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Frank Costello
Licensing Assistance Section
Nuclear Regulatory Commission
Region I
475 Allendale Road
King of Prussia, PA 19406-1415

Dear Mr. Costello,

Enclosed you will find our revised Quality Management Program for High Dose Rate (HDR) Brachytherapy. If your need any clarification, please feel free to call anytime.

Thank you for your cooperation

Sincerely,

Roger Tokars, MD
Medical Director
Radiation Safety Officer

Mitchell Jarosz, MS
Radiological Physicist

cc: William Walker, Ph.D.
Marcy Colkitt, Esq.

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QUALITY MANAGEMENT OF HIGH DOSE RATE BRACHYTHERAPY PROCEDURES

January 3, 1994

1. This quality management program applies to brachytherapy with computer controlled, high dose rate (HDR) Afterloading devices which contain sealed sources of Iridium-192. Only an authorized user (physician) and authorized physicist shall be involved in administering high dose brachytherapy treatments.

2. **The Written Directive**

An authorized user shall date and sign a written directive (prescription) prior to the administration of any brachytherapy dose from a high-dose-rate remote Afterloading device.[10CFR35.32(a)(1)][1] and {3.1.1}[2] This written directive shall be maintained for three years. The written directive must include:

a. The date
b. The patients' name
c. The total dose
d. The dose per fraction
e. The treatment site
f. The overall treatment period
g. Signature of the authorized user physician
h. Applicator

If, because of the emergent nature of the patient's condition, a delay in order to provide a written directive would jeopardize the patient's health, an oral directive will be acceptable provided that the information provided in the oral directive is documented immediately in the patient's record and a written directive is prepared within 24 hours of the oral directive.

Routine revisions to the written directive will be made prior to administration of the dose or next fractional dose.

In the event the written directive (prescription form) is not executed as directed (e.g., patient died, tumor regressed, etc.), revisions of such written directive shall be made by the authorized user prior to administration of the total prescribed dose.

The identity of the patient as the individual named in the written directive shall be verified by two independent methods. [10CFR35.32(a)(2)] and {3.1.2} The procedure used to identify the patient

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[1]Items in brackets [ ] are references to requirements in Title 10 Code of Federal Regulations, Part 35.

[2]Items in brackets { }are references to paragraph numbers of recommendations contained in USNRC Regulatory Guide 8.33, Quality Management Program.

shall be to ask the patient's name and confirm the name by at least one of the following by comparison with the corresponding information in the patient's record: birth date, address, social security number, signature, the name on the patient's ID Bracelet or hospital ID card, the name on the patient's medical insurance card, or a photograph of the patient's face.

3. The Treatment Plan

3.1 Treatment Planning and Dose Calculation Computer Programs

The authorized HDR physicist shall perform acceptance testing on each treatment planning or dose calculation computer program.{3.1.9} Acceptance testing shall be performed before the first use of a treatment planning or dose calculating computer program for brachytherapy high dose rate remote afterloading devices. A record of the testing and results shall be maintained for three years.

3.2 The Provisional Plan

The authorized user establishes the target volume in the patient using appropriate diagnostic techniques, which may include physical examination, x-ray fluoroscopy, x-ray film, CT, MRI, or nuclear medicine scans. On the basis of this information, with instruction from the authorized user, the physicist or dosimetrist devises a provisional treatment plan, this is, a provisional plan of the computerized source placement and dwell times needed to accomplish the distribution of absorbed dose desired.

3.3 The Pretreatment Procedures

At the completion of treatment plan preparation and prior to the initial treatment, the authorized user will review the plan with the authorized physicist to verify that the plan is consistent with the written directive. {3.1.3} This review will verify that the following items on the treatment plan and written directive:

a. Radioisotope
b. Number of source positions
c. Source strength
d. Treatment site
e. Total dose

Radiographs will be obtained to verify the position of dummy sources prior to treatment and shall be used in calculating the prescribed brachytherapy dose before insertion of the sealed source. {3.1.5}

Before administering treatment, the physicist shall verify that the specific details of the brachytherapy administration are in accordance with the written directive and plan of treatment. {3.1.3}

Dose calculations shall be checked before administering the prescribed brachytherapy dose. [10CFR35.25] and {3.1.6} The physicist shall ensure that an independent dose calculation check is

performed before execution of brachytherapy treatment. Computer-generated dose calculations shall be checked by examining the computer printout to verify that correct input data for the patient were used in the calculations (e.g., source strength and positions).

The computer-generated dose calculations for input into the brachytherapy afterloading device shall be checked to verify correct transfer of data from the computer (e.g., channel numbers, source positions, and treatment times) by the person entering the data and the authorized user.

If the authorized user determines that delaying treatment in order to perform the checks of dose calculations would jeopardize the patient's health because of the emergent nature of the patient's medical condition, the checks of these calculations shall be performed within 24 hours of the treatment. {3.1.8}

4. Treatment Administration

It is the authorized user's responsibility to ensure that the administration of the radioactive source(s) complies with the written directive and is given to the correct patient.

Each brachytherapy patient shall be monitored for radioactivity with a survey meter before and after each treatment and the result recorded and signed by authorized user and/or authorized physicist.

After each brachytherapy treatment, the authorized user shall date and sign or initial a written record of the administered dose in the patient's chart. This record shall be maintained for three years. [10CFR35.32(d)(2)] and {3.1.7}

Any individual who is uncertain about any aspect of the treatment shall seek guidance and ask questions before initiating any procedure. {3.1.4}

5. Unintended Deviation from the Written Directive

Unintended deviations from the written directive include misadministrations and recordable events which are defined in 10CFR35.2. When a misadministration occurs, notification of the NRC/Agreement State, the referring physician and the patient must follow guidelines given in 10CFR35.33.

When a "recordable event" occurs, all relevant facts must be assembled, appropriate action (if any) taken, and a record of the relevant facts and actions (if any) that were taken must be prepared within 30 days of recognizing the event. This record or report will be filed in the Center files.

Unintended deviations from the written directive will be investigated by the Center medical director with the assistance of the physicist.

6. Quality Management Program Review

A formal review of the quality management program will be made at least once every 12 months. [10CFR35.32(b)] and {3.1.10} The program will be reviewed by the authorized user(s), center medical director (if different from the authorized user) and the authorized center HDR physicist. Twenty five or 10% (which ever is the greater) of the written directives generated during the 12 month period under consideration will be reviewed.

The medical director will implement a quarterly review which is achieved by a dry run of emergency procedures submitted. The result of this exercise will be documented and will be made a part of the annual quality management program review.

The records of recordable events of administrations occurring in the 12 month period will be reviewed for promptness and thoroughness of the investigations, appropriateness of the action(s) taken (if any) and will include a review of the succeeding five written directives (if available) from similar administrations to evaluate the effect of any action that was taken.

The reviewers will evaluate the overall effectiveness of the quality management program and the need for modification of the program.

A report signed by the individuals performing the review, will be filed with the center medical director and maintained in the center files for three years.

Changes to the quality management program should be documented, implemented, and submitted to the NRC/Agreement State within 30 days.

7. Record Keeping

The written directive shall be maintained for three years.

A record of the acceptance testing on each treatment planning computer program for HDR remote afterloading device brachytherapys shall be maintained for three years.

Each brachytherapy patient shall be monitored for radioactivity with a survey meter before and after each treatment and the result recorded and signed by the authorized user and/or authorized physicist.

After each brachytherapy treatment, the authorized user shall date and sign or initial a written record of the administered dose in the patient's chart. This record shall be maintained for three years.

A record of "recordable events" will be filed in the Center files.

Records of all formal reviews of the quality management program will be maintained for three years.