

AUG 29 1994

MEDICAL CTR. OF CENTRAL MASS. (THE)
- MEMORIAL
119 BELMONT STREET
WORCESTER, MA 010652982

ATTN: NORIO HIGANO, M.D.

RE: Docket Number: 030-00234
License Number: 20-02452-03

Dear Dr. Higano:

This letter acknowledges receipt of your letter dated July 16, 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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PDR ADOCK 03000234
C PDR

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**THE
MEDICAL
CENTER OF
CENTRAL
MASSACHUSETTS**

119 Belmont Street
Worcester, MA
01605-2982

(508) 793-6611
FAX (508) 793-6324

July 16, 1994



James D. Dwyer
Quality Management Program Coordinator
U. S. Nuclear Regulatory Commission
Region I
475 Allendale Road
King of Prussia, PA 19404

Dear Mr. Dwyer:

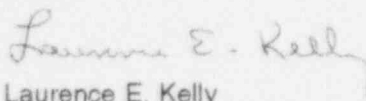
RE: LICENSE: 20-02452-03 TELETHERAPY

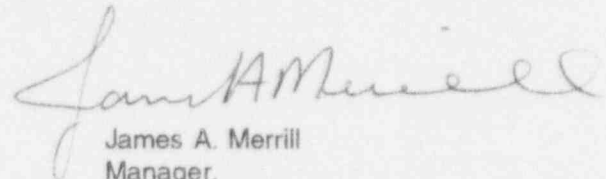
DOCKET #: 3000234

We are writing in response to your letter addressed to Dr. Norio Higano regarding your review of our Quality Management Program for Teletherapy. Attached is a revised QMP which, we believe, brings our program in compliance with NRC regulations.

Thank you for your help and attention and continued cooperation. If you have any questions or comments on this plan, please call Mr. Merrill or write to either of us.

Sincerely,


Laurence E. Kelly
Vice President,
Professional Services
[508] 793-5599


James A. Merrill
Manager,
Radiation Oncology
[508] 793-6550

Attachments

cc: Norio Higano, M.D.

/mjs

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AUG - 3 1994

QUALITY MANAGEMENT PROGRAM
FOR RADIATION ONCOLOGY

RE: LICENCE NUMBER: 20-02452-03

DOCKET NUMBER: 3000234

PROCEDURE FOR EACH TELETHERAPY PATIENT:

- A) 1. During initial visit the physician or nurse must identify the patient by name and by at least one of the following: date of birth, hospital number or social security number.
2. If the patient is to have radiation therapy, an instant photograph is taken of his/her face and treatment site. Note: Form #1
- B) 1. The finalized treatment directives must contain the prescription, plan of treatment, the treatment duration, as well as drawings and other special instructions. The dose prescription shall be written in the following format:

FX DOSE / # TREATMENTS / # WEEKS / TOTAL DOSE

A completed written directive will contain on the treatment chart: Patient name, patient age, sex, site, histology, field description number, dose prescription (as described above), date of directive signature of radiotherapist and dose fraction size.
Note: Form #24

2. An oral directive will be accepted provided that the information provided in the oral directive is documented immediately in the patients written record and a written directive is prepared within 24 hours of the oral directive.
3. Any revision to a written directive will be made prior to administration of the teletherapy dose or the next teletherapy fractional dose.
4. For teletherapy:
- a) Prior to each treatment, the radiotherapy technologist must identify each patient by name and photograph.
- b) Prior to initiation of radiation, the set-up parameters are verified to be in accordance to the treatment directives. note form #5
- C) All written directives will be verified for dose delivery accuracy with the following:
1. The dosimetrist will do the initial dose calculation which will include all beam modifying equipment.

cont Pg 2

2. All dosimetry calculations will have a secondary check for compliance to written directives and documented on form #2 by the physicist before the first treatment.
 3. A third check will also be conducted by the therapist. Week one on form #5 will be completed before the first treatment.
 4. Any new equipment that has any effect on patient treatment parameters will be initially acceptance tested after installation, for operational function.
 5. Determination of transmission factors for beam modifying devices will be done before first medical use and after replacement of teletherapy source.
 6. An independent check of full calibration measurements that resulted from source replacement, or when a spot check indicates that the output differs by more than 5%.
 7. Actual physical measurement of the teletherapy output for parameters not addressed in full calibration will be done prior to use on specific patients.
 8. Before the first treatment, physics will check the calculation for correctness and document on form #2. The physicist will also do weekly chart checks to check for correct daily entries. A therapist will do a third chart check before the first treatment to also verify physics numbers. The therapist will also do weekly chart checks to verify daily entries. This will be completed and recorded on form #5 by an employee that didn't do the initial calculation.
- D) Before the first treatment the therapist will fill out form #5 (week #1) and verify all items listed and that all specific details of the administration are in accordance with the written directive.
- E) If the therapist or dosimetrist need clarification on or guidance in understanding the written directive the therapist or dosimetrist will seek the physician who wrote the prescription. If not available the employees may seek advice from another radiation oncologist in the department.

cont Pg 3

F) All chart information will be maintained for a minimum of 3 years and will include the following:

1. A hand written record will be completed after each treatment, by the therapist, to include the following: accumulated total dose, dates treated, total days, treatment number, time or monitor units treated for that field, therapist initials and port film logs for that day. See form # 24A.
2. The dosimetrist will complete all other physical chart set up parameters and make all necessary chart diagrams to transfer treatment information to therapist before first treatment, or within 24 hours of first treatment in emergency cases. All parameters will be checked under section C 1,2,3, of this document.
3. A record and verified computerized treatment chart will be made on the completion of the patient treatment. This information will be a cross check for the physicist to insure written directive is achieved. This chart will include the following information: Patient name, date of treatments, field number, field name, energy, field sym of field, field size x & y, gantry position, collimator position, mu's treated, total dose given and total accumulated dose. See form # 24B.

G) All misadministration or recordable events will be evaluated and a written notification sent to NRC within 30 days after the discovery. All notification will include the following:

1. Assembling the relevant facts including the cause.
2. Identifying what, if any, corrective action is required to prevent recurrence.
3. Retaining a record in auditable form, for three years, of the relevant facts and what corrective action was taken.

H) In an annual review, a representative sample of the patient charts will be reviewed for misadministration or recordable events. This review will be done for both brachytherapy patients and teletherapy patients. This annual review will consist of a minimum of 3 people. One physicist, one radiation oncologist and one department manager. The sample size will be as follows:

Cont Pg 4

1. 20% of the total number of cases treated. If the cases are greater than 100 cases, 20 charts need to be examined.
 2. If the cases are between 20 and 100, 20 charts need to be examined.
 3. If the number of cases are under 20, all charts need to be reviewed.
 4. If a misadministration is found in any of the charts an escalation to 100 charts will be reviewed. If total number is under 100, all charts will be reviewed.
- I) Any modifications to this quality management plan will be submitted to the NRC within 30 days after the modification has been made
- J) All QMP inspection review records will be maintained for three years.

THE MED CENTER MEMORIAL
RADIATION ONCOLOGY NEW PATIENT START FORM

NOTE: ALL NEW PATIENT INFORMATION WILL BE KEPT IN RED
UNTIL FIRST TREATMENT. UNDER NO CIRCUMSTANCE
WILL ANY PART OF THIS TREATMENT RECORD BE SEPARATED
FROM THIS RED JACKET BEFORE FIRST TREATMENT.

TREATMENT SCHEDULE INFORMATION

PATIENT NAME: _____
DATE FIRST TREATMENT: _____
TIME FIRST TREATMENT: _____
DAY OF THE WEEK: _____

TECHNOLOGIST CHECK LIST

PATIENT ENTERED IN COMPUTER: _____ Y/N
PATIENT ENTERED IN RMS: _____ Y/N
FIELD INFORMATION IN RMS: _____ Y/N
NAME STICKERS MADE: _____ Y/N
PATIENT TATTOOED: _____ Y/N

PHYSICS CHECK LIST

PRIMARY PHYSICS CALCULATION _____ INITIAL
SECONDARY PHYSICS CALCULATION _____ INITIAL
BLOCKS CUT _____ INITIAL
OF BLOCKS _____ #
LOCATION OF BLOCKS _____ SHELVING/DRAW

SUPERVISOR FIRST DAY TREATMENT SET UP CHECK

SIGNATURE OF SUPERVISOR _____

MCCM MEMORIAL
RADIATION ONCOLOGY

TECHNOLOGIST CHART CHECK

PATIENT NAME _____

AREA TREATED _____

WEEK	1	2	3	4	5	6
PHOTO CONSENT						
ID PHOTO						
SITE PHOTO						
SCRIPT						
FIELD DIAGRAM						
ON CORD ? Y/N						
DOSE TO DATE						
TOTAL DOSE						
# OF FRACTIONS						
MU Vs. CALC						
F.S. Vs. PHYSICS						
SSD Vs PHYSICS						
DOSE Vs PHYSICS						
PORT FILM OKED						
BILLING TO DATE						
BOOK R.F YET						
OTHER						
OTHER						



866-0202 S-4/25

Patient:

ID: 866-0202 S-4/25

Form 24-B

Date	Elap	frac	Fld	Field	Station	E/M	MU	Site	Dose	Com	Tot	Y/Y1	Y2	X/X1	X2	Col	Gant	Stop	Access	Bill	Ed	RT	PF
25-04-94	0	1	1	AP PEL	2100C	18X	49.0	pros	48	48	48	9.0		9.0		270.0	0.0						RS
	0	1	2	PA PEL	2100C	18X	52.0	pros	54	54	102	9.0		9.0		270.0	180.2E						BB
	0	1	4	LT LAT	2100C	18X	57.0	PROS	39	39	141	9.0		9.0		270.0	90.1		IW15Y2				BB
	0	1	3	RT LAT	2100C	18X	57.0	PROS	39	39	180	9.0		9.0		269.9	270.2		IW15Y1				LV
26-04-94	1	2	1	AP PEL	2100C	18X	49.0	pros	48	96	228	9.0		9.0		270.0	359.9						MM
	1	2	2	PA PEL	2100C	18X	52.0	pros	54	108	287	9.0		9.0		270.0	179.8E		IW15Y1				MM
	1	2	3	RT LAT	2100C	18X	57.0	PROS	39	78	321	9.0		9.0		269.9	269.9		IW15Y2				MM
	1	2	4	LT LAT	2100C	18X	57.0	PROS	39	78	360	9.0		9.0		270.0	90.1						LV
27-04-94	2	3	1	AP PEL	2100C	18X	49.0	pros	48	144	408	9.0		9.1		270.0	359.9						RS
	2	3	2	PA PEL	2100C	18X	52.0	pros	54	162	462	9.0		9.1		270.0	179.9E						RS
	2	3	3	RT LAT	2100C	18X	57.0	PROS	39	117	501	9.0		9.1		269.9	270.1		IW15Y1				RS
	2	3	4	LT LAT	2100C	18X	57.0	PROS	39	117	540	9.0		9.1		270.0	90.1		IW15Y2				RS
28-04-94	3	4	1	AP PEL	2100C	18X	49.0	pros	48	192	588	9.0		9.0		270.0	9.0						MM
	3	4	2	PA PEL	2100C	18X	52.0	pros	54	216	642	9.0		9.0		269.9	180.0E		IW15Y1				LV
	3	4	3	RT LAT	2100C	18X	57.0	PROS	39	156	681	9.0		9.0		269.9	84.9		IW15Y2				MM
	3	4	4	LT LAT	2100C	18X	57.0	PROS	39	156	720	9.0		9.0		270.0	0.0						GLS
29-04-94	4	5	1	AP PEL	2100C	18X	49.0	pros	48	240	768	9.0		9.0		270.0	0.0						RS
	4	5	2	PA PEL	2100C	18X	52.0	pros	54	270	822	9.1		9.0		270.0	180.0E						RS
	4	5	3	RT LAT	2100C	18X	57.0	PROS	39	195	861	9.1		9.0		270.0	270.0		IW15Y1				RS
	4	5	4	LT LAT	2100C	18X	57.0	PROS	39	195	900	9.0		9.0		270.1	90.0		IW15Y2				RS
2-05-94	7	6	1	AP PEL	2100C	18X	49.0	pros	48	288	848	9.0		9.0		270.0	0.0						LV
	7	6	2	PA PEL	2100C	18X	52.0	pros	54	324	1002	9.1		9.0		270.0	179.8E		IW15Y1				LV
	7	6	3	RT LAT	2100C	18X	57.0	PROS	39	234	1041	9.1		9.0		270.0	270.3		IW15Y2				LV
	7	6	4	LT LAT	2100C	18X	57.0	PROS	39	234	1080	9.0		9.0		270.0	90.0						LV
3-05-94	8	7	1	AP PEL	2100C	18X	49.0	pros	48	336	1128	9.0		9.0		270.0	0.0						RS
	8	7	2	PA PEL	2100C	18X	52.0	pros	54	378	1182	9.0		9.0		269.9	180.1		IW15Y1				RS
	8	7	3	RT LAT	2100C	18X	57.0	PROS	39	273	1221	9.0		9.0		269.9	270.0		IW15Y2				BB
	8	7	4	LT LAT	2100C	18X	57.0	PROS	39	273	1260	9.0		9.0		270.0	90.1		IW15Y2				BB
4-05-94	9	8	1	AP PEL	2100C	18X	49.0	pros	48	384	1308	9.0		9.0		270.0	0.0						RS
	9	8	2	PA PEL	2100C	18X	52.0	pros	54	432	1362	9.1		9.0		270.0	180.1						RS
	9	8	3	RT LAT	2100C	18X	57.0	PROS	39	312	1401	9.1		9.0		270.0	270.2		IW15Y1				RS
	9	8	4	LT LAT	2100C	18X	57.0	PROS	39	312	1440	9.0		9.0		270.0	89.7		IW15Y2				RS
5-05-94	10	9	1	AP PEL	2100C	18X	49.0	pros	48	432	1488	9.0		9.1		270.0	0.0						GLS
	10	9	2	PA PEL	2100C	18X	52.0	pros	54	486	1542	9.0		9.1		269.8	180.1						GLS
	10	9	3	RT LAT	2100C	18X	57.0	PROS	39	351	1581	9.1		9.1		269.8	270.0		IW15Y1				GLS
	10	9	4	LT LAT	2100C	18X	57.0	PROS	39	351	1620	9.0		9.1		270.0	90.0		IW15Y2				GLS
6-05-94	11	10	1	AP PEL	2100C	18X	49.0	pros	48	480	1668	9.0		9.0		270.1	0.0						BB
	11	10	2	PA PEL	2100C	18X	52.0	pros	54	540	1722	9.1		9.0		270.0	180.1						FB

JUN 17 1994

MEDICAL CTR. OF CENTRAL MASS. (THE)
- MEMORIAL
119 BELMONT STREET
WORCESTER, MA 010652982

ATTN: NORIO HIGANO, M.D.

RE: Docket Number: 3000234
License Number: 20-02452-03
Plan File Date: 20-JAN-92
Region Number: 1

Dear Dr. Higano:

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 total dose
- the dose per fraction
- the treatment site
- an order for a specific patient
- 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 should include a policy for instruction of all workers to seek guidance if they do not understand how to carry out the written directive. Please include such a provision in your QMP.

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 CFR 35.32(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 review procedure does not provide an evaluation of: (a) an adequate representative sample of patient administrations, (b) all recordable events, and (c) all misadministrations since the last review as required in 10 CFR 35.32(b)(1). The number of patient cases to be sampled should be based on the principles of statistical acceptance sampling and should represent each modality performed in the institution (e.g., radiopharmaceutical, teletherapy, brachytherapy, and gamma stereotactic radiosurgery). You may develop a sampling procedure of your own; use the chart

provided in 10 CFR 32.110 (assuming an error rate of 2 percent); or a representative sample may be selected including (at a minimum): 20% 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.) Provide a copy of your revised QMP to include this provision.

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.

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

**THE
MEDICAL
CENTER OF
CENTRAL
MASSACHUSETTS**

119 Belmont Street
Worcester, MA
01605-2982

(508) 793-6511
FAX (508) 793-6324

January 20, 1992



U.S. Nuclear Regulatory Commission
Region 1
475 Allendale Road
King of Prussia, PA 19406-1415

030-00234

SUBJECT: Quality Management Program

License No. 20-02452-03 (Teletherapy)

License No. 20-02452-01 (Brachytherapy)

We have initiated our Quality Management Program as required in 10CFR35.32.

Enclosed is the copy.

Won Tak
Won K. Tak, M.D.
Director
Radiation Oncology Department

cc: Mr. Laurence Kelly

ML 10
JAN 24 1992

Quality Management Program
for
Radiation Oncology

Procedure for each teletherapy and brachytherapy patient:-

- A) 1. During initial visit the physician or nurse must identify the patient by name and by at least one of the following: date of birth, hospital number or social security number.
2. If the patient will have radiation therapy, an instant photograph is taken.
- B) 1. The finalized treatment directive must contain the prescription, plan of treatment, the treatment duration, as well as drawings and other special instructions.
2. For teletherapy:-
- a) Prior to each treatment, the radiotherapy technologist must identify each teletherapy patient by name and by photograph.
 - b) Prior to initiation of the radiation, the set-up parameters are verified to be in accordance to the treatment directive.
3. For brachytherapy:-
- a) The physician establishes the identity of the patient by name and by photograph.
 - b) The correctness of the source preparation is verified before delivery to the patient room. In case of more than one patient the preparation must be identified by name and room number.
 - c) The final treatment directive must include the treatment duration, the IN time/date and the projected OUT time/date.
4. a) All deviations from the therapy directive are to be noted in the chart and brought to the attention of the physician.
- b) Physics will conduct regular reviews of active charts, as well as at the end of the course of treatment.
6. Review of this quality management program will be part of the quarterly departmental quality assurance report. Modifications will be made to increase its efficacy.

January 1, 1992