ACCEPTANCE REVIEW MEMO (ARM)

Licensee: Heart Clinics Northwest **License No.:** 46-27704-01

Docket No.: 030-35760 **Mail Control No.:** 471170

Type of Action: Amend **Date of Requested Action:** 10-24-06

Reviewer Assigned: **ARM reviewer(s):** Torres

Response	Deficiencies Noted During Acceptance Review
	[ ] Open ended possession limits. Limit possession. Submit inventory. [ ] Submit copies of most recent leak test results. [ ] Add - delete IC license condition. Add IC paragraph in cover letter. [ ] Split license from cover letter. Add SUNSI marking to license. [ ] Ask the licensee if they have any type-amount of EPAct Material.

RJT

Reviewer's Initials: _____ **Date:** _____

☐Yes ☐No Unrestricted release Group 2 or >: Transfer memo to FCDB within 10 days.

☐Yes ☐No Decommissioning notification should be completed within 30 days.

☐Yes ☐No Termination request < 90 days from date of expiration

☐Yes ☐No Expedite (medical emergency, no RSO, location of use/storage not on license, RAM in possession not on license, other)

☐Yes ☐No TAR needed to complete action.

Branch Chief's and/or Sr. HP's Initials: _____ **Date:** _____

SUNSI Screening according to RIS 2005-31

☐Yes ☑No **Non-Publicly Available, Sensitive** if any item below is checked

General guidance:

_____RAM = or > than Category 3 (Table 1, RIS 2005-31), use Unity Rule
_____Exact location of RAM (whether = or > than Category 3 or not)
_____Design of structure and/or equipment (site specific)
_____Information on nearby facilities
_____Detailed design drawings and/or performance information
_____Emergency planning and/or fire protection systems

Specific guidance for medical, industrial and academic (above Category 3):

_____RAM quantities and inventory
_____Manufacturer's name and model number of sealed sources & devices
_____Site drawings with exact location of RAM, description of facility
_____RAM security program information (locks, alarms, etc.)
_____Emergency Plan specifics (routes to/from RAM, response to security events)
_____Vulnerability/security assessment/accident-safety analysis/risk assess
_____Mailing lists related to security response

Branch Chief's and/or Sr. HP's Initials: RJT **Date:** 11-13-06

Pre-Licensing Screening

Applicant Information: **Control No.** 471170

Name: Heart Clinics Northwest	Type of Request: Amend Program Code(s):
Location: WA	License No.: 46-27704-01 Docket No.: 030-35760

STEP 1–Radioactive Materials and Quantities Requested:

		Yes or No
Instructions for Step 1: **Complete Step 1 for all applications**. If all your responses in Step 1 are "No" then do not complete Step 2 (Screening Criteria). Sign and date the completed step-sheet and add it as the sensitive and non-publicly available OAR in ADAMS. If a "yes" response is indicated for any item in Step 1, also complete Step 2. If the type of use is subject to a Security Order or the requirements for increased controls, complete Step 3 (Item A or Item B) without delay.		
A.	The request is from a new applicant.	No
B.	NUREG-1556, Volume 20, Section 4.9 indicates a licensing site visit is needed for the requested type of use, e.g., (1) Type A broad scope license, (2) panoramic irradiator containing > 10000 curies, (3) manufacturers or distributors using unsealed radioactive material or significant quantities of sealed material, (4) radioactive waste brokers, (5) radioactive waste incinerators, (6) commercial nuclear laundries, and (7) any other application that in the judgement of the reviewer and cognizant supervisor involves complex technical issues, complex safety questions, or unprecedented issues that warrant a site visit.	No
C.	The applicant requested certain radionuclides and quantities that equal or exceed the Risk Significant Quantity (TBq) values in the table, below, that have been "highlighted" by the reviewer	No

Table of Risk Significant Quantities

(Category 2 Quantities, IAEA Safety Guide No. RS-G-1.9, Categorization of Radioactive Sources, August 2005)

Radionuclide	Risk Significant Quantity (TBq[1])	Risk Significant Quantity (Ci[1])	Radionuclide	Risk Significant Quantity (TBq[1])	Risk Significant Quantity (Ci[1])
Am-241	0.6	16	Pm-147	400	11,000
Am-241/Be	0.6	16	Pu-238	0.6	16
Cf-252	0.2	5.4	Pu-239/Be	0.6	16
Cm-244	0.5	14	Ra-226[2]	0.4	11
Co-60	0.3	8.1	Se-75	2	54
Cs-137	1	27	Sr-90 (Y-90)	10	270
Gd-153	10	270	Tm-170	200	5,400
Ir-192	0.8	22	Yb-169	3	81

[1] The primary values are TBq. The curie (Ci) values are for informational purposes only.

[2] The Atomic Energy Act, as amended by the Energy Policy Act of 2005, authorizes NRC to regulate Ra-226 and NRC is in the process of amending its regulations for discrete sources of Ra-226.

	Yes , No, or Not Applicable (NA)
Calculations of the Total Activity or the Unity Rule are attached to document whether or not the screening criteria in Step 2 were also completed to evaluate the application. **NOTE–If an amendment of an existing license is being requested, the calculations will include the previously authorized quantities for the radionuclide(s).**	
Total Activity–multiple activities are requested for a single radionuclide and the sum of the activities equals or exceeds the quantity of concern for the radionuclide	—
Unity Rule--multiple radionuclides are requested and the sum of the ratios equals or exceeds unity, e.g.,[(total activity for radionuclide A) ÷ (risk significant quantity for radionuclide A)] + [(total activity for radionuclide B) ÷ (risk significant quantity for radionuclide B)] ≥ 1.0.	—

Signature and Date for Step 1:

RJT 11/13/06

License Reviewer and Date

Heart Clinics NORTHWEST

Fellows
American College of Cardiology

www.heartclinicsnw.com

Nuclear Cardiology
Accredited Nuclear Cardiology Laboratory

MAIN OFFICE – The Heart Institute of Spokane
122 W 7th Avenue, Suite 310, Spokane, WA 99204
509-838-7711 • Fax 509-747-4664
William R. Bennett, MD
Andrew J. Boulet, MD
Eteri S. Byazrova, MD
Angelo S. Ferraro, MD
R. Dean Hill, MD
Michael D. Hostetler, MD
Nour Juratli, MD
Kevin M. Kavanaugh, MD
Timothy J. Lessmeier, MD
Eric C. Orme, MD
Michael E. Ring, MD
William F. Stifter, MD
Stephen T. Thew, MD
L. Douglas Waggoner, Jr., MD
Michael P. Williams, MD

NORTHSIDE
6002 N Mayfair, Second Floor, Spokane, WA 99208
509-489-7504 • Fax 509-482-9011
Amna T. Ahmed, MD
John P. Everett, MD
Marek Janout, MD
Keith A. Kadel, MD
Eric D. Stucky, MD

WALLA WALLA – St. Mary Medical Center
401 W Poplar, Cardiology Suite, Walla Walla, WA 99362
509-522-5731 • Fax 509-522-5747
Suwong Wongsuwan, MD

COEUR D'ALENE
700 Ironwood Drive, Suite 350
Coeur d'Alene, ID 83814
208-676-9913 • Fax 208-666-0885
Joseph A. Abate, MD
Dennis B. Cooke, MD
Ronald M. Fritz, DO
Carl L. Hanson, MD
Ronald D. Jenkins, MD
James Pataky, MD
Wolfgang J.T. Spyra, MD

SANDPOINT
606 N 3rd Avenue, Suite 203
Sandpoint, ID 83864
208-263-2505 • Fax 208-263-2908
Robert L. Holman, MD
Ronald D. Jenkins, MD

October 24, 2006

RECEIVED
OCT 27 2006
DNMS

Mr. Jack Whitten
Region IV
US Nuclear Regulatory Commission
611 Ryan Plaza Drive, Suite 400
Arlington, TX 76011

Dear Mr. Whitten:

We wish to amend our Radioactive Materials License, #46-27704-01; location 700 Ironwood Drive, Suite 370, Coeur d'Alene, ID 83814, to add Dr. Ronald Jenkins as an Authorized User. Dr. Jenkins is an Authorized User on our State of Washington Radioactive Materials License. Please find a copy of his Washington medical license and RAM license.

If you need any additional information, please call me at 509-838-7711.

Thank you,

Frank Ruppert, CNMT
Radiation Safety Officer
Heart Clinics Northwest, PS

FR:jk

Enclosures

P:\JoAnn\Correspondence\Ruppert\fr102406.doc

071170

STATE OF WASHINGTON

HEALTH PROFESSIONS QUALITY ASSURANCE DIVISION

THIS CERTIFIES THAT THE PERSON OR ESTABLISHMENT NAMED HEREON IS AUTHORIZED AS PROVIDED BY LAW TO

PHYSICIAN AND SURGEON

ACTIVE

JENKINS, RONALD D.
122 W SEVENTH AVE
SUITE 310
SPOKANE WA 99204

SECRETARY

NUMBER	DATE ISSUED	EXPIRATION DATE
MD00044644	02-18-05	07-20-07

STATE OF WASHINGTON

RADIOACTIVE MATERIALS LICENSE

Pursuant to the Nuclear Energy and Radiation Control Act, RCW 70.98, and the Radiation Control Regulations, chapters 246-220 through 246-254 WAC, and in reliance on statements and representations heretofore made by the licensee designated below, a license is hereby issued authorizing such licensee to transfer, receive, possess and use the radioactive material(s) designated below; and to use such radioactive materials for the purpose(s) and at the place(s) designated below. **This license is subject to all applicable rules and regulations** promulgated by the State of Washington Department of Health.

1. Licensee Name:	3. License Number:
HEART CLINICS NORTHWEST	**WN-M0202-1 Entirety** Amendment **No. 15** *Fee Code 15*
2. Address: Suite 310 122 West Seventh Avenue Spokane, Washington 99204	**4. Expiration Date:** 31 January 2009 **5. Reference Number(s):** 03-12-28, 04-03-01, 05-02-16, 05-02-41, 05-12-31, 06-01-26, 06-01-27, 06-06-08, & **06-09-43.**

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. Gadolinium 153.	C. Sealed source (manufactured or distributed under a specific license issued by an Agreement State, a Licensing State, and/or the U.S. Nuclear Regulatory Commission for which a valid Sealed Source & Device registry exists) specifically authorized and intended for quality assurance procedures for nuclear medicine imaging systems.	C. No single source to exceed 18.5 gigabecquerels (500 millicuries), maximum of five sources (92.5 gigabecquerels) at any one time.

License Number: WN-M0202-1
Amendment No. 15

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. 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).

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

    B. Radioactive material authorized in Subitems A-C of Items 6, 7, and 8 may be stored and/or used at ***Suite 110, 820 South McClellan, Spokane, Washington.***

    C. Radioactive material authorized in Subitems A-C of Items 6, 7, and 8 may be stored and/or used ***on the 2nd Floor, 6002 North Mayfair, Spokane, Washington.***

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 Frank Ruppert, CNMT.

State of Washington

Radioactive Materials License

License Number: WN-M0202-1
Amendment No. 15

AUTHORIZED USERS

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

A.	Angelo Steven Ferraro, M.D.;	Subitems A-C of Items 6, 7, and 8.
B.	Andrew James Boulet, M.D.;	Subitems A-C of Items 6, 7, and 8.
C.	Kevin Matthew Kavanaugh, M.D	Subitems A-C of Items 6, 7, and 8.
D.	Michael Hostetler, M.D.;	Subitems A-C of Items 6, 7, and 8.
E.	Michael P. Williams, M.D.;	Subitems A-C of Items 6, 7, and 8.
F.	John P. Everett, M.D.;	Subitems A-C of Items 6, 7, and 8.
G.	Lynn Douglas Waggoner, Jr., M.D.;	Subitems A-C of Items 6, 7, and 8.
H.	Robert Dean Hill, M.D.;	Subitems A-C of Items 6, 7, and 8.
I.	Amna Tahir Ahmed, MD;	Subitems A-C of Items 6, 7, and 8.
J.	Marek Janout, MD;	Subitems A-C of Items 6, 7, and 8.
K	**Ronald Dean Jenkins, M.D.;**	**Subitems A-C 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, Licensing 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, a Licensing 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 $\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.

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, an Agreement State, or a Licensing 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, an Agreement State, or a Licensing State to perform such services. Licensing State authorization applies to naturally occurring and accelerator produced radioactive material (NARM) only.

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

License Number: WN-M0202-1
Amendment No. 15

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, 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 will not be unintentionally administered to a pregnant or breast-feeding woman.

24. 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.

25. Radioactive gases as free gas or in solution to be administered to humans shall be procured from a supplier who distributes the product indicated for human use in accordance with the Federal Food, Drug and Cosmetic Act.

26. 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.

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.

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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 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 17 December 2003.

B. Letter & attachments dated 19 February 2004. RE: Add AUR for nuclear cardiology.

C. Letter and attachments dated 07 February 2005, and facsimiles received 14 February 2005, RE: add new location.

D. Letter and attachments dated 01 December 2005, RE: add new location.

E. Facsimile & attachments dated 12 January 2006. RE: Request to remove Suite 201, 6120 North Mayfair location, and Report of Closure with Certificate of Disposition dated 29 December 2005 and attachments dated 11 January 2006. RE: Decommissioning report with survey results and DOH Decommissioning Verification Report dated 27 January 2006.

F. Letter & attachments dated 30 May 2006; RE: Add AUR.

G Letter & attachments dated 19 September 2006. RE: Add AUR.

FOR THE STATE OF WASHINGTON DEPARTMENT OF HEALTH

Date: 21 September 2006

By C. DeMaris
C. DeMaris
Radioactive Materials Licensing

11-13-06
DATE

This is to acknowledge the receipt of your letter/application dated 10-24-06, and to inform you that the initial processing, which includes an administrative review, has been performed.

☒ There were no administrative omissions. Your application will be assigned to a technical reviewer. Please note that the technical review may identify additional omissions or require additional information.

☐ Please provide to this office within 30 days of your receipt of this card:

The action you requested is normally processed within 90 days.

☐ A copy of your action has been forwarded to our License Fee & Accounts Receivable Branch, who will contact you separately if there is a fee issue involved.

Your action has been assigned **Mail Control Number** 471170.
When calling to inquire about this action, please refer to this mail control number.
You may call me at 817-860-8103.

Sincerely,

Colleen Murnahan

Licensing Assistant

NRC FORM 532 (RIV)
(10-2006)

BETWEEN:

License Fee Management Branch, ARM
and
Regional Licensing Sections

(FOR LFMS USE)
INFORMATION FROM LTS

Program Code: 02201
Status Code: 0
Fee Category: 7C
Exp. Date: 20110731
Fee Comments: _____
Decom Fin Assur Reqd: N

LICENSE FEE TRANSMITTAL

A. REGION

1. APPLICATION ATTACHED
   Applicant/Licensee: HEART CLINICS NORTHWEST
   Received Date: 20061027
   Docket No: 3035760
   Control No.: 471170
   License No.: 46-27704-01
   Action Type: Amendment

2. FEE ATTACHED
   Amount: /
   Check No.: /

3. COMMENTS

Signed Colleen Murnahan
Date 11-03-06

B. LICENSE FEE MANAGEMENT BRANCH (Check when milestone 03 is entered /__/)

1. Fee Category and Amount: _____

2. Correct Fee Paid. Application may be processed for:
   Amendment _____
   Renewal _____
   License _____

3. OTHER _____
   _____

Signed _____
Date _____

Heart Clinics NORTHWEST
SUITE 310 • 122 WEST SEVENTH AVENUE
SPOKANE, WASHINGTON 99204-2334

US POSTAGE

Mr. Jack Whitten
Region IV
US Nuclear Regulatory Commission
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