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UNITED STATES OF AMERICA
NUCLEAR REGULATORY COMMISSION

BEFORE THE ATOMIC SAFETY AND LICENSING BOARD

OFFICE OF SECRETARY
~~DOCKETING~~ & SERVICE
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IN THE MATTER OF:	:	Docket No. 030-30485-EA
	:	
INDIANA REGIONAL CANCER CENTER,	:	
INDIANA, PENNSYLVANIA	:	
	:	
(Byproduct Material	:	
License No. 37-28179-01)	:	EA No. 93-284

RESPONSE TO NRC STAFF MOTION FOR
SUMMARY DISPOSITION AND MOTION FOR DISMISSAL

I. INTRODUCTION

Pursuant to the Order of the Atomic Safety and Licensing Board dated February 1, 1994, the Indiana Regional Cancer Center, Licensee, and James E. Bauer, M.D., by and through their counsel, Iles Cooper, Esquire, and Williamson, Friedberg & Jones hereby submit the following Response to NRC Staff Motion for Summary Disposition and Motion for Dismissal ("Staff's Motions"). In support hereof, the Indiana Regional Cancer Center ("IRCC") and James E. Bauer, M.D., ("Dr. Bauer") hereby state as follows:

11. ARGUMENT

A. RESPONSE TO MOTION FOR SUMMARY DISPOSITION

1. Staff has Presented No Substantive Argument Refuting Licensee's Claim that the Use by the Nuclear Regulatory Commission of the Alleged Conduct of Dr. James E. Bauer under License No. 37-28540-01 (HDR License) as a Basis for the Suspension of License No. 37-28179-01 (IRCC Strontium-90 License) is Unlawful as it Violates the Due Process Guaranties Embodied in the Fifth Amendment to the Unites States Constitution and is Improper Because Dr. Bauer's Alleged Conduct under License No. 37-28540-01 is Irrelevant and Immaterial with Regard to License No. 37-28179-01.

In the Motion for Summary Deposition section of Staff's Motions, the Nuclear Regulatory Commission ("NRC") Staff ("Staff") lists, pursuant to Section 2.749 of the NRC Regulations, what it contends are relevant material facts as to which there exists no genuine issue. See Staff's Motions at 5. Staff states that there is no genuine issue to be heard as to the following facts:

- "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. at 6325."

Staff's Motions at 5.

While IRCC and Dr. Bauer agree with Staff that the two (2) facts set forth immediately above are material and relevant to the instant motion, IRCC and Dr. Bauer contest any assertion that there is no genuine issue to be heard with regard to these facts. See Staff's Motions at 5. To the contrary, IRCC and Dr. Bauer vociferously object to the arguments which Staff sets forth under the heading "The Staff May, as a Matter of Law, Rely on Conduct Under One License as a Basis for Suspending a Different License." See Staff's Motions at 7.

In its argument, Staff utterly fails to provide a single credible reason as to why ". . . Dr. Bauer's alleged conduct under License No. 3728540-01 (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)." See Pre-Hearing Report at 2.

In the Motion for Summary Deposition section, Staff appears content to ramble about public health and safety, while providing absolutely no substantive justification for trammeling the Fifth Amendment due process rights of IRCC and Dr. Bauer. While Staff repeatedly invokes the protection of public health and safety as a basis for NRC action, it demonstrates its own lack of conviction in its position by stating that public health and safety was not a relevant factor to be considered by the NRC

when deciding those issues which should be central issues to be litigated in this proceeding. See Staff's Motions at 14.

In its argument, Staff, attempts to portray a deep and abiding concern for public health and safety. See Staff's Motions at 8 ("the Commission is empowered to issue orders to protect Health or minimize danger to life or property."); Staff's Motions at 9 (" . . . that the health and safety of the public will be protected."); Staff's Motions at 9 (" . . . insures that the public health and safety will be protected."); Staff's Motions at 10 (" . . . for the protection of the public health and safety"); Staff's Motions at 10 (" . . . for the protection of the public health and safety . . ."); Staff's Motions at 10 (" . . . the Commission has broad authority to protect the public health and safety. . ."); Staff's Motions at 10 (" . . . if the public health, safety or interests requires it . . ."); Staff's Motions at 10 (" . . . to protect public health and safety. . ."). However, when IRCC and Dr. Bauer seek to raise concern about public health and safety Staff easily saw fit to disavow the relevance of public health and safety. See Staff's Motions at 14. ("Whether the use of strontium-90 to treat skin lesions, itself, was a risk to the public health and safety is not relevant. . .").

In addition to eschewing a substantive discussion of due process in favor of a recitation of platitudes about public

health and safety, Staff also engages in creative statutory interpretation when necessary to ensure the emasculatation of the Fifth Amendment due process rights of IRCC and Dr. Bauer. Staff noted that ". . . 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." See Staff's Motions at 8. This statutory section cited by Staff, however, by its plain language, applies only to revocation proceedings, and does not "by implication" apply to license suspensions. See 42 U.S.C. §2236.

Similarly, Staff claims that ". . . 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." See Staff's Motions at 9. Again, Staff mischaracterizes the plain language of Section 186 of the AEA, which, as noted in the previous paragraph, only applies to revocation proceedings. See 42 U.S.C. §2236.

Immediately after the second mischaracterization of Section 186 of the AEA, Staff proceeds to torture the language of 10 C.F.R. §2.202(a)(1). Staff, having mischaracterized the language of Section 186 of the AEA to read that ". . . a license maybe suspended for any reason which would have warranted the refusal to grant the license initially," see Staff's Motions at 9, proceeds to use such mischaracterization to argue that 10 C.F.R.

§35.18, which addresses license issuance, is applicable to license suspension. Such statutory interpretation strains the plain language of that section beyond all recognition.

Finally, Staff sees fit to "read together" certain statutory sections in order to justify squelching the due process rights of IRCC and Dr. Bauer. Staff makes the incredible argument that it may somehow combine the purportedly broad authority of the NRC under 10 C.F.R. §2.202, to somehow, mystically justify utilizing Dr. Bauer's behavior under the HDR license as a basis for suspending the strontium-90 license. See Staff's Motions at 10. The reasons set forth by Staff simply do not justify the abrogation of Fifth Amendment due process rights of IRCC and Dr. Bauer which has occurred in the instant case.

Staff does not, in its Motion for Summary Disposition, overcome the simple fact that the two (2) licenses involved in the resolution of this issue are for different licensees, have different radiation safety officers, authorized the use of different radiative materials, and attempt to penalize licensee IRCC for the alleged conduct of a separate licensee.

B. RESPONSE TO MOTION FOR DISMISSAL

1. Rule 12 Of The Federal Rules Of Civil Procedure Is Not An Appropriate Basis For The Elimination Of Issues The Staff Seeks.

Staff attempts to use Rule 12(b)(6) of the Federal Rules of Civil Procedure as the a basis for the elimination Staff seeks of issues raised by IRCC. Staff misplaces its reliance in that regard, for Rule 12(b)(6) has nothing whatsoever to do with elimination of the pertinent defense issues. See Staff's Motions at 12. Rule 12(b)(6) states in pertinent part:

Every defense, in law or fact, to a claim for relief in any pleading, whether a claim, counterclaim, crossclaim, or third-party claim, shall be asserted in the responsive pleading thereto if one is required, except that the following defenses may at the option of the pleader be made by motion: . . . (6) failure to state a claim upon which relief can be granted . . .

Thus, the express terms of Rule 12(b)(6) demonstrate that this Rule does not measure the adequacy of a defense, such as the defenses relevant to the issues IRCC wishes to raise; rather, Rule 12(b)(6) provides the motion-practice vehicle by which a defense to a claim can be stated to the pleading of that claim. Thus, according to Wright and Miller, "[t]he purpose of a motion under Rule 12(b)(6) is to test the formal sufficiency of the statement of the claim for relief; it is not a procedure for resolving a contest about the facts or the merits of the case."

5A C.A. Wright & A. R. Miller, Federal Practice and Procedure §1356 at 294 (1990 & Supp. 1993).

As a consequence, Rule 12(b)(6) is inapplicable here because there is no claim for relief to which Staff can assert a defense under Rule 12(b)(6) either directly or by analogy. Indeed, if Rule 12(b)(6) is pertinent to this proceeding in any way, it is that it provides a mode of testing the legal adequacy of Staff's claim for the license suspension of IRCC based, in substantial part, on IRCC conduct.

For this reason, alone, NRC Staff's Motion for Dismissal should be dismissed in its entirety.

2. The Appropriate Question With Respect To The Elimination Of Issues The Staff Seeks Is Whether The Issues IRCC Has Raised Are Relevant To The License Suspension That Is The Subject Of This Proceeding.

In its Motion for Dismissal, Staff seeks to dismiss four (4) issues proposed by IRCC. See Staff's Motions at 12. The proper scope of the evidence in deciding the Motion for Dismissal is determined under 5 U.S.C. §556(d) ("Section 556(d)"). See In re: Radiation Technology, Inc., 10 N.R.C. 533, 1979 NRC LEXIS 24, *7 n.3 (1979). That provision states in pertinent part:

Except as otherwise provided by statute the proponent of a rule or order has the burden of proof. Any oral or documentary evidence may be

received, but the agency as a matter of policy shall provide for the exclusion of irrelevant, immaterial, or unduly repetitious evidence. A sanction may not be imposed or rule or order issued except on consideration of the whole record or those parts thereof cited by a party and supported by and in accordance with the reliable, probative, and substantial evidence.

(emphasis added).

Section 556(d) does not --- as it should if the elimination of issues Staff seeks were proper --- limit evidence at a sanction proceeding to evidence either directly supporting or directly contradicting express agency findings purported to support the sanction. Instead of limiting the contested issues to those selected by Staff, Section 556 prohibits only the irrelevant, the immaterial or the unduly repetitious. Moreover, by that reference to relevance and probity, Section 556(d) incorporates Rules 401 and 402 of the Federal Rules of Evidence as guiding principles for this proceeding. Those sections state:

Rule 401. Definition of "Relevant Evidence"

"Relevant evidence" means evidence having any tendency to make the existence of any fact that is of consequence to the determination of the action more probable or less probable that it would be without the evidence.

Rule 402. Relevant Evidence Generally Admissible;
Irrelevant Evidence Inadmissible

All relevant evidence is admissible, except as otherwise provided by the Constitution of the United States, by Act of Congress, by these rules, or by other rules prescribed by the Supreme Court pursuant to statutory authority. Evidence which is not relevant is not admissible.

Furthermore, agency regulations confirm a party's right to present a broad scope of relevant evidence; thus 10 C.F.R. §2.743(a) states:

Every party to a proceeding shall have the right to present such oral or documentary evidence and rebuttal evidence and to conduct . . . cross examination as may be required for full and true disclosure of the facts.

(emphasis added). Application of the foregoing governing principles --- directed, not as the agency would have to mere contradiction of stated contentions, but rather to "full and true disclosure of the facts" --- demonstrates the propriety of all the issues IRCC has raised with respect to its license suspension proceeding and requires the dismissal of Staff's motion on all points.

3. The Issues Raised By IRCC Are Relevant To The Purported Grounds Expressed In The License Suspension issued against it and therefore cannot Be Excluded From This Proceeding.

The license suspension order at issue in this proceeding identifies as its basis certain uses by IRCC and Dr. Bauer of strontium-90, information Dr. Bauer provided for the NRC, and behavior of Dr. Bauer under the HDR license. See Staff's Motions at 2,3.

IRCC submits that in accordance with 5 U.S.C. §556(d), Rules 401 and 402 of the Federal Rules of Evidence, and 10 C.F.R.

§2.743(a), the evidence underlying the issues Staff now seeks to exclude is relevant and probative, since: it has, at a minimum, 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 than it would be without the evidence; that, for that reason, it is required for a "full and true disclosure of the facts;" that there is no constitutional, statutory or other regulatory bar to its admissibility; and that, as a consequence, that evidence should be admitted in the license suspension proceeding.

For these reasons, Staff errs when it attempts to protect its contentions regarding the suspension of the strontium-90 license by limiting the issues IRCC may raise in its defense solely to issues based on direct contradiction of the purported indications, expressed by the NRC in the suspension order, of such a breakdown. No authority supports such a restriction.

In addition to lacking legality, as demonstrated above, the Staff's contention in this regard lacks also logic and fairness. Clearly, the suspension order does not state the entire universe of facts and issues relevant to determining the existence of any supposed violation of the strontium-90 license; nor are the purported facts the suspension order does state

necessarily available for fair assessment when viewed in the isolated context of the license suspension order.

For this reason, Staff's Motion for Dismissal should be dismissed in its entirety.

III. CONCLUSION

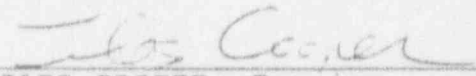
For the foregoing reasons, Licensee, the Indiana Regional Cancer Center, and James E. Bauer, M.D., respectfully request the Atomic Safety and Licensing Board to grant its Motion to Eliminate Basis for Suspension, eliminating the alleged conduct of Dr. Bauer under the HDR License as a basis for the suspension of the IRCC Strontium-90 License. and deny Staff's Motion for Summary Disposition and Motion for Dismissal.

Respectfully submitted,

WILLIAMSON, FRIEDBERG & JONES

DATED: March 31, 1994

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CERTIFICATE OF SERVICE

I hereby certify that copies of the foregoing Response To
NRC Staff Motion For Summary Disposition And Motion For Dismissal
have been served upon the following persons by U. S. Mail,
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