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RELATED CORRESPONDENCE

DOCKETED June 3, 1994
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UNITED STATES OF AMERICA
NUCLEAR REGULATORY COMMISSION

OFFICE OF SECRETARY
DOCKETING & SERVICE
ANCH

BEFORE THE ATOMIC SAFETY AND LICENSING BOARD

| | | |
|-------------------------------|---|-------------------------|
| 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 RESPONSES AND OBJECTIONS
TO OSC'S REQUEST FOR PRODUCTION OF
DOCUMENTS AND INTERROGATORIES DATED MAY 10, 1994

INTRODUCTION

Pursuant to 10 C.F.R. §§ 2.720, 2.740, and 2.744, the staff of the Nuclear Regulatory Commission (Staff) hereby files its responses and objections to Oncology Services Corporation's (Licensee) Request for Production of Documents and Interrogatories dated May 10, 1994.¹

¹ The parties agreed that the Staff's responses to this discovery request would be filed on June 3, 1994.

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STAFF RESPONSES AND OBJECTIONS TO LICENSEE'S INTERROGATORIES
AND REQUESTS FOR PRODUCTION OF DOCUMENTS

LICENSEE'S INTERROGATORIES AND REQUESTS FOR DOCUMENTS

INTERROGATORY 1

Define the following terms and/or phrases:

- a. "unsupervised HDR treatments"
- b. "supervised HDR treatments"
- c. "breakdown of corporate management"
- d. rely
- e. training
- f. "in-charge of HDR treatment"
- g. "in-service training"
- h. reasonable

STAFF'S RESPONSE

The Staff objects to interrogatory 1 on the ground that the information sought is the subject of a prior Board ruling in this proceeding. The Board ruled, in connection with the Staff's previous discovery requests which contained the same terms, that the Licensee should provide its answers based on what it believes is a reasonable interpretation of the Staff's discovery requests. Order (Ruling on Discovery Matters), May 6, 1994 at 6, 8, 9, 10-11.

INTERROGATORY 2

Identify each and every allegation and/or fact upon which the NRC relied in suspending the license of OSC and for each such allegation and/or fact provide the following, in specificity:

- a. The federal regulation, the license condition and/or any other law which the NRC asserts the licensee violated with respect to said fact or allegation;
- b. The identity of any NRC personnel who will testify about the (i) alleged factual situation and (ii) the application of the relevant federal regulation, license condition and/or any other law which the NRC asserts the licensee violated with respect to said fact or allegation;
- c. The legal theory by which the Staff asserts that the federal regulation, the license condition and/or other law applies with respect to said fact or allegation;
- d. Any and all documents which the NRC will rely on to support those matters identified pursuant to the NRC's response to question 2(a) herein; and
- e. Any and all facts which refute the NRC's allegation of "breakdown of corporate management".

STAFF'S RESPONSE

The facts the Staff relied upon in suspending the Licensee's license are set forth in the Suspension Order.

a. To the extent that the Staff asserted in the Suspension Order that a regulation or license condition was violated with respect to a fact listed in the Suspension Order, such regulation or license condition is set forth in the Suspension Order.

b. Information relevant to interrogatory 2b has already been provided to the Licensee. *See* "NRC Staff Responses and Objections to Licensee's Second Set of Interrogatories And Request for Production of Documents and NRC Staff Motion for Protective Order," March 31, 1994 at 2-3.

c. The Staff's explanation of how the facts in the Suspension Order violated a particular federal regulation, license condition, or other law, to the extent that a violation of regulation, license condition, or other law was cited in the Suspension Order, is set forth in the Suspension Order. In addition, the application of the Atomic Energy Act has been fully briefed

and decided before this Board. *Oncology Services Corporation*, LBP-94-2, 39 NRC 11, 21 (1994). Further explanation of the violations of federal regulations, license conditions, and other law cited as a basis in the Suspension Order, to the extent that the same facts are relied upon, is provided in the Notice of Violation (NOV) issued to Oncology Services Corporation on May 31, 1994.

The application of the Commission's regulations and the license conditions is also set forth in the Suspension Order, and additional information in this regard may be found in the NOV. In addition, the applicability of 10 C.F.R. Part 19 to the License is set forth in 10 C.F.R. § 19.2, and the applicability of 10 C.F.R. Part 20 to the License is set forth in 10 C.F.R. § 20.2. The applicability of 10 C.F.R. Part 35 is discussed below, in response to interrogatory 9.²

d. Documents responsive to interrogatory 2d have already been identified and made available to the Licensee. See "NRC Staff Response and Objections to Licensee's First Set of Interrogatories, First Request for Production of Documents, and First Request for Admissions," February 18, 1994 at 5-6. In addition, the Staff may rely on the following documents, which have already been provided to the Licensee:

Transcript of Interview of James E. Bauer, M.D. to the Incident Investigation Team (IIT), December 15, 1992
Transcript of Interview of Rudy Balko to the IIT, December 4, 1992
Transcript of Interview of Sharon Rickett to the IIT, December 4, 1992
Transcript of Interview of Robbie Ackerson to the IIT, December 4, 1992
Transcript of Interview of Greg Hay to the IIT, December 4-5, 1992

² Dr. Paperiello, who assisted in the preparation of the Staff's response to this interrogatory, as well as others, was unable to have his affidavit notarized. A signed, but unnotarized copy has been attached. A signed and notarized copy of the affidavit will be provided as soon as possible.

Transcript of Interview of David E. Cunningham to the IIT, December 17, 1992
Transcript of IIT entrance interview, dated December 3, 1992

e. Interrogatory 2e misstates the Staff's assertion in the Suspension Order. The Suspension Order stated that there was a "significant corporate management breakdown in the control of licensed activities." To the extent that interrogatory 2e is intended to refer to the above assertion in the Suspension Order, the Staff is unaware of any facts which refute the NRC's finding that a significant corporate management breakdown in the control of licensed activities occurred.

INTERROGATORY 3

Produce any and all documents used by the NRC to answer to interrogatory 2 above.

STAFF'S RESPONSE

See response to interrogatory 2d. In addition, the Licensee already has a copy of the Suspension Order.

INTERROGATORY 4

Identify the draftsman of 10 CFR Section 35.404a.

STAFF'S RESPONSE

Objection. Information sought in interrogatory 4 is not relevant to any issue in this proceeding and is not necessary for a proper decision. 10 C.F.R. § 2.720. The Staff did not cite the Licensee for a violation of section 35.404a. thus, the identity of the "draftsman" of section 35.404a is not relevant and not necessary for a proper decision in this proceeding. 10 C.F.R. § 2.720. See also *Oncology Services Corporation*, LBP-94-2, 39 NRC 11, 27 (1994).

INTERROGATORY 5

Produce any and all documents which relate in any manner, including the handbook and overhead materials or handouts for the following -- "NRC Teletherapy and Brachytherapy Course" given in April 1991 as well as any such similar courses given at any other time since 1990.

STAFF'S RESPONSE

Documents responsive to interrogatory 5 will be made available to the Licensee.

INTERROGATORY 6

Identify why the NRC didn't require as a specific OSC license condition that the licensee survey the patient at the conclusion of the treatment.

STAFF'S RESPONSE

The NRC did not requires a "specific OSC license condition that the licensee survey the patient at the conclusion of the treatment" for the following reasons: The NRC licensing staff reviewed the application and documents which were the basis of the issuance of the license to Oncology Services Corporation on August 3, 1990, in accordance with Policy and Guidance Directive FC 86-4; INFORMATION REQUIRED FOR LICENSING REMOTE AFTERLOADING DEVICES (FC 86-4.) The guidance did not address a requirement which would require a licensee to make a radiation survey of the patient with a radiation detection survey instrument at the end of treatment. However, under Section V of FC 86-4 "Facilities", Subitem C.4., the NRC licensing staff specifically asked for and received from Oncology Services Corporation a description of "Means of verifying source 'safe' condition (e.g., permanently installed radiation monitor)." OSC committed to the use of a PrimeAlert area wall monitor (radiation detection instrument). Thus, the NRC licensing staff concluded that adequate facilities existed to assure the safe condition of the source at the conclusion of the treatment.

Specific requirements in the NRC regulations may not be explicitly addressed during the licensing process and are not specifically incorporated into a license, but that fact does not constitute an exemption to such regulations, including the radiological survey requirement in 10 C.F.R. § 20.201.

In addition, pursuant to FC 86-4, the NRC licensing staff requested and received a submittal of emergency procedures which were referenced in Condition 17 of the license. License condition No. 17 requires, in part, that the Licensee conduct its program in accordance with the statements, representations, and procedures contained in documents, including any enclosures listed, including the Application dated June 1, 1990 and a letter dated August 2, 1990.

The License Application, Item 9.1.C.3 requires that a radiation monitor be mounted on the wall and will remain in place as a means of verify a source "safe" or "out" condition.

The License Application, Item 10.15.A.3 requires, in part, that all attending personnel must remain in the control area during actual treatment. They may not re-enter the treatment room until the source has returned to its container and the room radiation detector indicates that a safe condition prevails.

OSC provided additional regulatory commitments in a letter dated August 2, 1990, which is incorporated in the license under License Condition 17. The August 2, 1990 letter, Item No. 6 states that failure of the room radiation monitor will result in termination of the treatment

until the monitor is replaced or repaired. In the event of failure of the room monitor, no personnel will enter the room without a portable survey meter or audible dosimeter.³

INTERROGATORY 7

Identify why the NRC did not cite the licensee for Dr. Bauer's failure to survey the patient with a hand held survey meter at the conclusion of the patient's HDR treatment.

STAFF'S RESPONSE

The Suspension Order did as a basis rely on the fact that Dr. Bauer failed to survey the patient at the conclusion of the patient's HDR treatment.

Because of questions as to the applicability to HDR units of 10 CFR Part 35, Subpart G, which specifically requires that a survey of the patient be performed at the end of a brachytherapy treatment, at the time the Suspension Order was being prepared, the Staff did not specifically cite the Licensee for a violation of 10 CFR Part 35, Subpart G. In any event, the NRC Staff decided that it was not necessary to address any more specific requirements in the Suspension Order because there was a clear failure to perform the survey required by 10 CFR 20.201(b).

INTERROGATORY 8

Identify the individual who allegedly informed Dr. Bauer that the PrimeAlert was flashing.

STAFF'S RESPONSE

Robbie Ackerson told the IIT during an interview that she informed Dr. Bauer that the PrimeAlert flashed red. Robbie Ackerson also told the OI investigator that she told Dr. Bauer

³ Dr. Shanbaky, who assisted in the preparation of the Staff's response to interrogatory 6, was unable to have his affidavit notarized. A signed, but unnotarized, copy of his affidavit is attached. A signed and notarized affidavit will be forwarded as soon as possible.

that the PrimeAlert is flashing. Rudy Baiko told the OI investigator that when Dr. Bauer entered the treatment room, he told Dr. Bauer that the PrimeAlert had been or was flashing.

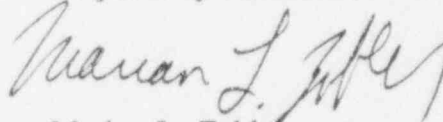
INTERROGATORY 9

Identify the legal theory upon which the Staff believes that 10 CFR Part 35 applies to the subject matter of the OSC license.

STAFF'S RESPONSE

In accordance with 10 C.F.R. §§ 35.1 and 30.33(a)(4) any applicant for a license for medical use of byproduct material must meet all applicable requirements set forth in Part 35. The term "medical use" is defined in 10 C.F.R. § 35.2 and clearly includes high dose rate brachytherapy.

Respectfully submitted,



Marian L. Zabler
Counsel for NRC Staff

Dated at Rockville, Maryland
this 3rd day of June, 1994

UNITED STATES OF AMERICA
NUCLEAR REGULATORY COMMISSION

BEFORE THE ATOMIC SAFETY AND LICENSING BOARD

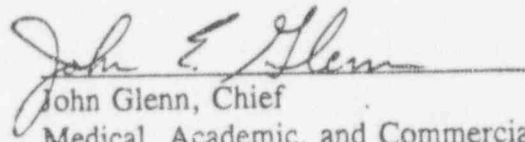
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|-----------------------------------|---|------------------------|
| In the Matter of |) | |
| ONCOLOGY SERVICES CORPORATION |) | Docket No. 030-31765 |
| |) | EA 93-006 |
| (Order Suspending Byproduct |) | |
| Material License No. 37-28540-01) |) | ASLBP No. 93-674-03-EA |

AFFIDAVIT OF JOHN GLENN

I, John Glenn, first being duly sworn, depose and state:

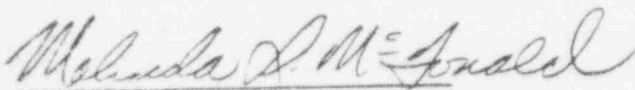
1. I am currently Chief, Medical, Academic, and Commercial Use Safety Branch, Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission.
2. I have participated and assisted in the preparation of the attached NRC Staff responses to Interrogatories 6 and 9 filed by Oncology Services Corporation in the above-captioned proceeding.

3. I hereby certify that the answers to the above numbered interrogatories are true and correct to the best of my information and belief.


John Glenn, Chief

Medical, Academic, and Commercial Use Safety Branch

Subscribed and sworn to before me
this 27 of May, 1994


Notary Public

My commission expires: 12/1/97

UNITED STATES OF AMERICA
NUCLEAR REGULATORY COMMISSION

BEFORE THE ATOMIC SAFETY AND LICENSING BOARD

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| |) | EA 93-006 |
| (Order Suspending Byproduct |) | |
| Material License No. 37-28540-01) |) | ASLBP No. 93-674-03-EA |

AFFIDAVIT OF GERARD KENNA

I, Gerard F. Kenna, first being duly sworn, depose and state:

1. I am an investigator in the Office of Investigations, Region I, Nuclear Regulatory Commission. I am the lead investigator assigned to the investigation of Oncology Services Corporation.
2. I have participated and assisted in the preparation of the attached NRC Staff response to Interrogatory 8 filed by Oncology Services Corporation in the above-captioned proceeding.

3. I hereby certify that the answer to the above numbered interrogatory is true and correct to the best of my information and belief.

Gerard F. Kenna

Gerard F. Kenna
Office of Investigations

Subscribed and sworn to before me
this 2nd of June, 1994

Richard J. Spina

Notary Public

My commission expires: 3/24/96

NOTARIAL SEAL

UNITED STATES OF AMERICA
NUCLEAR REGULATORY COMMISSION

BEFORE THE ATOMIC SAFETY AND LICENSING BOARD

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| In the Matter of |) | |
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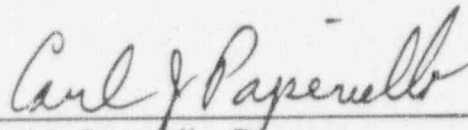
AFFIDAVIT OF CARL J. PAPERIELLO

I, Carl J. Paperiello, first being duly sworn, depose and state:

1. I am currently the Director, Division of Industrial and Medical Nuclear Safety, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission. I was the leader of the Incident Investigation Team chartered to investigate the incident which occurred at the Indiana Regional Cancer Center on November 16, 1992.

2. I have participated and assisted in the preparation of the attached NRC Staff responses to Interrogatories 2(c), 6, and 8 filed by Oncology Services Corporation in the above-captioned proceeding.

3. I hereby certify that the answers to the above numbered interrogatories are true and correct to the best of my information and belief.



Carl J. Paparella, Director
Division of Industrial and Medical Nuclear Safety

Subscribed and sworn to before me
this ___ of June, 1994

Notary Public

My commission expires: _____

June 3, 1994

UNITED STATES OF AMERICA
NUCLEAR REGULATORY COMMISSION

BEFORE THE ATOMIC SAFETY AND LICENSING BOARD

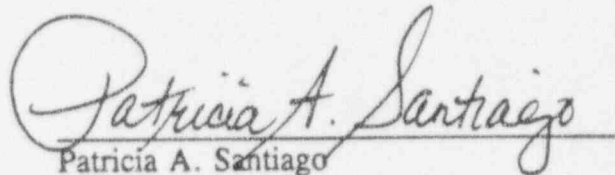
In the Matter of)
)
ONCOLOGY SERVICES CORPORATION) Docket No. 030-31765-EA
)
(Byproduct Material) EA No. 93-006
License No. 37-28540-01))

AFFIDAVIT OF PATRICIA A. SANTIAGO

I, Patricia A. Santiago, first being duly sworn, depose and state:

1. I am currently employed as the Assistant Director for Materials, Office of Enforcement, U.S. Nuclear Regulatory Commission.
2. I have participated and assisted in the preparation of the attached NRC Staff responses to interrogatories 2(a),(b),(c), and (e), and 7 filed by Oncology Services Corporation in the above-captioned proceeding.

3. I hereby certify that the answers to the above-numbered interrogatories and the request for admission are true and correct to the best of my information and belief.



Patricia A. Santiago
Assistant Director for Materials
Office of Enforcement

Subscribed and sworn to before me
this ____ of June, 1994

Notary Public

My commission expires: _____

UNITED STATES OF AMERICA
NUCLEAR REGULATORY COMMISSION

BEFORE THE ATOMIC SAFETY AND LICENSING BOARD

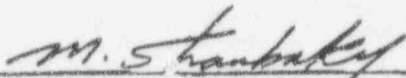
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| Material License No. 37-28540-01) |) | ASLBP No. 93-674-03-EA |

AFFIDAVIT OF MOHAMED SHANBAKY

I, Mohamed Shanbaky, first being duly sworn, depose and state:

1. I am currently employed as the Chief, Research & Development Section, Division of Radiation Safety and Safeguards, Region I, U.S. Nuclear Regulatory Commission.
2. I have participated and assisted in the preparation of the attached NRC Staff responses to Interrogatory 6 filed by Oncology Services Corporation in the above-captioned proceeding.

3. I hereby certify that the answer to the above numbered interrogatory is true and correct to the best of my information and belief.


Mohamed Shanbaky, Chief
Research & Development Section

Subscribed and sworn to before me
this ____ of June, 1994

Notary Public

My commission expires: _____

UNITED STATES OF AMERICA
NUCLEAR REGULATORY COMMISSION

DOCKETED
USNRC

'94 JUN -6 A9:16

BEFORE THE ATOMIC SAFETY AND LICENSING BOARD

OFFICE OF SECRETARY
DOCKETING & 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)
)
)

CERTIFICATE OF SERVICE

I hereby certify that copies of "NRC STAFF RESPONSES AND OBJECTIONS TO OSC'S REQUEST FOR PRODUCTION OF DOCUMENTS AND INTERROGATORIES DATED MAY 10, 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 3rd 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

Dr. Charles N. Kelber*
Administrative Judge
Atomic Safety and Licensing Board
U.S. Nuclear Regulatory Commission
Washington, D.C. 20555

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Kerry A. Kearney, Esq.
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Joseph W. Klein, Esq.
Counsel for Oncology Services Corp.
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Mellon Square
435 Sixth Avenue
Pittsburgh, PA 15219-1886

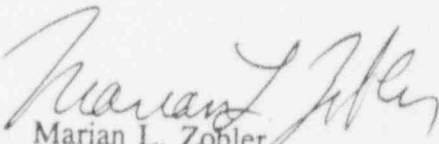
Dr. Peter S. Lam*
Administrative Judge
Atomic Safety and Licensing Board
U.S. Nuclear Regulatory Commission
Washington, D.C. 20555

Adjudicatory File (2)*
Atomic Safety and Licensing Board
U.S. Nuclear Regulatory Commission
Washington, D.C. 20555

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
Panel (1)*
U.S. Nuclear Regulatory Commission
Washington, D.C. 20555


Marian L. Zobler
Counsel for NBC Staff