

## MATERIALS LICENSE

Amendment No. 32

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		In accordance with letter dated August 26, 1983	
1. Abbott Laboratories Diagnostics Division		3. License number	12-00621-03 is amended in its entirety to read as follows:
2. North Chicago, IL 60064		4. Expiration date	July 31, 1990
		5. Docket or Reference No.	030-04038
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	
A. Any byproduct material between Atomic Nos. 1 thru 84, inclusive	A. Any	A. 1 curie of each byproduct material between Atomic Nos. 1 thru 84. Total possession not to exceed 5 curies.	
B. Iodine-125	B. Any	B. 75 curies	
C. Cesium-137	C. Sealed sources (Any source which has been evaluated and registered with the NRC or an Agreement State)	C. No single source to exceed 50 millicuries each. Total possession not to exceed 500 millicuries.	
D. Cesium-137	D. Sealed source (Any source approved by the NRC or an Agreement State for use in J.L. Shepherd Model 28-6A calibrator)	D. One source not to exceed 1 curie	

## 9. Authorized Use

- A. For pharmaceutical research and development as defined in Section 30.4(q), 10 CFR Part 30, including animal studies. To be used in manufacturing, processing and packaging of test kits for in vitro or laboratory testing and transfer or distribution to person authorized to possess the licensed material pursuant to the terms and conditions of an appropriate license issued by the Nuclear Regulatory Commission or an Agreement State.
- B. For storage only.

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9. Authorized Use (cont'd)

- C. To be used in NRC approved source holders for industrial process measurement of the flow level and/or density of materials.
- D. To be used for in-house calibration of the licensee's radiation detection instrumentation.

CONDITIONS

- 10. Licensed material shall be used only at facilities approved by the licensee's Corporate Radiation Safety Committee located at 1400 Sheridan Road, North Chicago, Illinois and Abbott Park, Route 32 (Waukegan Road) at Route 137 (Buckley Road) Lake County, Illinois except that:
  - A. Up to 2.5 curies of iodine-125 total contained in either vials or finished in vitro diagnostic kits may be stored prior to distribution, at the licensee's facility located at Abbott Laboratories, Diagnostic Division Distribution Center, Intersection of U.S. 41 and 22nd Street, North Chicago, Illinois.
  - B. Except for Building AP-15A at Abbott Park, no more than 8 curies of iodine-125 may be used or stored in any one building.
  - C. Records of evaluation and approval of facilities by the licensee's Corporate Radiation Safety Committee shall be maintained for review by the NRC.
- 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. Licensed material shall be used by or under the supervision of individuals designated by Abbott's Corporate Radiation Safety Committee, Ralph Robinson, Chairman.
  - B. The Radiation Protection Officer for the activities authorized by this license is R.L. Fredrickson.
  - C. Individuals approved by the licensee's committee to independently use licensed material shall have (in addition to required Abbott training) as a minimum education, experience and training equivalent to that outlined in Part 33.15(b), 10 CFR Part 33. Records of training and certification of competency of users by the licensee's committee shall be maintained for review by the NRC.
- 13. This license does not authorize distribution to person licensed pursuant to Sections 35.14 and 35.100 of 10 CFR Part 35.
- 14. Sealed sources containing licensed material shall not be opened.

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15. The licensee shall not use licensed material in or on human beings or in field applications where activity is released except as provided otherwise by specific condition of this license.
16. Experimental animals administered licensed materials or their products shall not be used for human consumption.
17. Individuals who work in or whose duties may require them to work in restricted areas or in the vicinity of licensed materials, shall be instructed in the items specified in 10 CFR 19.12 at the time of initial employment and at least annually thereafter.
18. 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.  
(3) 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. 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.

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19. The licensee shall establish "lock-out" procedures to assure that prior to maintenance or repair in or around equipment to which licensed gauges are mounted, steps are taken to terminate the radiation beams, (e.g., "lock-out" shutters, placement of "beam stoppers," etc.) to prevent individuals from entering the radiation beam.
20. Within ninety (90) days after date of this amendment, the licensee shall implement, maintain, and execute the response measures of his Radiological Contingency Plan submitted to the Commission on June 30, 1981, and supplemented by a submittal made on January 22, 1982, June 6, 1984 and May 10, 1985. The licensee shall also prepare and maintain implementing procedures for his Radiological Contingency Plan as necessary to implement the Plan. The licensee shall make no change in his Radiological Contingency Plan that would decrease the response effectiveness of the Plan without prior Commission approval as evidenced by license amendment. The licensee may make changes to his Radiological Contingency Plan without prior Commission approval if the changes do not decrease the response effectiveness of the Plan. The licensee shall maintain records of changes that are made to the Plan without prior approval for a period of two years from the date of the change and shall furnish the Chief, Material Licensing Branch, Division of Fuel Cycle and Material Safety, NMSS, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555, and the appropriate NRC Regional Office specified in Appendix D of 10 CFR Part 20, a report containing a description of each change within six months after the change is made.
21. 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."
21. 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 August 26, 1983; letters dated May 10, 1985 and June 25, 1985; the licensee's Radiological Contingency Plan dated June 30, 1981, as amended by letters dated January 22, 1982, June 6, 1984 and May 10, 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 23, 1985

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

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UNITED STATES  
NUCLEAR REGULATORY COMMISSION  
REGION III  
799 ROOSEVELT ROAD  
GLEN ELLYN, ILLINOIS 60137

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TO THE LICENSEE:

Enclosed is the NRC license or license amendment which you requested.

You are encouraged to carefully review your license or amendment upon receipt as special conditions may have been added to ensure that the changes requested meet NRC requirements.

Any future correspondence relating to your license should specifically reference your license number to expedite your inquiry.

Should you have any questions regarding your new license or amendment or require clarification, please contact the Materials Licensing Section at 312/790-5625 or 312/790-5743.

Materials Licensing Section

Enclosure: As Stated