

**MATERIALS LICENSE  
SUPPLEMENTARY SHEET**

License number

08-00942-05

Docket or Reference number

030-01314

Amendment No. 26

**"OFFICIAL RECORD COPY"**

V. A. Medical Center  
50 Irving Street, N.W.  
Washington, D.C. 20422

In accordance with letter dated June 25, 1985, License Number 08-00942-05 is amended as follows:

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

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| <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. Any byproduct material listed in Group V of Schedule A, Section 35.100 of 10 CFR 35</p> <p>E. Any byproduct material listed in Group VI of Schedule A, Section 35.100 of 10 CFR 35</p> <p>F. Xenon 133</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 radiopharmaceutical listed in Group V of Schedule A, Section 35.100 of 10 CFR 35</p> <p>E. Any sealed source listed in Group VI of Schedule A, Section 35.100 of 10 CFR 35</p> <p>F. Gas or gas in solution that is the subject of an active (i.e., not withdrawn or terminated) "New Drug Application" (NDA) approved by FDA or an active (i.e., not withdrawn, terminated or on "clinical hold") "Notice of Claimed Investigational Exemption for a New Drug" (IND) that has been accepted by FDA</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 6.A.</p> <p>B. 5 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. As necessary for uses authorized in Subitem 9.D.</p> <p>E. 400 millicuries total for sources authorized in Subitem 6.E.</p> <p>F. 300 millicuries</p> |
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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        |
| G. Any byproduct material with Atomic Nos. 3 through 83, inclusive | G. Any  | G. 25 millicuries of each byproduct material with Atomic Nos. 3 through 83, inclusive |
| H. Hydrogen 3  | H. Any  | H. 300 millicuries  |
| I. Cesium 137  | I. Sealed source (Nuclear Associates Inc. Model No. 64-715) | I. 10 millicuries   |
| J. Americium 241   | J. Sealed source (Radiochemical Center Model No. 64-715)    | J. 45 millicuries   |
| K. Iodine 125  | K. Any  | K. 45 millicuries   |
| L. Iodine 125  | L. Any as radioactive waste                                 | L. 30 millicuries   |

## 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. 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. Blood flow and pulmonary function studies.
- G. and H. (1) Medical research and tracer studies in humans as approved by a Radioactive Drug Research Committee established with the Food and Drug Administration.  
(2) Research and development as defined in Section 30.4(q), 10 CFR Part 30.
- I. through K. Research and development as defined in Section 30.4(q), 10 CFR Part 30.
- L. Held for decay-in-storage in accordance with the procedures described in letter dated December 5, 1980 or until transferred to authorized recipient.

Conditions 10., 11., 12., 13., 14., 15., 16., 17., 18., 19., 20., 21., 22., and 23 are amended to read as follows:

10. Licensed material shall be used only at the licensee's facilities, V. A. Medical Center, 50 Irving Street, N.W., Washington, D.C.
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."

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(12.continued)

**CONDITIONS**

12. A. Licensed material shall be used by, or under the supervision of, individuals designated by the Radiation Safety Committee, Frank Vieras, M.D., Chairman.
- B. The use of licensed material in or on humans shall be by a physician as defined in 10 CFR 35.3(b).
- C. Physicians designated to use licensed material in or on humans shall meet the training and experience criteria established in Appendix A of Regulatory Guide 10.8 (Revision 1), dated October 1980.
- D. The Radiation Protection Officer for the activities authorized by this license is John O. Bowman.
13. A. (1) Each sealed source acquired from another person and 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 contamination and/or leakage prior to use. 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.
- (3) Except for alpha sources, 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. Each sealed source fabricated by the licensee shall be inspected and tested for construction defects, leakage, and contamination prior to use or transfer as a sealed source. If the inspection or test reveals any construction defects or 0.005 microcurie or greater of contamination, the source shall not be used or transferred as a sealed source until it has been repaired, decontaminated and retested.
- C. 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 except that each source designed for the purpose of emitting alpha particles shall be tested at intervals not to exceed three months.

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**CONDITIONS**

- D. 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 or semipermanently 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.
- E. If the test required by Subsection A. or C. of this condition 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.
14. Sealed sources containing licensed material shall not be opened.
15. A. Detector cells containing titanium tritide foil shall only be used in conjunction with a properly operating temperature control mechanism which prevents foil temperatures from exceeding 225 degrees Centigrade.
- B. Detector cells containing scandium tritide foil shall only be used in conjunction with a properly operating temperature control mechanism which prevents foil temperatures from exceeding 325 degrees Centigrade.
16. In lieu of using the conventional radiation caution colors (magenta or purple on yellow background) as provided in Section 20.203(a)(1), Title 10, Code of Federal Regulations, Part 20, the licensee is hereby authorized to label detector cells and cell baths, containing licensed material and used in gas chromatography devices, with conspicuously etched or stamped radiation caution symbols without a color requirement.
17. The licensee shall not use licensed material in field applications where activity is released except as provided otherwise by specific condition of this license.
18. Patients containing Iodine 131 for the treatment of thyroid carcinoma shall remain hospitalized until the residual activity is 30 millicuries or less.
19. Pursuant to Section 20.106(b) and 20.302, 10 CFR 20, the licensee is authorized to dispose of carbon-14 and hydrogen 3 by incineration provided the gaseous effluent from incineration does not exceed the limits specified for air in Appendix B, Table 11, 10 CFR 20. Ash residues may be disposed of as ordinary waste provided appropriate surveys pursuant to 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 11, 10 CFR 20.

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CONDITIONS

20. The license may receive hydrogen 3 and carbon 14 as radioactive waste for the purpose of incineration from the Washington Hospital Center, 110 Irving Street, N. W. Washington, D.C., and the Children's Hospital, 111 Michigan Avenue, N.W., Washington, D.C.
21. 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.
22. 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."
23. 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 December 22, 1978; letters dated November 30, 1979, July 8, 1980, December 5, 1980, January 7, 1983, January 23, 1984, January 16, 1985, and June 25, 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

Original Signed By:

Jenny M. Johanson

Date AUG 15 1985

By

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