

CORRECTED COPY

MATERIALS LICENSE

Amendment No. 11

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.

<p>Licensee</p> <p>1. Mercy Health Center St. Joseph Unit</p> <p>2. Mercy Drive Dubuque, IA 52001</p>	<p>In accordance with application dated April 19, 1985</p> <p>3. License number 14-14623-01 is amended in its entirety to read as follows:</p> <p>4. Expiration date June 30, 1990</p> <p>5. Docket or Reference No. 030-10610</p>	
<p>6. Byproduct, source, and/or special nuclear material</p> <p>A. Any byproduct material listed in Groups I and II of Schedule A, Section 35.100 of 10 CFR 35</p> <p>B. Any byproduct material listed in Group III of Schedule A, Section 35.100 of 10 CFR 35</p> <p>C. Any byproduct material listed in Group IV of Schedule A, Section 35.100 of 10 CFR 35</p> <p>D. Iodine-131</p> <p>E. Any byproduct material listed in Section 31.11(a) of 10 CFR 31</p>	<p>7. Chemical and/or physical form</p> <p>A. Any radiopharmaceutical listed in Groups I and II of Schedule A, Section 35.100 of 10 CFR 35</p> <p>B. Any form listed in Group III of Schedule A, Section 35.100 of 10 CFR 35</p> <p>C. Any radiopharmaceutical listed in Group IV of Schedule A, Section 35.100 of 10 CFR 35</p> <p>D. 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</p> <p>E. Prepackaged kits</p>	<p>8. Maximum amount that licensee may possess at any one time under this license</p> <p>A. As necessary for uses authorized in Subitem 9.A</p> <p>B. 3 curies of each byproduct material authorized in Subitem 6.B</p> <p>C. As necessary for uses authorized in Subitem 9.C</p> <p>D. 250 millicuries</p> <p>E. 3 millicuries of each byproduct material authorized in Subitem 6.E</p>

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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. Treatment of thyroid carcinoma.
- E. In vitro studies.

CONDITIONS

- 10. Licensed material shall be used only at the licensee's facilities located at St. Joseph Unit, Mercy Drive, Dubuque, Iowa, and at Mercy Health Center, St. Mary's Unit, 1111 Third Street, S.W., Dyersville, Iowa.
- 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:

Sun Hwan Chi, M.D.	Groups I, II, III and IV Iodine-131 for treatment of thyroid carcinoma
Stephen Clifford, M.D.	Groups I, II, III and IV Iodine-131 for treatment of thyroid carcinoma
Robert B. Merrick, M.D.	Groups I, II, III and IV Iodine-131 for treatment of thyroid carcinoma
Michael T. Nelson, M.D.	Groups I, II and III Iodine-131 for treatment of hyperthyroidism, cardiac dysfunction and thyroid carcinoma <u>In vitro</u> studies

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Robert Roy Stenlund, M.D.

Groups I, II and III
Iodine-131 for treatment of
hyperthyroidism, cardiac
dysfunction and thyroid carcinoma
In vitro studies

James M. Mylrea, M.D.

Groups I, II and III
Iodine-131 for treatment of
hyperthyroidism, cardiac
dysfunction and thyroid carcinoma
Phosphorus-32 (soluble) for
treatment of polycythemia vera,
leukemia and bone metastases
In vitro studies

Gregory Brian Kapala, M.D.

Groups I, II and III
Iodine-131 for treatment of
hyperthyroidism, cardiac
dysfunction and thyroid carcinoma
In vitro 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
 - (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.

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16. 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.
17. The licensee may transport licensed material or deliver licensed material to a carrier for transport in accordance with the provisions of Title 10, Code of Federal Regulations, Part 71, "Packaging of Radioactive Material for Transport and Transportation of Radioactive Material Under Certain Conditions."
18. The licensee may use the Calicheck device for doing linearity tests of his dose calibrator provided he follows the procedures in the Calcorp, Inc., Manual dated May 2, 1982 or the licensee may use the Lineator device for doing linearity tests of his dose calibrator provided he follows the procedures in the Atomic Products Corporation Lineator Instructions Manual dated June 20, 1983.
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 April 19, 1985 and ALARA Program dated April 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 July 2, 1985

Original Signed

By James MullauerMaterials Licensing Section, Region III

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