

ACCEPTANCE REVIEW MEMO (ARM)

Licensee: St. Peter's Community Hospital **License No.:** 25-12453-02
Docket No.: 030-10917 **Mail Control No.:** 471395
Type of Action: Amend **Date of Requested Action:** 06-04-07
Reviewer Assigned: Rachel **ARM reviewer(s):** Cook

Response	Deficiencies Noted During Acceptance Review
	<input type="checkbox"/> Open ended possession limits. Limit possession. Submit inventory. <input type="checkbox"/> Submit copies of most recent leak test results. <input type="checkbox"/> Add - delete IC license condition. Add IC paragraph in cover letter. <input type="checkbox"/> Split license from cover letter. Add SUNSI marking to license. <input type="checkbox"/> Ask the licensee if they have any type-amount of EPAct Material.
✓	Request copy of WA state license or reviewer contact state of WA to verify Dr. Pfeffer as AU. <i>(See Attached Review Note)</i>

Reviewer's Initials: B. Brewer **Date:** 7/5/07

<input type="checkbox"/> Yes <input type="checkbox"/> No	Unrestricted release Group 2 or >: Transfer memo to FCDB within 10 days.
<input type="checkbox"/> Yes <input type="checkbox"/> No	Decommissioning notification should be completed within 30 days.
<input type="checkbox"/> Yes <input type="checkbox"/> No	Termination request < 90 days from date of expiration
<input type="checkbox"/> Yes <input type="checkbox"/> No	Expedite (medical emergency, no RSO, location of use/storage not on license, RAM in possession not on license, other)
<input type="checkbox"/> Yes <input type="checkbox"/> No	TAR needed to complete action.
Branch Chief's and/or Sr. HP's Initials: _____	
Date: _____	

SUNSI Screening according to RIS 2005-31	
<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Non-Publicly Available, Sensitive if <u>any</u> 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: <u>JMC</u>	
Date: <u>6/8/07</u>	

Pre-Licensing Screening

Applicant Information:

Control No. 471395

Name: St. Peter's Community Hospital	Type of Request: Amend Program Code(s):
Location: MT	License No.: 25-12453-02 Docket No.: 030-10917

STEP 1—Radioactive Materials and Quantities Requested:

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.	Yes or No
A. The request is from a new applicant.	N
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.	N
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	N

Table of Risk Significant Quantities

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

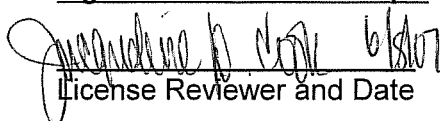
Radionuclide	Risk Significant Quantity (TBq ¹)	Risk Significant Quantity (Ci ¹)	Radionuclide	Risk Significant Quantity (TBq ¹)	Risk Significant Quantity (Ci ¹)
Am-241	0.6	16	Pm-147	400	11,000
Am-241/Be	0.6	16	Pu-238	0.6	16
Cf-252	0.2	5.4	Pu-239/Be	0.6	16
Cm-244	0.5	14	Ra-226 ²	0.4	11
Co-60	0.3	8.1	Se-75	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.

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).	Yes, No, or Not Applicable (NA)
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:



 License Reviewer and Date

July 5, 2007

St. Peter's Hospital
NRC License No. 28-12453-02

In reviewing the copy of Washington State Radioactive Material's License, in which Dr. Robert Pfeffer was authorized for any therapeutic procedures for which a written directive is required (WAC 246-240-201) and manual brachytherapy procedure (WAC 246-240-251), I compared the regulations to NRC Part 35 regulations. I determined that Washington State had implemented the revised Part 35 regulations. Additionally, the SRS Data Sheet indicated the effective date for the state's regulations was March 9, 2006 (recognition of specialty boards) and NRC review was documented on July 17, 2006 (ML061990221).

Based on my review of the Washington State license, I authorized Dr. Pfeffer for 10 CFR 35.300 and 35.400 materials.

A handwritten signature in cursive script, reading "Rachel S. Browder".

Rachel S. Browder, Health Physicist
Nuclear Materials Licensing Branch



St. Peter's Hospital

2475 Broadway • Helena, Montana 59601 • (406) 442-2480 • www.stpetes.org

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JUN 07 2007
DNMS

June 4, 2007

Nuclear Materials Licensing Branch
Nuclear Regulatory Commission
Region IV
611 Ryan Plaza, Suite 400
Arlington, Texas 76011-8064

Request for addition of one physician and the removal of two physicians to Radioactive Materials License #25-12453-02.

To Whom It May Concern:

Please add Robert Pfeffer, M.D., in the same categories as he is listed in on two Washington State Radioactive Material Licenses: WN-M0227-01, and WN-M005-01

Please remove Daniel Alzheimer, M.D., and Steven Todd, M.D. from our license.

If you have any questions, please contact Rod Knable, RT at 406-444-2330 or 406-980-0590.

Respectfully,

Randy Sibbitt, M.D.
Radiation Safety Officer
Diagnostic Imaging Department
St. Peter's Hospital
2475 Broadway
Helena, MT 59602

No 471395



St. Peter's Hospital

2475 Broadway • Helena, MT 59601

Facsimile Network
TELEFAX MESSAGE

To:

DATE: 6-26-07

Rachael Browden
Facility/Individual to whom information is being faxed
NRC
Fax Number 817 860 8188 Phone Number _____
Contact person at receiving facility

FROM:

ST. PETER'S HOSPITAL
Rod Knable - nuclear medicine
Department Mary Wadekamper - Quality Services
Fax Number 406 444 2153 Phone Number 406 444 2145
Contact person in department faxing information

Number of pages being faxed (including this page): 8

COMMENTS: _____
Dr Pfeffer's NRC license
for Dr Robert Pfeffer

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PLEASE SIGN AND RETURN: _____



STATE OF WASHINGTON RADIOACTIVE MATERIALS LICENSE

Page 1 of 11

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: <p style="text-align: center;">EMPIRE HEALTH SERVICES</p>	3. License Number: <p style="text-align: center;">WN-M005-1 Entirety AMENDMENT NO. 71</p> <p>(Fee Code 17)</p>
2. Address: <p style="text-align: center;">800 West Fifth Avenue Spokane, Washington 99204</p>	4. Expiration Date: <p style="text-align: center;">31 July 2009</p> <hr/> 5. Reference Number(s): 97-11-17, 97-11-30, 97-12-33, 04-07-04, 04-08-25, 04-12-52, 04-12-61, 04-12-66, 04-11-49, 04-12-34, 05-01-14, 05-01-15, 05-02-08, 05-02-62, 05-04-36, 05-06-52, 05-08-84, 05-09-52, 06-04-08, 06-06-57, 06-08-59, 06-08-55, 06-09-22, 06-09-23, 06-09-24, 07-02-25, & 07-02-26.

- | 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. |

State of Washington
Radioactive Materials License



Page 2 of 11

License Number: **WN-M005-1**
 Amendment No. 71

- | | | |
|---|--|--|
| <p>D. Any radioactive material authorized by WAC 246-240-251.</p> | <p>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 provided the requirements of WAC 246-240-066 are met.</p> | <p>D. As necessary for the uses authorized in Condition 9.D. subject to the Possession Limitations listed below:</p> |
| <p>E. Uranium (depleted).</p> | <p>E. Nickel, Titanium, or Cadmium-plated metal.</p> | <p>E. 200 kilograms.</p> |
| <p>F. Gadolinium 153.</p> | <p>F. 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.</p> | <p>F. No single source to exceed 18.5 gigabecquerels (500 millicuries), maximum of five sources (92.5 gigabecquerels) at any one time.</p> |

State of Washington
Radioactive Materials License



Page 3 of 11

License Number: WN-M00S-1
 Amendment No. 71

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.

SEALED MANUAL BRACHYTHERAPY SOURCE POSSESSION LIMITATIONS: Iridium-192, a maximum of 55.5 gigabecquerels (1.5 curies) at any one time; Cesium-137, a maximum of 92.5 gigabecquerels (2.5 curies) at any one time; and Cobalt-60, a maximum of 18.5 gigabecquerels (500 millicuries) at any one time.

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 therapeutic procedure authorized by WAC 246-240-201 for which a written directive is required.
 - D. Any manual brachytherapy procedure authorized by WAC 246-240-251.
 - E. To be used for shielding and/or collimation of gamma sources in the nuclear medicine Department.
 - F. 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-F of Items 6, 7, and 8 shall be stored and/or used *at the licensee's address in Item 2*.
 - B. Radioactive material authorized in subitems A-C, D (limited to permanent seed implants), E, & F of Items 6, 7, and 8 may be used and/or stored at *Valley Hospital & Medical Center, East 12606 Mission, Spokane, Washington 99210*.

State of Washington
Radioactive Materials License



Page 4 of 11

License Number: WN-M005-1
 Amendment No.71

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 Michael John Novak, CNMT.

AUTHORIZED USERS

13. Radioactive material as described in Subitems below shall be used by, or under the supervision of:
- | | |
|-----------------------------------|--|
| A. Margaret Jean Haddon, M.D.; | Subitems A-G of Items 6, 7, and 8. |
| B. Kenneth E. Symington, M.D.; | Subitems A, B, E, & F of Items 6, 7, and 8. |
| C. Lyle R. Wendling, M.D.; | Subitems A, B, E, & F of Items 6, 7, and 8. |
| D. Arthur S. Watanabe, M.D.; | Subitems A, B, E, & F of Items 6, 7, and 8. |
| E. Ronald J. Cocchiarella, M.D.; | Subitems A-C, E, & F of Items 6, 7, and 8. |
| F. Mark Terry, M.D.; | Subitems A-C, E, & F of Items 6, 7, and 8. |
| G. David J. Stagaman, M.D.; | Subitem B (<i>nuclear cardiology only</i>) of Items 6, 7, & 8. |
| H. Andrew Boulet, M.D.; | Subitem B (<i>nuclear cardiology only</i>) of Items 6, 7, & 8. |
| I. Bryan E. Fuhs, M.D.; | Subitem B (<i>nuclear cardiology only</i>) of Items 6, 7, & 8. |
| J. Kevin Matthew Cavanaugh, M.D.; | Subitem B (<i>nuclear cardiology only</i>) of Items 6, 7, & 8. |

State of Washington
Radioactive Materials License



Page 5 of 11

License Number: WN-M005-1
 Amendment No. 71

- | | | |
|--------|---|--|
| 13. K. | Angelo Ferraro, M.D.; | Subitem B (<i>nuclear cardiology only</i>) of Items 6, 7, & 8. |
| L. | Darren C. Hollenbaugh, M.D.; | Subitem B (<i>nuclear cardiology only</i>) of Items 6, 7, & 8. |
| M. | Laura Anne Gallup Hotchkiss, M.D.; | Subitems A, B, E, & F of Items 6, 7, and 8. |
| N. | Robert K. Fairbanks, M.D.; | Subitem D of Items 6, 7, and 8. |
| O. | Mark Wesley Reckson, M.D.; | Subitems A, B, E, & F of Items 6, 7, and 8. |
| P. | Paul Sherman Paulson, M.D.; | Subitems A, B, E & F of Items 6, 7, and 8. |
| Q. | George Dean Conger, M.D.; | Subitems A, B, E, & F of Items 6, 7, and 8. |
| R. | Randall Gordon Weissbuch, M.D.; | Subitems A-C, E, & F of Items 6, 7, and 8. |
| S. | Devon Lee Holder, M.D.; | Subitems A, B, E, & F of Items 6, 7, and 8. |
| T. | Robert David Pfeffer, M.D.; | Subitems C & D of Items 6, 7, and 8. |
| U. | Monte Fredrick Zarlingo, M.D.; | Subitems A, B, E, & F of Items 6, 7, and 8. |
| V. | Wayne T. Lamoreaux, M.D.; | Subitems C & D of Items 6, 7, and 8. |
| W. | Jayson Scott Brower, M.D.; | Subitems A, B, E, & F of Items 6, 7, and 8. |
| X. | Johan K. Ahn, M.D.; | Subitems A, B, E, & F of Items 6, 7, and 8. |
| Y. | Christopher M. Lee, M.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 is authorized to use licensed material for human use under the terms and conditions of this license, provided the visiting physician: | |

State of Washington
Radioactive Materials License



Page 6 of 11

License Number: **WN-M005-1**
Amendment No. **71**

14. A. 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.
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.

State of Washington
Radioactive Materials License



Page 7 of 11

License Number: WN-M005-1
Amendment No. 71

16. 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.

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.

WACs > Title 246 > Chapter 246-240 > Section 246-240-210

[246-240-207](#) << [246-240-210](#) >> [246-240-213](#)

WAC 246-240-210

Training for use of unsealed radioactive material for which a written directive is required.

Except as provided in WAC [246-240-078](#), the licensee shall require an authorized user of unsealed radioactive material for the uses authorized under WAC [246-240-201](#) to be a physician who:

(1) Is certified by a medical specialty board whose certification process has been recognized by the department, the U.S. Nuclear Regulatory Commission or an agreement state. (Specialty boards whose certification process has been recognized by the commission or an agreement state will be posted on the NRC's web page at <http://www.nrc.gov>.) To be recognized, a specialty board shall require all candidates for certification to:

(a) Successfully complete a residency training in a radiation therapy or nuclear medicine training program or a program in a related medical specialty that includes seven hundred hours of training and experience as described in subsection (2) of this section. Eligible training programs must be approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education or Royal College of Physicians and Surgeons of Canada or the Committee on Postgraduate Training of the American Osteopathic Association;

(b) Pass an examination, administered by diplomates of the specialty board, which tests knowledge and competence in radiation safety, radionuclide handling, quality assurance, and clinical use of unsealed by-product material; and

(c) Obtain written certification that the individual has achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized under WAC [246-240-201](#). The written certification must be signed by a preceptor authorized user who meets the requirements in WAC [246-240-210](#) or equivalent U.S. NRC or agreement state requirements. The preceptor authorized user, who meets the requirements in WAC [246-240-210](#) must have experience in administering dosages in the same dosage category or categories (i.e., this section) as the individual requesting authorized user status; or

(2) Has completed seven hundred hours of training and experience, including a minimum of two hundred hours of classroom and laboratory training, in basic radionuclide handling techniques applicable to the medical use of unsealed radioactive material requiring a written directive. The training and experience must include:

(a) Classroom and laboratory training in the following areas:

(i) Radiation physics and instrumentation;

(ii) Radiation protection;

(iii) Mathematics pertaining to the use and measurement of radioactivity;

(iv) Chemistry of radioactive material for medical use; and

(v) Radiation biology; and

(b) Work experience, under the supervision of an authorized user who meets the requirements in subsection (1) or (2) of this section, or equivalent U.S. NRC or agreement state requirements. A supervising authorized user, who meets the requirements in this subsection, must also have experience in administering dosages in the same dosage category or categories (i.e., this section) as the individual requesting authorized user status. The work experience must involve:

<p>Inside the Legislature</p> <ul style="list-style-type: none"> ★ Find Your Legislator ★ Visiting the Legislature ★ Agendas, Schedules and Calendars ★ Bill Information ★ Laws and Agency Rules ★ Legislative Committees ★ Legislative Agencies ★ Legislative Information Center ★ E-mail Notifications (Listserv) ★ Students' Page ★ History of the State Legislature
<p>Outside the Legislature</p> <ul style="list-style-type: none"> ★ Congress - the Other Washington ★ TV Washington ★ Washington Courts ★ OFM Fiscal Note Website



- (i) Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;
- (ii) Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters;
- (iii) Calculating, measuring, and safely preparing patient or human research subject dosages;
- (iv) Using administrative controls to prevent a medical event involving the use of unsealed radioactive material;
- (v) Using procedures to contain spilled radioactive material safely and using proper decontamination procedures;
- (vi) Eluting generator systems, measuring and testing the eluate for radionuclidic purity, and processing the eluate with reagent kits to prepare labeled radioactive drugs; and
- (vii) Administering dosages of radioactive drugs to patients or human research subjects involving a minimum of three cases in each of the following categories for which the individual is requesting authorized user status:
 - (A) Oral administration of less than or equal to 1.22 gigabecquerels (33 millicuries) of sodium iodide I-131;
 - (B) Oral administration of greater than 1.22 gigabecquerels (33 millicuries) of sodium iodide I-131. Experience with at least three cases in this also satisfies the requirement in (b)(vii)(A) of this subsection;
 - (C) Parenteral administration of any beta emitter or a photon-emitting radionuclide with a photon energy less than 150 keV for which a written directive is required; and/or
 - (D) Parenteral administration of any other radionuclide for which a written directive is required; and
 - (E) Has obtained written certification that the individual has satisfactorily completed the requirements in subsection (1)(a) and (b) of this section and has achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized under WAC 246-240-201. The written certification must be signed by a preceptor authorized user who meets the requirements in this section, or equivalent U.S. NRC or agreement state requirements. The preceptor authorized user, who meets the requirements in this subsection (2), must have experience in administering dosages in the same dosage category or categories (i.e., this section) as the individual requesting authorized user status.

[Statutory Authority: RCW [70.98.050](#). 06-05-019, § 246-240-210, filed 2/6/06, effective 3/9/06.]

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July 17, 2006

Mr. Terry C. Frazee, Western Regional Director
Division of Radiation Protection
Washington Department of Health
7171 Clearwater Lane, Bldg. 5
P.O. Box 47827
Olympia, WA 98504-7827

Dear Mr. Frazee:

We have reviewed the final revisions to the Washington regulations, Washington Administrative Code (WAC), Chapters 246-220 and 246-240, received by our office on June 27, 2006. These regulations were reviewed by comparison to the equivalent Nuclear Regulatory Commission (NRC) rules in 10 CFR Part 35 and the requirements of the two amendments identified in the enclosed State Regulation Status (SRS) Data Sheet. We discussed our review of the regulations with you on July 13, 2006.

As a result of our review, we have no comments. Please note that we have limited our review to regulations required for compatibility and/or health and safety. We have determined that this regulation, as published, meets the compatibility and health and safety category established in the Office of State and Tribal Programs (STP) Procedure SA-200.

The SRS Data Sheet summarizes our knowledge of other Washington regulations. Please let us know if you note any inaccuracies or have any comments on the information contained in the SRS Data Sheet. This letter, including the SRS Data Sheet, is posted on the STP Web Site: <http://www.hsrdo.ornl.gov/nrc/rulemaking.htm>.

If you have any questions regarding the review, the compatibility and health and safety categories, or any of the NRC regulations used in the review, please contact me, or Mr. Osiris Siurano of my staff at (301)415-2307 or e-mail: OSP@NRC.GOV.

Sincerely,

RA By KNSchneider For

Dennis K. Rathbun, Deputy Director
Office of State and Tribal Programs

Enclosures:
As stated

ML061990221

NRC Chronology Identification	FR Notice (Date Due For State Implementation)	RATS ID	Proposed (P) / Final (F) ² Rule / License Condition (LC) ML # ⁵	NRC Review / Y, N ² / Date / ML # ⁵	Final State Regulation ¹ (Effective Date) ⁶
Respiratory Protection and Controls to Restrict Internal Exposure-Part 20	64 FR 54543; 64 FR 55524; (2/2/03)	1999-3	F ML012770291	N 2/22/02 ML020570410	3/7/01
Energy Compensation Sources for Well Logging and Other Regulatory Clarifications-Part 39	65 FR 20337; (5/17/03)	2000-1	F ML030830470	N 4/18/03 ML031110100	7/3/03
New Dosimetry Technology-Parts 34, 36, 39	65 FR 63750; (1/8/04)	2000-2	F ML030830470	N 4/18/03 ML031110100	7/3/03
Requirements for Certain Generally Licensed Industrial Devices Containing Byproduct Material-Parts 30, 31, 32	65 FR 79162; (2/16/04)	2001-1	F ⁸ ML040430105	Y 8/31/06 ML062400063	
Revision of the Skin Dose Limit-Part 20	67 FR 16298; (4/5/05)	2002-1	F ML043510236	N 12/29/04 ML043650051	12/29/04
Medical Use of Byproduct Material-Parts 20, 32, and 35	67 FR 20249; (4/24/05)	2002-2	F ML061790303	N 7/17/06 ML061990221	3/9/06
★Financial Assurance for Materials Licensees – Parts 30, 40, 70	68 FR 57327 12/3/06	2003-1	F ML0707170180	N 2/01/07 ML070310005	02/12/07
Compatibility With IAEA Transportation Safety Standards and Other Transportation Safety Amendments – Part 71.	69 FR 3697; (10/01/07)	2004-1			
Security Requirements for Portable Gauges Containing Byproduct Material - Part 30	70 FR 2001; (7/11/08)	2005-1			
Medical Use of Byproduct Material - Recognition of Specialty Boards - Part 35	70 FR 16336; 71 FR 1926 (4/29/08)	2005-2	F ML061790303	N 7/17/06 ML061990221	3/9/06
Increased Controls for Risk-Significant Radioactive Sources (NRC Order EA-05-090) ⁷	70 FR 72128; (12/1/05)	2005-3	LC ML053220233	11/18/05 ML053220464	
Minor Amendments - Part 20,30,32,35,40 and 70	71FR15005 (3/27/09)	2006-1			

From SRS
Data Sheet
for State
of Washington
R. Broad
7/5/07

(FOR LFMS USE)
INFORMATION FROM LTS

Program Code: 02120
Status Code: 0
Fee Category: 7C
Exp. Date: 20130831
Fee Comments: CODE 23
Decom Fin Assur Req'd: N

BETWEEN:
License Fee Management Branch, ARM
and
Regional Licensing Sections

LICENSE FEE TRANSMITTAL

A. REGION

1. APPLICATION ATTACHED
Applicant/Licensee: ST. PETER'S COMMUNITY HOSPITAL
Received Date: 2007/06/07
Docket No: 3010917
Control No.: 471395
License No.: 25-12453-02
Action Type: Amendment

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

Signed *Colleen M. ...*
Date _____

3. COMMENTS
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 _____