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UNITED STATES OF AMERICA  
NUCLEAR REGULATORY COMMISSION

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DOCKETED  
USNRC

ATOMIC SAFETY AND LICENSING BOARD

Before Administrative Judges: '94 DEC -9 A 7:42

G. Paul Bollwerk, III, Chairman  
Dr. Charles N. Kelber  
Dr. Peter S. Lam

OFFICE OF SECRETARY  
DOCKETING & SERVICE  
BRANCH

In the Matter of

DR. JAMES E. BAUER

(Order Prohibiting  
Involvement in NRC-Licensed  
Activities)

Docket No. IA-94-011

ASLBP No. 94-696-05-EA

December 9, 1994

MEMORANDUM AND ORDER  
(Ruling on Prediscovery  
Dispositive Motions)

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The parties to this proceeding, petitioner James E. Bauer, M.D., and the NRC staff, have filed motions seeking dispositive resolution of certain issues concerning the May 10, 1994 staff enforcement order that is the locus of this litigation. In that order, the staff alleges that certain of Dr. Bauer's actions regarding regulated nuclear materials demonstrate he cannot conduct NRC-licensed activities in conformity with agency requirements. As a consequence, the immediately effective order imposes several restrictions on Dr. Bauer, including barring him from conducting any NRC-licensed activities for a period of five years.

In their dispositive motions, both parties seek a ruling on the jointly identified litigation issue of whether

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the order can be based on staff allegations regarding (1) Dr. Bauer's actions while serving as radiation safety officer (RSO) and sole authorized user on a byproduct materials license permitting the Indiana Regional Cancer Center (IRCC) to use a strontium-90 source to treat specified medical conditions, and (2) his involvement in a November 1992 misadministration incident at IRCC under a different NRC license authorizing the use of iridium-192 to provide high dose rate (HDR) brachytherapy treatments. In addition, the staff asserts that it is entitled to summary disposition on the jointly identified issue of whether the treatment of superficial skin lesions with strontium-90 violates the terms of IRCC's license. Finally, the staff asks for dismissal of eight other issues identified by Dr. Bauer as appropriate litigation questions.

For the reasons given below, we find that the staff is not precluded as a matter of law from relying on Dr. Bauer's purported involvement in the November 1992 incident or his alleged activities under the IRCC strontium-90 license as a basis for its May 1994 order. Further, on the joint issue of whether the treatment of superficial skin lesions with strontium-90 violates the terms of IRCC's license, we request that the parties address several questions regarding that matter. Finally, for the eight Dr. Bauer litigation issues that the staff seeks to expel, we conclude that three

should be consolidated with other issues and three should be dismissed in toto.

#### I. BACKGROUND

The May 1994 order at issue here is the third recent staff enforcement directive involving Dr. Bauer. The first was a January 1993 order that suspended the license of Oncology Services Corporation (OSC) authorizing it to provide iridium-192 HDR brachytherapy treatments at six OSC Pennsylvania facilities, including IRCC. See 58 Fed. Reg. 6825 (1993). One of the cited grounds for this suspension was a November 1992 incident at IRCC in which IRCC personnel allegedly failed to detect an iridium-192 source that remained in a patient's body after she received an HDR brachytherapy treatment with an Omnitron 2000 remote afterloader machine. The staff contended that as the authorized user under the license who was supervising the patient's treatment, Dr. Bauer did not conduct an adequate survey of the patient before permitting her to return to her nursing home, which resulted in significant radiation exposures to the patient and members of the general public. See id. at 6825-26.

In November 1993, the staff issued a second enforcement order that suspended IRCC's license to use a strontium-90 source to treat specified medical conditions and modified that license to preclude Dr. Bauer, the RSO and the only

authorized user named in the license, from undertaking any activities under the strontium-90 license. See 58 Fed. Reg. 61,932 (1993). The staff asserted that this suspension and modification was necessary because of the use of strontium-90 to treat skin lesions, an activity it contends was not authorized under the license, and the failure of Dr. Bauer during a November 1993 inspection to provide agency inspectors with accurate and complete information regarding skin lesion treatments. The staff also based this order on Dr. Bauer's purported involvement in the November 1992 brachytherapy treatment incident outlined in the January 1993 enforcement order. See id. at 61,932-33.

The third enforcement order, which is now before us, is directed solely to Dr. Bauer. See 59 Fed. Reg. 25,673 (1994). Relying essentially on the allegations regarding the brachytherapy treatment and strontium-90 use incidents specified in the two previous orders, the staff has directed that for five years Dr. Bauer cannot be named in any NRC license to act in any capacity or otherwise conduct any NRC-licensed activities. In addition, to permit the agency to monitor his compliance with regulatory requirements, for two years thereafter Dr. Bauer must inform the NRC within twenty days of accepting employment concerning, or otherwise becoming involved in, NRC-licensed activities. See id. at 25,673-74.

The licensees and/or Dr. Bauer sought a hearing to contest each of these three orders. The OSC and IRCC proceedings recently were dismissed prior to any dispositive adjudication on the merits based on licensee requests for termination of the licenses involved. See Oncology Services Corp. (Order Suspending Byproduct Material License No. 37-28540-01), LBP-94-29, 40 NRC 123 (1994); Indiana Regional Cancer Center (Order Modifying and Suspending Byproduct Material License No. 37-28179-01), LBP-94-36, 40 NRC \_\_\_\_ (Nov. 4, 1994). Dr. Bauer, however, continues to contest the validity of the May 1994 order in this proceeding.<sup>1</sup>

In that regard, acting pursuant to a Board directive, see Memorandum and Order (Initial Prehearing Order) (June 8, 1994) at 4-6 (unpublished), on June 24, 1994, Dr. Bauer and the staff filed a joint prehearing report in which they specified the central issues for litigation in this proceeding. See Joint Prehearing Report (June 24, 1994) at 1-6 [hereinafter Joint Prehearing Report]. Subsequently, in accord with a Board prehearing order, see Order (Establishing Schedule for Prediscovery Dispositive Motions and Filings Concerning Consolidation and Discovery) (July 1, 1994) at 1 (unpublished) [hereinafter Scheduling Order],

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<sup>1</sup> Although the Board was considering whether to consolidate this proceeding with the IRCC proceeding, see Scheduling Order at 1-2, the dismissal of the IRCC case renders that question moot.

both the staff and Dr. Bauer filed dispositive motions regarding a number of those issues, as well as responses and replies to those motions. See NRC Staff Motion for Summary Disposition and NRC Staff Motion for Dismissal (July 29, 1994) [hereinafter Staff Dispositive Motions]; Motion to Eliminate Basis for Suspension (July 29, 1994) [hereinafter Bauer Dispositive Motion]; Response to NRC Staff Motion for Summary Disposition and NRC Staff Motion for Dismissal (Aug. 29, 1994) [hereinafter Bauer Response]; NRC Staff's Response to Motion to Eliminate Basis for Suspension (Aug. 29, 1994) [hereinafter Staff Response]; NRC Staff's Reply to James E. Bauer's Response to NRC Staff's Motions (Sept. 12, 1994); Reply to NRC Staff's Response to Motion to Eliminate Basis for Suspension (Sept. 12, 1994) [hereinafter Bauer Reply].

In their dispositive motions, Dr. Bauer and the staff seek a ruling on the jointly identified central issue of whether, as a legal matter, the staff can rely on Dr. Bauer's purported involvement in the incidents concerning OSC's iridium-192 license and IRCC's strontium-90 license as bases for its May 1994 order barring him from all NRC-licensed activities for a five-year period (Joint Issue 4). Additionally, the staff requests that we enter summary disposition in its favor on the jointly identified issue of whether the treatment of superficial skin lesions

with strontium-90 constitutes a violation of the terms of IRCC's license (Joint Issue 1).

Finally, the staff asks that we dismiss eight of Dr. Bauer's proposed litigation issues. This includes issues concerning the medical appropriateness of using strontium-90 as a skin lesion treatment (Bauer Issue 16); the risk to the public health and safety from using strontium-90 for skin lesion treatments (Bauer Issue 17); the possibility that the Omnitron 2000 brachytherapy afterloader machine used during the November 1992 incident was defective (Bauer Issue 35); Omnitron's duty to notify Dr. Bauer and OSC about Omnitron 2000 source wire deterioration (Bauer Issue 37); Omnitron 2000 design, manufacturing, and/or warning defects as the cause of the November 1992 incident (Bauer Issue 38); unanticipated Omnitron 2000 retraction mechanism failure and Dr. Bauer's reliance on Omnitron procedures that did not anticipate such an emergency as causes of the November 1992 incident (Bauer Issue 40); the applicability of 10 C.F.R. Part 35, Subpart G to the use of iridium-192 as a brachytherapy remote afterloader sealed source in human HDR treatments (Bauer Issue 48); and, if 10 C.F.R. Part 35, Subpart G applies to the use of iridium-192 as a remote afterloader sealed source in human HDR treatments, the applicability of the specific survey requirement of 10 C.F.R. § 35.404(a) to such treatments (Bauer Issue 49).

## II. ANALYSIS

### A. Dr. Bauer Motion to Eliminate Basis and Staff Motion for Summary Disposition of Joint Issue 4

1. The Improper Bases Issue. The parties' prehearing report jointly identifies the following as the fourth issue for litigation in this proceeding:

Whether conduct which is subject to pending litigation, i.e., Dr. Bauer's alleged conduct under License No. 37-28540-01 (HDR license) and under License No. 37-28179-01 (strontium-90 license), can, as a matter of law, be a basis for the [May 10, 1994] Order Prohibiting Involvement in NRC-Licensed Activities.

Joint Prehearing Report at 2. Both the staff and Dr. Bauer seek a dispositive ruling in their favor on this issue.

In a pleading called "Motion to Eliminate Basis for Suspension," IRCC and Dr. Bauer contended in the IRCC proceeding that it was inappropriate to use allegations set forth in the OSC proceeding relating to activities under OSC's iridium-192 license as a basis for the November 1993 order regarding IRCC and Dr. Bauer's activities under the separate strontium-90 license because the allegations (1) had not been adjudicated; (2) were based solely upon hearsay; and (3) lacked any substantive relationship to the license suspension/modification at issue in the proceeding. See Indiana Regional Cancer Center (Order Modifying and Suspending Byproduct Material License No. 37-28179-01), LBP-94-21, 40 NRC 22, 28-31 (1994). In an identically

titled pleading, Dr. Bauer essentially reprises these themes. He asserts that the staff should be prevented from utilizing any of the allegations from either the January 1993 OSC order or the November 1993 IRCC order in support of the May 1994 order because (1) constitutional due process bars the use of unlitigated, hearsay allegations as the basis for an agency enforcement action; (2) Dr. Bauer has been deprived of his due process right to a timely opportunity to litigate these allegations; and (3) the allegations do not relate in any substantive way to the penalty in the May 1994 order, which bars Dr. Bauer from participating in all NRC-licensed activities. See Bauer Dispositive Motion at 4-11; see also Bauer Reply at 2-5.

Declaring that there are no material issues of fact relative to Joint Issue 4, the NRC staff asserts that it is entitled to summary disposition on this issue.<sup>2</sup> According to the staff, the Commission's wide-ranging authority under the Atomic Energy Act to protect the public health and safety, in conjunction with its authority under 10 C.F.R. § 2.202(a)(1) to consider any facts deemed sufficient grounds for a proposed action, is more than adequate to permit it to base the May 1994 order on Dr. Bauer's alleged

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<sup>2</sup> In two of its statements of material fact, the staff references the pendency of the OSC and IRCC litigation. See Staff Dispositive Motions at 5-6. As we noted above, however, those cases have been dismissed at the parties' request. See supra p. 5.

conduct under the separate iridium-192 and strontium-90 licenses. In addition, the staff declares that the "unlitigated" or "hearsay" nature of the allegations is no bar to their use because, in accordance with the requirements of due process, Dr. Bauer has been presented with understandable charges and a fair, timely opportunity to litigate those charges. The staff further maintains that Dr. Bauer's activities under the two licenses cannot be labelled as irrelevant or immaterial to the prohibition on participation in all licensed activities imposed by the May 1994 enforcement order because there is a sufficient nexus between his alleged actions and that sanction. See Staff Dispositive Motions at 8-12; Staff Response at 3-9. Finally, the staff asserts that if we agree with its arguments regarding Joint Issue 4, three related litigation issues propounded by Dr. Bauer -- Issues 19, 20, and 22 -- also must be summarily resolved in the staff's favor. See Staff Dispositive Motions at 8 n.3. Dr. Bauer has recorded those issues as follows:

19. Whether admission of evidence regarding Dr. Bauer's conduct on November 16, 1992 is improperly prejudicial given the posture of this proceeding and the confusion of issues likely to arise from the admission of that evidence?
20. Whether the admission of evidence regarding Dr. Bauer's conduct on November 16, 1992 amounts per se to a denial of the due process rights of Dr. Bauer?

. . . .

22. Whether allegations regarding Dr. Bauer's conduct on November 16, 1992 are admissible in this proceeding in that Dr. Bauer has [not] yet had the opportunity to contest any implication of fault at a hearing and there has been no finding of fault against him?

Joint Prehearing Report at 3-4.

2. The Board's Determination. As the staff points out, we previously have dealt with most of the substance of Dr. Bauer's claims regarding this issue in the IRCC proceeding. There we found that the "unlitigated" and "hearsay" nature of the staff's allegations concerning the November 1992 iridium-192 misadministration incident were not sufficient to bar their use as a basis for an enforcement order directed to IRCC and Dr. Bauer relative to IRCC's strontium-90 license. See Indiana Regional Cancer Center, LBP-94-21, 40 NRC at 30-31. Those findings are applicable here, and need not be repeated.

Two aspects of Dr. Bauer's claims do merit additional discussion, however. The first is his concern that he (along with licensees OSC and IRCC) has not been afforded a timely opportunity to contest the staff's allegations regarding the November 1992 misadministration incident and his alleged improper activities under the IRCC strontium-90 license. In this regard, Dr. Bauer correctly notes that some of these allegations involve events that occurred more

than two years ago and that their validity has not yet been litigated despite being the basis for several contested staff enforcement orders.

We conclude, however, that given the basis for and the current length of this delay, dismissal of the staff's allegations on constitutional due process grounds is not warranted. Claiming a constitutional deprivation arising from a delayed adjudication generally requires some showing of prejudice. See Oncology Services Corp. (Byproduct Material License No. 37-28540-01), CLI-93-17, 38 NRC 44, 50-51 (1993). As the Commission already has noted in this regard, "[i]t is certainly conceivable that the passage of time may affect some witnesses' memories. However, the extent of prejudice from any potentially faded memories is far from clear." Id. at 59. Dr. Bauer has not made any assertion regarding the memory of any particular witness or, indeed, made any other specific claim of prejudice arising from the delay. Moreover, it has been recognized that the pendency of a related criminal investigation -- the principal reason for the delay here, see Order (Granting Stay of Discovery) (July 18, 1994) (unpublished) -- provides an appropriate basis for postponing this litigation.<sup>3</sup> See Oncology Services Corp., CLI-93-17, 38 NRC at 53-56. We

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<sup>3</sup> Indeed, in this instance Dr. Bauer has relied upon the pending criminal investigation as a basis for obtaining the postponement of staff discovery. See Request to Stay Proceeding and Discovery (July 13, 1994) at 2-3.

thus are unable to conclude at this juncture that the delay that has accrued in adjudicating the staff's allegations constitutes a constitutional violation or mandates, as a matter of law, that we refuse to consider the staff's allegations.

The other matter that requires some explication is the question of the relationship of the staff's allegations to the penalty imposed. In our prior IRCC determination, we considered the issue of whether staff allegations regarding the November 1992 brachytherapy misadministration incident could be used as a basis for the November 1993 enforcement order regarding IRCC's strontium-90 license. We concluded there was a "sufficient nexus" between those allegations and the regulated activities that formed the focus of the staff's order such that we would not, as a matter of law, preclude the staff's use of the allegations. Indiana Regional Cancer Center, LBP-94-21, 40 NRC at 31.

Dr. Bauer's concern here is somewhat different -- i.e., that the allegations regarding his activities under licenses involving only iridium-192 and strontium-90 cannot be used as a basis to preclude him from all regulated activities. Analyzing this contention, however, we find that it warrants the same resolution we reached in the IRCC proceeding. If, for the purpose of ruling on Dr. Bauer's motion, we accept what has been pled by the staff in the order as true, the factual circumstances set forth in the order regarding

Dr. Bauer's involvement in the November 1992 incident and his activities under the strontium-90 license have a sufficient link to the challenged penalty to permit them to provide a basis for that penalty.

For both sets of allegations and the proposed penalty, the central connecting factor is Dr. Bauer and his activities with licensed materials. In each instance, it is alleged that Dr. Bauer, as an authorized user under the license in question, was substantially involved (either as a supervisor or the administering physician) in providing treatments employing licensed materials in a manner that the staff concludes was not in conformance with agency requirements. And, contrary to Dr. Bauer's assertion, the fact that the staff's allegations concern Dr. Bauer's activities under two separate licenses does not attenuate this link. Indeed, this broader base for the allegations seemingly provides more support for suspending Dr. Bauer's authority for "all" licensed activities than might be the case with allegations relating to activities under only one license.

Consequently, we deny Dr. Bauer's motion to eliminate the allegations regarding the November 1992 incident and Dr. Bauer's activities under the IRCC iridium-192 license as bases for the May 1994 enforcement order. Further, there being no material factual issues in dispute concerning Joint Issue 4, we find in favor of the staff on that issue. Of

demonstrating that the allegations it has put forward in support of its May 1994 order are sufficient to sustain that enforcement order, including the penalties imposed under the order. In turn, Dr. Bauer may offer any appropriate legal or factual information challenging those allegations in an effort to show that they are insufficient to sustain the order.

Finally, regarding the staff's assertion that the three related Dr. Bauer issues should be dismissed, as we found previously in the IRCC proceeding, those issues embody particular arguments about why Dr. Bauer should prevail on the general issue set forth in Joint Issue 4. See Indiana Regional Cancer Center, LBP-94-21, 40 NRC at 32. As there, we conclude that by addressing those assertions in ruling in the staff's favor on Joint Issue 4, those particular issues are for all practical purposes moot and so can be dismissed from this proceeding.

C. Staff Motion for Summary Disposition of Joint Issue 1

In addition to the improper bases issue, the staff seeks summary disposition concerning the first issue jointly identified by the parties for litigation in this proceeding. The parties delineate this issue as "[w]hether the treatment of superficial skin lesions with strontium-90 is a violation of License No. 37-28179-01?" Joint Prehearing Report at 1.

In support of its motion for summary disposition on this issue, the staff sets forth two statements of material

fact not in issue. The first declares that section 9 of the license, which is entitled "Authorized Use," contains the following statement regarding the licensed strontium-90:

"For use in Atlantic Research Corporation Model B1 Medical Eye Applicator for treatment of superficial eye conditions."

See Staff Dispositive Motion at 5.<sup>4</sup> The second staff statement asserts that "[t]here are no other authorized uses for the strontium-90 in License No. 37-28179-01." Id. The staff argues that because these statements are true, it is entitled to summary disposition in its favor on Joint Issue 1.

In response, Dr. Bauer points to section 13 of the license, which states that "[t]his license is based on the licensee's statements and representations listed below:

A. Application dated March 28, 1988." Dr. Bauer asserts that because paragraph 6 in the attachment to IRCC's March 1988 application states that the purpose for which licensed material will be used is "[t]reatment of superficial tissues of the eye and skin," the staff's section 13 declaration that the license was based on the IRCC application means that the application's statement of purpose was incorporated into the license in its entirety and cannot now be disavowed by the staff. See Bauer Response at 2.

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<sup>4</sup> A copy of NRC License No. 37-28179-01 containing this provision and IRCC's March 1988 application for the license are included as Attachments 1 and 2, respectively, to the staff's motion.

In reviewing the parties' arguments, we find that neither has addressed a matter that may be pivotal in resolving their conflicting interpretations.

Section 2.103(b) of 10 C.F.R. provides that if the staff determines that an application for a materials license does not meet statutory or regulatory requirements, the staff is to issue a notice of denial or proposed denial that informs the applicant of the reasons for the staff's action and offers the opportunity for a hearing on the denial or proposed denial. In this instance, as we have noted, IRCC applied for the authority to provide both eye and skin treatments. If, as the staff asserts, it intended that IRCC should not receive the requested authority to provide skin treatments, the following questions merit further exploration:

1. Under 10 C.F.R. § 2.103(b), was IRCC entitled to notice that its request for authority to provide skin treatments was not being granted and that it had a right to a hearing on that determination?
2. If IRCC was entitled under section 2.103(b) to the notice described in question 1, was IRCC given that notice and how was that notice provided?
3. If IRCC was entitled under section 2.103(b) to the notice described in question 1 but that notice was not provided, what impact does the failure to provide that notice have on the staff's assertion that License No. 37-28179-01 issued to IRCC does not provide authority for skin treatments?

As the proponent of the motion for summary disposition from which these questions arise, the staff will have the initial opportunity to address them. Dr. Bauer will then

have an opportunity to respond. The schedule for the parties' filings regarding these questions is set forth below.

B. Staff Motion to Dismiss

In addition to its summary disposition requests, the staff has moved for dismissal of eight issues identified by Dr. Bauer as central to this litigation. Dr. Bauer has delineated these issues as follows:

16. Whether the use of strontium-90 as treatment for skin lesions on the two identified patients was medically appropriate treatment?
17. Whether there was any risk to the public health, safety or other interest by virtue of the use of strontium-90 as treatment for skin lesions on the two identified patients?  
.....
35. Whether the Omnitron 2000 HDR unit was defective?  
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37. Whether despite Omnitron's knowledge of deterioration of the source wire due to a chemical reaction resulting from its packaging, Omnitron failed to notify Dr. Bauer of the defect and OSC was not otherwise informed of the possibility of deterioration?
38. Whether any of the Omnitron 2000 design, manufacturing and/or warning defects was a cause of the November 16, 1992 incident?  
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40. Whether the November 16, 1992 incident at IRCC occurred because of an unanticipated failure of the Omnitron 2000 retraction mechanism and a reliance by Dr. Bauer on Omnitron procedures which did not anticipate or cover this emergency?

. . . .

48. 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").
49. If 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 treatment of humans (HDR) then whether the specific survey requirement of 10 C.F.R. § 35.404(a) applies to Iridium-192 HDR.

Joint Prehearing Report at 3-6. As we have previously established in the OSC and IRCC proceedings, if it can be shown there is no set of facts that would entitle Dr. Bauer to relief relative to these proposed issues, then dismissal is appropriate. See Indiana Regional Cancer Center, LBP-94-21, 40 NRC at 33 & n.4; Oncology Services Corp. (Order Suspending Byproduct Material License No. 37-28540-01), LBP-94-2, 39 NRC 11, 23 & n.8 (1994).<sup>5</sup>

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<sup>5</sup> As he did in the IRCC proceeding, Dr. Bauer asserts that dismissal of these issues is inappropriate because they constitute defenses. Compare LBP-94-21, 40 NRC at 33 n.4

(continued...)

1. Bauer Issues 16 and 17. Bauer Issues 16 and 17 concerning the medical appropriateness and public health and safety risk of using strontium-90 as a skin lesion treatment are identical to issues posed in the IRCC proceeding. See Indiana Regional Cancer Center, LBP-94-21, 40 NRC at 32-33. There, we refused to dismiss these issues, finding that in assessing whether the bases assigned support an order in terms of both the type and duration of the enforcement action, a relevant factor may be the public health and safety significance, including the medical appropriateness, of the specified bases. See id. at 33-34. Because the same result obtains here, we decline to dismiss Bauer Issues 16 and 17 as well.

2. Bauer Issues 35, 37, 38, and 40. Bauer Issues 35, 37, and 38 regarding the Omnitron 2000 remote afterloader also are identical to issues previously specified for litigation, although in the OSC proceeding. See Oncology Services Corp., LBP-94-2, 39 NRC at 28. As was described earlier, the Omnitron 2000 afterloader was in use at the time of the November 1992 incident that resulted in an IRCC brachytherapy patient receiving a significant (and

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<sup>5</sup>(...continued)  
with Bauer Response at 3-5. As we noted there, as well as in the OSC proceeding, consistent with the analogous agency rules regarding contentions filed by intervenors, see 10 C.F.R. § 2.714(d)(2)(ii), these issues are subject to dismissal under the appropriate circumstances. See LBP-94-21, 40 NRC at 33 n.4.

apparently fatal) radiation overdose. The focus of these issues is the condition of the machine at the time of the incident (i.e., was it defective) and the duties and actions of the manufacturer relative to that condition (i.e., did Omnitron know of any defect and fail to warn users, including OSC and IRCC personnel, about such an imperfection).

As in the OSC proceeding, in framing its May 1994 enforcement order relative to the November 1992 incident the staff has not put forth any charges that dictate an inquiry into whether the Omnitron artherloader was defective or whether the machine's manufacturer breached some duty to warn about the purported defect. Instead, looking to the time after the iridium-192 source became detached from the Omnitron machine and lodged in the patient, the staff has charged that Dr. Bauer "failed to cause a survey to be performed which was required by 10 CFR 20.201 and which could have prevented the exposures [to the patient and other members of the public.]" 59 Fed. Reg. at 25,673. As then effective,<sup>6</sup> section 20.201 provided that "[e]ach licensee

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<sup>6</sup> Beginning on January 1, 1994, section 20.201 and various other provisions of 10 C.F.R. Part 20 were replaced by revised standards. See 58 Fed. Reg. 67,657 (1993). Section 20.1501, the apparent analog to section 20.201, now provides in pertinent part:

(a) Each licensee shall make or cause to be made, surveys that --

(continued...)

shall make or cause to be made such surveys as (1) may be necessary for the licensee to comply with the regulations in this part, and (2) are reasonable under the circumstances to evaluate the extent of radiation hazards that may be present." 10 C.F.R. § 20.201(b). Given the staff's reliance on this provision, a central matter in controversy thus becomes whether Dr. Bauer's actions relative to such a survey were "reasonable under the circumstances."

We concluded in the OSC proceeding that these "defect" issues focusing on the condition of the Omnitron afterloader at IRCC and the knowledge of Omnitron personnel about the afterloader's condition had nothing to do with this question (or any other relevant matter regarding the staff's order). We found the pertinent "circumstances" were those existing at the time of the incident relative to the actual state of knowledge of OSC personnel, including Dr. Bauer, about the Omnitron afterloader and any possible Omnitron afterloader defects and problems. As a consequence, the "defect" issues put forth by OSC (and by Dr. Bauer here) shed no light on

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<sup>6</sup>(...continued)

(1) May be necessary for the licensee to comply with the regulations in this part; and

(2) Are reasonable under the circumstances to evaluate --

(i) The extent of radiation levels; and

(ii) Concentrations or quantities of radioactive materials; and

(iii) The potential radiological hazards that could be present.

any relevant issue. As we noted, "for the purposes of this action, even if it is assumed that the answers to each of these three 'defect' issues is 'yes,' we would be no closer to resolving the focal issue of whether the actions of OSC personnel regarding the survey were 'reasonable under the circumstances.'" Oncology Services Corp., LBP-94-2, 39 NRC at 29. The same is true in this proceeding regarding these issues. We thus dismiss Bauer Issues 35, 37, and 38 as not relevant to this proceeding.<sup>7</sup>

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<sup>7</sup> In contesting the staff's request to dismiss these and other issues, Dr. Bauer also makes the general argument that his right to raise issues as part of his defense cannot be limited solely to those matters that directly contradict the bases set forth by the staff in its enforcement order. According to Dr. Bauer, the staff's "Order does not state the entire universe of facts and issues relevant to determining the existence of any supposed violation of the HDR license or the IRCC strontium-90 license . . . ." Bauer Response at 8-9 (footnote omitted).

As we have noted elsewhere, the Commission has made it clear that in proceedings involving challenges to staff enforcement orders, the overarching matter for consideration is whether the order should be sustained and "our authority pursuant to this directive is to consider 'whether the facts in the order are true and whether the remedy selected is supported by those facts.'" Oncology Servs. Corp., LBP-94-2, 39 NRC at 25 (quoting Boston Edison Co. (Pilgrim Nuclear Power Station), CLI-82-16, 16 NRC 44, 45 (1982), aff'd, Bellotti v. NRC, 725 F.2d 1380 (D.C. Cir. 1983)). The bases asserted in an enforcement order thus do provide the principal framework for the proceeding. As a consequence, any legal or factual issue a party wants to propose in challenging (or supporting) an enforcement order must bear some relationship to those bases by tending to establish, either alone or with other issues, that some explicit or implicit legal or factual predicate to the order should not (or should) be sustained. Further, a party called upon to demonstrate this relationship must be able to do so by more than a bald pronouncement that the issue is "relevant." Cf. (continued...)

Bauer Issue 40, the wording of which was not the subject of litigation in the OSC proceeding, is stated somewhat differently than Issues 35, 37, and 38 in that it does not refer to "defects." Instead, as the staff points out, this issue would have us inquire into whether the November 1992 incident occurred because of (1) the "unanticipated failure" of the Omnitron 2000 retraction mechanism, and (2) Dr. Bauer's reliance on Omnitron procedures that did not anticipate or cover that emergency. See Staff Dispositive Motion at 1c. The staff asserts that both portions should be dismissed, the first because it raises a "defect" issue and the second because it is better covered by other issues.

Viewing the two subparts of this issue separately, we conclude that the first suffers from the same problem plaguing Bauer Issues 35, 37, and 38. A "yes" answer would not provide any relevant information regarding the focal matter of whether Dr. Bauer acted reasonably under

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<sup>7</sup>(...continued)  
Advanced Medical Sys., Inc. (One Factory Row, Geneva, Ohio 44041), CLI-94-6, 39 NRC 285, 308 (1994) (mere assertions of dispute over material facts do not invalidate grant of summary disposition).

section 20.201 relative to taking a survey.<sup>8</sup> Thus, this portion of the issue can be dismissed.

The second segment of Issue 40 must be treated somewhat differently. As we noted in the OSC proceeding, Dr. Bauer's actual state of knowledge about the afterloader may be relevant in determining whether his actions relative to taking a survey were "reasonable under the circumstances." As the staff recognizes in its dismissal motion, see Staff Dispositive Motion at 16, under this formulation it is possible that information regarding Dr. Bauer's reliance on Omnitron procedures could be relevant to this litigation. The staff also asserts, however, that the second statement in Bauer Issue 40 is duplicative of other issues that the staff has not made part of its dismissal request and so should be dismissed. See id. at 16-17. We agree. Nonetheless, to ensure that the particular theme of this issue is not lost, we include certain of its language in another concern -- Bauer Issue 36 -- to incorporate fully

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<sup>8</sup> As we have indicated previously, what Dr. Bauer knew about possible Omnitron 2000 defects and failures is generally relevant to determining whether his actions relative to any survey were reasonable under 10 C.F.R. § 20.201(b). See supra p. 22. Although it might be argued that the use of the term "unanticipated" in the first part of Bauer Issue 40 is directed at such an inquiry, the question of Dr. Bauer's knowledge about and reasonable reliance regarding the performance of the Omnitron 2000 is more properly framed in Bauer Issue 36, as it refers to reliance on the "specific features of the Omnitron," and Bauer Issue 33, which refers to purported Omnitron training that the Omnitron 2000 "source wire could not break." Joint Prehearing Report at 5.

the concept behind this portion of Issue 40. The wording of this amended issue is set forth below.<sup>9</sup>

3. Bauer Issues 48 and 49. Bauer Issues 48 and 49 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. In the OSC 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. The staff asks that we dismiss those issues from this proceeding as well.

In this case, as in the OSC proceeding, 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.<sup>10</sup> We found in the OSC proceeding that dismissal was

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<sup>9</sup> If either party disagrees with our formulation of this issue (or Bauer Issue 8 discussed below), it is free to seek timely reconsideration of the matter. See 10 C.F.R. § 2.771.

<sup>10</sup> As is evidenced by his Issues 9, 45 and 47, to complete his "section 35.404(a) compliance" rationale, Dr. Bauer apparently will seek to establish that a PrimAlert radiation monitor mounted on the wall of the IRCC

(continued...)

appropriate because this matter was more clearly articulated through other issues; however, 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. The terms of amended Issue 8 are set forth below.

### III. CONCLUSION

After considering the parties' filings, we have concluded that under the particular circumstances here, there is no current legal impediment to the staff relying upon allegedly improper conduct detailed in one enforcement action as a basis for a different enforcement action. We thus deny Dr. Bauer's request that the staff be precluded from using the cited circumstances regarding the November 1992 incident and his actions concerning the IRCC strontium-90 license as bases for its May 1994 enforcement order. Moreover, finding no material issues in dispute, we

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<sup>10</sup>(...continued)  
brachytherapy treatment room was a "radiation survey detection instrument" within the meaning of section 35.404(a) that afforded compliance with 10 C.F.R. § 20.201.

grant the staff's summary disposition motion on the same point. This ruling in favor of the staff also compels us to dismiss related Bauer Issues 19, 20, and 22 as moot.

In contrast, we find that we now are unable to resolve the staff's request for summary disposition on Joint Issue 1. To aid us in reaching that determination, however, we ask the parties to address several questions regarding the applicability and impact of 10 C.F.R. § 2.103(b) to the issue of what medical conditions Dr. Bauer was authorized to treat under the IRCC strontium-90 license.

Finally, acting on the staff's motion to dismiss, we grant the staff request relative to Bauer Issues 35, 37, 38, 40, 48, and 49, albeit with the condition that Bauer Issues 8 and 36 are to be reworded to incorporate certain concepts from Bauer Issues 40, 48, and 49. On the other hand, having found they involve matters that may entitle Dr. Bauer to some relief, we deny the staff's motion to dismiss Bauer Issues 16 and 17.

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For the foregoing reasons, it is this ninth day of December 1994, ORDERED, that

1. Dr. Bauer's July 29, 1994 motion to eliminate basis is denied.

2. The staff's July 29, 1994 motion for summary disposition is granted as to Joint Issue 4, and related Bauer Issues 19, 20, and 22 are dismissed as moot.

3. Regarding Joint Issue 1 that is the subject of the staff's July 29, 1994 motion for summary disposition, on or before Friday, January 6, 1995, the staff shall file a pleading addressing the questions set forth at page 17 supra. Dr. Bauer shall have up to and including Friday, February 3, 1995, within which to file a response to that pleading. In addition to regular service by mail on each Board member and the opposing party, each party should send a copy of its pleading to the Board and the opposing party by facsimile transmission or other means that will ensure receipt by 4:30 p.m. EST on the day of filing.

4. The staff's July 29, 1994 motion to dismiss is granted as to Bauer Issues 35, 37, 38, 40, 48, and 49, and is denied as to Bauer Issues 16 and 17.

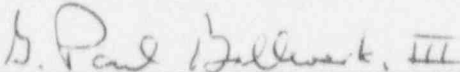
5. Bauer Issue 36 is amended to incorporate language from Bauer Issue 40 so that Issue 36 reads as follows:

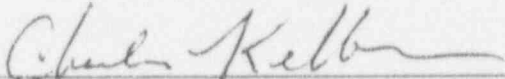
36. Whether reliance by Dr. Bauer on specific features of the Omnitron and on Omnitron procedures that did not anticipate or cover a failure of the Omnitron 2000 retraction mechanism was reasonable in November 1992?

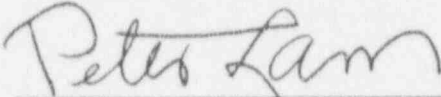
6. Dr. Bauer Issue 8 is amended to incorporate language from Bauer Issues 48 and 49 so that Issue 8 reads as follows:

8. 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?

THE ATOMIC SAFETY  
AND LICENSING BOARD<sup>11</sup>

  
\_\_\_\_\_  
G. Paul Bollwerk, III, Chairman  
ADMINISTRATIVE JUDGE

  
\_\_\_\_\_  
Charles N. Kelber  
ADMINISTRATIVE JUDGE

  
\_\_\_\_\_  
Peter S. Lam  
ADMINISTRATIVE JUDGE

Rockville, Maryland

December 9, 1994

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<sup>11</sup> Copies of this memorandum and order are being sent this date to counsel for Dr. Bauer by facsimile transmission and to staff counsel by E-mail transmission through the agency's wide area network system.

UNITED STATES OF AMERICA  
NUCLEAR REGULATORY COMMISSION

In the Matter of

JAMES E. BAUER

Docket No.(s) IA-94-011

CERTIFICATE OF SERVICE

I hereby certify that copies of the foregoing LB MEMO & ORDER (LBP-94-40) have been served upon the following persons by U.S. mail, first class, except as otherwise noted and in accordance with the requirements of 10 CFR Sec. 2.712.

Office of Commission Appellate  
Adjudication  
U.S. Nuclear Regulatory Commission  
Washington, DC 20555

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

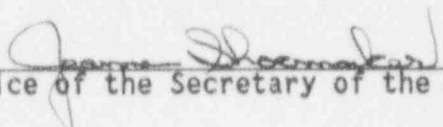
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Administrative Judge  
Peter S. Lam  
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P. O. Box 607  
Indiana, PA 15701

Dated at Rockville, Md. this  
9 day of December 1994

  
Office of the Secretary of the Commission