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

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AUG 29 1994

Enery Navarrete, M.D.
Attn: Enery Navarrete, M.D.
No. 69 Ulises Martinez Street
Humacao, PR 00661

RE: License Number: 52-19738-02
Docket Number: 030-29950
Plan File Date: Feb. 22, 1993
NRC Region: II

Dear Dr. Enery Navarrete:

This refers to the review of your written Quality Management Program (QMP) for the Strontium-90 Eye Applicator 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 your submission, it appears your QMP for the Strontium-90 Eye Applicator may not fully meet all objectives in 10 CFR 35.32. You should review the following comments to determine if your program requires additional modification.

1. The Quality Management Rule, 10 CFR 35.32, requires that a Quality Management Program (QMP) be submitted for applicable modalities. Please provide a QMP that contains the policies and procedures for your Strontium-90 Eye Applicator program. Please provide certification that your program has been implemented. In your QMP, also include your method and frequency for training/instruction of supervised individuals for implementation of your program as required in 10 CFR 35.25.

2. Strontium-90 Eye Applicators are listed under 10 CFR 35.400 as brachytherapy. 10 CFR 35.32(a)(1) requires that QMPs for brachytherapy include a procedure for the preparation of written directives prior to administration of any brachytherapy dose. The written directive must be an order for a specific patient, dated and signed by an authorized user or physician under the supervision of an authorized user. Your QMP must include a written policy that requires that such a written directive be prepared for each patient. Written directives for Strontium-90 Eye Applicators must include: the radioisotope, the treatment site and either the total dose, or source strength and treatment time.

3. Revisions to written directives for Strontium-90 Eye Applicators may be made provided that the revision is dated and signed by an authorized user prior to the administration of the dose. Your QMP should include a policy/procedure that requires that revisions to written directives will be made prior to administration of the dose with the Strontium-90 Eye Applicator.

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4. 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 cndition, 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.

5. If, because of the emergent nature of the patient's condition, a delay in order to provide a written directive would jeopardize the patients 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.

6. Procedures to verify the patient's identity by more than one method prior to administration, as required by 10 CFR 35.32(a)(2), have not been adequately addressed in your QMP. Your QMP must include a policy/procedure to require that, prior to each Strontium-90 Eye Applicator administration, the patient's identity will be verified by more than one method as the individual named in the written directive.

7. Your submittal does not include adequate policies/procedures that ensure that final plans of treatment and related calculations for Strontium-90 Eye Applicator treatments are in accordance with the written directive as required by 10 CFR 35.32(a)(3). Your procedures should include:

   a. a plan of treatment prepared in accordance with the respective written directive

   b. procedures for performing a check of dose calculations

   c. a procedure for assessing the quantity of material left after decay

   d. a procedure that describes the method used to time the administration

8. Your submittal for Strontium-90 Eye Applicator brachytherapy does not include adequate policies/procedures to ensure that each administration is in accordance with the written directive. Your procedures should include:

   a. verification, before administering the dose, that the specific details of the administration are in accordance with the written directive and plan of treatment. The prescribed treatment site, and either the total dose, or source strength and treatment time should be confirmed by the person administering the treatment to verify agreement with the written directive and treatment plan.

b. prompt recording, by the authorized user, of the source strength and exposure time, or the total dose, and sign or initial the patient's chart or appropriate record.

9. Your QMP for Strontium-90 Eye Applicator brachytherapy must include policies/procedures to identify and evaluate any unintended deviations from a written directive and to institute corrective actions to be taken after the deviation has been identified as required by 10 CFR 35.32 (a)(5).

10. Please include policies/procedures to institute corrective actions to be taken after an unintended deviation has been identified.

11. Your submittal does not provide adequate procedures to conduct periodic reviews of your QMP as required by 10 CFR 35.32(b). Your procedure should include the time intervals for your reviews (in months) and describe your representative sample. These reviews should be conducted at intervals no greater than 12 months. Program reviews must include an evaluation of a representative sample of all patient administrations, and should include all recordable events and misadministrations. Your QMP review should include provisions to expand the review in the event that unidentified reportable events or misadministrations are found. Your QMP should describe your procedure for evaluating each of these reviews, and for making modifications to meet the objective of the QMP. Regulatory Guide 8.33, Section 6 (enclosed) may be of help in developing procedures for review of your QMP.

12. Your QMP review does not provide for an adequate representative sample of patient administrations as required in 10 CFR 35.32(b)(1)(i). 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; 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.

13. In your QMP, please 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.

14. Your QMP must include 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).

15. Please include a provision to submit modifications to your QMP to the NRC within 30 days after the modification has been made.

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16. Your QMP should include assurance that records of each review and evaluation must be maintained for three years.

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.

NRC will review these matters during your next routine NRC inspection to determine whether violations of NRC requirements occurred. Enforcement action may be taken at that time. Therefore, you should take prompt corrective action to address any deficiency to ensure your QMP and how it is implemented meet the objectives in 10 CFR 35.32.

Please be advised that this QMP for Strontium-90 Eye Applicators 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
D. M. Collins

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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