

License: 25-01051-01  
Docket: 030-62389  
Control: 585360

**Cook, Jackie**

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**From:** Chris <chrisfitz65@hotmail.com>  
**Sent:** Monday, February 09, 2015 4:06 PM  
**To:** Cook, Jackie  
**Subject:** Information for RIA Billings Clinic 25-01051-01  
**Attachments:** Confirmation of AU approvals for Beam Therapy (2).pdf; Terakedis AU for Billings Clinic MT (2).pdf; UT # 1800001 amendment # 60 (3).pdf; Ed Slowey HDR Training.pdf

Good Afternoon Ms. Cook,

Please find attached training material and information for Dr. Breanne Tereakedis and Thomas Edward Slowey.

Please note Dr. Tereakedis is not listed of the University of Utah, but I did obtain an letter from their RSO that Dr. Tereakedis was authorized on their license for 35.400 and 35.600 uses.

Thank you for your assistance with this request.

Chris Fitz  
RSO Billings Clinic

**PUBLIC**  
 Immediate Release  
 Normal Release

**NON-PUBLIC**  
 A.3 Sensitive-Security Related  
 A.7 Sensitive Internal  
 Other: \_\_\_\_\_

Reviewer: JAC Date: 2/10/15



October 13, 2014

Chris Fitz, RSO  
Billings Clinic  
2800 10<sup>th</sup> Ave North  
Billings, MT 59107

Subject: Confirmation of Authorized User Status for Breanne Terakedis, M.D.

Dear Mr. Fitz:

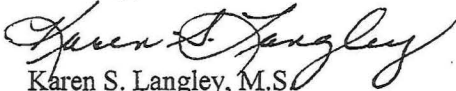
The University of Utah has been issued a Medical and Academic Broadscope Radioactive Materials License by the State of Utah, Division of Radiation Control. This license allows the University's Radiation Safety Committee (RSC) to name qualified individuals as Authorized Users (AU) for medical use of radioactive materials. An individual so named must meet the same qualifications as found in 10 CFR 35.

Dr. Terakedis has been named by the RSC at the University of Utah, an AU for use under Utah Administrative Code R313-32 [incorporating 10 CFR 35. 400 (for manual brachytherapy sources), and 35.600 (High Dose Rate After Loader) by reference].

Notwithstanding the statement found in Utah Administrative Code R313-30(3)(c), the University of Utah RSC has specific permission granted by the Director of the State of Utah, Division of Radiation Control, to name an individual as an AU for External Beam Therapeutic Radiation Machines. Dr. Terakedis has been named, by the RSC at the University of Utah, an AU for External Beam Therapeutic Radiation Machines for use under Utah Administrative Code R313-30.

If you have any questions, please contact me at (801) 581-6141.

Sincerely,

  
Karen S. Langley, M.S.  
Director and Radiation Safety Officer

Attachment: University of Utah Broadscope Radioactive Material License # UT 1800001  
Therapeutic Radiation Machine Authorized Users

cc: Breanne Terakedis RU File #820.0 (w/o attachment)



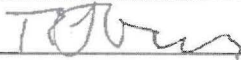
# Billings Clinic

## Varian VariSource 200 HDR System


### Annual Training as Required by NRC 35.610 (d) and (e)

Date: 11-11-2014

The below personnel were present in the annual review of the operating and emergency procedures for the Varian VariSource 200 HDR system.

Name (Print)	Signature
ED SLOWEY	

Instructors:

 11-14-14 11:25

Dennis Cheek, PhD DABR  
Medical Physicist



# Billings Clinic

## Varian VariSource 200 HDR System

### Annual Training as Required by NRC 35.610 (d) and (e)

Date: 11-14-14

#### A. Radiation Safety

##### a. Radiation Limits

##### i. Occupational Limits

1. Whole body = 5 rem/year
2. Lens of eye = 15 rem/year
3. Extremities = 50 rem/year
4. Skin = 50 rem /year
5. Embryo/Fetus = 0.5 rem over whole pregnancy

##### ii. Member of General Public = 0.1 rem/year

##### b. Radiation badges: All HDR personal should be wearing ring and whole body badges during all HDR procedures.

##### c. How to reduce your exposure in any radiation situation.

- i. Time: If you decrease the amount of time you spend near the source of radiation, you will decrease the amount of radiation exposure you receive.
- ii. Distance: The farther away you are from a radiation source, the less exposure you will receive. Exposure is directly proportional to  $1/\text{distance}^2$ .
- iii. Shielding: If you increase the shielding around a radiation source, it will decrease your exposure.

#### B. Emergency Procedures ( The following (in italics) is taken directly from the VariSource: Series 200 HDR Remote Afterloader System User Manual P/N: TM59781000 Issue 3: 04/01)

*Emergency equipment to be made readily available at all times:*

- *Two pairs of long handled forceps (~30 cm)*
- *Shielded container*
- *Heavy duty cable cutters*
- *Emergency personnel dosimeters*
- *Portable survey meter*
- *Stop watch or timer*

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*Should a system malfunction occur which affects source travel, the retract mechanism will automatically attempt to place the active source wire in the safe and parked position within 30 seconds. If retraction has not occurred after 50 seconds, the message 'manual retract' will be indicated on the Console Box and the console indicates that emergency procedures are required. This process is described in detail in Figure 6-1 along with other possible emergency failure modes and associated error messages.*

*It should be noted that operation of the Manual Retract Handle will only be effective in the following case:*

- The machine has failed to park the Active wire and the message "Retract failure, possible emergency. Check source status" is displayed*

*AND*

- The manual retract handle is NOT turning.*

*In this case of a retract failure, users should follow procedure A below. In any other instance users should follow procedure B below:*

- A. This procedure should be followed if the hand wheel is not turning, radiation is present and a retract failure is indicated:*

- Enter the room with a portable survey meter and a personal dosimeter.*
- Turn the hand wheel in the direction of the arrow through at least 8 revolutions, or until the independent radiation monitor no longer detects radiation. If after at least 8 revolutions of the hand wheel radiation is still detected by the room monitor or portable survey meter, continue with procedure B outline below.*

- B. This procedure should be followed either if the hand wheel is turning, radiation is present and a retract failure is indicated or no retract failure is indicated and the hand wheel is not turning.*

- Enter the room with a portable survey meter and personal dosimeter.*
- If an end of the wire is visually detectable in a catheter, grasp the source in the catheter with long handled forceps. Cut the catheter above and below the source and place the removed section in a suitably shielded container.*

*· If the end of the wire cannot be seen or radiation is still present,, if possible, all applicators/catheters should be removed from the patient without disconnection at any point. Care should be taken in this procedure to use forceps wherever possible, and maintain the maximum distance from the patient and the Afterloader. Following removal, if possible, the catheters / Applicators should be placed in a shielded container.*

*In all cases above remove the patient from the immediate area, survey the patient, and if safe to do so evacuate the patient from the room. Post a warning and notify all emergency contacts immediately. Since, in most jurisdictions, you will be expected to report on estimated exposure to staff and patient as a result of the incident, you would be advised to estimate times and dose rates involved to produce a reasonable estimate of exposure to all concerned.*

C. Additional Topics Covered:

- a. Audio/Video monitors, Emergency Stops, Last Man out Switch
- b. Emergency stops
- c. Clinically used applicators
- d. Backup battery supply
- e. Independent treatment room radiation monitor location
- f. Survey meter – Inovision 451B – (approximately 4600 mR/hr at 1 meter is source is out)
- g. Stopwatch (estimate time of patient/personnel exposure)
- h. Emergency container
- i. Emergency retraction procedure
- j. Location of emergency contacts

**Cook, Jackie**

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**From:** Chris <chrisfitz65@hotmail.com>  
**Sent:** Monday, February 09, 2015 4:55 PM  
**To:** Cook, Jackie  
**Subject:** REQUEST FOR ADDITIONAL INFORMATION (RAI) FOR AMENDMENT REQUEST DATED NOV. 15, 2014 LICENSE NO. 25-01051-01

Good Afternoon Ms. Cook,

Per your request dated Friday, February 6, 2015.

1) We request approval for both Sirtex Medical SIR-Spheres microspheres and Nordon (Canada) Inc. Model TheraSpheres including Mark III administration set and Accessory Kit.

2) We commit to following the additional license commitments on the yttrium-90 microspheres using the "Microsphere Brachytherapy Sources and Devices" licensing guidance, Revised June 2012.

Thank you for your assistance with this amendment.

Chris Fitz, RSO  
Billings Clinic

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Reviewer: goc Date: 2/10/15