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, 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	
1. **Mallinckrodt Nuclear Medicine LLC**	In accordance with letter dated **February 22, 2016**, 3. License No. 24-04206-05MD is amended in its entirety to read as follows:
2. 2703 Wagner Place Maryland Heights, Missouri 63043	4. Expiration Date: July 31, 2022
	5. Docket No. 030-10801 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. Iodine-131	A. Sodium Iodide I-131 capsules (NDA 16-517)	A. Not applicable
B. Iodine-131	B. Sodium Iodide I-131 aqueous solution (NDA 16-515)	B. Not applicable
C. Molybdenum-99/Technetium-99m	C. Molybdenum-99/Technetium-99m generators [Mallinckrodt Ultra-TechneKow™ Dry Top Eluting DTE and Ultra-TechneKow™ V4 Generators (NDA No. 17-243)]	C. No single generator to exceed 19.0 curies at the time of shipment
D. Indium-111	D. Indium Chloride In-111 sterile solution (NDA 20-314 and 19-841)	D. Not applicable
E. Thallium-201	E. Thallous Chloride Tl-201 sterile solution (NDA 18-150)	E. Not applicable
F. Gallium-67	F. Gallium Citrate Ga-67 sterile solution (NDA 18-058)	F. Not applicable
G. Iodine-123	G. Sodium Iodide I-123 solution absorbed into sucrose within a gelatin capsule (NDA 17-909 and NDA 17-910)	G. Not applicable
H. Xenon-133	H. Xenon Xe-133 gas (NDA 18-327)	H. Not applicable

MATERIALS LICENSE
SUPPLEMENTARY SHEET

License No.
24-04206-05MD

Docket or Reference No.
030-10801

Amendment No. 48

9. Authorized Use:

Pursuant to Section 32.72 and 32.74 of 10 CFR Part 32, the licensee is authorized to distribute the byproduct material described in Items 6 and 7 of this license to persons licensed pursuant to Sections 35.100, 35.200 and 35.300 of 10 CFR Part 35, or under equivalent licenses of Agreement States, for the Sections indicated below:

A. and B.	Sections 35.100, 35.200 or 35.300.
C.	Section 35.200 or for distribution to commercial nuclear pharmacies.
D. through H.	Sections 35.100 or 35.200.

CONDITIONS

10. Each product distributed under this license shall not contain, as of the assay date (labeled size at calibration), more than the quantity of byproduct material listed in the table contained in Attachment D to the licensee's letter dated March 16, 2015.

11. The licensee may distribute material from the licensee's facilities located at 2703 Wagner Place, Maryland Heights, Missouri.

12. This license does not authorize possession or use of licensed material.

13. The Radiation Safety Officer (RSO) for this license is Manuel Diaz.

14. The licensee shall notify the U. S. Nuclear Regulatory Commission within thirty (30) days of the termination of a "Notice of Claimed Investigational Exemption for a New Drug (IND) for licensed material described in Items 6 and 7.

15. The licensee may transport licensed material in accordance with the provisions of 10 CFR Part 71, "Packaging and Transportation of Radioactive Material."

16. Any proposed change to shielding that will increase the radiation levels of the packaging shall be submitted to the NRC for review. Any proposed change to labeling that will cause a change to radioactive markings or labeled activity, other than position and increasing the size of symbols and wording, shall be submitted to NRC for review.

MATERIALS LICENSE
SUPPLEMENTARY SHEET

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Amendment No. 48

17. Except as specifically provided otherwise by this license, the licensee shall manufacture, package, label and distribute licensed material described in Items 6 and 7 of this license and 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. Letter dated April 28, 2011 (with attachments) (ML111220490)
B. Letter dated February 7, 2012 (with attachments) (ML120390356)
C. Letter dated August 30, 2012 (ML12249A442)
D. Application dated March 5, 2013 (re: labeling revisions) (ML13067A379)
E. Letter dated July 11, 2013 (including attached SEC Form 8-K dated June 28, 2013) (ML13196A098)
F. Letter dated July 18, 2013 (ML13200A380)
G. Application dated July 24, 2014 (ML14209A090)
H. Application dated August 22, 2014 (re: RSO Delegation of Authority) (ML14239A329)
I. Letter dated October 27, 2014 (re: Figures 1 and 2 organization charts) (ML14322A998)
J. Letter dated March 16, 2015 (ML15077A494)
K. Letter dated September 21, 2015 (ML15265A509)
L. Letter dated February 22, 2016 (ML16076A387)

FOR THE U. S. NUCLEAR REGULATORY COMMISSION

Date MAY 17 2016

By _____

Bryan A. Parker
Materials Licensing Branch
Region III