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Oakland General Hospital
ATTN: Mr. Robert Deputat
Vice President Operations
27351 Dequindre Avenue
Madison Heights, MI 48071

License No. 21-11494-01
Docket No. 030-02101

Dear Mr. Deputat:

This refers to your Quality Management Program (QMP) dated December 27, 1993, that describes policies and procedures for radiopharmaceutical therapy and brachytherapy. A review of the QMP was performed to determine whether it meets NRC requirements. Based on your submission, it appears your QMP is adequate for conduct of brachytherapy. However, certain other aspects of your QMP, if implemented as written, may not fully meet all objectives in 10 CFR 35.32. Please review the following comments, revise you program as required, and submit those revisions to this office prior to initiating radiopharmaceutical therapy or use of radioiodine over 30 microcuries.

- The description in your program of a written directive for radiopharmaceutical therapy for radiopharmaceuticals other than sodium iodide I-125 or I-131 does not appear to include the radiopharmaceutical name and the route of administration as defined in 10 CFR 35.2.

- The description in your Radiopharmaceutical Uses program of policies and procedures to verify the patient's identity by more than one method prior to administration does not appear to be complete. 10 CFR 35.32(a)(2) requires that your program include a policy and procedure for verifying the patient's identity by more than one method prior to each radiopharmaceutical administration.

- The description in your Radiopharmaceutical Uses program of policies and procedures to ensure that each administration is in accordance with the written directive does not appear to be sufficient to meet the requirements in 10 CFR 35.32(a)(4). The person administering the radiopharmaceutical should compare the radiopharmaceutical, dosage, and route of administration with the written directive prior to the administration.

- The description in your program of your policy and procedure to expand the number of cases reviewed when a misadministration or recordable event is uncovered during the periodic review of your QMP does not appear to be adequate.

- The description in your program of your policies and procedures does not appear to include the retention of records for three years as required in 10 CFR 35.32(d).

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To meet the requirements in 10 CFR 35.32, you may choose to utilize the procedures described in Regulatory Guide 8.33 (enclosed), or develop 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.

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 are required to submit those modifications to this Office within 30 days pursuant to 10 CFR 35 32(e). The NRC will review implementation of your QMP at the next regular inspection of your facility.

Thank you for your cooperation in this matter. If you have any questions, please call Evelyn Matson at (708) 829-9822 or Jack Grobe at (708) 829-9837.

Sincerely,

Original Signed by Roy J. Caniano

Roy J. Caniano, Chief
Nuclear Materials Safety Branch

bcc:
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