FRONTIER
CANCER CENTER
AND BLOOD INSTITUTE

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DNMS

October 30, 2012

Michelle Simmons
Health Physicist
U.S. Nuclear Regulatory Commission
Division of Nuclear Materials Safety

RE: Amendment Request for Frontier Cancer Center License Number 25-29392-01

Dear Ms. Simmons:

We respectfully request an amendment to the above referenced license for the following additions:

We wish to add Kathleen A. Ryan, M.D. as Authorized User for 35.300, *Medical Use of Unsealed Byproduct Material for Which a Written Directive is Required.* Dr. Ryan is currently on the Materials License for St. Vincent Healthcare in Billings, MT (License Number 25-07553-01). A copy of this license is attached to help expedite the amendment process.

We wish to add Yttrium 90 (^{90}Y) in the chemical form of ^{90}Y-labeled ibritumomab tiuxetan (^{90}Y-Zevalin) for radioimmunotherapy of non-Hodgkin's lymphoma. Zevalin was developed by IDEC Pharmaceuticals and the Biologic License Application was approved by the Food and Drug Administration on February 19, 2002. Zevalin falls within the category described in 10 CFR 35.300, *Medical Use of Unsealed Byproduct Material for Which a Written Directive is Required.*

Authorized Users

Each dose will be delivered as a unit dose for patient injection. Doses will be administered by the licensed Authorized User (AU), Kathleen A. Ryan, M.D.

Possession Limit

The requested possession limit is:

— 200 mCi ^{90}Y Ibritumomab Tiuxetan

The administered ^{90}Y dose will be either 0.3 or 0.4 mCi/kg (depending on patient weight and baseline blood platelet count), not to exceed 32 mCi.

Ordering, Receipt, Opening and Preparing for Administration

A written directive from the AU physician will be obtained prior to ordering any therapeutic dose. The RSO shall ensure inventory control and supervision of safety tasks. Existing procedures will be used for RSO review of associated delegated tasks and inventory tracking.

PUBLIC
☐ Immediate Release
☑ Normal Release

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

Reviewer: [signature] Date: 11/7/12

ML 5 7 9 3 5 6

The ^{90}Y-Zevalin will be received from an authorized nuclear pharmacy in unit-dose (liquid in syringe) form, ready for administration. All packages will be received, surveyed and opened in accordance with our standard operating procedures for this activity as stated in the RML. These tasks will be conducted in the Hot Lab. Personnel who handle these materials will be properly monitored with individual monitoring devices (body and extremity).

The syringes will be appropriately shielded (e.g., Lucite or acrylic) to minimize exposure during handling. Once the radiopharmaceutical has been logged in, the dosage amount will be checked against the written directive, communicated to the APU, and stored until use in the Hot Lab.

Dose Administration

An injection station (i.e., small table) will be set up in either injection room 1 or injection room 2. The injection station will be covered with plastic backed absorbent paper. The floor underneath the site of injection will also be covered.

The patient will be identified using two methods of identification (e.g., driver's license and social security number). For female patients, verification of the patient's pregnancy and/or lactation status will be determined prior to administration of the dose.

All doses will be administered in the injection station by the AU. Personnel administering the dose and/or attending the dose administration of ^{90}Y-Zevalin will wear appropriate radiation monitoring devices (ring badges and whole body dosimetry as appropriate). ^{90}Y-Zevalin will be infused either by direct IV infusion from the syringe by hand or by use of a metered syringe pump. Appropriate Lucite or Plexiglas shielding will be utilized.

Post-Administration Survey

After the procedure is completed, surveys of the area and equipment will be performed and recorded. Contaminated areas will be secured and/or cleaned as appropriate and consistent with our previously-approved RML licensing conditions. Contaminated equipment and materials will be placed in storage in the Hot Lab for decay for at least ten half lives, after which time they will be surveyed with a GM survey instrument calibrated with a pancake probe. If radiation levels are indistinguishable from background (when measured in a normal background area), the materials will be discarded in routine trash, provided all radiation labels are removed or obliterated. Precautions related to activities such as handling contaminated items or excreta, use of shielding, labeling, etc., will also be incorporated into our radiation safety training program.

Patient Release

^{90}Y-Zevalin is administered on an outpatient basis. The amount of administered ^{90}Y meets the criteria specified in Column 1 of Table U.1 of NUREG-1556, Vol. 9, Rev. 2 for release of patients based on administered activity. The following instructions will be provided to patients to minimize exposure to family members and the general public:

Expansion of Radiation Protection Program

Precautions related to safe handling of unsealed radioactive materials will be incorporated into our existing radiation protection program. In addition to the procedures described above, we commit to implementing those model procedures of NUREG-1556, Vol. 9, Rev. 2 that are directly applicable to ^{90}Y-Zevalin use, specifically:

Appendix M — Model Procedures for an Occupational Dose Program
Appendix O — Model Procedures for Ordering and Receiving Packages
Appendix R — Model Procedure for Area Surveys
Appendix T — Model Procedure for Safe Use of Unsealed Licensed Material
Appendix W — Model Procedure for Waste Disposal by Decay-In-Storage and Licensed Material Return

We hope that this information is sufficient for you to complete a timely review of our amendment request. Please contact Justin Sherman at 406-238-6883 if you require any additional information.

Sincerely,

Justin Sherman, M.S.
Medical Physicist
Radiation Safety Officer

FRONTIER
CANCER CENTER
AND BLOOD INSTITUTE
Department of Radiation Oncology
406-238-6883 (Phone)
419-618-3466 (Cell)
406-238-6961 (Fax)
jsherman@frontiercancer.com

No. 5793566

NRC FORM 374

U.S. NUCLEAR REGULATORY COMMISSION

Amendment No. 82

MATERIALS LICENSE

Pursuant to the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974 (Public Law 93-438), and Title 10, Code of Federal Regulations, Chapter I, Parts 30, 31, 32, 33, 34, 35, 36, 39, 40, and 70, and in reliance on statements and representations heretofore made by the licensee, a license is hereby issued authorizing the licensee to receive, acquire, possess, and transfer byproduct, source, and special nuclear material designated below; to use such material for the purpose(s) and at the place(s) designated below; to deliver or transfer such material to persons authorized to receive it in accordance with the regulations of the applicable Part(s). This license shall be deemed to contain the conditions specified in Section 183 of the Atomic Energy Act of 1954, as amended, and is subject to all applicable rules, regulations, and orders of the Nuclear Regulatory Commission now or hereafter in effect and to any conditions specified below.

Licensee	In accordance with letter dated January 11, 2012
1. St. Vincent Healthcare	3. License number 25-07553-01 is amended in its entirety to read as follows:
2. P.O. Box 35200 Billings, Montana 59107-5200	4. Expiration date April 30, 2015
	5. Docket No. 030-02396 Reference No.

6. Byproduct, source, and/or special nuclear material	7. Chemical and/or physical form	8. Maximum amount that licensee may possess at any one time under this license
A. Any byproduct material permitted by 10 CFR 35.100	A. Any	A. As needed
B. Any byproduct material permitted by 10 CFR 35.200	B. Any	B. As needed
C. Any byproduct material permitted by 10 CFR 35.300	C. Any	C. 500 millicuries
D. Any byproduct material permitted by 10 CFR 35.400	D. Sealed sources (3M Model Nos. 6500, 6501, 6502, 6503 and 6504; Bard Brachytherapy Model STM-1251; Theragenics Model 200; Best Medical International Model 81-01 Series and Model 2301; Amersham Health, Medi-Physics, Inc., Model 6711 Oncoseed™)	D. 1500 millicuries
E. Any byproduct materials identified in 10 CFR 31.11	E. Prepackage Kits	E. 10 millicuries
F. Strontium-90 permitted by 10 CFR 35.400	F. Sealed sources (Amersham Corporation Model SIA.20)	F. 90 millicuries
G. Depleted uranium	G. Metal	G. 999 kilograms

9. Authorized use:

A. Any uptake, dilution and excretion study permitted by 10 CFR 35.100.
B. Any imaging and localization study permitted by 10 CFR 35.200.
C. Any use permitted by 10 CFR 35.300.
D. Any manual brachytherapy procedure permitted by 10 CFR 35.400.
E. In vitro studies.
F. Strontium-90 for ophthalmic radiation therapy permitted by 10 CFR 35.400.
G. For use as shielding material in Molybdenum-99/Technetium-99m generators.

M 5 7 9 3 5 6

MATERIALS LICENSE
SUPPLEMENTARY SHEET

License Number
25-07553-01

Docket or Reference Number
030-02396

Amendment No. 82

CONDITIONS

10. Licensed material may be used or stored only at the licensee's facilities located at:

    A. 1233 North 30th Street, Billings, Montana,

    B. Yellowstone Surgery Center, 1144 North 28th Street, Billings, Montana, for material listed in Items 6.B. and 6.D.

11. The Radiation Safety Officer for this license is Christopher Fitz.

12. Licensed material is only authorized for use by, or under the supervision of:

    A. Individuals permitted to work as an authorized user, authorized nuclear pharmacist, and/or authorized medical physicist in accordance with 10 CFR 35.13 and 35.14.

    B. The following individuals are authorized users for the material and medical uses indicated:

Authorized Users	Material and Use
Joseph C. Apostol, M.D.	35.200
Mitchell E. Gallagher, M.D.	35.100; 35.200; 31.11
Joseph P. Dillard, M.D.	35.100; 35.200; 31.11
Robert Rex Dietz, M.D.	35.100; 35.200; 35.300
Kathleen A. Ryan, M.D.	35.100; 35.200; 35.300
John M. Schallenkamp, M.D.	35.400; Strontium-90 for ophthalmic radiation therapy
Christopher Goulet, M.D.	35.400; Strontium-90 for ophthalmic radiation therapy
John V. Hanson, M.D.	35.100; 35.200; 31.11; oral administration of sodium iodide I-131 in quantities less than or equal to 33 millicuries
John S. Brandon, M.D.	35.100; 35.200; oral administration of sodium iodide I-131
Robert L. Stears, M.D.	35.100; 35.200

    C. The following individual is an authorized medical physicist:

Authorized Medical Physicist	Material and Use
Dennis A. Cheek, Ph.D.	Strontium-90 in an ophthalmic applicator for activity calculation

13. In addition to the possession limits in Item 8, the licensee shall further restrict the possession of licensed material to quantities below the minimum limit specified in 10 CFR 30.35(d) for establishing financial assurance for decommissioning.

MATERIALS LICENSE
SUPPLEMENTARY SHEET

License Number
25-07553-01

Docket or Reference Number
030-02396

Amendment No. 82

14. The licensee is authorized to transport licensed material in accordance with the provisions of 10 CFR Part 71, "Packaging and Transportation of Radioactive Material."

15. Except as specifically provided otherwise in this license, the licensee shall conduct its program in accordance with the statements, representations, and procedures contained in the documents, including any enclosures, listed below. This license condition applies only to those procedures that are required to be submitted in accordance with the regulations. Additionally, this license condition does not limit the licensee's ability to make changes to the radiation protection program as provided for in 10 CFR 35.26. The U.S. Nuclear Regulatory Commission's regulations shall govern unless the statements, representations, and procedures in the licensee's application and correspondence are more restrictive than the regulations.

A.	Application dated October 21, 2004	(ML063180067)
B.	Letter dated November 23, 2004	(ML043280649)
C.	Letter dated April 18, 2005	(ML051150232)
D.	Facsimile dated April 22, 2005	(ML051150214)
E.	Facsimile dated October 17, 2005	(ML062920135)
F.	Letter dated November 27, 2006	(ML063380384)
G.	E-Mail dated December 4, 2006	(ML063380368 and ML063380384)
H.	Letter dated July 27, 2009	(ML092380334)
I.	September 29, 2011	(ML11285A149)

FOR THE U.S. NUCLEAR REGULATORY COMMISSION

/RA/

Date: May 30, 2012

By: _____
Lizette Roldán-Otero, Ph.D., Health Physicist
Nuclear Materials Safety Branch B
Region IV
Arlington, Texas 76011-4511

No. 5 7 9 3 5 6

FRONTIER
CANCER CENTER
AND BLOOD INSTITUTE
1315 Golden Valley Circle
Billings, MT 59102

RETURN SERVICE
REQUESTED

RECEIVED
NOV - 1 2012
DNMS

U.S. Nuclear Regulatory Commission
Region IV
1600 E. Lamar Blvd.
Arlington, TX 76011-4511

RECEIVED
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REGION IV

IN*WPMP 76011

M57935 6

NRC FORM 532
(1-2012)

U. S. NUCLEAR REGULATORY COMMISSION

DATE

11/05/2012

NAME AND ADDRESS OF APPLICANT AND/OR LICENSEE	LICENSE NUMBER
Frontier Cancer Centers and Blood Institute ATTN: Mary Beery Chief Operating Officer P.O. Box 30976 Billings, Montana 59107	25-29392-01
	MAIL CONTROL NUMBER 579356
	LICENSING AND/OR TECHNICAL REVIEWER ch

This is to acknowledge the receipt of your:

☑ LETTER and/or ☐ APPLICATION DATED: 10/30/2012

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)
✓ 11/5/12

BETWEEN:

Accounts Receivable/Payable
and
Regional Licensing Branches

[FOR ARPB USE]
INFORMATION FROM WBL

Program Code: 02230
Status Code: Pending Amendment
Fee Category: 7C
Exp. Date:
Fee Comments:
Decom Fin Assur Reqd: N

License Fee Worksheet - License Fee Transmittal

A. REGION

1. APPLICATION ATTACHED

Applicant/Licensee:	FRONTIER CANCER CENTERS AND BLOOD INSTITUTE
Received Date:	11/01/2012
Docket Number:	3038298
Mail Control Number:	579356
License Number:	25-29392-01
Action Type:	Amendment

2. FEE ATTACHED

Amount: _____

Check No.: _____

3. COMMENTS

Signed: Carol L. Hein

Date: 11/5/12

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: _____