

## MATERIALS LICENSE

Amendment No. 03

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. Radiologists, Inc.<br><br>6724 Troost<br>Suite 900<br>Kansas City, MO 64131                 | In accordance with application dated November 15, 1985  |  |
|  | 3. License number 24-20047-01 is amended in its entirety to read as follows:  |  |
|  | 4. Expiration date January 31, 1991   |  |
|  | 5. Docket or Reference No. 030-17683  |  |
| 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 listed in Groups I and II of Schedule A, Section 35.100 of 10 CFR 35 | A. Any radiopharmaceutical listed in Groups I and II of Schedule A, Section 35.100 of 10 CFR 35   | A. As necessary for uses authorized in Subitem 9.A                             |
| B. Iodine-131  | B. Any iodide that has been manufactured, labeled, packaged, and distributed in accordance with a specific license issued pursuant to Section 32.72 of 10 CFR Part 32 or a specific license issued to a manufacturer by an Agreement State pursuant to equivalent State regulations | B. 30 millicuries  |
| C. Gadolinium-153  | C. Sealed source(s) (Lunar GD Series)   | C. 3 curies (2 sources not to exceed 1.5 curies each)                          |

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**MATERIALS LICENSE  
SUPPLEMENTARY SHEET**

License number

24-20047-01

Docket or Reference number

030-17683

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6. Byproduct, source,  
and/or special nuclear  
material

D. Xenon-133

7. Chemical and/or  
physical form

D. 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

8. Maximum amount that  
licensee may possess  
at any one time  
under this license

D. 250 millicuries

9. Authorized Use

A. Any diagnostic procedure listed in Groups I and II of Schedule A, Section 35.100  
of Title 10, Code of Federal Regulations.

B. For treatment of hyperthyroidism and cardiac dysfunction.

C. One source to be used as a component of Lunar Radiation Corporation Model DP3 Spine  
Scanner for measuring bone mineral content in humans. One source in its shipping  
container for replacement in the spine scanner.

D. Blood flow studies. Pulmonary function studies.

CONDITIONS

10. Licensed material shall be used only at the licensee's facilities located at  
6724 Troost, Suite 900, Kansas City, Missouri.

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

Roger W. Lambie, M.D.

Groups I and II

Xenon-133

Iodine-131 for treatment of  
hyperthyroidism and cardiac  
dysfunction

Gadolinium-153

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Edwin M. Herman, M.D.

Groups I and II

Xenon-133

Iodine-131 for treatment of  
hyperthyroidism and cardiac  
dysfunction

Gadolinium-153

Mordecai Kopperman, M.D.

Groups I and II

Xenon-133

Iodine-131 for treatment of  
hyperthyroidism and cardiac  
dysfunction

Gadolinium-153

Curtis S. Hammerman, M.D.

Groups I and II

Xenon-133

Iodine-131 for treatment of  
hyperthyroidism and cardiac  
dysfunction

Gadolinium-153

12. A. (1) The source(s) specified in Item(s) 7.C. 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 persons, 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 to removable contamination, the 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 III, 799 Roosevelt Road, Glen Ellyn, Illinois 60137, ATTN: Chief, Nuclear Materials Safety and Safeguards 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.

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- 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.
13. Sealed sources containing licensed material shall not be opened or removed from their respective source holders by the licensee.
14. Airflow rates in the ventilation system in areas where xenon-133 is used or stored shall be measured at least semi-annually to determine that system performance meets the specifications submitted in application dated November 15, 1985.
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 November 15, 1985 (with attachments) and
- B. Letter dated January 7, 1986 (with attachment).

For the U.S. Nuclear Regulatory Commission

Date

JAN 24 1986

Original Signed  
By J. R. Madera  
Materials Licensing Section, Region III

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