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1 February 2011

Penny Lanzisera
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Region I
King of Prussia, PA 19406

47-31304-02
03037863

Dear Ms. Lanzisera:

Here is the additional material covering policies and procedures as well as emergency procedures for our new Varian Gamma Med iX HDR machine, to support our request to amend our NRC license.

Thank you.

David S. Shimm MD

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RADIATION ONCOLOGY DEPARTMENT

POLICY/PROCEDURE: HDR Program
POLICY # HDR-1 **Rev. 0 - 11/10/2009 DO**

POLICY/PURPOSE:

Specific operational guidelines are to be followed when initiating the High Dose Rate (HDR) Remote After loading Program. This policy provides an outline for staff qualifications, clinical scope, radiation safety procedures and documentation to assure that the HDR Program provides optimum patient care and a safe environment for everyone involved in the process.

1. Qualifications

   Qualifications for the radiation oncology staff to perform HDR procedures follows The American College of Radiologist (ACR) Standard for the Performance of HDR Brachytherapy, section III; The ACR Standard for the Performance of Brachytherapy Physics: Remotely-Loaded HDR Sources; and recommendations by the American Association of Physicist in Medicine (AAPM) Task Group 59.

   a. The radiation oncologist must be an authorized user on the cancer center's NRC radioactive material license or must have appropriate training and perform HDR procedures under the direction of the authorized radiation oncologist.
   b. The medical physicist must be an authorized user on the cancer center's NRC radioactive material license and has experience in the subfield of Therapeutic Radiological Physics or must have appropriate training and perform HDR procedures under the direction of the authorized medical physicist.
   c. Medical dosimetrists will be involved in the brachtherapy program after receiving appropriate brachytherapy training.
   d. Radiation therapists must fulfill state licensing requirements and should have Radiologic Therapeutic Technologist (RTT) certification in addition to receiving appropriate brachytherapy training.
   e. Radiation oncology nurses be licensed by the state.
   f. The Radiation Safety Officer, medical physicist, or designated manufacturer representative will provide initial and annual/ongoing educational programs for new and existing staff. The program will include but not be limited to:

i. The safe operation, including emergency procedures, of HDR applicators and HDR remote after-loading equipment and sources as appropriate to the individual's responsibilities.
ii. Treatment techniques and new developments in radiation oncology and brachytherapy.

2. **Clinical Scope**
   a. The radiation oncologist will establish the following criteria:
      i. Patient selection criteria
      ii. Exclusion criteria for HDR brachytherapy
      iii. Criteria for contraindications of HDR brachytherapy
   b. The Radiation Safety Committee will review the HDR Program as part of their routine meetings.
3. **Quality Assurance**
   Sources
   a. Direct calibration of sources will be independently verified by using the well ionization chamber.
   b. All sealed sources received will be wipe tested by the vendor prior to initial use unless there is a certification from the vendor that the sealed sources were tested within the last six months by the vendor. Autoradiographs are performed prior to use to verify positional accuracy.
   c. Sources 100 μCi or more of beta or photon emitters will be leak tested every six months by the vendor.
   d. Sealed sources which show removable contamination of 0.005 μCi or more must be removed from use immediately.
   e. The medical physicist will maintain the scientific records regarding the source description, calibration and current stated activity for the duration mandated by the state of West Virginia.
   f. Acceptability limits for sources have been established by the medical physicist as well as course of action if the source strength does not fall within these limits.
   g. All radioactive sealed sources are returned to the vendor for disposal or contracted to an authorized broker.
   h. A source Inventory Log kept by the physicist in the department will be used to track when sources are removed and returned from the HDR unit storage area. The log will contain the following:
      - Date and time removed
      - Date and time returned
      - Source type and strength
      - Signed and dated

   Instrumentation
   a. The well ionization chamber is calibrated at least every 2 years and the calibration is traceable to the National Institute of Standards and Technology.

b. Survey meters are calibrated annually.
c. Intracavitary applicators will be radiographically inspected prior to first use by physicist and physically inspected prior to each use by physicist or individual supervised by Physicist.

4. Radiation Safety

Personnel and Patients

a. All personnel assisting with procedures involving sealed radioactive materials will wear body badge at all times to monitor any exposure. Badges will be stored onsite in a low background area. Personal monitoring devices will be changed out on a monthly basis.
b. No pregnant staff members will be involved in brachytherapy procedures, with the exception of treatment planning and simulations not involving radioactive materials.
c. All personnel assisting with procedures involving sealed radioactive materials (Ir-192) will never touch the sources and will use long handled forceps for source handling. All loading and unloading of sources will be done remotely.

5. HDR Radiation Safety/Quality Control Procedures and Documentation

The following policies and procedures are in place to address the aspects of radiation safety and quality control for HDR procedures.

HDR Operating and Safety Procedures
HDR Emergency Procedures
HDR Roles and Responsibilities
HDR Written Directive and Treatment Record
HDR Pre-Treatment QA Checklist and Patient Survey

RADIATION ONCOLOGY
POLICY/PROCEDURE: HDR Emergency
Policy # HDR-2

POLICY/PURPOSE:

It is the policy of this facility to provide guidelines for the safe operation and control of radioactive materials used with the HDR unit and to provide proper response to emergency and abnormal situations. A qualified Radiation Therapist, Radiation Oncologist and Medical Physicist will be present during patient treatments. The Medical Physicist and Radiation Oncologist present will serve as emergency contacts during cases, and in the event of a radiation emergency, the Radiation Safety Officer will be notified.

PROCEDURE:

1. The following emergency supplies will be available during HDR treatments:
   Inside the treatment room
   - Long handled tongs/forceps
   - Flashlight
   - Suture removal kit
   - Wire cutting pliers
   - Lead container

   Outside the treatment room at the console
   - "Caution-High Radiation Area" and "Caution-Radioactive materials" signs
   - Ionization survey meter

2. The following steps should be followed if error messages and emergency indicators (audible and visible alarms) are observed at the console during treatment:
   a. Press the emergency off button at the console
   b. Open the door to activate the interlock that retracts the source
   c. Enter the room with a portable survey meter and observe the radiation levels in the room
   d. Press the emergency off button on the unit inside the room
   e. If the survey indicates the source is in the patient, manually retract the source by using the hand crank
   f. Survey to confirm the source is in the afterloader (if the source is in the patient, follow steps j-o)
   g. Survey the patient before removing from the room
   h. Remove the patient from the treatment area
   i. Survey the patient again with the survey meter outside the treatment area

j. If the source is still in the patient, the radiation oncologist, using the tongs/forceps, should remove the catheter and place it in the emergency container
k. Place the shield cover on top of the lead container
l. Move the patient away from the lead container but still in the shielded treatment room and survey the patient to ensure the source is out
m. Remove the patient from the room and survey with the survey meter
n. Lock or block the treatment room door and post "Danger-Open Radiation Source-Keep Out" sign
o. Notify the Radiation Safety Officer

3. The following Physician Surgical Intervention Procedures for Small Intraluminal Tube or Large Intracavitary Applicators are to be performed by the radiation oncologist (with minimal staff present to help) providing the source is in the applicator and has not ruptured, all attempts have been made to remove the source from the applicator and the applicator can be removed in a medically safe manner:
    a. Release the tube or applicator from any retaining device
    b. Using the tongs/forceps, grasp the tube/applicator near the connection to the source guide tube
    c. Extract the tube/applicator from the patient
    d. With a second set of tongs/forceps, grasp the tube/applicator near its end and place it into the emergency container
    e. Place the shield cover on top of the lead container
    f. Move the patient away form the lead container but still in the shielded treatment room and survey the patient to ensure the source is out
    g. Remove the patient from the room and survey with the GM meter
    h. Lock or block the treatment room door and post the "Danger-Open Radiation Source- Keep Out" Sign
    i. Notify the Radiation Safety Officer

4. The following Physician Surgical Intervention Procedures for Sutured Catheter or Needle Applicators are to be performed by the radiation oncologist (with minimal staff present to help) providing the source is in the applicator and has not ruptured, all attempts have been made to be removed in a medically safe manner:
    a. Identify at the console, by display or by visible inspection by the CCTV of the transparent source guide tubes, the source guide tube that contains the source drive cable and source and the catheter or needle to which it is attached
    b. Using the suture removal kit, work as quickly as possible to cut all sutures retaining the identified catheters and needles
    c. Using the tongs/forceps, grasp the catheter or needle and carefully extract it form the patient and place it into the lead container
    d. Do not grasp the catheter or needles with your hand (if the patient could bleed, a second person should have swabs available to apply compression)
    e. Place the shield cover on top of the lead container

f. Move the patient away form the lead container but still in the shielded treatment room and survey the patient to ensure the source is out
g. Remove the patient form the room and survey with the GM meter
h. Lock or block the treatment room door and post "Danger-Open Radiation Source-Keep Out!" sign
i. Notify the Medical Physicist and the Radiation Safety Officer

5. The following steps should be followed if a radiation survey reveals the source is not in the patient, the safe, or the lead container:
   a. Evacuate the patient quickly
   b. Survey the bottom of personnel's feet to ensure no radioactive material is being tracked out of the treatment room
   c. Lock or block the treatment room door and post the "Danger-Open Radiation Source-Keep Out!" sign
   d. Notify the Radiation Safety Officer (the vendor will assume responsibility for source retrieval)

6. Procedures for handling conventional emergencies such as loss of power will be provided by the manufacturer. Backup batteries or power packs designed to retract the source during a power failure and to provide power to the computer to retain memory and treatment information on the partially delivered treatment are just some of the items that will be provided via manufacturer guidelines. Backup batteries will be tested quarterly.

7. All personnel authorized to operate the HDR unit will familiarize themselves with the meanings of status lamps, audible alarms and printed or displayed messages that indicate malfunctions, if the number of error codes is large, training will focus on recognizing those that are most likely to occur during routine treatments. A complete status code list will be readily available to the console for instant access during emergencies.

8. If the post-treatment survey reveals residual activity, the Medical Physicist and the Radiation Safety Officer will be contacted immediately, and the patient will be contained in a shielded area.

9. Emergency resuscitation for the radioactive patient:
   - Notify the RSO after notifying the resuscitation team
   - Resuscitation procedures will be performed without regard to the radiation
   - The resuscitation team will be limited to the minimum team members necessary to perform the procedure (and pregnant members will be excluded, if possible)
   - The team will stand back away from the patient when possible
   - The radioactive sources will be removed as soon as the situation permits
   - A list of the team members involved will be documented
   - Team members with a personal monitoring device will wear them

- HDR personnel will wear proper dosimetry as discussed in the HDR Program. Therefore during emergency procedures personnel monitoring will already be in place.

RADIAITON ONCOLOGY
POLICY/PROCUDURE: HDR Roles and Responsibilities
POLICY # HDR-3

POLICY/PURPOSE:

High dose Rate (HDR) Remote Afterloading is a treatment procedure that requires a coordinated radiation oncology team. Each team member's role is important and necessary to provide the safest and highest quality treatment for the patient. The following roles and responsibilities are based on recommendations by the AAPM and standards set by accrediting organizations.

1. The following terminology is utilized in state and federal regulation and are defined as:
    a. Authorized User- A physician licensed by the state who meets the written applicable requirements of the state and federal regulations including the facility Radioactive Material License.
    b. Authorized Medical Physicist-a medical physicist experienced in the sub field of Therapeutic Radiological Physics
    c. Radiation Safety Officer-An individual who has a knowledge of and the authority and responsibility to apply appropriate radiation protection rules, standards and practices, who must be specifically authorized on a radioactive material license, and who is the primary contact with the agency.
    d. Radiation Safety Committee-A committee to advise administration on all matters relating to the procurement, preparation, use, and storage of radioactive material used for the diagnosis or treatment of disease.

2. The HDR team is made up of the radiation oncologist, medical physicist, dosimetrist, radiation oncology nurse and the radiation therapist. All members of the team will be adequately trained to notice errors in planning or setup of the HDR system and will be trained for emergency procedures for the HDR system.

3. The radiation oncologist is authorized by NRC to use HDR unit. Radiation oncologist not experienced in HDR will train with an experienced radiation oncologist and/or visit facilities with ongoing programs before treating patients with the HDR unit. The radiation oncologist is responsible for:

    a. Reviewing the patient history
    b. Defining the procedure

c. Selecting and placing the applicators
d. Performing the HDR procedure
e. Working with the physicist/dosimetrist to define active dwell positions and target volume
f. Writing and signing the prescription
g. Defining optimization criteria
h. Reviewing and signing the treatment plan
i. Authorizing treatment
j. Responding to emergencies as directed by the physicist
k. Disconnecting the patient and removing the applicator

An authorized user and licensed medical physicist will be in the immediate vicinity at all times during the HDR treatment.

4. The NRC authorized medical physicist, will have received vendor-supplied training for the treatment unit and radiotherapy treatment planning system (TPS). The medical physicist is responsible for:

a. Consulting with the physician about the patient
b. Commissioning new applicators
c. Verifying positional parameters
d. Supervising treatment planning
e. Performing manual calculations
f. Checking calculations
g. Reviewing treatment plans
h. Checking the setup
i. Reviewing daily HDR QA
j. Checking treatment unit programming and monitoring treatment progress
k. Reviewing and supervising emergency procedures
l. Presenting a mandatory annual in-service, which includes but is not limited to:
    i. The safe operation, including emergency procedures, of HDR applicators and HDR remote after-loading equipment and sources as appropriate to the individual's responsibility
    ii. Treatment techniques and new developments in radiation oncology and brachytherapy

An authorized user and licensed medical physicist will be in the immediate vicinity at all times during the HDR treatment.

5. The medical dosimetrist, with a training in brachytherapy treatment planning, will have vendor-supplied or from in-house trainer (trained medical physicist) training on operating the HDR TPS. The dosimetrist will work closely with the medical physicist to develop detailed written procedures that specify which program options are to be used. The dosimetrist is responsible for:

a. Consulting with the physician about the patient
b. Reviewing the radiographs and prescription
c. Planning the treatment via the TPS
d. Preparing the transfer medium for the treatment plan
e. Calculating the HDR positional programming parameters

6. The licensed radiation therapist will have vendor-supplied training on the HDR unit or the equivalent from an in-house trainer (trained medical physicist). The radiation therapist may work with the radiation oncology nurse to schedule the patient, test and package the applicators and assist the physician. The radiation therapist is responsible for:

    a. Notifying medical physics regarding routine and non routine treatments
    b. Documenting the implant
    c. Labeling applicators
    d. Recording simulation marker identity
    e. Measuring localization parameters
    f. Connecting unit to the catheters
    g. Monitoring treatment progress
    h. Securing the treatment device

7. The Radiation Safety Officer (RSO) is responsible for communicating with regulatory agencies if necessary. The RSO will review and approve all HDR operational and emergency procedures.

8. Staff Responsibilities:
   Cancer Center staff working with sealed radioactive sources must meet the ACR qualifications of personnel working in brachytherapy. Technical staff will have completed and documented radiation safety education.
    a. Physician- The physician is responsible for the choice and placement of after-loading applicators, loading and unloading the radioactive sources and prescribing the dose. Only NRC authorized physicians who have been granted radioactive material privileges from the Radiation Safety Committee may prescribe sealed sources for brachytherapy procedures.
    b. Radiation Safety Officer (RSO) - The RSO is responsible for maintaining and updating the Radioactive Materials License and providing continuing education and in-services for brachytherapy procedures. The RSO will respond to questions and emergency situations involving brachytherapy procedures.
    c. Medical Physicist- Only NRC authorized medical physicists; those meeting the brachytherapy standards set by the ACR, will be involved in the management to sealed radioactive materials and implant procedures. The medical physicist will develop, implement, supervise and review policies and procedures involving sealed sources and maintain proper documentation.

d. Dosimetrist and Therapist- Properly trained staff will be involved in the handling, loading the transporting of radioactive materials. Treatment planning and simulation are also part of the brachytherapy procedure.

RADIATION ONCOLOGY
POLICY/PROCEDURE: HDR Operating, Pre-treatment Safety Check Procedures
POLICY # HDR-4

POLICY/PURPOSE:

It is the policy of this facility to provide safe operation and control of radioactive materials used with the HDR unit and to provide proper response to emergency and abnormal situations. Specific operational procedures are to be followed when initiation the High Dose Rate (HDR) Remote Afterloading Program to ensure that all those responsible for delivery of treatment are fluent in programming and operation of the HDR system.

PROCEDURE:

1. **System Security**
   a. The HDR unit is secured from unauthorized user by a key system. Keys will be removed when not in use.
   b. The device containing the actual radioactive source will be secured in the treatment area via a locked door and a locked cable to prevent operation beyond the designated treatment area or removal from the facility.
   c. The treatment console area is a restricted area within the radiation oncology department accessible to authorized personnel only.

2. **Source Safety**
   a. The vendor will perform installation and replacement of sources contained in the HDR unit at less than six-month intervals. The vendor will provide documentation at the time of installation for compliance and acceptability. All sources removed at the time of exchange will be returned to the vendor.
   b. Maintenance or repair operations involving work on the source safe, the source driving unit or other mechanisms that could expose the source, reduce the shielding around the source or compromise the safety of the unit and result in increased radiation levels shall only be performed by persons specifically authorized by the NRC.
   c. "Inactive or "In Storage" sources are not required to have periodic leak testing until they are returned to use, or shipped to vendor.

3. **Room Safety and Postings**
   This facility meets the following safety requirements for the HDR Program:
   a. A door posted with "Caution-High Radiation Area" and "Caution-Radioactive Materials" controls access to the room housing the

HDR unit. In addition, posted on the HDR unit is a "Caution-Radioactive Material" label.

b. A permanent radiation monitor capable of continuous monitoring of the source status is installed.
c. Continuous viewing and intercom systems to allow for patient observation during treatment are in place.
d. Restricted area controls such as signs, locks, visible/audible alarms, door warning lights indicating "Radiation On" are installed.
e. HDR system is equipped with an electrical interlock system that retracts the source when door is opened and does not allow resumption of the treatment unless the door is closed and the interlock is reset.
f. The HDR system is equipped with a mechanism that ensures that the system can only operate with the key. The console keys are not accessible to unauthorized persons.

4. **HDR operating procedure**

I. The HDR unit will be stored in a closet inside the HDR treatment room. The storage area will be locked when the unit is unattended. The door key will be kept in the medical physicist office and will be available only to the authorized operator(s).
II. Pre-treatment safety checks will be performed on the day of the treatment.
III. Only the patient under treatment will be in the treatment room during activation of the HDR unit for treatment. Patient identification will be verified by two independent means.
IV. The following pre-treatment checks are to be performed before initiating HDR treatment:

a. Verify that the source activity and calibration date are correct on the printouts;
b. Verify the correct patient file name in the case of multiple patient files on the same disk;
c. Verify that the printout matches the one shown on the afterloader printout;
d. The planned dwell times should be verified before initiating treatment;
e. Ensure that in multiple-channel treatment each catheter is connected to the correct machine channel. Catheters should be marked and verified that the treatment plan and the afterloader match as far as which catheter is which;
f. Verify correctness of the patient information on printouts;
g. Verify dwell positions with catheter measurements;
h. Ensure that all catheters are fully seated into the machine connectors, with the connector plunger fully extended;
i. Before positioning the active source into the patient treatment catheter, the dummy source wire will be run into each treatment catheter to verify that

the catheter is not blocked or kinked. The HDR afterloader will not run the active source into the catheter if the dummy wire encounters resistance.

j. The following pre-treatment checks are to be performed before initiating HDR treatment:
k. For each catheter channel run, check total source dwell time using manual timer and verify that the manual timer measurement agrees with the total programmed dwell time.
l. Treatment planning computer disk with the plan data stored for each patient's treatment will be labeled with the corresponding patient's name and identification number. If these disks are reused, they will be re-labeled in accordance with the manufacturer's instructions.
m. Immediately after each use of the HDR device, the physicist will ensure the source has been returned to the full-shielded position and will perform a survey of the device and the patient. The survey will include the patient, connectors, applicators, full length of guide tubes, and the external surface of the device to ensure that the source is fully retracted.
n. The post-treatment survey will be recorded on an appropriate survey form and the report maintained for a period of at least 3 years.
o. If the radiation monitor or post-treatment patient survey indicated that the source is not fully retracted to a shielded position in the device, personnel (authorized physician and physicist) will immediately implement the applicable emergency procedures (posted at the HDR console and in the treatment room). If other emergencies occur during HDR treatment (e.g. electrical power loss, applicator dislodge, timer failure) authorized HDR personnel will immediately implement the applicable emergency procedure.
p. No treatment procedure will be continued for which a de-coupled or jammed source cannot be removed expeditiously from the patient and placed in the shielded container available in the room.
q. During all patient treatments using HDR device, both the authorized physician and the medical physicist must be physically present. Physical presence, for this purpose is defined as within audible range of normal human speech.

5. HDR Pre-treatment Safety Checks Procedure

The HDR pre-treatment safety checks are performed before treatment on any day that the HDR procedure is to be carried out.

a. Verify the treatment door, radiation door light bulb and prime alert are viewable through the convex mirror.
b. Verify that the TV monitors at the control console are operational

c. Check that the two-way intercom is operational by one person in the room at the location of patient treatment and the other at console
d. Verify that the radiation survey meter is functional
e. Verify that the emergency basket is stocked and the emergency storage container in place [forceps/tongs, cutters/scissors, suture removal kit, and "CAUTION RADIATION AREA" tape]
f. By visualization, check that the source guide tubes are free of kinks, etc and use length measuring gauge to measure the combined length of the tubes and the applicator to be within 1mm of expected length.
g. Verify that the control console pass self-diagnostic checks when key switch is first turned
h. Verify that all lights /status indicators on HDR console are operational
i. Attach one end of a source guide tube to Permadoc system and the other end to channel 2 (**incorrect channel**). Clear any personnel in room. Turn on ceiling light and adjust TV camera with MF 21 so that "check ruler" with labels 1,2, and 3 SOURCE PSTNs are clearly visible. Run AFTERLOADER, HDR on patient list. Copy and save. This will program:

Positions	1, 9, 19
Length	130
Step size	0.5 mm
Dwell times	10 secs for positions 1 and 9 sec for positions 21, 60 secs for position 19

Confirm program and dwell times, press START to initiate treatment, and verify that Error Code appears on screen and that there was no radiation

j. Attach the source position check ruler to channel 1 (**correct channel**). Press START to initiate treatment.
k. Verify that the ends of the live and dummy sources align with the marked distance indicators to within 1 mm of 130, 126, and 121
l. While the source is dwelling at position 121, check the door light, interrupt key, door interlock, and emergency stop. The source should return to position 121 after each restart. Check the accuracy of the dwell time using stop watch during the last restart. At the end of the run, use power extension cord and plug it onto the power outlet outside the room. Re-run warm-up and unplug the cord from the outlet while the source is dwelling.
m. From (i) through (l) verify that the radiation area monitor (primer alert at the door) and inside room via TV monitor) were functional, the door light on, the door interlock operational, the interrupt button on the console functioned properly, the emergency STOP button near the HDR console operational, the stop watch was operational, the source extracted with power cord unplugged, verify that manual stop clock/watch was operational.

n. On the printout: verify that the date, time were correct, source activity was within 0.02Ci of posted decayed activity, the paper supply in the console printerwas sufficient for the day's.
o. Results of these tests will be recorded on the morning checklist

6. Recordable Event of Misadministration

Any unintended deviation from the written directive will be identified and evaluated in terms of a "recordable event" or a "misadministration."

7. Periodic Reviews

(a) Brachytherapy cases will be reviewed at intervals no greater than 12 months by an "authorized physician" and/or an "authorized physicist." A representative number of cases corresponding to lot tolerance defective of 2%, using the acceptance sampling table of 10 CFR 32.110, will undergo this review which will consist of checking that the delivered radiation dose was in accordance with the written directive and plan of treatment.

If a recordable event or misadministration is uncovered during the periodic review, the number of cases to be reviewed will be expanded to include all cases for that calendar year.

(b) The QMP will be reviewed on an annual basis to determine the effectiveness of the program and to identify actions to make the program more effective.
(c) A written summary of this annual review will be submitted to the Radiation Safety Officer and the Radiation Safety Committee for review and final approval.
(d) Any modification made to the QMP will be reported to the appropriate NRC Regional Office (or the state if governed by Agreement State) within 30 days after modification has been made. Ministerial changed authorized under 19 CFR35 will not require the notification of the NRC.