

**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, 37, 39, 40, 70 and 71, 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.

<p>Licensee</p> <p>1. Pharmacia &amp; Upjohn Company LLC</p>		<p>In accordance with letter dated March 22, 2018.</p>	<p>4. Expiration Date: October 31, 2022</p>	
<p>2. 7000 Portage Road PORT-41-016 Kalamazoo, MI 49001</p>		<p>3. License number: 21-32848-04 is amended in its entirety to read as follows:</p>	<p>5. Docket No.: 030-38566 Reference No.:</p>	
<p>6. Byproduct, source, and/or special nuclear material</p> <p>A. Cesium-137</p> <p>B. Cesium-137</p> <p>C. Cesium-137</p> <p>D. Cesium-137</p>	<p>7. Chemical and/or physical form</p> <p>A. Sealed Sources (Kay-Ray/Sensall, Inc. Model 7700-Y Series)</p> <p>B. Sealed Sources (Thermo Fisher Scientific, Model 696894)</p> <p>C. Sealed Sources (Thermo Process Instruments, L.P., Model 57157C; 696894)</p> <p>D. Sealed Sources (QSA Global, Inc., Model CDC.700; CDC.711M)</p>	<p>8. Maximum amount that licensee may possess at any one time under this license</p> <p>A. 5 millicuries per source and 10 millicuries total</p> <p>B. 100 millicuries per source and 120 millicuries total</p> <p>C. 50 millicuries per source and 50 millicuries total</p> <p>D. 10 millicuries per source and 20 millicuries total</p>	<p>9. Authorized use</p> <p>A. For use in Kay-Ray/Sensall, Inc. Model 7062BP fixed gauging devices to perform level measurements.</p> <p>B. For use in Thermo Fisher Scientific, Model 5200 fixed gauging devices to perform level measurements.</p> <p>C. For use in Thermo Process Instruments, L.P., Model 5201 fixed gauging devices to perform level measurements.</p> <p>D. For use in Thermo Process Instruments, L.P., Model 5205 fixed gauging devices to perform level measurements.</p>	

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**CONDITIONS**

10. Licensed material may be used or stored only at the licensee's facilities located at: 7000 Portage Road, Kalamazoo, Michigan, 49001.
11. The Radiation Safety Officer (RSO) for this license is Timothy J. Fedewa, CSP.
12. Licensed material shall only be used by, or under the supervision of, individuals who have received the training described in the application dated July 17, 2012, and have been designated in writing by the Radiation Safety Officer. 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 and detector cells 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. In the absence of a registration certificate, sealed sources shall be tested for leakage and/or contamination at intervals not to exceed 6 months, or at such other intervals as specified.
- 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 185 becquerels (0.005 microcuries) of radioactive material on the test sample. If the test reveals the presence of 185 becquerels (0.005 microcuries) 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.

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- E. Analysis of leak test samples and/or contamination shall be performed by persons specifically licensed by the U.S. Nuclear Regulatory Commission or an Agreement State to perform such services. The licensee is authorized to collect leak test samples but not perform the analysis.
- F. Records of leak test results shall be kept in units of becquerels (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 3 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. Records of test results shall be maintained for 3 years from the date of each test.
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.

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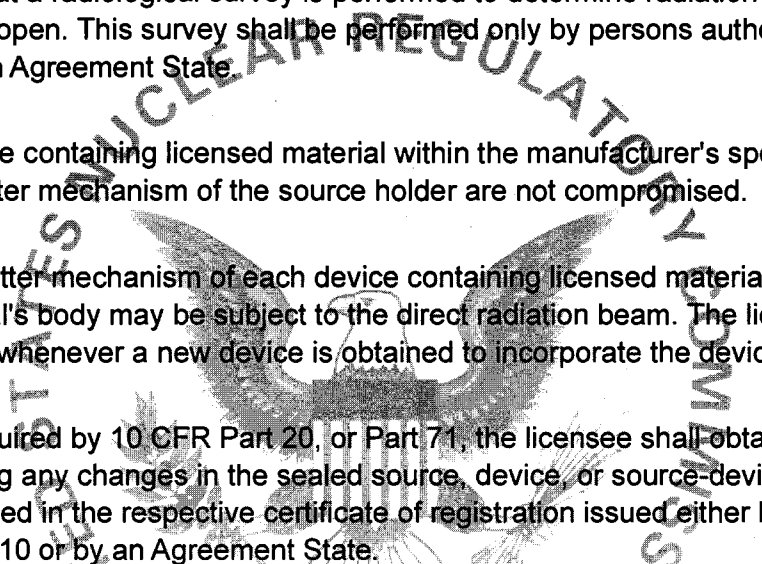
18. The licensee may initially mount a gauge, if permitted by the certificate of registration issued by the U.S. Nuclear Regulatory Commission or an Agreement State, and under the following conditions:
- A. The gauge must be mounted in accordance with written instructions provided by the manufacturer.
  - 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 conditions (e.g., the package was not damaged).
  - 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. Nuclear 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 licensed material and that do not result in the potential for any portion of the body to come into contact with the primary beam or result 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, shielding, or any other component related to the radiological safety of the device, except as provided otherwise by specific condition of this license.

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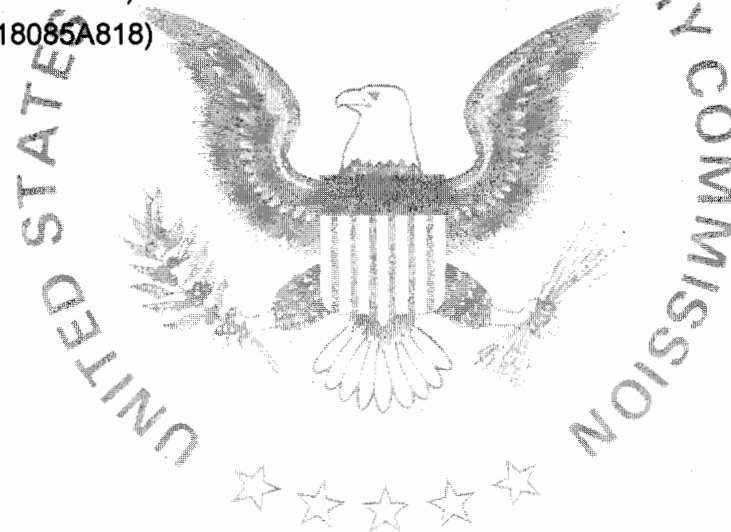
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20. Prior to initial use and after installation, relocation, dismantling, alignment, or any other activity involving the source or removal of the shielding, the licensee shall assure that a radiological survey is performed to determine radiation levels 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. Nuclear 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.
22. The licensee shall assure that the shutter mechanism of each device containing licensed material 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 Part 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 U.S. Nuclear Regulatory Commission pursuant to 10 CFR 32.210 or by an Agreement State.
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24. 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. This license condition applies only to those procedures that are required to be submitted in accordance with the regulations. 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. Letter dated July 30, 2012 including enclosed application dated July 17, 2012 (ML12213A397)
  - B. Letter dated June 20, 2013 (ML13204A187)
  - C. Letter dated March 22, 2018 (ML18085A818)



FOR THE U.S. NUCLEAR REGULATORY COMMISSION

Date: MAY 04 2018By: *Frank P.D. Tran*  
Frank P.D. Tran  
Region 3