

MATERIALS LICENSE

Amendment No. 32

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		In accordance with application dated July 17, 1987	
1. Laboratory of Clinical Medicine		3. License number 40-15027-01 is amended in its entirety to read as follows:	
2. 1212 South Euclid Sioux Falls, South Dakota 57105		4. Expiration date July 31, 1989	
		5. Docket or Reference No. 030-08451	
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. Any byproduct material identified in 10 CFR 35.100	A. Any radiopharmaceutical identified in 10 CFR 35.100	A. As needed	
B. Any byproduct material identified in 10 CFR 35.200	B. Any radiopharmaceutical identified in 10 CFR 35.200	B. As needed	
C. Any byproduct material identified in 10 CFR 35.500	C. Sealed sources for diagnostic devices identified in 10 CFR 35.500	C. 1.5 curies per source	
D. Any byproduct material identified in 10 CFR 31.11	D. Prepackaged Kits	D. As needed	
E. Cesium-137	E. Sealed sources (Technical Operations Model 77302)	E. Not to exceed 165 millicuries per source	

9. Authorized Use:

- A. Medical use described in 10 CFR 35.100.
- B. Medical use described in 10 CFR 35.200.
- C. Medical use described in 10 CFR 35.500.
- D. In vitro studies.
- E. For use in Technical Operations Model 773 calibrator for calibration of licensee's instruments.

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REG4 LIC30
40-15027-01 PDR

**MATERIALS LICENSE
SUPPLEMENTARY SHEET**

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CONDITIONS

10. Location of use:

- A. Licensed materials shall be used only at Morton Addition, RR3, Sioux Falls, South Dakota; 310 Belle Avenue, Mankato, Minnesota; 1150 Sixth Avenue, Des Moines, Iowa; and 1437 S. E. Cortina, Ankeny, Iowa.
- B. Licensed materials listed in Sections 35.100, 35.200 (excluding generators), and 35.500 may also be used at any hospital provided the technical requirements in Section 35.80 of 10 CFR Part 35 are satisfied.

11. Radiation Safety Officer: Roger M. Rae.

12. Authorized Users:

- A. Shanteri U. Nayak, M.D., for material identified in 10 CFR 35.100, 35.200, and 35.500; and for in vitro studies.
- B. W. A. Boade, M.D., for material identified in 10 CFR 35.100, 35.200, and 35.500; and for in vitro studies.
- C. Richard A. Jaqua, M.D., for material identified in 10 CFR 35.100, 35.200, and 35.500; and for in vitro studies.
- D. B. T. Pitt-Hart, M.D., for material identified in 10 CFR 35.100, 35.200, and 35.500; and for in vitro studies.
- E. Richard D. Schultz, M.D., for material identified in 10 CFR 35.100, 35.200, and 35.500; and for in vitro studies.
- F. Karl H. Wegner, M.D., for material identified in 10 CFR 35.100, 35.200, and 35.500; and for in vitro studies.
- G. J. B. Crespo, M.D., for material identified in 10 CFR 35.100, 35.200, and 35.500; and for in vitro studies.
- H. Khosro Tigrani, M.D., for material identified in 10 CFR 35.100, 35.200, and 35.500; and for in vitro studies.

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12. (continued)

I. Charles Flohr, M.D., for material identified in 10 CFR 35.100, 35.200, and 35.500; and for in vitro studies.

J. John O. Judge, M.D., for material identified in 10 CFR 35.100, 35.200, and 35.500; and for in vitro studies.

13. Notwithstanding the requirements of Section 35.49 of Title 10, Code of Federal Regulations, Part 35, the licensee may receive licensed material in prepared individual patient doses and as technetium-99m eluate or as mixed with reagent kits from St. Joseph Hospital, Mitchell, South Dakota; McKennan Hospital, Sioux Falls, South Dakota; or Sioux Valley Hospital, Sioux Falls, South Dakota.

14. Licensee shall conduct and maintain records of the following audits:

A. Unannounced semiannual radioisotope handling and radiation safety audit of each technician operating a mobile nuclear van.

B. Monthly accountability review of daily dispensing and disposal logs maintained by each technician.

15. A. (1) The sources specified in Items 7.C. and 7.E. shall be tested for leakage and/or contamination at intervals not to exceed 6 months. Any source received from another person which is not accompanied by a certificate indicating that a test was performed within 6 months before the transfer 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. Any source in storage and not being used need not be tested. When the source is removed from storage for use or transfer to another person, it shall be tested before use or transfer.

C. The test shall be capable of detecting the presence of 0.005 microcurie of radioactive material on the test sample. If the test reveals the presence of 0.005 microcurie or more of removable contamination, the

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15. (continued)

source shall be removed from service and decontaminated, repaired, or disposed of in accordance with Commission regulations. A report shall be filed within 5 days of the date the leak test result is known with the U.S. Nuclear Regulatory Commission, Region IV, 611 Ryan Plaza Drive, Suite 1000, Arlington, Texas 76011, ATTN: Chief, Nuclear Materials and Emergency Preparedness Branch. The report shall specify the source involved, the test results, and corrective action taken. Records of leak test results shall be kept in units of microcuries and shall be maintained for inspection by the Commission. Records may be disposed of following Commission inspection.

- D. Tests for leakage and/or contamination shall be performed by the licensee or by other persons specifically licensed by the Commission or an Agreement State to perform such services.
16. The licensee may use the Calicheck device for doing linearity tests of its dose calibrator provided it follows the procedures in the Calcorp, Inc., Manual dated March 2, 1982.
17. The licensee may transport licensed material in accordance with the provisions of 10 CFR Part 71, "Packaging and Transportation of Radioactive Material."
18. This license is based on the licensee's statements and representations as follows:
- A. Application dated July 18, 1983
 - B. Letter dated November 22, 1983
 - C. Application dated October 26, 1984
 - D. Letter dated September 4, 1985
 - E. Application dated September 6, 1985
 - F. Letter dated December 27, 1985
 - G. Letter dated March 18, 1986
 - H. Letter dated May 6, 1986
 - I. Letter dated August 15, 1986
 - J. Letter dated September 23, 1986
 - K. Application dated July 17, 1987

FOR THE U.S. NUCLEAR REGULATORY COMMISSION

Original signed by
JACK E. WHITTENDate AUG 27 1987

By

Nuclear Materials Licensing Section
Region IV
Arlington, Texas 76011

11/1

DELIVERED: LICENSE FEE MANAGEMENT BRANCH AND
REGIONAL LICENSING SECTIONS

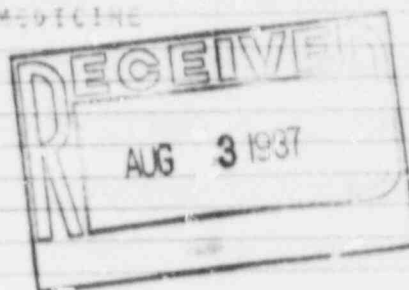
PROGRAM CODE: 32220
STATUS CODE: 3
FEE CATEGORY: 7C
EXP. DATE: 19890731
FEE COMMENTS:

LICENSE FEE TRANSMITTAL

03 008451

1. REGION *IV*

1. APPLICATION ATTACHED
APPLICANT/LICENSER: LAB. OF CLINICAL MEDICINE
APPLICATION DATE: 870727
CONTROL NO.: 461545
LICENSE NO.: 40-15027-01
ACTION TYPE: AMENDMENT



2. FEE ATTACHED *\$120*
AMOUNT:
CHECK NO.: *026713*

3. COMMENTS

SIGNED *Laura Hurler*
DATE *7/27/87*

3. LICENSE FEE MANAGEMENT BRANCH (CHECK WHEN MILESTONE 03 IS ENTERED) *1/1*

1. FEE CATEGORY AND AMOUNT: *7C (\$120)*

2. CURRENT FEE PAID. APPLICATION MAY BE PROCESSED FOR:
AMENDMENT ☒
RENEWAL ☐
LICENSE ☐

3. OTHER

SIGNED *M. Hurler*
DATE *7/27/87*