

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

JUN 23 1994

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

FROM: Thomas T. Martin
Regional Administrator

SUBJECT: AUGMENTED TEAM INSPECTION CHARTER FOR THE
REVIEW OF THE WILLIAM W. BACKUS HOSPITAL
BRACHYTHERAPY MISADMINISTRATION

On June 21, 1994, William W. Backus Hospital in Norwich, Connecticut, implanted 112 seeds of iodine-125 in a patient for the treatment of prostate cancer. Shortly after the sources were implanted, the dosimetrist at the hospital noted an error in the activity of the seeds while reviewing the records of receipt. A written prescription had been prepared on June 16, 1994 for 112 seeds with activities of 0.43 millicuries per seed. The chief nuclear medicine technologist ordered the seeds from a commercial nuclear pharmacy by phone. The pharmacy actually sent 112 seeds with activities of 4.49 millicuries per seed. When the error was discovered, a decision was made to remove the seeds. On June 21, most of the seeds were removed, however, approximately 42 seeds remained in the patient.

The Division of Radiation Safety and Safeguards (DRSS) is assigned the responsibility for the overall conduct of the augmented inspection. Enclosure 1 represents the charter for the AIT and details the scope of the inspection. The inspection shall be conducted in accordance with NRC Management Directive 8.3, NRC Inspection Manual 2800, Inspection Procedures 83822, 87100 and 87103, Regional Office Instruction 1010.1 and this memorandum.

Dr. Ronald Bellamy is appointed as the AIT leader. Other AIT members are identified in Enclosure 2. DRSS is responsible for the timely issuance of the inspection report, the identification and processing of potentially generic issues and the identification and completion of any enforcement action warranted as a result of the team's review.



Thomas T. Martin
Regional Administrator

Enclosures:

1. Augmented Inspection Team Charter
2. Team Composition

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ENCLOSURE 1

AUGMENTED INSPECTION TEAM CHARTER

The general objectives of this AIT are to:

1. Conduct a thorough and systematic review of the circumstances surrounding the brachytherapy misadministration at William W. Backus Hospital on June 21, 1994, including an incident chronology detailing the sequence of events associated with the therapy treatment.
2. Assess the safety significance of the event and communicate to Regional and Headquarters management the facts and safety concerns related to the event so that appropriate follow-up actions can be taken. Include an analysis of the actual and potential dose consequences.
3. Collect, analyze, and document factual information and evidence sufficient to determine the causes(s), conditions, and circumstances pertaining to the event.
4. Examine the procedural and management failures and identify associated root causes. Evaluate the training, surveys and supervision associated with the medical personnel's detection and response to the error in the activity of the sources.
5. Prepare a report documenting the results of this review for the Regional Administrator within thirty days of the completion of the inspection.

In addition to the above, in coordination with NMSS, examine and assess the adequacy of the NRC procedures and processes for responding to on-going events including a medical emergency. Document any lessons learned and recommended changes in a separate document within sixty days of completion of the inspection.

ENCLOSURE 2

TEAM COMPOSITION

The assigned team members are as follows:

Team Manager:	Charles W. Hehl, DRSS
Onsite Team Leader:	Ronald R. Bellamy, DRSS
Onsite Team Members:	Ihor M. Czerwinskyj, DRSS Sattar Lodhi, DRSS
Medical Consultants:	Dr. Melvin Griem (6/22 only) Dr. Judith Stitt (6/23 -)
INEL Consultants:	TBD

June 23, 1994

Docket No. 030-01287
License No. 06-11734-02
CAL No. 1-94-010

William W. Backus Hospital
ATTN: Mr. Brian J. Smithwick
Vice President
326 Washington Street
Norwich, Connecticut 06360

Dear Mr. Smithwick:

SUBJECT: CONFIRMATORY ACTION LETTER 1-94-010

On June 21, 1994, the NRC became aware that a therapeutic misadministration occurred at your facility involving the implantation of iodine-125 seeds with an activity approximately 10 times the activity ordered in the written prescription.

Pursuant to meetings between yourself, Mr. Michael T. Moore, President and Chief Executive Officer, Mr. Thomas P. Pipicelli, Executive Vice President and Chief Operating Officer and Ms. Nancy J. Budds, Vice President and Dr. Ronald Bellamy, Chief, Nuclear Materials Safety Branch on June 22 and 23, 1994 at your facility, it is our understanding that you have taken (or will take) the following actions (which will be completed by the dates specified):

1. Immediately suspend all brachytherapy treatments. Submit a report on the therapy misadministration pursuant to 10 CFR 35.33 (a)(2).
2. Identify the root causes of the event, propose corrective actions, and prepare a schedule for completion of the corrective actions.
3. Complete the corrective actions as identified in Item 2. above.
4. Further, we understand that you will not resume the brachytherapy program until you receive written authorization from the NRC Region I office.

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

- a) Notify me immediately if your understanding differs from that set forth above;
- b) Notify me if for any reason you cannot complete the actions within the schedule specified in Item 2 above and advise me in writing of your modified schedule in advance of the change; and
- c) Notify me in writing when you have completed the actions addressed in Item 3 above.

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.

The responses directed by this letter are not subject to the clearance procedures of the Office of Management and Budget as required by the Paperwork Reduction Act of 1980, Pub. L. No. 96-511.

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. Accordingly, your response should not, to the extent possible, include any personal privacy, proprietary, or safeguards information so that it can be released to the public and placed in the NRC Public Document Room.

Sincerely,

Original Signed By:

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

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

bcc:

Region I Docket Room (w/concurrences)

H. Thompson, DEEDS

J. Lieberman, OE

C. Paperiello, NMSS

J. Glenn, NMSS

S. Lewis, OGC

T. Martin, RI

W. Kane, RI

C. Hehl, RI

S. Shankman, RI

R. Bellamy, RI

J. Johansen, RI

D. Holody, RI

K. Smith, RI

D. Chawaga, RI

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