State of Washington

Radioactive Materials License

As stated in the Nuclear Energy and Radiation Act, Revised Code of Washington 70.98, and the Radiation Protection Regulations, chapters 246-220 through 246-254 of the Washington Administrative Code, and in reliance on statements and commitments made by the licensee identified below, a license is issued authorizing the licensee to transfer, receive, possess and use the radioactive material authorized below; and to use such radioactive material for the purpose(s) and at the place(s) authorized below. **This license is subject to all applicable rules and regulations issued by the State of Washington Department of Health.**

1. Licensee Name:	3. License Number:
NORTHWEST HOSPITAL AND MEDICAL CENTER	**WN-M004-1 Entirety** Amendment No. **85** Fee Code 17
2. Address: 1550 North 115th Street Seattle, Washington 98133	**4. Expiration Date:** 29 February 2020 **5. Reference Number(s):** 15-01-45, 15-06-26, 16-04-11, 16-04-49, 16-05-48, 16-06-27, 17-09-03, 17-09-29, 18-02-13, 18-09-24, 18-10-18, **19-01-05.**

6. Radioactive Material (element and mass number).	7. Chemical and/or Physical Form.	8. Maximum quantity licensee may possess at any one time.
A. Any radioactive material authorized by WAC 246-240-151.	A. Any.	A. As necessary for the uses authorized in Condition 9.A.
B. Any radioactive material authorized by WAC 246-240-157.	B. Any.	B. As necessary for the uses authorized in Condition 9.B.
C. Any radioactive material authorized by WAC 246-240-201.	C. Any.	C. As necessary for the uses authorized in Condition 9.C.
D. Plutonium 238.	D. Sealed Source (Cordis Pacemaker model 184A).	D. No single source to exceed 250 milligrams (4.25 curies), 750 milligrams (12.75 curies) total.

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Radioactive Materials License

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CONDITIONS

In addition to the restrictions in Item 6 and the possession limits in Item 8, the licensee shall further restrict their possession of licensed material to quantities below the limits specified in WAC 246-235-150, Schedule C which require consideration of the need for an emergency plan for responding to release of licensed material and to quantities below the minimum limit specified in WAC 246-235-075 for establishing decommissioning financial assurance.

9. Authorized use.

   A. Any uptake, dilution, or excretion study authorized by WAC 246-240-151 for which a written directive is not required.

   B. Any imaging or localization study authorized by WAC 246-240-157 for which a written directive is not required.

   C. Any procedure authorized by WAC 246-240-201 for which a written directive is required.

   D. To perform *follow-up procedures* on patients with already implanted pacemakers, and to return explanted pacemakers to the manufacturer.

10. A. Radioactive material authorized in subitems A-D of Items 6, 7, and 8 shall be used and/or stored ***at the licensee's address in Item 2.***

    B. Radioactive material authorized in Subitems B (*Technetium 99m and Thallium 201 only),* & D of Items 6, 7, and 8 may be used and/or stored at ***The Northwest Hospital & Medical Center-Cardiac Imaging Center—McMurray Building,*** Suite 200, 1536 North 115th, Seattle, Washington 98133.

11. The licensee shall comply with the provisions of chapter 246-220 WAC, "Radiation Protection -- General Provisions"; chapter 246-221 WAC, "Radiation Protection Standards"; chapter 246-222 WAC, "Radiation Protection -- Worker Rights"; chapter 246-231 WAC, "Packaging and Transportation of Radioactive Material"; chapter 246-232 WAC, "Radioactive Material -- Licensing Applicability,"; chapter 246-235 WAC, "Radioactive Material -- Specific Licenses"; chapter 246-240 WAC "Radiation Protection -- Medical Use of Radioactive Material"; chapter 246-247 WAC, "Radiation Protection -- Air Emissions"; chapter 246-249 WAC , "Radioactive Waste -- Use of the Commercial Disposal Site", and chapter 246-254 WAC, "Radiation Protection — Fees.".

12. The Radiation Safety Officer for this program shall be Phillip Campbell, CHP, MHP, RRPT.

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AUTHORIZED USERS

13. Radioactive material described in Subitems below shall be used by, or under the supervision of:

A.	Gregory James Allen, M.D.;	Subitems A & B of Items 6, 7, & 8.
B.	Ray Spalding Jensen, M.D.;	Subitems A-C of Items 6, 7, & 8.
C.	Julie Popp Heyn, M.D.;	Subitem B (*nuclear cardiology only*) of Items 6, 7, and 8.
D.	William Jeffrey Stanley, M.D.;	Subitem B (*nuclear cardiology only*) of Items 6, 7, and 8.
E.	Marko Yakovlevitch, M.D.;	Subitem B (*nuclear cardiology only*) of Items 6, 7, and 8.
F.	James Michael Schmitt, M.D.;	Subitem B (*nuclear cardiology only*) of Items 6, 7, and 8.
G.	Thomas Moore Richardson, Jr., M.D.;	Subitem B (*nuclear cardiology only*) of Items 6, 7, and 8.
H.	Michael Hung-Minh Duong, M.D.;	Subitem B (*nuclear cardiology only*) of Items 6, 7, and 8.
I.	Chetan Pungoti, M.D.;	Subitem B (*nuclear cardiology only*) of Items 6, 7, and 8.
J.	Thomas Jason Sawyer, M.D.;	Subitem B (*nuclear cardiology only*) of Items 6, 7, and 8.
K.	**Fatemeh (Sanaz) Behnia, M.D.;**	**Subitems A-C of Items 6, 7, & 8.**
L.	**David H. Lewis, M.D.;**	**Subitems A-C of Items 6, 7, & 8.**
M.	**Manuela Crstina Matesan, M.D.;**	**Subitems A-C of Items 6, 7, & 8.**
N.	**Hubert J. Vesselle, Ph.D., M.D.;**	**Subitems A-C of Items 6, 7, & 8.**

14. A. For a period not to exceed sixty (60) days in any one calendar year, a visiting physician is authorized to use licensed material under the terms and conditions of this license, provided the visiting physician:

    1. Has the prior written permission of the licensee's Administrator and its Radiation Safety Committee; and

    2. Is specifically named as an authorized user on an Agreement State or U.S. Nuclear Regulatory Commission license which authorizes human use; and

    3. Performs only those procedures, which the physician is specifically authorized to perform pursuant to the license issued by an Agreement State or the U.S. NRC.

    B. The licensee shall maintain for inspection by the Department copies of the written permission specified in License Condition 14.A.1, and any of the licenses specified in License Condition 14.A.2 and 14.A.3 for a period of at least five (5) years from the date permission is granted under License Condition 14.A.1.

15. Radioactive material to be administered to humans shall be the subject of an FDA-approved "New Drug Application" (NDA) or an FDA-accepted "Notice of Claimed Investigational Exemption for a New Drug" (IND).

16. A. Technetium 99m separated from Molybdenum 99 either by elution of a Molybdenum 99/Technetium 99m generator or by an extraction process shall be tested to detect and quantify Molybdenum 99 activity prior to administration to patients.

    B. The licensee shall not administer to patients Technetium 99m containing more than 5550 becquerels (0.15 microcurie) of Molybdenum 99 per 37 megabecquerels (1.0 millicurie) of Technetium 99m. The limit for Molybdenum 99 contamination represents maximum values and Molybdenum 99 contamination should be kept as low as reasonably achievable (ALARA) below these limits.

    C. In the absence of a certificate from a supplier for Technetium 99m which specifies the quantity of Molybdenum 99, the licensee shall establish written procedures for personnel performing tests to detect and quantify Molybdenum 99 contamination. These procedures shall include all necessary calculations and steps to be taken if activities of Molybdenum 99 in excess of limits specified in Condition 16.B are detected.

16. D. Personnel performing tests to detect and quantify Molybdenum 99 contamination shall be given specific training in performing these tests prior to conducting such tests.

E. The licensee shall maintain records of the results of each test performed to detect and quantify Molybdenum 99 contamination and records of training given to personnel for performing these tests. These records shall be maintained for inspection by the Department for three (3) years following the performance of the tests and the training of personnel.

17. A. Radioactive material to be administered to humans shall be assayed for activity to determine the dose within 20% accuracy prior to administration to patients. Doses which vary by more than ±20% of the prescribed dose shall not be administered.

B. The licensee shall establish written procedures for personnel to perform assays to an accuracy of 20% prior to being administered to patients.

C. The licensee shall record the results of each assay performed to determine the activity of each dose administered to a patient. Records shall be maintained for inspection by the Department for three (3) years following the performance of the assay.

18. A. 1. Each sealed source containing licensed material shall be tested for leakage and/or contamination at intervals not to exceed six (6) months. In the absence of a valid leak test certificate (or copy) from a transferor documenting that such a test has been made within six (6) months prior to the transfer, a sealed source received from another person shall not be put into use until tested and acceptable results received.

2. Notwithstanding the periodic leak test required by this condition, any licensed sealed source is exempt from such leak tests when the source contains 100 microcuries (3.7 megabecquerels) or less of beta and/or gamma emitting material or 10 microcuries (370 kilobecquerels) or less of alpha emitting material.

B. The test shall be capable of detecting the presence of 185 becquerels (0.005 microcurie) of radioactive material on the test sample. The test sample shall be taken from the sealed source, or from the surfaces of the device in which the sealed source is permanently mounted or stored, on which one might expect contamination to accumulate. Records of leak test results shall be kept in units of becquerels (or microcuries) and maintained for inspection by the Department.

18. C. If the test reveals the presence of 185 becquerels (0.005 microcuries) or more of removable contamination, the licensee shall immediately withdraw the sealed source from use and shall cause it to be decontaminated and repaired or to be disposed in accordance with Department regulations. A report shall be filed within five (5) days of the test with the Department describing the equipment involved, the test results, and the corrective action taken.

D. The licensee is authorized to perform leak test sampling in accordance with their Radioactive Materials License Application. The analysis shall be performed by persons specifically authorized by the Department, the U.S. Nuclear Regulatory Commission, or an Agreement State to perform such services. Alternatively, leak test samples may be collected and/or analyzed by other persons specifically authorized by the Department, the U.S. Nuclear Regulatory Commission or an Agreement State to perform such services.

19. The licensee shall conduct a physical inventory at least every six months to account for all sealed sources received and possessed under the license. Records shall include, but not be limited to, the nuclide, activity, serial number, actual physical location of the source(s), and the clearly legible name of the person performing the inventory. Records shall be kept for inspection by the Department.

20. Sealed sources containing licensed material shall not be opened, breached, or physically modified in any way.

21. The transport of licensed material by the licensee, or the delivery of licensed material to a carrier for transport, shall be in accordance with chapter 246-231 WAC, "Packaging and Transportation of Radioactive Material."

22. The licensee may use the "Calicheck" or "Lineator" device(s) and system(s) to perform required linearity tests of the dose calibrator(s) provided the requirements of the respective instruction manuals are adhered to. The manuals, respectively, are from Calcorp (March 1982 or subsequent revisions) or from Atomic Products Corporation (June 1983 or subsequent revisions).

23. The licensee shall establish and implement policies and procedures to provide reasonable assurance that a radiopharmaceutical or the radiation from radioactive material will not be unintentionally administered to a pregnant or breast-feeding woman.

24. Patients administered any radioactive material for therapeutic purposes shall be released according to criteria specified in U.S. Nuclear Regulatory Commission Regulatory Guide 8.39 "Release of Patients Administered Radioactive Materials", April 1997 or subsequent edition, or Appendix U "Model Procedure for Release of Patients or Human Research Subjects Administered Radioactive Material" of NuReg-1556, Volume 9, Revision 2, Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Medical Use Programs.

25. The licensee shall conduct a radioiodine bioassay program in accordance with criteria set forth in U.S.NRC Regulatory Guide 8.20, "Applications of Bioassay for Radioiodine", Revision 2 dated September 2014. When radioiodine capsules are used exclusively, radioiodine bioassays are required only when capsules are opened or crushed.

26. The licensee's emergency procedures shall follow procedures outlined in the Washington State Radiation Emergency Handbook revised May 2014 or subsequent revisions, or other procedures specifically approved by License Condition.

27. The requirements of WAC 246-240-128 notwithstanding, medical licensees may store sealed sources of Cobalt-57, Germanium-68, or Gadolinium-153 until decayed to background. These sources may then, after appropriate removal or obliteration of any and all markings showing the source to be radioactive, and after appropriate documented surveys to show no levels greater than background, dispose of such sources via regular trash. Records of surveys shall be maintained for inspection by the department.

28. The licensee shall respond in the manner, and within the time frame, specified to any and all Department correspondence necessary to keep the license and related information current.

    Where the licensee has submitted proposed corrective action, such action shall be fully implemented in a timely manner, unless the Department has subsequently modified the licensee's proposed corrective action.

29. Except as specifically provided by this license, the licensee shall possess and use radioactive material described in Items 6, 7, and 8 of this license, any disclaimers notwithstanding, in accordance with statements, representations, and procedures contained in the documents listed below. The Department's "Rules and Regulations for Radiation Protection" shall govern the licensee's statements in applications or letters, unless the statements are more restrictive than the regulations.

    A. Application and attachments dated 26 January 2015.

29. B. Letter & attachments dated 8 June 2015. RE: Add new nuclear cardiology AUR.

C. Letter & attachments dated 22 March 2016. RE: Add new AUR.

D. Letter & attachments dated 26 April 2016. RE: Change RSO.

E. Email dated 6 May 2016 from licensee, and amendment request from Providence- Everett dated 7 June 2016. RE: Delete one authorized use location (activities to continue unabated at that location under the auspices of WN-M0135-1, Providence-Everett).

F. Amendment request dated 21 August 2017 (received 5 September 2017), and email dated 15 September 2017. RE: Add one of two requested new AUR (second to be done at a later date).

G. Email and attachments dated 8 February 2018. RE: add new AUR.

H. Letter and attachments dated 6 September 2018. RE: Add new AUR.

I. Letter and attachments dated 19 October 2018. RE: change RSO.

J. Email and attachment dated 2 January 2019. RE: Remove 15 AUR's and add 4 AUR's.

FOR THE STATE OF WASHINGTON DEPARTMENT OF HEALTH

Date: 04 January 2019

By _____
Tristan Hay PhD
Radioactive Materials Licensing

Department of State Health Services

RADIOACTIVE MATERIAL LICENSE

Pursuant to the Texas Radiation Control Act and Texas Department of State Health Services (Agency) regulations on radiation, 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 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 Agency now or hereafter in effect and to any conditions specified below.

LICENSEE	This license is issued in response to correct an error
1. Name: RESOLUTE HOSPITAL COMPANY LLC ATTN CARL R KEENER PHD 2. Address: 555 CREEKSIDE CROSSING NEW BRAUNFELS TX 78130	3. License Number: L06632 — Amendment Number: 05 PREVIOUS AMENDMENTS ARE VOID 4. Expiration Date: April 30, 2024

RADIOACTIVE MATERIAL AUTHORIZED

5. Radioisotope	6. Form of Material	7. Maximum Activity	8. Authorized Use
A. Any radioactive material with a half-life < 120 days, except positron emitters	A. Any radiopharmaceutical, except gas and aerosol	A. As needed for diagnostic purposes	A. Any diagnostic use as indicated in Title 25 TAC° §289.256(ff) (hh) and (kk), in unit dose only.
B. Tc-99m	B. DTPA as an aerosol	B. 50 millicuries	B. Lung imaging studies using a commercially available radio-aerosol generator in accordance with the manufacturer's instructions.
C. Xe-133	C. Any radiopharmaceutical	C. 40 millicuries	C. Pulmonary function studies and lung imaging.
D. I-131	D. Sodium iodide (in capsule form only)	D. 200 millicuries	D. Treatment of hyperthyroidism and thyroid cancer as indicated in 25 TAC §289.256(kk).

° Texas Administrative Code (TAC)

9. Radioactive material shall only be stored and used at:

Site Number	Location
000	New Braunfels – 555 Creekside Crossing

10. Each site shall maintain documents and records pertinent to the operations at that site. Copies of all documents and records required by this license shall be maintained for Agency review at Site 000.

11. The licensee shall comply with the provisions (as amended) of Title 25 Texas Administrative Code (TAC) §289.201, §289.202, §289.203, §289.204, §289.205, §289.251, §289.252, §289.256 and §289.257.

Department of State Health Services

RADIOACTIVE MATERIAL LICENSE

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12. Radioactive material may be used only by the individuals listed below for the uses specified:

A. All diagnostic uses authorized by the license, including oral administration of sodium iodide I-131 requiring a written directive in quantities less than or equal to 33 millicuries; therapy with I-131 for hyperthyroidism and thyroid cancer.

Alden Bailey, M.D.
Robert Daehler, M.D.
Polly B. Hansen, M.D.
Wendy J. Whitford, D.O.

B. All diagnostic uses authorized by the license, excluding oral administration of sodium iodide I-131 requiring a written directive in quantities less than or equal to 33 millicuries.

Aaron Bailey, M.D.
Michael Barker, M.D.
Amy E. Benson, M.D.
Robert Bruton, M.D.
Margo F. Cervantes, M.D.
Robert C. Chandler, M.D.
Morgan G. Dunne, M.D.
Phillip Fortenberry, M.D.
John H. Lampe, M.D.
Christina McCune, M.D.
Claire Mckay, D.O.
David Mitchell, M.D.
Carlos Morales, M.D.
Christopher J. Muniz, M.D.
Justin Muhlenberg, M.D.
Paul C. Nevitt, M.D.
Daniel Pacheco, M.D.
Ankitkumar H. Patel, M.D.
Greg Ramsey, M.D.
David A. Riesz, M.D.
Rise P. Ross, M.D.
David H. Rotter, M.D.
Steven C. Scarpino, M.D.
Vineet Seth, M.D.
Anthony Smith, M.D.
Jeremy Smolik, M.D.
Joseph B. Sutcliffe III, M.D.
Allan L. Truax, M.D.
Rajiv Vasan, M.D.
Richard W. Walton, M.D.
Yun Sean Xie, M.D.

C. Diagnostic nuclear cardiology.

Jamison N. Wyatt, M.D.
Jason Yoho, M.D.

13. The individual designated to perform the functions of Radiation Safety Officer (RSO) for activities covered by this license is Carl R. Keener, Ph.D.

14. The licensee shall not open sealed sources containing radioactive material.

15. The licensee shall maintain a current copy of the safety evaluation from "The Registry of Radioactive Sealed Sources and Devices" for each sealed source received under authority of this license, in excess of 1 millicurie of beta/gamma-emitting material or 10 microcuries of alpha-emitting material.

16. Injections of radiopharmaceuticals in patient care areas of the hospital which are outside of the authorized use areas shall be documented in a separate log to include the following:

A. Time and date of each injection.

B. Room number and injecting technologist's name.

C. Removable contamination survey results based on a completed radiation safety survey of the injection area, to be performed immediately after the injection.

D. Survey evaluation for authorizing release of the injection area for unrestricted use.

Department of State Health Services

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17. Medical Radiologic Technologists working as Nuclear Medicine Technologists under the authority of this license that are not:

    A. Certified or eligible to be certified by the Nuclear Medicine Technology Certification Board (CNMT),

    B. Registered or eligible for registry by the American Registry of Radiological Technology in nuclear medicine (ARRT(N)),

    C. A graduate of or a student supervised and operating in a program approved by the Joint Review Committee on Educational Programs in Nuclear Medicine Technology (JRCNMT), or

    D. X-ray technologists cross trained in nuclear medicine in accordance with procedures in the licensee letter received February 25, 2014.

    Shall have obtained 2 years of full time work experience in nuclear medicine prior to January 1, 2007. This work experience must be certified in writing by an authorized physician user.

18. Except as specifically provided otherwise by this license, the licensee shall possess and use the radioactive material authorized by this license in accordance with statements, representations, and procedures contained in the following:

    Application dated December 3, 2013
    Letter received February 25, 2014,
    Letter dated April 1, 2014, and
    Business Information Form dated December 3, 2013.

    Title 25 TAC §289 shall prevail over statements contained in the above documents unless such statements are more restrictive than the regulations.

ASH: ash

FOR THE DEPARTMENT OF STATE HEALTH SERVICES

Date August 29, 2017

J. Scott Kee, Program Coordinator
Medical and Academic Licensing Program