

TETON CANCER INSTITUTE

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AUG 25 2014

DNMS

US NRC Region IV  
ATTN: DNMS Licensing Assistant  
1600 East Lamar Boulevard  
Arlington, TX 76011-4511

**Request for License Amendment**

Dear DNMS Licensing Assistant,

Mountain View Hospital, Teton Cancer Institute, Radiation Oncology is requesting additional 35.290 authorization for Dr. Steven J. Todd. Please find attached the completed Form 313 AUD that demonstrates the proctoring provided by Dr. Michael C. Biddulph.

If you have any questions, please do not hesitate to contact me.

Thank you,  
David Theel, M.S.  
RSO, Medical Physicist  
License # 11-35120-01

*David Theel* 8-22-14

Mountain View Hospital  
2325 Coronado Street  
Idaho Falls, Idaho 83404

Teton Cancer Institute  
Radiation Oncology  
1550 Hoopes Avenue  
Idaho Falls, Idaho 83404

**PUBLIC**

- ☐ Immediate Release  
☒ Normal Release

**NON-PUBLIC**

- ☐ A.3 Sensitive-Security Related  
☐ A.7 Sensitive Internal  
☐ Other: \_\_\_\_\_

Reviewer: JMO Date: 8/29/14

STEVEN J. TODD, MD • CALVIN J. MCALLISTER, MD • MICHAEL F. CALLAGHAN, MD

RADIATION ONCOLOGY  
1550 HOOPES AVE.  
IDAHO FALLS, ID 83404  
TETONCANCER.COM  
INFO@TETONCANCER.COM  
208.542.7220

584657

**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, 37, 39, 40, 70 and 71, 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		
1. Mountain View Hospital		3. License number 11-35120-01
2. 2325 Coronado Street Idaho Falls, Idaho 83404		4. Expiration date March 31, 2024
		5. Docket No. 030-38701 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. 2 curies total
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.		

**CONDITIONS**

10. Licensed material may be used and/or stored only at the licensee's facilities located at Mountain View Hospital, Teton Cancer Institute, 1550 Hoopes Avenue, Idaho Falls, Idaho.
11. The Radiation Safety Officer for this license is David Theel, M.S.
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.



**MATERIALS LICENSE  
SUPPLEMENTARY SHEET**License Number  
11-35120-01Docket or Reference Number  
030-38701**(CORRECTED COPY)**

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

<u>Authorized Users</u>	<u>Material and Use</u>
Michael C. Biddulph, M.D.	35.100; 35.200
Michael T. Callaghan, M.D.	35.300
Calvin Jon McAllister, M.D.	35.300
Steven J. Todd, M.D.	35.300

13. For sealed sources not associated with 10 CFR Part 35 use, the following conditions apply:

- A. Sealed sources shall be tested for leakage and/or contamination at intervals not to exceed the intervals specified in the certificate of registration issued by the U.S. Nuclear Regulatory Commission under 10 CFR 32.210 or under equivalent regulations of an Agreement State.
- B. Notwithstanding Paragraph A of this Condition, sealed sources designed to primarily emit alpha particles shall be tested for leakage and/or contamination at intervals not to exceed 3 months.
- C. In the absence of a certificate from a transferor indicating that a leak test has been made within the intervals specified in the certificate of registration issued by the U.S. Nuclear Regulatory Commission under 10 CFR 32.210 or under equivalent regulations of an Agreement State, prior to the transfer, a sealed source received from another person shall not be put into use until tested and the test results received.
- D. Sealed sources need not be tested if they contain only hydrogen-3; or they contain only a radioactive gas; or the half-life of the isotope is 30 days or less; or they contain not more than 100 microcuries of beta- and/or gamma-emitting material or not more than 10 microcuries of alpha-emitting material.
- E. Sealed sources need not be tested if they are in storage and are not being used; however, when they are removed from storage for use or transferred to another person and have not been tested within the required leak test interval, they shall be tested before use or transfer. No sealed source shall be stored for a period of more than 10 years without being tested for leakage and/or contamination.
- F. The leak test shall be capable of detecting the presence of 0.005 microcurie (185 becquerels) of radioactive material on the test sample. If the test reveals the presence of 0.005 microcurie (185 becquerels) or more of removable contamination, a report shall be filed with the U.S. Nuclear Regulatory Commission in accordance with 10 CFR 30.50(c)(2), and the source shall be removed immediately from service and decontaminated, repaired, or disposed of in accordance with Commission regulations. The report shall be filed within 5 days of the date the leak test result is known with the U.S. Nuclear Regulatory Commission, Region IV, 1600 East Lamar Boulevard, Arlington, Texas 76011-4511, ATTN: Director, Division of Nuclear Materials Safety. The report shall specify the source involved, the test results, and corrective action taken.



**MATERIALS LICENSE  
SUPPLEMENTARY SHEET**License Number  
11-35120-01Docket or Reference Number  
030-38701**(CORRECTED COPY)**

- G. Tests for leakage and/or contamination, including leak test sample collection and analysis, shall be performed by the licensee or by other persons specifically licensed by the U.S. Nuclear Regulatory Commission or an Agreement State to perform such services.
- H. Records of leak test results shall be kept in units of microcuries and shall be maintained for 3 years.
14. Sealed sources containing licensed material shall not be opened or sources removed from source holders by the licensee.
15. 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.
16. The licensee is authorized to transport licensed material in accordance with the provisions of 10 CFR Part 71, "Packaging and Transportation of Radioactive Material."
17. 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 November 27, 2013 (ML13361A128)
- B. Letter dated February 28, 2014 with enclosures (ML14056A331)

FOR THE U.S. NUCLEAR REGULATORY COMMISSION

Date April 29, 2014By 

Roberto J. Torres, Senior Health Physicist  
Nuclear Materials Safety Branch B  
Region IV  
Arlington, Texas 76011-4511

**AUTHORIZED USER TRAINING AND EXPERIENCE  
AND PRECEPTOR ATTESTATION**  
(for uses defined under 35.100, 35.200, and 35.500)  
[10 CFR 35.190, 35.290, and 35.590]APPROVED BY OMB: NO. 3150-0120  
EXPIRES: (05/31/2015)

Name of Proposed Authorized User

Steve J Todd

State or Territory Where Licensed

Idaho

Requested Authorization(s) (check all that apply)

- ☒ 35.100 Uptake, dilution, and excretion studies
- ☒ 35.200 Imaging and localization studies
- ☐ 35.500 Sealed sources for diagnosis (specify device) \_\_\_\_\_

**PART I -- TRAINING AND EXPERIENCE**  
(Select one of the three methods below)

\* Training and Experience, including board certification, must have been obtained within the 7 years preceding the date of application or the individual must have obtained related continuing education and experience since the required training and experience was completed. Provide dates, duration, and description of continuing education and experience related to the uses checked above.

☐ **1. Board Certification**

- a. Provide a copy of the board certification.
- b. If using only 35.500 materials, stop here. If using 35.100 and 35.200 materials, skip to and complete Part II Preceptor Attestation.

☒ **2. Current 35.390 Authorized User Seeking Additional 35.290 Authorization**

- a. Authorized user on Materials License 11-35120-01 meeting 10 CFR 35.390 or equivalent Agreement State requirements seeking authorization for 35.290.
- b. Supervised Work Experience.  
(If more than one supervising individual is necessary to document supervised work experience, provide multiple copies of this section.)

Description of Experience	Location of Experience/License or Permit Number of Facility	Clock Hours	Dates of Experience*
Eluting generator systems appropriate for the preparation of radioactive drugs for imaging and localization studies, measuring and testing the eluate for radionuclidic purity, and processing the eluate with reagent kits to prepare labeled radioactive drugs	Mountain View Hospital, 2325 Coronado Street, Idaho Falls, Idaho 83404 / 11-35120-01	10	July 14-15, 2014

**Total Hours of Experience:**

Supervising Individual

Michael C. Biddulph

License/Permit Number listing supervising individual as an authorized user

11-35120-01

Supervisor meets the requirements below, or equivalent Agreement State requirements (check all that apply).

- ☒ 35.290      ☐ 35.390 + generator experience in 32.290(c)(1)(ii)(G)



## AUTHORIZED USER TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued)

☐ 3. Training and Experience for Proposed Authorized User

## a. Classroom and Laboratory Training.

Description of Training	Location of Training	Clock Hours	Dates of Training*
Radiation physics and instrumentation			
Radiation protection			
Mathematics pertaining to the use and measurement of radioactivity			
Chemistry of byproduct material for medical use <i>(not required for 35.590)</i>			
Radiation biology			
Total Hours of Training:			

b. Supervised Work Experience (completion of this table is not required for 35.590).  
(If more than one supervising individual is necessary to document supervised work experience, provide multiple copies of this section.)

Supervised Work Experience		Total Hours of Experience:	
Description of Experience Must Include:	Location of Experience/License or Permit Number of Facility	Confirm	Dates of Experience*
Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys		<input type="checkbox"/> Yes <input type="checkbox"/> No	
Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters		<input type="checkbox"/> Yes <input type="checkbox"/> No	

## AUTHORIZED USER TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued)

## 3. Training and Experience for Proposed Authorized User (continued)

## b. Supervised Work Experience. (continued)

Description of Experience Must Include:	Location of Experience/License or Permit Number of Facility	Confirm	Dates of Experience*
Calculating, measuring, and safely preparing patient or human research subject dosages		<input type="checkbox"/> Yes <input type="checkbox"/> No	
Using administrative controls to prevent a medical event involving the use of unsealed byproduct material		<input type="checkbox"/> Yes <input type="checkbox"/> No	
Using procedures to contain spilled byproduct material safely and using proper decontamination procedures		<input type="checkbox"/> Yes <input type="checkbox"/> No	
Administering dosages of radioactive drugs to patients or human research subjects		<input type="checkbox"/> Yes <input type="checkbox"/> No	
Eluting generator systems appropriate for the preparation of radioactive drugs for imaging and localization studies, measuring and testing the eluate for radionuclidic purity, and processing the eluate with reagent kits to prepare labeled radioactive drugs		<input type="checkbox"/> Yes <input type="checkbox"/> No	

Supervising Individual

License/Permit Number listing supervising individual as an  
authorized userSupervisor meets the requirements below, or equivalent Agreement State requirements (*check one*).☐ 35.190    ☐ 35.290    ☐ 35.390    ☐ 35.390 + generator experience in 35.290(c)(1)(ii)(G)

## c. For 35.590 only, provide documentation of training on use of the device.

Device	Type of Training	Location and Dates

## d. For 35.500 uses only, stop here. For 35.100 and 35.200 uses, skip to and complete Part II Preceptor Attestation.

**AUTHORIZED USER TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued)**

**PART II – PRECEPTOR ATTESTATION**

**Note:** This part must be completed by the individual's preceptor. The preceptor does not have to be the supervising individual as long as the preceptor provides, directs, or verifies training and experience required. If more than one preceptor is necessary to document experience, obtain a separate preceptor statement from each. (Not required to meet training requirements in 35.590)

By checking the boxes below, the preceptor is attesting that the individual has knowledge to fulfill the duties of the position sought and not attesting to the individual's "general clinical competency."

**First Section**

**Check one of the following for each use requested:**

For 35.190

Board Certification

☒ I attest that Steven Todd, M.D. has satisfactorily completed the requirements in  
Name of Proposed Authorized User

10 CFR 35.190(a)(1) and has achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized under 10 CFR 35.100.

**OR**

Training and Experience

☐ I attest that \_\_\_\_\_ has satisfactorily completed the 60 hours of training and  
Name of Proposed Authorized User

experience, including a minimum of 8 hours of classroom and laboratory training, required by 10 CFR 35.190(c)(1), and has achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized under 10 CFR 35.100.

For 35.290

Board Certification

☒ I attest that Steven Todd, M.D. has satisfactorily completed the requirements in  
Name of Proposed Authorized User

10 CFR 35.290(a)(1) and has achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized under 10 CFR 35.100 and 35.200.

**OR**

Training and Experience

☐ I attest that \_\_\_\_\_ has satisfactorily completed the 700 hours of training  
Name of Proposed Authorized User

and experience, including a minimum of 80 hours of classroom and laboratory training, required by 10 CFR 35.290(c)(1), and has achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized under 10 CFR 35.100 and 35.200.

**Second Section**

**Complete the following for preceptor attestation and signature:**

☒ I meet the requirements below, or equivalent Agreement State requirements, as an authorized user for:

☒ 35.190    ☒ 35.290    ☐ 35.390    ☐ 35.390 + generator experience

Name of Preceptor	Signature	Telephone Number	Date
Michael C. Bidduph	Michael C. Bidduph MD	542-5000	8/18/14
License/Permit Number/Facility Name			
11-35120-01 / Mountain View Hospital			



RIDIT

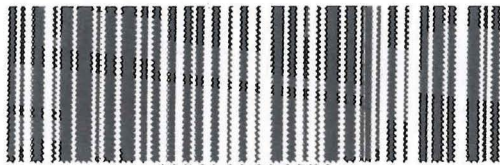
FROM: Tetot Cancer Institute  
CARR: Federal Express  
TRK#: 9114901230803373068745  
RCVD: 8/25/2014 1044

TO: HILL, Carol  
PH:  
BDG:  
RM:  
PCS: 1

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1550 Hoopes Avenue  
Idaho Falls, Idaho 83404

TO: US NRC Region IV  
Attn DNMS Licensing Asst  
1600 East Lamar Boulevard  
Arlington Tx 76011-4511

Label 228, July 2013

FOR DOMESTIC AND INTERNATIONAL USE



DATE  
08/28/2014

NAME AND ADDRESS OF APPLICANT AND/OR LICENSEE

Mountain View Hospital  
ATTN: David Theel, MS MP  
Radiation Safety Officer  
2325 Coronado Street  
Idaho Falls, ID 83404

LICENSE NUMBER

11-35120-01

MAIL CONTROL NUMBER

584657

LICENSING AND/OR TECHNICAL REVIEWER

cmurnahan

*cm*

This is to acknowledge the receipt of your:

☒ LETTER and/or ☐ APPLICATION

DATED: rec'd 8/25/14

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 Blvd.  
Arlington, TX 76011-4511  
(817) 200-1103 or (817) 200-1140

*emailed to  
lic. 8-28-14*



BETWEEN:

Accounts Receivable/Payable  
and  
Regional Licensing Branches

[ FOR ARPB USE ]  
INFORMATION FROM WBL

Program Code: 02120  
Status Code: Pending Amendment  
Fee Category: 7C  
Exp. Date: 03/31/2024  
Fee Comments:  
Decom Fin Assur Req'd: N

## License Fee Worksheet - License Fee Transmittal

### A. REGION

#### 1. APPLICATION ATTACHED

Applicant/Licensee: Mountain View Hospital  
Received Date: 08/25/2014  
Docket Number: 3038701  
Mail Control Number: 584657  
License Number: 11-35120-01  
Action Type: Amendment

#### 2. FEE ATTACHED

Amount: \_\_\_\_\_

Check No.: \_\_\_\_\_

#### 3. COMMENTS

Signed: \_\_\_\_\_

Date: \_\_\_\_\_

### 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: \_\_\_\_\_