE	TITLE	DATE
		ML3P

6/15/84

R III staff –

Rec'd response to deficiency letter re: this application for a new nuclear pharmacy. Response must be reviewed; quick review indicates that def. ltr. is needed for COLOR samples of labels. Don't know what else is needed. "Early" draft of review is in Pending folder. Call me if you have questions.

Pat Vacca

FTS: 427-4112

NRC Form 374
(8-82)

U.S. NUCLEAR REGULATORY COMMISSION

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); and to import such byproduct and source material. 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. ~~ABC Nuclear Pharmacy, Inc.~~ OHIO ISOTOPES INC, Att: Steven R. Lefevre, RPh ~~5678 Connecticut~~ Avenue, N.W. 2. ~~Washington, D.C. 20000~~ 2937 Switzer Road Columbus, Ohio (614) 475-0319 43219	3. License number XX-XXXXX-XXMD 4. Expiration date March 31, 1989 5. Docket or Reference No.

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. ~~30~~ curies
B. Any byproduct material listed in Section 31.11(a) of 10 CFR 31	B. Prepackaged in vitro diagnostic test kits	B. ~~20~~ millicuries total possession limit

Enclosure 1

MATERIALS LICENSE
SUPPLEMENTARY SHEET

License number: XX-XXXXX-XXMD

Docket or Reference number:

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
C. Any byproduct material authorized under Section 35.14(d)(4) of 10 CFR Part 35	C. Any sealed source listed in Section 35.14(d)(4) of 10 CFR Part 35 that has been manufactured, labeled, packaged, and distributed in accordance with a specific license issued pursuant to Section 32.74 of 10 CFR Part 32 or a specific license issued to a manufacturer by an Agreement State pursuant to equivalent State regulations	C. ~~50~~ 30 millicuries total for all sources authorized under Subitem 6.C.
D. Xenon 133	D. 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	D. ~~X curies~~ a 1500 mCi
E. Iodine 131	E. Any form listed in Groups I through V of Schedule A, Section 35.100 of 10 CFR 35	E. ~~250~~ 300 millicuries
F. Technetium 99m	F. Any form listed in Groups I and II of Schedule A, Section 35.100 of 10 CFR 35	F. ~~50~~ 30 curies

MATERIALS LICENSE
SUPPLEMENTARY SHEET

License number: XX-XXXXX-XXMD

Docket or Reference number:

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
G. Any byproduct material, except Iodine 131 and Technetium 99m, listed in Group I of Scheulde A, Section 35.100 of 10 CFR Part 35	G. Any form listed in Group I of Schedule A, Section 35.100 of 10 CFR 35	G. ~~30~~ 50 millicuries total possession limit
H. Any byproduct material, except Iodine 131 and Technetium 99m, listed in Group II of Schedule A, Section 35.100 10 CFR 35	H. Any form listed in Group II of Schedule A, Section 35.100 of 10 CFR 35	H. ~~100~~ 150 millicuries total possession limit
I. Any byproduct material, except Iodine 131, listed in Group IV of Schedule A, Section 35.100 of 10 CFR Part 35	I. Any form listed in Group IV of Schedule A, Section 35.100 of 10 CFR 35	I. ~~200~~ 300 millicuries total possession limit

9. Authorized use

A. Production of technetium-99m pertechnetate. Redistribution of generators to authorized recipients in accordance with statements, representations and procedures contained in application dated February 1, 1984.

B. Redistribution to ~~general and~~ specific licensees in accordance with statements, representations, and procedures contained in application dated February 1, 1984.

C. Instrument calibration. Redistribution of sources to specifically authorized recipients. Pursuant to Section 32.74, 10 CFR 32, the licensee is authorized to redistribute sources to persons licensed pursuant to Section 35.14 and Section 35.100, 10 CFR 35, or under equivalent licenses of Agreement States.

D. Distribution to authorized recipients.

E. Dispensing and/or distribution to authorized recipients.

F. 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.

G. through I. Dispensing and/or distribution of prepared radiopharmaceuticals to authorized recipients.

Pursuant to Sections 32.72 and 32.73, 10 CFR 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:

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9. Authorized use (continued)

A. Molybdenum 99/technetium 99m generators may be redistributed to persons licensed pursuant to Group III.

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

CONDITIONS

10. Licensed material shall be used only at 5678 Connecticut Avenue, N.W., Washington, D. C.

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, John Smith, Mary Brown or Fred Jones.

B. At least one individual who meets the requirements in Condition 12.A. shall be physically present at the authorized place of use whenever licensed material is used.

C. The Radiation Protection Officer for the activities authorized by this license is John Smith.

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.

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Docket or Reference number

CONDITIONS

14. continued

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 I, 631 Park Avenue, King of Prussia, Pennsylvania 19406 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, 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 February 1, 1984.

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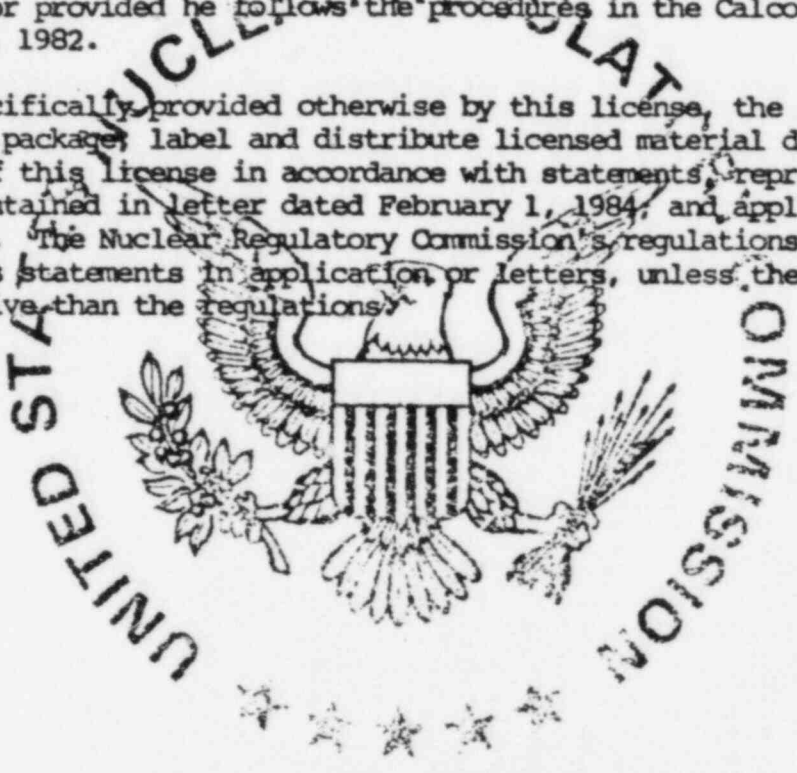
CONDITIONS

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. The licensee may use the Calicheck device for doing linearity tests of his dose calibrator provided he follows the procedures in the Calcorp, Inc., Manual dated March 2, 1982.

23. 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 letter dated February 1, 1984, and application dated March 1, 1984. The Nuclear Regulatory Commission's regulations shall govern the licensee's statements in application or letters, unless the statements are more restrictive than the regulations.



FOR THE U. S. NUCLEAR REGULATORY COMMISSION

VOID

Date March 1, 1984

By Material Licensing Branch
Division of Fuel Cycle and Material Safety
Washington, D. C. 20555