SENTARA

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August 28, 2007

MS16
K-8

U.S. Nuclear Regulatory Commission
Region I Office, Division of NMSS
Attn: Materials Licensing
475 Allendale Road
King of Prussia, PA 19406

45-09087-01
03003330

RE: Mail Control 140819

Dear Ms. Gabriel,

In response to your e-mail inquiry regarding our recent request to add Dr. Song Kuk Kang as an authorized user, we are submitting this additional information for license number 45-09087-01.

We have requested authorization of Dr. Song Kuk Kang for HDR brachytherapy in accordance with 10 CFR 35.600, specifically, use of the Nucletron HDR afterloading brachytherapy unit. Dr. Kang completed an ACGME-approved residency in radiation oncology at Duke University Medical Center in 2003, which included the training and experience required by 35.690(b)(1) and (2). These documents were previously submitted.

At this hospital since April 2007, Dr Kang has received training from the vendor, AU and AMP on this license regarding the following HDR tasks: full calibration measurements, periodic spot-checks, treatment planning, emergency procedures, survey meters and dose administration. The vendor training certificate is enclosed. Under Dr. Michael Miller's direct supervision, Dr. Kang has been involved in a Tandem & Rings gyn case (5 fractions), two bronchial cases (1 fraction each), and a MammoSite case (10 fractions). Dr. Miller hereby attests that Dr. Kang has satisfactorily completed the requirements in paragraph 10 CFR 35.690(b)(1) and (2) and has achieved a level of competency sufficient to function independently as an authorized user for the medical use of remote HDR afterloaders authorized under 10 CFR 35.600.

For more information, please do not hesitate to our Radiation Safety Officer, Sandy Wolff, at (757) 388-3030 or pager (888) 341-5703.

Sincerely,

Michael Miller, D.O.
Authorized User
Sentara Careplex Hospital

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REGION 1
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NMSS/RGN1 MATERIALS-002

Nucletron

Field Training Report

Nucletron Corporation, Service Department, 8671 Robert Fulton Drive, Columbia, MD 21046 PH: 410-872-4400 Fax: 410-312-4196

Customer: Sentara Careplex Hospital	Charge Type: ☑ Contract ☐ No Charge ☐ Bill ☐ Install ☐ Warranty ☐ Other
Address: 3000 Coliseum Drive, Hampton, VA 23666	Call Number: 221869 ☐ Rtn. Visit Required
Phone No.: 757 827 2444	Course Instructor: Paul Stehle
PO No.:	Date in: 28-Aug-07 Out: 28-Aug-07
	Time in: Out:

Training Given

mHDR V2 Annual Emergency Procedures In-Service

Attendance Registration

Name	Title	Department	Signature
David Weimer	Physicist	Rad Oncology	Tue Aug 2007 08/ 28/ 07 10:18:51
Laura Bradby	Therapist	Rad Oncology	Tue Aug 2007 08/ 28/ 07 10:00:46
Beth Armstrong	Therapist	Rad Oncology	Tue Aug 2007 08/ 28/ 07 10:01:55
Song Kang	Physician	Rad Oncology	Tue Aug 2007 08/ 28/ 07 10:19:09

Remarks

For Office Use Only - This Is Not An Invoice

Travel Charged	Hrs	Airline		Travel Expenses (Meals, Tolls, etc)
Regular Charged	Hrs	Rental Car		
Overtime Charged	Hrs	Hotel		
O/T (Sundays & Holidays)	Hrs	No of Miles	$0.00	

We certify that the training noted in this document has been carried out in accordance with the manufacturer's instructions by Nucletron's authorized representative and with proper supervision by:

Course Instructor: Tue Aug 2007 08/28/07 09:48:20

Customer: Tue Aug 2007 09/28/07 10:56:10

In Case of Emergency

Roles

Device Operator
The operator's responsibility will be to assist the authorized user in removing the source/applicator from the patient and removing the patient from the treatment area.

Medical Physicist
The medical physicist's responsibility will be to survey, locate, and retrieve the source.

Authorized User
Will be assisted by the medical physicist and device operator, in the removal and extraction of the source/applicator and the removal of the patient from the treatment area.

Procedure

1. **If a problem is encountered during the treatment that necessitates the termination of the treatment, press the Interupt button on the treatment console. If the source retracts, go to Step 7, otherwise Step 2.**
2. **Press the red "Open" button to open the vault door. If the source retracts, go to Step 7. If the door interlock fails to cause the source to retract, proceed to Step 3.**
3. **Press the red Emergency Stop button on the treatment console. If the source retracts, go to Step 7, otherwise Step 4.**
4. **Enter the room with a portable survey meter set at the highest setting. If no notable exposure readings are noted and subsequent surveys confirm source has been retracted to safe, go to Step 7. If high exposure readings are noted, the source has not been retracted, go to Step 5.**
5. **Press the red Emergency Off button located on the maze wall. If the source retracts, go to Step 7, otherwise Step 6.**
6. **Lift the Access Panel and manually retract the source using the Gold hand crank. If the source retracts, go to Step 7, otherwise proceed to remove the source/applicator from the patient and insert it into the shielded emergency container.**
7. **Contact the personnel listed on the Emergency Contact list, if not already present. In addition, contact the Nucletron representative listed on Nucletron's Emergency Procedures.**

Attachment 14

SUPPLEMENTAL EMERGENCY PROCEDURES

Roles

Device Operator
The device operator will be trained by the device manufacturer or their representative, to recognize and identify all significant errors. In the unlikely event of equipment failure, it will be the responsibility of the device operator and the medical physicist to assess the situation and determine the appropriate course of action. In the unlikely event of equipment failure during a treatment, the operator's responsibility will be to assist the authorized user in removing the source/applicator from the patient and removing the patient from the treatment area.

Medical Physicist
The medical physicist will be trained by the device manufacturer or their representative, to recognize and identify all significant errors. In the unlikely event of equipment failure, it will be the responsibility of the medical physicist and device operator to assess the situation and determine the appropriate course of action. In the unlikely event of equipment failure during a treatment, the medical physicist's responsibility will be to survey, locate, and retrieve the source.

Authorized User
In the unlikely event of equipment failure during a treatment, the authorized user's responsibility will be to attend to the safety and medical needs of the patient. The medical physicist and device operator will assist the authorized user in the removal and extraction of the source/applicator and the removal of the patient from the treatment area.

Procedure

If the source becomes decoupled or dislodged during a patient treatment, attempt to return the source to the safe by:

1. **Observe at the console error message and Emergency indicators (audible and visible alarm).**

2. **Press the red Emergency Stop button on the treatment console. If the source retracts, go to Step 7, otherwise Step 3.**

3. **Press the red "Open" button to open the vault door. If the source retracts, go to Step 7. If the door interlock fails to cause the source to retract, proceed to Step 4.**

4. **Enter the room with a portable survey meter set at the highest setting. If no notable exposure readings are noted and subsequent surveys confirm source has been retracted to safe, go to Step 7. If high exposure readings are noted, the source has not been retracted, go to Step 5.**

5. **Press the red Emergency Off button located on the maze wall. If the source retracts, go to Step 7, otherwise Step 6.**

6. **Lift the Access Panel and manually retract the source using the Gold hand crank. If the source retracts, go to Step 7, otherwise proceed to remove the source/applicator from the patient and insert it into the shielded emergency container. Instructions for different source/applicator removal are listed below.**

7. **Contact the personnel listed on the Emergency Contact list, if not already present. In addition, contact the Nucletron representative listed on Nucletron's Emergency Procedures.**

FOR INTRALUMINAL TUBE AND INTRACAVITY APPLICATION

1. **Using the long-handled forceps, the Authorized User will grasp the applicator/intraluminal tube near the connection to the source transfer tube of the applicator and extract the applicator/intraluminal tube from the patient. The applicator/tube can be left hanging from the HDR unit.**

2. **Remove the patient from the interior of the treatment room to the maze, away from the HDR unit, but still in the shielded portion of the maze. Survey the patient with the survey meter to confirm that the source has been removed.**

3. **Once the patient has been removed from the treatment room, the medical physicist should insert the source/applicator into the shielded emergency container, using the long-handled forceps.**

4. **Lock the door; post the door with the sign "Danger – Open Radiation Source – Keep Out."**

5. **List personnel in the room and the amount of time spent there.**

FOR SUTURED CATHETER OR NEEDLE APPLICATIONS

1. **Identify the channel number that contains the source, using the Error Code from the printout.**

2. **Use the suture removal kit, cut all sutures retaining the identified catheter/needle, or if necessary, the device holding the catheters and needles.**

3. **Remove contrast from the applicator with a syringe if it is a Mammosite procedure.**

4. **Using the forceps, grasp the catheter/needle/applicator and carefully extract it from the patient. The catheter/needle/applicator can be left hanging from the HDR unit. Sterile supplies will be available for the authorized user to use to care for the sutured area.**

5. **Remove the patient from the interior of the treatment room to the maze, away from the emergency container, but still in the shielded portion of the maze. Survey the patient with the survey meter to confirm that the source has been removed.**

6. **Once the patient has been removed from the treatment room, the medical physicist should insert the catheter/needle/applicator into the shielded emergency container, using the long-handled forceps.**

7. **Lock the door; post the door with the sign: " Danger – Open Radiation Source – Keep out."**

8. **List personnel in the room and amount of time spent there.**