

**Yale-New Haven  
Hospital**

20 York Street, New Haven, CT 06504

Certified Mail/RR

March 29, 1994

Charles W. Hehl, Director  
Division of Radiation Safety and Safeguards  
U.S. Nuclear Regulatory Commission  
Region 1  
475 Allendale Road  
King of Prussia, PA 19406-1415

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

Dear Mr. Hehl:

This is in reference to your letter dated February 28, 1994 received by us on March 7, 1994 regarding your response to the Site Visit Assessment Report and the Yale-New Haven Hospital Improvement Plan.

In response to your request, we are pleased to provide you further information item-by-item:

**Item 1:**

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;
  - 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

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- 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.

Your Query:

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.

Our Response:

All four of these items were carefully evaluated by the Site Visit Team and in their assessment no changes are warranted on these issues. We have written to the Site Visit Chairman, Dr. Sternick, for a confirmation of this statement (see enclosed letter). It should be noted that these issues are continuously reviewed by our Radiation Safety Office and the Radiation Safety Committee.

**Item 2: 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."

Your Query:

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.

Our Response:

This structure has always been in place prior to the Site Visit. A change in the structure was considered by the Site Visit Team. They, however, decided to maintain the existing structure because its strengths outweighed its weaknesses.

**Item 2: 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."

Your Query:

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.

Our Response:

This position has already been filled. The new employee will start work in a few weeks.

**Item 2: 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."

Your Query:

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.

Our Response:

For brachytherapy procedures, the persons who have been designated as being responsible for radiation surveillance and observation are: Radiation Safety Officer, Health Physicists, Radiation Safety Technician, Radiological Physicists, Medical Dosimetrists and Radiation Therapy Technologist. These persons are well-trained and experienced in radiation safety aspects of brachytherapy. Persons designated for providing these services are approved and trained by the Radiation Safety Office and Radiation Safety Committee.

For radiopharmaceutical treatments, the Radiation Safety Office is responsible for procedures using more than 30 mCi and a designated Nuclear Medicine Technologist is responsible for procedures using less than 30 mCi. The designated person is approved and trained by the Radiation Safety Office and Radiation Safety Committee.

**Item 2: 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."

**Your Query:**

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.

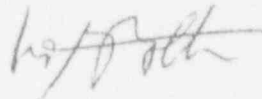
**Our Response:**

This position was filled on March 1, 1994, with Dr. Lange taking on this responsibility.

Please consider this to be our quarterly report to you submitted on March 31, 1994. Our next quarterly report to you will be sent on June 31, 1994. If you deem another schedule to be more appropriate, we will be glad to comply. Please advise us if the proposed schedule is acceptable to you.

Looking forward to closing this matter to your satisfaction. Please write to us if you have any further concerns.

Sincerely,



Norman Roth  
Vice President, Administration

NR/tm  
Enclosure

cc: Ravinder Nath, Chief, Radiological Physics  
Michael Bohan, Radiation Safety Officer  
Robert Lange, Chair, Radiation Safety Committee

**Yale-New Haven  
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20 York Street, New Haven, CT 06504

March 16, 1994

Edward S. Sternick, Ph.D.  
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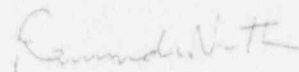
Dear Dr. Sternick:

We have received a response from the NRC regarding the site visit conducted at Y-NHH last May. The NRC requests an evaluation of item #1 as stated in their letter of February 28, 1994 (copy enclosed herewith).

It is my understanding that these issues were reviewed in-depth by the site visit team and no recommendations for change were deemed necessary. Would you please review this matter at your earliest convenience.

Many thanks for your time and effort.

Sincerely yours,



Ravinder Nath, Ph.D.  
Chief, Radiological Physics  
Dept. of Therapeutic Radiology