

U.S. NUCLEAR REGULATORY COMMISSION

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 style="text-align: center;">Licensee</p> <p>1. XingImaging LLC, a Mitro Company</p> <p>2. 55 Church Street New Haven, CT 06510</p>	<p>In accordance with application dated May 31, 2024,</p> <p>3. License No.: 06-35755-01</p>	<p>4. Expiration Date: August 31, 2039</p> <p>5. Docket No.: 030-39383 Reference No.:</p>
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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	9. Authorized use
A. Any byproduct material permitted by 10 CFR 35.100	A. Any	A. As Needed	A. For use in uptake, dilution and excretion studies permitted by 10 CFR 35.100.
B. Any byproduct material permitted by 10 CFR 35.200	B. Any	B. As Needed	B. For use in imaging and localization studies permitted by 10 CFR 35.200.
C. Fluorine-18	C. Any	C. 8 curies total	C. For research and development as defined in 10 CFR 30.4 excluding animal studies, tracer and field studies.
D. Copper-64	D. Any	D. 200 millicuries total	D. For research and development as defined in 10 CFR 30.4 excluding animal studies, tracer and field studies.

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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	9. Authorized use
E. Zirconium-89	E. Any	E. 200 millicuries total	E. For research and development as defined in 10 CFR 30.4 excluding animal studies, tracer and field studies.
F. Technetium-99m	F. Any	F. 500 millicuries total	F. For research and development as defined in 10 CFR 30.4 excluding animal studies, tracer and field studies.
G. Indium-111	G. Any	G. 200 millicuries total	G. For research and development as defined in 10 CFR 30.4 excluding animal studies, tracer and field studies.



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CONDITIONS

10. Licensed material shall be used or stored at the licensee's facilities located at: 55 Church Street, Suites 500 and B05, New Haven, Connecticut, 06510
11. The Radiation Safety Officer (RSO) for this license is John P. Seibyl, M.D.
12. A. Individuals permitted to work as authorized users 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> |
|---|---|
| John P. Seibyl, M.D. | 10 CFR 35.100, 10 CFR 35.200, CU64, F18, IN111, TC99M, ZR89 |
13. In addition to the possession limits in Item 8, the licensee shall further restrict the possession of licensed material to quantities below the minimum limit in 10 CFR 30.35(d) for which decommissioning financial assurance is required.

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14. 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 statements, representations, and procedures that are required to be submitted in accordance with the regulations. Additionally, this license condition does not limit the licensee's ability to make changes to the radiation protection program as provided for in 10 CFR 35.26. The U.S. Nuclear Regulatory Commission's regulations shall govern unless the statements, representations, and procedures in the licensee's application and correspondence impose on the licensee requirements that are more restrictive than or in addition to the regulations.

- A. Application dated May 31, 2024 [ML24163A047]
- B. Letter dated August 8, 2024 [ML24233A028]



FOR THE U.S. NUCLEAR REGULATORY COMMISSION

Date: August 29, 2024By: _____
Robin Elliott
Region 1