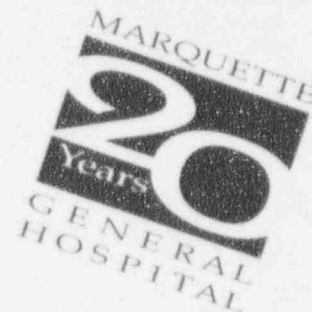




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Robert C. Neldberg

Chief Executive Officer / Administrator

March 23, 1994

U.S. Nuclear Regulatory Commission
Region III
John A. Grobe, Chief
Nuclear Materials Inspection
Section 2
801 Warrenville Road
Lisle, IL 60532-4351

SUBJECT: Reply to a Note of Failure of Quality Management Program to Prevent Misadministration

As a result of the misadministration reported on November 19, 1993, the Quality Management Program was reviewed to determine how to prevent a similar misadministration in the future. As a result, a procedure (see enclosure) was written for "Preparation of Afterloading Tubes for Brachytherapy Procedures" as outlined in our letter of November 26, 1993. This has since been reviewed and approved by the Quality Management Program Committee. This procedure is also included in the Radiation Oncology Policy and Procedures Manual as well as the Hospital Quality Management Program.

To date the success of this change can be measured by the fact that no subsequent misadministrations have occurred.

As written in the procedure, a physicist, dosimetrist or M.D. must approve the catheter at simulation. Once the name tag is attached, it is double checked at each step of the process (by a physicist) up to insertion into the patient to verify its correctness.

This procedure was implemented on December 2, 1993, and will be reviewed on a quarterly basis by myself, as Radiation Safety Officer, the Quality Management Program Committee and the Radiation Safety Committee for any possible deficiencies.

If there are any questions regarding this matter you may contact me at (906) 225-3102.

Sincerely,

Richard F. Moreland, Ph.D.
Radiation Safety Officer

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MARQUETTE GENERAL HOSPITAL

MARQUETTE, MICHIGAN

RADIATION ONCOLOGY DEPARTMENT

Subject: Preparation of After- Procedure No.: 723-023

loading Tubes for Brachytherapy Effective Date: 12/93

Procedures Revision Date: _____

Distribution: Executive Director,

Asst. Adm., Program Director

Richard F. Moreland
Authorized By

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The patient will be brought to the Simulator in Radiation Oncology Department. Prior to taking orthogonal films, the simulator therapist will insert a full length afterloading tube all of the way into the tandem such that the tip of the tube is touching the internal tip of the tandem. An ink mark will then be placed at a point where the tube projects out of the open end of the tandem. The tube will then be removed, cut to length, and the dummy sources will be inserted into the tube followed by a plunger of appropriate length. Cut the plunger such that it projects out of the open end of the tube by .5 cm.

A Physicist, Dosimetrist or M.D. must be present to verify the correct insertion of the prepared tube prior to taking the orthogonal films. Next the cap will be tightened to the tandem to assure that the tube will not move during the procedure. The patient will then be flouroscoped to assure correct placement of the tandem and/or avoids. Orthogonal films will be taken utilizing the same SFD for each film. The magnification tray should be left in unless seeds are used in which a case a 20 x 20 cm field size will be set to verify the magnification factor. Following approval of the orthogonal films, the afterloading tube will be removed, a tape label placed at the inferior end of the afterloading tube and the patients name written on it. The tube, with label, and any spacers will then be given to the physicist for loading.

END OF PROCEDURE

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