NRC Form 374A (5-84) U.S. NUCLEAR REGULATORY COMMISSION

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MATERIALS LICENSE
SUPPLEMENTARY SHEET

License number: 18-16979-01
Docket or Reference number: 030-12006
Amendment No. 10

St. Joseph Hospital
297 Center Street
Bangor, Maine 04401

In accordance with application dated May 30, 1985, License Number 18-16979-01 is amended as follows:

Items 6., 7., 8. and 9. are amended to read:

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 6.A.
B. Any byproduct material listed in Group III of Schedule A, Section 35.100 of 10 CFR 35	B. Any form listed in Group III of Schedule A, Section 35.100 of 10 CFR 35	B. 2 curies of each byproduct material authorized in Subitem 6.B.
C. Xenon 133	C. Gas or gas in solution that is the subject of an active (i.e., not withdrawn or terminated) "New Drug Application" (NDA) approved by FDA or an active (i.e., not withdrawn, terminated or on "clinical hold") "Notice of Claimed Investigational Exemption for a New Drug" (IND) that has been accepted by FDA	C. 100 millicuries
D. Gadolinium 153	D. Sealed source (Gulf Nuclear, Inc., Model GD-1	D. Not to exceed 1.5 curies per source
E. Iodine 125	E. Sealed source (AECL Models C-234 or C-324 or Amersham Model IMC.P2)	E. Not to exceed 300 millicuries per source

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 in Lunar Radiation Corporation Model DP3 bone mineral analyzer.
E. For use in Lunar Radiation Corporation Model SP2 bone mineral analyzer.

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(continued)

Conditions 12. and 15. are amended to read:

12. 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:

Robert P. Andrews, M.D.	Groups I, II and III Xenon 133 Iodine 125 and Gadolinium 153 sealed sources for diagnosing bone maladies
Richard L. Field, M.D.	Groups I, II and III Xenon 133 Iodine 125 and Gadolinium 153 sealed sources for diagnosing bone maladies
Charles T. Lynch, Jr., M.D.	Groups I, II and III Xenon 133 Iodine 125 and Gadolinium 153 sealed sources for diagnosing bone maladies
Douglas F. Cowan, M.D.	Groups I, II and III Xenon 133 Iodine 125 and Gadolinium 153 sealed sources for diagnosing bone maladies
Donald E. Factor, M.D.	Groups I, II and III Xenon 133 Iodine 125 and Gadolinium 153 sealed sources for diagnosing bone maladies
John Michael Long, M.D.	Groups I, II and III Xenon 133 Iodine 125 and Gadolinium 153 sealed sources for diagnosing bone maladies
Hugh J. Cuggiano, M.D.	Groups I, II and III Xenon 133 Iodine 125 and Gadolinium 153 sealed sources for diagnosing bone maladies
Michael S. Pancoe, M.D.	Groups I, II and III Xenon 133 Iodine 125 and Gadolinium 153 sealed sources for diagnosing bone maladies
Michael D. Halber, M.D.	Groups I, II and III Xenon 133 Iodine 125 and Gadolinium 153 sealed sources for diagnosing bone maladies

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(12. continued)

	CONDITIONS
Frank L. D'Amelio, M.D.	Groups I, II and III Xenon 133 Iodine 125 and Gadolinium 153 sealed sources for diagnosing bone maladies

15. Except as specifically provided otherwise by this license, the licensee shall possess and use licensed material described in Items 6, 7, and 8 of this license in accordance with statements, representations, and procedures contained in application dated October 21, 1981, and letters dated January 8, 1982, February 26, 1982, March 8, 1982, October 30, 1984, January 23, 1985, and May 30, 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.

Conditions 16., 17. and 18. are added:

16. A. (1) Each sealed source containing gadolinium 153 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) The periodic leak test required by this condition does not apply to sealed sources that are stored and not being used. The sources excepted from this test shall be tested for leakage prior to any use or transfer to another person unless they have been leak tested within six months prior to the date of use or transfer.

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 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. The licensee is authorized to collect leak test samples in accordance with the procedures described in the licensee's application dated May 30, 1985, for analysis by Siemens Gammasonics, Inc. Alternatively, leak test samples may be collected and/or analyzed by other persons specifically authorized by the Commission or an Agreement State to perform such services.

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(continued) CONDITIONS

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

18. The licensee shall conduct a physical inventory every six (6) months to account for all bone mineral analyzer 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 licensed material, location of bone mineral analyzer sealed sources and the date of the inventory.

For the U.S. Nuclear Regulatory Commission

Original Signed By:
John E. Glenn

Date AUG 05 1985

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