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March 3, 1994

UNITED STATES OF AMERICA
NUCLEAR REGULATORY COMMISSION

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BEFORE THE ATOMIC SAFETY AND LICENSING BOARD

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

NRC STAFF RESPONSE TO FIRST REQUEST FOR
PRODUCTION OF DOCUMENTS AND ADMISSIONS DIRECTED
TO THE NRC STAFF AND NRC STAFF MOTION FOR A PROTECTIVE ORDER

INTRODUCTION

Pursuant to 10 C.F.R §§ 2.742 and 2.744, the staff of the Nuclear Regulatory Commission (Staff) hereby files its response to "Licensee's First Set of Interrogatories, First Request for Production of Documents, and First Request for Admissions Directed to the NRC Staff." In addition, the Staff moves the Atomic Safety and Licensing Board for a protective order.

GENERAL OBJECTION

Pursuant to 10 C.F.R. § 2.744, the Staff generally objects to the production of certain documents because they are exempt from disclosure under 2.790(a) and are not necessary for a proper determination. Included herewith is a motion for a protective order.

The regulations governing the production of NRC records and documents, 10 C.F.R. §§ 2.741(e) and 2.744(a), provide that a record or a document may be withheld from disclosure

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if it is exempted from disclosure under section 2.790 and the disclosure is not necessary to a proper decision in the proceeding.¹ Section 2.790, in turn, provides that certain NRC records and documents may be exempt from disclosure. Section 2.790(a)(7) provides that records or information compiled for law enforcement purposes are exempt from disclosure under certain circumstances. As discussed below, certain documents obtained by or in the possession of the NRC Office of Investigations (OI) have been compiled for law enforcement purposes.

The NRC's Office of Investigations is investigating the issue of false statements made by Dr. James E. Bauer, the Radiation Safety Officer (RSO) and only authorized user listed on Byproduct Material License No. 37-28179-01 (strontium-90 license). This issue was referred to the Assistant United States Attorney (AUSA) for the Western District of Pennsylvania. See Letter to Roger A. Fortuna, Deputy Director, Office of Investigations, U.S. Nuclear Regulatory Commission from Constance M. Bowden, AUSA, dated February 22, 1994, attached hereto as Attachment 1. A preliminary decision that the issue referred to DOJ warrants a criminal investigation into possible violations of federal law has been made. *Id.*

The documents obtained by or in the possession of OI in connection with which a protective order is sought are not necessary for a proper determination in this proceeding -- none of the documents provides the bases for the Staff's Order Modifying and Suspending the strontium-90 license. In accordance with 10 C.F.R. § 2.744(c), if the Board so requests, the

¹ The Staff does not assert that, under the broad definition of relevance under discovery, the documents are not relevant. 10 C.F.R. § 2.744(1). However, as discussed below, these documents are not necessary for a proper determination in this proceeding. See *Consumers Power Co. (Palisades Nuclear Power Facility)*, ALJ-80-1, 12 NRC 117, 119 (1980)(discussion of section 2.744(d) and the difference between a determination of relevance and a determination of necessary for a proper determination in this proceeding).

Staff will produce, *in camera, ex parte*, to the Board the protected documents so that the Board may determine the relevancy of the documents, whether such documents are exempt from disclosure under section 2.790, and whether the disclosure of such documents are necessary for a proper determination in this proceeding.

NRC STAFF RESPONSE TO LICENSEE'S
REQUEST FOR PRODUCTION OF DOCUMENTS

REQUEST FOR PRODUCTION 1

Any and all documents, including any notes taken by the inspectors during the November 1993 inspection, which support, relate to and/or refute the basis for the Suspension Order.

RESPONSE

In accordance with 10 C.F.R. §§ 2.744 and 2.790, the following documents are available in the NRC Public Document Room (PDR):

- 1) Letter to James E. Bauer, Medical Director, Indiana Regional Cancer Center from Charles W. Hehl, Director, Division of Radiation Safety and Safeguards, dated December 3, 1993.
Accession Number 9312090024
- 2) Inspection Report No. 030-30485/93-01.
Accession Number 9312090029

The following document will be made available for inspection and copying either at the NRC Region I Offices in King Of Prussia, Pennsylvania, or at the NRC headquarters in Rockville, Maryland, unless other arrangements are made by agreement of the parties.

- 1) Note to File from Penny Nessen and Steve W. Shaffer, subject: Inspection at Indiana Regional Cancer Center, November 11, 1993, dated November 12, 1993.

REQUEST FOR PRODUCTION 2

Any and all documents relating to or referring to License No. 37-28179-01.

RESPONSE

In accordance with 10 C.F.R. §§ 2.744 and 2.790, the following documents are available in the PDR:

- 1) Materials License No. 37-28179-01, dated April 25, 1988.
Accession Number 8903170207.
- 2) Application for Material License, dated March 3, 1988.
Accession Number 8903170215.
- 3) Confirmatory Action Letter 1-93-021 to James E. Bauer, M.D., Indiana Regional Cancer Center, dated November 12, 1993.
Accession Number 9312020071.
- 4) Order Modifying and Suspending License (Effective Immediately) and Demand for Information issued to the Indiana Regional Cancer Center, dated November 16, 1993.
Accession Number 9311190428.
- 5) Demand for Information issued to Dr. James E. Bauer, Medical Director, Indiana Regional Cancer Center, dated November 16, 1993.
Accession Number 9311180262.

The following documents will be made available for inspection and copying at either at the NRC Region I Offices in King Of Prussia, Pennsylvania, or at the NRC headquarters in Rockville, Maryland, unless other arrangements are made by agreement of the parties:

- 1) Memorandum for Ronald R. Bellamy, Chief, Nuclear Materials Safety Branch, Region I from John E. Glenn, Chief, Medical, Academic, and Commercial Use Safety Branch, Division of Industrial and Medical Nuclear Safety, Office of Nuclear Materials Safety and Safeguards, subject: Technical Assistance Request: Indiana Regional Cancer Center - License Number 37-28179-01, dated December 2, 1993.
- 2) Regional Technical Assistance Request Form.

- 3) Letter to Frank Costello, Nuclear Materials Safety Branch, Region I, Nuclear Regulatory Commission from Marcy L. Colkitt, dated November 15, 1993.
- 4) Letter to Marcy L. Colkitt, Esq. from James Lieberman, Director, Office of Enforcement, Nuclear Regulatory Commission, dated December 30, 1993.

REQUEST FOR PRODUCTION 3

Any and all documents, studies and/or NRC/FDA commissioned publications relating to the medical use of strontium-90.

RESPONSE

In accordance with 10 C.F.R. §§ 2.744 and 2.790, the following documents responsive to this request which are in the Staff's possession or control are available in the PDR:

- 1) Memorandum for Melvin L. Griem, M.D., Vincent P. Collkins, M.D., Edward W. Webster, Ph.D., Peter R. Almond, Ph.D. from Patricia C. Vacca, Material Licensing Branch, subject: Review of Application to Use a Strontium-90 Plaque to Treat Skin Cancer, dated July 16, 1984.
Accession Number 8501250474.
- 2) Letter to G.A. Doener, M.D., President, Radiology Ultrasound Nuclear Consultants, P.A. from John E. Glenn, Ph.D., Chief, Nuclear Materials Section B, Division of Engineering and Technical Programs, dated November 27, 1984 (plus attachments)
Accession Number 8501250469.
- 3) Transcript of the Advisory Committee on the Medical Use of Isotopes, November 1-2, 1993.
Accession Numbers 9312080244, 9312080246.

The documents numbers 1 and 2 were generated as a result of an application for authorization to use a strontium-90 applicator for skin cancers. For further information on this specific proceeding, the Licensee is directed to *Radiology Ultrasound Nuclear Consultants, P.A.* (Strontium-90 Applicator), LBP-88-3, 27 NRC 220 (1988).

REQUEST FOR PRODUCTION 4

Any and all documents used by the staff to answer Requests for Admissions set forth herein.

RESPONSE

In accordance with 10 C.F.R. §§ 2.744 and 2.790, the following documents are available in the PDR:

- 1) Inspection Report No. 030-30485/93-001, dated December 2, 1993.
- 2) Note to File from Perny Nessen and Steve W. Shaffer, subject: Inspection at Indiana Regional Cancer Center, November 11, 1993, dated November 12, 1993.

STAFF RESPONSE TO LICENSEE'S REQUESTS FOR ADMISSIONS

REQUEST 1

Prior to the November 11, 1993 inspection, Dr. Mohamed Shanbaky was aware that Dr. Bauer had used strontium-90 to treat superficial skin lesions.

RESPONSE

Deny.

REQUEST 2

If the Answer to Number 1 above is anything other than an unqualified admission, describe all circumstances in detail as to why the answer to Number 1 above is not an unqualified admission.

RESPONSE

The response to Request number 1, above, is not an unqualified admission because prior to November 11, 1993, Dr. Shanbaky was not aware that Dr. Bauer had used strontium-90 to treat superficial skin lesions.

REQUEST 3

Prior to November 11, 1993, Penny Nessen was aware that Dr. Bauer had used strontium-90 to treat superficial skin lesions.

RESPONSE

Deny.

REQUEST 4

If the Answer to Number 3 above is anything other than an unqualified admission, describe all circumstances in detail as to why the answer to Number 3 above is not an unqualified admission.

RESPONSE

The response to Request number 3, above, is not an unqualified admission because prior to November 11, 1993, Penny Nessen was not aware that Dr. Bauer had used the strontium-90 source to treat superficial skin lesions. On November 11, 1993, P. Nessen and S. Shaffer (henceforth, the inspectors) learned, for the first time, from review of the licensee's patient scheduling log and corresponding patient files that at least two patients had been treated for skin lesions with the strontium-90 source.

REQUEST 5

An internal NRC document prepared by the NRC relating to the facts of the November 11, 1993 inspection contains factual errors.

RESPONSE

Deny.

REQUEST 6

If the Answer to Number 5 above is anything other than an unqualified admission, describe all circumstances in detail as to why the answer to Number 5 above is not an unqualified admission.

RESPONSE

The response to Request number 5, above, is not an unqualified admission because to the best of the inspectors' knowledge, no NRC document relating to the facts of the November 11, 1993 inspection contain factual errors.

REQUEST 7

Charlene Santus did not speak with Dr. Bauer about the patient log(s) prior to turning over requested patient log(s) to the inspectors on November 11, 1993.

RESPONSE

Admit, to the best of the inspectors current knowledge and belief.

REQUEST 8

If the Answer to Number 7 above is anything other than an unqualified admission, describe all circumstances in detail as to why the answer to Number 7 above is not an unqualified admission.

RESPONSE

The response to Request number 7, above, is not an unqualified admission because the inspectors have no current knowledge of any conversations between Ms. Santus and Dr. Bauer regarding patient treatment logs prior to their arrival at the Indiana Regional Cancer Center.

REQUEST 9

Marcy L. Colkitt asked the inspectors during the November 11, 1993 inspection if there was any other information and/or documents they needed.

RESPONSE

Admit.

REQUEST 10

If the Answer to Number 9 above is anything other than an unqualified admission, describe all circumstances in detail as to why the answer to Number 9 above is not an unqualified admission.

RESPONSE

A response to this request is not necessary since the response to Request number 9, above, is an admission.

REQUEST 11

It is possible that the inspectors on November 11, 1993 initially only requested patient charts where strontium-90 was used to treat eye patients.

RESPONSE

Deny.

REQUEST 12

If the Answer to Number 11 above is anything other than an unqualified admission, describe all circumstances in detail as to why the answer to Number 11 above is not an unqualified admission.

RESPONSE

The response to Request number 11, above, is not an unqualified admission because on November 11, 1993, the inspectors did not initially only request patient charts where strontium-90 was used to treat eye patients. The inspectors asked Dr. James Bauer what he used his strontium-90 source for. He stated that he used the source for treatments of pterygium, an eye condition. The inspectors additionally asked him how many patients he had treated using the strontium-90 source that year. He stated that he treated about six patients a year. The

inspectors asked him if he used the strontium-90 source for any other treatment modality. He stated that he used the source to treat pterygium.

The inspectors further asked Dr. Bauer for the last six patient treatment files using this source. Dr. Bauer provided the inspectors with one patient file that showed treatment for pterygium in June and July of 1993. Dr. Bauer was asked again to provide the last six patient files. He provided four additional files for patients who had been treated for pterygium in 1989, 1990, and 1991. The inspectors, then, asked Dr. Bauer for the other five files for the patients which Dr. Bauer had stated he had treated in 1993. Dr. Bauer stated that he didn't believe that any more patients were treated in 1993 other than the one provided.

The inspectors asked the secretary for the last six patient files, to which the secretary stated, after discussions with Dr. Bauer, that Dr. Bauer told her that he was mistaken on the number of patients he had treated in 1993 and that he thought that the patient file he had provided to the inspectors indicating treatment in June and July 1993 was the last treatment performed. The inspectors then asked the secretary for and received a patient scheduling log for 1993. The scheduling log indicated that two patients had been treated recently (September, October, and up to November 11, 1993) with the strontium-90 source. The inspectors asked for the specific patient files, to which the secretary stated that she would have to check with the doctor prior to providing the files. The secretary also told the inspectors that it would take some time to find the files since she did not know where they were. The secretary eventually provided the two files requested. Upon review of the files, by the inspectors, the patients were found to have been treated with the strontium-90 source for skin lesions.

REQUEST 13

During the November 11, 1993 inspection Dr. Bauer did not deny that he used strontium-90 to treat superficial skin lesions.

RESPONSE

Neither admit or deny.

REQUEST 14

If the Answer to Number 13 above is anything other than an unqualified admission, describe all circumstances in detail as to why the answer to Number 13 above is not an unqualified admission.

RESPONSE

The response to Request number 13, above, is not an unqualified admission because after the inspectors determined, from the review of the patient scheduling log and corresponding patient files, that Dr. Bauer had used the source for treatments of skin lesions, Dr. Bauer admitted that he had used the source for skin lesions. As described in response to Request number 12, above, Dr. Bauer did not inform the inspectors that he had used the strontium-90 source for treatments of skin lesions, when directly asked by the inspectors if he used the strontium-90 source for any other treatment modality.

REQUEST 15

At the time the inspectors left Indiana Regional Cancer Center on November 11, 1993, the inspectors had received all requested documentation from the Licensee.

RESPONSE

Admit.

REQUEST 16

If the Answer to Number 15 above is anything other than an unqualified admission, describe all circumstances in detail as to why the answer to Number 15 above is not an unqualified admission.

RESPONSE

A response to this request is not necessary since the response to Request number 15, above, is an admission.

REQUEST 17

Dr. James Bauer did not direct any of the Indiana Regional Cancer Center staff to withhold any information from the inspectors on November 11, 1993.

RESPONSE

Neither admit or deny.

REQUEST 18

If the Answer to Number 17 above is anything other than an unqualified admission, describe all circumstances in detail as to why the answer to Number 17 above is not an unqualified admission.

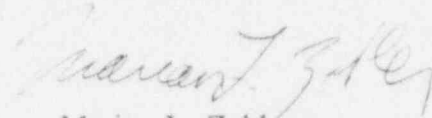
RESPONSE

The response to Request number 17, above, is not an unqualified admission because the inspectors do not know and did not ask whether Dr. Bauer directed his staff to withhold any information from the inspectors on November 11, 1993.

NRC STAFF MOTION FOR A PROTECTIVE ORDER

Pursuant to section 2.749(c) of the Commission's regulations, the Staff hereby requests that the Board enter a protective order directing that the production of certain documents requested by the Licensee in this proceeding need not be produced. The bases for the motion are set forth by the Staff, above, in the General Objection portion of this response.

Respectfully submitted,



Marian L. Zobler
Counsel for NRC Staff

Dated at Rockville, Maryland
this 3rd day of March, 1994

U.S. Department of Justice



United States Attorney
Western District of Pennsylvania

635 United States Post Office & Courthouse
Pittsburgh, Pennsylvania 15219

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February 22, 1994

Roger A. Fortuna
Deputy Director
Office of Investigations
U.S. Nuclear Regulatory Commission
Washington D.C. 20555

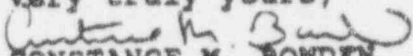
Dear Mr. Fortuna:

On January 13, 1994, I spoke with Barry R. Letts, Region I Field Office Director, Office of Investigations, U.S. Nuclear Regulatory Commission, regarding a referral to my office of a potential criminal matter. The discussion involved, among other things, the issue of false statements made by Dr. James E. Bauer, Medical Director, Indiana Regional Cancer Center (IRCC) to NRC inspectors during an inspection at the IRCC on November 11, 1993. During the week of January 24, 1994, I received, pursuant to my request, certain documents, including transcripts of statements obtained by the NRC Office of Investigations (OI), regarding the referred matter. Based on my discussion with Mr. Letts and my review to date of the documents, I have made a preliminary decision that this matter warrants a criminal investigation into possible violations of federal law.

At this time, I believe that the release of certain documents could adversely impact the criminal investigation. These documents contain information regarding the same facts which are likely to be the subject of the criminal investigation of the referred matter. In addition, these documents contain statements from individuals who are likely to be called as witnesses. It is, therefore, necessary to delay the production of these documents in order to protect the criminal investigative process. For this reason, the NRC staff should request a protective order delaying the production of the documents until the criminal investigation into the referred matter is completed,

or until such time it is determined that it is no longer
necessary to protect them.

Very truly yours;


CONSTANCE M. BOWDEN

Assistant U. S. Attorney