

DOCKETED
USNRC

UNITED STATES
NUCLEAR REGULATORY COMMISSION

'94 MAY 31 P3:39

In the Matter of
James Bauer, M.D.

)
)
)

OFFICE OF SECRETARY
DOCKETING & SERVICE
IA 94-011 BRANCH

ANSWER AND REQUEST FOR HEARING OF
JAMES E. BAUER, M.D. M.DIV. TO MAY 10, 1994
ORDER PROHIBITING INVOLVEMENT IN NRC-LICENSED
ACTIVITIES (EFFECTIVE IMMEDIATELY)

James E. Bauer, M.D., M.Div. files this Answer and Request for Hearing to May 10, 1994 Order Prohibiting Involvement In NRC-Licensed Activities (Effective Immediately) and in support thereof states as follows:

1. It is denied that Dr. Bauer willfully and/or intentionally violated License No. 37-28179-01.
2. It is admitted that Dr. Bauer used the strontium-90 source for the treatment of superficial eye and skin lesions.
3. It is denied that Dr. Bauer violated 10 CFR 30.9 and 30.10. Dr. Bauer believed that he was providing complete and accurate answers and information and that he was authorized under the license to perform the treatments to superficial skin lesions.

4. It is further denied that Dr. Bauer failed to cause an adequate survey to be made in November 1992. To the contrary, Dr. Bauer's conduct in November 1992 was at all times reasonable and did not constitute a violation of any applicable regulation.

Based on the above, as well as the fact that: (1) no radiation safety violations were found during the inspection; (2) the use of strontium-90 for the treatment of superficial skin lesion is appropriate; (3) no individuals were harmed in any manner; (4) there was absolutely no risk to public health and safety; (5) Dr. Bauer believed he was permitted to use the strontium-90 source for superficial skin lesion treatment; (6) Dr. Bauer fully and truthfully responded to all questions; and (7) Dr. Bauer provided all requested information to the inspectors, the May 10, 1994 Order should not have been issued and should be overruled.

Further, James E. Bauer, M.D. requests a hearing on the May 10, 1994 Order.

Respectfully submitted,




Marcy L. Colkitt
Pa. I.D. No. 53447
P.O. Box 607
Indiana, PA 15701-0607

Counsel for James E. Bauer, M.D.

Date: May 26, 1994

VERIFICATION

I, James E. Bauer, M.D., M. Div., verify that the information contained in the foregoing Answer and Request for Hearing of James E. Bauer, M.D., M.Div. to May 10, 1994 Order Prohibiting Involvement in NRC-Licensed Activities (Effective Immediately) is true and correct to the best of my knowledge, information or belief.


James E. Bauer, M.D., M. Div.

DOCKETED
USNRC

'94 MAY 31 P3:40

CERTIFICATE OF SERVICE

This 26th day of May, 1993, the foregoing ^{Answer and} Request for Hearing of James E. Bauer, M.D., M.Div. to May 10, 1994 Order Prohibiting Involvement In NRC-Licensed Activities (Effective Immediately) was served on the following as indicated below:

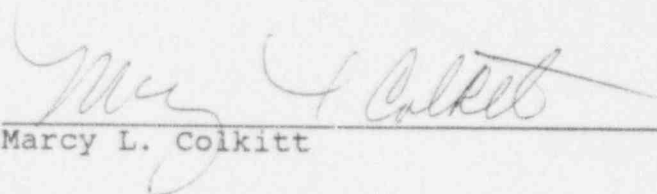
OFFICE OF SECRETARY
DOCKETING & SERVICE
BRANCH

James Lieberman, Esquire
Director, Office of Enforcement
U.S. Nuclear Regulatory Commission
Washington, D.C. 20555
(via U.S. Mail)

Mr. Lawrence J. Chandler
Assistant General Counsel for Hearings
U.S. Nuclear Regulatory Commission
Washington, D.C. 20555
(via U.S. Mail)

Thomas J. Martin, Regional Administrator
Nuclear Regulatory Commission
Region I
475 Allendale Road
King of Prussia, PA 19406
(via U.S. Mail)

Secretary
U.S. Nuclear Regulatory Commission
Attn: Chief, Docketing and Service Section
Washington, D.C. 20555
(via Overnight UPS - original and two copies)



Marcy L. Colkitt

C:\WP51\BAUERPDG

or consequences from radiological accidents.

The licensing action discussed in this memorandum involves only modification of the radon barrier design. These changes will not result in adverse environmental impacts. As environmental report is not required from the licensee since the amendment does not meet the criteria of 10 CFR 51.60(b)(2).

3. *Notice of Opportunity To Request Hearing:* In accordance with Title 10, Code of Federal Regulations, Part 2 (10 CFR 2), paragraph 2.1205(c)(1), interested parties are hereby notified that they may request a hearing pursuant to the procedures set forth in 10 CFR 2.1205 within thirty (30) days of the publication of this notice.

Signed in Rockville, Maryland this 5th day of May 1994.

Robert L. Johnson,

Acting Chief, HLUR.

[FR Doc. 94-11928 Filed 5-16-94; 8:45 am]

BILLING CODE 7590-01-M

NUCLEAR REGULATORY COMMISSION

[IA 94-011]

Order Prohibiting Involvement in NRC-Licensed Activities (Effective Immediately)

1

Dr. James Bauer, M.D. (Dr. Bauer) is listed as the Radiation Safety Officer (RSO) and sole authorized user on NRC License No. 37-28179-01 (license) issued to the Indiana Regional Cancer Center (Licensee) located in Indiana, Pennsylvania. Byproduct License No. 37-28179-01 was issued by the Nuclear Regulatory Commission (NRC or Commission) pursuant to 10 CFR parts 30 and 35, and authorizes the Licensee to use a strontium-90 source for the treatment of superficial eye conditions in accordance with the conditions specified therein. The license, originally issued on April 25, 1988, was due to expire on April 30, 1993, but remained in effect, pursuant to 10 CFR 30.37(b), based on a timely request for renewal that was received by the NRC on April 5, 1993. By an Order Modifying and Suspending License (Effective Immediately), issued November 16, 1993, the license was modified to prohibit Dr. Bauer from engaging in activities under the license and to suspend the Licensee's authority to receive and use licensed material.

II

On November 11, 1993, the NRC performed an inspection at the Licensee's facility in Indiana, Pennsylvania. During the inspection, the NRC found that Dr. Bauer had used the Licensee's strontium-90 source to perform treatments of two patients for skin lesions on several occasions between September and November 1993, even though the license does not authorize the use of the strontium-90 for any purpose other than the treatment of superficial eye conditions. Since the use of the strontium-90 source for treatment of skin lesions not involving the eye is not authorized by the license, a violation of the license occurred.

Prior to identifying that violation during the inspection, the inspectors asked Dr. Bauer, as the Radiation Safety Officer and only authorized user listed on the license, about the treatment modalities for which the strontium-90 source was used. Dr. Bauer stated that the source had been used for the treatment of pterygium, an eye condition. When the inspectors asked Dr. Bauer whether the source had ever been used for any other modality, he again replied that the source had been used to treat pterygium.

The inspectors then requested records of the last six patients who received treatment with the strontium-90 source. The records provided to the inspectors reflected only eye treatments. Subsequently, the inspectors performed a review of the patient treatment log maintained by Dr. Bauer's secretary, as well as a review of records of additional patient treatments. The inspectors learned that the records initially provided were not for the last six patients treated, and that the records of the last six patient treatments included treatments for superficial lesions of the skin using the strontium-90 source, including a treatment that occurred on the day of the inspection before the inspection took place.

Dr. Bauer's failure to inform the inspectors that he had used the strontium-90 source to treat lesions of the skin, when specifically asked if the source was used for any purpose other than superficial eye treatments, caused the Indiana Regional Cancer Center to violate the requirements of 10 CFR 30.9, in that Dr. Bauer failed to provide information that was complete and accurate in all material respects to the NRC. In addition, in view of Bauer's use of the strontium-90 source for treatment of skin lesions prior to and on the day of the inspection, Dr. Bauer's communications to the inspector also constitute a violation of 10 CFR 30.10,

in that Dr. Bauer deliberately provided to the NRC information that he knew to be incomplete or inaccurate in some material respect.

Previously, Dr. Bauer was involved in an incident in November 1992 at the Indiana Regional Cancer Center, as an authorized user and the supervisor of a treatment with a High Dose Rate Remote Afterloader (under Byproduct Materials License No. 37-28540-01 issued to Oncology Services Corporation), that resulted in a patient being exposed to significant levels of radiation, and numerous other members of the public being exposed to unnecessary radiation. Dr. Bauer had failed to cause a survey to be performed which was required by 10 CFR 20.201 and which could have prevented the exposures.

Based on the above, the NRC issued a Demand for Information (Demand) to Dr. Bauer on November 16, 1993. The Demand required Dr. Bauer to state: (1) Why the NRC should not issue an Order prohibiting Dr. Bauer's involvement in all NRC licensed activities; and (2) if such an Order should not be issued, why the NRC should have confidence that Dr. Bauer would comply with all Commission requirements. The Demand also required Dr. Bauer to state each institution and location at which Dr. Bauer engages in licensed activities.

In a letter dated January 5, 1994, Dr. Bauer, through his counsel, responded to the Demand for Information. The response stated that Dr. Bauer was a highly competent board certified radiation oncologist and radiologist with in excess of thirty years of experience in the safe use of radioactive materials; listed a number of areas where the licensee was found to be in compliance with NRC requirements and noted that there were no radiation safety violations, no harm to any individuals, and no risk to the public health and safety; stated that Dr. Bauer believed he was permitted to use the strontium-90 source for superficial skin lesion treatments; stated that Dr. Bauer fully and truthfully responded to all questions, and provided all requested information to the inspectors during the November 11, 1993 inspection; noted that the NRC had not attempted to levy any civil penalty for Dr. Bauer's alleged "failure to do an adequate survey in November 1992", and stated that the NRC has admitted that Dr. Bauer did not violate any license condition in November 1992 by allegedly failing to do an adequate survey; noted that the licensee's past performance has been exemplary; stated that there is no basis for the NRC to believe that Dr. Bauer will not comply with all Commission requirements, noting that he has in the

past and will at all times in the future continue to use his best efforts to fully comply with all Commission requirements; stated that there has never been any finding that Dr. Bauer willfully or negligently violated any federal regulations or that he improperly uses radioactive material; and argued that to bar Dr. Bauer from any future licensed activities would constitute a travesty of justice to Dr. Bauer, the patients who rely on him, and society in general.

III

Based on the above, and after giving due consideration to his response to the Demand for Information, it appears that Dr. Bauer has engaged in deliberate misconduct that has caused the Licensee to be in violation of 10 CFR 30.9; deliberately provided to NRC inspectors information that he knew to be incomplete or inaccurate in some respect material to the NRC, in violation of 10 CFR 30.10; and failed to conduct a required survey on November 16, 1992, which resulted in unnecessary radiation exposure to members of the public and a significant misadministration. The NRC must be able to rely on the Licensee and its employees, especially its authorized users and Radiation Safety Officer, to comply with all NRC requirements, including the requirement to provide information to the NRC that is complete and accurate in all material respects. Dr. Bauer's action in causing the Indiana Regional Cancer Center to violate 10 CFR 30.9 and his violation of 10 CFR 30.10 through deliberate misrepresentations to the NRC, as well as his failure to perform the required survey noted above, have raised serious doubt as to whether he can be relied upon to comply with NRC requirements and to provide complete and accurate information to the NRC.

Dr. Bauer is the sole authorized user and the Radiation Safety Officer on NRC License No. 37-28179. As such, Dr. Bauer is required to know the requirements of the License and adhere to them. Dr. Bauer is not permitted to select those requirements that he will follow.

Consequently, I lack the requisite reasonable assurance that licensed activities can be conducted in compliance with the Commission's requirements and that the health and safety of the public will be protected, if Dr. Bauer were permitted at this time to be named in any capacity on an NRC license or were permitted to otherwise perform licensed activities. Therefore, the public health, safety and interest require that Dr. Bauer be prohibited from being named on an NRC license in

any capacity and from otherwise performing licensed activities for a period of five years from the date of this order. For an additional two years, the public health, safety, and interest require that Dr. Bauer be required to notify the NRC of any involvement in licensed activities to assure that the NRC can monitor the status of Dr. Bauer's compliance with the Commission's regulatory requirements. Furthermore, pursuant to 10 CFR 2.202, I find that the significance of the violations and Dr. Bauer's conduct described above is such that the public health, safety and interest require that this Order be immediately effective.

IV

Accordingly, pursuant to sections 81, 161b, 161f, 162 and 166 of the Atomic Energy Act of 1954, as amended, and the Commission's regulations in 10 CFR 2.202 and 10 CFR 30.10, *It is Hereby Ordered*, Effective Immediately, That:

A. Dr. James Bauer, M.D., is prohibited for five (5) years from the date of this Order from being named on an NRC license in any capacity or from otherwise performing NRC-licensed activities.

B. For an additional two year period following the five year prohibition in Paragraph IV.A. above, Dr. Bauer shall, within 20 days of his acceptance of an employment offer involving NRC-licensed activities or becoming involved in NRC-licensed activities, provide notice to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555, of the name, address, and telephone number of the employer or the licensed entity where the licensed activities are or will be conducted.

The Director, Office of enforcement, may, in writing, relax or rescind any of the above conditions upon demonstration by Dr. Bauer of good cause.

V

In accordance with 10 CFR 2.202, Dr. Bauer must, and any other person adversely affected by this Order may, submit an answer to this Order, and may request a hearing on this Order, within 20 days of the date of this Order. The answer may consent to this Order. Unless the answer consents to this Order, the answer shall, in writing and under oath or affirmation, specifically admit or deny each allegation or charge made in this Order and shall set forth the matters of fact and law on which Dr. Bauer or other person adversely affected relies and the reasons as to why the Order should not have been issued. Any answer or request for a hearing shall be submitted to the Secretary, U.S. Nuclear Regulatory Commission, Attn: Chief, Docketing and Service Section,

Washington, DC 20555. Copies also shall be sent to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, Washington, DC 20555, to the Assistant General Counsel for Hearings and Enforcement at the same address, to the Regional Administrator, NRC Region I, 475 Allendale Road, King of Prussia, PA 19406 and to Dr. Bauer if the answer or hearing request is by a person other than Dr. Bauer. If a person other than Dr. Bauer requests a hearing, that person shall set forth with particularity the manner in which his or her interest is adversely affected by this Order and shall address the criteria set forth in 10 CFR 2.714(d).

If a hearing is requested by Dr. Bauer or a person whose interest is adversely affected, the Commission will issue an Order designating the time and place of any hearing. If a hearing is held, the issue to be considered at such hearing shall be whether this Order should be sustained.

Pursuant to 10 CFR 2.202(c)(2)(i), Dr. Bauer, or any other person adversely affected by this Order, may, in addition to demanding a hearing, at the time the answer is filed or sooner, move the presiding officer to set aside the immediate effectiveness of the Order on the ground that the Order, including and need for immediate effectiveness, is not based on adequate evidence but on mere suspicion, unfounded allegations, or error.

In the absence of any request for hearing, the provisions specified in Section IV above shall be final 20 days from the date of this Order without further order or proceedings. An answer or a request for hearing shall not stay the immediate effectiveness of this order.

Dated at Rockville, Maryland this 10th day of May 1994.

For the Nuclear Regulatory Commission,
Hugh L. Thompson, Jr.,
Deputy Executive Director for Nuclear Materials Safety, Safeguards and Operations Support.

[FR Doc. 94-11929 Filed 5-16-94; 8:45 am]
 BILLING CODE 7510-01-M

SECURITIES AND EXCHANGE COMMISSION

Forms under Review by the Office of Management and Budget

Agency Clearance Officer: John J. Lane, (202) 942-8800.

Upon Written Request, Copy Available From: Securities and Exchange Commission, Office of Filings and Information Services, 450 Fifth Street, NW., Washington, DC 20549.