

14721

February 28, 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)	
)	
(Byproduct Material)	EA No. 93-284
License No. 37-28179-01))	
)	

NRC STAFF MOTION FOR SUMMARY
DISPOSITION AND MOTION FOR DISMISSAL

INTRODUCTION

Pursuant to the Atomic Safety and Licensing Board's (Board) "Order (Prehearing Conference Order)" (Board Order) the Nuclear Regulatory Commission staff (Staff) hereby moves the Board to grant summary disposition on an issue relevant to the above-captioned proceeding. For the reasons set forth below, the Staff is entitled to a decision on the issue in its favor, as a matter of law. In addition, the Staff moves the Board to dismiss certain other issues proposed by the Indiana Regional Cancer Center (Licensee or IRCC) and Dr. James E. Bauer because, even if the facts assumed in those issues are true, they cannot provide the Licensee or Dr. Bauer with any relief.

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BACKGROUND

The IRCC is the holder of Byproduct License No. 37-28179-01 (strontium-90 license) issued by the Nuclear Regulatory Commission pursuant to 10 C.F.R. Parts 30 and 35. The strontium-90 license authorizes the Licensee to use a strontium-90 source for the treatment of superficial eye conditions at the Licensee's facility in Indiana, Pennsylvania.

On November 16, 1993, the Staff issued an Order Modifying and Suspending License (Effective Immediately)" (Suspension Order).¹ 58 Fed. Reg. 61932 (November 23, 1993). The Suspension Order suspended the strontium-90 license until further order. In addition, the Suspension Order modified the strontium-90 license to prohibit James E. Bauer, the RSO and only authorized user named on the strontium-90 license from engaging in activities under the license. Suspension Order at 5; 58 Fed. Reg. 61933. The Suspension Order was based, in part, on the fact that the Licensee had used its strontium-90 source to perform patient treatments for skin lesions on several occasions between September and November 1993, despite the fact that the strontium-90 license does not authorize the use of the source for any purpose other than the treatment

¹ The Staff also issued with the Suspension Order, a Demand for Information, requiring the Licensee to explain why the strontium-90 license should not be revoked. Suspension Order at 8; 58 Fed. Reg. 61933.

In addition, the Staff issued, on November 16, 1993, a Demand for Information to Dr. James E. Bauer, requiring Dr. Bauer to explain why the NRC should not issue an order prohibiting Dr. Bauer from all NRC licensed activities. "Demand for Information," at 5.

of superficial eye conditions. *Id.* at 1-2; 58 Fed. Reg. at 61932. In addition, Dr. Bauer failed to inform the NRC, in violation of section 30.9 of the Commission's regulations, that he had used strontium-90 to treat skin lesions when specifically asked by the NRC inspectors whether the source had been used for any purpose other than superficial eye treatments. *Id.* at 2-3; 58 Fed. Reg. at 61932-33. The Suspension Order was also based on an incident in November 1992 at the IRCC involving a patient treatment using a High Dose Rate (HDR) Afterloader that resulted in a patient being exposed to significant levels of radiation and numerous other members of the general public being exposed to unnecessary radiation. In that event, Dr. Bauer failed to cause an adequate survey to be made which could have prevented the exposures.² *Id.* at 3; 58 Fed. Reg. 61932.

On December 2, 1993, the Licensee filed, together with Dr. Bauer, its answer to the Suspension Order.³ "Answer of James E. Bauer, M.D., M. Div. and Indiana Regional Cancer Center to November 16th Order Suspending License No. 37-28179-01 of Indiana Regional Cancer Center," December 2, 1993. On December 14, 1993, a Board was designated. 58 Fed. Reg. 67427 (December 21, 1993). On December 17, 1993, the

² The November 1992 incident at the IRCC in which Dr. Bauer failed to perform an adequate survey, was cited as one basis for the "Order Suspending License (Effective Immediately)" issued to Oncology Services Corporation, who is the license holder for the HDR iridium-192 source (HDR license). 58 Fed. Reg. 6825 (February 2, 1993).

³ Accompanying the answer was a letter requesting a hearing by the Licensee. Although no specific mention was made of a hearing request on behalf of Dr. Bauer, the Board construed the hearing request in the letter to encompass a request for a hearing on Dr. Bauer's behalf. Board Order at 1-2 n.1. Both Dr. Bauer and the Licensee are, therefore, parties to this proceeding.

Board issued a "Memorandum and Order (Initial Prehearing Order)" (Memorandum and Order). In its Memorandum and Order, the Board requested that the parties file a joint prehearing report (report) containing, *inter alia*, a statement outlining the central issues for litigation in this proceeding. Memorandum and Order at 4-5. In addition, the Board scheduled a prehearing conference for January 26, 1994, at which the Board would consider various matters regarding the conduct of this proceeding. *Id.* at 5-6.

The prehearing report, filed on January 18, 1994, listed 10 issues which the parties agreed were central issues for litigation in this proceeding. Additionally, the report listed 14 issues, proposed by the Licensee and Dr. Bauer, which the Staff did not agree were central issues for litigation. The prehearing conference was held on January 26, 1994, and on February 1, 1994, the Board issued its Order. In its Order, the Board provided that "the parties shall have up to and including Monday, February 28, 1994, within which to file a dispositive motion relative to any of the issues specified in the parties' January 18, 1994 joint prehearing report." *Id.* at 1.

DISCUSSION

MOTION FOR SUMMARY DISPOSITION

STATEMENT OF MATERIAL FACTS AS TO WHICH
THERE IS NO GENUINE ISSUE TO BE HEARD

Pursuant to section 2.749 of the Commission's regulations, below is a list of those material facts relevant to the instant motion as to which there is no genuine issue to be heard.

1. The Suspension Order relied upon as a basis, *inter alia*, for suspending and modifying the strontium-90 license, Dr. Bauer's conduct under License No. 37-28540-01 issued to Oncology Services Corporation (HDR license). Suspension Order at 2, 3-4; 58 Fed. Reg. at 61932-33.
2. Dr. Bauer's conduct under the HDR license is the subject of pending litigation regarding the order suspending the HDR license issued to Oncology Services Corporation. "Order Suspending License (Effective Immediately)," 58 Fed. Reg. 6825.

A. Legal Standards Governing Summary Disposition

Section 2.749 of the Commission's regulations provides that any party may move for a decision by the presiding officer in that party's favor as to all or any part of the matters involved in the proceeding. 10 C.F.R. § 2.749(a). Summary disposition is favored by the Commission as "an efficacious means of avoiding unnecessary and possibly

time-consuming hearings on demonstrably insubstantial issues." *Wisconsin Elec. Power Co.* (Point Beach Nuclear Plant, Unit 1), ALAB-696, 16 NRC 1245, 1263 (1982) (citation omitted). Summary disposition is appropriate where it is shown that the movant is entitled to judgment as a matter of law, and where there is no genuine issue of material fact. 10 C.F.R. § 2.749(d); *see also*, *Florida Power and Light*, (Turkey Point Generating, Units Nos. 3 and 4), ALAB-660, 14 NRC 987, 1003 (1981). The movant seeking summary disposition has the burden of demonstrating the absence of any genuine issue of material fact. *Georgia Power Co.* (Vogtle Electric Generating Plant, Units 1 and 2), ALAB-872, 26 NRC 127, 133 (1987). A party opposing the motion may not rely on a simple denial of material facts stated by the movant but must set forth specific facts showing that there is a genuine issue. 10 C.F.R. § 2.749(b); *Cleveland Elec. Illuminating Co.* (Perry Nuclear Power Plant, Units 1 and 2), ALAB-841, 24 NRC 64, 93 (1986).

In accordance with the Commission's regulation governing summary disposition, the Staff has recited, above, the facts material to the issue of "[w]hether Dr. Bauer's alleged conduct under License No. 37-28540-01 (HDR license), which is subject to pending litigation, can as a matter of law, be a basis for the suspension of License No. 37-281709-01 (Strontium-90 license)?" There can be no dispute regarding those facts. Summary disposition on this issue is, therefore appropriate. Further, as discussed below, the Staff may, as a matter of law, rely upon, as a basis for suspending the strontium-90 license, the conduct of Dr. Bauer under the HDR license, even though Dr. Bauer's

conduct under the HDR license is subject to pending litigation. The Staff is, accordingly, entitled to a decision in its favor as a matter of law on this issue.

B. The Staff May, as a Matter of Law, Rely on Conduct Under One License as a Basis for Suspending a Different License

The report filed by the parties noted the issue of "[w]hether Dr. Bauer's alleged conduct under License No. 37-28540-01 (HDR license), which is subject to pending litigation, can as a matter of law, be a basis for the suspension of License No. 37-281709-01 (Strontium-90 license)?"⁴ Report at 2. As discussed below, the Staff

⁴ The report also contained several issues which the Staff did not agree were central issues for litigation in this proceeding because they all related to the over-arching legal issue which is the subject of this motion. Thus, if the Board grants the Staff's motion, these issues should also be dismissed. These issues are:

4. Whether allegations regarding Dr. Bauer's conduct on November 12, 1992 are relevant to this proceeding in that they involve a different source, a different license, and an entirely distinguishable factual setting?
5. Whether admission of evidence regarding Dr. Bauer's conduct on November 12, 1992 is improperly prejudicial given the posture of this proceeding and the confusion of issues likely to arise from the admission of that evidence?
6. Whether admission of evidence regarding Dr. Bauer's conduct on November 12, 1992 amounts *per se* to a denial of the due process rights of Dr. Bauer and the Licensee?
7. Whether admission of evidence into this proceeding regarding Dr. Bauer's conduct on November 12, 1992 amounts to a denial of due process rights of Dr. Bauer and the Licensee because Dr. Bauer and the Licensee have been denied the opportunity to review material in the NRC's possession regarding Dr. Bauer's conduct on November 12, 1992?

(continued...)

may, as a matter of law, rely upon, as a basis for suspending the strontium-90 license, the conduct of Dr. Bauer under the HDR license, even though Dr. Bauer's conduct under the HDR license is subject to pending litigation.

The Commission's authority under the Atomic Energy Act of 1954, as amended, (AEA) is uniquely broad. *Oncology Services Corp.*, LBP-94-2, 39 NRC ____, slip op. at 13 (January 24, 1994), citing *Siegel v. AEC*, 400 F.2d 778, 783 (D.C. Cir. 1968). Under sections 161b and 161i of the AEA, the Commission is empowered to issue orders to protect health or minimize danger to life or property. 42 U.S.C. § 2201. In addition, under section 186a of the AEA, the Commission may revoke, and by implication suspend, a license for, *inter alia*, any failure to observe any regulation of the Commission. 42 U.S.C § 2236. Similarly, the Commission's regulation regarding the issuance of orders provides that when issuing orders, the Staff may consider any facts deemed to be sufficient ground for the proposed action. 10 C.F.R. § 2.202(a)(1). Based on both the AEA and the Commission's regulations, the Staff may consider conduct by a licensee or RSO under a different license which supports the Staff's conclusion that a suspension of the license at issue is warranted.

⁴(...continued)

8. Whether allegations regarding Dr. Bauer's conduct on November 12, 1992 are admissible in this proceeding in that Dr. Bauer has yet had the opportunity to contest any implication of fault at a hearing and there has been no finding of fault against him?

Report at 3-4.

The Suspension Order, here, states, *inter alia*, that the Staff lacked the requisite reasonable assurance that the Licensee's current operations could be conducted under License No. 37-28179-01 (strontium-90 license) in compliance with the Commission's requirements and that the health and safety of the public will be protected. Suspension Order at 4; 58 Fed. Reg. at 61933. The Staff found that Dr. Bauer, the RSO and only authorized user listed on the strontium-90 license, was either unable or unwilling to assure that Commission requirements are being and will be followed. *Id.* One fact cited in the Suspension Order as a basis for the above findings was Dr. Bauer's conduct under the HDR license, where he failed to cause an adequate survey to be made during the incident on November 16, 1992 at the IRCC, in violation of section 20.201(b). *Id.* at 3-4; 58 Fed. Reg. at 61932-33; Letter to Marcy Colkitt from James Lieberman, NRC, dated December 30, 1993. Because Dr. Bauer's conduct during the November 16, 1992 incident at the IRCC under the HDR license cast doubt on his ability to follow the Commission's regulations and to conduct licensed activities under the strontium-90 license in a manner which ensures that the public health and safety will be protected, the Staff appropriately considered that conduct when suspending the strontium-90 license.

In addition, section 186 of the AEA provides that a license may be suspended for any reason which would have warranted the refusal to grant the license initially. Section 35.18, "License Issuance," of the Commission's regulations provides that a license for the medical use of byproduct material will be issued if, *inter alia*, it is found that the applicant is equipped and committed to observe the safety standards established by the Commission

for the protection of the public health and safety. 10 C.F.R. § 35.18(c). Thus, when considering a license application, the Staff must be free to consider any action of the applicant and/or other individuals named on the license application which bear on the ability of the applicant or individuals to conduct licensed activities safely and in accordance with the Commission's regulations. *Hamlin Testing Laboratories, Inc.*, 2 A.E.C. 423, 428 (1964), *aff'd* 351 F.2d 62 (6th Cir. 1966). *See also Randall C. Orem, D.O.*, CLI-93-14, 37 NRC 423, 431 (1993) (Dissenting Views of Commissioner Curtiss). Since Dr. Bauer's activities as an authorized user under the HDR license cast doubt on whether he is equipped and committed to observe the safety standards established by the Commission for the protection of the public health and safety, the Staff properly considered those activities when suspending the strontium-90 license.

Finally, the Staff may rely upon Dr. Bauer's conduct under the HDR license even though that conduct is the subject of pending litigation. As discussed above, the Commission has broad authority to protect the public health and safety by suspending a license. In addition, section 2.202 of the Commission's regulations provides that if the public health, safety, or interest requires it, the Staff may make an order immediately effective, without a prior hearing. An immediately effective order remains in effect even if the licensee against whom the order is issued requests a hearing challenging the basis for the order. 10 C.F.R. § 2.202. Reading the Commission's broad authority to protect public health and safety together with the provisions of section 2.202, it follows that the Staff may issue an order suspending a license based, in part, on findings that are the

subject of pending litigation. Unless and until it is determined that the Staff's findings are incorrect, the Staff must be able to take the necessary actions based on its findings to protect the public health and safety.

The Staff's consideration of findings that are subject to pending litigation does not violate the Licensee's or Dr. Bauer's due process rights. Both the Licensee and Dr. Bauer were given adequate notice of the basis for the Suspension Order. In addition, they were provided with the opportunity to challenge the immediate effectiveness of the Suspension Order, and the opportunity to request a hearing on the Suspension Order; such request for a hearing was, in fact, made by both the Licensee and Dr. Bauer.

In summary, the Staff properly relied, as a basis for the Suspension Order issued to the IRCC, on the conduct of Dr. Bauer under the HDR license. In addition, there is no genuine issue as to any material fact related to the issue which is the subject of this motion. The Staff is, therefore, entitled to summary disposition, in its favor, on the issue of whether Dr. Bauer's alleged conduct under License No. 37-28540-01 (HDR license), which is subject to pending litigation, can as a matter of law, be a basis for the suspension of License No. 37-281709-01 (strontium-90 license).

MOTION FOR DISMISSAL

A. Four Issues Proposed By The Licensee Should Be Dismissed

Four issues proposed by the Licensee and Dr. Bauer as central issues to be litigated in this proceeding should be dismissed because the facts assumed in these issues, even if true, cannot entitle the Licensee or Dr. Bauer to any relief. These issues are:

1. Whether the use of the strontium-90 as treatment for skin lesions on the two identified patients was medically appropriate treatment?
2. Whether there was any risk to the public health, safety or other interest by virtue of the use of the strontium-90 as treatment for skin lesions on the two identified patients?
3. Whether provision of the patient treatment log constitutes provision of complete and accurate information by the Licensee to the NRC?
14. Whether substantial patient need exists for Strontium-90 treatment at IRCC?

Report at 3-4.

Dismissal is appropriate where, as here, there is no set of facts which would entitle the non-moving party to relief. *See* Fed. R. Civ. P. 12(b)(6) (Defense of failure to state a claim upon which relief may be granted). *See also Hishon v. King & Spalding*, 467 U.S. 69, 73 (1984). Dismissal of certain of the proposed issues pursuant to the principles which govern motions to dismiss for failure to state a claim upon which relief can be granted is appropriate in this proceeding. *See Oncology Services Corp.*, LBP-94-2 at 19 n.8. The above issues proposed by the Licensee and Dr. Bauer should be dismissed because there is no set of facts which would entitle either party to any relief. A favorable decision with respect to these issues could not result in the lifting of the license suspension

or modification, nor would any of these issues pose a valid defense to the Suspension Order. These proposed issues, therefore, should be dismissed.

Issue 1 should be dismissed because even if true, the facts assumed in that issue cannot entitle the Licensee or Dr. Bauer to any relief. Whether or not the use of strontium-90 for the treatment of skin lesions was medically appropriate (issue 1), has no relevance to the basis of the Suspension Order. The Suspension Order was based on three findings: the use of licensed material in a manner not authorized by the strontium-90 license; incomplete and inaccurate statements made to the NRC inspectors by the Licensee's RSO and only authorized user, Dr. Bauer, in violation of NRC requirements (10 C.F.R. § 30.9); and, the November 16, 1992 incident at the IRCC in which Dr. Bauer failed to cause an adequate survey to be made in violation of NRC requirements (10 C.F.R. § 20.201(b)). Suspension Order at 3-4; 58 Fed. Reg. 61932-33. This led to the Staff's conclusion that it lacked the requisite assurance that the Licensee's current operations under the strontium-90 license could be conducted in compliance with the Commission's requirements and that the health and safety of the public would be protected. *Id.* Even if the use of strontium-90 to treat skin lesions were medically appropriate, such use was not authorized by the strontium-90 license. In addition, the appropriateness of using strontium-90 to treat skin lesions has no relevance to the Staff's finding that Dr. Bauer provided incomplete and inaccurate statements to the NRC during the November 11, 1993 inspection or to the Staff's finding regarding Dr. Bauer's conduct

during the November 16, 1992 incident. Thus, issue 1 should be dismissed because it cannot provide the Licensee or Dr. Bauer with any relief.

Issue 2 misstates the risk to the public health and safety which was the basis for the Suspension Order. The Suspension Order stated that, based on the three findings cited in the Suspension Order, the Staff no longer had reasonable assurance that the Licensee would be able to conduct licensed activities in a manner which ensures that the public health and safety will be protected, that the RSO and authorized user failed to provide accurate and complete information, and that the RSO and authorized user apparently was unwilling or unable to comply with the Commission's regulations and requirements. Suspension Order at 3-4; 58 Fed. Reg. 61932-33. The NRC, in discharging its responsibility to protect the public health and safety must be assured that a licensee will adhere to the Commission's regulations and provide complete and accurate information to the NRC. *Hamlin Testing*, 2 A.E.C. at 428; *Randall C. Orem*, CLI-93-14, 77 NRC at 431. Whether the use of strontium-90 to treat skin lesions, itself, was a risk to the public health and safety is not relevant to the finding that the Staff could no longer be assured that the Licensee and Dr. Bauer would follow the Commission's regulations or the terms of its license. Issue 2, therefore, should be dismissed because even if the facts assumed in it are true, those facts cannot entitle the Licensee or Dr. Bauer to any relief.

Issue 3, whether provision of the patient treatment log constitutes provision of complete and accurate information by the Licensee to the NRC, misstates the Staff's finding regarding the failure of Dr. Bauer to provide complete and accurate information.

The Staff found that Dr. Bauer failed to provide complete and accurate information when he failed to inform the NRC 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 during the November 11, 1993 inspection. Suspension Order at 2, 3; 58 Fed. Reg. 61932-33. That the NRC inspectors subsequently requested and obtained patient treatment logs, has no relevance to the issue of whether Dr. Bauer failed to provide complete and accurate information when questioned by the NRC inspectors. Issue 3, therefore, should be dismissed because, even if the facts assumed in the issue are true, they cannot provide the Licensee or Dr. Bauer with any relief.

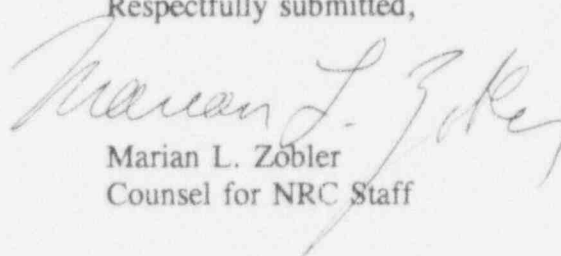
Issue 14, whether substantial patient need exists for strontium-90 treatment at the IRCC, should be dismissed because, even if the facts assumed in issue 14 are true, they cannot provide the Licensee or Dr. Bauer with any relief. Whether or not there exists a patient need for strontium-90 treatment, has no relevance to the Staff's determination that the Licensee and Dr. Bauer are unable to perform licensed activities in conformance with the Commission's rules and regulations. *Oncology Services Corp.*, LBP-94-4, at 25. The facts in issue 14, therefore, cannot entitle the Licensee with any relief; issue 14 should be dismissed.

In summary, the four proposed issues discussed above should be dismissed because even if the facts assumed in each of the issues are true, those facts cannot entitle the Licensee or Dr. Bauer to any relief. Those issues should, therefore, be dismissed.

CONCLUSION

For the reasons set forth above, the Staff's motion for summary disposition should be granted and the Staff's motion to dismiss should be granted.

Respectfully submitted,

A handwritten signature in cursive script, appearing to read "Marian L. Zobler".

Marian L. Zobler
Counsel for NRC Staff

Dated at Rockville, Maryland
this 28th day of February, 1994

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CONFIDENTIAL
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No. 37-28179-01))

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CERTIFICATE OF SERVICE

I hereby certify that copies of "NRC STAFF MOTION FOR SUMMARY DISPOSITION AND MOTION FOR DISMISSAL" in the above-captioned proceeding have been served on the following through deposit in the Nuclear Regulatory Commission's internal mail system, or by express mail as indicated by an asterisk, this 28th day of February, 1994:

G. Paul Bollwerk, III, Chairman
Administrative Judge
Atomic Safety and Licensing Board
U.S. Nuclear Regulatory Commission
Washington, D.C. 20555

Dr. Peter S. Lam
Administrative Judge
Atomic Safety and Licensing Board
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Washington, D.C. 20555

Dr. Charles N. Kelber
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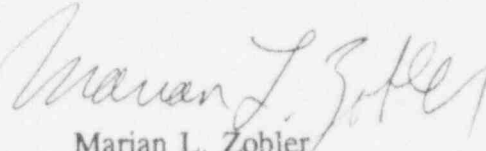
Office of the Secretary (2)
U.S. Nuclear Regulatory Commission
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Marian L. Zabler
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