

APR 13 1994

Docket No. 030-01244
License No. 06-00819-03
EAs 92-241 and 93-016

Mr. Norman G. Roth, Vice President
Yale-New Haven Hospital
20 York Street
New Haven, Connecticut 06504

Dear Mr. Roth:

This is in reference to your letter dated March 29, 1994, submitted in response to our letter dated February 28, 1994.

In Item 1 of our letter we noted that the Site Visit Assessment Report, which was submitted to us with your letter dated August 24, 1993, did not specifically address several areas required by the April 26, 1993 Order. The areas not addressed were: (1) the assessment of your program for training and retraining of individuals working with NRC licensed materials; (2) the assessment of your method for approving individuals for the use of licensed materials and developing procedures for the safe use of licensed materials; (3) the assessment of your program for training and qualifying all individuals involved in managing, supervising, inspecting and auditing licensed activities; and (4) the assessment of your program of surveillance and audits to determine compliance by individual users of licensed materials with NRC regulations, the conditions of the NRC licenses, your Quality Management program, and your procedures for the safe use of radioactive materials.

In your response, you stated that all four of these items were reviewed by the Site Visit Team and that, in their assessment, no changes were warranted on these issues. Furthermore, you enclosed a letter dated March 16, 1994, from Dr. Ravinder Nath of your staff to the Site Visit Team Chairman, which requested confirmation of this statement. Please submit a copy of the response from the Site Visit Team Chairman to this office when the response is received.

In Item 2 of our letter, we requested additional information on the implementation of four of the recommendations made by the Site Visit Team. Recommendation #1 of the Assessment Report recommended that Yale-New Haven Hospital:

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"Maintain the Radiation Safety Office under the Radiation Safety Officer, reporting to the Chief of Radiological Physics for technical direction and performance auditing. In addition, the RSO must be given the clear responsibility and authority to report directly to any of the highest levels of Administration whenever he deems it necessary to ensure against serious misadministrations or violation of regulations that might jeopardize the Y-NHH reputation and the licenses needed to operate."

In your Improvement Plan you stated that this structure was already in place and that no further action was needed. Furthermore, in your March 29, 1994 letter, you stated that the structure was in place prior to the Site Visit. It appears from the Team's recommendation that they were satisfied with the Radiation Safety Officer reporting to the Chief of Radiological Physics for technical direction and performance auditing; however, the Team seemed to be making the recommendation that the Radiation Safety Officer needed to be given the "clear responsibility and authority to report directly to any of the highest levels of Administration whenever he deems it necessary". Please confirm that your Radiation Safety Officer presently has the clear responsibility and authority to report directly to the highest level of Administration if deemed necessary. Please provide an organization chart which describes this authority.

We have reviewed your implementation of recommendations #3, #7 and #8 and have no further questions at this time.

We will consider closure of the Order following receipt of the requested information. Until the Order is closed, you must continue to provide the written quarterly status reports required by Section V.D of the Order. The present reporting schedule is acceptable.

In accordance with 10 CFR 2.790 of the NRC's "Rules of Practice", a copy of this letter will be placed in the NRC's Public Document Room.

Thank you for your cooperation.

Sincerely,
Original Signed By
Susan Frant Shankman

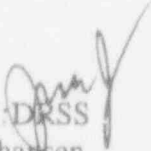



Charles W. Hehl, Director
Division of Radiation Safety
and Safeguards

cc:
Public Document Room (PDR)
Nuclear Safety Information Center (NSIC)
State of Connecticut

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Dwyer
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UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION I
475 ALLENDALE ROAD
KING OF PRUSSIA, PENNSYLVANIA 19406-1415

February 28, 1994

Docket No. 030-01244
License No. 06-00819-03
EAs 92-241 and 93-016

Mr. Norman G. Roth, Vice President
Yale-New Haven Hospital
20 York Street
New Haven, Connecticut 06504

Dear Mr. Roth:

This is in reference to your letter dated August 24, 1993, which enclosed the Site Visit Assessment Report and the Yale-New Haven Hospital Improvement Plan, submitted in response to our Confirmatory Order Modifying License (Effective Immediately) (Order) issued on April 26, 1993. This letter is also in reference to your letter dated November 16, 1993, which enclosed your Quarterly and Final Report on the implementation of the Improvement Plan.

We have reviewed the Assessment Report, Improvement Plan, and the Quarterly and Final Report. Prior to closing the Order we require additional information in the following areas:

1. The Assessment Report does not specifically address the following Items required by the Order:
 - Item V.B.2 requires an assessment of the Licensee's program for training and retraining individuals working with NRC licensed materials, in NRC regulations, in the conditions of the license, in the Licensee's QM program, and in safe practices for using licensed material;
 - Item V.B.3 requires an assessment of the Licensee's methods of approving individuals for the use of licensed materials and developing procedures for the safe use of licensed materials;

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- Item V.B.4 requires an assessment of the Licensee's program for training and qualifying all individuals involved in managing, supervising, inspecting and auditing licensed activities; and
- Item V.B.5 requires an assessment of the Licensee's program of surveillance and audits to determine compliance by individual users of licensed materials with NRC regulations, the conditions of the NRC licenses, the Licensee's QM program, and the Licensee's own procedures for the safe use of radioactive materials.

If your Independent Assessment Team reviewed these areas as prescribed by the Order, please submit an addendum to the Assessment Report which describes the Team's findings. If your Independent Assessment Team did not review these areas, you have not fully complied with the terms of the Order and you must provide us with justification for these actions.

2. Regarding the recommendations made in the Assessment Report:

- Recommendation #1

"Maintain the Radiation Safety Office under the Radiation Safety Officer, reporting to the Chief of Radiological Physics for technical direction and performance auditing. In addition, the RSO must be given the clear responsibility and authority to report directly to any of the highest levels of Administration whenever he deems it necessary to ensure against serious misadministrations or violation of regulations that might jeopardize the Y-NHH reputation and the licenses needed to operate."

In your Improvement Plan you stated that this structure was already in place and that no further action is needed. Was this structure in place prior to the Assessment? If so, why did the Site Visit Team make this recommendation? If the structure was put in place following the Assessment, please describe the specific actions taken in response to this recommendation.

- Recommendation #3

"Provide the Radiation Safety Office with a full-time Administrative Secretary totally dedicated to the large number of record-keeping and administrative tasks required to maintain the program at a high level."

In your Improvement Plan you committed to creating the position of Radiation Safety Technician to provide administrative and technical support for the Radiation Safety Program. In your Quarterly and Final Report you stated that the position had been created but not yet filled. Please provide a timetable for filling this position.

- Recommendation #7

"Have a member of the Radiation Safety Office present during each room preparation and sealed source or radiopharmaceutical treatment, to provide continuous radiation surveillance as well as observation of all procedures and practices to meet radiation safety requirements."

In your Improvement Plan you committed to having a member of the Radiological Physics section present during the above mentioned procedures. Members of the Radiological Physics section are not necessarily members of the Radiation Safety Office. Section V.C of the Order requires that you provide justification for alternate or no corrective action if any specific recommendation is not adopted. Please provide your justification for having a member of the Radiological Physics Section present during the above mentioned procedures, rather than a member of the Radiation Safety Office as recommended in the Assessment Report.

- Recommendation #8

"Create a Clinical Diagnostic Physicist position. This should be a reasonably high level appointment requiring Board Certification in Diagnostic Physics and appropriate clinical experience to carry out the duties of this position."

In your Improvement Plan you committed to creating the position of Diagnostic Imaging Physicist. In your Quarterly and Final Report you stated that the position had been approved but not yet filled. Please provide a timetable for filling this position.

We will consider closure of the Order following receipt of the requested information. Until the Order is closed, you must continue to provide the written quarterly status reports required by Section V.D of the Order.

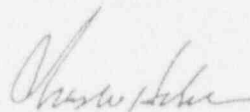
Yale-New Haven Hospital

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In accordance with 10 CFR 2.790 of the NRC's "Rules of Practice", a copy of this letter will be placed in the NRC's Public Document Room.

Thank you for your cooperation.

Sincerely,



Charles W. Hehl, Director
Division of Radiation Safety
and Safeguards

cc:

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State of Connecticut

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