

March 31, 1997

CAL No. 1-97-013

Mr. Dexter D. Dix, Center Director
Veterans Administration Medical Center
1601 Kirkwood Highway
Wilmington, DE 19805

SUBJECT: CONFIRMATORY ACTION LETTER

Dear Mr. Dix:

During an inspection conducted on March 26, 1997, by Richard McKinley and Michelle Beardsley of the NRC Region I office, the inspectors identified one occasion where the authorized user failed to prepare a written directive prior to the administration of an iodine-131 dosage greater than 30 microcuries. This is an apparent violation of 10 CFR 35.32(a)(1) and your written Quality Management Program.

Pursuant to a telephone conversation between you and Mohamed Shanbaky, Ph.D. of this office on March 27, 1997, it is our understanding that you will take the following actions which will be completed in accordance with the schedule specified.

1. Provide training in your Quality Management Program procedures to all Nuclear Medicine staff including authorized users, physicists, and technologists. Training will be completed prior to your next administration of iodine-131 in a dosage which requires a written directive.
2. Institute procedures to ensure that a second individual verifies the details of the written directive prior to the administration of iodine-131 to a patient. This action will be completed prior to the next administration of iodine-131 in a dosage which requires a written directive.
3. Conduct quarterly audits to verify full adherence to your written Quality Management Program. The initial audit will be conducted prior to April 15, 1997. Subsequent quarterly audits will be conducted for a period of one year. The records of these audits will be maintained for inspection by NRC.

Pursuant to Section 182 of the Atomic Energy Act, 42 U.S.C. 2232, you are required to:

- 1) Notify me immediately if your understanding differs from that set forth above;
- 2) Notify me if for any reason you cannot complete the actions within the specified schedule and advise me in writing of your modified schedule in advance of the change; and

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Mr. Dexter D. Dix
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- 3) Notify me in writing when you have completed the actions addressed in this Confirmatory Action Letter.

Issuance of this Confirmatory Action Letter does not preclude issuance of an order formalizing the above commitments or requiring other actions on the part of the licensee; nor does it preclude the NRC from taking enforcement action for violations of NRC requirements that may have prompted the issuance of this letter. In addition, failure to take the actions addressed in this Confirmatory Action Letter may result in enforcement action.

In accordance with 10 CFR 2.790 of the NRC's "Rules of Practice," a copy of this letter and your response will be placed in the NRC Public Document Room (PDR). To the extent possible, your response should not include any personal privacy, proprietary, or safeguards information so that it can be placed in the PDR without redaction. If personal privacy or proprietary information is necessary to provide an acceptable response, then please provide a bracketed copy of your response that identifies the information that should be protected and a redacted copy of your response that deletes such information. If you request withholding of such material, you must specifically identify the portions of your response that you seek to have withheld and provide in detail the bases for your claim of withholding (e.g., explain why the disclosure of information will create an unwarranted invasion of personal privacy or provide the information required by 10 CFR 2.790(b) to support a request for withholding confidential commercial or financial information). If safeguards information is necessary to provide an acceptable response, please provide the level of protection described in 10 CFR 73.21.

Sincerely,

Original Signed By:
Francis M. Costello

A. Randolph Blough, Director
Division of Nuclear Materials Safety

Docket No. 030-01301
License No. 07-09495-01

cc:
Francis K. Herbig
Department of Veterans Affairs
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Mr. Dexter D. Dix
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