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

OFFICIAL RECORD COPY

OCT 03 1994

V. A. MEDICAL CENTER
ATTN: CLAYTON MATTHEWS
MOUNTAIN HOME, TN 37684

RE: Docket Number: 030-19242
License Number: 41-19792-01
Plan File Date: 21-JAN-92
Region Number: 2

Dear Mr. Matthews:

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 Brachytherapy

1. A written QMP must be established and maintained for each Brachytherapy use as required in 10 CFR 35.32(f)(1). Please submit your QMP for your Brachytherapy program.

2. Please be advised that multiple misadministrations and other errors have occurred due to sources that are inaccurately placed or have moved. In addition, wrong organs have been irradiated as a result of unintentional and undetected movement of the source, once implanted. Each licensee should review their procedures to ensure that source positions are verified and frequently checked.

Regarding I-125 and /or I-131 > 30 microcuries

1. 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, and, for any administration of quantities greater than 30 microcuries of either I-125 or I-131, the dosage. Your QMP is missing procedures to require that the written directive for I-125 and/or I-131 > 30 microcuries:

   - be an order for a specific patient

   - contains the dosage to be administered

2. A commitment to retain each written directive and a record of each administered radiopharmaceutical dosage for three years after the date of administration is required in 10 CFR 35.32(d). Describe the procedure for an authorized user or a qualified individual under the supervision of an authorized user (e.g., a nuclear medicine physician,

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physicist or technologist), after administering a radiopharmaceutical, to make, date, sign or initial a written record that documents the administered dosage in an auditable form.

3. Your QMP for NaI I-125 or I-131 >30 microcuries 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.

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

5. 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.

6. 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).

Regarding Therapeutic Radiopharmaceutical other than I-125 and/or I-131

1. 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, and, for a therapeutic use of a radiopharmaceutical other than I-125 or I-131, the radio pharmaceutical, dosage, and route of administration. Your QMP is missing procedures to require that the written directive include:

   - the radiopharmaceutical
   - the dosage
   - the route of administration
   - an order for a specific patient

2. A commitment to retain each written directive and a record of each administered radiopharmaceutical dosage for three years after the date of administration is required in 10 CFR 35.32(d). Describe the procedure for an authorized user or a qualified individual under the supervision of an authorized user (e.g., a nuclear medicine physician, physicist or technologist), after administering a radiopharmaceutical, to make, date, sign or initial a written record that documents the administered dosage in an auditable form.

3. Your QMP for Therapeutic Radiopharmaceutical other than I-125 or I-131 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.

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

5. 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.

6. 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).

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).

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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