

State of Washington
Radioactive Materials License



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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.

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|--|---|
| 1. Licensee Name: <p style="text-align: center;">SEATTLE CANCER CARE ALLIANCE</p> | 3. License Number: <p style="text-align: center;">WN-M0225-1 Renewal Amendment No. 26</p> |
| 2. Address: <p style="text-align: center;">825 Eastlake Avenue Seattle, Washington 98109</p> | 4. Expiration Date: <p style="text-align: center;">29 February 2016</p> <hr/> 5. Reference Number(s): <p style="text-align: center;">11-01-29 & 11-02-20.</p> |

| 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 246-240-157. | A. Any. | A. As necessary for the uses authorized in Condition 9.A. |
| B. Any radioactive material authorized by WAC 246-240-201. | B. Any. | B. As necessary for the uses authorized in Condition 9.B. |
| C. Yttrium 90. | C. Liquid Reference Source. | C. 4070 megabecquerels (110 millicuries). |
| D. Iridium 192. | D. Sealed Source (Varian Medical Systems model VS2000). | D. No single source to exceed 481 giga-becquerels (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.

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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.

9. Authorized use.
- A. Any imaging or localization study authorized by WAC 246-240-157 for which a written directive is not required.
 - B. Any procedure authorized by WAC 246-240-201 for which a written directive is required.
 - C. To be used for beta-emitter calibration of the dose calibrator.
 - D. 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-D of Items 6, 7, and 8 shall be stored and/or used ***at the licensee's address in Item 2.***
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 246-235 WAC, "Radioactive Materials -- Specific Licenses"; chapter 246-240 "Radiation Protection -- Medical Use of Radioactive Material"; chapter 246-247 WAC, "Radiation Protection -- Air Emissions"; chapter 246-231 WAC, "Packaging and Transportation of Radioactive Material"; and chapter 246-249 WAC, "Radioactive Waste -- Use of the Commercial Disposal Site".
12. The Radiation Safety Officer for this program shall be Sheryl Ann Gray, CNMT.

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

- | | |
|-------------------------------------|------------------------------------|
| A. James Hawkins Caldwell, M.D.; | Subitems A-C of Items 6, 7, and 8. |
| B. Janet Frances Eary, M.D.; | Subitems A-C of Items 6, 7, and 8. |
| C. Edward Young Kim, M.D.; | Subitem D of Items 6, 7, and 8. |
| D. Janice Nam Kim, M.D.; | Subitem D of Items 6, 7, and 8. |
| E. Wui-Jin Koh, M.D.; | Subitem D of Items 6, 7, and 8. |
| F. George E. Laramore, M.D., Ph.D.; | Subitem D of Items 6, 7, and 8. |
| G. David Howard Lewis, M.D.; | Subitems A-C of Items 6, 7, and 8. |
| H. Jay Justin Liao, M.D.; | Subitem D of Items 6, 7, and 8. |
| I. David A. Mankoff, M.D.; | Subitems A-C of Items 6, 7, and 8. |
| J. Satoshi Minoshima, M.D.; | Subitems A-C of Items 6, 7, and 8. |
| K. Wil Borchers Nelp, M.D.; | Subitems A-C of Items 6, 7, and 8. |
| L. Shilpen Patel, M.D.; | Subitem D of Items 6, 7, and 8. |
| M. Joseph G. Rajendran, M.D.; | Subitems A-C of Items 6, 7, and 8. |
| N. Kenneth J. Russel, M.D.; | Subitem D of Items 6, 7, and 8. |

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13. O. Andrew Thomas Shields, M.D.; Subitems A-C of Items 6, 7, and 8.
P. Audrey B. Tran, M.D.; Subitem D of Items 6, 7, and 8.
Q. Hubert Jean Vesselle, M.D.; Subitems A-C of Items 6, 7, and 8.
R. Waylene Ann Wang, M.D.; Subitem D of Items 6, 7, and 8.

AUTHORIZED MEDICAL PHYSICISTS (Non-Human Use Only)

- S. Yong Choi, Ph.D.; Subitem D of Items 6, 7, and 8.
T. Gregory John Courlas, M.E.; Subitem D of Items 6, 7, and 8.
U. Amanda Marie Jackson, M.S.; Subitem D of Items 6, 7, and 8.
V. Darryl Glenn Landon Kaurin, Ph.D.; Subitem D of Items 6, 7, and 8.
W. Saikanth Mahendra, M.S.; Subitem D of Items 6, 7, and 8.
X. Gene Elizabeth Robertson, M.S.; Subitem D of Items 6, 7, and 8.
Y. Lawrence Edward Sweeney, Ph.D.; Subitem D 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

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14. A. 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.
- 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 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.

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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 $\pm 20\%$ 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.
- 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.

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18. 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. 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.
22. 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."
23. 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).
24. 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.

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25. When unsealed radioactive material is used or injected in an area outside the normal nuclear medicine area, such as treadmill rooms, the emergency department, or patient rooms, an appropriate contamination survey shall be performed and documented for inspection by the Department.
26.
 - A. Patients containing brachytherapy sources, permanent or temporary, shall remain hospitalized until a documented source count, and surveys made with an appropriate radiation detection instrument, indicate that all sources have been accounted for. The results of these surveys and source counts shall be recorded and maintained for inspection by the Department for five (5) years from the time the sources are implanted.
 - B. 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.
27. The licensee shall conduct a radioiodine bioassay program in accordance with criteria set forth in Washington State Regulatory Guide 8.20, "Bioassay Program Criteria for I-125 and I-131". When radioiodine capsules are used exclusively, radioiodine bioassays are required only when capsules are opened or crushed.
28. 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 recommendations.

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 120 days and a maximum of 1000 wire extensions (or the manufacturer's current limit on wire extensions, whichever is more restrictive), whichever occurs first. Records of each source extension shall be maintained for inspection by the Department.

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29. 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.
30. 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).

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30. 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.
31. The manufacturer's written radiological safety and operating instructions shall be made available, and a copy given, to each person responsible for operation of the *Gamma Knife* system.
32. The licensee's emergency procedures shall follow procedures outlined in the Washington State Radiation Emergency Handbook revised November 1991 or subsequent revisions, or other procedures specifically approved by License Condition.
33. Therapy treatments utilizing any *High Dose-Rate Afterloader System* shall be conducted in accordance with the provisions of U.S. Nuclear Regulatory Commission Regulatory Issue Summary 2005-23 "Clarification of the Physical Presence Requirement During Gamma Stereotactic Radiosurgery Treatments". Specifically, only in the physical presence of the HDR Treatment team (Authorized User-Physician, and Medical Physicist), *after* those team members have received and documented all required training from the vendor. "Physical Presence" is defined in RIS 2005-23.
34. 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.

35. 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 6 January 2011.
 - B. Letter & attachments dated 9 February 2011.

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FOR THE STATE OF WASHINGTON DEPARTMENT OF HEALTH

Date: 14 February 2011

By 
C. DeMaris
BTH Radioactive Materials Licensing