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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
DOCKETING & SERVICE
BRANCH

IN THE MATTER OF : DOCKET NO. IA-94-011
:
DR. JAMES BAUER : ASLBP No. 94-696-05 EA
:
(Order Prohibiting Involvement, :
in NRC-Licensed Activities) :

ANSWER IN OPPOSITION TO NRC STAFF'S
PETITION FOR PARTIAL RECONSIDERATION

I. INTRODUCTION

Pursuant to 10 C.F.R. §2.771, James E. Bauer, M.D., ("Dr. Bauer"), by and through his counsel, Marcy L. Colkitt, Esquire, and Jonathan P. Phillips, Esquire, hereby submits the following Answer in Opposition to NRC Staff's Petition for Partial Reconsideration ("Staff's Petition"). In support hereof, Dr. Bauer states the following:

I. BACKGROUND

On July 29, 1994, the Staff of the United States Nuclear Regulatory Commission ("NRC Staff" or "Staff") filed its "NRC Staff Motion for Summary Disposition and NRC Staff Motion for Dismissal ("Staff's Dismissal Motion"). In the Staff's Dismissal Motion, the Staff requested, *inter alia*, that the Atomic Safety and Licensing Board ("Board") dismiss eight (8) issues proposed by Dr. Bauer as central litigation issues. See Staff's Dismissal Motion at 12-17. Included among these eight (8) issues were Issues 48 and 49 contained in the Joint Prehearing Report. See Joint Prehearing Report, June 24, 1994 ("Joint Prehearing Report").¹

¹ Issue 48 reads: "Whether the regulations in 10 C.F.R. Part 35 Subpart G 'Sources for Brachytherapy' apply to the use of Iridium-192 as a sealed source in a brachytherapy remote afterloader for the High Dose Radiation Treatment of humans ('HDR')." See Joint Prehearing Report at 6.

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On August 29, 1994, Dr. Bauer filed his "Response to NRC Staff Motion for Summary Disposition and NRC Staff's Motion for Dismissal" ("Dr. Bauer's Response").

On December 9, 1994, the Board issued its Memorandum and Order (Ruling on Pre-Hearing Prediscovery Dispositive Motions ("Board's Order"). In the Board's Order, the Board ruled, *inter alia*, that Joint Prehearing Report Issue No. 8 be amended to incorporate language from Joint Prehearing Report Issues 48 and 49. See Board's Order at 27 ("Because Bauer Issues 48 and 49, in combination with Bauer Issue 8, best articulate this 'section 35.404(a) compliance' issue, we incorporate their essential elements into Issue 8."). See also, Board's Order at 30. As modified by the Board, Issue 8 now reads:

"Regarding the use of Iridium-192 as a sealed source in a brachytherapy remote afterloader for the High Dose Radiation treatment of humans ("HDR"):

- a. Is 10 C.F.R. Part 35, Subpart G, including the specific survey requirement in section 35.404(a), applicable?
- b. As a matter of law, does fulfilling any of the applicable survey requirements in 10 C.F.R. Part 35, Subpart G, control and/or satisfy the reasonableness standard in 10 C.F.R. §20.201?"

See Board's Order at 30.

With regard to Joint Prehearing Report Issues 48 and 49, the Board noted that those two issues present the questions:

"... whether the provisions of Subpart G of 10 C.F.R. Part 35 apply generally to the use of iridium-192 as a brachytherapy remote afterloader sealed source in human HDR treatments and, if so, whether the specific survey requirement of 10 C.F.R. §35.404(a) applies to iridium-192 HDR treatments."

Issue 49 states: "If the regulations in 10 CFR Part 35 Subpart G 'Sources for Brachytherapy' apply to the use of Iridium-192 as a sealed source in a Brachytherapy afterloader of the treatment of humans (HDR) than whether the specific survey of ten C.F.R. §35.404(a) applies to Iridium-192 HDR." See Joint Prehearing Report at 6.

See Board's Order at 26. The Board went on to note that "in the QSC proceeding, we dismissed these issues because we found that the matters they sought to raise were better stated in other specified issues. See LBP-94-2, 39 NRC at 26-27." See Board's Order at 26.

With regard to Joint Prehearing Report Issue 8, the Board stated that:

"... whether compliance with 10 C.F.R. Part 35, Subpart G, and in particular section 35.404(a), would satisfy any survey requirement under 10 C.F.R. Part 20, including section 20.201, has been identified as an issue that the party contesting the staff enforcement order wants to raise."

See Board's Order at 26. The Board went on to note that "[w]e found in the QSC proceeding that dismissal [of the issue] was appropriate because this matter was more clearly articulated through other issues..." See Board's Order at 26, 27.

Most importantly with regard to Joint Prehearing Report Issues 8, 48, and 49, the Board acknowledged that those issues were so dismissed in the QSC proceeding because the same issues were better stated elsewhere among QSC issues. See Board's Order at 26, 27.

The Board went on to state that, with regard to the instant matter:

"... Dr. Bauer has not incorporated all those other issues here. To ensure again that the relevant issues for litigation are stated as clearly as possible, in this instance we sanction a somewhat different approach. Because Bauer Issues 48 and 49, in combination with Bauer Issue 8, best articulate this 'section 35.404(a) compliance' issue, we incorporate their essential elements into Issue 8."

See Board's Order at 27.

III. ARGUMENT

A. The Atomic Safety And Licensing Board's Modification Of Joint Prehearing Report Issue 8 Satisfactorily Articulates Those Issues Set Forth Originally As Issues 8, 48, And 49 Of The Joint Prehearing Report.

The Board's Modification of Joint Prehearing Report Issue 8 satisfactorily articulates those issues set forth originally as Joint Prehearing Report Issues 8, 48, and 49. The Staff, in Staff's Petition states that "[t]he Staff agrees that the issue of 'section 35.404(a) compliance' is appropriately articulated by the Board's modification of Bauer Issue 8, subpart b and does not object to its admission as an issue for litigation in this proceeding." See Staff's Petition at 4. The Staff then goes on to contend that "... subpart a of Bauer Issue 8, which raises the issue of whether Part 35, Subpart G, including the specific survey requirement of section 35.404 (a), applies, in general, to HDR, does not clearly express the 'section 35.404(a) compliance' issue" See Staff's Petition at 5.

Although quick to challenge subpart a of modified Issue 8, the Staff can offer no justification for its position other than variously formulated incantations to the effect that "... Part 35, Subpart G, including the specific survey requirements of section 35.404 (a), as a general matter, to HDR is not relevant to this proceeding." See Staff's Petition at 5. The Staff's position with regard to subpart a of the modified Issue 8 smacks of disingenuity, particularly in light of the fact that the Staff has no objection to subpart b of modified Issue 8. It is the height of intellectual dishonesty to approve the language of subpart b pertaining to

"... applicable survey requirements in 10 C.F.R. Part 35, Subpart G..." without approving of the language contained in subpart a pertaining to the determination of which survey requirements in 10 C.F.R. Part 35, Subpart G are applicable. See Staff's Petition at 3.

The Staff's intellectual dishonesty is made plainly apparent by the very fact that its May 10, 1994 Order Prohibiting Involvement in NRC-Licensed Activities (Effective Immediately) ("Staff's Order") does rely upon supposed improprieties upon the part of Dr. Bauer with regard to the conduct of radiation surveys.

The Staff's Order claims that "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." See Staff's Order at 4. The Staff's Order also contends that Dr. Bauer "... 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." See Staff's Order at 6. Finally, in the Staff's Order, it is stated that "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." See Staff's Order at 6. See also, Staff's Dismissal and Motion at 10.

Simply put, the Staff has not hesitated to claim that Dr. Bauer's conduct under the HDR license as such conduct pertains to radiation surveys, is, relevant in the QSC matter, the Indiana Regional Cancer Center matter, as well as the instant matter. See, generally, NRC's Staff's Response to Motion to Eliminate Basis for Suspension. Having chosen to base its

initial Staff's Order in this matter in part upon Dr. Bauer's conduct under the HDR license, including his supposed failure to conduct an adequate radiation survey, the Staff cannot now be heard to claim that such behavior, and regulatory provisions whose interpretation may dictate the propriety of such behavior, are suddenly irrelevant.

The Board's treatment of Joint Prehearing Statement Issues 8, 48, and 49, including the formulation of the modified Issue 8, is well reasoned and keeps before the Board those issues whose resolution will afford justice in the instant matter.

IV. CONCLUSION.

For the reasons set forth above, Dr. Bauer requests that the Board decline to reconsider its modification of Joint Prehearing Report Issue 8 and decline any invitation to delete subpart a of modified Issue 8.

Respectfully submitted,

DATED: December 28, 1994



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CERTIFICATE OF SERVICE

I hereby certify that a true and correct copy of the foregoing pleading was furnished to the following by telefax and U.S. First Class Mail, the 28th day of December, 1994.

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