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RELATED CORRESPONDENCE

UNITED STATES OF AMERICA
NUCLEAR REGULATORY COMMISSION

June 14, 1994

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USNRC

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OFFICE OF SECRETARY
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BEFORE THE ATOMIC SAFETY AND LICENSING BOARD

In the Matter of	)	
	)	
INDIANA UNIVERSITY SCHOOL OF MEDICINE	)	Docket No. 030-09792-CivP
INDIANAPOLIS, INDIANA	)	ASLBP No. 94-689-02-CivP
	)	
(Byproduct Material License No. 13-02752-08)	)	EA No. 93-111

NRC STAFF RESPONSE TO
INDIANA UNIVERSITY SCHOOL OF MEDICINE
REQUEST FOR ADMISSIONS

INTRODUCTION

On June 1, 1994, Indiana University School of Medicine (Licensee) served "Interrogatories and Request for Production of Documents and Request for Admissions" on the NRC staff (Staff). Pursuant to 10 C.F.R. § 2.742(b), the Staff hereby files its response to Licensee's Request for Admissions. The Staff notes that it need answer interrogatories only if the presiding officer, in this case the Licensing Board, orders the Staff to do so based on findings that answers to the interrogatories are necessary to a proper decision in the proceeding and that answers to the interrogatories are not reasonably obtainable from any other source. 10 C.F.R. § 2.720(h)(2)(ii) (1994). The Staff notes further that the Staff is not a party that answers interrogatories pursuant to 10 C.F.R. § 2.740b. In addition, 10 C.F.R. § 2.744 governs the production of NRC records and documents. Notwithstanding the above regulations, and without waiving any

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objections, the Staff has agreed to respond to the Licensee's discovery requests on the following schedule. Responses to Licensee's Interrogatories and Request for Production of Documents are, pursuant to 10 C.F.R. § 2.740b(b) and 10 C.F.R. § 2.741(d), respectively, not due to be filed by the Staff until on or before June 20, 1994, and July 1, 1994, respectively.

Under 10 C.F.R. § 2.742(a), a party may file a written request "for the admission of the truth of any specified relevant matter of fact." Several of the admissions requested by the Licensee are requests for admissions regarding matters of law, and are objectionable under § 2.742(a) because they do not relate to a "matter of fact". The Staff, however, has responded to each such request to the best of its ability, and has included legal argument if needed to clarify the Staff responses.

STAFF RESPONSE TO LICENSEE'S
REQUEST FOR ADMISSIONS

LICENSEE'S REQUEST FOR ADMISSIONS

1. The term "overall treatment period" is not defined in 10 C.F.R. § 35 (*sic*).

STAFF RESPONSE

Admit.[1]

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.

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[1] The Staff has responded to the request as it relates to 10 C.F.R. Part 35.

STAFF RESPONSE

Admit.[2]

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.

STAFF RESPONSE

Denied. The term "overall treatment period" is explicitly set forth in 10 C.F.R. § 35.2 as being part of a written directive for teletherapy. Insofar as the Quality Management (QM) rule (10 C.F.R. § 35.32) requires a licensee to complete a written directive for teletherapy, the term is part of the regulations. The staff's position on how that term is defined is set forth in the Statement of Considerations to which Licensee request for admission 3 refers.

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

STAFF RESPONSE

Admit.

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

STAFF RESPONSE

Admit.[3]

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[2] As a general matter, it should be noted that while statements of consideration are not part of a regulation and compliance with such statements by licensees is not required, they do constitute the Commission's views or interpretations of the regulation upon its adoption and, as such, are analogous to statutory legislative histories.

[3] As a general matter, it should be noted that compliance with a Regulatory Guide by a licensee is one way to establish compliance with a regulation. As relevant here, Regulatory Guide 8.33 provides guidance to licensees and applicants for developing a quality management program that meets the specific objectives of 10 C.F.R. § 35.32.

(continued...)

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.

STAFF RESPONSE

The Staff can neither admit or deny this request for admission. The Licensee must establish and maintain a Quality Management Program (QMP) that contains policies and procedures to ensure that the specific objectives in 10 C.F.R. § 35.32 are met. The regulations do not specifically address extenuating circumstances such as staff shortages and emergency treatments but the QMP must provide high confidence that radiation from byproduct material will be administered as directed by the authorized user for all administrations under all circumstances.

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

STAFF RESPONSE

The Staff can neither admit or deny this request for admission. The NRC does not, in general, make determinations regarding what constitutes an emergency treatment and did not do so in this case. The NRC recognizes that whether a treatment is considered an emergency is a medical decision made by the physician authorized user.

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

STAFF RESPONSE

Deny. In general, compliance with 10 C.F.R. § 35.32 can not be determined by reviewing the written QMP outside the full context of the Licensee's implemented policies and procedures. In this case, the Licensee's written QMP dated October 25, 1993, does not incorporate policies and procedures which address the situation that occurred on November 13 and 14, 1992. Specifically, for any emergency treatment initiated at the close of normal working hours but completed before the next normal working hours (initiated late Friday afternoon and

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[3](...continued)
However, licensees are not required to establish their programs in accordance with the Regulatory Guide but may use other sources or experience to develop a performance-based program that meets the objectives of the rule.

completed on Saturday or Sunday), there is no check other than the authorized user's approval prior to the initial treatment. Since this practice by the Licensee has resulted in at least one misadministration, there is not high confidence that this procedure will, in the future, assure that the calculated administered dose is the same as the prescribed dose.

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

STAFF RESPONSE

Deny. With regard to Regulatory Guide 8.33, in order to satisfy the requirements of 10 C.F.R. § 35.32, a licensee's implementation of its program would have to be adequate to ensure high confidence that all administrations are in accordance with the written directive. The Licensee has not adopted all the recommendations in Regulatory Guide 8.33. In addition, as noted in the Staff's response to Licensee request for admission 8, for an emergency treatment, there is no check other than the authorized user's approval prior to treatment, contrary to the recommendations of Regulatory Guide 8.33. Moreover, as noted in the Staff's Response to the Licensee's request for admission 5, a regulatory guide is not a substitute for a regulation and compliance with a regulatory guide is not required. However, establishment and implementation of a program in accordance with a regulatory guide is one way by which a licensee may establish compliance with a regulation.

Respectfully submitted,

Robert M. Weisman

Robert M. Weisman
Counsel for NRC Staff

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

UNITED STATES OF AMERICA
NUCLEAR REGULATORY COMMISSION

June 14, 1994

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	)	
INDIANAPOLIS, INDIANA	)	ASLBP No. 94-689-02-CivP
	)	
(Byproduct Material License No. 13-02752-08)	)	EA No. 93-111
	)	

AFFIDAVIT OF JOHN E. GLENN

I, John E. Glenn, first being duly sworn, depose and state:

1. I am currently Chief, Medical, Academic, and Commercial Use Safety Branch, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission.

2. I have participated and assisted in the preparation of the attached "NRC Staff Response to Indiana University School of Medicine Request for Admissions" in the above-captioned proceeding, including responses to Requests for Admission 1 through 9.

3. I hereby certify that the information provided with regard to the above responses are true and correct to the best of my knowledge, information and belief.

John E. Glenn

Subscribed and sworn to before me
this 14th day of June, 1994.

Notary Public

My commission expires: 12/1/97

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CERTIFICATE OF SERVICE

I hereby certify that copies of "NRC STAFF RESPONSE TO INDIANA UNIVERSITY SCHOOL OF MEDICINE REQUEST FOR ADMISSIONS" filed in the above-captioned proceeding have been served on the following by deposit in the United States mail, first class, or as indicated by an asterisk through deposit in the Nuclear Regulatory Commission's internal mail system or, as indicated by a double asterisk, by facsimile transmission and deposit in the United States mail, first class, this 14th day of June 1994:

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

Dr. Peter S. Lam*
Atomic Safety and Licensing Board Panel
U.S. Nuclear Regulatory Commission
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Adjudicatory File (2)*
Atomic Safety and Licensing Board
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Washington, D.C. 20555

Office of the Secretary (2)*
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Attn: Docketing and Service Section

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Robert M. Weisman

Robert M. Weisman
Counsel for NRC Staff