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UNITED STATES OF AMERICA FILE OF SECRETARY NUCLEAR REGULATORY COMMISSION FINE & SERVICE

## BEFORE THE ATOMIC SAFETY AND LICENSING BOARD

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

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

Indiana Regional Cancer Center files this Response to NRC Staff's Second Set of Interrogatories and Requests for the Production of Documents and incorporates by reference into each and every response the following general objections.

#### GENERAL OBJECTIONS

The Licensee objects to any request to the extent it seeks to obtain privileged information, work product material or irrelevant information/responses. The Licensee objects to each and every request herein because each is based on the improper attempt by the NRC to bring into this action unadjudicated and contested facts from an entirely separate proceeding. This litigation involves only the use of strontium-90. This matter is currently before the Board. Without waiving this obligation, responses have been

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provided. Further, the Licensee is continuing its review of this matter and reserves the right to supplement and/or revise any and all responses contained herein prior to the hearing.

# 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?

#### RESPONGE:

The PrimeAlert did light up while the patient was in the treatment room but quit while the patient was still in the room.

## INTERROGATORY 2

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

#### RESPONSE:

See response to Interrogatory 1 above.

## 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?

#### RESPONSE:

Dr. Bauer did not see the PrimeAlert light up.

#### 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?

## RESPONSE:

See response to Interrogatory C10 of June 10, 1994 Response of OSC to NRC Staff's First Set of Interrogatories and Request for

Production of Documents and Request for Admissions (hereinafter June 10, 1994 Response).

## INTERROGATORY 5

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

#### RESPONSE:

See response to Interrogatories 3 and 4 herein.

#### 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.

#### RESPONSE:

See response to Interrogatory 4 herein.

#### INTERROGATORY 7

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

#### RESPONSE:

Objection. The Licensee objects to this Interrogatory because it is vague and unclear and therefore unanswerable because it requests the Licensee to identify "all individuals present during the November 16, 1994 incident." The Licensee does not know what location is being referred to or the duration of the 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 10ft the treatment room at the IRCC.

#### RESPONSE:

See response to Interrogatory 4 herein.

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.

#### RESPONSE:

The room was surveyed by the wall-mounted survey meter and it indicated no radiation.

## REQUEST FOR PRODUCTION OF DOCUMENTS 1

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

#### RESPONSE:

None.

#### INTERROGATORY 10

If the response to Interrogatory 9 is in the negative, did Dr. Bauer cause a survey, as defined in 10 C.F.F. § 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.

#### RESPONSE:

See response to Interrogatory 9 herein.

## REQUEST FOR DOCUMENT PRODUCTION 2

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

#### RESPONSE:

None.

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

#### PONSE:

Dr. Bauer was aware of the significance of a continuing flashing PrimeAlert.

#### 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?

#### RESPONSE:

Dr. Bauer understood the significance of a continuing flashing PrimeAlert to indicate the presence of radiation.

#### 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?

#### RESPONSE:

See response to Interrogatory C4 of June 10, 1994 Response. The error message did not indicate an emergency.

## 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.

#### RESPONSE:

See response to Interrogatory 13 herein.

## INTERROGATORY 15

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

#### RESPONSE:

See response to Interrogatory 13 herein.

#### INTERROGATORY 16

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

#### RESPONSE:

See response to Interrogatory 13 herein.

#### 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.

#### RESPONSE:

See response to Interrogatory 13 herein.

## 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.

#### RESPONSE:

The PrimeAlert was not understood by the IRCC personnel to be ineffective on November 16, 1992.

#### 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?

#### RESPONSE:

Objection. The suspension order only cites 10 CFR 20.201(b) and no other section of Part 20. Therefore, the request is overly broad and irrelevant. However, to the extent 20.201(b) governs, no further survey than that done by the Licensee was required under that subsection.

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?

#### RESPONSE:

See response to Interrogatory 19 herein.

## 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?

#### RESPONSE:

See response to Interrogatory 19 herein.

#### 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.

#### RESPONSE:

See response to Interrogatory 19 herein.

#### 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?

#### RESPONSE:

See response to Interrogatory 19 herein.

#### 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.

#### RESPONSE:

See response to Interrogatory 19 herein.

#### 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?

#### RESPONSE:

See response to Interrogatory 19 herein.

## 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.

#### RESPONSE:

See response to Interrogatory 19 herein.

#### 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)?

#### RESPONSE:

No, it is not the Licensee's belief that 10 CFR Part 20 is totally inapplicable to the Byproduct Materials 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?

#### RESPONSE:

See response to Interrogatory 27 above.

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

#### RESPONSE:

No, it is not Dr. Bauer's belief that 10 CFR Part 20 is totally inapplicable 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.

#### RESPONSE:

See response to Interrogatory 29 above.

Respectfully submitted,

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Counsel for the Indiana Regional Cancer Treatment Center and Dr. James E. Bauer

Dated: June 15, 1994

## VERIFICATION

The undersigned, James E. Bauer, M.D., varifies that the foregoing Response To NRC Staff's Second Set Of Interrogatories And Requests For The Production Of Documents is true and correct to the best of his knowledge, information or belief.

James & Laured, 4.8.

## CERTIFICATE OF SERVICE 94 JUN 20 P2:00

I HEREBY CERTIFY that a true and correct copy of the Y Response To NRC Staff's Second Set Of Interrogatories And Requests For The Production Of Documents was served this 15th day of June, 1994 by U.S. Mail, postage prepaid, or as otherwise indicated:

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