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RELATED CORRESPONDENCE

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USNRC

UNITED STATES OF AMERICA
NUCLEAR REGULATORY COMMISSION

BEFORE THE ATOMIC SAFETY AND LICENSING BOARD ⁹⁴ JUN -8 P2:55

OFFICE OF SECRETARY
DOCKETING & SERVICE
BRANCH

In the Matter of)	
)	
INDIANA UNIVERSITY SCHOOL)	Docket No. 030-09792-CivP
OF MEDICINE)	
INDIANAPOLIS, INDIANA)	ASLBP No. 94-689-02-CivP
)	
(Byproduct Material License)	
No. 13-02752-08))	

INDIANA UNIVERSITY SCHOOL OF MEDICINE
INTERROGATORIES AND REQUEST FOR PRODUCTION
OF DOCUMENTS AND REQUEST FOR ADMISSIONS

Pursuant to 10 C.F.R. §§ 2.740(b) and 2.741 of the Commission's regulations, the Indiana University School of Medicine (Licensee) hereby requires that the NRC staff (Staff) respond to the following interrogatories,¹ and produce for inspection and copying, the documents requested.² In addition, pursuant to 10 C.F.R. § 2.742 of the

¹Pursuant to 10 C.F.R. § 2.740b(b), the Licensee must serve a copy of the answers and objections to the interrogatories upon the Staff within 14 days after service of the interrogatories. If the interrogatories are served upon the Licensee by mail, the Licensee shall have an additional five days in which to respond. See 10 C.F.R. § 2.710 (rules for computing time). In addition, the answers must be filed with the Secretary of the Commission and must be served on the presiding officer. 10 C.F.R. § 2.740b(a).

²With respect to the Staff's request for the production of documents, the Commission's regulations at 10 C.F.R. § 2.741(d) provide that the party upon whom such a request is served shall serve upon the party submitting the request a written response within 30 days after the service of the request. The Commission's regulations concerning the computation of time apply to requests for production of documents as well as to interrogatories. 10 C.F.R. § 2.710.

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Commission's regulations, the Licensee hereby files its requests for admissions of the truth of the matters specified below in the Request For Admissions portion of this document.³

Each interrogatory shall be answered separately and fully, in writing, and under oath or affirmation and shall include all pertinent information available to the Staff, or its representatives, based upon the personal knowledge of the person answering. The production of the documents requested herein shall take place at the University Counsel Office, Indiana University, 318 Fesler Hall, 1120 South Drive, Indianapolis, Indiana, unless other arrangements are made, by agreement, in this regard.

INSTRUCTIONS

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

³The Commission's regulations at 10 C.F.R. § 2.742(b) provide that each requested admission shall be deemed made unless, within a time designated by the presiding officer or the Commission, and not less than ten days after service of the request or such further time as may be allowed on motion, the party to whom the request is directed serves on the requesting party its response as provided in section 2.742. The time period set forth in section 2.742 for service of the admission shall be computed in accordance with the Commission's regulations at 10 C.F.R. § 2.710, which provide that under certain circumstances, a party shall have additional time for responding. In this proceeding the Board has provided that responses to admissions will be due ten days after receipt thereof. See Prehearing Conference Order "Issues and Schedules," dated April 18, 1994, at page 2.

person who is believed to have accurate information with respect thereto.

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

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 Staff 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 in the

event the assertion of a privilege is challenged by the Licensee. This description by the Staff 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 Staff'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 Staff, 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/her location at the time the communication was made;
- f. each person to whom the communication was made, and his/her 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. 13-02752-08.

8. "Staff" means in the context of this discovery request the NRC staff.

9. "Misadministration," in the context of this discovery request, refers to the 100 percent increase over the prescribed teletherapy radiation dose to a 31 month old patient which occurred at the Licensee's facility on November 13, 1992.

10. "Order" refers to the Order Imposing Civil Monetary Penalty, dated January 18, 1994. 59 Fed. Reg. 4123 *et seq.* (January 28, 1994).

11. "Violation," in the context of this discovery request, refers to the violation stated in the Notice of Violation and Proposed Imposition of Civil Penalty, dated October 7, 1993, and restated in the Appendix portion of the Order.

12. The Licensee requests that document produced in compliance with this request be accompanied with a specific indication as to the particular paragraphs of the Licensee's

discovery request under which the documents are being produced.

13. "Licensee" means in the context of this discovery request the Indiana University School of Medicine.

INTERROGATORY 1

A. Has the Staff ever been instructed, influenced, directed, encouraged or pressured by any person, entity, organization or group of persons, either inside the NRC or outside the NRC, to increase enforcement actions against, oversight of, or review of medical licensees, or the Licensee?

B. Has the Staff ever communicated with any person or entity, either internal or external, about enforcement actions against medical licensees, or the Licensee, or about 10 C.F.R. 35.32 as concerning medical licensees or the Licensee?

C. Identify all documentation the Staff is relying on in responding to Interrogatory 1A.

D. Identify all documentation the Staff is relying on in responding to Interrogatory 1B.

REQUEST FOR PRODUCTION OF DOCUMENTS 1

Provide copies of documents identified in response to Interrogatory 1C and 1D.

INTERROGATORY 2

A. Have the NRC Staff of the Office of Enforcement, Rockville, MD, and NRC Region III Office Staff ever communicated about the Licensee?

B. Identify all documentation the Staff is relying on in responding to Interrogatory 2A.

C. Have the NRC Staff of the Office of Enforcement, Rockville, MD, and NRC Region III Office Staff ever disagreed with one another about the alleged violation by the

Licensee or the appropriate enforcement action?

D. Identify all documentation the Staff is relying on in responding to Interrogatory 2C.

REQUEST FOR PRODUCTION OF DOCUMENTS 2

Provide copies of documents identified in response to Interrogatory 2B and 2D.

INTERROGATORY 3

A. Did the Staff ever received any comments or communications concerning the addition of the term "overall treatment period" or its meaning during or after the notice and comment period for the QMP rule (finally published at 56 *Fed. Reg.* 34104)?

B. If the response to 3A is affirmative, or affirmative in part, identify all documentation the Staff is relying on in responding to Interrogatory 3A.

C. If the response to 3A is negative, what was the basis for the Staff's decision to add the term "overall treatment period" as a part of the written directive?

D. Identify all documentation the Staff is relying on in responding to Interrogatory 3C.

E. Does the Staff contend that the interpretation of the term "overall treatment period" as a number of fractions compromises or otherwise diminishes the effectiveness of the written directive?

F. If the response to 3E is affirmative, what is the basis for that contention?

G. Identify all documentation the Staff is relying on in responding to Interrogatory 3E.

REQUEST FOR PRODUCTION OF DOCUMENTS 3

Provide copies of documents identified in response to Interrogatory 3

INTERROGATORY 4

A. Were any comments received by the Staff recommending that the number of treatment fractions be deleted from the contents of the written directive during or after the notice and comment period for the QMP rule (finally published at 56 *Fed. Reg.*

34104)?

B. If the response to 4A is affirmative, identify all documentation the Staff is relying on in responding to Interrogatory 4A.

C. If the response to 4A is negative, what was the basis for the Staff's decision to delete the number of treatment fractions from the contents of the written directive?

D. Identify all documentation the Staff is relying on in responding to Interrogatory 4C.

E. Does the Staff contend that interpreting the term "overall treatment period" as a period of time rather than the number of fractions reduces the likelihood of a misadministration?

F. If the response to 4D is affirmative, what is the basis for that contention?

G. Identify all documentation the Staff is relying on in responding to Interrogatory 4E.

H. Does the Staff contend that the Licensee's interpretation of the term "overall treatment period" caused or contributed to the cause of the misadministration in question?

I. If the response to 4H is affirmative, what is the basis for that contention?

J. Identify all documentation the Staff is relying on in responding to Interrogatory 4H.

REQUEST FOR PRODUCTION OF DOCUMENTS 4

Provide copies of documents identified in response to Interrogatory 4.

INTERROGATORY 5

A. Does the Staff contend that medical licensees are more subject to error during times of emergent treatment and staff shortages?

B. If the response to 5A is affirmative, what is the basis for that contention?

D. If the response to 5A is negative, what is the basis for the statement by the Staff that at certain times "the licensee is more subject to error such as with staff

shortages and emergent treatments"? (See Appendix of the "ORDER IMPOSING CIVIL MONETARY PENALTY" dated January 18, 1994)

C. Identify all documentation the Staff is relying on in responding to Interrogatory 5A.

REQUEST FOR PRODUCTION OF DOCUMENTS 5

Provide copies of documents identified in response to Interrogatory 5.

INTERROGATORY 6

A. When the Staff approves a physician as an authorized user on a ⁶⁰Co teletherapy license, does that approval allow the physician to prescribe, plan, and administer the treatment?

B. Identify all documentation the Staff is relying on in responding to Interrogatory 6A.

C. If the response to 6A is negative in whole or in part, exactly what does the Staff's approval of an authorized user allow that user to do and what limitations are placed upon the authorized user?

D. Identify all documentation the Staff is relying on in responding to Interrogatory 6C.

REQUEST FOR PRODUCTION OF DOCUMENTS 6

Provide copies of documents identified in response to Interrogatory 6.

INTERROGATORY 7

A. It appears that the intent of footnote 1 of 10 C.F.R. 35.32 is to avoid delays in administering a treatment because of the emergent nature of the patient's condition when an authorized user is not available to provide a written directive. Does the Staff contend that under the same circumstances (i.e., an emergency treatment situation) it is a violation of the QMP regulations to delay the treatment until a physicist or other individual is summoned to check the written directive, treatment plan, and calculations which have been prepared and checked by an authorized user?

- B. If the response to 7A is affirmative, what is the basis for that contention?
- C. Identify all documentation the Staff is relying on in responding to Interrogatory 7A.
- D. Do the QMP regulations specifically prohibit licensees from including statements in their QMP which address emergency treatments or staff shortages?
- E. If the response to 7D is affirmative, what is the basis for that contention?
- F. Identify all documentation the Staff is relying on in responding to Interrogatory 7E.

REQUEST FOR PRODUCTION OF DOCUMENTS 7

Provide copies of documents identified in response to Interrogatory 7.

INTERROGATORY 8

- A. Were the changes incorporated into the Licensee's Quality Assurance/Quality Control Program (QA/QCP) as a result of a May 1990 misadministration reviewed by Staff?
- B. What was the result of that review?
- C. Identify all documentation the Staff is relying on in responding to Interrogatory 8A and 8B.
- D. Was a QMP submitted by the Licensee in accordance with 10 C.F.R. 35.32(f)(2)?
- E. Was the Licensee's QMP reviewed by the Staff before the November 13, 1992, misadministration?
- F. If the response to 8E is affirmative, what were the results of that review?
- G. Identify all documentation the Staff is relying on in responding to Interrogatory 8F.

REQUEST FOR PRODUCTION OF DOCUMENTS 8

Provide copies of documents identified in response to Interrogatory 8.

INTERROGATORY 9

Identify any person the Staff intends to call as a witness at the evidentiary hearing in this proceeding.

INTERROGATORY 10

With respect to any person listed in response to Interrogatory 9, 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 vita*, or statement of professional qualifications may be provided.

INTERROGATORY 11

Identify any persons who have knowledge of the facts concerning the matters in controversy herein, including, but not limited to, all persons from whom the Staff has obtained or attempted to obtain written or oral statements, whether or not the Staff intends to call that person as a witness in this proceeding.

INTERROGATORY 12

A. Does the Staff contend that it has the authority to require medical licensees or the Licensee to perform an independent review by a physics staff member during staff shortages or emergency treatment?

B. If the response is affirmative or affirmative in part, what is the basis for that contention?

C. Identify all documentation the Staff is relying on in responding to Interrogatory 12A and 12B.

REQUEST FOR PRODUCTION OF DOCUMENTS 12

Provide copies of documents identified in response to Interrogatory 12.

INTERROGATORY 13

A. Does the Staff contend that the treatment commencing on November 13, 1992

was not an emergency?

B. If the response is affirmative or affirmative in part, what is the basis for that contention?

C. Identify all documentation the Staff is relying on in responding to Interrogatory 13A and 13B.

REQUEST FOR PRODUCTION OF DOCUMENTS 13

Provide copies of documents identified in response to Interrogatory 13.

INTERROGATORY 14

A. Does the Staff contend that the Licensee's QMP may not waive review of dose calculations by a physics staff member for extenuating circumstances such as staff shortages and emergency treatments?

B. If the response is affirmative or affirmative in part, what is the basis for that contention?

C. Identify all documentation the Staff is relying on in responding to Interrogatory 14A and 14B.

REQUEST FOR PRODUCTION OF DOCUMENTS 14

Provide copies of documents identified in response to Interrogatory 14.

INTERROGATORY 15

A. Does the Staff contend that the QMP regulations prohibit the Licensee's QMP from waiving review of dose calculations by a physics staff member for extenuating circumstances such as staff shortages and emergency treatments?

B. If the response is affirmative or affirmative in part, what is the basis for that contention?

C. Identify all documentation the Staff is relying on in responding to Interrogatory 15A and 15B.

REQUEST FOR PRODUCTION OF DOCUMENTS 15

Provide copies of documents identified in response to Interrogatory 15.

INTERROGATORY 16

A. Does the Staff contend that the Licensee's QMP does not currently comply with the regulations or accompanying regulatory guide?

B. If the response is affirmative or affirmative in part, what is the basis for that contention?

C. Identify all documentation the Staff is relying on in responding to Interrogatory 16A and 16B.

REQUEST FOR PRODUCTION OF DOCUMENTS 16

Provide copies of documents identified in response to Interrogatory 16.

INTERROGATORY 17

A. Does the Staff contend that if the Licensee's QMP, in effect November 13, 1992, had required an independent review by a physics staff member of the accuracy of all dosimetric calculations for treatments that are delivered in less than four fractions the misadministration would not have occurred?

B. If the response is affirmative or affirmative in part, what is the basis for that contention?

C. Identify all documentation the Staff is relying on in responding to Interrogatory 17A and 17B.

REQUEST FOR PRODUCTION OF DOCUMENTS 17

Provide copies of documents identified in response to Interrogatory 17.

REQUEST FOR ADMISSIONS

1. The term "overall treatment period" is not defined in 10 C.F.R. § 35.
2. The Statement of Considerations for the QMP rule (56 *Fed. Reg.* 34104) is not

part of the QMP regulations and compliance with the Statement of Consideration by the Licensee is not required.

3. The term "overall treatment period" as set out in the Statement of Considerations for the QMP rule (56 *Fed. Reg.* 34104) is not part of the QMP regulations and compliance with the term as defined therein is not required.

4. The term "overall treatment period" is not defined in Regulatory Guide 8.33.

5. Regulatory Guide 8.33 is not a substitute for regulations, and compliance with it is not required.

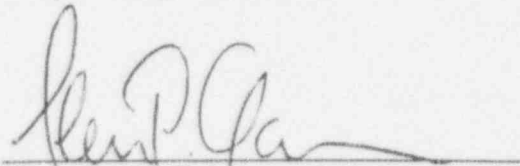
6. 10 C.F.R. 35.32 does not prohibit a Licensee's QMP from waiving independent review of dose calculations by a physics staff member for extenuating circumstances such as staff shortages and emergency treatments.

7. The treatment delivered on November 13, 1992 was an emergency.

8. The Licensee's QMP is currently in compliance with the QMP regulations.

9. The Licensee's QMP is currently in compliance with the Regulatory Guide 8.33.

Respectfully submitted,



Thomas P. Gannon
Attorney for Indiana University
School of Medicine

Dated at Indianapolis, Indiana
this 1st day of June, 1994

UNITED STATES OF AMERICA
NUCLEAR REGULATORY COMMISSION

DOCKETED
USMRC

BEFORE THE ATOMIC SAFETY AND LICENSING BOARD

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(Byproduct Material License)
No. 13-02752-08))

Docket No. 030-09792-CivP

ASLBP No. 94-689-02-CivP

CERTIFICATE OF SERVICE

I hereby certify that copies of Indiana University School of Medicine's Interrogatories and Request for Production of Documents and Request for Admissions in the above-captioned proceeding have been served on the following by, unless otherwise indicated, deposit in the United States mail, first class, this 1st day of June 1994:

Robert M. Weisman (Via Express Mail)
Bernard M. Bordenick

Office of the General Counsel
U.S. Nuclear Regulatory Commission
Washington, DC 20555

James P. Gleason, Chairman
Atomic Safety and Licensing Board Panel
U.S. Nuclear Regulatory Commission
Washington, DC 20555

Dr. Peter S. Lam
Atomic Safety and Licensing Board
Panel
U.S. Nuclear Regulatory Commission
Washington, DC 20555

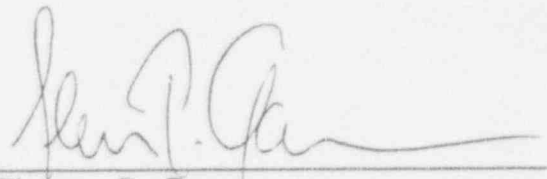
Adjudicatory File (2)
Atomic Safety and Licensing Board
U.S. Nuclear Regulatory Commission
Washington, DC 20555

Thomas D. Murphy
Atomic Safety and Licensing Board
U.S. Nuclear Regulatory Commission
Washington, DC 20555

Office of the Secretary (2)
U.S. Nuclear Regulatory Commission
Washington, DC 20555
Attn: Docketing and Service Section

Atomic Safety and Licensing Board
Panel (1)
U.S. Nuclear Regulatory Commission
Washington, DC 20555

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



Thomas P. Gannon
Attorney for Indiana University
School of Medicine