

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. St. Peter's Hospital</p> <p>2. 2475 Broadway Helena, MT 59601</p>	<p>In accordance with letter dated February 13, 2018</p> <p>3. License number: 25-12453-02 is amended in its entirety to read as follows:</p>	<p>4. Expiration Date: February 29, 2024</p>	
		<p>5. Docket No.: 030-10917 Reference No.:</p>	
<p>6. Byproduct, source, and/or special nuclear material</p> <p>A. Any byproduct material permitted by 10 CFR 35.100</p> <p>B. Any byproduct material permitted by 10 CFR 35.200</p> <p>C. Any byproduct material permitted by 10 CFR 35.300</p> <p>D. Palladium-103 permitted by 10 CFR 35.400</p>	<p>7. Chemical and/or physical form</p> <p>A. Any</p> <p>B. Any</p> <p>C. Any</p> <p>D. Sealed Sources (IsoAid, L.L.C., Model IAPd-103A (Advantage™ Pd-103))</p>	<p>8. Maximum amount that licensee may possess at any one time under this license</p> <p>A. As Needed</p> <p>B. As Needed</p> <p>C. 500 millicuries total</p> <p>D. 15 millicuries per source and 4 curies total</p>	<p>9. Authorized use</p> <p>A. For use in uptake, dilution and excretion studies permitted by 10 CFR 35.100.</p> <p>B. For use in imaging and localization studies permitted by 10 CFR 35.200.</p> <p>C. For any use permitted by 10 CFR 35.300.</p> <p>D. For any manual brachytherapy procedure permitted by 10 CFR 35.400 for which the patient can be released under the provisions of 10 CFR 35.75.</p>

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SUPPLEMENTARY SHEET**

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Docket or Reference Number
030-10917

Amendment No. 48

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| <p>6. Byproduct, source, and/or special nuclear material</p> <p>E. Cobalt-57</p> <p>F. Gadolinium-153</p> | <p>7. Chemical and/or physical form</p> <p>E. Sealed Sources (Isotope Products Laboratories, Model PHI-057; QSA Global, Inc., Model CTC.P2)</p> <p>F. Sealed Sources (Isotope Products Laboratories, Model A3409 or A3432)</p> | <p>8. Maximum amount that licensee may possess at any one time under this license</p> <p>E. 50 microcuries per source and 150 microcuries total</p> <p>F. 10 millicuries per source and 30 millicuries total</p> | <p>9. Authorized use</p> <p>E. For use with the Symbia Series of integrated SPECT or SPECT/CT systems for performance of automated quality control of the nuclear camera system.</p> <p>F. For use with the Symbia Series of integrated SPECT or SPECT/CT systems for performance of automated quality control of the nuclear camera system.</p> |
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CONDITIONS

10. Licensed material may be used or stored at the licensee's facilities located at:
- A. St. Peter's Hospital, 2475 Broadway, Helena, Montana (6.A.- 6.F.), and
 - B. St. Peter's Medical Group Broadway (SPMGB), Cardiology Clinic, 2550 Broadway, Helena, Montana (6.A., 6.B., 6.E., and 6.F.)
11. The Radiation Safety Officer (RSO) for this license is E. Jefferson Fairbanks, Ph.D.

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12. Licensed material shall only be used by, or under the supervision of:

- A. Individuals permitted to work as authorized users, authorized nuclear pharmacists, and/or authorized medical physicists, in accordance with 10 CFR 35.13 and 10 CFR 35.14.
- B. The following individuals are authorized users for the material and medical uses as indicated:

<u>Authorized User(M.D.,D.O.,etc.)</u>	<u>Material and Use</u>
Andrew C. Cupino, M.D.	35.300; 35.400
Christopher M. Gabel, M.D.	35.100; 35.200
Robert Raymond Phillips, M.D.	35.200
Brian R. Robinson, D.O.	Oral administration of sodium-iodide I-131
James Kennedy Tarver, M.D.	35.200

13. For sealed sources not associated with 10 CFR Part 35 use, the following conditions apply:

- 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. Notwithstanding Paragraph A of this Condition, sealed sources designed to primarily emit alpha particles shall be tested for leakage and/or contamination at intervals not to exceed 3 months.
- C. 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.

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- D. Sealed sources need not be tested if they contain only hydrogen 3; or they contain only a radioactive gas; or the half-life of the isotope is 30 days or less; or they contain not more than 100 microcuries of beta- and/or gamma-emitting material or not more than 10 microcuries of alpha-emitting material.
- E. 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.
- F. 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.
- G. 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.
- H. Records of leak test results shall be kept in units of becquerels (microcuries) and shall be maintained for 3 years.
14. 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.
15. Sealed sources containing licensed material shall not be opened or sources removed from source holders by the licensee, except as specifically authorized.

