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Wayne State University

DMC Grace Hospital

August 12, 1996

US Nuclear Regulatory Commission
Region III
801 Warrenville Rd
Lisle IL 60532-4351

Attn: Nuclear Materials Licensing

Dear Sir/Madam,

Please find attached a copy of our revised Quality Management Program for HDR-remote afterloading brachytherapy under NRC license # 21-00998-01.

The revision to the QMP and its subsequent implementation was made on July 24, 1996 to make it more applicable to our HDR brachytherapy program.

Sincerely,

Julie M. Zuby, Director
Pulmonary and Oncology Services

Burt Weyhing, M.D.
Radiation Safety Officer

Archana Somnay, M.S.
Clinical Physicist
Assistant Radiation Safety Officer

cc:
J Feldmeier, S Heller, P McDermott, R Alecu, C Orton.

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QUALITY MANAGEMENT PROGRAM - ADDENDUM

HDR BRACHYTHERAPY SECTION

Section 35.32 of the NRC regulations related to the human use of radioactive materials mandates that each licensee establish a quality management program. In compliance with 10 CFR Part 35, Several department procedures are herein identified as comprising a Quality Management Program (QMP) for HDR remote afterloading.

This section of the quality management program pertains only to high dose rate (HDR) remote afterloading brachytherapy. The section titled "BRACHYTHERAPY SECTION" (previously submitted and approved) continues to apply to all other forms of brachytherapy permitted by our NRC license (#21-00998-01).

For the purpose of this document the term "therapist" means radiation therapy technologist.

Objective 1: The treatment prescription

Purpose: to provide prescriptions in a consistent format for the efficient and accurate treatment of patients.

Procedure

i) The treatment prescription must be completed by the authorized user physician prior to treatment (except in an emergency in which case the policy stated in §vi below must be followed).The "prescription" must fulfill the NRC requirement of a "written directive". It must include:

A) the radioisotope
B) the anatomical area of treatment
C) the dose per fraction and the total dose
D) the fractionation
E) any dosimetry orders.

ii) All prescriptions must be *signed* and *dated* by the authorized user physician prior to treatment. All prescriptions written by a physician working under the supervision of an authorized user physician, must be countersigned by the authorized user physician, prior to treatment. All hold treatment and resume treatment orders must be signed by a authorized user physician.

iii) All prescriptions must be written in black or blue ink.

iv) All prescriptions must be written neatly and within the provided lines so that they are clear and understandable. If further space is needed for prescriptions, it must be continued on an additional prescription page.

v). If the phrase "per plan" is included in the prescription, then the plan must be signed and dated by the authorized user physician prior to treatment.

vi) 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 hrs of the oral directive.

vii) All prescriptions are to be dated the day they are written. All addenda to the prescription must be in chronological order and dated.

viii) Oral revisions to the prescriptions must be recorded in the chart immediately and a revised written prescription obtained within forty eight hours.

Objective 2: Patient Identity

Purpose: before a treatment is administered, the identity of the patient for whom the treatment has been prescribed must be established.

Procedure:

i) It is the responsibility of the therapist to clearly establish the identity of the patient.

ii) The procedure used to identify the patient will be to 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.

Objective 3: Before Treatment

Purpose:

To establish and maintain a system of quality assurance with regard to patient dose calculations. All calculations are to be verified. The details of the treatment must be checked for agreement with the prescription and the plan of treatment before the treatment is administered. Any question about the prescription or plan must be resolved before continuing.

Procedure:

i) The treatment planning software will be tested following the acceptance testing protocol of the manufacturer. This is a test of the entire system including digitizer, software and basic physical constants and data used by the planning system. This test will be made before patient use every time a new version of the software is installed. The results of these tests will be recorded and maintained in a reviewable form. These tests are the responsibility of an authorized physicist.

ii) Prior to any high dose rate brachytherapy treatment, radiographs of the applicator(s) with nonradioactive dummy sources in place will be taken and used to calculate the proposed dose distribution. In some cases, the geometry of the sources within the applicator may be fixed, in which case the dose distribution may be pre-calculated for a standard pattern of loading. In these cases, radiographs are not necessary.

iii) The treatment plan must be reviewed by a qualified person before the first treatment fraction. This individual must be different than the one who produced the original plan. The individual performing the check must verify that the planned treatment is consistent with the prescription. The plan must be checked for appropriate use and transfer of all pertinent data and for arithmetic errors whenever manual calculations are involved. Whenever reasonably feasible, a manual calculation must be performed to verify the computer calculated dose at one or more spatial points.

iv) Verification of the correct positioning of the applicators, catheters, needles, etc. will be determined prior to treatment by either direct observation (whenever possible, e.g. interstitial treatment), palpation or if appropriate, radiography (either fluoroscopy , plain film or CT).

v) Prior to any fractionated treatment the therapist must verify the fractionation schedule by examining the prescription. The therapist must check to see that all prior fractions have been properly accounted for, ie. that the charted cumulative dose is correct and that the impending treatment fraction is truly called for by the prescription.

Objective 4: Treatment Delivery

Purpose: to ensure that the treatment delivered is in accord with the prescription.

Procedure:

i) During all HDR patient treatments, both the authorized user and an authorized medical physicist

must be physically present at the treatment console. Therapists must not treat unless these two individuals are present.

ii) Before every treatment the physicist will verify that the treatment programmed at the treatment planning console is in accordance with the treatment plan and will sign the printout. Among those items checked must be the source activity, the dose per fraction, the channels to be used, the dwell times, the total treatment time and the dwell positions.

iii) The therapist must review the planned treatment prior to administration with the authorized physicist and the authorized physician. The accuracy of the treatment site must be confirmed by reviewing the documentation, such as the prescription, technical notes, photographs, and the simulation films when applicable. The radioisotope, total dose, dose per fraction, the numbering of the channels and their anatomical destination must all be confirmed by reviewing the prescription, setup instructions and technical notes before treatment. Any questions or uncertainties must be resolved before initiating treatment.

iv) Each HDR brachytherapy patient treatment must be documented in the patient's chart. The therapist delivering the treatment will record the total treatment time, the administered dose for that fraction, and the cumulative dose in the treatment chart in the same manner as external beam treatments are recorded. Initials are to appear in the initial column. If there is more than one machine involved in the treatment of a particular patient, initials of staff from both the machines are to appear.

v) All therapists initialing the chart are equally responsible for all aspects of that patient's treatment. All therapists must also realize that their initials signify that the treatment was, in all regards, properly delivered, and that, further, the therapists are also identifying themselves with the initialing procedure. A corresponding signature is to be written in the legend section of the treatment chart.

vi) After every HDR brachytherapy procedure the patient must be surveyed with a survey meter before being released. The radiation technology therapist and the physicist are jointly responsible for this survey.

Objective 5 After Treatment - Identification of Dose Deviations and Periodic Review of HDR QMP

Purpose: To identify and evaluate any prescription deviations and to take corrective action whenever appropriate.The quality management program must be reviewed annually and the records of these reviews maintained in an auditable form. A sample of HDR treatments will be evaluated for compliance with the prescription (written directive).

Procedure:

i) The treatment chart for all patients undergoing brachytherapy procedures must be checked by a qualified person (oncology physician, physicist, dosimetrist or therapist) after the completion of the procedure (or treatment course in case of a fractionated treatment) to ensure that the treatment was delivered in accordance with the written directive. All the specific details of the procedure must be verified in so far as possible.

ii) A prescription deviation will be determined to be a misadministration or a recordable event according to the criteria established by the Nuclear Regulatory Commission in 10 CFR part 35. Any event suspected of being a misadministration must be reported to the radiation safety officer, or a physicist immediately.

Following 10 CFR part 35.2 a misadministration means the administration of a brachytherapy dose:

A) involving the wrong patient or human research subject, wrong radioisotope, or wrong treatment site, or;

B) involving a sealed source that is leaking, or;

C) when for a temporary implant one or more sealed sources are not removed upon the completion of the procedure; or

D) when the calculated administered dose differs from the prescribed dose by more than 20 percent of the prescribed dose.

The NRC defines a recordable event as the administration of:

A) radiation without a written directive where a written directive is required.

B) radiation without daily recording of each administered radiation dose in the appropriate record;

C) a brachytherapy radiation dose when the calculated administered dose differs from the prescribed dose by more than 10 percent of the prescribed dose.

iii) The NRC requirements for notifications, reports, and records of misadministrations are given in 10 CFR 35.33. In summary, the NRC must be informed by telephone within one day (NRC Operations Center: 301-816-5100) and in writing within 15 days. In addition, there are requirements for notifying the patient and referring physician.

iv) All recordable events must be evaluated within 30 days after discovery. A recordable event must be responded to by (1) assembling the relevant facts in an attempt to determine the cause, (2)

identifying what, if any, corrective action is required (such as "in-service" training, emergency drills, etc.) to prevent recurrence and implementing such action and (3) retaining a record of the event, cause and corrective action for th e years.

v) The annual QMP review must consist of a representative and statistically significant sample of patient treatments and must also include all misadministrations and recordable events. The number of cases selected for review must be determined by the following guidelines:

A) > 100 HDR patients annually -------	20% of the total will be evaluated
B) 20 - 100 HDR patients annually ----	20 charts will be reviewed
C) < 20 HDR patients annually ---------	all charts will be evaluated

vi) During the annual QMP review the reviewer must record on an established form whether the follow ere correct for each sampled chart: the radioisotope, treatment site, and total dose. Any deviations of these parameters from the prescription (written directive) must be immediately reported to the Quality Assurance Committee.

vii) For each prescription deviation identified the cause of the deviation must be determined and action recommended to avoid recurrence.

viii) On at least an annual basis the Quality Assurance Committee will formally recommend any necessary changes to the department's QMP.

ix) Any changes to the QMP must be submitted to the NRC within 30 days of this implementation. Records of the QMP review will be maintained for three years.