Simmons, Michelle

From: Kay Kassel <kkassel@alliancehealthcareservices-us.com>
Sent: Tuesday, September 13, 2016 2:26 PM
To: Simmons, Michelle
Subject: [External_Sender] RE: NRC License No. 50-23214-01
Attachments: Bellingham Amendment 3 2015.pdf

Hello Michelle,
Nice speaking with you today. I have attached the Alliance WA RAM license on which I am the RSO. As we discussed, this license has 131I as an authorized use.
Please let me know if this is sufficient to meet your needs.
Sincerely,
Kay Kassel

Kay Kassel MS CNMT
Corporate Radiation Safety Officer
Alliance HealthCare Services
Direct: 561-701-1311
Fax: 480-212-8560
kkassel@alliancehealthcareservices-us.com

From: Simmons, Michelle [mailto:Michelle.Simmons@nrc.gov]
Sent: Tuesday, September 13, 2016 3:18 PM
To: Kay Kassel
Subject: FW: NRC License No. 50-23214-01

NRC License No.: 50-23214-01
Docket No.: 030-20372
Control No.: 591850

This is in reference to your letter dated August 30, 2016, requesting to name Ms. Kassel as Radiation Safety Officer on your license. In order to add Ms. Kassel as RSO, she will to complete additional training for Iodine I-131 permitted by 35.300. Please complete the attached form and submit it to the NRC.

Please provide this information by **October 4, 2016**. You may fax your signed response to 817-200-1263, referencing mail control 591850. When you send the fax, you may wish to leave a voicemail or e-mail message to alert me to look for it. If you are submitting your response by email, the response must be submitted in pdf format. Please send me an e-mail or call me at 817-200-1590 if you have any questions.

Michelle Simmons
Health Physicist
US NRC
1600 East Lamar Blvd.
Arlington, Texas 76011
817-200-1590

PUBLIC
☐ Immediate Release
☑ Normal Release

NON-PUBLIC
☐ A.3 Sensitive-Security Related
☐ A.7 Sensitive Internal
☐ Other:

Reviewer: MS Date: 9/19/16

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:
Alliance Healthcare Services, Inc.	**WN-M0315-1 Entirety** Amendment No. **3** Fee Code 15
2. Address: Suite 400 100 Bayview Circle Newport Beach, California 92660	**4. Expiration Date:** 30 April 2019 **5. Reference Number(s):** 14-02-21, 14-03-11, 14-03-12, 14-08-41, 14-08-46, 15-03-05, & **15-05-35.**

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. Fluorine 18.	B. Any.	B. As necessary for the uses authorized in Condition 9.B.
C. Technetium 99m	C. Liquid.	C. As necessary for the uses authorized in Condition 9.C.
D. Any radioactive material authorized by WAC 246-240-110.	D. Sealed Source for quality assurance use..	D. As necessary for the uses authorized in Condition 9.D.
E. Iodine 131.	E. Sodium Iodide (capsule only).	E. Not to exceed 740 megabecquerels (20 millicuries).

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

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

   C. To be used for quality assurance purposes related to dose calibrator use. No human use of this material is authorized.

   D. To be used for quality assurance testing for imaging systems, dose calibrators, and/or survey instrumentation.

   E. To be used for thyroid function studies and/or the treatment of hyperthyroidism or thyroid carcinoma.

10. A. Radioactive materials authorized in Subitems A-D of Items 6, 7, and 8 shall be stored and/or used ***at Suite 201, 2930 Squalicum Parkway, Bellingham, Washington 98225***.

    B. Radioactive materials authorized in Subitems A-E of Items 6, 7, and 8 shall be stored and/or used ***at Suite 100, 6808 220th Street SW, MountLake Terrace, Washington 98043.***

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 Corporate Radiation Safety Officer for this program shall be **Kay Kassel, CNMT**.

The Local/Onsite Radiation Safety Officer for the Bellingham location shall be Lars Gustaf Crabo, M.D.

The Local/Onsite Radiation Safety Officer for the MountLake Terrace location shall be Scott Joseph McCorkell, M.D.

AUTHORIZED USERS

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

A.	Lars Gustaf Crabo, M.D.;	Subitems A-D of Items 6, 7, and 8.
B.	Peter Christopher Buetow, M.D.;	Subitems A-D of Items 6, 7, and 8.
C.	Dag Andre Jensen, M.D.;	Subitems A-D of Items 6, 7, and 8.
D.	Jason Marsh Stoane, M.D.;	Subitems A-D of Items 6, 7, and 8.
E.	David George Ashley, M.D.;	Subitems A-D of Items 6, 7, and 8.
F.	Gregery Deke Kienzle, M.D.;	Subitems A-D of Items 6, 7, and 8.
G.	Scott Joseph McCorkell, M.D.;	Subitems A-E of Items 6, 7, and 8.
H.	Alan Neil Schwartz, M.D.;	Subitems A-E 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 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

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

14. A. 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. 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.

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.

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.

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. 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 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. **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.**

25. 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.

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26. 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.

27. 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.

28. 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 10 February 2014, ALARA attachment dated 21 February 2014, & RSO Delegation of Authority form dated 7 March 2014.

    B. Application and attachments dated 18 August 2014. RE: Add second use location, in MountLake Terrace.

    C. Email & attachments dated 19 August 2014. RE: RSO Duties and WD form.

    D. Letter dated 23 February 2015. RE: Delete one AUR, increase I-131 limit.

    E. **Letter & attachments dated 14 May 2015. RE: Change Corporate RSO.**

FOR THE STATE OF WASHINGTON DEPARTMENT OF HEALTH

Date: 27 May 2015

By C. DeMaris
TH Radioactive Materials Licensing