

**From:** Richard McKinley  
**To:** CChipley@srmedicalcenter.org  
**Date:** 10/31/05 12:49PM  
**Subject:** License amendment

License No.:55-17986-01  
Docket No:03013764  
Control No: 137712

Dear Mr. Chipley:

Please respond to the following questions we have regarding your request to add an HDR to your license.

Please note that you may not reply to this letter by return e-mail. Your reply must be in writing by letter or facsimile (610-337-5269). If we do not receive a reply from you within 30 calendar days from the date of this e-mail, we will assume that you do not wish to pursue your application.

1. Please submit a copy of Charles Chipley's certificate from the American Board of Radiology, or a copy of a broadscope permit or NRC/Agreement State license listing Mr. Chipley as an authorized medical physicist for HDR and brachytherapy activities.
2. Please submit the manufacturer's names and model numbers for the I-125 and Pd-103 sealed sources. Note that if the Pd-103 is accelerator produced, then it must be licensed by the State.
3. Please describe your method and facility for receiving and storing the I-125 and Pd-103 seeds, and confirm that the seeds are kept in shielded shipping containers until they are used.
4. Please confirm that you will have a NaI survey instrument, or describe equivalent instrumentation, for locating lost brachytherapy seeds.
5. Item 5 of your application requests authorization to use the GammaMed Plus HDR unit. Please note that this will be listed in Item 9 of your license as Varian Medical Systems GammaMed Plus 3/24. Confirm that the requested source is the Varian Medical Systems model GammaMed 232. We will authorize possession of 2 sources, 1 not to exceed 15 curies and 1 not to exceed 10 curies. Our understanding is that the FDA restricts HDR sources to no more than 10 curies at the time of use.
6. Confirm that all authorized users and all authorized medical physicists will receive the Varian vendor training for use of the GammaMed Plus unit before first clinical use. Confirm that training will include a drill of emergency procedures and that this will be repeated annually. Confirm that your Radiation Safety Officer will receive training in radiation safety aspects of HDR use and will participate in drills of emergency procedures.
7. Appendix A (Operating Procedures) of your application states that the authorized user and either the medical physicist or RSO will be physically present during all HDR patient treatments. Please note the requirements of 10 CFR 35.615(f)(2) requires the physical presence of an authorized medical physicist (AMP) during initiation and continuation of all patient treatments. Current NRC regulations do not permit the RSO to substitute for the AMP. Confirm that you will comply with 10 CFR 35.615(f)(2).
8. 10 CFR 35.12(c)(2) requires the submission of procedures described in 10 CFR 35.643. With regard to Spot Checks, the procedures you submitted described what spot checks will be performed. Please provide specific step-by-step procedures regarding how the following is verified and what acceptance criteria is used.
  - a) Electrical interlocks (e.g., send source out, push open door, and verify that interlock causes source to retract)

- b) Source exposure indicator lights
- c) Viewing and intercom systems
- d) Presence, availability, and identification of emergency response equipment
- e) Radiation monitors
- f) Timer accuracy evaluation
- g) Clock(date and time) in units computer
- h) Decayed source activity in units' computer

9. Page 18 of your application describes safety features of your proposed HDR facility. Please describe the method to secure the HDR unit when it is not in use and is located in either the treatment or storage room(e.g., are the rooms locked). Also, please confirm that all conduits are installed at an angle (e.g. 45 ).

10. Item 10. F. of your Radiation Safety Program addresses personnel monitoring. Confirm that extremity monitoring be provided to individuals who may be called upon to respond to an emergency involving an unretracted or stuck HDR source.

11. Please note that we did not review the Appendix A discussion of Monthly Safety/Interlock Checks or Appendix B (Source Calibration Procedures), as submission of these procedures was not required. Therefore, these procedures will not be a condition of your license. However, it was noted that not all tests required by 10 CFR 35.633 were included in your full calibration procedures and that your procedures suggested monthly calibrations instead of quarterly.

12. Appendix C of your application addresses Emergency Procedures. Please update your HDR emergency procedures to include the names of individuals responsible for implementing corrective actions, as required by 10 CFR 35.610(a)(4)(i). As required by 10 CFR 35.610(a)(4)(iii), update these procedures to include the names and telephone numbers of the authorized users, AMP's, and RSO to be contacted if the HDR unit or console operates abnormally. Also, please clarify in the procedures when the unretracted or detached source should be placed in the shielded container.

13. Has there been a change in name or ownership at this institution? If so, please submit answers to the questions in Appendix G of NUREG 1556, Volume 9. A more complete explanation of these questions is contained in NUREG 1556, Volume 15.

14. Confirm that Dr. Williamson is licensed to practice medicine in the U.S. Virgin Islands.

15. Describe the type of area radiation monitoring equipment that you use.

16. Confirm that the emergency source container is constructed of lead, or the equivalent, and that the container is large enough to accommodate an applicator containing the source.

17. Describe the method for restricting access to the roof during HDR use, or provide shielding thicknesses to ensure that public dose limits are not exceeded.

18. Provide a description of treatment rooms for low dose rate brachytherapy treatments that ensures that public dose limits are not exceeded. Otherwise, confirm that only outpatients will be treated.

If you have any questions about these items, please call me at (610)337-5102, or email me at [rwm1@nrc.gov](mailto:rwm1@nrc.gov).

Sincerely,  
Richard McKinley  
Health Physicist  
NRC, Region I  
CC: Rwm1

**Mail Envelope Properties**

(436661DC.2C1 : 16 : 27049)

**Subject:** Schneider Regional Medical Center, 55-17986-01, 03013764, Control  
No. 137712

**Creation Date:** Mon, Oct 31, 2005 1:26 PM

**From:** Richard McKinley

**Created By:** RWM1@nrc.gov

**Recipients**

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LAT (LAT)

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**Route**

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**Files**

MESSAGE  
License amendment.mlm

**Size**

1490  
12255

**Date & Time**

Monday, October 31, 2005 1:26 PM  
Monday, October 31, 2005 1:21 PM

**Options**

**Expiration Date:** None  
**Priority:** Standard  
**Reply Requested:** No  
**Return Notification:** None

**Concealed Subject:** No  
**Security:** Standard