central peninsula hospital

21 February 2012

RECE
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DNMS

United States Nuclear Regulatory Commission
Region IV
Nuclear Materials Safety Branch
611 Ryan Plaza Drive, Suite 400
Arlington Texas 76011-8064

Re: Request for amendment to license number 50-29075-01

To Whom This May Concern:

We respectfully request that our radioactive materials license be amended as follows:

- Addition of the following physicians (please see attached radioactive materials license from the State of Washington) as authorized users for 35.100, 35.200, 35.300 and Gd-153:
  - Jedidiah Jonah Malan, MD
  - Leah Naomi Kiviat, MD

- Additional designation on our license (35.300) to allow oral administration of sodium iodide as per the attached State of Washington license for:
  - Kelley Lynn Cline, MD
  - Daniel Duong Pham, MD

- Finally, please delete the following physicians from our license since they no longer practice with us:
  - William Roberts, MD
  - Christopher Reed, MD
  - Michael Scott Fortney, MD

I know you will contact me if you require additional information or have any questions pertaining to our requested amendment.

Kindest Regards,

← need signature

Katherine A Leslie, BS, RDMS, CRA, RT(R)(CT)
Imaging Services Director
907.714.4590 direct line
kleslie@cpgh.org

CPH is a member of the Planetree Alliance.

5770 21

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:
SKAGIT VALLEY HOSPITAL	WN-M0196-1 Entirety Amendment No. 23 Fee Code 17
2. Address:	4. Expiration Date:
1415 East Kincaid Street Mount Vernon, Washington 98273	30 June 2016 5. Reference Number(s): 11-05-59, 11-07-12, 11-07-13, & 11-11-08.

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. Iodine-125, Cesium-131, and/or Palladium-103.	D. Any source or device listed in the Sealed Source & Device Registry (SSD), or research sealed source used in accordance with an active Investigational Device Exemption (IDE) accepted by the FDA.	D. As necessary for the uses authorized in Condition 9.D.

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E.	Gadolinium 153.	E.	Sealed source (manufactured or distributed under a specific license issued by an Agreement 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.	E.	No single source to exceed 18.5 gigabecquerels (500 millicuries), maximum of five sources (92.5 gigabecquerels) at any one time.

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. For interstitial treatment of cancer as a permanent implant.

E. 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).

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10. Radioactive materials authorized in Subitems A-E 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 Feiyu Xue, M.D.

AUTHORIZED USERS

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

A.	Lori Anne Ahrens, M.D.;	Subitems A, B, & E of Items 6, 7, and 8.
B.	Stephen J. Bartok, M.D.;	Subitems A, B, & E of Items 6, 7, and 8.
C.	John Thomas Burke, M.D.;	Subitems A, B, & E of Items 6, 7, and 8.
D.	Laurence Delmon Cambron, M.D.;	Subitems A, B, & E of Items 6, 7, and 8.
E.	Karen Dec, M.D.;	Subitems A, B, & E of Items 6, 7, and 8.
F.	Muneer Janak Desai, M.D.;	Subitems A, B, & E of Items 6, 7, and 8.
G.	Michael Scott Fortney, M.D.;	Subitems A, B, & E of Items 6, 7, and 8.
H.	Scott Douglas Harrison, M.D.;	Subitems A, B, & E of Items 6, 7, and 8.
I.	Jonathan Andrew Jaksha, M.D.;	Subitems A, B, & E of Items 6, 7, and 8.
J	Jesse Jennings Kincaid, M.D.;	Subitems A, B, & E of Items 6, 7, and 8.
K.	Mark Allison Studley, M.D.;	Subitems A, B, & E of Items 6, 7, and 8.

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13.	L.	Jamie Ryan Wong, M.D.;	Subitems A, B, & E of Items 6, 7, and 8.
	M.	Herman Poating Wu, M.D.;	Subitems A, B, & E of Items 6, 7, and 8.
	N.	Feiyu Xue, M.D.;	Subitems A-C, & E of Items 6, 7, and 8.
	O.	Kelley Lynn Cline, M.D.;	Subitems A, B, C (*I-131 <33mCi only*) & E of Items 6, 7, and 8.
	P.	Jeffrey Ellis Feld, M.D.;	Subitem B of Items 6, 7, and 8.
	Q.	Daniel Duong Pham, M.D.;	Subitems A, B, C (*I-131 <33mCi only*) & E of Items 6, 7, and 8.
	R.	Michal Anne Whiton, M.D.;	Subitem D of Items 6, 7, and 8.
	S.	David Abraham Kantorowitz, M.D.;	Subitem D of Items 6, 7, and 8.
	T.	**Jedidiah Jonah Malan, M.D.;**	**Subitems A, B, C (*I-131 <33mCi only*) & E of Items 6, 7, and 8.**
	U.	**Leah Naomi Kiviat, M.D.;**	**Subitems A, B, C (*I-131 <33mCi only*) & E of Items 6, 7, and 8.**

AUTHORIZED MEDICAL PHYSICISTS (Non-Human Use Only)

	V.	Mehran Ron Zaini, 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 ±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 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.

3. Notwithstanding the periodic leak test required by this condition, sealed Iodine 125, Cesium 131, and/or Palladium 103 therapy seeds need not be so tested when in final storage for decay and subsequent disposal.

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. 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. 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.

25. 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.

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26. 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.

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. 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.

29. 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.

30. 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 24 May 2011.

    B. Email & attachments dated 22 June 2011.

    C. Attachment B dated 24 June 2011.

    D. Letter & attachments dated 17 October 2011. RE: Add two new AUR.

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State of Washington

Radioactive Materials License

License Number: WN-M0196-1
Amendment No. 23

FOR THE STATE OF WASHINGTON DEPARTMENT OF HEALTH

Date: 9 November 2011

By C. DeMarls
Radioactive Materials Licensing

No 577021

Feb. 9. 2012 11:55AM nuclear No. 4024 P. 10

central peninsula hospital

250 Hospital Place, Soldotna, AK 99669
(907) 714-4404 • www.cpgh.org

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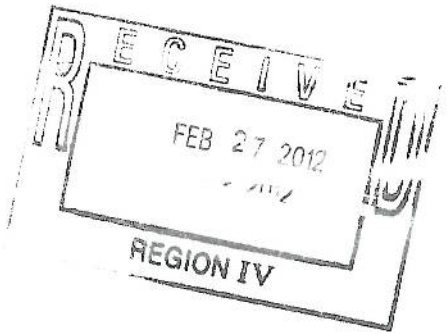
United States Nuclear Regulatory
Commission Region IV
Nuclear Materials Safety Branch
611 Ryan Plaza Drive, Suite 400
Arlington Texas 76011-8064



#577021

NRC FORM 532
(1-2012)

U. S. NUCLEAR REGULATORY COMMISSION

DATE

02/28/2012

NAME AND ADDRESS OF APPLICANT AND/OR LICENSEE	LICENSE NUMBER
Central Peninsula General Hospital ATTN: Katherine A. Leslie Imaging Services Director 250 Hospital Place Soldotna, Alaska 99669	50-29075-01
	MAIL CONTROL NUMBER 577021
	LICENSING AND/OR TECHNICAL REVIEWER ch

This is to acknowledge the receipt of your:

☑ LETTER and/or ☐ APPLICATION DATED: 02/21/2012

The initial processing, which included an administrative review, has been performed.

☑ AMENDMENT ☐ TERMINATION ☐ NEW LICENSE ☐ RENEWAL

☑ There were no administrative omissions identified during our initial review.

☐ This is to acknowledge receipt of your application for renewal of the material(s) license identified above. Your application is deemed timely filed, and accordingly, the license will not expire until final action has been taken by this office.

☐ Your application for a new NRC license did not include your taxpayer identification number. Please fill out NRC Form 531, located at the following link:

http://www.nrc.gov/reading-rm/doc-collections/forms/nrc531.pdf

Send the completed NRC Form 531, by facsimile, to the following number: (301) 415-5387

A copy of your action has been emailed to our License Fee and Accounts Receivable Branch, in our Headquarters office in Rockville, MD. You will be contacted separately if there is a fee issue involved.

Your application has been assigned the above listed **MAIL CONTROL NUMBER.** When calling to inquire about this action, please refer to this control number. Your application has been forwarded to a technical reviewer. Please note that the technical review, which is normally completed within 180 days for a renewal application (90 days for all other requests), may identify additional omissions or require additional information. If you have any questions concerning the processing of your application, our contact information is listed below:

Region IV
U. S. Nuclear Regulatory Commission
DNMS/NMSB - B
1600 E. Lamar Boulevard
Arlington, TX 76011-4511
(817) 200-1103 or (817) 200-1140

NRC FORM 532
(1-2012)

BETWEEN:

Accounts Receivable/Payable
and
Regional Licensing Branches

[FOR ARPB USE]
INFORMATION FROM LTS

Program Code: 02121
Status Code: Pending Amendment
Fee Category: 7C
Exp. Date: 08/31/2014
Fee Comments:
Decom Fin Assur Reqd: N

License Fee Worksheet - License Fee Transmittal

A. REGION

1. APPLICATION ATTACHED

Applicant/Licensee: CENTRAL PENINSULA GENERAL HOSPITAL
Received Date: 02/27/2012
Docket Number: 3033614
Mail Control Number: 577021
License Number: 50-29075-01
Action Type: Amendment

2. FEE ATTACHED

Amount: _____

Check No.: _____

3. COMMENTS

Signed: Carol L Hiee

Date: 2/28/12

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: _____