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.**

<table>
<thead>
<tr>
<th>1. Licensee Name:</th>
<th>3. License Number:</th>
</tr>
</thead>
<tbody>
<tr>
<td>SEATTLE CANCER CARE ALLIANCE</td>
<td>WN-M0225-1 Entirety Amendment No. 39</td>
</tr>
<tr>
<td>Fee Code 17</td>
<td>16-01-33, 16-02-39, 16-07-20, 16-10-29, &amp; 17-06-23.</td>
</tr>
<tr>
<td>2. Address:</td>
<td>4. Expiration Date:</td>
</tr>
<tr>
<td>825 Eastlake Avenue</td>
<td>28 February 2021</td>
</tr>
<tr>
<td>Seattle, Washington 98109</td>
<td>5. Reference Number(s):</td>
</tr>
<tr>
<td></td>
<td>16-01-33, 16-02-39, 16-07-20, 16-10-29, &amp; 17-06-23.</td>
</tr>
</tbody>
</table>

6. Radioactive Material (element and mass number).

A. Any radioactive material authorized by WAC 246-240-151.

B. Any radioactive material authorized by WAC 246-240-157.

C. Yttrium 90.

D. Gadolinium 153.

7. Chemical and/or Physical Form.

A. Any.

B. Any.

C. Liquid Reference Source.

D. Sealed source (manufactured or distributed under a specific license issued by an Agreement State or the U.S. NRC specifically authorized for quality assurance procedures for nuclear medicine imaging systems.

8. Maximum quantity licensee may possess at any one time.

A. As necessary for the uses authorized in Condition 9.A.

B. As necessary for the uses authorized in Condition 9.B.

C. 4070 megabecquerels (110 millicuries).

D. No single source to exceed 18.5 gigabecquerels (500 millicuries), maximum of five sources, 92.5 gigabecquerels (2.5 curies) at any one time.
E. Any radioactive material authorized by WAC 246-240-201.

F. Radium 223.

G. Iridium 192.

E. Any.

F. Radium 223 Cl₂.

G. Sealed Source (Varian Medical Systems model VS2000 from Best Medical Belgium S.A., Mallinckrodt Medical BV, or Alpha-Omega Services, Inc).

E. As necessary for the uses authorized in Condition 9.E.

F. As necessary for the uses authorized in Condition 9.F.

G. No single source to exceed 481 gigabecquerels (13 curies), maximum of 740 gigabecquerels (20 curies).

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.

NOTE: The licensee is exempt from activity limitation restrictions in Item 8 and from decommissioning financial assurance requirements for possession of licensed material in sealed sources in quantities greater than the limits in WAC 246-235-075 for the purpose of source exchange only. This exemption is granted for no more than thirty days for any single source exchange.


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. To be used for beta-emitter calibration of the dose calibrator.
9. D. To be used for quality assurance purposes related to operation of nuclear medicine medical imaging systems. Such sources shall normally, except for replacement, be permanently mounted on the imaging system(s).

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

F. For treatment of skeletal metastases in accordance with Integrated Clinical Study Protocol BAY 88-8223/15995, version 5.0 dated 31 October 2012 (or subsequent approved versions).

G. One source to be used in Varian VariSource ix™ HDR (High Dose Rate) model 200S brachytherapy afterloader for the intraluminal, interstitial, superficial, gynecological, and/or intracavitary treatment of cancer in humans; and one source in its shipping container to be in possession of the licensee as necessary for replacement of the source in the HDR unit. NOTE: It is understood that, when shipped, a single HDR source may be up to 13 curies in activity. However, NO SOURCE shall be installed in the unit, or used, until it has a maximum activity of eleven curies or less.

The source(s) shall not be transported or stored in teflon-lined containers.

Relocation of the HDR unit is not authorized without appropriate written amendment.

10. Radioactive materials authorized in Subitems A-G of Items 6, 7, and 8 shall be stored and/or used at the licensee’s address in Item 2.

12. The Radiation Safety Officer for this program shall be Janice Nam Kim, M.D.

The Associate Radiation Safety Officer for this program shall be Trang Doan Marquez, M.S.

13. Radioactive material authorized by Subitem G shall be used only by those physicians authorized for sealed source therapy and who have received and documented all required training from the manufacturer. In addition, at least three test runs of the device, related equipment, and software must be successfully completed and documented prior to actual patient use.

**AUTHORIZED USERS**

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

A. Fatemah Behnia, M.D.; Subitems A-F of Items 6, 7, and 8.

B. Li-Ming Christine Fang, M.D.; Subitem G of Items 6, 7, and 8.

C. Eli David Finkelstein, M.D.; Subitems E-G of Items 6, 7, and 8.

D. Edward Young Kim, M.D.; Subitem G of Items 6, 7, and 8.

E. Janice Nam Kim, M.D.; Subitem G of Items 6, 7, and 8.

F. Wui-Jin Koh, M.D.; Subitem G of Items 6, 7, and 8.

G. George Ernest Laramore, M.D., Ph.D.; Subitem G of Items 6, 7, and 8.

H. David Howard Lewis, M.D.; Subitems A-F of Items 6, 7, and 8.

I. Jay Justin Liao, M.D.; Subitem G of Items 6, 7, and 8.

J. Manuela-Cristina Matesan, M.D.; Subitems A-F of Items 6, 7, and 8.

K. Nina Andrea Mayr, M.D.; Subitem G of Items 6, 7, and 8.

L. Shilpen Patel, M.D.; Subitem G of Items 6, 7, and 8.

M. Joseph Gnanaprasad Rajendran, M.D.; Subitems A-F of Items 6, 7, and 8.
O. Andrew Thomas Shields, M.D.; Subitems A-F of Items 6, 7, and 8.
P. Audrey Bach Tran, M.D.; Subitem G of Items 6, 7, and 8.
Q. Hubert Jean Vesselle, M.D.; Subitems A-F of Items 6, 7, and 8.
R. Waylene Ann Wang, M.D.; Subitem G of Items 6, 7, and 8.

**AUTHORIZED MEDICAL PHYSICISTS (Non-Human Use Only)**

S. Ning Cao, Ph.D.; Subitem G of Items 6, 7, and 8.
T. Alan Michael Kalet, Ph.D.; Subitem G of Items 6, 7, and 8.
U. Juergen Meyer, Ph.D.; Subitem G of Items 6, 7, and 8.
V. Lori Ann Young, Ph.D.; Subitem G of Items 6, 7, and 8.

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

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 or authorized medical physicist on an Agreement State or U.S. Nuclear Regulatory Commission license which authorizes human use; and

3. Performs only those procedures, which the physician or authorized medical physicist is specifically authorized to perform pursuant to the license issued by an Agreement State or the U.S. Nuclear Regulatory Commission.
14. 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 upon each elution 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 the limits specified in Condition 16.B are detected.

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.
17. 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.

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

20. 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.

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 “Calichek” 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.


25. Patients treated with High Dose Rate (HDR), Medium Dose Rate (MDR), Pulsed Dose Rate (PDR), or Low Dose Rate (LDR) afterloader therapy systems shall be surveyed with a properly calibrated and operable high-range dose rate survey meter immediately after each treatment prior to release to ensure that no sealed sources remain in the patient. Such surveys shall be documented and those documents maintained for inspection by the Department.
26. 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 Radiolodine”, Revision 2 dated September 2014. When radioiodine capsules are used exclusively, radioiodine bioassays are required only when capsules are opened or crushed.

HDR THERAPY

27. Each HDR unit shall be fully inspected and serviced during initial source loading and at intervals not to exceed three years to assure proper function of the source exposure mechanism. This inspection and servicing must be performed by persons specifically authorized to do so by the Department, the U.S. Nuclear Regulatory Commission, or an Agreement State. A written report of the inspection and/or servicing must be maintained on file for inspection by the Department.

Each HDR unit shall be serviced and “retired” or removed from service according to the manufacturer’s recommendation.

The source wire(s) shall not be cut or altered by the licensee.

The working life of any single HDR source shall be limited to a maximum of the manufacturer’s current limit on wire extensions which is 1000 cycles for the Varian model VS2000 source assembly. Records of each source extension shall be maintained for inspection by the Department.

28. Therapy treatments utilizing any HDR afterloader system shall be conducted only in the physical presence of the entire HDR Treatment team (Authorized User/Physician and Medical Physicist, at a minimum), after those team members have received and documented all required training from the vendor.

29. The manufacturer’s written radiological safety and operating instructions shall be made available to each person responsible for operation of the HDR system.

30. The requirements of WAC 246-240-372 notwithstanding, performance of required quarterly Quality Assurance tests may be conducted at four month intervals to coincide with any four month interval source exchange(s).
31. Thorough training instruction including participation in actual drills of the emergency procedures shall be provided initially and at least every 12 months thereafter for all unit operators, Authorized Medical Physicists, and Authorized Users. Records of the topics, duration, attendees, and dates of training, as well as by whom the training was provided, shall be maintained for inspection by the Department.

32. Prior to initiation of any treatment program, and immediately subsequent to each installation of an HDR unit, radiation dose rate surveys and tests shall be performed in accordance with the following requirements:

A. A dose rate survey shall be made of:

1. The HDR source housing with the HDR source in the “parked” or shielded position. The maximum and average dose rate levels at one meter from the HDR source, in the “parked” position, shall not exceed, respectively, 10 millirem (100 microsieverts) per hour, and 2 millirem (20 microsieverts) per hour.

2. All areas circumjacent to the treatment room(s) with the HDR source in the unshielded or “on” position. The survey shall be performed with an appropriate phantom in place, and shall clearly establish:

   a. That radiation levels in restricted areas are not likely to cause personnel exposure in excess of the limits specified in WAC 246-221-010 “Radiation Protection--General Provisions”; and

   b. That radiation levels in unrestricted areas do not exceed the limits specified in WAC 246-221-010.

B. Tests shall be made to ensure the proper operation of:

1. Electrical interlocks and visual indicators on all entrance doors to the treatment room(s);

2. The HDR source “on-off” (or, “exposed-not exposed”) indicators, both at the source housing and at the HDR unit control panel;

3. Guide tubes, source/wire applicators, dwell positions, and the HDR treatment unit timing device(s).
32. C. A written report of the results of the tests and surveys required by this License Condition, including the make, model, serial number, and most recent calibration date of the survey instrument used, shall be sent to the Department no later than 30 days following each installation of an HDR.

33. A. An AU and an AMP must be present in the control room for, at a minimum, the initiation of all treatments involving the unit;
   
   B. An AMP must be present in the HDR area for the duration of all HDR treatments (HDR area comprised of the control/planning room, office area, and HDR room itself); and
   
   C. An authorized user or a physician under the supervision of an authorized user, who has been trained in the operation and emergency procedures of the unit must be physically present during the continuation and full duration of all treatments.

**ALPHA-EMITTER (XOFIGO) THERAPY FOR METASTASES**

34. A. Radioactive material authorized in Subitem F of Items 6, 7, and 8 shall be used only by, or under the supervision of, physicians authorized on this license for radiopharmaceutical therapy who have completed review of the manufacturer’s (Bayer’s) instructions for use.

   B. An appropriate setting for the licensee’s dose calibrator for Ra-223 shall be determined prior to first human use using a NIST-traceable solution of Ra-223 Cl₂. Testing for geometry for this use is not required.

   C. Patients treated with Ra-223 Cl₂ are eligible for immediate release by the licensee.

35. 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 and disposal shall be maintained for inspection by the department.

36. The licensee’s emergency procedures shall follow those outlined in the Washington State Radiation Emergency Handbook revised May 2014, or subsequent revisions, or other procedures specifically approved by License Condition.
37. 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.

38. 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 25 January 2016.

B. Email & attachments dated 16 February 2016.

C. Letter & attachments dated 12 July 2016. RE: Add new/former AUR for HDR use, change RSO, add new ARSO.

D. Letter dated 25 October 2016. RE: Delete four current AMP.

E. Letter & attachments dated 13 June 2017. RE: Add one new Tx AUR, delete one AMP.

FOR THE STATE OF WASHINGTON DEPARTMENT OF HEALTH

Date: 22 June 2017

By [Signature]
C. DeMaris
Radioactive Materials Licensing