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UNITED STATES OF AMERICA
NUCLEAR REGULATORY COMMISSION

OFFICE OF SECRETARY
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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 REPLY TO IRCC'S RESPONSE TO 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), dated February 1, 1994, the Nuclear Regulatory Commission staff (Staff) hereby replies to the Indiana Regional Cancer Center (Licensee) and Dr. Bauer's "Response to NRC Staff Motion For Summary Disposition and Motion For Dismissal," dated March 31, 1994 (Licensee's Response). For the reasons set forth below, the Board should grant the "NRC Staff Motion for Summary Disposition and Motion to Dismiss," dated February 28, 1994 in its entirety.

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BACKGROUND

On January 18, 1994, the parties filed a joint prehearing report, which listed 10 issues that 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. On February 1, 1994, the Board issued an Order which provided:

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. Any response to a dispositive motion shall be filed on or before Thursday, March 31, 1994, and a reply to any response shall be filed on or before Friday, April 15, 1994.

Board Order at 1-2. On February 28, 1994, the Staff filed together two motions: a Motion For Summary Disposition (Staff's Summary Disposition Motion) with respect to an issue relevant to the proceeding, and a Motion to Dismiss (Staff's Motion to Dismiss) certain issues proposed by the Licensee and Dr. Bauer. On the same date, the Licensee and Dr. Bauer filed a "Motion to Eliminate Basis For Suspension" (Licensee and Dr. Bauer's Motion to Eliminate). On March 31, 1994, the Staff filed its response to the Licensee and Dr. Bauer's Motion to Eliminate, and the Licensee and Dr. Bauer filed their Response to the Staff's Summary Disposition Motion and the Staff's Motion to Dismiss. The Staff's reply to the Licensee and Dr. Bauer's Response is set forth below.

DISCUSSION

I. Staff's Motion For Summary Disposition

In their Response, the Licensee and Dr. Bauer contest the Staff's assertion that there is "no genuine issue to be heard with regard to [the] facts" set forth by the Staff in its Motion.

Response at 3. The Licensee and Dr. Bauer also argue that the Staff has not provided any credible reason why, as a matter of law, the Staff can rely on conduct under another license to support the strontium-90 license Suspension Order. In support of this latter argument, the Licensee and Dr. Bauer assert that section 186a of the Atomic Energy Act of 1954, as amended (AEA), is not applicable to license suspension, and that the Staff, having thus mischaracterized section 186a, incorrectly relies on 10 C.F.R. § 35.18 as support for its Summary Disposition Motion. Response at 5-6. The Licensee and Dr. Bauer set forth two unrelated reasons why the Staff's Summary Disposition Motion should not be granted. The Licensee and Dr. Bauer claim that 10 C.F.R. § 2.202 does not provide support for the Staff's Summary Disposition Motion, and that the Licensee and Dr. Bauer's Fifth Amendment due process rights are being violated. Response at 5-6. All of these arguments are without merit.

As stated above, the Licensee and Dr. Bauer first contest the Staff's assertion that there is no genuine issue to be heard with regard to the facts cited by the Staff in its Summary Disposition Motion as relevant to the issue which is the subject of the motion. Response at 3. However, the Licensee and Dr. Bauer do not argue that any particular material fact which is relevant to the issue in question is in dispute. In addition, the Licensee and Dr. Bauer agree with the Staff that the facts are material and relevant to the Staff's Motion. *Id.* In light of the Licensee and Dr. Bauer's failure to argue that there are material facts in dispute, the Staff's assertion that there is no genuine issue of fact to be heard is correct, and the Licensee and Dr. Bauer's argument to the contrary is without merit.

The Licensee and Dr. Bauer next claim that the Staff has failed to provide "a single credible reason" as to why Dr. Bauer's alleged conduct under the HDR license, which is subject to pending litigation, can, as a matter of law, be a basis for the suspension of the strontium-90 license. *Id.* at 3. As argued in the Staff's Summary Disposition Motion, the AEA empowers the Staff with broad authority to issue orders to protect the public health and safety. *See* Staff's Summary Disposition Motion at 8, *citing Siegel v. AEC*, 400 F.2d 778, 783 (D.C. Cir. 1968). It follows that the AEA's broad grant of authority to the Commission encompasses the authority to consider all conduct within its scope of awareness in acting to protect public health and safety. The Staff specifically cited to AEA sections 161b, 161i, and 186a in support of its position that it has ample authority to rely on conduct under one license as a basis for suspending a different license. Staff's Summary Disposition Motion at 8-10. Nowhere in their Response do the Licensee and Dr. Bauer challenge that sections 161b and 161i of the AEA do not impart broad authority to the Staff.

Instead, in support of their general argument, the Licensee and Dr. Bauer contend that section 186a of the AEA does not apply to license suspensions, and, therefore, the Staff's references to 10 C.F.R. § 2.202(a)(1) and 10 C.F.R. § 35.18, are incorrect. Response at 5-6. The Licensee and Dr. Bauer assert that Section 186a of the AEA applies strictly to license revocation proceedings, and not to license suspensions. *Id.* at 5. To support their argument, the Licensee and Dr. Bauer cite to the "plain language" of the statute. *Id.* This argument ignores Commission precedent. Although the wording of section 186a does not specify "suspension," Commission case law has held that the power to revoke clearly includes the power

to impose the lesser penalty of suspension. *Oncology Services Corp.*, LBP-94-2, 39 NRC ____, slip op. at 13 (January 24, 1994) (section 186a permits license revocation and, by necessary implication, suspension). The Licensee and Dr. Bauer offer no explanation as to why the holding of the atomic safety and licensing board in the *Oncology* case should not apply in the instant proceeding. Therefore, the Staff was correct in its assertion that section 186a applies to license suspensions. Staff's Summary Disposition Motion at 8.

In support of their general argument, the Licensee and Dr. Bauer also argue that the Staff uses its above-stated "mischaracterization" of section 186 "to argue that 10 C.F.R. § 35.18, which addresses license issuance, is applicable to license suspension." Response at 6. In light of the failure of the Licensee and Dr. Bauer's argument that section 186a does not apply to license suspensions, the instant argument must also fail. In its Summary Disposition Motion, the Staff argued that section 186a of the AEA states that a license may be revoked and, by necessary implication, suspended because of conditions revealed "which would warrant the Commission to refuse to grant a license on an original application." Summary Disposition Motion at 9-10. With respect to those conditions which would warrant the Commission to reject an original license application, the Commission's regulations at 10 C.F.R. § 35.18 establish criteria for "License Issuance." That provision states 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 public health and safety. 10 C.F.R. § 35.18(c). Therefore, the Staff's reference to

10 C.F.R. § 35.18 was appropriate, and the Licensee and Dr. Bauer's argument to the contrary is without merit.

Finally, the Licensee and Dr. Bauer also claim that the Staff is not truly sincere with respect to its concern for health and safety, because the Staff has objected to the inclusion of some issues in the instant proceeding related to safety.¹ Response at 3-4. Contrary to the Licensee and Dr. Bauer's assertion, the Staff does not "disavow the relevance of public health and safety." Response at 4. In fact, the Staff in the instant proceeding, motivated by its lack of reasonable assurance that public health and safety will be protected, issued an order suspending the Licensee's strontium-90 license and modifying the license to remove Dr. Bauer from activities under the license. Suspension Order at 4; 58 Fed. Reg. 61932.

The Staff asserted that, in the limited context of this enforcement proceeding, certain issues raised by the Licensee and Dr. Bauer are not relevant. Staff's Motion to Dismiss at 14. The Staff objected to the inclusion of the issue of 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. *Id.* at 12, 14. The Staff made this objection, not in an attempt to disavow the relevance of public health and safety, but, rather because the scope of enforcement proceedings may be limited to the issues underlying the Suspension Order. See *Boston Edison Co.* (Pilgrim Nuclear Power Station), CLI-82-16, 16 NRC 44 45 (1982). As discussed *infra*, the Licensee and

¹ In particular, the Licensee and Dr. Bauer refer to the Staff's Motion in which the Staff sought dismissal of the issue of the existence of 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. *Id.* at 4.

Dr. Bauer's claim that the facts underlying this issue are relevant since they have the tendency to make the existence of "any misuse of strontium-90, or any supposed misbehavior of Dr. Bauer in providing information to the NRC, or in acting under the HDR license" less true than without the facts is without merit. See Discussion, *infra*, at 11-12. Moreover, the Suspension Order was not based on the risk inherent in the use of the strontium-90 as treatment for skin lesion, but rather, the Suspension Order was based in part on the risk that information provided to the NRC will not be complete and accurate in all material respects and that the Licensee's operations would not be conducted in compliance with the Commission's regulations. Suspension Order at 3-4; 58 Fed. Reg. 61932-33. Therefore, the Staff was correct to assert that the issue of 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 is not relevant to the proceeding.²

The Licensee and Dr. Bauer claim that the Staff, in its Summary Disposition Motion, combines its authority "under 10 C.F.R. §2.202, to somehow, mystically justify" utilizing conduct under the HDR license as a basis for the suspension of the strontium-90 license. Response at 6. There is nothing mystical about the Staff's argument at all. In its Motion, the Staff refers to the Commission's regulations at 10 C.F.R. § 2.202, which provide a mechanism for the Commission to issue an immediately effective order to a licensee. See Staff's Summary

² The NRC, in discharging its responsibility for the protection of 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 Laboratories, Inc.*, 2 AEC 423, 428 (1964), *aff'd* 357 F.2d 632 (from viewpoint of public health and safety, no area imaginable requires stricter adherence to rules and regulations than that dealing with radioactive materials) (6th Cir. 1966). See also *Randall C. Orem, D.O.*, CLI-93-14, 37 NRC 423,431 (1993) (Dissenting Views of Commissioner Curtiss).

Disposition Motion at 10-11. In issuing immediately effective orders, the Staff may issue an order before the basis of that order has been litigated in a hearing. It follows, therefore, that the Staff can rely on facts, such as Dr. Bauer's conduct under the HDR license, which are subject to pending litigation. Thus, Dr. Bauer and the Licensee's argument is without merit, because the Staff's discussion of section 2.202 bears a logical relationship to the Commission's ability to use prior, unadjudicated conduct as a basis for an order.

The Licensee and Dr. Bauer, in their Response, offer nothing to support their broad claim that their Fifth Amendment due process rights are in jeopardy. The Licensee and Dr. Bauer have failed to address the Staff's specific showing that they were provided with notice and an opportunity to be heard on the Suspension Order. Staff's Summary Disposition Motion at 11. The Staff provided the Licensee and Dr. Bauer with adequate notice of the bases for the Suspension Order. The Licensee and Dr. Bauer were also given an 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 addition, they were provided with an opportunity, of which they chose not to avail themselves, to challenge the immediate effectiveness of the Suspension Order. The Staff has afforded the Licensee and Dr. Bauer all the process that they are due. *See Metropolitan Edison Co.*, (Three Mile Island Nuclear Station, Unit 1), CLI-85-2, 21 NRC 316 (1985). The Licensee and Dr. Bauer's claim is, therefore, unfounded.

In summary, the Licensee and Dr. Bauer's arguments against the Staff's Summary Disposition Motion are unfounded and do not refute the Staff's showing that it is entitled to judgment as a matter of law 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). The Staff is, therefore, entitled to summary disposition, in its favor, on that issue.

II. Staff's Motion to Dismiss

In its Motion, the Staff, relying on the standards which govern motions filed pursuant to Rule 12(b)(6) of the Federal Rules of Civil Procedure, requested that the Board dismiss four issues proposed by the Licensee and Dr. Bauer as central issues to be litigated in this proceeding.³ Staff's Motion to Dismiss at 12. The Licensee and Dr. Bauer claim that Rule 12(b)(6) "is not an appropriate basis for the elimination of issues the Staff seeks" and that Rule 12(b)(6) is inapplicable here because "there is no claim for relief to which the Staff can assert a defense under Rule 12(b)(6)". Response at 7-8. The Staff does not base its Motion to Dismiss on Rule 12(b)(6) of the Federal Rules of Civil Procedure, but, rather, draws upon

³ These issues were:

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?

Staff Motion to Dismiss at 12.

principles contained in Rule 12(b)(6) in its argument that dismissal of the four issues is appropriate in that no set of facts underlying these issues would entitle the Licensee and Dr. Bauer to relief.

In making their argument, the Licensee and Dr. Bauer ignore case law to the contrary. The Board has the authority to entertain the Staff's Motion to Dismiss and to apply the principles of Rule 12(b)(6). See *Oncology Services Corp.*, LBP-94-2 at 19 n.8. In *Oncology*, the Atomic Safety and Licensing Board held that the Staff was correct in its observation that, "if after all factual allegations in these issues are presumed to be true and all reasonable inferences are made in favor of [the licensee], there is no set of facts that would entitle [the licensee] to relief on these issues, dismissal is appropriate." *Id.* Thus, the Staff's reliance on the standards of Rule 12(b)(6) was appropriate.

The Licensee and Dr. Bauer assert that the appropriate standard to apply with respect to the elimination of issues is that contained in 5 U.S.C. § 556(d). Response at 8-10. The Staff agrees that evidence which is relevant, material, and reliable is admissible. 10 C.F.R. § 2.743(c). The standard advanced by the Licensee and Dr. Bauer, however, is limited in its application to the admissibility of evidence and does not extend to the determination of appropriate issues. See 1 Wigmore on Evidence § 2 (permitting a fact to become a proposition is not an evidentiary process). Further, even under the standard advanced by the Licensee and Dr. Bauer, the evidence pertaining to the issues the Staff seeks to eliminate may properly be excluded because the evidence is not material to the issues upon which the Suspension Order is based. See 10 C.F.R. § 2.743(c); see also 5 U.S.C. § 556(d) (agency shall provide for exclusion of

immaterial and irrelevant evidence). The evidence underlying the four issues the Staff seeks to dismiss is not material because the issues themselves, the propositions to which the evidence is directed, are not relevant to the proceeding. See I Wigmore on Evidence § 2 (immaterial evidence is excluded on the ground that it tends to establish a proposition that has no legal significance).

The Licensee and Dr. Bauer claim that the evidence underlying the issues the Staff wishes to dismiss has "the tendency to make the existence of any misuse of strontium-90, or any supposed misbehavior of Dr. Bauer in providing information to the NRC, or in acting under the HDR license, less probable that it would be without the evidence." Response at 11. The facts underlying the four issues the Staff seeks to eliminate have no relation whatsoever to the proceeding.⁴ Even if the facts underlying the four issues were true, they do not have the tendency to make the existence of the facts set forth in the Suspension Order any less true.

The facts underlying issue 1, whether or not the use of strontium-90 for the treatment of skin lesions was medically appropriate, have no relevance to the bases of the Suspension Order. Even if the use of strontium-90 to treat skin lesions were medically appropriate, such use was not authorized by the license. Thus, the facts underlying this issue have no tendency to make the Staff's finding that Dr. Bauer performed activities with the strontium-90 source that were not authorized by the license, the Staff's finding that Dr. Bauer failed to provide complete and

⁴ The Licensee and Dr. Bauer confuse the facts underlying the order in the present proceeding with those in the HDR proceeding. In their Response the Licensee and Dr. Bauer state that the Staff seeks to limit issues solely to those based on direct contradiction "of the purported indications, expressed by the NRC in the suspension order, of such a breakdown." Response at 11. The Suspension Order did not cite to a "breakdown."

accurate information to the NRC during the November 11, 1993 inspection, or the Staff's finding regarding Dr. Bauer's conduct during the November 16, 1992 incident more or less true. Therefore, the facts underlying this issue would not be relevant.

Similarly, the facts underlying issue 2, whether there was any risk to the public health, safety or other interest by virtue of the use of the strontium-90 for treatment of skin lesions, have no relevance to this proceeding. Even if there were no risk by virtue of the use of strontium-90 for the treatment of the skin this fact does not have the tendency to make the existence of the unauthorized use of strontium-90, the misbehavior of Dr. Bauer in providing information to the NRC, or the actions of Dr. Bauer regarding the November 16, 1992 incident at the IRCC any less probable than without the evidence. As a consequence of the findings in the Suspension Order, the Staff lacked reasonable assurance that the public health and safety will be protected, that Dr. Bauer will provide accurate and complete information, and that the Licensee's operations can be conducted in compliance with the Commission's requirements. Suspension Order at 3-4; 58 Fed. Reg. 61932-33. The issue of whether the use of strontium-90 to treat skin lesions, itself, was a risk to the public health and safety was not necessary to the Staff's determination that it lacked reasonable assurance that the public health and safety will be protected. Therefore, the facts underlying this issue are not relevant or material to this proceeding.

The facts underlying issue 3, whether provision of the patient treatment log constitutes provision of complete and accurate information by the Licensee to the NRC, do not tend to make the existence of the facts underlying the bases of the Suspension Order any less true than they

would be without the evidence. In particular, the Staff's finding that Dr. Bauer failed to provide complete and accurate information is based on Dr. Bauer's failure to inform the NRC inspectors that he had used the strontium-90 source to treat skin lesions, when the inspectors specifically asked him if the source was used for any purpose other than superficial eye treatments. Suspension Order at 2, 3; 58 Fed.Reg. 61932-33. Thus, even if the Licensee had provided a patient treatment log, this fact does not tend to make Dr. Bauer's statements to the inspectors any more or less true. Therefore, the facts underlying the issue are not relevant or material, even under the Licensee and Dr. Bauer's proposed standard.

The facts underlying issue 14, whether substantial patient need exists for strontium-90 treatment at IRCC, are not relevant or material, because these facts have no tendency to make the existence of the unauthorized use of strontium-90, the misbehavior of Dr. Bauer in providing information to the NRC, or the actions of Dr. Bauer regarding the November 16, 1992 incident at the IRCC any less probable than they would be without the evidence. The Order was based on three facts, not one of which related to patient need. Therefore, it is inconceivable that facts pertaining to the issue of patient need would cause any of the facts underlying the basis of the Suspension Order to be any less probable than without the evidence. *See Onocology*, LBP-94-2 at 25.

In summary, the four proposed issues discussed above should be dismissed pursuant to the principles of Rule 12(b)(6) of the Federal Rules of Civil Procedure. Section 556(d) of the APA is an evidentiary standard and is not appropriate in the context of issue elimination. In accordance with the principles of Rule 12(b)(6), the four issues should be dismissed because,

even if the facts assumed in each one of them are true, those facts cannot entitle the Licensee or Dr. Bauer to any relief.

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,

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Dated at Rockville, Maryland
this 15th day of April, 1994

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UNITED STATES OF AMERICA
NUCLEAR REGULATORY COMMISSION

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BEFORE THE ATOMIC SAFETY AND LICENSING BOARD OFFICE OF SECRETARY
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(Byproduct Material) EA No. 93-284
License No. 37-28179-01)

CERTIFICATE OF SERVICE

I hereby certify that copies of "NRC STAFF REPLY TO IRCC'S RESPONSE TO 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 15th day of April, 1994:

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