December 19, 2023

U.S. Nuclear Regulatory Committee Region III
Material Licensing Section
2443 Warrenville Road, Suite 210
Lisle, Illinois 60532

Re: Radioactive Material License: 13-12367-01
Norton Clark Hospital

To Whom it May Concern:

This letter is an amendment for the above mentioned radioactive material license. See the requests below:

1. Please remove Dr. Boyd as the Radiation Safety Officer on the license
2. Please add Jodi Daves as the Radiation Safety Officer (RSO).
    a. See attached radioactive material license listing Jodi Daves as the RSO indicating the requirements as listed in 35.50

If you require further information, please contact the Radiation Safety Officer, Jodi Daves, at jodidaves@gmail.com.

Sincerely,

Kathleen Exline

Kathleen Exline
CAO

RECEIVED DEC 29 2023

Duties and Responsibilities of the Radiation Safety Officer

Norton Clark Hospital Radioactive Material License 13-12367-01

The duties and responsibilities of the Radiation Safety Officer (RSO) include ensuring radiological safety and compliance with the NRC and DOT regulations and the terms and conditions of the license. Model procedures for describing the RSO's duties and responsibilities appear below. The RSO is responsible for ensuring the safe use of radiation. Responsibilities include managing the Radiation Protection Program; identifying radiation protection problems; initiating, recommending, or providing corrective actions; verifying implementation of corrective actions; stopping unsafe activities; and ensuring compliance with regulations. Applicants may either adopt these model procedures or develop alternative procedures to meet the requirements of 10 CFR 35. Typically, these duties and responsibilities include ensuring the following:

- Unsafe activities involving licensed material are stopped;
- Radiation exposures are ALARA;
- Up-to-date radiation protection procedures in the daily operation of the licensee's byproduct material program are developed, distributed, and implemented;
- Possession, use, and storage of licensed material are consistent with the limitations in the license, the regulations, the SSDR certificate(s), and the manufacturer's recommendations and instructions;
- Individuals installing, relocating, maintaining, adjusting, or repairing devices containing sealed sources are trained and authorized by the Kentucky specific license or an NRC or other Agreement State license;
- Personnel training is conducted and is commensurate with the individual's duties regarding licensed material;
- Documentation is maintained to demonstrate that individuals are not likely to receive, in1 year, a radiation dose in excess of 10% of the allowable limits or that personnel monitoring devices are provided;
- When necessary, personnel monitoring devices are used and exchanged at the proper intervals, and records of the results of such monitoring are maintained;
- Licensed material is properly secured;
- Documentation is maintained to demonstrate, by measurement or calculation, that the total effective dose equivalent to the individual likely to receive the highest dose from the licensed operation does not exceed the annual limit for members of the public;
- Proper authorities are notified of incidents such as loss or theft of licensed material, damage to or malfunction of sealed sources, and fire;
- Medical events and precursor events are investigated and reported to the NRC, cause(s) and appropriate corrective action(s) are identified, and timely corrective action(s) are taken;

- If violations of regulations, license conditions, or program weaknesses are identified, effective corrective actions are developed, implemented, and documented;
- Licensed material is transported, or offered for transport, in accordance with all applicable U.S. Dept. of Transportation requirements;
- Licensed material is disposed of properly;
- Appropriate records are maintained; and
- An up-to-date license is maintained, and amendment and renewal requests are submitted in a timely manner.

DELEGATION OF AUTHORITY

You, Jodi Daves, have been appointed the Radiation Safety Officer and are responsible for ensuring the safe use of radiation. You are responsible for managing the radiation safety program; identifying radiation safety problems, initiating, recommending, or providing corrective actions; verifying implementation of corrective actions; stopping unsafe activities; and ensuring compliance with the regulations and the terms and conditions of the license and commitments contained therein. You are hereby delegated the authority necessary to meet those responsibilities, including prohibiting the use of radioactive material by employees who do not meet the necessary requirements and shutting down operations where justified by radiation safety. You are required to notify management of situations where staff is not cooperating and not addressing radiation safety issues. In addition, you are free to raise issues with the NRC at anytime.

Kathleen Exline

Kathleen Exline
CAO Norton Clark Hospital

12/19/23
Date

I accept the above responsibilities,

Jodi Daves M.S dABR

Jodi Daves
Radiation Safety Officer

12/21/23
Date

Cabinet for Health and Family Services
Commonwealth of Kentucky
Department for Public Health
275 E Main Street
Frankfort, KY 40621

Andy Beshear
Governor

Eric C. Friedlander
Secretary

Steven J. Stack, MD
Commissioner

Radioactive Material License

Norton Hospital
Norton Radiology Mailbox N-61
PO Box 35070
Louisville,KY 40232-5070

Attention: Scott Sims
Telephone: (502) 629-7629

Pursuant to KRS 211.842 et seq., the Kentucky Cabinet for Health and Family Services regulations 902 KAR Chapter 100, and in reliance on statements and representations heretofore made by the licensee, a license is hereby issued to receive, acquire, own, possess and transfer radioactive material listed below; and to use such radioactive material for the purpose(s) and at the place(s) designated below. This license is subject to all applicable rules, regulations, and orders of the Cabinet for Health and Family Services, now or hereinafter in effect and to any conditions specified below.

3.	License Number: Amendment No:	202-031-26 148
4.	Expiration Date:	February 28, 2024
5.	Reviewer:	81

Cabinet for Health and Family Services
Commonwealth of Kentucky
Department for Public Health
275 E Main Street
Frankfort, KY 40621

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6. Licensed Material	7. Form	8. Possession Limit
A. Any byproduct material permitted by 10 CFR 35.100	A. Any	A. As Needed
B. Any byproduct material permitted by 10 CFR 35.200	B. Any	B. As Needed
C. Any byproduct material permitted by 10 CFR 35.300	C. Any	C. 3 Curies total
D. Iodine-125 permitted by 10 CFR 35.400	D. Sealed source (Bards Brachytherapy Inc. Models: STM 1251 And Theraseed Agx 100; Isoaid Model: IAI-125A)	D. 500 Millicuries total
E. Palladium-103 permitted by 10 CFR 35.400	E. Sealed source (Theragenics Corporation Model: Theraseed model 200)	E. 1 Curies total
F. Cesium-131 permitted by 10 CFR 35.400	F. Sealed source (Isoray model: CS-1)	F. 500 Millicuries total
G. Yttrium-90 permitted by 10 CFR 35.1000	G. Microspheres (BWXT ITG Canada, INC. model Thera-Sphere y-90 glass microsphere)	G. 6.5 Curies total

H. Yttrium-90 permitted by 10 CFR 35.1000	H. Microspheres (Sitex Wilmington, LLC, Sitex Medical Limited, Or Ansto Radiopharmaceuticals And Industrials, Model Sir-Spheres)	H. 2 Curies total
I. Iodine-125 permitted by 10 CFR 35.1000	I. Sealed source (Isoaid model: IAI-125a or Best Medical International, Inc. model 2301)	I. 300 Microcuries per source and 15 Millicuries total
J. Yttrium-90 permitted by 10 CFR 35.1000	J. Microspheres (ABK Biomedical Inc. Model: Eye90 IDE# G230077)	J. 6.5 Curies total

9. Authorized Use

A. For use in uptake, dilution and excretion studies permitted by 10 CFR 35.100.

B. For use in imaging and localization studies permitted by 10 CFR 35.200.

C. For any use permitted by 10 CFR 35.300.

D. For any manual brachytherapy procedure permitted by 10 CFR 35.400.

E. For any manual brachytherapy procedure permitted by 10 CFR 35.400.

F. For any manual brachytherapy procedure permitted by 10 CFR 35.400.

G. Therasphere for permanent brachytherapy using delivery system as listed in sealed source and device registry NR-220-D-131-2.

H. Sir-Sphere for permanent brachytherapy using delivery system as listed in sealed source and device registry MA-1229-D-101-S.

I. For any use permitted by 10 CFR 35.1000 for which a patient can be released under the provisions of 10 CFR 35.75.

J. For any use permitted by 10 CFR 35.1000 for which a patient can be released under the provisions of 10 CFR 35.75

10. The licensee shall comply with the provisions of the Kentucky Cabinet for Health and Family Services Administrative Radiation Regulations 902 KAR Chapter 100.
11. Radioactive material shall be used only at the licensee's facilities located at:
    1. Norton Hospital, 200 E. Chestnut Street, Louisville, Ky 40202
    2. Norton Children's, 231 E. Chestnut Street, Louisville, Ky 40202
    3. Norton Medical Pavilion, 315 E. Broadway, Louisville, Ky 40202
    4. Norton Cancer Institute, 676 S. Floyd Street, Louisville, Ky 40202
12. Copies of records required pursuant to 902 KAR Chapter 100 or conditions of the license shall be maintained for inspection by the Cabinet at 200 E. Chestnut Street, Louisville, Ky 40202 and 676 S. Floyd Street, Louisville, Ky 40202
13. The radiation safety officer for the activities authorized by this license is Jodi Daves.
14. The associate radiation safety officer for the activities authorized by this license is Rhonda Haub, CNMT.
15. Sealed sources containing radioactive material shall not be opened or removed from their respective source holders by the licensee, except as specifically authorized.
16. In addition to the possession limits in Item 8, the licensee shall further restrict the possession of radioactive material to quantities below the minimum limit specified in 902 KAR 100:042, Sections 11, 12, and 13 for establishing decommissioning financial assurance.
17. The licensee shall comply with the provisions described in the Nuclear Regulatory Commission's most current licensing guidance for Yttrium-90 microsphere brachytherapy sources and devices Therasphere and Sir-spheres.
18. The licensee shall comply with the provisions described in the manufacturer's full prescribing information for Xofigo Radium-223 Dichloride injection for intravenous use as approved by the FDA in accordance with 902 KAR 100:072, section 79.

19. The licensee shall comply with the provisions described in the Investigational New Drug (IND) protocol accepted by the FDA for use in research.
20. The licensee may transport radioactive material, or deliver radioactive material to a carrier for transport, in accordance with the provisions of 902 KAR 100:070, and other departments of the Commonwealth of Kentucky having jurisdiction.
21. This license and the right to possess or utilize radioactive material granted by this license issued under 902 KAR Chapter 100 shall not be transferred, assigned, or otherwise disposed of, through transfer of control of a license to a person unless the Cabinet, after securing full information, finds that the transfer is in accordance with the requirements of 902 KAR Chapter 100 and gives its consent, in writing, in accordance with 902 KAR 100:040, Section 11.
22. Tests for leakage and/or contamination shall be performed by persons specifically authorized by the Cabinet, U.S. Nuclear Regulatory Commission, or an Agreement State.
23. The licensee shall comply with the provisions described in the Nuclear Regulatory Commission's most current licensing guidance for low activity radioactive seeds used for localization of non-palpable lesions and lymph nodes.
24. Licensed material shall only be used by, or under the supervision of:
A. Individuals permitted to work as an authorized user, authorized medical physicist, and authorized nuclear pharmacist in accordance with 10 CFR 35.13 and 10 CFR 35.14 (902 KAR 100:072).

B. The following individuals are authorized users for medical use as indicated:

Authorized User:	Material and use: 902 KAR 100:072:
Stewart C. Hoertz, M.D.	10 CFR 35.100, 10 CFR 35.200 and 10 CFR 35.300 limited to oral administration of Sodium Iodide I-131, and 10 CFR 35.1000 limited to Iodide-125 for radioactive seed localization
Edward C. Crase, M.D.	10 CFR 35.100; 35.200

Ibrahim Fahsah, M.D.	10 CFR 35.100; 35.200
James N. Hiken, M.D.	10 CFR 35.100; 35.200
Brian C. Jones, M.D.	10 CFR 35.100; 35.200
Vesna Kriss, M.D.	10 CFR 35.100; 35.200
Karen K. Moeller, M.D.	10 CFR 35.100; 35.200
Syed Raza, M.D.	10 CFR 35.100; 35.200
Anil K. Sharma, M.D.	10 CFR 35.100; 35.200
Janet L. Smith, M.D.	10 CFR 35.100; 35.200
Matthew Sweat, M.D.	10 CFR 35.100; 35.200
Daniel Stewart, M.D.	10 CFR 35.100; 35.200
Marilee Benson, M.D.	10 CFR 35 .100, 10 CFR 35 .200, 10 CFR 35.300 limited to oral administration of Sodium Iodide I-131 in quantities less than or equal to 33 Millicuries
John T. Burger, M.D.	10 CFR 35 .100, 10 CFR 35 .200, 10 CFR 35.300 limited to oral administration of Sodium Iodide I-131 in quantities less than or equal to 33 Millicuries
Rebecca Feller, M.D.	10 CFR 35 .100, 10 CFR 35 .200, 10 CFR 35.300 limited to oral administration of Sodium Iodide I-131 in quantities less than or equal to 33 Millicuries
Lawrence Kelly, M.D.	10 CFR 35 .100, 10 CFR 35 .200, 10 CFR 35.300 limited to oral administration of Sodium Iodide I-131 in quantities less than or equal to 33 Millicuries

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Commonwealth of Kentucky
Department for Public Health
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Durrett Carter Craddock, M.D.	10 CFR 35.100, 10 CFR 35.200, 10 CFR 35.300 limited to oral administration of Sodium Iodide I-131
Alan Northington, M.D.	10 CFR 35.100, 10 CFR 35.200, 10 CFR 35.300 limited to oral administration of Sodium Iodide I-131
Greg S. Walton, M.D.	10 CFR 35.100, 10 CFR 35.200, 10 CFR 35.300 limited to oral administration of Sodium Iodide I-131
Trevor Holland, M.D.	10 CFR 35.100, 10 CFR 35.200, 10 CFR 35.300 limited to oral administration of Sodium Iodide I-131
Brian D. Stoll, M.D.	10 CFR 35.300, 10 CFR 35.400
Michael J. Hahl, M.D.	10 CFR 35.300, 10 CFR 35.400 and 10 CFR 35.1000 limited to Yttrium-90 Sir-Spheres , Yttrium-90 Therasphere and Yttrium-90 Eye90.
Yong Cha, M.D.	10 CFR 35.300, 10 CFR 35.400
Mark Cornett, M.D.	10 CFR 35.300, 10 CFR 35.400 AND 10 CFR 35.1000 limited to Iodine-125 for radioactive seed localization
Terry E. Williams, M.D.	10 CFR 35.100, 10 CFR 35.200 and 10 CFR 35.300 limited to oral administration of Sodium Iodide I-131, and 10 CFR 35.1000 limited to Iodide-125 for radioactive seed localization

Bradley Williams, M.D.	10 CFR 35.100, 10 CFR 35.200 and 10 CFR 35.300 limited to oral administration of Sodium Iodide I-131, and 10 CFR 35.1000 limited to Iodide-125 for radioactive seed localization
Sarah H. Callahan, M.D.	10 CFR 35.100, 10 CFR 35.200 and 10 CFR 35.300 limited to oral administration of Sodium Iodide I-131, and 10 CFR 35.1000 limited to Iodide-125 for radioactive seed localization
Amanda Carricato, M.D.	10 CFR 35.100, 10 CFR 35.200, 10 CFR 300 to oral administration of Sodium Iodine I-131 in quantities less than or equal to 33 Millicuries, 10 CFR 35.1000 limited to Iodine-125 for radioactive seed localization
Arpit Agrawal, M.D.	10 CFR 35.100; 35.200
Melissa H. Potts, M.D.	10 CFR 35.100; 35.200
Armand Rothschild, M.D.	10 CFR 35.100; 35.200
Wayne Shugoll, M.D.	10 CFR 35.100; 35.200
William M. Skaggs, M.D.	10 CFR 35.100; 35.200
Steve Raible, M.D.	10 CFR 35.100; 35.200
C. Gregory Henes, M.D.	10 CFR 35.100; 35.200
Ponnattu Cherian, M.D.	10 CFR 35.100; 35.200
Jacob Nunamaker, M.D.	10 CFR 35.100; 35.200
John T. Kenny, M.D.	10 CFR 35.100; 35.200
Aaron Spalding, M.D., PH.D	10 CFR 35.300, 10 CFR 35.400

Comeron Ghobadi, M.D.	10 CFR 35.100, 10 CFR 35.200, 10 CFR 35.300 limited to oral administration of sodium iodide I-131.
Brittany Albers, M.D.	10 CFR 35.100, 10 CFR 35.200, 10 CFR 35.300 limited to oral administration of sodium iodide I-131
Melissa P Smith, M.D.	10 CFR 35.100, 10 CFR 35.200, 10 CFR 35.300 limited to oral administration of sodium iodide I-131
Nathaniel Thomson, D.O.	10 CFR 35.100, 10 CFR 35.200, 10 CFR 35.300 limited to oral administration of sodium iodide I-131
Basel M Altoos, M.D.	10 CFR 35.300, 10 CFR 35.400, and 10 CFR 35.1000 limited to Yttrium-90 Theraspheres and Yttrium-90 Eye90

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. The Cabinet for Health and Family Services regulations, 902 KAR Chapter 100, shall govern unless statements, representations, and procedures in the licensee's application and correspondence are more restrictive than the regulation.

A. Application dated December 17, 2021, Signed by DeeAnn Clark, Chief Administrative Officer.

Letters Dated:
1. August 1, 2023, signed by Scott Sims, Director, Medical Imaging (Linearity frequency change to annual)
2. August 9, 2023, email from Rhonda Haub, ARSO (copies of Signature Authorization forms)
3. August 11, 2023, signed by Scott Sims, Director, Medical Imaging and Jodi Daves, M.S. dABR (Add Y-90 Eye90 to license)

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Commonwealth of Kentucky
Department for Public Health
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License Number:202-031-26 Amendment:148 Radioactive Material License

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Manager
Radiation Health Branch

Eric C. Friedlander

Secretary
Cabinet for Health and Family Services

Date Issued:August 23, 2023