MELATED CORRESPONDENCE

March PO 1994 ED

UNITED STATES OF AMERICA NUCLEAR REGULATORY COMMISSION

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BEFORE THE ATOMIC SAFETY AND LICENSING BOARD CKETING A SERVICE

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

NRC STAFF'S FIRST SET OF INTERROGATORIES AND REQUEST FOR PRODUCTION OF DOCUMENTS AND REQUEST FOR ADMISSIONS

Pursuant to 10 C.F.R. §§ 2.740, 2.740b, 2.741, and 2.742 of the Commission's regulations, the NRC staff (Staff) hereby requires that the Indiana Regional Cancer Center (IRCC or Licensee) and Dr. James E. Bauer¹ respond to the following interrogatories and

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. The Staff requests that where appropriate, Dr. Bauer and the Licensee provide separate answers. If both Dr. Bauer and the Licensee agree to an answer to a particular interrogatory, the Staff requests that, in their response, this agreement is so noted. In addition, the Staff requests that the appropriate affidavits be provided certifying that the answers provided are true and correct. See 10 C.F.R. § 2.740b(b).

requests for admissions² 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, their 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 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,

Responses to request for admissions should be provided within a time designated by the presiding officer and not less then ten days after service of the request. See 10 C.F.R. § 2.742. Since there has been no time designated by the presiding officer to respond to requests for admissions, the Staff will accept responses to its requests for admissions at the same time the Licensee and Dr. Bauer provide their responses to the Staff's interrogatories, 14 days after service. 10 C.F.R. § 2.740b.

and names of witnesses which become known, in accordance with 10 C.F.R. § 2.740(e)(1) and (2).3

- 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.
- Unless there is an indication to the contrary, the plain and usual definition
 of each word used in this discovery request should be used.
- 6. 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.
- 7. 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

³ Under 10 C.F.R. § 2.740(e), parties are required, under certain circumstances, to supplement responses to discovery requests.

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.
- 8. 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;
 - 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.
- 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 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 dranents are being produced.

INTERROGATORIES AND REQUESTS FOR PRODUCTION OF DOCUMENTS

INTERROGATORY 1

- a) Identify any person the Licensee intends to call as a witness in this proceeding.
- b) Identify any person Dr. Bauer intends to call as a witness in this proceeding.

INTERROGATORY 2

With respect to any person listed in response to interrogatory 1, state the details of that person's education, employment history and asserted area of expertise, or, in the alternative, a copy of such person's curriculum vitae may be provided.

INTERROGATORY 3

Identify any persons4 who have knowledge of the facts concerning:

- a. The use of the strontium-90 source at the IRCC.
- b. Any incomplete or inaccurate statements made by Dr. James E. Bauer to the NRC.
- c. any other fact touching upon the matters in controversy herein, including, but not limited to, all persons from whom the Licensee and/or Dr. Bauer has obtained or attempted to obtain written or oral statements, whether or not the Licensee and/or Dr. Bauer intends to call that person as a witness in this proceeding.

INTERROGATORY 4

- a) Identify all documents the Licensee intends to rely on in this proceeding.
- b) Identify all documents Dr. Bauer intends to rely on in this proceeding.

⁴ Pursuant to 10 C.F.R. § 2.740(e)(1)(i), a party is under a duty to supplement its response to any question directly addressed to the identity and location of persons having knowledge of discoverable matters.

REQUEST FOR PRODUCTION 1

Provide copies of all of the documents identified response to interrogatory 4.

INTERROGATORY 5

As to each document identified in response to interrogatory 4, state whether or not the Licensee and/or Dr. Bauer intends to seek to move each such document into the record as evidence in this proceeding.

INTERROGATORY 6

As to each document identified in response to Interrogatory 4, state what fact or opinion the Licensee and/or Dr. Bauer intend to establish if the document is admitted into evidence.

INTERROGATORY 7

- a) Identify the individual who allegedly specifically asked the NRC inspectors on November 11, 1993, if any additional information was requested.
 - b) Explain the identified individual's relationship with the IRCC.
 - c) Identify this individual's title within the IRCC.
 - d) Provide a detailed description of this individual's duties.
- e) Identify any and all documents regarding this individual's relationship with the IRCC.

REQUEST FOR PRODUCTION 2

Provid copies of all of the documents identified in response to interrogatory 7.

INTERROGATORY 8

- a) Describe the employment relationship between the IRCC and Dr. Bauer as of November 11, 1993.
 - b) Identify any and all documents related to this employment relationship.

REQUEST FOR PRODUCTION 3

Provide copies of all of the documents identified in response to interrogatory 8.

INTERROGATORY 9

- a) Identify the owner(s) of the strontium-90 source.
- b) Identify the owner(s) of the eye-applicator.

INTERROGATORY 10

- a) Explain the Licensee's and Dr. Bauer's assertion in their Answer, dated December 2, 1993, to the Order Modifying and Suspending License that "Inspector Nessen was aware that Dr. Bauer had used strontium-90 to treat superficial skin lesions for many years and even referred to that fact specifically."
 - b) When did Inspector Nessen referred to that fact specifically?
 - c) Identify any and all documents supporting the response to this interrogatory.

REQUEST FOR PRODUCTION 4

Provide copies of all documents identified in response to interrogatory 10.

INTERROGATORY 11

- a) Prior to November 11, 1993, did Dr. Bauer inform Dr. Mohamed Shanbaky that Dr. Bauer had used strontium-90 to treat skin lesions?
- b) If yes, describe the circumstances under which Dr. Bauer so informed Dr. Shanbaky, include any and all dates of any conversations between Dr. Bauer and Dr. Shanbaky regarding this matter.
- c) Identify any and all documents supporting your response to this interrogatory.

REQUEST FOR PRODUCTION 5

Provide copies of all of the documents identified in response to interrogatory 11.

INTERROGATORY 12

- a) Describe the basis for Dr. Bauer's belief that the license authorized the use of strontium-90 to treat skin lesions.
 - b) Identify any and all documents supporting the response to this interrogatory.

REQUEST FOR PRODUCTION 6

Provide copies of all of the documents identified in response to interrogatory 12.

INTERROGATORY 13

- a) Describe the basis for Dr. Bauer's belief that it is medically appropriate to use strontium-90 to treat skin lesions.
 - b) Identify any and all documents supporting the response to this interrogatory.

REQUEST FOR PRODUCTION 7

Provide copies of all of the documents identified in response to interrogatory 13.

INTERROGATORY 14

Was Dr. Bauer asked, during the November 11, 1993 inspection by the NRC inspectors, whether he used the strontium-90 source for any treatment modality other than superficial eye treatments?

INTERROGATORY 15

Provide the dates of each treatment of skin lesions by Dr. Bauer at the IRCC using the strontium-90 source.

INTERROGATORY 16

- a) Identify the individual(s) who provided responses to all of the Staff's discovery requests contained herein on behalf of the Licensee.
- b) For each individual identified, provide their title and a detailed description of their duties.
- c) Identify each discovery request(s) to which each individual provided the answers or any portion thereof.
- d) Identify any and all documents relating to the employment relationship between the identified individual(s) and the Licensee.

REQUEST FOR PRODUCTION 8

Provide copies of all documents identified in response to interrogatory 16.

INTERROGATORY 17

For each individual identified in response to interrogatory 16, identify any and all documents and persons consulted in preparing the answers to the Staff's discovery requests.

REQUEST FOR PRODUCTION 9

Provide con as of all documents identified in response to interrogatory 17.

REQUEST FOR PRODUCTION 10

Provide a copy of the patient treatment log for 1993.

REQUEST FOR PRODUCTION 11

skin lesions with the strontium-90 source from Dr. Bauer at the IRCC.

REQUEST FOR PRODUCTION 12

Provide copies of any and all documents relied upon by the Licensee or Dr. Bauer in preparing their *esponses to the Staff's discovery requests.

REQUEST FOR ADMISSIONS⁵

REQUEST 1

Dr. Bauer used the strontium-90 source to treat skin lesions at the IRCC.

REQUEST 2

Dr. Bauer had used the strontium-90 source to treat skin lesions at the IRCC on November 11, 1993, the day of the NRC inspection.

REQUEST !

The license only authorizes the use of strontium-90 for the treatment of superficial eye conditions.

⁵ This request for admissions may be supplemented or enlarged upon completion of discovery.

REQUEST 4

Dr. Bauer's use of the strontium-90 source to treat skin lesions at the IRCC constituted a violation of the license.

Respectfully submitted,

Marian L. Zobler Counsel for NRC Staff

Dated at Rockville, Maryland this 17th day of March, 1994

UNITED STATES OF AMERICA NUCLEAR REGULATORY COMMISSION

'94 MAR 18 ATO :22

BEFORE THE ATOMIC SAFETY AND LICENSING BOARD TO SECRETARY DOCKETING & SERVICE

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

CERTIFICATE OF SERVICE

I hereby certify that copies of "NRC STAFF'S FIRST SET OF INTERROGATORIES AND REQUEST FOR PRODUCTION OF DOCUMENTS AND REQUEST FOR ADMISSIONS" 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 17th day of March, 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

Dr. Peter S. Lam Administrative Judge Atomic Safety and Licensing Board U.S. Nuclear Regulatory Commission Washington, D.C. 20555 Iles Cooper, Esq.*
Counsel for Indiana Regional
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Washington, D.C. 20555
Attn: Docketing and Service Section

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Adjudicatory File (2)
Atomic Safety and Licensing Board
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Office of Commission Appellate
Adjudication (1)
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Marian L. Zobler

Counsel for NRC Staff