Christiana Care Health Services Policies and Procedures: A Quality Management Program for HDR Brachytherapy

Purpose

This policy is written to promote high confidence that brachytherapy radiation treatments using the microSelectron HDR unit will be administered as directed by the authorized user, and in doing so, insure that patient, staff, and public are not exposed to unnecessary radiation.

To achieve these goals, the following policies shall be followed:

1. Prior to each fraction of administration, a written directive, that is, an order in writing for a specific patient, will contain the following information:

   - The treatment site.
   - Radioisotope (Ir-192) and the dose to be delivered.
   - This directive will be dated and signed by the authorized physician user in the patient chart.

2. The following procedures will be used to verify the identity of the patient as the individual named in the written directive according to Christiana Care Policy:

A. Verification of patient identity with known identity:

Inpatients

1. Two of the following unique identifiers will be used as part of the procedure of patient identification for any patient encounter for care or service at Christiana Care:

   - Comparing a patient's stated name with:
     - Patient ID band, or
     - The name on a doctor's order for treatment, or name on in-room treatment information monitor.
   - Any patient specific identifier such as date of birth, a valid driver's license, social security number, address, telephone number, or assigned account number.
   - Medical record number

2. Check patient information on chart forms with chart when:

   - documenting on a chart or referencing a diagnostic report
   - retrieving information from transferring agency document
   - transcribing information from one source to another

Outpatients

I. The patient will be identified prior to care, treatment, or service.

A. Verification of identity prior to registration into Department of Radiation Oncology

1 The registration clerk will verify patient identity using a photo ID, with patient verbalizing
. their own name and date of birth or social security number.

2 If photo ID is not available, patient will verbalize two of the following identifiers:
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- Their own name
- Date of birth
- Social security number
- Address
- Telephone number

These identifiers will be compared to established records on file for verification.

B. Verification of identity prior to photo ID completion and input into medical record (includes electronic medical record).

1 Staff taking ID photo will have patient verbalize two of the following unique identifiers:
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- Comparing a patient's stated name with the name on the medical record.
- Any patient specific identifier such as date of birth, a valid driver's license, Social Security number, address, telephone number, or assigned account number.

3. Before each treatment day, the medical physicist / dosimetrist /Radiation therapist will perform a QA check. The checks will include among other safety checks as outlined in the Daily QA document in **Appendix: A**.

    A. Monitors and door interlock.

    B. Emergency off button.

    C. Treatment interrupt button.

    D. Radiation monitor.

    E. Treatment unit read-out of time, date and current source strength.

    F. A test run to demonstrate reproducibility of source positioning and accuracy of dwell line setting and normal termination of treatment.

    G. Verify that the source position simulator is functional and the dummy wire is not kinked.

4. The authorized physician user will confirm the specific details of the brachytherapy administration with the medical physicist or dosimetrist prior to administration of the treatment.

5. All personnel involved in the delivery of treatments with the microSelectron HDR unit will be properly trained and be documented in personnel file before being allowed to participate in the treatment delivery.

    A. The Nucletron Service Engineer or an authorized Medical Physicist will conduct annual training for emergency procedures.

B. Workers will be encouraged to ask questions about what to do or how it should be done rather than continuing the procedure when there is doubt.

C. Emphasis will be placed on misadministration of dose prescribed and radiation safety.

6. Verification of the position of the non-radioactive "dummy" sources will be done on an imaging device for dosimetry and isodose calculations. Several methods are used to reconstruct the spatial localization of an intraluminal catheter from its radiographic images. These may include standard orthogonal reconstruction, variable angle reconstruction, or computed tomography techniques.

7. For all patient treatment requiring a treatment distance other than the standard reference distance of 1500 mm, the physicist or dosimetrist shall use a source position simulator (SPS) to measure accurately the catheter reference distance. This distance shall be verified independently by a Radiation Therapist who will be assisting the Physicist/dosimetrist in the procedure.

8. In the event of the malfunctioning of the Source Position Simulator or a transfer tube a backup for an SPS or transfer tube will be readily available.

9. A copy of the document outlining the reference treatment distances (source to catheter tip distance) for all the applicators shall be posted in the simulation room as well as the treatment planning area.

10. The treatment plan will be performed by a physicist or qualified medical dosimetrist under the supervision of the physicist or radiation oncologist. The physicist or qualified medical dosimetrist will check the dose calculations for the following:

    A. Treatment planning computer printout to verify that correct input data for the patient were used in the calculations; e.g., source strength and position.

    B. The printed output from the treatment unit will be checked to verify the correct transfer of data from the treatment planning computer; e.g., channel numbers, source positions and treatment times.

    C. After the authorized physician user approves the plan, the physicist or dosimetrist will initial the plan to verify agreement with the physician's prescribed treatment.

11. Implementing further steps of the Universal Protocol for each HDR treatment fraction requires that a 'time-out' process occurs in-room, prior to treatment initiation and involving 2 or more out of a team of radiation oncologist, medical physicist, radiation therapist, nurse. The purpose of the time out is "to verbally conduct a final verification of the correct patient, positioning, procedure, site, correct applicator or catheter(s), and correct sequenced transfer tube connections. There shall be no barrier to any of the team members speaking up if there is any concern about a possible error. Concern, expressed by anyone cannot be dismissed; it can only be addressed, corrected, resolved when 100% agreement is achieved.
    The radiation oncologist shall, only then, out of the treatment room, initiate the actual HDR treatment fraction. After the completion of each treatment, the authorized physician user will date and sign or initial a written record of the calculated administered dose in the patient's chart. At the end of the treatment a Physicist/dosimetrist shall survey the patient and the treatment room for residual radioactivity and ensure safe return of the source into the HDR unit. The results of the survey shall be documented in a separate log for every patients treated.

12. An acceptance test will be performed by an independent physicist on the treatment planning computer before the first use of the treatment planning system. The following hand calculations will be done on the system to check accuracy and verifiability:

    A. Check dose to a point due to a single source of unit activity for multiple times.

    B. Check a range of activities and times, to ascertain dynamic range of the algorithm.

    C. Check dose at multiple distances.

D. Cross check point calculation against isodose calculations.

13. An annual review of the HDR treatments will be performed.

    A. A representative sample of patient administrations.

    B. All recordable events.

    C. All mis-administrations.

    D. The evaluation will determine the effectiveness of the quality management program and, if required, make modifications to meet the objectives set in these policies.

    E. A record of each review, including the evaluations and findings of the review, will be maintained in a separate binder.

    F. Any deviations from the written directives will be identified and the action required to prevent recurrence will be noted. The actions may include new or revised policies, new or revised procedures, additional training or increased supervisory review of work. .

    G. Records of the annual review will be maintained in the QA minutes for the month when the report is rendered.

14. An authorized physician user must be on the premises when treatment is being delivered to the patient. There will always be a medical physicist and/or a dosimetrist to watch the patient and to deliver the treatment.

15. Records of the evaluation and audits will be maintained for a minimum of three (3) years. The records will be located in the Medical Physics Section.

16. Recordable events will be reported within 30 days and will include all of the facts, causes and any corrective action taken. Records will be kept for three (3) years.

17. Misadministration requirement will be strictly followed:

    A. Within 24 hours of occurrence, the NRC, the Delaware Department of Health will be notified as well as the physician.

    B. The patient will be notified upon the physician's approval and given a copy of a written report.

    C. If the referring physician or patient cannot be reached within 24 hours, the licensee will notify the patient as soon as possible.

    D. Records will be maintained for five years.

18. Each written directive and a record of each administered radiation dose will be maintained in legible form for three (3) years.

19. On going periodic QA: Besides the daily QA, the following periodic quality assurance tests shall be performed on the HDR system:

    A. A monthly QA as outlined in **Appendix B** including the following shall be performed:

        1. An autoradiograph to verify source position accuracy
        2. An absolute measurement of source activity
        3. All safety checks and operational checks outlined in daily QA
        4. The proper functioning of the SPS device including the cumulative resistance check using the SPS QA device

B. A quarterly QA process including the following:

1. Quarterly source exchange QA including all the safety and operational checks as outlined in the daily and the monthly QA
2. Timer accuracy and linearity test for the treatment time range
3. Inspection of all the transfer tubes and applicators for integrity and functionality
4. Room survey and HDR unit survey for ambient radiation levels upon new source installation
5. Monitoring and evaluation of the completed daily and monthly QA processes.
6. Ensure proper functioning of the treatment planning computer data back up system.

A. The following tests will be done annually:

1. Constancy checks on the dosimetry system
2. Verification of the length of the transfer tubes to ensure that it is within +/- 1mm of the vendor specified length.
3. Inspection of the applicators and connectors to ensure integrity and functionality.

Appendix A:

CHRISTIANA CARE HEALTH SYSTEM/ RADIATION ONCOLOGY
HDR REMOTE AFTER LOADER – DAILY QA

Date_____

1. Audio/visual communication

Date and time on printout	Yes____No____
Is two-way communication acceptable?	Yes____No____
Are video cameras functional and positioned correctly?	Yes____No____

2. Radiation monitor

Radiation monitor on?	Yes____No____
Monitor indicates radiation present when source exposed?	Yes____No____

3. Survey meter constancy

Survey meter manufacturer and model number_____Serial Number_____

Battery checks OK?	Yes____No____
Operational check with Cs-137 source OK?	Yes____No____

4. Warning lights/alarms

Light above door illuminates when source exposed, extinguishes when source retracts?	Yes____No____
"Treatment" light illuminates when source exposed, extinguishes when source retracts?	Yes____No____

5. Door interlock

Opening door retracts exposed source?	Yes____No____
Open door inhibits resumption of exposure?	Yes____No____

6. Security

Interrupt button terminates exposure?	Yes____No____
"Armed" LED on master switch illuminated?	Yes____No____
Emergency stop at console terminates exposure?	Yes____No____
Reset required before exposure can be resumed?	Yes____No____
Emergency stops in room require reset?	Yes____No____
Emergency response equipment checked?	Yes____No____
Exposed source retracts when power supply is cut off?	Yes____ No____

7. Operational tests

Paper supplies adequate?	Yes____No____
Unit can read and run a patient file?	Yes____No____
Source Position Simulator casing and cable inspected	Yes____No____
Source position verified (check ruler)?	Yes____No____
Printout shows exposure resumed as expected after interruptions?	Yes____No____
Timer accuracy verified?	Yes____No____
Source Activity verified?	Yes____No____

Signature_____

Appendix:B

CHRISTIANA CARE HEALTH SYSTEM

Department of Radiation Oncology

Monthly QA for MicroSelectron HDR unit **S/N:31503**

Source Activity check

Date	03/09/10	Production No:	105002	Temperature	20.2
Batch Number	HDR021910	Source Number	D36C-1744	Pressure	29.96
Activity from Calibration Certificate:	10.34	Ci	Ctp	0.9926	
Date of Manufacture's Calbration:	03/02/10				

Well Chamber Source Calibration

Leakage current reading: 0

Determine position of maximum well chamber response (10^-8Amp scale)

Source Position	Reading	Source Position	Reading
1450	8.459	1470	8.497
1455	8.507	1475	8.435
1460	8.531		
1465	8.529		

Take three readings at position of maximum response

Rdg 1	8.531
Rdg 2	8.531
Rdg 3	8.532
Average of 3 reading	8.531

Average of three readings minus leakage	8.531E-08	
Well Chamber manufacturer and model number:	Standard Imaging: Model HDR 1000 Plus	
Well Chamber Serial number: A041803, Calibration date:	06/19/08	
Air Kerma calibration factor	4.96E+11	micro Gray/m^2/A
Apparent activity Calibration factor	1.166E+08	Ci/A
A(ion)	0.9980	
Well chamber Calibration date:	06/19/2008	
Electrometer manufacturer and model number:	Standard Imaaging-CDX2000A	
Electrometer Serial Number: B9700214 Calibration Date:	06/19/08	
Calibration Factor	1.000E+00	A/unit reading

Air kerma OR		
Calculated Activity= Average Reading x Ctp x Cwell x Celect x Aion	(Ci)	9.854
Time Calibration performed		15:20
Stated activity at the time of calibration:	(Ci)	9.682
Percent difference from measured activity (should be with in +/-5%)		1.74

Mechanical/Operational Checks

1. Audio/visual communication

Date and time on printout correct?	**Yes / No**
Is two-way communication acceptable?	**Yes / No**
Are video cameras functional and positioned correctly?	**Yes / No**

2. Radiation monitor

Radiation monitor on?	**Yes / No**
Monitor indicates radiation present when source exposed?	**Yes / No**

3. Survey meter constancy

Survey meter manufacturer and model number_____Serial Number_____

Battery checks OK?	**Yes / No**
Operational check with Cs-137 source OK?	**Yes / No**

4. Warning lights/alarms

Light above door illuminates when source exposed, extinguishes when source retracts?	**Yes / No**
"Treatment" light illuminates when source exposed, extinguishes when source retracts?	**Yes / No**

5. Door interlock

Opening door retracts exposed source?	**Yes / No**
Open door inhibits resumption of exposure?	**Yes / No**

6. Security

Interrupt button terminates exposure?	**Yes / No**
"Armed" LED on master switch illuminated?	**Yes / No**
Emergency stop at console terminates exposure?	**Yes / No**
Reset required before exposure can be resumed?	**Yes / No**
Emergency stops in room require reset?	**Yes / No**
Emergency response equipment checked?	**Yes / No**
Exposed source retracts when power supply is cut off?	**Yes / No**

7. Operational tests

Unit can read and run a patient file?	**Yes / No**
Exposure inhibited if catheter not in programmed channel?	**Yes / No**
Source activity verified?	**Yes / No**
Source position verified (check ruler)?	**Yes / No**
Auto radiograph OK?	**Yes / No**
Timer Accuracy verified?	**Yes / No**
Source Position Simulator casing and cable inspected	**Yes / No**
Source Position Simulator cumulative resistance checked	**Yes / No**
Emergency source container and handling kit in place	**Yes / No**

QA performed by: **Date:**