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UNITED STATES OF AMERICA
NUCLEAR REGULATORY COMMISSION

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BEFORE THE ATOMIC SAFETY AND LICENSING BOARD

OFFICE OF SECRETARY
REGULATING & SERVICE
BRANCH

In the Matter of)
)
ONCOLOGY SERVICES CORPORATION) Docket No. 030-31765-EA
)
(Byproduct Material) EA No. 93-006
License No. 37-28540-01)

NRC STAFF'S RESPONSE TO BOARD ORDER DATED MAY 26, 1994

INTRODUCTION

Pursuant to the Atomic Safety and Licensing Board's (Board) Order (Ruling on Discovery Matters), dated May 26, 1994 (Board Order), the Staff of the Nuclear Regulatory Commission (Staff) provides the following information regarding the provision of notes.

BACKGROUND

On March 8, 1994, the Licensee filed its "Request for Production of Documents dated March 8, 1994" (Licensee's Request). The Staff responded to the Licensee's Request on April 7, 1994. "NRC Staff's Response and Objections to Licensee's Request for Production of Documents Dated March 8, 1994 and NRC Staff's Motion for Protective Order" (Staff's Response). On April 22, 1994, the Licensee filed a "Motion to Compel and Reply to NRC Staff's Response and Objections to Licensee's Request for Production of Documents dated March 8, 1994 and NRC Staff's Motion for Protective

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Order." The Staff filed its reply to the Licensee's Motion on May 9, 1994. The Board issued its Order on May 26, 1994.

DISCUSSION

In its Request, the License requested:

Any and all transcripts, statements, notes and/or summaries of statements made to the Nuclear Regulatory Commission, the IIT Team, the Office of Investigations and/or any other department/agent/agency of the Nuclear Regulatory Commission in connection with the investigation of Oncology Services Corporation.

Request at 1. In response to this Request, the Staff provided the Licensee with 29 transcripts of interviews and/or reports of interview. In addition, the Staff provided the Licensee with copies of handwritten notes of statements taken by investigators from the NRC Offices of Investigations and the Inspector General. In its Response, the Staff stated that "The IIT members did not retain any notes which may be responsive to the Licensee's Request, nor did the NRC inspectors who inspected the Licensee's Exton and Mahoning Valley facilities." Response at 4. In its Order, the Board ordered, among other things, the Staff to "identify any IIT member and inspector notes that were retained but which the staff has identified as not responsive to OSC's request, and . . . explain why those notes are not responsive to OSC's request." Board Order at 6.

Below is a list of documents retained by the Incident Investigation Team (IIT) which are either handwritten and could be considered "notes," or are specifically designated as notes. The responsiveness of each document is discussed in turn.¹

¹ Due to the nature of some of the information contained in these notes, if deemed responsive to the Licensee's Request by the Board, the Staff by discussing the responsiveness of these notes, does not waive its right to object to their production, in whole or in part, on other grounds pursuant to 10 C.F.R. § 2.744.

1) Dr. Flynn's Notes Taken from the Scenery Hill Manor (SHM) Nursing Home Records

These notes were taken by the IIT's medical consultant from the Scenery Hill Manor Nursing Home records. They are not notes of any statements provided to the IIT. They are, therefore, not responsive to the Licensee's Request.

2) SHM Nursing Home Nurse's Notes

These notes were written by the nurses at the Scenery Hill Manor Nursing Home regarding the patient who died after treatment at the Indiana Regional Cancer Center on November 16, 1992. These notes are not notes of any statements provided to the IIT. They are, therefore, not responsive to the Licensee's Request.

3) SHM Detailed Blood Samples Taken - Employees

This document is a handwritten list of individuals from whom blood samples were taken. This document is not a note of any statements made to the IIT and is, therefore, not responsive to the Licensee's Request.

4) SHM Patient Contact - Most Frequent

This document is a handwritten list of individuals who had frequent contact with the patient at the nursing home. This document is not a note of any statements made to the IIT and is, therefore, not responsive to the Licensee's Request.

5) SHM - Total Employee List

This document is a handwritten list of individuals employed at the SHM nursing home. This document is not a note of any statements made to the IIT and is, therefore, not responsive to the Licensee's Request.

6) SHM - Patient Contact - Infrequent.

This document is a handwritten list of individuals who had infrequent contact with the patient at the nursing home. This document is not a note of any statements made to the IIT and is, therefore, not responsive to the Licensee's Request.

7) SHM - Housekeepers

This documents is a handwritten list of housekeepers at the nursing home, with an approximation of how long the housekeepers were in contact with the patient. This

document is not a note of any statements made to the IIT and is, therefore, not responsive to the Licensee's Request.

8) OSC Pre-op/Post-op Contact - Discharge Instructions - Nursing Discharge Summary

These documents contain notes regarding the patient. They are not notes of any statements provided to the IIT. They are, therefore, not responsive to the Licensee's Request.

- 9) Rudy Balko - Response to Questions (L. Ostrom) December 8, 1992
- 10) Written Questions to Resolve for Rudy Balko

These documents are handwritten questions and handwritten responses to those questions from Rudy Balko to the IIT. These documents are not notes of statements made to the IIT and are, therefore, not responsive to the Licensee's Request. In addition, these documents were provided to the Licensee on April 1, 1994.

11) Coupling Catheter and Tubing descriptions (signed out to Southwest Research Institute, San Antonio, TX)

This document is a handwritten description of the coupling catheter and tubing. This document also contains a price list of various equipment from Omnitron. This document is not a note of statements made to the IIT and is, therefore, not responsive to the Licensee's Request.

12) Note to File From P. Nessen - Discussion on Omnitron Use.

This note appears to be a note of a discussion between an IIT member and an NRC staff member regarding the location and use of the Omnitron 2000 at other facilities. This note is not responsive to the Licensee's request, since it is not a note of a "statement" made to the IIT, but rather a notation of information provided to the IIT by a member of the NRC Staff. In addition, since the note is regarding the use of the Omnitron 2000 at other facilities, it is not relevant to this proceeding.

13) Notes to File from C. Jones, IIT/NRC, regarding possible radiation exposure at SHM, dated 12/23/92, 12/24/92, and 12/29/92.

These notes discuss the attempts by an IIT member to identify the names of individuals who had visited the patient and to verify the amount of time each individual spent with the patient. These notes are not notes of statements made to the IIT and are, therefore, not responsive to the Licensee's Request.

14) Note to File from R. Gastorf, contract, dated 12/18/92; subject: Removal of Catheters by Dr. Bauer.

This note to file memorializes a discussion with Dr. Bauer regarding the identification of which catheter was removed by Dr. Bauer. This note was not provided because it is not relevant to any issue in this proceeding and not necessary for a proper decision in this proceeding.

15) Note to File from P. Nessen - Ambulance Measurements to be Used in Dose Calculations, Discussion with Victoreen PrimAlert-10, Discussions with Adjacent Doctor's Office (Dr. Pinkerton, adjacent to IRCC), Discussion with H. Glasser of Nuclear Associates, Discussion with Chief Technician, Schuykill Cancer Center.

This note is not responsive to the Licensee's Request because it is not a note of a statement made to the IIT. This note contains information obtained by the IIT through discussions with certain individuals, but this note is not a note of any statements made to the IIT.

16) Note to File from C. Jones 1/11/93, subject: Phone Conversation with R. Bellamy, RI and K. McAdoo, SHM.

This note to file discusses the responses to NRC's advertisement in the local Indiana, PA newspaper regarding the identification of individuals who had contact with the patient. Several individuals are listed and their contact with the patient is discussed. This note does not contain notes of statements made to the IIT and is, therefore, not responsive to the Licensee's Request.

17) Note to Region I from C. Jones, IIT, dated 1/29/93; subject: Individuals Exposed to the Iridium-192 source, November 16 - December 1, 1992 and designations of personnel mentioned in IIT report.

This typewritten documents is a list of individuals exposed to the source, as well as a partially handwritten list of the designation of personnel mentioned in the IIT report. This note does not contain notes of statements made to the IIT and is, therefore, not responsive to the Licensee's Request.

18) Initial Meeting Roster

This is a handwritten list of individuals who attended the initial meeting of the IIT. This note does not contain notes of statements made to the IIT and is, therefore, not responsive to the Licensee's Request.

19) OSC-IIT Meeting Roster, 12-02-92, 3:30 pm.

This is a handwritten list of individuals who attended a meeting with OSC and the IIT. This note does not contain notes of statements made to the IIT and is, therefore, not responsive to the Licensee's Request.

- 20) Photograph Log Sheet: BFI Carnegie, PA & Warren, OH
- 21) Photograph Log Sheet: Scenery Hill Nursing Home & Ambulance
- 22) Photograph Log Sheet: Indiana Regional Cancer Center
- 23) Photograph Log Sheet: Indiana Regional Cancer Center
- 24) Photograph Log Sheet: Indiana Regional Cancer Center
- 25) Photograph Log Sheet: Indiana Regional Cancer Center
- 26) Photograph of Omnitron's Lab Facility, with Log Sheet

These documents are handwritten log sheets of photographs taken by the IIT. Since these documents are not notes of statements made to the IIT, they are not responsive to the Licensee's Request.

- 27) Statement from BFI Driver Making the Pick-up at SHM.

This is a handwritten statement made by a BFI driver. This statement was not provided to the Licensee because it was not relevant to any issue in this proceeding and not necessary for a proper decision in this proceeding.

- 28) Attendance sheet for Exit Meeting, December 17, 1992, Harrisburg Hotel, Harrisburg, Pennsylvania.

This is a handwritten list of individuals who attended the exit meeting on December 17, 1992. It is not a note of any statement made to the IIT, and is, therefore, not responsive to the Licensee's Request.

- 29) Written statements from BFI employees.

These are two handwritten statements from BFI employees regarding the pickup from the Scenery Hill Nursing home of waste. These statements were not provided because they are not relevant to any issue in this proceeding and not necessary for a proper decision in this proceeding.

- 30) NRC Region I Swipe Analysis Equipment

This document consists of two record sheets of an analysis performed by the NRC Region I. Attached to this these records is a handwritten note regarding two samples. Since this document is not a note of any statement made to the IIT, it is not responsive to the Licensee's Request.

31) Response to questions for G. Hay, Consulting Physicists, IRCC

This document consists of handwritten responses from Greg Hay to typewritten questions from the IIT. It is not a note of any statement made to the IIT. In addition, this document was provided to the Licensee on April 1, 1994.

32) Written responses to questions asked by the IIT to the IRCC staff.

This document consists of handwritten responses from Greg Hay to typewritten questions from the IIT. It is not a note of any statement made to the IIT. In addition, this document was provided to the Licensee on April 1, 1994.

33) Answer to questions from M. Shanbaky, IIT/NRC to J. Bauer, IRCC, relating to catheter used on 11/16/92

This document consists of handwritten responses to questions regarding the use and location of catheters used during the November 16, 1992 incident. It is not a note of a statement made to the IIT, therefore, it is not responsive to the Licensee's Request.

34) Licensing Guidance for reviewing HDR applications from Region IV.

This document includes, among other things, a handwritten note regarding the licensing of the use of HDR afterloaders. It is not a note of a statement made to the IIT, therefore, it is not responsive to the Licensee's Request.

35) Final Comments on Section 6.2 of NUREG-1480 from Dr. Flynn.

This document consists of handwritten notes and comments on Section 6.2 of NUREG-1480. It is not a note of a statement made to the IIT, therefore, it is not responsive to the Licensee's Request.

36) Handouts from meeting with Southwest Research Institute 12/17/92

This document contains handwritten notations on the meeting handouts. It is not a note of a statement made to the IIT, therefore, it is not responsive to the Licensee's Request.

37) Inventory Log of source wire - Omnitron/Edgerly facility (3/23/91-9/16/92)

This is a handwritten inventory log, as such, it could be considered a note. However, it is not a note of a statement made to the IIT, therefore, it is not responsive to the Licensee's Request.

38) Telefax to T. Rich, IIT/NRC from Omnitron dated 12/29/92, subject: testing of source wire.

This is a handwritten note regarding the testing of the source wire. It is not, however, a note of a statement made to the IIT. It is, therefore, not responsive to the Licensee's Request.

- 39) All SHM Nursing Home documents for patient:
- A. Admitted 11/19/91; Discharged 3/6/92
 - B. Admitted 03/19/92; Discharged 4/20/92
 - C. Admitted 8/27/92; Deceased 11/21/92
 - D. Hospital Records, 8/92 to 11/21/92

These documents contain notes from the nursing home regarding the patient. They do not contain any notes from statements made to the IIT. These documents, therefore, are not responsive to the Licensee's Request.

- 40) SHM - Patient's Report Sheets - 11/16/92-11/20/92

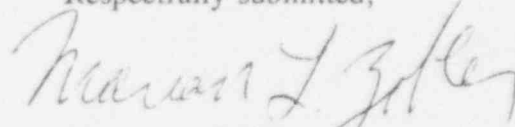
This document contain handwritten notes regarding the patient from the nursing home. These notes do not contain any notes of statements made to the IIT. This document, therefore, is not responsive to the Licensee's Request.

- 41) OSC Treatment Plan
Afterloader Calculations 2E.9.2(c)
Treatment Verification & Personal Information - 2000 Version 3.0

In addition to the information listed in this document, this document contains a handwritten statement from Greg Hay regarding the incident on November 16, 1992. It does not appear that this statement has been provided to the Licensee. It is, therefore, attached hereto.

The NRC inspectors who inspected the Licensee's Exton and Mahoning Valley facilities did not retain any notes from their inspection. Thus, there are no notes from those inspections to provide to the Licensee. The Staff, in its Response, did not mean to imply, as could be inferred from the Staff's language, that the NRC inspectors retained some notes from their inspections but that these notes were not responsive to the Licensee's request.

Respectfully submitted,

A handwritten signature in cursive script that reads "Marian L. Zabler". The signature is written in dark ink and is positioned above the printed name and title.

Marian L. Zabler
Counsel for NRC Staff

Dated at Rockville, Maryland
this 6th day of June, 1994

12.1.92

11:00 Got call from Pat at ICL. STATING THAT NURSING HOME CALLED & SAID THAT THERE WAS RADIOACTIVE WASTE AT BFI. IN CARNEGIE. I LEFT JOHNSON & ARRIVED AT ICL AT 11:40. CHECKED OMNITRON & SURVEY METER, THEN RAN FILM TEST. PRIMALET DID NOT WORK AND FILM CAME OUT BLACK. 11:50 CALLED BFI, THEY WILL RETURN CALL, 12:00 CALLED NRC. AND GAVE EXPLANATION THAT 3.7Ci Ir 192 SOURCE WAS MISSING & WAS AT BFI TRADING HOURS IN CARNEGIE. ASK NRC IF I SHOULD PICK UP? I HAD A PIC & FRAGS & SURVEY METER. THEY SAID THEY WILL CALL BACK. CALLED DAVID CUNNINGHAM, HE DID NOT THINK SOME COULD COME OF USE, KEEP INFORMED. CALLED OMNITRON - THEY DIDN'T BELIEVE SOURCE WAS GONE "THATS IMPOSSIBLE" WILL CALL BACK.

Talked to Technologists & NURSE ABOUT LAST TREATMENT ON MRS. COLGAN DONE ON 11-16-92. I WAS NOT HERE FOR TREATMENT.

As they told me before, the last catheter failed to load IT LOADED THE DUMMY, BUT NOT THE SOURCE. DR. BAUER THEN REMOVED THIS CATHETER (^{192}Ir), AND THE PATIENT RETURNED TO THE NURSING HOME. I CAME IN THAT EVENING, AND NOTED THE PLAN WITH ONLY 4 CATHETERS. I CALLED OMNITRON & THEY INSTRUCTED ME ON HOW TO SUBSTITUTE AT THE SOURCE FOR THE 5th CATHETER AND THEN RECALCULATE WITH ACTUAL TREATMENT TIMES GIVEN. I DID THIS AND THEN I RAN A TEST SEQUENCE THROUGH THE OMNITRON TO MAKE SURE THAT IT DID NOT STICK. IT RAN FINE AND I ADJUSTED THE DOSE IN THE CHART. THE TECHNOLOGISTS DIDN'T TELL ME UNTIL 12-1-92 THAT WHEN THE OMNITRON WAS

IN THE PARKED POSITION THE PRIMEALERT WAS FLASHING.
I ASKED THEM WHY DIDN'T THEY TAKE THE SURVEY
METER INTO THE ROOM & SURVEY THE PATIENT.
THEY BELIEVED THAT THE PRIMEALERT WAS MALFUNCTIONING AS
DEFER AND DID NOT REMEMBER THAT THEY SHOULD SURVEY
THE PATIENT.

NRC CALLED BACK AND TALKED TO ME & THEN DR. BARN 1:00-1:10. THEY TOLD
BARN TO GO GET THE SOURCE.

DR. BARN & I ARRIVED AT BMI AT ABOUT 3:00 AND SPIKE TO THE

JANE McNEADY. SHE SHOWED US WHERE THE BOX WAS LOCATED
ABOUT 150-200 YARDS FROM ANY BUILDINGS AND IT WAS INSIDE A
STEEL GARBAGE CAN WITH A SURVEY METER & RED 784MR/hr. (B²
OR U)
IT TOOK US 70 SECONDS TO LOCATE THE SOURCE. IT WAS IN
THE TOP OF THE BOX IN THE 3RD BAG THAT WAS REMOVED.

THERE WERE 4 CATHETERS IN THIS BAG. 3 WERE IN A
GAUZE WRAP & ONE WAS BY ITSELF, THE SOURCE WAS IN
THE CATHETER WITH THE SOURCE. IT TOOK 90 MINUTES TO TRANSPORT
THE SOURCE BACK TO INDIANA. THE DOSE RATE IN THE DRIVERS SEAT
WAS .6 MR/hr.

BEI SAID IT TOOK 3 PEOPLE ABOUT 1 HOUR TO LOCATE THE
HOT BOX AS IT WAS 20 BOXES DEEP IN A 40' TRAILER.
THEY ESTIMATED THAT THEY WERE ON THE AVERAGE 6-8 FEET FROM
THE BOX WITH THE SOURCE.

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BEFORE THE ATOMIC SAFETY AND LICENSING BOARD

OFFICE OF SECRETARY
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In the Matter of)
)
ONCOLOGY SERVICES CORPORATION) Docket No. 030-31765-EA
)
(Byproduct Material) EA No. 93-006
License No. 37-28540-01))
)

CERTIFICATE OF SERVICE

I hereby certify that copies of "NRC STAFF'S RESPONSE TO BOARD ORDER DATED MAY 26, 1994" in the above-captioned proceeding have been served on the following by deposit in the United States mail, first class, or as indicated by an asterisk through deposit in the Nuclear Regulatory Commission's internal mail system this 6th day of June, 1994:

G. Paul Bollwerk, III, Chairman*
Administrative Judge
Atomic Safety and Licensing Board
U.S. Nuclear Regulatory Commission
Washington, D.C. 20555

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Washington, D.C. 20555

Dr. Peter S. Lam*
Administrative Judge
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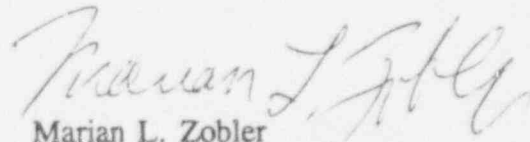
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Adjudicatory File (2)*
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U.S. Nuclear Regulatory Commission
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Office of the Secretary (2)*
U.S. Nuclear Regulatory Commission
Washington, D.C. 20555
Attn: Docketing and Service Section

Office of Commission Appellate
Adjudication (1)*
U.S. Nuclear Regulatory Commission
Washington, D.C. 20555

Atomic Safety and Licensing Board
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Marian L. Zobler
Counsel for NRC Staff