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

AUG 29 1994

SAN JUAN CITY HOSPITAL
NUCLEAR MEDICINE UNIT
HOSPITAL MUNICIPAL
P.O. BOX BR
RIO PIEDRAS, PR 00928

ATTN: M.M. PALACIOS DELOZANO

RE: Docket Number: 030-03517
License Number: 52-06121-02
Plan File Date: 01-MAR-93
Region Number: 2

Dear M.M. PALACIOS DELOZANO:

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

1. A written QMP must be established and maintained for each I-125 and /or I-131 > 30 microcuries use as required in 10 CFR 35.32(f)(1). Please provide your QMP for your NaI I-125 or I-131 >30 microcuries.

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

1. A written QMP must be established and maintained for use of Radio pharmaceuticals for therapy other than I-125 and I-131 as required in 10 CFR 35.32(f)(1). Please submit your QMP for your Radiopharmaceutical therapy.

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.

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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

SEND TO	OFC	RII:DRSS	RII:DRSS	RII:DRSS
	NAME	JPelchat	JPPotter	DMCollins
PDR?	DATE	08/29/94	08/29/94	08/29/94
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