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RELATED CORRESPONDENCE

DOCKETED
May 18 1994
USNRC

UNITED STATES OF AMERICA
NUCLEAR REGULATORY COMMISSION

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BEFORE THE ATOMIC SAFETY AND LICENSING BOARD

OFFICE OF SECRETARY

In the Matter of)	
)	
INDIANA REGIONAL CANCER CENTER)	Docket No. 030-30485-EA
INDIANA, PENNSYLVANIA)	
)	
(Byproduct Material)	EA No. 93-284
License No. 37-28179-01))	
)	

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

Pursuant to 10 C.F.R. §§ 2.740b and 2.741 of the Commission's regulations, the staff of the Nuclear Regulatory Commission (Staff) hereby requires that the Indiana Regional Cancer Center (IRCC or Licensee) and Dr. James E. Bauer¹ respond to the following interrogatories and produce 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 or Dr. Bauer, its representatives, or counsel, based upon the personal knowledge of the person answering. The production of the documents requested herein shall take place at

¹ Since the Licensee and Dr. Bauer are represented by the same counsel and since the Order Modifying and Suspending License No. 37-28179-01, involves the conduct of Dr. Bauer, the Staff is directing these discovery requests to both the Licensee and Dr. Bauer in the interest of saving time and avoiding duplicative answers.

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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 or Dr. Bauer does not have specific, complete, and accurate information with which to answer any interrogatory, the Licensee or Dr. Bauer 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 and Dr. Bauer are 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.

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

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 comments, notes, remarks, and other material that may have been added to the document after its initial preparation.

6. If the Licensee or Dr. Bauer 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. "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.

3. "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.

4. "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/or Dr. Bauer; 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.

5. "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.

6. "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.

7. "License" means in the context of this discovery request NRC Byproduct Material License No. 37-28179-01.

8. "Licensee" means in the context of this discovery request the Indiana Regional Cancer Center.

9. "The November 16, 1992 Incident" means in the context of this discovery request the incident at the Indiana Regional Cancer Center (IRCC) on November 16, 1992, in which a radioactive source was left inside a patient receiving treatment using an Omnitron 2000 HDR Afterloader.

INTERROGATORIES AND REQUESTS
FOR THE PRODUCTION OF DOCUMENTS

INTERROGATORY 1

During the November 16, 1992 incident, did the wall area radiation monitor (PrimeAlert) flash the red alarm signal before the patient left the treatment room at the IRCC?

INTERROGATORY 2

If the response to interrogatory 1 is in the negative, explain in detail the basis for the negative response.

INTERROGATORY 3

If the response to interrogatory 1 is in the affirmative, did James E. Bauer, M.D. see the PrimeAlert flash the red alarm signal before the patient left the treatment room at the IRCC?

INTERROGATORY 4

If the response to interrogatory 3 is in the negative, was Dr. Bauer informed, while the patient was still in the treatment room at the IRCC, that the PrimeAlert had flashed the red alarm signal?

INTERROGATORY 5

If the response to interrogatory 3 is in the negative, explain the basis for the negative response.

INTERROGATORY 6

If the response to interrogatory 4 is in the affirmative, identify the individual who so informed Dr. Bauer that the PrimeAlert had flashed the red alarm signal, approximately when Dr. Bauer (before or after Dr. Bauer entered the treatment room) was so informed, and provide, in detail, what Dr. Bauer was told.

INTERROGATORY 7

Identify all individuals present during the November 16, 1992 Incident.

INTERROGATORY 8

Identify all individuals present during the November 16, 1992 Incident who saw the PrimeAlert flash the red alarm signal before the patient left the treatment room at the IRCC.

INTERROGATORY 9

If the response to interrogatory 3 or 4 is in the affirmative, did Dr. Bauer perform a survey, as defined in 10 C.F.R. § 20.201(a), of the area, after becoming aware that the PrimeAlert had flashed the red alarm signal? If yes, explain in detail the basis for the affirmative response. Describe the survey allegedly performed by Dr. Bauer, including the results of such survey and identify any records, as defined in 10 C.F.R. § 20.401(b), or other documents created or maintained concerning such survey.

REQUEST FOR PRODUCTION OF DOCUMENTS 1

Provide copies of all records and/or documents identified in response to interrogatory 9.

INTERROGATORY 10

If the response to interrogatory 9 is in the negative, did Dr. Bauer cause a survey, as defined in 10 C.F.R. § 20.201(a), of the treatment room to be performed after becoming aware that the PrimeAlert red alarm signal? If yes, explain in detail the basis for the affirmative response. Describe any such survey Dr. Bauer allegedly caused to be performed, including the results of such survey and identify any records, as defined by 10 C.F.R. § 20.401(b), or other documents created or maintained concerning such survey. Identify the individual(s) who performed such survey.

REQUEST FOR DOCUMENT PRODUCTION 2

Provide copies of all records and/or documents identified in response to interrogatory 10.

INTERROGATORY 11

Prior to and including November 16, 1992, was Dr. Bauer aware of the significance of a PrimeAlert red alarm signal?

INTERROGATORY 12

If the answer to interrogatory 11 is in the affirmative, what was Dr. Bauer's understanding as to the significance of a PrimeAlert red alarm signal?

INTERROGATORY 13

During the November 16, 1992 Incident were difficulties encountered concerning the treatment of the patient using the Omnitron 2000 High Dose Rate Afterloader, including but limited to the listing of error messages from the Omnitron 2000 HDR Afterloader?

INTERROGATORY 14

If the response to interrogatory 13 is in the affirmative, describe the difficulties encountered concerning the treatment of the patient using the Omnitron 2000 High Dose Rate Afterloader.

INTERROGATORY 15

If the response to interrogatory 13 is in the negative, describe the basis for the negative response.

INTERROGATORY 16

During the November 16, 1992 Incident, was Dr. Bauer informed of the difficulties described in response to interrogatory 14?

INTERROGATORY 17

If the response to interrogatory 16 is in the affirmative, describe what Dr. Bauer was told regarding those difficulties. Identify the individual(s) who so informed Dr. Bauer and approximately when Dr. Bauer was so informed.

INTERROGATORY 18

During the November 16, 1992 Incident did the PrimeAlert fail or malfunction? If yes, describe, in detail, how the PrimeAlert failed or malfunctioned. Identify all individuals present at the IRCC during the November 16, 1992 Incident who were aware that the PrimeAlert had failed or malfunctioned.

INTERROGATORY 19

Is it the Licensee's assertion that during the November 16, 1992 Incident a survey was not necessary in order to comply with the regulations in 10 C.F.R. Part 20?

INTERROGATORY 20

If the response to interrogatory 19 is in the affirmative, explain the basis for the Licensee's assertion that a survey was not necessary in order to comply with the regulations in 10 C.F.R. Part 20?

INTERROGATORY 21

Is it the Licensee's assertion that during the November 16, 1992 Incident the performance of a survey was not reasonable under the circumstances to evaluate the extent of radiation hazards that may have been present?

INTERROGATORY 22

If the response to interrogatory 21 is in the affirmative, explain the basis for the Licensee's assertion that performance of a survey was not reasonable under the circumstances to evaluate the extent of the radiation hazards that may have been present.

INTERROGATORY 23

Is it Dr. Bauer's assertion that during the November 16, 1992 Incident a survey was not necessary in order to comply with the regulations in 10 C.F.R. Part 20?

INTERROGATORY 24

If the response to interrogatory 23 is in the affirmative, explain the basis for Dr. Bauer's assertion that a survey would not have been necessary in order to comply with the regulations in 10 C.F.R. Part 20.

INTERROGATORY 25

Is it Dr. Bauer's assertion that during the November 16, 1992 Incident performance of a survey was not reasonable under the circumstances to evaluate the extent of the radiation hazards that may have been present?

INTERROGATORY 26

If the response to interrogatory 25 is in the affirmative, explain the basis for Dr. Bauer's assertion that performance of a survey was not reasonable under the circumstances to evaluate the extent of radiation hazards that may have been present.

INTERROGATORY 27

Is it the Licensee's belief that 10 C.F.R. Part 20 does not apply to Oncology Services Corporation's Byproduct Material License No. 37-28540-01 (HDR License)?

INTERROGATORY 28

If the response to interrogatory 27 is in the affirmative, describe the basis for the Licensee's belief that Part 20 does not apply to the HDR License?

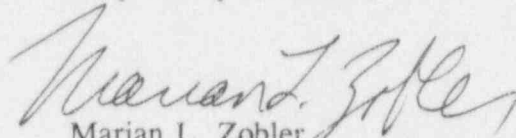
INTERROGATORY 29

Is it Dr. Bauer's belief that 10 C.F.R. Part 20 does not apply to the HDR License?

INTERROGATORY 30

If the response to interrogatory 29 is in the affirmative, describe the basis for Dr. Bauer's belief that Part 20 does not apply to the HDR License.

Respectfully submitted,


Marian L. Zobler
Counsel for NRC Staff

Dated at Rockville, Maryland
this 18th day of May, 1994

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USNRC

UNITED STATES OF AMERICA
NUCLEAR REGULATORY COMMISSION '94 MAY 19 11:43

BEFORE THE ATOMIC SAFETY AND LICENSING BOARD

OFFICE OF SECRETARY
DOCKETING & SERVICE
BRANCH

In the Matter of)	
)	
INDIANA REGIONAL CANCER CENTER)	Docket No. 030-30485-EA
INDIANA, PENNSYLVANIA)	
)	
(Byproduct Material)	EA No. 93-284
License No. 37-28179-01))	

CERTIFICATE OF SERVICE

I hereby certify that copies of "NRC STAFF'S SECOND SET OF INTERROGATORIES AND REQUESTS FOR THE PRODUCTION OF DOCUMENTS" in the above-captioned proceeding have been served on the following through deposit in the Nuclear Regulatory Commission's internal mail system, or by facsimile transmission as indicated by an asterisk, this 18th day of May, 1994:

G. Paul Bollwerk, III, Chairman
Administrative Judge
Atomic Safety and Licensing Board
U.S. Nuclear Regulatory Commission
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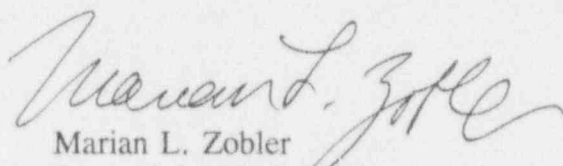
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Office of the Secretary (2)
U.S. Nuclear Regulatory Commission
Washington, D.C. 20555
Attn: Docketing and Service Branch

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

Atomic Safety and Licensing Board
Panel (1)
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Adjudicatory File (2)
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Counsel for NRC Staff