

## MATERIALS LICENSE

Amendment No. 21

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.

**"OFFICIAL RECORD COPY"**

Licensee

In accordance with letter dated  
June 2, 1986,3. License number 07-14850-01 is amended in  
its entirety to read as follows:

4. Expiration date October 31, 1987

5. Docket or  
Reference No. 030-075656. Byproduct, source, and/or  
special nuclear material7. Chemical and/or physical  
form8. Maximum amount that licensee  
may possess at any one time  
under this licenseA. Any byproduct material  
listed in Groups I and  
II of Schedule A, Section  
35.100 of 10 CFR 35B. Any byproduct material  
listed in Group III of  
Schedule A, Section  
35.100 of 10 CFR 35

C. Xenon 133

A. Any radiopharmaceutical  
listed in Groups I and  
II of Schedule A, Section  
35.100 of 10 CFR 35B. Any form listed in Group  
III of Schedule A, Section  
35.100 of 10 CFR 35C. 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withdrawn or terminated)  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withdrawn, terminated or  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 In-  
vestigational Exemption  
for a New Drug" (IND)  
that has been accepted  
by FDA

D. Sealed Source

A. As necessary for uses  
authorized in  
Subitem 9.A.B. 3 curies of each  
byproduct material  
authorized in  
Subitem 6.B.

C. 200 millicuries

D. Americium 241

D. 2 millicuries

8801220526 870820  
REG1 LIC30  
07-14850-01 PDR

ML18

MATERIALS LICENSE  
SUPPLEMENTARY SHEET

License number

07-14850-01

Docket or Reference number

030-07565

CORRECTED COPY

Amendment No. 21

9. Authorized use

- A. Any diagnostic procedure listed in Groups I and II of Schedule A, Section 35.100, Title 10, Code of Federal Regulations.
- B. Preparation and use of radiopharmaceuticals for any diagnostic procedure listed in Group III of Schedule A, Section 35.100 of Title 10, Code of Federal Regulations.
- C. Blood flow and pulmonary function studies.
- D. For use as an Anatomical marker.

CONDITIONS

10. Licensed material shall be used only at 640 South Governors Avenue, Dover, Delaware.

11. Licensed material listed in Item 6 above is authorized for use by, or under the supervision of, the following individual(s) for the materials and uses indicated:

Mahendra Parikh, M.D.

Groups I, II and III

Xenon 133

Americium 241 as an anatomical marker

Kisan Y. Karapurkar, M.D.

Groups I, II and III

Xenon 133

Americium 241 as an anatomical marker

Craig L. Taylor, M.D.

Groups I, II and III

Xenon 133

Americium 241 as an anatomical marker

12. The licensee is authorized to hold radioactive material with a physical half-life of less than 65 days for decay-in-storage before disposal in ordinary trash provided:

- A. Radioactive waste to be disposed of in this manner shall be held for decay a minimum of 10 half-lives.
- B. Before disposal as normal waste, radioactive waste shall be surveyed to determine that its radioactivity cannot be distinguished from background. All radiation labels shall be removed or obliterated.
- C. Generator columns shall be segregated so that they may be monitored separately to ensure decay to background levels prior to disposal.

13. For a period not to exceed 60 days in any calendar year, a visiting physician is authorized to use licensed material for human use under the terms of this license, provided the visiting physician:

- A. Has the prior written permission of the hospital's Administrator and Radiation Safety Committee, and
- B. Is specifically named as a user on a Nuclear Regulatory Commission license authorizing human use, and

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CORRECTED COPY

Amendment No. 21

(13. continued)

CONDITIONS

- C. Performs only those procedures which the physician is specifically authorized to perform pursuant to a license issued by the Nuclear Regulatory Commission.

The licensee shall maintain for inspection by the Commission copies of the written permission specified in A. above and of the license(s) specified in B. and C. above for a period of 5 years from the date permission is granted under A. above.

14. A(1) The sources or detector cells specified in Item 7.D shall be tested for leakage and/or contamination at intervals not to exceed 6 months. Any source or detector cell 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 or detector cell is exempt from such leak tests when the source or detector cell contains 100 microcuries or less of beta and/or gamma emitting material or 10 microcuries or less of alpha emitting material.
- B. Any source or detector cell in storage and not being used need not be tested. When the source or detector cell 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 source or detector cell 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 I, ATTN: Chief, Nuclear Materials Safety and Safeguards Branch, 631 Park Avenue, King of Prussia, Pennsylvania 19406. 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.

MATERIALS LICENSE  
SUPPLEMENTARY SHEET

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Amendment No. 21

(continued)

CONDITIONS

15. Except as specifically provided otherwise in this license, the licensee shall conduct its program in accordance with the statements, representations, and procedures contained in the documents including any enclosures, listed below. The Nuclear Regulatory Commission's regulations shall govern unless the statements, representations and procedures in the licensee's application and correspondence are more restrictive than the regulations.

- A. Application dated March 17, 1982
- B. Letter dated August 30, 1982
- C. Letter received April 1, 1983
- D. Letter received July 20, 1983
- E. Letter dated August 18, 1983
- F. Letter dated June 2, 1986
- G. Letter dated July 14, 1986

For the U.S. Nuclear Regulatory Commission  
Original Signed By:

Jack Davis

Date 20 AUG 1987

By

Nuclear Materials Safety and  
Safeguards Branch, Region I  
King of Prussia, Pennsylvania 19406