



September 19, 2013

License No.: 19-00296-10
Docket No.: 030-01786
Control No.: 577840

Ms. Weidner,

The following information is supplied in response to your e-mail letter of September 4, 2013.

1. Attachment E describes your HDR Treatment Day Machine QA. It appears that two of the items described in 35.643(d) are not addressed in your procedure. Specifically, clock (date and time) and decayed source activity in the unit's computer. Please describe how you verify these items and confirm that they will be done as part of your HDR Treatment Day Machine QA.

The HDR Treatment Day Machine QA checklist (see attachment) was recently updated to clarify that the date and time listed at the top refer to the values from the treatment planning computer system (TCS). These values are independently verified at the time of treatment by a radiation therapy technologist who was not involved with the treatment planning. The decayed source activity is independently verified by a second technologist, an AMP, and/or the AU.

2. Please confirm that if HDR spot check results indicate a malfunction of any system, you will lock the control console in the off position and not use the unit except as may be necessary to repair, replace, or check the malfunctioning system.

We confirm that if any HDR check indicates a malfunction, the AMP who has possession of the console control key will immediately lock the console, remove and secure the key, and notify the Division of Radiation Safety (DRS) and the Authorized User that a malfunction has occurred. The HDR will not be used for patient treatment until the reason for the malfunction has been determined and corrective actions have been implemented.

3. In your reply to question 3. You stated that, "The shielded door power supply can be inactivated while in the closed position by a hidden switch if the HDR is to be left unattended in the therapy room." 10 CFR 20.1802 states, in part that, the licensee shall control and maintain constant surveillance of licensed material that is in a controlled area and that is not in storage. Describe:
 - a. how you will control and maintain constant surveillance of the unattended HDR unit

The HDR is kept in the NRC-approved storage location under lock and key unless removed to the NRC-approved treatment room for source exchange, maintenance, quality assurance measurements, or patient treatment. The shielded door power supply has the inactivation feature described above. However, when in the treatment room, the HDR is attended or under surveillance by staff in the control room **at all times**.

If you have any questions or need additional information, please let me know.

Sincerely,

A handwritten signature in cursive script that reads "Nancy E. Newman". The signature is written in black ink and is positioned above the typed name.

Nancy E. Newman
Radiation Safety Officer, NIH

RADIATION ONCOLOGY BRANCH - NATIONAL CANCER INSTITUTE
GYN HDR BRACHYTHERAPY QUALITY ASSURANCE CHECKLIST

Nucletron MicroSelectron, S/N 31253 Radioactive Source: ¹⁹²Ir

PATIENT NAME: _____

IMPLANT SITE: _____

Treatment	1			2			3		
	AU	RTT	AMP	AU	RTT	AMP	AU	RTT	AMP
Daily QA done									
Data Transferred									
TCS Clock Date									
TCS Clock Time									
Patient ID Checked									
Plan ID									
Assay Source Activity (A ₀)	(Cl) (Kn)			(Cl) (Kn)			(Cl) (Kn)		
Assay Date									
Elapsed Days									
Decay Factor*									
Current Activity (A)	(Cl) (Kn)			(Cl) (Kn)			(Cl) (Kn)		
Calc by									
Calc Check by									
# of Dwell positions T/O (Rt, Lt, T Cylinder (C)	Rt Lt T C			Rt Lt T C			Rt Lt T C		
Step size									
Dwell Time Check									
Plan Signed by Two People									
AU Sign Isodose Distribution									
AU Sign Written Directive									
Reference Dose									
Spot Calc Check Done									
Transfer Tube R(1), L(2), T or C (3)									
Operator understands Rx									
Treatment Summary Print and Check									
Survey Performed									
HDR Unit and Keys Secured									
GMP by (Initial)									

Pre Treatment

Post Tx