

PRODUCT MATERIAL LICENSE

Amendment No. 45

Pursuant to the Atomic Energy Act of 1954 and Title 10, Code of Federal Regulations, Chapter 1, Parts 30, 32, 33, 34, and 35, and in reliance on statements and representations heretofore made by the licensee, a license is hereby issued authorizing the licensee to receive, acquire, own, possess, transfer and import byproduct material listed below; and to use such byproduct material for the purpose(s) and at the place(s) designated below. 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 Atomic Energy Commission now or hereafter in effect and to any conditions specified below.

<p style="text-align: center;">Licensee</p> <p>1. Department of the Army Walter Reed Army Medical Center (WRAMC) 2. Washington, D. C. 20012</p>	<p>In accordance with application dated June 18, 1974,</p> <p>3. License number 08-01738-02 is amended in its entirety to read as follows:</p> <hr/> <p>4. Expiration date August 31, 1979</p> <hr/> <p>5. Reference No.</p>
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<p>6. Byproduct material (element and mass number)</p> <p>A. Any byproduct material with Atomic Nos. 3-83, inclusive</p>	<p>7. Chemical and/or physical form</p> <p>A. Any</p>	<p>8. Maximum amount of radioactivity which licensee may possess at any one time</p> <p>A. 400 millicuries of each except:</p> <table border="0"> <tr><td>Iodine 131</td><td>2000 millicuries</td></tr> <tr><td>Xenon 133</td><td>5000 millicuries</td></tr> <tr><td>Krypton 85</td><td>5000 millicuries</td></tr> <tr><td>Gold 198</td><td>1000 millicuries</td></tr> <tr><td>Phosphorus 32</td><td>2000 millicuries</td></tr> <tr><td>Sulfur 35</td><td>1000 millicuries</td></tr> <tr><td>Carbon 14</td><td>2000 millicuries</td></tr> <tr><td>Iodine 125</td><td>1000 millicuries</td></tr> <tr><td>Iridium 192</td><td>[REDACTED]</td></tr> </table> <p>Total not to exceed 26 curies</p>	Iodine 131	2000 millicuries	Xenon 133	5000 millicuries	Krypton 85	5000 millicuries	Gold 198	1000 millicuries	Phosphorus 32	2000 millicuries	Sulfur 35	1000 millicuries	Carbon 14	2000 millicuries	Iodine 125	1000 millicuries	Iridium 192	[REDACTED]
Iodine 131	2000 millicuries																			
Xenon 133	5000 millicuries																			
Krypton 85	5000 millicuries																			
Gold 198	1000 millicuries																			
Phosphorus 32	2000 millicuries																			
Sulfur 35	1000 millicuries																			
Carbon 14	2000 millicuries																			
Iodine 125	1000 millicuries																			
Iridium 192	[REDACTED]																			
<p>B. Hydrogen 3 C. Cesium 137 D. Molybdenum 99</p>	<p>B. Any C. Sealed sources D. Molybdenum 99/ Technetium 99m Generators (E. R. Squibb and Sons Model Nos. 08871 and 09650; Abbott Labs. Model Nos. 7721 and 6724; NEN Pharmaceuticals Model No. NRP-196; Mallinckrodt Chemical Works Model Nos. 006 through 012 and 100 through 106; Cambridge Nuclear Corp. Model No. CN-4291; and Amersham/Searle Corp. Model Nos. GTC-50, GTC-100, GTC-200, GTC-300, and GTC-400)</p>	<p>B. 10,000 millicuries C. [REDACTED] D. 10 curies</p>																		

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Information in this record was deleted in accordance with the Freedom of Information Act, exemptions 2
FOIA 2006-0238

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Supplementary Sheet

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6. Byproduct material (element and mass number)	7. Chemical and/or physical form	8. Maximum amount of radio activity licensee may possess at any one time
E. Technetium 99m	E. Pertechnetate	E. 5 curies
F. Neptunium 237	F. Any	F. 10 millicuries
G. Americium 241	G. Any	G. 100 microcuries
H. Polonium 210	H. Any	H. 15 millicuries
I. Cesium 137	I.	I.
	Sealed	
	Sources	
J. Cobalt 60	J. Sealed Sources	J.
K. Strontium 90	K. Sealed Sources in Gas Chromatograph Devices	K.
L. Cesium 137	L.	L. 1 source of
	Sealed Source	
M. Americium 241	M. Any	M.
N. Americium 241	N. Sealed Sources	N.

9. Authorized use

- A. through E. Medical research, diagnosis and therapy. Research and development as defined in Section 30.4(q), 10 CFR 30, "Rules of General Applicability to Licensing of Byproduct Material."
- F. through K. Research and Development as defined in Section 30.4(q), 10 CFR Part 30, "Rules of General Applicability to Licensing of Byproduct Material."
- L. For use in Calibration for calibration of instruments at the Health Physics Calibration Range, Walter Reed Army Medical Center.
- M. For use as standards or reference sources.
- N. Medical research.

CONDITIONS

- 10. Byproduct material shall be used only at Walter Reed Army Medical Center, Washington, D. C.; Forest Glen Section and Annex, Walter Reed Army Medical Center, Montgomery County, Maryland; Fort Detrick, Maryland; Fort Myer, Virginia; and Walter Reed Army Institute of Research Animal Holding Facility, Fort Meade, Maryland.

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U. S. ATOMIC ENERGY COMMISSION
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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. A. Byproduct material shall be used by, or under the supervision of, individuals designated by the Walter Reed Army Medical Center Radioisotope Committee.
B. The use of byproduct material in or on humans shall be by a physician.
13. 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 byproduct material and used in gas chromatography devices, with conspicuously etched or stamped radiation caution symbols without a color requirement.
14. Notwithstanding the labeling requirements of Section 20.203(f), 10 CFR Part 20, (or comparable Agreement State regulations) the licensee is authorized to receive, possess, and use byproduct material received under the American College of Pathologists Nuclear Medicine Quality Control Program with labeling as proposed in letter dated April 17, 1974.
15. Experimental animals administered radioactive materials or their products shall not be used for human consumption.
16. A. Except as otherwise specifically provided by this license, byproduct material to be administered to humans shall be procured in prepackaged, precalibrated form from a supplier who manufactures or repackages the product under appropriate pharmaceutical controls related to assay, identity, quality, purity, sterility, and nonpyrogenicity.
B. Byproduct material prepared by the licensee may be used in humans, provided the product is produced under pharmaceutical controls related to assay, identity, quality, purity, sterility, and nonpyrogenicity in accordance with application dated June 18, 1974.
17. Patients containing Cobalt 60, Iridium 192, and/or Cesium 137 implants shall remain hospitalized until the implants are removed.
18. 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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19. A(1) Each sealed source acquired from another person and containing byproduct 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, the sealed source 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 contamination 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 byproduct 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.
- 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.

