SEP 29 1994

V. A. MEDICAL CTR.
BUILDING
NORTHPORT, NY 117682290

ATTN: ROBERT V. GRANDO, M.D. D.A.B.R.

RE: Docket Number: 030-19473
License Number: 31-13511-05

Dear Dr. Grando:

This letter acknowledges receipt of your letter dated August 24, 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

OFFICIAL RECORD COPY - C:\D\QM-ACK\002208.ACK - 09/19/94

ML 10

SEP 2 9 1994

DEPARTMENT OF VETERANS AFFAIRS
HEALTH PHYSICS PROGRAMS (115HP)
915 NORTH GRAND BLVD.
ST. LOUIS, MO 63106

ATTN: FRANCIS K. HERBIG

RE: Docket Number: 030-19473
License Number: 31-13511-05

Dear Mr. Herbig:

This letter acknowledges receipt of your letter dated September 7, 1994, which enclosed a letter dated August 24, 1994 from Mr. Robert Grando, Radiation Safety Officer of the VA Medical Center in Northport, New York. Mr. Grando's letter was written in response to our June 17, 1994 letter which addressed deficiencies in their Quality Management Program (QMP). Their implementation of the QMP and its adequacy will be reviewed as part of the next NRC inspection. This inspection will include a review of their August 24, 1994 letter and any resulting changes to their QMP.

This QMP will not be incorporated into their license by condition. They have the flexibility to make changes to their quality management program without obtaining prior NRC approval. However, modifications to their 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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ML 10

030-17473

DEPARTMENT OF VETERANS AFFAIRS
Medical Center
St Louis MO 63125

In Reply Refer To:

September 7, 1994

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

The enclosed correspondence from the Northport, New York VA Medical Center (#31-13511-05) has been received and is forwarded to your office for processing. If there are questions, please contact the facility.

Please provide a copy of any correspondence relative to licensing actions for this Medical Center to:

Department of Veterans Affairs
Health Physics Programs (115HP)
915 North Grand Blvd.
St. Louis, MO 63106

Sincerely,

Cindy Butowsky
for Francis K. Herbig
Health Physics Programs

ML 10

SEP 12 1994

NOTE TO DMB:

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

LICENSE NUMBER: 31-13511-05

DOCKET NUMBER: 030-19473

THIS SHEET MAY BE DISCARDED AFTER PROCESSING.

THANK YOU!

DEPARTMENT OF VETERANS AFFAIRS
Medical Center (632)
79 Middleville Road
Northport NY 11768-2290

In Reply Refer To: 632/11G

August 24, 1994

U.S. Nuclear Regulatory Commission
Region I
Nuclear Material Section B
475 Allendale Road
King of Prussia, Pennsylvania 19406

Docket Number 3019473
License Number 31-13511-05

SUBJ: Response to QMP review

1. We received a review of our Quality Management Program for teletherapy, dated June 17, 1994 (attached). We have modified our written procedures to correct the weaknesses outlined in the review. A copy of our revised QMP is attached for your review. The new sections are in brackets.

2. There were five changes which were requested. I will quote sections from the review in this response.

A) Request
"Your QMP is missing procedures to require that the written directive include: the overall treatment period."

Response
The definition of Written Directive in our old QMP included the overall treatment period. We have now added to the Documentation section of Treatment Planning (II.B) in our new QMP to include the overall treatment period.

B) Request
"Your procedures should include instructions for: acceptance testing on each treatment planning or dose calculating computer program that could be used for dose calculations."

Response
We have added a new paragraph (IV A) to the Patient-Dose-Calculation-checks section of our QMP. This specifies that a physicist must test new dose calculating programs.

C) Request
"must include policy/procedures to identify and evaluate any unintended deviations from a written directive..."

ML 10

SEP -2 1994

Response
Our old QMP had three sections (IV B,C,D) which addressed the identification of deviations from the written directive. We have added a new section (IV,F,1) to more specifically cover the identification and evaluation of unintended deviations.

D) Request
"Your QMP must include policies/procedures to institute corrective actions to be taken after an unintended deviations has been identified."

Response
Our QMP was modified and now includes the specific instruction that corrective action must be taken after an unintended deviation is identified (IV,F,1).

E) Request
"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."

Response
A new paragraph (VII,B,4) was added to our QMP. This specifies that if a misadministration or recordable event is uncovered during our annual review, then the number of charts reviewed will be increased to 10% or at least 30 charts.

If there are any questions regarding this response, then please call me at (516) 261-4400 extension 7558. Thank you.

Robert Grando

ROBERT GRANDO
Physicist/RSO

Attachments: 2

RG/ad

UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION I
475 ALLENDALE ROAD
KING OF PRUSSIA, PENNSYLVANIA 19406-1415

V. A. MEDICAL CTR.
BUILDING
NORTHPORT, NY 117682290

JUN 17 199

ATTN: ROBERT V. GRANDO, M.D. D.A.B.R.

RE: Docket Number: 3019473
License Number: 31-13511-05
Plan File Date: 22-MAY-92
Region Number: 1

Dear Dr. Grando:

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 overall treatment period

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

Your QMP for teletherapy must include policies/procedures to identify and evaluate any unintended deviations from a written directive as required by 10 CFR 35.32(a)(5). Please include such a provision in your QMP.

Your QMP must include policies/procedures to institute corrective actions to be taken after an unintended deviation has been identified.

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.

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,

James P. Dwyer
Quality Management Program Coordinator
Region I

Enclosure: As stated

DVA MEDICAL CENTER, NORTHPORT, NY

RADIOLOGY SERVICE

Q U A L I T Y M A N A G E M E N T P R O G R A M

RADIATION ONCOLOGY SECTION

I. DEFINITIONS (source 10CFR35.2 unless noted)

A. "Authorized user" means a physician, dentist, or podiatrist who is identified as an authorized user on a Commission or Agreement State license that authorizes the medical use of byproduct material.

B. "Full Calibration" means all the measurements performed on a teletherapy unit that are listed here.
(1) The output within +/-3 percent for the range of field sizes and for the distance or the range of distances used for medical use;
(2) The coincidence of the radiation field and the field indicated by the light beam localizing device;
(3) The uniformity of the radiation field and its dependence on the orientation of the useful beam;
(4) Timer constancy and linearity over the range of use;
(5) On-off error; and
(6) The accuracy of all distance measuring and localization devices in medical use. (Source 10CFR35.632(b))

C. "Medical use" means the intentional internal or external administration of byproduct material, or the radiation therefrom, to human beings in the practice of medicine in accordance with a license issued by a State or Territory of the United States, the District of Columbia, or the Commonwealth of Puerto Rico.

D. Misadministration means the administration of a teletherapy radiation dose;
(1) Involving the wrong patient, wrong mode of treatment, or wrong treatment site;
(2) When the treatment consists of three or fewer fractions and the calculated total administered dose differs from the total prescribed dose by more than 10 percent of the total prescribed dose;
(3) When the calculaed weekly administered dose is 30 percent greater than the weekly prescribed dose; or
(4) When the calculated total administered dose differs from the total prescribed dose by more than 20 percent of the total prescribed dose.

E. "Output" means the exposure rate, dose rate, or a quantity related in a known manner to these rates from a teletherapy unit for a specified set of exposure conditions.

F. "Prescribed dose" means the total dose and dose per fraction as documented in the written directive.

G. "Recordable event" means the administration of a teletherapy radiation dose when the calculated weekly administered dose is 15 percent greater than the weekly prescribed dose.

H. "Written directive" means an order in writing for a specific patient, dated and signed by an authorized user prior to the administration of radiation, containing the following information: the total dose, dose per fraction, treatment site, and overall treatment period.

II. TREATMENT PLANNING

A. Determination of Written Directive
Before prescribing a teletherapy procedure, the authorized user or the physician under the supervision of an authorized user will personally review the patient's case to: (1) establish that radiation is indicated for the patient's medical condition; and (2) determine the most appropriate treatment strategy for the patient.

B. Documentation
The authorized user or the physician under the supervision of an authorized user will date and sign a written directive that may include: (1) treatment modality (e.g. Cobalt-60); (2) treatment volume; (3) portal, field or arc arrangement; (4) total dose at a specified location; (5) dose per fraction or the number of fractions; (6) any blocks, wedges or bolus [; (7) overall treatment period].

C. Compare Final Plan to Written Directive
The authorized user or the physician under the supervision of an authorized user will approve the final treatment plan to assure that: (1) the treatment plan and calculations are in accordance with the written directive; (2) the treatment plan provides sufficient information and direction to carry out the written directive.

D. Revisions to Written Directives
A written revision to an existing written directive may be made for any therapeutic procedure provided that the revision is dated and signed by an authorized user or physician under the supervision of an authorized user prior to the administration of the teletherapy dose, or the next teletherapy fractional dose.

E. Oral Directives
If, because of the emergent nature of the patient's medical 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 contained 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.

F. Oral Revisions
If, because of the patient's medical condition, a delay in order to provide a written revision to an existing written directive would jeopardize the patient's health, an oral revision to an existing written directive will be acceptable, provided that the oral revision is documented immediately in the patient's record and a revised written directive is dated and signed by the authorized user within 48 hours of the oral revision.

G. Retention of Records
Each written directive shall be retained in an auditable form for three years after the date of administration.

III. WHEN THE PATIENT ARRIVES FOR RADIATION DOSE

A. Seek Guidance If in Doubt
Workers should seek guidance if they do not understand how to carry out the written directive, or if they have any problem with legibility, or if they have questions about what to do or how to do it. Continue the procedure, only after the doubt has been removed.

B. Patient Identification
Before administering a teletherapy dose, verify the patient's identity by asking the patient's name, and ID number (last four digits of Social Security number), or read the name and ID number on the patient's bracelet. After a photograph has been made, it is sufficient to ask the patient's name and confirm that it is the same person as the photograph. Proceed with the procedure if the identity matches the written directive.

C. Treatment Set-Up Verification
Before administering each dose, the patient's chart shall be checked to determine that details of the administration are in accordance with the written directive and treatment plan. Details include treatment site, beam orientation, and dose per fraction.

D. Documentation of Radiation Treatment
After each administered dose fraction, a qualified person (e.g. radiation therapy technologist) shall record in the patient's chart, details of the administered dose fraction. The details shall include the date, the initials of the person who administered the dose, and for each field: (1) the treatment time; (2) the dose administered; and (3) the cumulative dose administered.

IV. PATIENT DOSE CALCULATION CHECKS

[A. Software Acceptance Testing
Before new treatment planning or dose calculating computer programs are relied on for patient dose calculations, they shall be tested by a physicist. The testing shall include comparisons to prior programs or prior methods. The new computer dose calculation shall also be compared to a measurement of output made by a calibrated ionization chamber.]

[B]. [When will patient dose first be checked]
1. If prescribed dose exceeds three fractions. The dose calculations shall be checked within three working days after administering the first fraction.
2. If prescribed dose is three fractions or less. The dose calculations shall be checked before administering the first fraction.

[C]. [When will patient dose be routinely checked]
During the patient's course of radiation treatment and after the last fraction, the dose calculations shall be checked once a week.

[D]. Who will perform [first and routine] checks
The dose calculations shall be checked by an authorized user, an oncology physician, a physicist, a dosimetrist, or a radiation therapy technologist, who whenever possible did not make the original calculations.

[E]. What will be [done for first and routine] check

1. Manual dose calculations should be checked for: (a) arithmetic errors; (b) appropriate transfer of data from the written directive, treatment plan, tables, and graphs; (c) appropriate use of all pertinent data in the calculations (e.g. block factor).

2. Computer-generated dose calculations should be checked by examining the computer printout to verify that the correct data for the patient were used in the calculations (e.g., patient contour, patient thickness at the central ray, depth of target, depth dose factors, treatment distance, portal arrangement, field sizes, or beam-modifying factors). Alternatively, the dose should be manually calculated to a single key point and the results compared to the computer-generated dose calculations.

[F]. Recording and reporting problems

[1. Identification and Evaluation
Any deviation from a written directive shall be classified according to definitions in this program (Section 1). The deviation will be evaluated during Radiation Oncology Service's weekly chart rounds. The discussion, recommendations and follow-up will be made part of the minutes of the monthly Radiation Oncology QA meeting. Corrective action must be taken after an unintended deviation is identified.]

[2]. Recordable events
(The definition is in Section I).
Within thirty days after discovery of a recordable event, the authorized user and/or qualified persons shall evaluate the event and: (a) assemble relevant facts including the cause; (b) identify what, if any, corrective action is required to prevent recurrence; and (c) retain a record, in auditable form, for three years, of the relevant facts and what corrective action, if any was taken.

[3]. Misadministrations
(The definition is in Section I).
(a) No later than the next calendar day after discovery of the misadministration, notify by telephone the NRC Operations Center (301-951-0550).

(b) No later than twenty-four hours after the discovery of the misadministration, notify the referring physician. Also notify the patient within that time unless the referring physician informs the patient, or unless, based on medical judgement, telling the patient would be harmful. Notifying the patient without first consulting the referring physician is not required. If the referring physician or patient cannot be reached within 24 hours, then notify the patient as soon as possible thereafter. Do not delay any approprite medical care for the patient, including any necessary remedial care as a result of the misadministration, because of any delay in notification.

(c) Within fifteen days after discovery of the misadministration, submit a written report to the appropriate NRC Reginal Office listed in 10CFR30.6. The written report must include the Medical Center's name; the prescribing physician;s name; a brief description of the event; why the event occurred; the effect on the patient; what improvements are needed to prevent recurrence; actions taken to prevent recurrence; whether we notified the patient, or the patient's responsible relative or guardian (this person will be subsequently referred to as "the patient" in this section), and if not, why not, and if the patient was notified, what information was provided to the patient. The report must not include the patient's name or other information that could lead to identification of the patient.

(d) If the patient was notified, also furnish, within 15 days after discovery of the misadministration, a written report to the patient by sending either:

(i) A copy of the report that was submitted to the NRC; or

(ii) A brief description of both the event and the consequences as they may affect the patient, provided a statement is included that the report submitted to the NRC can be obtained from our Medical Center.

(e) Retain a record of each misadministration for five years. The record must contain the names of all individuals involved (including the prescribing physician, allied health personnel , the patient, and the patient's referring physician), the patient's social security number or identification number if one has been assigned, a brief description of the misadministration, why it occurred, the effect on the patient, what improvements are needed to prevent recurrence, and the actions taken to prevent recurrence.

V. OUTPUT EVALUATION

A. Transmission Factors

If a transmission factor for a beam-modifying device (e.g. nonrecastable block, recastable block material, bolus, and split-beam blocking device) is NOT determined during Full Calibration, then that transmission factor should be determined before the first medical use of the beam-modifying device and after replacement of the source.

B. Field Sizes

If a field size is outside the range of field sizes used for output measurements in the most recent Full Calibration, then a measurement of output for that new field size shall be made prior to its medical use.

C. Output Deviations

1. Action level

Whenever Full Calibration or a spot-check measurement indicates that the output differs by more than FIVE PERCENT from the output obtained at the previous Full Calibration (same source) corrected for readioactive decay.

2. Action to be taken.

Have an independent check of the output for a single specified set of exposure conditions performed. The check should be performed within thirty days of the measurement that indicated the deviation.

3. How the check should be done.

(i) A dosimetry system should be used that was not used for either the reference Full Calibration or the devient measurement. A physicist other than the person who performed the reference Full Calibration should perform the independent check; or

(ii) A thermoluminescence dosimetry service available by mail that is designed for confirming teletherapy doses and that is accurate within five percent may be used. A physicist (or an oncology physician, dosimetrist, or radiation therapy technologist who has been instructed) should perform this independent check.

VI. EXEMPTIONS FOR CHECKS

A. Checks that may be postponed.

1. The dose calculation check for a prescribed dose that is administered in three fractions or less.
2. The independent teletherapy output check.

B. Justification for postponement.
If delaying treatment to perform checks would jeopardize the patient's health because of the emergent nature of the patient's medical condition.

C. Length of postponement.
The checks of calculations or output should be performed within two working days of the treatment that would have been delayed.

VII. REVIEWS OF QUALITY MANAGEMENT PROGRAM

A. Summary of dose calculation checks
1. To be done quarterly.
2. Data shall include the number of errors in total dose or fractional dose, each error expressed as a percentage of the prescribed dose, whether the number of errors have deviated from the trend, and why there is a change from the trend.
3. This review is also identified as Radiology Indicator #8 (attachment VII A).
4. The Chief of Radiology shall read and initial each quarterly review.

B. Review of Quality Management Program
1. To be done annually.
2. A summation shall include the number of recordable events, and misadministrations.
3. A probe into the effectiveness of the program shall include the review of five percent of the patients' charts or at least fifteen. The charts shall be selected at random from cases performed since the previous review. For each of the charts there will be a check of dose calculations and a comparison of the written directive to the reported administered fraction and total dose.
[4. If a misadministration or recordable event that wasn't noted during routine checks is uncovered during this review, then expand this review for that year to ten percent of patient's charts or at least thirty.]

C. Documentation
1. Reports of these reviews shall be prepared by a physicist, a radiation oncologist, a dosimetrist, or a radiation therapy technologist.
2. Records of these reviews shall be retained in an auditable form for three years.

VIII. EVALUATION OF REVIEWS

A. Frequency and Persons Responsible
The reports and reviews of section VII shall be submitted annually to the Chief of Radiology, and the Health Services Review Organization.

B. Evaluation Process
The Chief of Radiology and a representative of HSRO shall evaluate the reports and reviews. They shall determine the effectiveness of this Quality Management Program, and if required for objectives of the Program, make modifications.

C. Documentation
Records of evaluations and findings shall be retained in an auditable form for three years.

IX. MODIFICATIONS OF QUALITY MANAGEMENT PROGRAM

All modifications of the Quality Management Program shall be furnished to the NRC at the address below within thirty days after the modification has been made.

U.S. Nuclear Regulatory Commission
Region I
Nuclear Material Section B
475 Allendale Road
King of Prussia, Pennsylvania 19406

HEALTH CARE REVIEW PROGRAM
NORTHPORT VA MEDICAL CENTER
RADIOLOGY (114) QUALITY ASSURANCE MONITOR - PART B

INDICATOR #8

1. Results:

2. Do the results meet the expected standards? If not, what action is planned?

3. Do these results differ from your trend? If so, please comment.

4. What, if any, further action is required? (Attach additional material as required.)

REVIEWED BY:

SERVICE/SECTION CHIEF _____ DATE _____

HEALTH CARE REVIEW BOARD _____ DATE _____

CHIEF OF STAFF/CEB _____ DATE _____

NORTHPORT VA MEDICAL CENTER
QUALITY ASSURANCE MONITOR - PART A

ATTACHMENT VII A

SERVICE: RADIOLOGY (114)

QUARTER/YEAR 1988
INDICATOR #: 8

1. SCOPE AND ASPECT OF CARE (the major diagnostic and therapeutic modalities provided by your service; types of patients served and providers of care).

Review prescribed and delivered dose of Radiation.

2. INDICATOR (this identifies one important aspect of the care delivered by your service; it is a definable, measurable dimension of the appropriateness and the quality of patient care).

100% compliance with corrections on weekly review.

3. CRITERIA (service's statement of what they consider the appropriate aspects of the indicator that defines the quality of care).

Precise or correct fractionation of dose prescribed.

4. THRESHOLD FOR ACTION (either the literature recommendation for the appropriate standard of care should be cited, or the services goal for the appropriate standard of care should be included here).

Review deviations

5. DATA COLLECTION:

a) Sample size - All patients receiving radiation treatments.

b) Person responsible for data collection - Physicist

c) Person responsible for review of data - Chief. Radiology Service -

d) Frequency of collection: monthly or quarterly - weekly

e) Data source - Patients' dose distribution chart.

SERVICE CHIEFS/SECTION CHIEF

8/2/88
DATE

APPROVE/DISAPPROVE for Health Care Review Board

A D Chavez MD
for CHAIR, HEALTH CARE REVIEW BOARD

6/7/89
DATE