

CRITTENTON**CANCER
CENTER**

1901 Star Batt Drive


Rochester Hills, MI 48309

August 8, 2011

Response to an Apparent Violation in Inspection Report 03002157/2011001(DNMS);
EA-11-165

- 1) **Reason for Apparent violation:** The physicist made an error in the manual entry of the step-size into the treatment-planning computer. The treatment plan required 5mm step size. The SAVI cases could not be transferred automatically because we have a 3-Channel HDR Unit and the current software does not support automatic transfer of plan data. The Nucletron system defaults to a 2.5mm step-size and the physicist did not change it to 5mm. Written procedures did not specifically address verification of the step size before treatment delivery.
- 2) **Corrective steps that have been taken:** Use of a checklist and verbal call out of treatment parameters before each treatment. Revision of policy to address the manual entry of treatment data and the use of a checklist to check step size, dwell positions and all treatment parameters before actual treatment delivery. Education of staff about revised policy that addressed need for verbal and visual confirmation of treatment parameters before each treatment. Staff has been educated about the need for a "time out" to review checklist before treatment delivery and is sensitive to the potential for error with manual entry of data
- 3) **Corrective steps that will be taken to avoid future errors:** 1) Use of the checklist with sign off prior to each treatment to avoid the errors associated with manual data entry 2) Confirmation with verbal call out of treatment parameters dwell time, step size and treatment plan 2) Inclusion of HDR cases in chart rounds to review treatment plan, delivery and quality assurance
- 4) **Date of full compliance- 2/28/11-** Staff completed review of revised policy and new checklist and is aware of issues and concerns about need for timeout and checklist use before each treatment.

Respectfully Submitted,

Frank D. Sottile, M.D.
Chief Medical Officer
Crittenton Hospital Medical Center

RECEIVED AUG 2 2 2011

1901 Star Batt Drive
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Objective:

To ensure the identity of the patient as the individual for whom treatment has been prescribed and to ensure that the details of the treatment are in agreement with the prescription and the plan of treatment.

Scope:

All personnel involved in the treatment of patients

Policy:

Before a radiation treatment is administered, either by external beam teletherapy or any form of brachytherapy, the identity of the patient will be established as follows. The practitioner will ask the patient's name and confirm the name and at least one of the following by comparison with the corresponding information in the patient's chart: photograph of the patient's face, birth date, address, social security number, signature, the name on the patient's ID bracelet or hospital ID card, or the name on the patient's medical insurance card.

The accuracy of the treatment site will be confirmed by reviewing the documentation, such as the prescription, technical notes, photographs, and the simulation film, when applicable.

The dose, timer or monitor unit setting, machine parameters, ancillary aids, etc. (or, for brachytherapy, the radioisotope, treatment site, total dose, number of sources, source strengths, and loading pattern) will all be confirmed by reviewing the prescription, setup instructions and technical notes before treatment.

- a. Check both manual and computer-generated dose calculations
- b. For the first HDR treatment use a check list that verifies that the programmed treatment agrees with the treatment plan, this will include dwell times, step-size, source strength, total time, treatment site. For subsequent HDR treatments verbally check the programmed dwell times, step-size, source strength, total time and treatment site with the treatment plan. Include HDR treatment charts in departmental chart rounds.
- c. Verify that any computer-generated dose calculations are correctly transferred into the consoles of therapeutic medical units
- d. Confirmation of the radionuclide for brachytherapy
- e. Confirmation of the dose per fraction and number of fractions for teletherapy
- f. Confirmation of target coordinate settings for gamma knife

Administrative Responsibility:

The Manager of Radiation Oncology has overall administrative responsibility and authority for administration of this policy. Divisional management has day-to-day.

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HDR Procedure- Pre treatment checklist

Patient Name _____ **Medical Record Number** _____

Date of Treatment _____ **Fraction** _____

Prior to each patient treatment:

The Medical Physicist will perform the following checks before each patient is treated.

- Verify that the Physician's written prescription is in the chart and that the plan agrees with the prescription.
- Verify source activity and calibration date on treatment planning printouts
- Verify step-size and length parameter
- Verify patient identity and correct patient file name
- Verify source activity from planning system matches the activity on the HDR printout and the manual decay calculation
- Plan dwell times verified by physician and physicist
- If multiple channels are used, verify that the correct catheter is connected to the correct machine channel
- Verify correctness of patient information on printouts
- Insure that all catheter connections from the after loader to patient are as straight as possible
- Insure that all catheters are fully seated into the machine connectors
- Verify that the Daily QA has been performed and verified by a physicist.

Physician

Physicist



Title: Identifying Patients and Confirming Prescription Before Treatment

Policy #: ROC 315 QMP

Effective Date: 11/05

Review Date: 01/11

Supercedes:

Department: Radiation Oncology Center

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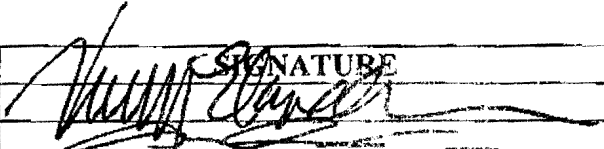
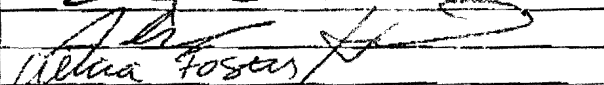
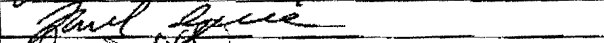
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<u>Sponsored by:</u>	Jay Burmeister, Chief of Physics		
	<i>Name / Title</i>	<i>Signature</i>	<i>Date</i>

<u>Approved by:</u>	Mara Jelich, Manager, Radiation Oncology Center		
	<i>Name / Title</i>	<i>Signature</i>	<i>Date</i>

ROC POLICY 315
Date of Modification February 28, 2011

My signature below indicates that I have read the above named policy.

NAME	SIGNATURE
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