

## U.S. NUCLEAR REGULATORY COMMISSION

**Amendment No. 01****MATERIALS LICENSE**

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, 36, 39, 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 <b>April 8, 2013</b>	
1. Pharmacia & Upjohn Company LLC		3. License number 21-32848-04	
2. 7000 Portage Road Kalamazoo, MI 49001		4. Expiration date October 31, 2022	
		5. Docket No. 030-38566 Reference No.	
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. Cesium-137	A. Sealed sources registered either with NRC under 10 CFR 32.210 or with an Agreement State and incorporated in a compatible gauging device as specified in Item 9 of this license.	A. 4 sources not to exceed 20 millicuries each, 2 sources not to exceed 5 millicuries each, 1 source not to exceed 50 millicuries and 1 source not to exceed 100 millicuries. Total not to exceed 240 millicuries.	

## 9. Authorized use:

- A. For use in Kay Ray Model 7062BP, TN Technologies Models 5200 and 5205, and Thermo Measure Tech Model 5201 source holders for level measurements.

CONDITIONS

10. Licensed material may be used only at the licensee's facilities located at 7000 Portage Road, Kalamazoo, Michigan.
11. The Radiation Safety Officer (RSO) for this license is **Mary M. Murphy**.
12. Licensed material shall be used by, or under the supervision of individuals who have received the training described in the application dated July 17, 2012. The licensee shall maintain records of individuals designated as users for 3 years following the last use of licensed material by the individual.
13. A. Sealed sources shall be tested for leakage and/or contamination at intervals not to exceed the intervals specified in the certificate of registration issued by the U.S. Nuclear Regulatory Commission under 10 CFR 32.210 or by an Agreement State.

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- B. In the absence of a certificate from a transferor indicating that a leak test has been made within the intervals specified in the certificate of registration issued by the U.S. Nuclear Regulatory Commission under 10 CFR 32.210 or by an Agreement State, prior to the transfer, a sealed source received from another person shall not be put into use until tested and the test results received.
- C. Sealed sources need not be tested if they are in storage and are not being used. However, when they are removed from storage for use or transferred to another person, and have not been tested within the required leak test interval, they shall be tested before use or transfer. No sealed source shall be stored for a period of more than 10 years without being tested for leakage and/or contamination.
- D. The leak test shall be capable of detecting the presence of 0.005 microcurie of radioactive material on the test sample. If the test reveals the presence of 0.005 microcurie or more of removable contamination, a report shall be filed with the U.S. Nuclear Regulatory Commission in accordance with 10 CFR 30.50(c)(2), and the source shall be removed immediately from service and decontaminated, repaired, or disposed of in accordance with Commission regulations. The report shall be filed within 5 days of the date the leak test result is known with the appropriate U.S. Nuclear Regulatory Commission, Regional Office referenced in Appendix D of 10 CFR Part 20. The report shall specify the source involved, the test results, and corrective action taken.
- E. Tests for leakage and/or contamination shall be performed by persons specifically licensed by the Commission or an Agreement State to perform such services. In addition, the licensee is authorized to collect leak test samples but not perform the analysis: analysis of leak samples must be performed by persons specifically licensed by the Commission or an Agreement State to perform such services.
- F. Records of leak test results shall be kept in units of microcuries and shall be maintained for 3 years.
14. Sealed sources containing licensed material shall not be opened or sources removed from source holders by the licensee, except as specifically authorized.
15. The licensee shall conduct a physical inventory every 6 months, or at other intervals approved by the U.S. Nuclear Regulatory Commission, to account for all sealed sources and/or devices received and possessed under the license. Records of inventories shall be maintained for 5 years from the date of each inventory, and shall include the radionuclides, quantities, manufacturer's name and model numbers, and the date of the inventory.
16. A. Each gauge shall be tested for the proper operation of the on-off mechanism (shutter) and indicator, if any, at intervals not to exceed 6 months or at such longer intervals as specified in the certificate of registration issued by the U.S. Nuclear Regulatory Commission pursuant to 10 CFR 32.210 or the equivalent regulations of an Agreement State.
- B. Notwithstanding the periodic on-off mechanism (shutter) and indicator test, the requirement does not apply to gauges that are stored, not being used, and have the shutter lock mechanism in a locked position. The gauges exempted from this periodic test shall be tested before use.

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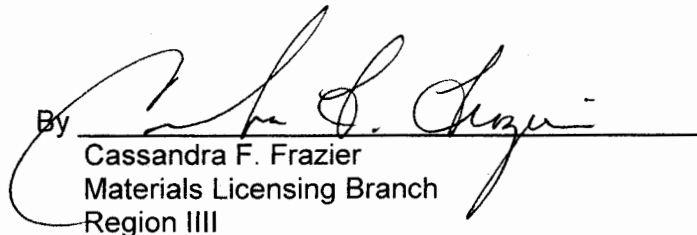
17. The following services shall not be performed by the licensee: installation, initial radiation surveys, relocation, removal from service, dismantling, alignment, replacement, disposal of the sealed source and non-routine maintenance or repair of components related to the radiological safety of the gauge (i.e., the sealed source, the source holder, source drive mechanism, on-off mechanism (shutter), shutter control, shielding). These services shall be performed only by persons specifically licensed by the U.S. Nuclear Regulatory Commission or an Agreement State to perform such services.
18. The licensee may initially mount a gauge if permitted by the certificate of registration issued by the U.S. Nuclear Regulatory Commission or an Agreement State and under the following conditions:
- A. the gauge must be mounted in accordance with written instructions provided by the manufacturer;
  - B. the gauge must be mounted in a location compatible with the "Conditions of Normal Use" and "Limitations and/or Other Considerations of Use" in the certificate of registration issued by the U.S. Nuclear Regulatory Commission or an Agreement State;
  - C. the on-off mechanism (shutter) must be locked in the off position, if applicable, or the source must be otherwise fully shielded;
  - D. the gauge must be received in good condition (i.e., package was not damaged); and
  - E. the gauge must not require any modification to fit in the proposed location.
- Mounting does not include electrical connection, activation or operation of the gauge. The source must remain fully shielded and the gauge may not be used until it is installed and made operational by a person specifically licensed by the U.S. Regulatory Commission or an Agreement State to perform such operations.
19. A. The licensee may maintain, repair, or replace device components that are not related to the radiological safety of the device containing byproduct material and that do not result in the potential for any portion of the body to come into contact with the primary beam or in increased radiation levels in accessible areas.
- B. The licensee may not maintain, repair, or replace any of the following device components: the sealed source, the source holder, source drive mechanism, on-off mechanism (shutter), shutter control, or shielding, or any other component related to the radiological safety of the device, except as provided otherwise by specific condition of this license.
20. Prior to initial use and after installation, relocation, dismantling, alignment, or any other activity involving the source or removal of the shielding, the licensee shall assure that a radiological survey is performed to determine radiation levels in accessible areas around, above, and below the gauge with the shutter open. This survey shall be performed only by persons authorized to perform such services by the U.S. Regulatory Commission or an Agreement State.
21. The licensee shall operate each device containing licensed material within the manufacturer's specified temperature and environmental limits such that the shielding and shutter mechanism of the source holder are not compromised.

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22. The licensee shall assure that the shutter mechanism of each device is locked in the closed position during periods when a portion of an individual's body may be subject to the direct radiation beam. The licensee shall review and modify, as appropriate, its "lock-out" procedures whenever a new device is obtained to incorporate the device manufacturer's recommendations.
23. Except for maintaining labeling as required by 10 CFR Part 20, or 71, the licensee shall obtain authorization from the U.S. Nuclear Regulatory Commission before making any changes in the sealed source, device or source-device combination that would alter the description or specifications as indicated in the respective certificate of registration issued either by the Commission pursuant to 10 CFR 32.210 or by an Agreement State.
24. The licensee is authorized to transport licensed material in accordance with the provisions of 10 CFR Part 71, "Packaging and Transportation of Radioactive Material."
25. Except as specifically provided otherwise in this license, the licensee shall conduct its program in accordance with the statements, representations, and procedures contained in the documents, including any enclosures, listed below. The U.S. Nuclear Regulatory Commission's regulations shall govern unless the statements, representations, and procedures in the licensee's application and correspondence are more restrictive than the regulations.
- A. Application dated July 17, 2012; and
- B. Letters dated July 30, 2012, and **June 20, 2013**.

FOR THE U.S. NUCLEAR REGULATORY COMMISSION

Date JUN 27 2013

By   
Cassandra F. Frazier  
Materials Licensing Branch  
Region III