



UNITED STATES
NUCLEAR REGULATORY COMMISSION

REGION IV

611 RYAN PLAZA DRIVE, SUITE 400
ARLINGTON, TEXAS 76011-8064

January 29, 1997

Kootenai Medical Center
ATTN: David E. Davenport, M.D.
Radiation Safety Officer
2003 Lincoln Way
Coeur d'Alene, ID 83814-2677

SUBJECT: NOTIFICATION OF AUTHORIZED USER (§35.14)

Dear Dr. Davenport:

In accordance with 10 CFR 35.14, your letter dated January 9, 1997, is accepted as notification that you have permitted the individuals (Dr. Arnie Meekin and Dr. Edward Petruzzello) named in your letter referenced above to work as an authorized user pursuant to 10 CFR 35.13(b)(1). No further correspondence on this matter is required.

Please note that the notification process permits an individual to leave and return without further notification; however, notification is required when the authorized user's arrangement or commitment with the licensee is terminated (permanently discontinues performance of duties under the license).

If you have any questions regarding the above, please contact me at 817-860-8100.

Your cooperation is appreciated.

Sincerely,

Original Signed By
Jacqueline D. Burks

Jacqueline D. Burks
Health Physicist
Nuclear Materials Licensing Branch

License: 11-27307-01
Docket: 030-32264
Control:466300

200095

1/1

JAN 29 1997

DOCUMENT NAME: LAAUNOTIFYKOOTENAILTR

To receive a copy of this document, indicate in the box "C" - Copy without attachment/enclosure "E" - Copy with attachment/enclosure "N" - No Copy

RIV:NMLB	N						
JDBurks	JDBurks						
01/29/97							

(FOR LEMS USE)
INFORMATION FROM LTS

BETWEEN:

License Fee Management Branch, ARM
and
Regional Licensing Sections

Program Code: 02120

Status Code: 0

Fee Category: 7C 2B

Exp. Date: 20011031

Comments:

Decom Fin Assur Req'd: N

LICENSE FEE TRANSMITTAL

A. REGION

1. APPLICATION ATTACHED

Applicant/Licensee: KOOTENAI MEDICAL CENTER
Received Date: 9/01/97
Docket No.: 3032264
Control No.: 465300
License No.: 11-27307-01
Action Type: Notifications

2. FEE ATTACHED

Amount: 4
Check No.: 4

3. COMMENTS

Signed
Date

Bilgis Gruzynski
11/2/97

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

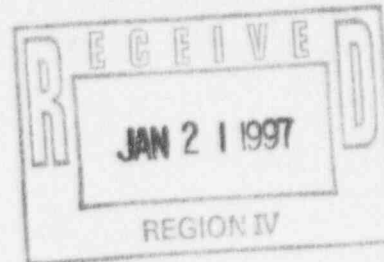


North Idaho Cancer Center

A service of Kootenai Medical Center.

January 9, 1997

Vivian Campbell, Health Physicist
Nuclear Materials Licensing Section
611 Plaza Drive, Suite 400
Arlington, TX 76011



Dear Ms. Campbell:

I am writing to add two physicians to our radioactive materials license. Dr. Arnie Meekin and Dr. Edward Petruzzello are being added to our radiation oncology practice and will be sharing coverage. They will not be doing any procedures in Idaho but may be required to remove cesium sources on occasion, thus we are asking permission to amend them to our license.

The addition of Drs. Meekin and Petruzzello to our radioactive materials license has been approved by the Radiation Safety Committee and it is my understanding that they may be added as physicians with a letter to you and a copy of the radioactive materials license for which they are a member in the state of Washington at Holy Family Hospital. I will enclose a copy of the Holy Family Radioactive Materials license. Please contact me if any further information or action is required.

Sincerely,

David E. Davenport, M.D.

DED:jb

700 Ironwood Drive
Coeur d'Alene, Idaho 83814
208/666-3800

Radiation Therapy - A joint service of Kootenai Medical Center and Sacred Heart Medical Center.

VHA.

Member of Voluntary Hospitals of America, Inc.

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see 7-10-96

State of Washington

Radioactive Materials License



Page 1 of 8 Pages

Pursuant to the Nuclear Energy and Radiation Control Act, RCW 70.98, and the Radiation Control Regulations, Chapters 246-220 through 246-255 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.** AMENDMENT NO. 37

1. Licensee Name HOLY FAMILY HOSPITAL	3. License Number WN-M040-1 (RENEWAL)
2. Address 5633 North Lidgerwood Spokane, Washington 99207	4. Expiration Date 31 July 2001.
	5. Reference number(s) 96-06-33.

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 as defined in Groups I and II of Schedule A, WAC 246-235-120. | A. Any radiopharmaceutical as defined in Groups I and II of Schedule A, WAC 246-235-120. | A. As necessary for the uses authorized in Condition 9.A. |
| B. Any radioactive material as defined in Group III of Schedule A, WAC 246-235-120. | B. Any form as defined in Group III of Schedule A, WAC 246-235-120. | B. 2.0 curies (74 gigabecquerels) of each radionuclide authorized in Condition 9.B. |
| C. Any radioactive material as defined in Groups IV and V of Schedule A, WAC 246-235-120. | C. Any radiopharmaceutical as defined in Groups IV and V of Schedule A, WAC 246-235-120. | C. As necessary for the uses authorized in Condition 9.C. |
| D. Any radioactive material as defined in Group VI of Schedule A, WAC 246-235-120. | D. Any source or device listed in Group VI of Schedule A, WAC 246-235-120. | D. As necessary for the uses authorized in Condition 9.D. |
| E. Palladium 103. | E. Sealed Source (Theragenics model 200). | E. As necessary for the uses authorized in Condition 9.E. |
| F. Xenon 133. | F. Gas or gas in solution. | F. 200 millicuries (7.4 gigabecquerels). |
| G. Technetium 99m. | G. Pentetate sodium as an aerosol. | G. As necessary for the uses authorized in Condition 9.G. |

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H. Cobalt 57.

H. Sealed source (manufactured or distributed under a specific license issued by a Licensing State or an Agreement State specifically intended for use associated with quality assurance procedures for Gamma Cameras or Dose Calibrators).

H. No single source to exceed 22 millicuries (814 megabecquerels).

I. Uranium (depleted).

I. Cadmium, Nickel, or Titanium-plated metal.

I. 150 kilograms.

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CONDITIONS

9. Authorized use.

- A. Any diagnostic procedure as defined in Groups I and II of Schedule A, WAC 246-235-120.
- B. Preparations and use of radiopharmaceuticals for any diagnostic procedure as defined in Group III of Schedule A, WAC 246-235-120, including Molybdenum 99/Technetium 99m generators (approved models) for preparation of Technetium 99m.
- C. Any therapeutic procedure as defined in Groups IV and V of Schedule A, WAC 246-235-120. Where pure beta emitters such as P-32 or Sr-89 are used, only unit dose is authorized.
- D. Any therapeutic procedure as defined in Group VI of WAC 246-235-120, Schedule A.
- E. For interstitial treatment of cancer as a permanent implant.
- F&G. To be used for pulmonary imaging studies.
- H. To be used for quality assurance procedures for gamma cameras or dose calibrators.
- I. To be used as shielding and/or collimation in Varian series linear accelerator(s).

10. Radioactive materials shall be stored and/or used at the licensee's address in Item 2.

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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 246-239 WAC, "Radiation Protection -- Nuclear Medicine"; Chapter 246-240 WAC, "Radiation Protection - Medical Therapy"; and Chapter 246-247 WAC, "Radiation Protection -- Air Emissions".
12. The Radiation Safety Officer for this program shall be Joseph Michael Seamon, M.S.
13. Radioactive material as described in Subitems below shall be used by, or under the supervision of:

A. F.A. Meekin, M.D.;	Subitems C-E & I of Items 6, 7, and 8.
B. E.J. Petruzello, M.D.;	Subitems A-I of Items 6, 7, and 8.
C. Phillip W. Curtis, M.D.;	Subitems A-C, F, & G of Items 6, 7, and 8.
D. Angelo G. Lurus, M.D.;	Subitems A-C (Group IV only) & F-H of Items 6, 7, and 8.
E. X.J. Zielinski, M.D.;	Subitems A-C & F-H of Items 6, 7, and 8.
F. H.M. Hirsch, M.D.;	Subitems A-C (Group IV only) & F-H of Items 6, 7, and 8.
G. J.J. Murphy, M.D.;	Subitems A-C (Group IV only) & F-H of Items 6, 7, and 8.
H. Lee F. Fletcher, M.D.;	Subitems A, B, & F-H of Items 6, 7, and 8.
I. Harold K. Cathcart, D.O.;	Subitems A & C of Items 6, 7, and 8.
J. Larry K. Hatch, M.D.;	Subitems A-C (Group IV only) & F-H of Items 6, 7, and 8.
K. L.R. Bernard, M.D.;	Subitems A, B, & F-H of Items 6, 7, & 8.
L. T.J. Allerding, M.D.;	Subitems A-C (Group IV only) & F-H of Items 6, 7, and 8.
M. Dennis E. Venzon, M.D.;	Subitems A-C & F-H of Items 6, 7, and 8.
N. Bryan E. Fuhs, M.D.;	Subitems A, B, & F-H of Items 6, 7, and 8.

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AMENDMENT NO. 37

O. Eric D. Stucky, M.D.; Subitems A,B,& F-H of Items 6, 7, and 8.

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

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).

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.

- 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 0.15 microcurie (5550 becquerels) of Molybdenum 99 per millicurie (37 megabecquerels) of Technetium 99m. The limits for Molybdenum 99 contamination represent maximum values and Molybdenum 99 contamination should be kept as low as reasonably achievable (ALARA) below these limits.

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- 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 17.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 record training given to personnel performing these tests. These records shall be maintained for inspection by the department for two (2) years following the performance of the tests and the training of personnel.
18. A. Radioactive material to be administered to humans shall be assayed for activity to determine the dose within 10% accuracy prior to administration to patients. Doses which vary by more than $\pm 10\%$ of the prescribed dose shall not be administered.
- B. The licensee shall establish written procedures for personnel to perform assays to an accuracy of 10% 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 two (2) years following the performance of the assay.
19. 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.

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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.

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

- b. The test shall be capable of detecting the presence of 0.005 microcurie (185 becquerels) 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 microcuries (or becquerels) and maintained for inspection by the department.

- c. If the test reveals the presence of 0.005 microcurie (185 becquerels) 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.

20.

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

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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 WAC 246-232-090, "Transportation".
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. When unsealed radioactive material is used or injected in an area outside the normal nuclear medicine area, such as treadmill rooms or patient rooms, an appropriate contamination survey shall be performed and documented for inspection by the department.
24. Patients administered Iodine 131 (or any IND/NDA-approved therapeutic radiopharmaceutical) for therapeutic purposes shall remain hospitalized until the residual activity (for Iodine 131) is 30 millicuries (1.11 gigabecquerels) or less or the measured dose rate from the unshielded patient is less than 5 millirem (50 microsieverts) per hour at a distance of one meter.
25. Patients containing brachytherapy sources other than permanent implants shall remain hospitalized until a documented source count, and surveys made with an appropriate radiation detection instrument, indicate that all implants have been removed. 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 implants are removed.
26. The licensee shall conduct a radioiodine bioassay program in accordance with the 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.
27. 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.

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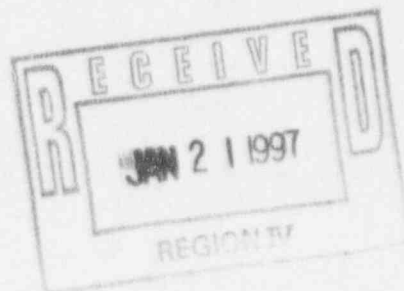
AMENDMENT NO. 37

28. The licensee shall respond in the manner, and within the time frame, specified to any and all department correspondence, including compliance letters resulting from inspections or investigations, and licensing 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.

29. 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 21 June 1996.



FOR THE STATE OF WASHINGTON DEPARTMENT OF HEALTH

Date 26 June, 1996

By C. DeMaris

C. DeMaris
Radiation Health Physicist