

## MATERIALS LICENSE

Amendment No. 39

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 November 29, 1983	
1. Miles Laboratories, Inc.		3. License number 13-02249-01 is amended in its entirety to read as follows:	
2. P.O. Box 40 Elkhart, IN 46515		4. Expiration date	July 31, 1990
		5. Docket or Reference No.	030-04336
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 with Atomic Nos. 1 through 83, inclusive	A. Any	A. As authorized in 33.100, Schedule A, Column I of 10 CFR Part 33. Total possession limited to the sum of the ratios for all radionuclides possessed (excluding those listed below) shall not exceed unity.	
B. Nickel-63	B. Foil or plated sources (which have been evaluated and registered with the NRC or an Agreement State)	B. No single source to exceed 15 millicuries	
C. Cesium-137	C. Sealed sources (which have been evaluated and registered with the NRC or an Agreement State)	C. No single source to exceed 1 curie. Not to exceed 20 curies total.	
D. Krypton-85	D. Sealed source (which have been evaluated and registered with the NRC or an Agreement State)	D. No single source to exceed 1 curie. Not to exceed 10 curies total.	

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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

E. Hydrogen-3

E. Plated/Foil source  
(which have been  
evaluated and registered  
with the NRC or an  
Agreement State)

E. No single source  
to exceed 200  
millicuries each

9. Authorized Use

- A. For pharmaceutical research and development as defined in Section 30.4(q), 10 CFR Part 30, including animal studies and in-house instrument calibration. 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. and E. For use in gas chromatographs (which have been evaluated by the NRC or an Agreement State) for sample analysis.
- C. and D. For use in source holders (which have been evaluated and registered with the NRC or an Agreement State) for industrial process measurements of flow, level and/or density of materials.

CONDITIONS

10. Licensed materials may be used or stored at facilities which have been evaluated and approved by the licensee's radiation safety officer at 1127 Myrtle Street, Elkhart, Indiana; 3400 Middlebury Street, Elkhart, Indiana; 1301 North Nappanee Court, Elkhart, Indiana; 430 South Beiger, Mishawaka, Indiana; 4315 South Lafayette, South Bend, Indiana and 4718 Yender Avenue, Lisle, Illinois.
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 materials may be used by or under the supervision of individuals designated by the licensee's Radiation Safety Officer, Kenyon D. Yoder.
13. This license does not authorize commercial distribution to persons licensed pursuant to Sections 35.14 and 35.100 of 10 CFR Part 35.
14. 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.

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15. Experimental animals administered licensed materials or their products shall not be used for human consumption.
16. Sealed, plated, or foil sources containing licensed material shall not be opened.
17. 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.
18. A. (1) Each sealed, plated or foil 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 those sealed sources as specified by the manufacturer and specifically authorized by the Commission or an Agreement State may be leak tested at intervals not to exceed three years. 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) 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 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. Installation, relocation, removal from service, and initial radiation survey of devices containing licensed material shall be performed only by Kenyon D. Yoder in accordance with the manufacturer's instruction manual and recommendations, by the device manufacturer, or by other persons specifically authorized by the Commission or an Agreement State to perform such services. Maintenance and repair of devices, and installation, replacement, and disposal of sealed sources containing licensed material used in devices shall be performed only by the device manufacturer or by other persons specifically authorized by the Commission or an Agreement State to perform such services.
20. 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.
21. 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.
22. 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.
23. 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."
24. 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 letter dated June 11, 1985 (with attachments). 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 George M. McCann

Materials Licensing Section, Region III

Date July 23, 1985

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