Kootenai Medical Center

2003 Lincoln Way
Coeur d'Alene, Idaho 83814
208.666.2000 **tel**
www.kootenaihealth.org

October 6, 2008

Jacqueline D. Cook
Senior Health Physicist
Nuclear Materials Safety Branch B
U.S. Nuclear Regulatory Commission, Region IV
611 Ryan Plaza Drive, Suite 400
Arlington TX 76011-8064

Re: License # 11-27307-01

Dear Ms. Cook:

Please amend the reference license to include Karie-Lynn Kelly, M.D., as an authorized user under Part 35.600 Remote after-loader unit(s). You will find attached to the enclosed NRC Form 313A that provides preceptor attestation signed by J. Lance Griffith, M.D., who is an authorized user under Idaho license # 11-27307-01, Dr. Kelly's ABR certification in Radiation Oncology and training documentation. The training provided Dr. Kelly specifically covered the HDR unit authorized in the reference license.

If you have further questions or concerns regarding this amendment request, please call Dr. David E. Davenport (RSO) at (208) 666-3800.

Sincerely,

Joe Morris, FACHE
Chief Executive Officer
Kootenai Health

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NRC FORM 313A (AUS) (10-2007) U.S. NUCLEAR REGULATORY COMMISSION

AUTHORIZED USER TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (for uses defined under 35.400 and 35.600) [10 CFR 35.490, 35.491, and 35.690]

APPROVED BY OMB: NO. 3150-0120
EXPIRES: 10/31/2008

Name of Proposed Authorized User	State or Territory Where Licensed

Requested Authorization(s) (check all that apply)

- ☐ 35.400 Manual brachytherapy sources
- ☐ 35.400 Ophthalmic use of strontium-90
- ☑ 35.600 Remote afterloader unit(s)
- ☐ 35.600 Teletherapy unit(s)
- ☐ 35.600 Gamma stereotactic radiosurgery unit(s)

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. For 35.600, go to the table in 3.e. and describe training provider and dates of training for each type of use for which authorization is sought.

c. Skip to and complete Part II Preceptor Attestation.

☐ **2. Current 35.600 Authorized User Requesting Additional Authorization for 35.600 Use(s) Checked Above**

a. Go to the table in section 3.e. to document training for new device.

b. Skip to and complete Part II Preceptor Attestation.

☐ **3. Training and Experience for Proposed Authorized User**

a. Classroom and Laboratory Training ☐ 35.490 ☐ 35.491 ☐ 35.690

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			
Radiation biology			
Total Hours of Training:			

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AUTHORIZED USER TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued)

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

b. Supervised Work and Clinical Experience for 10 CFR 35.490 *(If more than one supervising individual is necessary to document supervised work experience, provide multiple copies of this page.)*

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		☐ Yes ☐ No	
Checking survey meters for proper operation		☐ Yes ☐ No	
Preparing, implanting, and safely removing brachytherapy sources		☐ Yes ☐ No	
Maintaining running inventories of material on hand		☐ Yes ☐ No	
Using administrative controls to prevent a medical event involving the use of byproduct material		☐ Yes ☐ No	
Using emergency procedures to control byproduct material		☐ Yes ☐ No	

Clinical experience in radiation oncology as part of an approved formal training program	Location of Experience/License or Permit Number of Facility	Dates of Experience*
Approved by: ☐ Residency Review Committee for Radiation Oncology of the ACGME ☐ Royal College of Physicians and Surgeons of Canada ☐ Committee on Postdoctoral Training of the American Osteopathic Association		
Supervising Individual	License/Permit Number listing supervising individual as an Authorized User	

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AUTHORIZED USER TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued)

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

c. Supervised Clinical Experience for 10 CFR 35.491

Description of Experience	Location of Experience/License or Permit Number of Facility	Clock Hours	Dates of Experience*
Use of strontium-90 for ophthalmic treatment, including: examination of each individual to be treated; calculation of the dose to be administered; administration of the dose; and follow up and review of each individual's case history			

Supervising Individual	License/Permit Number listing supervising individual as an Authorized User

d. Supervised Work and Clinical Experience for 10 CFR 35.690

☐ Remote afterloader unit(s) ☐ Teletherapy unit(s) ☐ Gamma stereotactic radiosurgery unit(s)

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*
Reviewing full calibration measurements and periodic spot-checks		☐ Yes ☐ No	
Preparing treatment plans and calculating treatment doses and times		☐ Yes ☐ No	
Using administrative controls to prevent a medical event involving the use of byproduct material		☐ Yes ☐ No	
Implementing emergency procedures to be followed in the event of the abnormal operation of the medical unit or console		☐ Yes ☐ No	
Checking and using survey meters		☐ Yes ☐ No	
Selecting the proper dose and how it is to be administered		☐ Yes ☐ No	

NRC FORM 313A (AUS) (10-2007) U.S. NUCLEAR REGULATORY COMMISSION

AUTHORIZED USER TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued)

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

d. Supervised Work and Clinical Experience for 10 CFR 35.690 (continued)

Clinical experience in radiation oncology as part of an approved formal training program	Location of Experience/License or Permit Number of Facility	Dates of Experience*
Approved by: ☐ Residency Review Committee for Radiation Oncology of the ACGME ☐ Royal College of Physicians and Surgeons of Canada ☐ Committee on Postdoctoral Training of the American Osteopathic Association		

Supervising Individual	License/Permit Number listing supervising individual as an Authorized User

e. For 35.600, describe training provider and dates of training for each type of use for which authorization is sought.

Description of Training	Training Provider and Dates		
	Remote Afterloader	Teletherapy	Gamma Stereotactic Radiosurgery
Device operation	Gammamed Mammosite treatment delivery		
Safety procedures for the device use	Gammamed HDR Emergency procedures		
Clinical use of the device	Gammamed HDR for me		

Supervising Individual. *If training provided by Supervising Individual (If more than one supervising individual is necessary to document supervised work experience, provide multiple copies of this page.)*	License/Permit Number listing supervising individual as an Authorized User
Jon Lance Griffith	WN-M-031-1

Authorized for the following types of use:

☒ Remote afterloader unit(s) ☐ Teletherapy unit(s) ☐ Gamma stereotactic radiosurgery unit(s)

f. Provide completed Part II Preceptor Attestation.

NRC FORM 313A (AUS) U.S. NUCLEAR REGULATORY COMMISSION
(10-2007)

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.

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 requested authorization:

For 35.490:

Board Certification

☐ I attest that _____ has satisfactorily completed the requirements in
Name of Proposed Authorized User

35.490(a)(1) and has achieved a level of competency sufficient to function independently as an authorized user of manual brachytherapy sources for the medical uses authorized under 10 CFR 35.400.

OR

Training and Experience

☐ I attest that _____ has satisfactorily completed the 200 hours of
Name of Proposed Authorized User

classroom and laboratory training, 500 hours of supervised work experience, and 3 years of supervised clinical experience in radiation oncology, as required by 10 CFR 35.490(b)(1) and (b)(2), and has achieved a level of competency sufficient to function independently as an authorized user of manual brachytherapy sources for the medical uses authorized under 10 CFR 35.400.

For 35.491:

☐ I attest that _____ has satisfactorily completed the 24 hours of
Name of Proposed Authorized User

classroom and laboratory training applicable to the medical use of strontium-90 for ophthalmic radiotherapy, has used strontium-90 for ophthalmic treatment of 5 individuals, as required by 10 CFR 35.491(b), and has achieved a level of competency sufficient to function independently as an authorized user of strontium-90 for ophthalmic use.

Second Section

For 35.690:

Board Certification

☐ I attest that _____ has satisfactorily completed the requirements in
Name of Proposed Authorized User

35.690(a)(1).

OR

Training and Experience

☐ I attest that _____ has satisfactorily completed 200 hours of classroom
Name of Proposed Authorized User

and laboratory training, 500 hours of supervised work experience, and 3 years of supervised clinical experience in radiation therapy, as required by 10 CFR 35.690(b)(1) and (b)(2).

AND

NRC FORM 313A (AUS) (10-2007) U.S. NUCLEAR REGULATORY COMMISSION

AUTHORIZED USER TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued)

Preceptor Attestation (continued)

Third Section

For 35.690: (continued)

[X] I attest that Carrie-Lynn Kelly (Name of Proposed Authorized User) has received training required in 35.690(c) for device operation, safety procedures, and clinical use for the type(s) of use for which authorization is sought, as checked below.

[X] Remote afterloader unit(s) [ ] Teletherapy unit(s) [ ] Gamma stereotactic radiosurgery unit(s)

AND

Fourth Section

[X] I attest that Carrie-Lynn Kelly (Name of Proposed Authorized User) has achieved a level of competency sufficient to achieve a level of competency sufficient to function independently as an authorized user for:

[X] Remote afterloader unit(s) [ ] Teletherapy unit(s) [ ] Gamma stereotactic radiosurgery unit(s)

Fifth Section

Complete the following for preceptor attestation and signature:

[✓] I meet the requirements in 10 CFR 35.490, 35.491, 35.690, or equivalent Agreement State requirements, as an authorized user for:

[ ] 35.400 Manual brachytherapy sources [ ] 35.600 Teletherapy unit(s)

[ ] 35.400 Ophthalmic use of strontium-90 [ ] 35.600 Gamma stereotactic radiosurgery unit(s)

[✓] 35.600 Remote afterloader unit(s)

Name of Preceptor	Signature	Telephone Number	Date
J. LANCE GRIFFITH	J. Lance Griffith	509.474.3356	9-2-8

License/Permit Number/Facility Name

WA. STATE WM-301-1

The American Board of Radiology

Organized through the cooperation of the
American College of Radiology, the American Roentgen Ray Society,
the American Radium Society, the Radiological Society of North America,
the Section on Radiology of the American Medical Association,
the American Society for Therapeutic Radiology and Oncology, the Association of
University Radiologists, and American Association of Physicists in Medicine
Hereby certifies that

Karie-Lynn Kelly, MD

Has pursued an accepted course of graduate study
and clinical work, has met certain standards and qualifications and
has passed the examinations conducted under the authority of
The American Board of Radiology
On this second day of June, 2018

All Eligible

Thereby demonstrating to the satisfaction of the Board
that she is qualified to practice the specialty of

Radiation Oncology

H. Reed Quarnberg, MD
President

Richard L. Morin
Secretary-Treasurer

Chairman, Board of Trustees

Certificate No. 51818

Valid through 2018

VARIAN medical systems | BRACHYTHERAPY

Certificate of Attendance

Presented To:

Kootenai Cancer Center

Coeur d'Alene, ID

David Davenport, MD; Karie-Lynn Kelly, MD
Robert J. Matthews; Neil Eitel
Justin Zugish; Mike Shirey
Brenda Wild; Holly Shimmel

For Attending the Training Course on GammaMedPlus 3/24 ™ HDR Afterloader

Training Course Dates: July 31-August 1, 2008

Trainer: John Morrison , Varian Medical Systems

Varian BrachyTherapy – The Better Solution.

PARTNERS FOR Life

Mp 4 7 2 0 2 5

ACCEPTANCE REVIEW MEMO (ARM)

Licensee: Kootenai Medical Center **License No.:** 11-27307-01

Docket No.: 030-32264 **Mail Control No.:** 472025

Type of Action: Amend **Date of Requested Action:** 10-06-2008

Reviewer Assigned: **ARM reviewer(s):** J. Cook

Response	Deficiencies Noted During Acceptance Review
	[ ] Open ended possession limits. Submit inventory. Limit possession. [ ] Submit copies of latest leak test results. [ ] Add IC L.C./Fingerprint LC, add SUNSI markings to license. [ ] Confirm with licensee if they have NARM material.

Reviewer's Initials: _____ **Date:** _____

☐Yes ☐No Request for unrestricted release Group 2 or >. Consult with Bravo Branch.

☐Yes ☐No Termination request < 90 days from date of expiration

☐Yes ☐No Expedite (medical emergency, no RSO, location of use/storage not on license, RAM in possession not on license, other)

☐Yes ☐No TAR needed to complete action.

Branch Chief's and/or HP's Initials: _____ **Date:** _____

SUNSI Screening according to RIS 2005-31

☐Yes ☑No **Sensitive and Non-Publicly Available** if any item below is checked

General guidance:

_____RAM = or > than Category 3 (Table 1, RIS 2005-31), use Unity Rule
_____Exact location of RAM [suite #, bldg. #, location different from mailing address] (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 HP's Initials: _____ **Date:** DEC 12 2008

DEC 17 2008

DATE

This is to acknowledge the receipt of your letter/application dated 10-06-08, and to inform you that the initial processing, which includes an administrative review, has been performed.

☒ There were no administrative omissions. Your application will be assigned to a technical reviewer. Please note that the technical review may identify other omissions or require additional information.

☐ Please provide to this office within 30 days of your receipt of this card:

The action you requested is normally processed within 90 days.

☐ A copy of your action has been forwarded to our License Fee & Accounts Receivable Branch, who will contact you separately if there is a fee issue involved.

Your action has been assigned **Mail Control Number** 472025.
When calling to inquire about this action, please refer to this mail control number.
You may call me at 817-860-8103.

Sincerely,

Colleen Mirnahan

Licensing Assistant

NRC FORM 532 (RIV)
(10-2008)

BETWEEN:

License Fee Management Branch, ARM
and
Regional Licensing Sections

(FOR LFMS USE)
INFORMATION FROM LTS

Program Code: 02230
Status Code: O
Fee Category: 7C EX 2B
Exp. Date: 20120131
Fee Comments: _____
Decom Fin Assur Reqd: N

LICENSE FEE TRANSMITTAL

A. REGION

1. APPLICATION ATTACHED
   Applicant/Licensee: KOOTENAI MEDICAL CENTER
   Received Date: 20081016
   Docket No: 3032264
   Control No.: 472025
   License No.: 11-27307-01
   Action Type: Amendment

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

3. COMMENTS

Signed Colleen Murnahan
Date 12-09-08

B. LICENSE FEE MANAGEMENT BRANCH (Check when milestone 03 is entered /__/)

1. Fee Category and Amount: _____

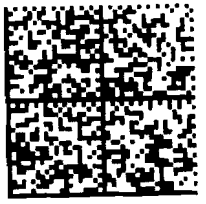
2. Correct Fee Paid. Application may be processed for:
   Amendment _____
   Renewal _____
   License _____

3. OTHER _____
   _____

Signed _____
Date _____

...ministration
Kootenai Health

2003 Lincoln Way
Coeur d'Alene, Idaho 83814



Jacqueline D. Cook
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