

AUG 22 1994

ST. ELIZABETH'S HOSPITAL OF BOSTON
736 CAMBRIDGE STREET
BOSTON, MA 02135

ATTN: FRANK KRASIN, PH.D.

RE: Docket Number: 030-17823
License Number: 20-06579-02

Dear Dr. Krasin:

This letter acknowledges receipt of your letter dated July 20, 1994, in response to our letter which addressed deficiencies in your Quality Management Program (QMP). Your implementation of the QMP and its adequacy will be reviewed as part of the next NRC inspection. This inspection will include a review of your letter referenced above and any resulting changes to your QMP.

This QMP will not be incorporated into your license by condition. You have the flexibility to make changes to your quality management program without obtaining prior NRC approval. However, modifications to your program must be submitted to this Office within 30 days as required by 10 CFR 35.32(e).

Thank you for your cooperation in this matter; no reply is required in response to this letter.

Sincerely,

Original Signed By:
James P. Dwyer

James P. Dwyer
Quality Management Program Coordinator
Region I

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NOTE TO DMB:

THE ATTACHED DOCUMENTS ARE TO BE PROCESSED AS ONE QUALITY
MANAGEMENT PACKAGE.

LICENSE NUMBER: 20-06577-02

DOCKET NUMBER: 030-17823

THIS SHEET MAY BE DISCARDED AFTER PROCESSING.

THANK YOU!

St Elizabeth's Hospital

of Boston

736 Cambridge Street Boston, Massachusetts 02135 617/789-3000

United States Nuclear Regulatory Commission
Region 1
Attn: James P. Dwyer
475 Allendale Road
King of Prussia, Pennsylvania 19406-1415

Re: Docket Number: 3017823
License Number: 20-06579-02
Plan File Date: 27--Jan-92
Region Number: 1

Dear Mr. Dwyer:

As requested by the NRC we have revised our quality management program for teletherapy. Please find attached three pages showing our revised quality management program for teletherapy at St. Elizabeth's Medical Center of Boston.

Sincerely,

F. Krasin

Frank Krasin, PhD
Chief Medical Physicist

July 20, 1994
Date

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JUL 25 1994

QUALITY MANAGEMENT PROGRAM FOR TELEETHERAPY

1. The objectives of the Quality Management Program are to assure that:
 - a. A written directive is prepared before treatment.
 - b. The patient's identity is verified, by more than one method, as the individual named in the written directive, before each treatment fraction.
 - c. Final plans for treatment are in accordance with the respective written directive.
 - d. Each treatment fraction is in accordance with the written directive.
 - e. Any unintended deviation from the written directive is evaluated, and appropriate action is taken.
2. The Radiation Safety Officer and Radiation Therapy Department shall have the authority and responsibility to establish and implement the Quality Management Program. Directives contained herein remain responsive to the JCAHO and NRC.
3. Prior to treatment, a written directive issued by an authorized user will be prepared, signed, and dated for any radiation therapy:

A written directive is defined as an order, in writing, for a specific patient, dated and signed by an authorized user prior to treatment, containing the following information:

- a. patient's name
- b. patient identification number, if available
- c. treatment plan
- d. total dose
- e. any special precautions

Except in emergent situations as defined in Part 17 below, no teletherapy treatment shall be administered by any personnel in the absence of a signed directive containing the above elements.

4. Prior to treatment, the patient's identity is verified by more than one method as the patient named in the written directive. The person responsible for the treatment will perform the verification.

Verification of identity must include at least two of the following methods coupled with a review of the patient's record:

- a. the patient shall be asked to state and spell his/her name
- b. the patient shall be asked to state his/her birth date

- c. the patient shall be asked to state his/her Social Security Number
- d. the patient shall be asked to state his/her address
- e. the patient shall be asked for identification, i.e. driver's license
- f. the inpatient's wrist identification band shall be checked for name and patient number (SSN)
- g. check against a photograph of the patient's face in the treatment record

If the information obtained from any two of these methods does not correspond to the information on the patient's record, the treatment shall not be performed until conclusive verification is obtained.

5. The person treating the patient shall read the written directive before initiating treatment. If any portion of the written directive is unclear to that person, (s)he must contact the specific authorized user who provided the directive for clarification. The radiation dose shall not be administered until the intent of the written directive is thoroughly understood by the administering person.
6. The individual in Part 5 above shall verify that the specific details of the treatment are in accordance with the written directive.
7. Revisions to written directives may be made for any treatment provided that the revision is dated and signed by an authorized user prior to the treatment and that all other above conditions are followed.
8. All written directives will be retained in an auditable form for a period of three years.
9. After treatment a responsible party shall make, date, sign or initial a written record that documents the treatment in an auditable form to be retained for three years.
10. Within 30 days after discovery of a recordable event the Radiation Safety Officer will evaluate and respond to each recordable event by: (a) assembling the relevant facts including the cause, (b) identifying what, if any, corrective action is required to prevent recurrence and (c) retaining a record, in an auditable form, for three years, of the relevant facts and what corrective action was taken.
11. All teletherapy treatments will be reviewed at intervals not to exceed 12 months. This review will include:
 - (a) At least 20% of all cases if the number of cases performed is greater than 100, 20 cases if the number of cases is between 20 and 100, and all, if the number of cases is less than 20.

- (b) All recordable events.
- (c) All misadministrations since the last review.

12. In the event of the discovery of a misadministration or a recordable event as a result of the periodic review, all teletherapy treatments will be reviewed.
13. The effectiveness of this plan will be evaluated by looking at the total number of misadministrations and/or recordable events versus the total number of administrations performed. Any increase in the occurrence rate will prompt the Radiation Safety Officer to make modifications to meet the objectives of the program.
14. All modifications to this QM program will be submitted to the NRC within 30 days after the modification has been made.
15. All reviews of this program will be retained in an auditable form for a period of three years.
16. Training will be conducted for all employees evolved in the quality management program.
17. Oral directives or amendments are permissible when a patient's medical condition is such that his/her health would be jeopardized by the delay needed for originating or revising a written directive. When oral directives or amendments are employed, the information contained in the oral directive is immediately documented in the patient's record and the original written directive is prepared within 24 hours of the oral issue. In the situation of an oral revision of an existing written directive, it must be revised, dated and signed by the authorized user within 48 hours of the oral revision.
18. Following teletherapy treatment a dated and signed written note is entered into the patient's record documenting the treatment.
19. If any unintended deviation from the written directive is identified, it is evaluated, and appropriate action taken. Upon identification of an unintended deviation, whether a recordable event or a misadministration, an investigation of the incident shall be made. The cause of the incident shall be determined and, if appropriate, corrective procedures will be implemented. Documenting and reporting of the unintended deviation shall be in accordance with the reporting rules of 10 CFR Part 35.

JUN 17 1994

ST. ELIZABETH'S HOSPITAL OF BOSTON
736 CAMBRIDGE STREET
BOSTON, MA 02135

ATTN: FRANK KRASIN, PH.D.

RE: Docket Number: 3017823
License Number: 20-06579-02
Plan File Date: 27-JAN-92
Region Number: 1

Dear Dr. Krasin:

This refers to the review of your written Quality Management Program (QMP) submitted in accordance with 10 CFR 35.32. A review of the QMP was performed to determine whether policies and procedures have been developed to meet the objectives of the rule. Based on this submission, there appear to be significant weaknesses and potential substantial failure of your QMP to meet the objectives in 10 CFR 35.32 in that:

Regarding Teletherapy

Your QMP is missing procedures to require that the written directive include:

- the dose per fraction
- the overall treatment period
- the date and signature of an authorized user

A footnote to 10 CFR 35.32(a)(1) provides that an oral revision to a written directive is acceptable if, because of the patient's condition, a delay in order to provide a written revision to an existing written directive would jeopardize the patient's health. Oral revisions must be documented immediately in the patient's record and a revised written directive must be signed and dated by an authorized user or physician under the supervision of an authorized user within 48 hours of the oral revision. Please include such a policy in your QMP.

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. Please include such a policy in your QMP.

Revisions to written directives for teletherapy may be made provided that the revision is dated and signed by an authorized user prior to the administration of the teletherapy dose or the next teletherapy fractional dose. Your QMP must include a policy/procedure that requires that revisions to written directives will be made prior to administration of the teletherapy dose or next teletherapy fractional dose.

Your submittal does not include adequate policies/procedures that ensure that final plans of treatment and related calculations for teletherapy are in accordance with the written directive as required by 10 CFR 35.32(a)(3). Your procedures should include instructions for:

- acceptance testing on each treatment planning or dose calculating computer program that could be used for dose calculations
- an independent check of full calibration measurements that resulted from source replacement, or when spot check measurement indicates that the output differs by more than 5% from the output obtained at the last full calibration corrected mathematically for radioactive decay
- determination of transmission factors for beam modifying devices before the first medical use of the beam-modifying device and after replacement of the source
- physical measurements of the teletherapy output for treatment parameters not addressed in the most recent full calibration measurement
- performance of a check of dose calculations (i.e., computer-generated dose calculations and/or manual dose calculations)
- checking the dose calculations prior to administration of the total dose for prescribed doses that are to be administered in fractions. An authorized user or qualified individual under the supervision of an authorized user (e.g. a radiation therapy physicist, oncology physician, dosimetrist, or radiation therapy technologist), who whenever possible, did not make the original calculations, should check the dose calculations. Your procedures should include both a

consideration of the number of fractions and a specified time within which the check should be performed

Your QMP should ensure that before administering each teletherapy dose or dose fraction, that the specific details of the administration are in accordance with the written directive and plan of treatment. In particular, the treatment site and the dose per fraction should be confirmed by the person administering the teletherapy treatment to verify agreement with the written directive and plan of treatment.

Your QMP must include a commitment to retain each written directive and a record of each administered radiation dose for three years after the date of administration as required in 10 CFR 35.32(d). Describe the procedure for a qualified individual under the supervision of an authorized user (e.g., an oncology physician, radiation therapy physicist, dosimetrist, or radiation therapy technologist) after administering a dose or dose fraction, to make a written record. Your procedure should describe what this record will include.

As required in 10 CFR35.32(c), the licensee shall evaluate and respond, within 30 days after discovery of the recordable event, to each recordable event by: (a) assembling the relevant facts including the cause, (b) identifying what, if any, corrective action is required to prevent recurrence, and (c) retaining a record, in an auditable form, for three years, of the relevant facts and what corrective action was taken. Please include such a provision in your QMP.

Your QMP should include a procedure to expand the number of cases reviewed when a misadministration or recordable event is uncovered during the periodic review of your QMP. Please include such a provision in your QMP.

Describe your procedures to evaluate the effectiveness of the QMP, and, if necessary, to make modifications to meet the objectives of the program as required by 10 CFR 35.32 (b)(2).

Please provide assurance that modifications to your QMP will be submitted to the NRC within 30 days after the modification has been made as required by 10CFR 35.32(e).

Please provide assurance that records of each QMP review and evaluation will be maintained for three years as required in 10 CFR 35.32 (b)(3).

To meet the requirements in 10 CFR 35.32, you may choose to utilize the procedures described in Regulatory Guide 8.33(enclosed), or submit procedures that are equivalent. If you choose to use Regulatory Guide 8.33, be certain that the procedures you select are adjusted to meet

the specific needs of your program as necessary. Additionally, you are reminded that training and/or instruction of supervised individuals in your QMP is required by 10 CFR 35.25.

Due to the apparent failure of your written QMP to meet the objectives in 10 CFR 35.32, you must immediately modify your written QMP to address the items listed above, and provide those modifications to your NRC regional office within 30 days of the date of this letter. NRC will review these matters during your next routine NRC inspection to determine whether violations of NRC requirements have occurred. Enforcement action may be taken at that time for failure to meet the requirements of 10 CFR 35.32.

Please be advised that this QMP will not be incorporated into your license by condition. This allows you the flexibility to make changes to your quality management program without obtaining prior NRC approval. When modifications are made to your program, you should submit any changes to your QMP to this Office within 30 days as required by 10 CFR 35.32(e).

Your QMP was reviewed by an NRC contractor following a standard review plan and related checklist provided by the NRC staff. This letter outlining the findings of that review was prepared by the contractor utilizing standard paragraphs previously reviewed and approved by NRC headquarters and regional management. If you have any questions about this review, you may call me at (610)337-5309. Thank you for your cooperation in this matter.

Sincerely,

**Original Signed By:
James P. Dwyer**

James P. Dwyer
Quality Management Program Coordinator
Region I

Enclosure: As stated

St Elizabeth's Hospital

of Boston

736 Cambridge Street Boston, Massachusetts 02135 617/789-3000

030-17823
20-06579-02


January 27, 1992

U.S. Nuclear Regulatory Commission
Region I
475 Allendale Road
King of Prussia, PA 19406

Gentlemen:

Please find attached a copy of our quality management program in our Radiation Therapy Department. This program has been implemented to meet the directives of 10 CFR 35.32 as published in the Federal Register of July 1991. Please contact Dr. Frank Krasin, Cobalt RSO, at (617)789-2470 if further information is required.

Sincerely,



David Balkcom
Vice President
Clinical Support Services

/cb

Attachment

QUALITY MANAGEMENT PROGRAM REGARDING

1. Teletherapy treatment.

REFERENCE: FEDERAL REGISTER NOTICE PUBLISHED 7/25/91 and 10 CFR 35.32

A quality management program is hereby established in order to meet the directives of 10 CFR 35.32 as published in the Federal Register of July 1991.

The objectives of the quality management program are to assure that:

1. A written directive is prepared before treatment begins;
2. The patient's identity is verified, by more than one method, as the individual named in the written directive, before each treatment;
3. Final plans for treatment and relative calculations for therapy are in accordance with the respective written directive;
4. Each treatment fraction is in accordance with the written directive, and
5. Any unintended deviation from the written directive is evaluated, and appropriate action is taken.

IMPLEMENTATION

1. In regard to a written directive for teletherapy treatment, the referring physician consults with the oncology physician in regard to appropriate treatment, and the oncologist prescribes the treatment. The consulting radiation oncologist will prepare a written directive for the patient with the desired dose and treatment area specified. When the requisition for the treatment arrives from the referring physician, it will be attached to the directive written by the radiation oncologist for comparison by the therapy physicist. Any question or area of uncertainty must be resolved before proceeding. A treatment plan will then be prepared by the therapy physicist and reviewed with the radiation oncologist before treatment begins. All involved will follow that treatment plan and the treatment proposed will be reviewed periodically throughout the schedule.
2. The patient's identity must be verified by more than one method. Following are suggested methods of identification:
 - asking the patient to spell his/her name
 - checking the patient's ID bracelet, if present
 - asking for photo ID or other ID
3. Each such treatment must be within 10% of the written directive.

Quality Management Program
Page 2

4. Any unintended deviation from the written directive must be evaluated and appropriate action taken.
5. Each recordable event must be fully recorded, evaluated, and corrective action taken within 30 days by the RSO.
6. Each misadministration shall be reported by the RSO to the appropriate authorities in accordance with the regulations.

ADMINISTRATIVE PROCEDURES RELATIVE TO THIS PROGRAM:

1. A copy of this management program shall be submitted to NRC prior to January 27, 1992.
2. Accompanying that submission, written certification shall be made to the NRC indicating that the quality management program has been implemented.
3. This quality management program will be reviewed at intervals of no greater than 12 months.
4. Records of review of the quality management program, each written directive, each treatment plan for teletherapy will be retained. Each recordable event, and each misadministration will be retained.
5. The written directive for such teletherapy treatment will be attached to the medical records copy of the patient record and sent to Medical Records for permanent filing.