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RELATED CORRESPONDENCE

June 14, 1994
DOCKETED
USNRC

UNITED STATES OF AMERICA
NUCLEAR REGULATORY COMMISSION

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BEFORE THE ATOMIC SAFETY AND LICENSING BOARD OFFICE OF SECRETARY
MARKETING & 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 SECOND SET OF INTERROGATORIES, REQUESTS
FOR PRODUCTION OF DOCUMENTS, AND REQUESTS FOR ADMISSIONS

Pursuant to 10 C.F.R. §§ 2.740b, 2.741, and 2.742 of the Commission's regulations, the NRC staff (Staff) hereby requires that Oncology Services Corporation (Licensee) respond to the following interrogatories, and produce for inspection and copying, documents requested below.¹

Each interrogatory shall be answered separately and fully, in writing, and under oath or affirmation and shall include all pertinent information available to the Licensee, its representatives, or counsel, based upon the personal knowledge of the person

¹ These discovery requests were previously served on the Licensee on December 27, 1993. Pursuant to the Board's "Order (Prehearing Conference Order)," February 1, 1994 (Board Order), the Staff indicated that due to the then pending referral to the Department of Justice (DOJ), these discovery requests need not be answered by the Licensee. "NRC Staff Identification of Staff Interrogatories Not Related to the Department of Justice Referral," February 7, 1994. Since DOJ has declined the referral, the Staff resubmits the above discovery requests. In addition, the Staff refiles discovery requests which were inadvertently omitted from the list of discovery requests which did not involve the referral to DOJ. The original interrogatory numbers have been retained. The Staff also, in a separate section, is filing new interrogatories and document production requests.

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answering. The production of the documents requested herein shall take place at the Office of General Counsel, U.S. Nuclear Regulatory Commission, 11555 Rockville Pike, Room 15-B-18, Rockville, Maryland, unless other arrangements are made, by agreement, in this regard.

INSTRUCTIONS

1. To the extent that the Licensee does not have specific, complete, and accurate information with which to answer any interrogatory, the Licensee should so state, and the interrogatory should be answered to the extent information is available, identifying each person who is believed to have accurate information with respect thereto.

2. Each interrogatory shall be deemed to be continuing, and the Licensee is required seasonably to supplement answers with additional facts, documents, information, and names of witnesses which become known, in accordance with 10 C.F.R. § 2.740(e)(1) and (2).²

3. The words "and" and "or" shall be construed either conjunctively or disjunctively so as to bring within the scope of these discovery requests any information that might otherwise be construed to be outside their scope.

4. Wherever appropriate, the singular form of a word shall be interpreted in the plural, and vice versa, so as to bring within the scope of these discovery requests any information that might otherwise be construed to be outside their scope.

²Under 10 C.F.R. § 2.740(e), parties are required, under certain circumstances, to supplement responses to discovery requests.

5. Please produce a copy of each document requested in the form and condition in which it exists on the date of service of this request, including all comments, notes, remarks, and other material that may have been added to the document after its initial preparation.

6. If the Licensee objects to or claims a privilege (*e.g.*, attorney-client, work product, or other) with respect to any interrogatory or document request, in whole or in part, or seeks to withhold documents or information because of the alleged proprietary or other nature of the data, please set forth all reasons and the underlying factual basis for the objection or claim of privilege in sufficient detail to permit the Atomic Safety and Licensing Board to determine the validity of the objection or claim of privilege. This description by the Licensee should include with respect to any document:

- a. author, addressor, addressee, and recipients of indicated and "blind" copies together with their job titles;
- b. date of preparation;
- c. subject matter;
- d. purpose for which the document was prepared;
- e. all persons to whom distributed, shown, or explained;
- f. present custodian;
- g. all persons believed to have a copy of the document; and
- h. the nature of the privilege or objection asserted.

7. For any document or part of a document that was at one time, but is no longer, in the Licensee's possession, custody, or control, or which is no longer in

existence, or which cannot be located or produced, identify the document, state where and how it passed out of existence or why it can no longer be located or produced and the reasons therefore, and identify each person having knowledge concerning such disposition or loss and the contents of the document, and identify each document evidencing its prior existence and/or any fact concerning its nonexistence or loss.

DEFINITIONS AND GUIDELINES TO BE
USED IN RESPONDING TO THIS DISCOVERY REQUEST

1. "Communication" shall mean correspondence, contact, discussion, or any other kind of written or oral exchange between two or more persons or entities including, but not limited to, all telephone conversations, face-to-face meetings or conversations, visits, conferences, and internal and external discussions, and exchange of a document or documents.

2. "Computer file" means all computer files of whatever type without regard to the manner in which the file is stored.

3. "Concerns", "Concerning", or another derivative thereof, includes referring to, responding to, relating to, pertaining to, in connection with, comprising, memorializing, commenting on, regarding, discussing, showing, describing, reflecting, analyzing, supporting, contradicting, and constituting.

4. "Document" or "writing" as used herein shall mean any written matter, whether produced, reproduced or stored on paper, cards, tapes, disks, belts, charts, film, computer storage devices or any other medium and shall include, without limitation, matter in the form of books, reports, studies, statements, speeches, notebooks,

agreements, appointment calendars, working papers, manuals, memoranda, notes, procedures, orders, instructions, directions, training materials, records, correspondence, diaries, plans, diagrams, drawings, periodicals, lists, telephone logs, minutes, photographs, and any published materials and shall also include, without limitation, originals, copies (with or without notes or changes thereon) and drafts.

5. "Identify" when used in reference to a natural person means to set forth the following:

- a. his/her name;
- b. his/her last known residential address;
- c. his/her last known business address;
- d. his/her last employer;
- e. his/her title or position;
- f. his/her area of responsibility;
- g. his/her business, professional, or other relationship with the Licensee;

and

h. If any of the above information is changed subsequent to the time period referenced in a particular interrogatory, set forth in the answer, and label appropriately, current information as well as the information applicable to the time period referenced in the interrogatory.

6. "Identify" when used in reference to a document shall mean to set forth the following:

- a. its title;
- b. its subject matter;
- c. its date;

- d. its author;
- e. its addressee;
- f. its file designation or other identifying designation; and
- g. its present location and present custodian.

7. "Identify" with respect to a contact or communication shall set forth the following:

- a. the date of the communication;
- b. the place of the making and place of receipt of the communication;
- c. the type and means of communication;
- d. the substance of the communication;
- e. each person making a communication, and his location at the time the communication was made;
- f. each person to whom the communication was made, and his location at the time the communication was made;
- g. all other persons present during, participating in, or receiving the communication and the location of each such person at the time;
- h. each document concerning such communication; and
- i. each document upon which the communication is based or which is referred to in the communication.

8. "Identify" when used with respect to a computer file shall set forth the following:

- a. the full file name including extension;
- b. the number of bytes in the file;

- c. the date and time of file creation;
- d. a statement of the purpose for which the file can be used;
- e. the computer equipment necessary or convenient to use the file;

9. "License" means in the context of this discovery request NRC Byproduct Material License No. 37-28540-01.

10. "Licensee" means in the context of this discovery request Oncology Services Corporation.

11. "Personnel" means in the context of this discovery request those individuals working at the specified facility, whether or not directly employed by the Licensee.

12. Unless indicated otherwise, the Licensee should apply the plain and common meaning to each word or term used in these discovery requests.

13. The Staff requests that documents produced in compliance with this request be accompanied with a specific indication as to the particular paragraphs of the Staff's discovery request under which the documents are being produced.

I. INTERROGATORIES AND REQUESTS FOR PRODUCTION OF DOCUMENTS PREVIOUSLY FILED

C. Interrogatories Relative to the violation of 10 C.F.R. 20.201(b) survey requirement

INTERROGATORY 1

Explain how each of the following facts, if true, demonstrates that the IRCC personnel's, including Dr. James E. Bauer's,³ actions were reasonable under the circumstances to evaluate the extent of radiation hazards that may be present, pursuant

³ This interrogatory had been modified, in accordance with the Board's Order to exclude any reference to Dr. Bauer's conduct. The Staff resubmits this interrogatory to specifically include Dr. Bauer's conduct. The Licensee need only respond to this interrogatory as it relates specifically to Dr. Bauer's conduct.

to 10 C.F.R 20.201(b) on November 16, 1992. Provide the names of all individuals who can testify that these facts are true and provide all supporting documentation, to the extent that this information has not already been provided in response to another interrogatory. If information has been provided in response to another interrogatory, reference the responsive interrogatory or interrogatories.

a. The NRC approved Omnitron training, operating manual and/or emergency procedures.

b. All treating personnel at IRCC including the Medical Director/Authorized User, the physicist and both technologists received training from Omnitron using the Omnitron emergency procedures and Omnitron operating manual.

c. Dr. Bauer, as well as all Omnitron-trained Authorized Users, were trained pursuant to Omnitron's course that the source wire could not break.

d. The treating personnel at IRCC followed the emergency procedures in the Omnitron manual.

e. The physician/authorized user systematically reviewed the redundant Omnitron internal safety check alerts.

f. The Omnitron 2000 High Dose Rate (HDR) afterloader was defective.

g. Reliance by IRCC personnel on specific features of the Omnitron was reasonable on November 16, 1992.

h. The Licensee was not informed by Omnitron and the Licensee did not know otherwise of the possibility of deterioration despite Omnitron's knowledge of deterioration of the source wire due to a chemical reaction resulting from its packaging.

i. The treating personnel relied on the internal safety devices of the Omnitron 2000 which due to multiple machine failures incorrectly indicated source retraction.

j. The Omnitron 2000 design, manufacturing and/or warning defects was a cause of the November 16, 1992 incident in which the source wire broke.

k. The November 16, 1992 incident at IRCC occurred because of an unanticipated failure of the Omnitron 2000 retraction mechanism and a reliance by the authorized user on Omnitron procedures which did not anticipate or cover this emergency.

1. Prior to November 16, 1992, the emergency scenario that the Omnitron source wire breaks was neither expected nor reasonably anticipated by the Licensee in general and the IRCC treating personnel in particular.

INTERROGATORY 2

What other facts, other than the ones listed above, does the Licensee intend to rely upon to demonstrate that the IRCC personnel, including Dr. Bauer's, complied with 10 C.F.R. § 20.201(b)?⁴

INTERROGATORY 4

Describe all the difficulties the IRCC personnel encountered with the HDR treatment on November 16, 1992. Describe any and all indications the IRCC personnel received from the Omnitron 2000 unit regarding these difficulties, including whether these indications provided any information regarding the presence of radiation. Identify the IRCC personnel who were aware of these indications. Did any of the personnel identified, above, inform the IRCC Medical Director/Authorized User of these indications? If yes, describe what the Medical Director/Authorized User was told.

INTERROGATORY 5

Describe all indications regarding the difficulty of the HDR treatment on November 16, 1992 received by the IRCC personnel, other than the ones from the Omnitron 2000 unit. Did any of the above-described indications provide any information regarding the presence of radiation? Did any of the personnel identified above inform the IRCC Medical Director/Authorized User of these indications? If yes, describe what the Medical Director/Authorized User was told.

INTERROGATORY 9

Identify the IRCC personnel who saw the room radiation monitor (PrimeAlert) flash red during the November 16, 1992 incident. When did the above-identified personnel first notice the room radiation monitor flashing red.

⁴ This interrogatory had been modified, in accordance with the Board's Order to exclude any reference to Dr. Bauer's conduct. The Staff resubmits this interrogatory to specifically include Dr. Bauer's conduct. The Licensee need only respond to this interrogatory as it relates specifically to Dr. Bauer's conduct.

INTERROGATORY 10

Identify the IRCC personnel, present at the IRCC on November 16, 1992, who were aware of the fact that the room radiation monitor (PrimeAlert) flashed red during the November 16, 1992 incident. Explain:

- a. when did the above-identified personnel first become aware of the fact that the room radiation monitor had flashed red;
- b. how the above-identified personnel became aware of the fact that the room radiation monitor had flashed red; and
- c. if the above-identified personnel were informed by another individual at the IRCC, identify that individual(s).

INTERROGATORY 11

On November 16, 1992, did any of the IRCC personnel unplug, disable, reset, disengage, or otherwise adjust the room radiation monitor? If yes:

- a. identify who unplugged, disabled, reset, disengaged, or otherwise adjusted the room radiation monitor on November 16, 1992;
- b. describe his or her actions regarding the room radiation monitor; and
- c. the reasons for the above-described action.

INTERROGATORY 12

During the November 16, 1992 incident at the IRCC, did any of the IRCC personnel present believe that the room radiation monitor was not functioning? If yes, identify the individual(s) who believed that the monitor was not functioning.

INTERROGATORY 13

During the November 16, 1992 incident at the IRCC, did any of the IRCC personnel present believe that the room radiation monitor had signaled a false alarm? If yes, identify the individual(s) who believed that the monitor had signaled a false alarm.

INTERROGATORY 17

Explain how the Licensee intends to establish that License Condition 17 was not violated by the IRCC's personnel, including Dr. Bauer's, failure to enter the treatment room without either a portable survey meter or an audible dosimeter on November 16, 1992 when difficulty with the treatment was encountered.

INTERROGATORY 18

Assuming that fulfillment of any applicable survey requirements of 10 C.F.R. Part 35, Subpart G satisfies the survey requirement of 10 C.F.R. § 20.201(b), explain how the IRCC personnel satisfied any of the applicable survey requirements of 10 C.F.R. Part 35, Subpart G.

E. Interrogatories Relative to Corporate Management Breakdown

INTERROGATORY 4

Identify the personnel from the facilities listed on the License who attended the corporate training in Atlantic City in August, 1992. Provide all supporting documentation.⁵

INTERROGATORY 7

Describe the in-service training provided by Dr. Cunningham, including:

- a. a list of subjects covered;
- b. the approximate length of time devoted to each subject; and
- c. the date of this training.

⁵ This interrogatory was inadvertently modified to exclude any reference to the authorized user at the Leighton facility. The Staff resubmits this interrogatory, as originally submitted, to specifically reference the authorized user. The Licensee need only respond to this interrogatory as it relates to the authorized user.

Identify the personnel from each of the facilities listed on the License who attended this training. How often was this training provided at each of the facilities listed on the License?⁶

INTERROGATORY 10

Identify the personnel from each of the facilities listed on the license who attended the refresher training described above in response to Interrogatory E9.⁷

INTERROGATORY 12

Describe any other radiation safety training provided by the Licensee, its employees, agents, contractors, or assignees provided to the personnel at the Exton and Lehighton facilities prior to December 8, 1992. Identify the personnel from each of the facilities who attended this training. How often was this training provided?⁸

INTERROGATORY 25

Prior to December 8, 1992, had Dr. David J. Moylan, Medical Director of the Lehighton facility and authorized user under the License, read the terms and conditions of the License?

INTERROGATORY 26

Prior to December 8, 1992, was Dr. David J. Moylan aware that Dr. Cunningham was the RSO named on the License?

⁶ This interrogatory was inadvertently modified to exclude any reference to the authorized user at the Lehighton facility. The Staff resubmits this interrogatory, as originally submitted, to specifically reference the authorized user. The Licensee need only respond to this interrogatory as it relates to the authorized user.

⁷ This interrogatory was inadvertently modified to exclude any reference to the authorized user at the Lehighton facility. The Staff resubmits this interrogatory, as originally submitted, to specifically reference the authorized user. The Licensee need only respond to this interrogatory as it relates to the authorized user. In addition, the reference to interrogatory E9 refers to the Staff's interrogatory E9 from the Staff's discovery requests dated December 27, 1993.

⁸ This interrogatory was inadvertently modified to exclude any reference to the authorized user at the Lehighton facility. The Staff resubmits this interrogatory, as originally submitted, to specifically reference the authorized user. The Licensee need only respond to this interrogatory as it relates to the authorized user.

INTERROGATORY 27

Did Dr. David J. Moylan indicate during the December 8, 1992 inspection to an NRC inspector that he had not read the terms and conditions of the License and was not aware that Dr. Cunningham was the RSO named on the License? If no, describe any conversation which took place on December 8, 1992 between Dr. Moylan and NRC inspectors.

REQUEST FOR ADMISSIONS⁹

2. During the November 16, 1992 incident at the IRCC, Dr. Bauer was aware that the room radiation monitor had flashed red, indicating the presence of radiation.

If the response to request for admission 2 is anything other than an unqualified admission, explain the basis for the response provided.

3. Dr. Bauer and the radiation therapy technologists at the IRCC knew and understood, on November 16, 1992, the significance of the alarm ("red flash") on the room radiation monitor.

If the response to request for admission 3 is anything other than an unqualified admission, explain the basis for the response provided.

II. NEW INTERROGATORIES AND REQUESTS FOR THE PRODUCTION OF DOCUMENTS

INTERROGATORY 1

a) Is it the Licensee's belief that Part 20 of Title 10 of the Code of Federal Regulations does not apply to the License or the Licensee?

b) If the response to interrogatory 1a is in the affirmative, describe the basis for the Licensee's belief that Part 20 does not apply to the License or the Licensee.

c) Identify any and all documents relied upon by the Licensee to support its response to interrogatory 1b.

⁹ The above requests for admissions have been modified since the Staff's initial filing on December 27, 1993.

INTERROGATORY 2

- a) Is it the Licensee's belief that Part 35 (other than Subpart G of Part 35) of Title 10 of the Code of Federal Regulations does not apply to the License or the Licensee?
- b) If the response to interrogatory 2a is in the affirmative, describe the basis for the Licensee's belief that Part 35 does not apply to the License or the Licensee.
- c) Identify any and all documents relied upon by the Licensee to support its response to interrogatory 2b.

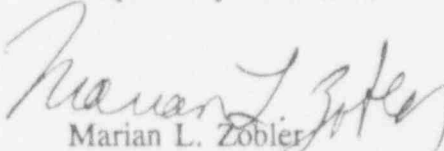
INTERROGATORY 3

- a) Is it the Licensee's belief that Part 19 of Title 10 of the Code of Federal Regulations does not apply to the License or the Licensee?
- b) If the response to interrogatory 3a is in the affirmative, describe the basis for the Licensee's belief that Part 19 does not apply to the License or the Licensee.
- c) Identify any and all documents relied upon by the Licensee to support its response to interrogatory 3b.

REQUEST FOR PRODUCTION OF DOCUMENTS

Provide copies of all documents identified in response to interrogatories II.1, II.2, and II.3.

Respectfully submitted,


Marian L. Zoblir
Counsel for NRC Staff

Dated at Rockville, Maryland
this 14th day of June, 1994

UNITED STATES OF AMERICA
NUCLEAR REGULATORY COMMISSION

DOCKETED
USNRC

'94 JUN 15 A10:36

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'S SECOND SET OF INTERROGATORIES, REQUESTS FOR PRODUCTION OF DOCUMENTS, AND REQUESTS FOR ADMISSIONS" in the above-captioned proceeding have been served on the following by facsimile transmission, or as indicated by an asterisk through deposit in the Nuclear Regulatory Commission's internal mail system this 14th day of June, 1994:

G. Paul Bollwerk, III, Chairman*
Administrative Judge
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U.S. Nuclear Regulatory Commission
Washington, D.C. 20555

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Dr. Peter S. Lam*
Administrative Judge
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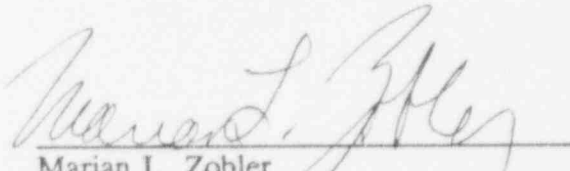
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