



UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION II
101 MARIETTA STREET, N.W., SUITE 2900
ATLANTA, GEORGIA 30323-0199

SEP 13 1994

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I. GONZALEZ MARTINEZ ONCOLOGIC HOSP
ATTN: JOSE C. PACHECO, M.S.
P.O. BOX 1811
HATO REY, PR 00919

RE: Docket Number: 030-14696
License Number: 52-13471-02
Plan File Date: 19-FEB-93
Region Number: 2

Dear Jose C. Pacheco, M.S.:

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

1. Your QMP is missing procedures to require that the written directive include:
 - the total dose
 - the overall treatment period
2. 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.
3. 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.
4. 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

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- 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.
5. 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
 - 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
 6. 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.
 7. 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.
 8. Your QMP must include policies/procedures to institute corrective actions to be taken after an unintended deviation has been identified.
 9. 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.
 10. Your submittal for teletherapy does not provide adequate procedures to conduct periodic reviews of your QMP as required by 10 CFR 35.32(b). You must include the time intervals for your reviews. These reviews

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should be conducted at intervals no greater than 12 months.

11. 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.
12. 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.
13. 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).
14. 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 10 CFR 35.32(e).
15. 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.

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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).

Thank you for your cooperation in this matter. If you have any questions, please call Mr. John M. Pelchat at 404/331-5083.

Sincerely,

ORIGINAL SIGNED BY
JOHN P. POTTER.

for Douglas M. Collins, Chief
Nuclear Materials Safety and
Safeguards Branch
Division of Radiation Safety
and Safeguards

Enclosure:
Reg. Guide 8.33, "Quality
Management Program"

bcc: Document Control Desk

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