

MATERIALS LICENSE

Amendment No. 31

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. St. Vincent Charity Hospital	In accordance with application dated March 27, 1985
2. 2351 East 22nd Street Cleveland, OH 44115	3. License number 34-01856-01 is amended in its entirety to read as follows:
	4. Expiration date May 31, 1990
	5. Docket or Reference No. 030-02689
6. Byproduct, source, and/or special nuclear material	7. Chemical and/or physical form
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
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
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
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
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
	8. Maximum amount that licensee may possess at any one time under this license
	A. As necessary for uses authorized in Subitem 9.A
	B. 2 curies of each byproduct material authorized in Subitem 6.B
	C. As necessary for uses authorized in Subitem 9.C
	D. As necessary for uses authorized in Subitem 9.D
	E. 1 curie total for all sources authorized in Subitem 6.E

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| 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. Any byproduct material listed in Section 31.11(a) of 10 CFR 31 | F. Prepackaged kits | F. 3 millicuries of each byproduct material authorized in Subitem 6.F |
| G. Xenon-133 | G. 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 | G. 1200 millicuries |
| H. Uranium (Depleted in Uranium 235) | H. Cadmium plated metal | H. 140 kilograms |

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.
- 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. In vitro studies.
- G. Blood flow studies. Pulmonary function studies.
- H. To be used as shielding in linear accelerator.

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CONDITIONS

10. Licensed material shall be used only at the licensee's facilities located at 2351 East 22nd Street, Cleveland, 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:
- Robert J. Porter, M.D. Groups I, II, III, IV, V and VI
Xenon-133
In vitro studies
- John L. Porter, M.D. Groups I, II, III and VI
In vitro studies
Iodine-131 for treatment of hyperthyroidism
Soluble Phosphorus-32 for therapy
Xenon-133
- Fritz H. Schulz, M.D. Groups I, II, III and VI
In vitro studies
Iodine-131 for treatment of hyperthyroidism
Soluble Phosphorus-32 for therapy
Xenon-133
- Mary E. Mohr, M.D. Groups I, II, III, IV and VI
In vitro studies
Gold-198 for therapy
Xenon-133
- Dong Kim, M.D. Group VI
- Victor A. Ceicys, M.D. Groups I, II and III
Iodine-131 for treatment of hyperthyroidism, cardiac dysfunction, and thyroid carcinoma
Xenon-133
In vitro studies

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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. 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 27, 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.

For the U.S. Nuclear Regulatory Commission

Date May 10, 1985

Original Signed
By George M. McCann
Materials Licensing Section, Region III

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