

## MATERIALS LICENSE

Amendment No. 34

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. Providence Hospital

2. 16001 West Nine Mile Road  
Southfield, MI 48076In accordance with letter dated  
August 25, 19833. License number 21-02802-03 is amended in  
its entirety to read as follows:

4. Expiration date June 30, 1990

5. Docket or  
Reference No. 030-020226. 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 35A. Any radiopharmaceutical  
listed in Groups I  
and II of Schedule A,  
Section 35.100 of  
10 CFR 35A. As necessary for  
uses authorized  
in Subitem 9.AB. Any byproduct material  
listed in Group III 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 35B. 4 curies  
of each byproduct  
material authorized  
in Subitem 6.BC. Any byproduct material  
listed in Group IV of  
Schedule A, Section  
35.100 of 10 CFR 35C. Any radiopharmaceutical  
listed in Group IV of  
Schedule A, Section  
35.100 of 10 CFR 35C. As necessary for  
uses authorized  
in Subitem 9.CD. Any byproduct material  
listed in Group V of  
Schedule A, Section  
35.100 of 10 CFR 35D. Any radiopharmaceutical  
listed in Group V of  
Schedule A, Section  
35.100 of 10 CFR 35D. As necessary for  
uses authorized  
in Subitem 9.DE. Any byproduct material  
listed in Group VI of  
Schedule A, Section  
35.100 of 10 CFR 35E. Any sealed source  
listed in Group VI of  
Schedule A, Section  
35.100 of 10 CFR 35E. 1 curie  
total for all  
sources authorized  
in Subitem 6.E8506100726 850522  
REG LIC30  
21-02802-03 PDR

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**MATERIALS LICENSE  
SUPPLEMENTARY SHEET**

License number  
21-02802-03

Docket or Reference number  
030-02022

Amendment No. 34

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

F. Xenon-133

7. Chemical and/or  
physical form

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

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

F. 2 curies

G. Any byproduct material  
listed in Section  
31.11(a) of 10 CFR 31

G. Prepackaged kits

G. 8 millicuries  
of each byproduct  
material authorized  
in Subitem 6.G

H. Uranium (Depleted in  
Uranium 235)

H. Cadmium plated metal

H. 205 kilograms

I. Strontium-90

I. Sealed source  
(ICN Model No. 75143)

I. One source not  
to exceed 50  
millicuries

J. Sulfur-35

J. Any

J. 1 millicurie

**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.

**MATERIALS LICENSE**  
**SUPPLEMENTARY SHEET**

License number	21-02802-03
Docket or Reference number	030-02022
Amendment No.	34

- 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. and J. To be used for In vitro studies.
- H. To be used as shielding in linear accelerator.
- I. To be used for the treatment of superficial eye diseases.

CONDITIONS

10. Licensed material shall be used only at the licensee's facilities located at 16001 West Nine Mile Road, Southfield, Michigan.
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:
- |                          |  |
|--------------------------|--|
| Thomas P. James, M.D.    | Groups I, II, III, IV, V and VI<br>Xenon-133<br><u>In vitro</u> studies                            |
| Phillip E. Perkins, M.D. | Groups I, II, III, IV and V<br>Strontium-90 eye applicator<br>Xenon-133<br><u>In vitro</u> studies |
| Boris Silberberg, M.D.   | Group I<br><u>In vitro</u> studies   |
| Marcus S. Feldman, M.D.  | Group VI   |
| Clarence B. Vaughn, M.D. | <u>In vitro</u> studies  |
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

**MATERIALS LICENSE**  
**SUPPLEMENTARY SHEET**

License number	21-02802-03
Docket or Reference number	030-02022
Amendment No. 34	

- (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. A. (1) Each sealed source containing licensed material, other than Hydrogen 3, with a half-life greater than thirty days and in any form other than gas 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) 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. 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 five (5) days of the test with the U. S. Nuclear Regulatory Commission, Region III, 799 Roosevelt Road, Glen Ellyn, Illinois 60137, describing the equipment involved, the test results, and the corrective action taken.
- D. Tests for leakage and/or contamination shall be performed by the licensee or by other persons specifically authorized by the Commission or an Agreement State to perform such services.
16. Patients containing Cobalt 60, Cesium 137 or Iridium 192 implants shall remain hospitalized until a source count and surveys made with an appropriate radiation detection instrument indicate that all implants have been removed. The results of these surveys shall be recorded and maintained for inspection by the Commission for five (5) years from the time the implants are removed.



**MATERIALS LICENSE  
SUPPLEMENTARY SHEET**

License number  
21-02802-03

Docket or Reference number  
030-02022

Amendment No. 34

17. 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.
18. 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 ten (10) half-lives.
  - B. Prior to disposal as normal waste, radioactive waste shall be monitored to determine that its radioactivity cannot be distinguished from background with typical low-level laboratory survey instruments. All radiation labels will 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.
19. 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 May 10, 1985, letter dated August 25, 1983 (with attachments), and Model ALARA Program as contained in Appendix O of Regulatory Guide 10.8, October 1980. 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

Original Signed

By Patricia J. Whiston

Materials Licensing Section, Region III

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Date May 22, 1985