NRC Form 374
(5-84)

U.S. NUCLEAR REGULATORY COMMISSION

MATERIALS LICENSE

Amendment No. 35

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. Christ Hospital	In accordance with application dated March 22, 1985 3. License number 34-03831-02 is amended in its entirety to read as follows:
2. 2139 Auburn Avenue Cincinnati, OH 45219	4. Expiration date July 31, 1990
	5. Docket or Reference No. 030-02725

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. 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. 6 curies of each byproduct material authorized in Subitem 6.B
C. Any byproduct material listed in Group IV of Schedule A, Section 35.100 of 10 CFR 35	C. Any radiopharmaceutical listed in Group IV of Schedule A, Section 35.100 of 10 CFR 35	C. As necessary for uses authorized in Subitem 9.C
D. Any byproduct material listed in Group V of Schedule A, Section 35.100 of 10 CFR 35	D. Any radiopharmaceutical listed in Group V of Schedule A, Section 35.100 of 10 CFR 35	D. As necessary for uses authorized in Subitem 9.D
E. Any byproduct material listed in Group VI of Schedule A, Section 35.100 of 10 CFR 35	E. Any sealed source listed in Group VI of Schedule A, Section 35.100 of 10 CFR 35	E. 2.5 curies total for all sources authorized in Subitem 6.E

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MATERIALS LICENSE
SUPPLEMENTARY SHEET

License number: 34-03831-02
Docket or Reference number: 030-02725
Amendment No. 35

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
F. Xenon-133	F. 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	F. 800 millicuries
G. Carbon-14	G. Any	G. 15 millicuries
H. Hydrogen-3	H. Any	H. 240 millicuries
I. Iodine-125	I. Any	I. 80 millicuries
J. Phosphorus-32	J. Any	J. 50 millicuries
K. sulfur-35	K. Any	K. 40 millicuries
L. Selenium-75	L. Any	L. 3 millicuries
M. Cesium-137	M. Sealed source (Technical Operations Model 77302 or New England Nuclear Model NER-570)	M. 165 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. 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. Any therapeutic procedure listed in Group IV of Schedule A, Section 35.100 of Title 10, Code of Federal Regulations.

COPY

MATERIALS LICENSE
SUPPLEMENTARY SHEET

License number: 34-03831-02
Docket or Reference number: 030-02725
Amendment No. 35

9. Authorized Use (cont'd)

D. Any therapeutic procedure listed in Group V of Schedule A, Section 35.100 of Title 10, Code of Federal Regulations.

E. Any procedure listed in Group VI of Schedule A, Section 35.100 of Title 10, Code of Federal Regulations.

F. Blood flow studies. Pulmonary function studies.

G. through K. In vitro laboratory studies.

L. Animal studies.

M. For use in Technical Operations Model 773 calibrator to calibrate the licensee's survey meters.

CONDITIONS

10. Licensed material shall be used only at the licensee's facilities located at 2139 Auburn Avenue, Cincinnati, Ohio. Licensed material may also be used for in vitro and animal studies at the licensee's facilities located at the James N. Gamble Institute of Medical Research, Cincinnati, Ohio.

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. 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:

Henry J. Kenkel, M.D.	Groups I, II, III, IV, V and VI Xenon-133 In vitro studies Cesium-137 instrument calibrator
Vincent J. Seiwert, M.D.	Groups I, II and III Xenon-133
Ralph M. Scott, M.D.	Group VI
Sunantha Ploysongsang, M.D.	Group VI
Marcel Pons, Ph.D.	In vitro studies
Olga M. Rochovansky, Ph.D.	In vitro studies
Steven L. Wechsler, Ph.D.	In vitro studies

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MATERIALS LICENSE
SUPPLEMENTARY SHEET

License number: 34-03831-02
Docket or Reference number: 030-02725

Amendment No. 35

Ann B. Bjornson, Ph.D.	In vitro studies Animal studies
Charles G. Massion, M.D.	In vitro studies
David C. Hohnadel, Ph.D.	In vitro studies
Clifford G. Born, M.S.	Cesium-137 instrument calibrator
Joseph L. Hall, M.S.	Cesium-137 instrument calibrator
Kathyryn Ann Weichert, M.D.	Group VI

13. For a period not to exceed sixty (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 its Medical Isotopes Committee, and

    (b) Is specifically named as a user on a Nuclear Regulatory Commission license authorizing human use, and

    (c) Performs only those procedures for which he is specifically authorized by a Nuclear Regulatory Commission license.

    The licensee shall maintain for inspection by the Commission, copies of the written permission specified in Subitem (a) above and of the license(s) specified in Subitems (b) and (c) above. These records shall be maintained for five (5) years from the time the licensee grants its permission under Subitem (a) above.

14. Licensed material shall be used in accordance with the provisions of Section 35.14(b)(c)(e) and (f) of Title 10, Code of Federal Regulations.

15. Patients containing Iodine 131 for the treatment of thyroid carcinoma (or patients containing therapeutic quantities of Gold 198) shall remain hospitalized until the residual activity is 30 millicuries or less.

16. Pursuant to Sections 20.106(b) and 20.302, 10 CFR 20, the licensee is authorized to dispose of licensed material by incineration provided the gaseous effluent from incineration does not exceed the limits specified for air in Appendix B, Table II, 10 CFR 20. Ash residues may be disposed of as ordinary waste provided appropriate surveys pursuant to Section 20.201 are made to determine that concentrations of licensed material appearing in the ash residues do not exceed the concentrations (in terms of microcuries per gram) specified for water in Appendix B, Table II, 10 CFR 20.

17. The licensee shall establish a bioassay program for individuals handling millicurie amounts of iodine-131 in accordance with frequencies and procedures contained in Regulatory Guide 8.20, "Applications of Bioassay for I-125 and I-131."

MATERIALS LICENSE
SUPPLEMENTARY SHEET

License number
34-03831-02

Docket or Reference number
030-02725

Amendment No. 35

18. Individuals involved in operations which utilize, at any one time, more than 100 millicuries of Hydrogen 3 in a non-contained form, other than metallic foil, shall have bioassays performed within one week following a single operation and at weekly intervals for continuing operations. NRC "Guidelines For Bioassay Requirements For Tritium," dated October 19, 1977, will be followed.

19. The "XenAlert" system shall be claibrated annually in accordance with the manufacturers procedures.

20. 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 March 22, 1985; and letters dated September 22, 1983 (with attachments), December 1, 1983, April 3, 1984, and June 21, 1985 (with attachments). 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.

For the U.S. Nuclear Regulatory Commission

Date _____

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

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