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June 21, 1994

RELATED CORRESPONDENCE

DOCKETED
USNRC

UNITED STATES OF AMERICA
NUCLEAR REGULATORY COMMISSION

'94 JUN 22 P3:24

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))	
)	

NRC STAFF'S THIRD SET OF INTERROGATORIES
AND REQUESTS FOR THE PRODUCTION OF DOCUMENTS

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

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 answering. The production of the documents requested herein shall take place at the Office of the 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.

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PDR ADOCK 03031765
C PDR

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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).¹

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.

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

¹Under 10 C.F.R. § 2.740(e), parties are required, under certain circumstances, to supplement responses to discovery requests.

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.

NRC STAFF'S INTERROGATORIES AND
REQUEST FOR THE PRODUCTION OF DOCUMENTS

INTERROGATORY 1

Describe the substance of the expected testimony of each of the following individuals identified in the Licensee's Response to NRC Staff's First Set of Interrogatories and Requests for Production for Documents and Request for Admissions, dated June 10, 1994, (Response), in response to the Staff's interrogatory A1:

James Bauer, M.D.
Rudy Balko
Sharon Rickett
Greg Hay
Dave Cunningham, Ph.D.
William Ying, Ph.D.
Paula Salanitro
David Moylan, M.D.
Robbie Ackerson
Richard Yelovich, M.D.
Mark Batog
Lorraine Copenhagen
Richard Croley
Karen Wagner
Amirul Hoque, Ph.D.
Mitch Jarosz
Dr. Mohamed Shanbaky
James Lieberman, Esquire
Donna Green
Ann Wright
Abne Hasan, M. D.
Bernard Rogers, M.D.
Connie Shope
Connie Hawkins
Robert H. Davis, Ph.D.
Abdurrahman Unal, M.D.

Roger P. Tokars, M.D.
John Glenn, Ph.D.
Carl Paperiello, Ph.D.
Daniel Flynn, M.D.
Judith Joustra
Pamela Henderson
Pat Santiago
Jerry Derdel, M.D.
Susan Shankman, Ph.D.

INTERROGATORY 2

Identify each and every individual "GammaMed Personnel" referenced in the Licensee's Response to the Staff's interrogatory A1 who the Licensee intends to call as witnesses in this proceeding. Describe, in detail, the substance of the expected testimony of the identified "GammaMed Personnel."

INTERROGATORY 3

Identify, including the title and date, "any and all documents produced to the Licensee by the NRC," referenced by the Licensee in its Response to the Staff's interrogatory A4, as documents the Licensee intends to rely upon in this proceeding.

INTERROGATORY 4

Identify, including the title and date, "any and all official NRC documents, including drafts," referenced by the Licensee in its Response to the Staff's interrogatory A4, as documents the Licensee intends to rely upon in this proceeding.

INTERROGATORY 5

Describe, in detail, the "aspects of radiation safety" in which the Licensee claims it instructed the personnel at the IRCC in its Response to the Staff's interrogatory B2.

INTERROGATORY 6

In its Response to the Staff's interrogatory B3, the Licensee states that "instruction was provided by Rudy Balko, [and] Sharon Rickett." In connection with that statement, describe, in detail, the instruction provided by Rudy Balko, including, but not limited to, to whom Mr. Balko provided such instruction. Describe, in detail, the instruction provided by Sharon Rickett, including but not limited to, to whom Ms. Rickett provided such instruction.

INTERROGATORY 7

Describe, in detail, Greg Hay's general physics responsibilities referenced in the Licensee's Response to the Staff's interrogatory B10.

INTERROGATORY 8

Describe, in detail, "any and all facts and circumstances surrounding the November 16, 1992 incident," referenced in the Licensee's Response to the Staff's interrogatory C2, which demonstrate that the IRCC personnel's actions, including the actions of Dr. Bauer, complied with 10 C.F.R. § 20.201(b).

INTERROGATORY 9

Describe, in detail, the emergency procedures, referenced in the Licensee's Response to the Staff's interrogatory C3, followed by the IRCC personnel on November 16, 1992.

INTERROGATORY 10

Explain why, if none of the IRCC personnel believed that the room radiation monitor had signaled a false alarm, as indicated by the Licensee in its Response to the Staff's interrogatory C12, the IRCC personnel ignored the signal from the room radiation monitor.

INTERROGATORY 11

Do any of the safety alerts and/or alarms on the Omnitron 2000 HDR afterloader measure the presence of radiation? If yes, identify which alerts or alarms measure the presence of radiation.

INTERROGATORY 12

In its Response to the Staff's interrogatory C11, the Licensee states that Rudy Balko believed the "plug" to the PrimeAlert was loose. In connection with that statement, explain, in detail, why Mr. Balko believed the "plug" was loose. Describe the "plug" on the PrimeAlert that Mr. Balko believed was loose, include a description of the purpose and/or function of this "plug."

INTERROGATORY 13

Describe, in detail, the survey that was performed that was referenced in the Licensee's Response to the Staff's interrogatory C18. Explain the basis of the Licensee's assertion, in its Response to the Staff's interrogatory C18, that under either 10 C.F.R. section 35, subpart G or 10 C.F.R. § 20.201(b), no greater survey than the one allegedly performed was required.

INTERROGATORY 14

Define the term "emergency condition" as used in the Licensee's Response to the Staff's interrogatory C17.

INTERROGATORY 15

Describe, in detail, "any and all other circumstances existing prior to January 20, 1993," referenced in the Licensee's Response to the Staff's interrogatory E2, that indicate there was an absence of a significant corporate management breakdown in the control of licensed activities prior to January 20, 1993.

INTERROGATORY 16

Identify each and every license term and condition of which Dr. Moylan was generally aware as of December 8, 1992.

INTERROGATORY 17

In its Response to the Staff's interrogatory E29, the Licensee states that "License Condition 17, in part, requires a review of the situation where the source does not retract." In connection with that statement, is it the Licensee's assertion that a "review"

includes a simulated emergency, that is, a dry run? If yes, explain, in detail, the basis for the Licensee's assertion. Identify any and all documents which support the Licensee's assertion. In connection with the Licensee's explanation, define the Licensee's understanding of the terms "dry run" and "simulated emergency."

INTERROGATORY 18

Is it the Licensee's assertion that a PrimeAlert is a survey instrument? If yes, explain, in detail, the basis for the Licensee's assertion. Identify any and all documents that support the Licensee's assertion.

INTERROGATORY 19

Did the Omnitron training provided to the Licensee's personnel include a dry run of the source not retracting at the end of treatment? If yes, identify the personnel at each of the Licensee's facilities listed on the License who received the Omnitron training which included this dry run. Identify any and all documents supporting the Licensee's response.

INTERROGATORY 20

Were the personnel at the Licensee's Exton facility trained by Dr. Ying in HDR sessions that occurred between November 1991 and February 1992? If yes, how many times did Dr. Ying visit the Licensee's Exton facility. Did any of the training provided by Dr. Ying include training in the terms and conditions of the license, and/or the Licensee's Quality Management Program? Identify any and all documents supporting the Licensee's Response.

INTERROGATORY 21

Is Dr. Ying an authorized user under the License? Explain, in detail, the basis for the Licensee's response. Identify any and all documents supporting the Licensee's response.

INTERROGATORY 22

Which Lehighton (Mahoning Valley) and Exton personnel received the Omnitron training? Identify any and all documents that indicate Omnitron training was provided to these individuals.

INTERROGATORY 23

Describe, in detail, the training provided to the Licensee's personnel by GammaMed. Did this training include basic radiation safety training? If yes, describe, in detail, the basic radiation safety training provided. Identify the Licensee's personnel who received such training from GammaMed. Identify any and all documents which support the Licensee's Response.

INTERROGATORY 24

Did the physicist at the Licensee's Exton facility receive additional calibration training on the HDR unit in Harrisburg, Pennsylvania or some other location? If yes, identify who provided this additional calibration training. When was this training provided. Did the Licensee pay for this training? Identify any and all documents supporting the Licensee's response.

INTERROGATORY 25

In its Response to the Staff's interrogatory E9, the Licensee states "Dr. Cunningham reviewed operations relating to HDR usage and physics at meetings." In connection with this statement, did Dr. Cunningham's review of operations relating to HDR usage and physics at meetings include:

- a. The correct use and operation of a portable survey meter, including how to interpret the readings of a survey meter in order to determine the presence of a radioactive source in a patient or in the area;
- b. The correct use and operation of wall-mounted radiation survey meters;
- c. The correct use and operation of door interlocks;
- d. The correct use and operation of patient audio-visual communications systems;
- e. Training in the License;
- f. Training in the License Conditions; and
- g. Training in the NRC regulations.

Identify any and all documents supporting the Licensee's response.

INTERROGATORY 26

As of December 8, 1992, were the technologists at the Licensee's Exton and Lehighton (Mahoning Valley) facilities trained in and familiar with the required procedures and actions necessary to comply with the relevant license conditions and regulations? If

yes, explain, in detail, the basis of the Licensee's response. Identify any and all documents supporting the Licensee's response.

INTERROGATORY 27

As of December 8, 1992, did ongoing individualized, apprentice type training by the Medical Directors/Authorized User, Physicists, and others occur at all or some of the Licensee's facilities listed on the License? If yes, describe, in detail, where and how this type of training was provided. For each of the facilities listed on the License, identify the individual(s) who provided this type of training and to whom this training was provided. Identify any and all documents supporting the Licensee's response.

INTERROGATORY 28

As of November 16, 1992, were any HDR treatments performed by the IRCC personnel prior to the completion of the proper training under the pertinent regulations and license conditions? If no, identify the pertinent regulations and license conditions the IRCC personnel were trained in and when the IRCC personnel received this training?

INTERROGATORY 29

In "Response of Oncology Services Corporation ("OSC") to Order of NRC Dated January 20, 1993 Suspending By-Product Material License Number 37-28540-01," dated February 8, 1993 (Answer), the Licensee states "[a]n in-service was provided by Dr. Cunningham on HDR including basic radiation safety, training requirements, HDR emergency response, film badge use, distances, shielding and time and survey meter use." Answer at 4. As used by the Licensee in its Answer, define the term "in-service." When

was this "in-service" provided? Identify the personnel from the Licensee's facilities listed on the License who received this "in-service." Identify any and all documents supporting the Licensee's response to this interrogatory.

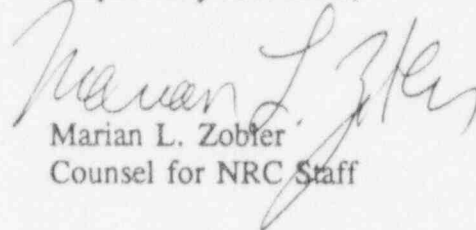
REQUEST FOR PRODUCTION 1

Provide a copy of the resume or curriculum vitae for Sidney A. Goldblatt, M.D., Director of Medical Laboratories, who signed the "Colgan Autopsy dated December 21, 1992," referenced in the Licensee's Response to the Staff's interrogatory A4.

REQUEST FOR PRODUCTION 2

Provide a copy of every document identified in response to the above interrogatories. If a document has already been provided, please indicate that such document has already been provided and identify such document by title and date.

Respectfully submitted,


Marian L. Zobler
Counsel for NRC Staff

Dated at Rockville, Maryland
this 21st day of June, 1994

UNITED STATES OF AMERICA
NUCLEAR REGULATORY COMMISSION

DOCKETED
USNRC

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

CERTIFICATE OF SERVICE

I hereby certify that copies of "NRC STAFF'S THIRD SET OF INTERROGATORIES AND REQUESTS FOR THE PRODUCTION OF DOCUMENTS" 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 21st 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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Dr. Peter S. Lam*
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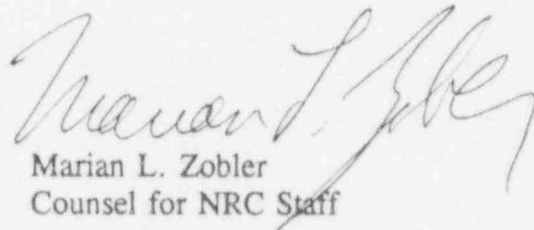
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Adjudicatory File (2)*
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U.S. Nuclear Regulatory Commission
Washington, D.C. 20555

Office of the Secretary (2)*
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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 NRC Staff