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UNITED STATES OF AMERICA
NUCLEAR REGULATORY COMMISSION

ATOMIC SAFETY AND LICENSING BOARD

Before Administrative Judges:

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

EXEMPTED
USNRC

LBP-94-2

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In the Matter of
ONCOLOGY SERVICES CORPORATION

(Order Suspending
Byproduct Material
License No. 37-28540-01)

Docket No. 030-31765-EA

EA 93-006

ASLBP No. 93-674-03-EA

January 24, 1994

MEMORANDUM AND ORDER

(Ruling on Parties' Pre-discovery Motions
to Dismiss or for Summary Disposition)

In a July 15, 1993 memorandum and order, the Board requested that the NRC staff and licensee Oncology Services Corporation (OSC) consider whether certain of the nearly one hundred issues previously identified by OSC for litigation in this license suspension proceeding are subject to motions to dismiss or for summary disposition. The staff now asks that we dismiss twelve OSC issues while OSC maintains that it is entitled to summary disposition on five of these issues.

For the reasons set forth below, we deny OSC's summary disposition motion and grant the staff's dismissal request as to ten of the twelve issues.

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I. BACKGROUND

By order dated January 20, 1993, the staff suspended OSC's byproduct materials license authorizing the use of sealed-source iridium-192 for high dose rate (HDR) human brachytherapy treatments at six OSC facilities in Pennsylvania. One of the principal bases for the staff's suspension determination is a November 16, 1992 incident at OSC's Indiana (Pennsylvania) Regional Cancer Center (IRCC). Following treatment at IRCC, an HDR brachytherapy patient was returned to her nursing home with a iridium-192 source mistakenly lodged in the area of her abdomen. Also cited by the staff in support of license suspension are the results of December 8, 1992 inspections of OSC facilities in Lehigh and Exton, Pennsylvania, and a December 18, 1992 letter in which OSC's radiation safety officer (RSO) allegedly improperly delegated corporate health and safety responsibilities to OSC satellite facilities.

According to the staff, the factual circumstances surrounding these matters, as described in the suspension order, "demonstrate a significant corporate management breakdown in the control of licensed activities." 56 Fed. Reg. 6825, 6826 (1993). While noting that the agency was continuing to investigate OSC's activities, the staff nonetheless found that

as a result of the information available to date and the incident in which an

iridium-192 source was unknowingly left within a patient, [the staff] lack[s] the requisite reasonable assurance that [OSC's] current operations can be conducted under [its license] in compliance with the Commission's requirements and that the health and safety of the public, including [OSC's] employees and patients, will be protected.

Id. at 6827. Based on these findings, the staff imposed an immediately effective suspension of OSC's license.

This proceeding was convened in response to OSC's timely request for a hearing to contest the order. In response to the first of three staff requests for a delay of the proceeding to permit the agency to complete its investigations of the November 1992 incident and related matters, we issued a March 1993 memorandum and order postponing discovery by the parties.¹ See LBP-93-6, 37 NRC 207, vacated in part as moot, CLI-93-17, 38 NRC 44 (1993). At the same time, in an effort to have the parties begin defining the parameters of this proceeding, the Board directed that they file a joint prehearing report setting forth, among other things, the "central" issues for litigation. See id. at 221, 223. OSC specified ninety-nine

¹ Subsequently, we granted two additional staff delay requests, postponing discovery through early December 1993. See LBP-93-10, 37 NRC 455, aff'd, CLI-93-17, 38 NRC 44 (1993); LBP-93-20, 38 NRC 130 (1993). On November 16, the staff informed the Board that it was not requesting any further delays in the proceeding as a result of the investigations. See Letter from M. Zobler, NRC staff, to the Licensing Board (Nov. 16, 1993).

issues. See Joint Prehearing Report (May 5, 1993) at 2-7, 8-16 [hereinafter Prehearing Report]. The staff agreed with the wording of nineteen of these issues, see id. at 3-4, 6, 8-9, 11-12, 14-16, but objected to the remaining eighty, see NRC Staff's Objections to Issues Proposed by [OSC] (May 11, 1993).²

After reviewing these staff objections and OSC's response thereto, we issued the previously referenced July 15 memorandum and order. In it we directed that as to thirty-seven of the OSC issues, either the staff or OSC should provide a filing that requested dismissal or summary disposition of particular issues or that outlined why those issues are not appropriate for further Board consideration at present. See Memorandum and Order (July 15, 1993) at 10, 13-14 (unpublished) [hereinafter July 15, 1993 Order]. We also indicated that either party was free to include any of the other prehearing report issues in any dispositive motion it filed. See id. at 3 n.1.

On August 16, 1993, both the staff and OSC filed such motions. The staff initially asked that we dismiss thirty-one of the thirty-two issues we had identified for its specific consideration, as well as an additional seven OSC issues not referenced by the Board. See NRC Staff's Motion

² The staff proposed nine issues, but OSC agreed to the wording of only one. See Prehearing Report at 1-2, 7-8. None of these staff issues are the subject of OSC's pending dispositive motion.

to Dismiss Certain Issues Proposed by [OSC] (Aug. 16, 1993) at 9-32 [hereinafter Staff Motion to Dismiss]. For its part, OSC moved for summary disposition regarding the five issues that we had asked it to address further. See Response of [OSC] to the July 15, 1993 Order of the [Licensing Board] (Requesting Further Party Filings on Controverted Issues) and Motion of [OSC] for Summary Judgment with Respect to Certain of Those Issues (Aug. 16, 1993) at 10-20 [hereinafter OSC Summary Disposition Motion].

Both parties subsequently filed a response opposing the other's dispositive motion and a reply to those responses. As part of its response, the staff requested that we dismiss the five issues designated by OSC for summary disposition. See NRC Staff's Response to [OSC's] Motion for Summary Judgment with Respect to Certain Issues and NRC Staff Motion to Dismiss (Sept. 16, 1993) at 30-33 [hereinafter Staff Summary Disposition Response/Motion to Dismiss]. Additionally, with its reply to the staff's response, OSC filed a motion to strike the staff's additional dismissal request. See Reply of Licensee [OSC] to NRC Staff's Response to [OSC's] Motion for Summary Judgment with Respect to Certain Issues and Motion of [OSC] to Strike the NRC Staff's September 16, 1993 Motion to Dismiss as Untimely, Unauthorized and Prejudicial (Oct. 1, 1993) at 19-20 [hereinafter OSC Reply to Staff Summary Disposition Response/Motion to Strike].

After reviewing these various pleadings, we issued a November 17, 1993 memorandum and order in which we denied OSC's motion to strike the staff's additional dismissal request. See Memorandum and Order (Denying OSC Motion to Strike Additional Staff Motion to Dismiss Certain OSC Issues and Permitting Further OSC Response to Additional Motion to Dismiss; Requesting Additional Filings Regarding NRC Staff Motions to Dismiss Certain OSC Issues) at 3-4 (Nov. 17, 1993) (unpublished) [hereinafter November 17, 1993 Order]. We also directed that the staff provide additional information relative to its pending dismissal motions. See id. at 4-8. This request was prompted by statements in the staff's reply to OSC's response to the staff's initial motion to dismiss indicating that for certain of the issues specified by OSC, the staff's dismissal request was predicated on its belief that these issues had been raised prematurely. See NRC Staff's Reply to [OSC's] Response to NRC Staff's Motion to Dismiss Certain Issues Proposed by [OSC] (Oct. 1, 1993) at 5-7. As presented by the staff, "dismissing" such an issue now would not necessarily foreclose OSC from later attempting to introduce evidence regarding that issue as part of its challenge to the staff's January 1993 enforcement order.

Noting that the intent of our July 15 order was to identify those issues that either party believed could be conclusively resolved at this point in the proceeding, in

our November 17 memorandum and order we asked that the staff again review the issues for which it requested dismissal and specify which, if any, were now subject to definitive resolution. See November 17, 1993 Order at 6-7. In its November 29 response to this request, the staff has indicated that twelve of OSC's issues currently are subject to "dismissal" under the terms of our November 17 issuance. See NRC Staff Response to the [Licensing Board's] Order Dated November 17, 1993 (Nov. 29, 1993) at 5-7 [hereinafter Staff Response to November 17, 1993 Order]. Five of these are the same issues for which OSC seeks summary disposition in its favor. See id. at 6 n.2. In its reply to the staff's response, OSC reiterates its position that none of these twelve issues is subject to dismissal. See Response of Licensee [OSC] to Staff Filings of November 29, 1993 and September 6, 1993 (Dec. 13, 1993) at 3-6 [hereinafter OSC Response to November/September Staff Filings].

We consider the twelve issues specified in the staff's November 29 response as being ripe for decision at this time.³

³ If it finds it appropriate to do so, the staff may renew its dismissal request relative to any of the other issues specified in its motions, subject to any time limitations we place on filing dispositive motions.

II. ANALYSIS

A. OSC Summary Disposition Motion

1. The OSC Issues. In analyzing the parties' motions, we begin with OSC's summary disposition request because it potentially is dispositive of the staff's request to dismiss the same five issues. In our July 15 order, we asked that, given its response to the staff's objections to five of its issues -- OSC Legal Issues n, s, t, v, and x -- OSC give further consideration to whether it should seek summary disposition regarding those issues. See July 15, 1993 Order at 10-14. Those issues were specified by OSC as follows:

OSC Legal Issue n. Whether the RSO not visiting the Lehighton facility during a period of 6-9 months constitutes a violation of 10 C.F.R. § 35.21, 10 C.F.R. § 35.20 or any applicable conditions of the license?

OSC Legal Issue s. Whether, under any applicable regulations or licensing conditions, an appropriate corporate radiation safety communication must be issued before any media disclosure of an event?

OSC Legal Issue t. Whether the failure to issue an appropriate corporate radiation safety communication prior to media disclosure of an event constitutes a basis to support an effective immediately suspension order?

OSC Legal Issue v. Assuming that OSC voluntarily suspended licensed HDR operations at Exton and Lehighton, whether there was any specific regulatory requirement that OSC inform the physicists at Exton and Lehighton of the November 1992 IRCC incident via "corporate radiation safety communication" designed to prevent "the recurrence of an event such as the November 16, [1992] event," during the period of voluntary suspension and prior to the time that OSC and Dr. Cunningham, the RSO, had an understanding of what had occurred on November 16, 1992?

OSC Legal Issue x. Whether 10 CFR Parts 20, 30, or 35 or any license conditions require a licensee to establish and implement a periodic corporate audit program?

See Prehearing Report at 4-6.

2. The Parties' Positions. In its summary disposition filing, OSC asserts that, for purposes of its motion, it will assume that the factual allegations made by the staff regarding each of these issues is correct, i.e., that the RSO did not visit the Leighton facility for six to nine months; that physicists at the Leighton and Exton facilities learned of the November 1992 IRCC incident from the media rather than a corporate radiation safety communication; and that OSC did not have a periodic corporate audit program in place. See OSC Summary Disposition Motion at 13. According to OSC, even with this assumption, these "Visitation, Audit, and Communication grounds" (as OSC labels them) cannot constitute a basis for the staff's finding in its enforcement order that there has been a "significant corporate management breakdown" warranting license suspension. OSC maintains that in each instance the staff has failed to indicate that the purported improper actions violate any specific statutory provision, regulation, license condition, technical specification, or order so as to constitute a proper basis for an enforcement action. Indeed, OSC suggests that this question of a lack of authority has far-reaching implications for this case

because, as with these issues, the agency's reliance upon "corporate mismanagement" as the general basis for its suspension action likewise has no foundation in a specific regulatory requirement that would provide grounds for instituting an enforcement action. See id. at 13-14.

OSC cites three grounds in support of its position. See id. at 14-20. First, it contends that three provisions in the Atomic Energy Act of 1954 (AEA), sections 161b, 182a, and 186a, 42 U.S.C. §§ 2201(a), 2232(a), 2236(a), mandate that to establish a binding norm by which a licensee must abide, the agency has to promulgate an explicit regulatory requirement, i.e., a rule, order, technical specification, or license provision, and that such requirements can only be prospective in application. OSC also declares that 10 C.F.R. Part 2, app. C., § VI.C(2)(a), cited in the staff's objections to OSC's issues as supporting the agency's authority to suspend OSC's license, is a "policy statement" rather than a rule. This, OSC asserts, means that it can have no binding effect.

Finally, OSC contends that any finding that the matters set forth in these issues constitute a basis for an enforcement action would violate its right to due process under the Constitution's fifth amendment. According to OSC, because there is no specific regulatory requirement covering the conduct involved in these issues, the Commission has violated OSC's rights by failing to provide it with notice

of the legally binding standard to which it must conform its conduct. By the same token, OSC asserts that even if section VI.C(2)(a) of appendix C is a legally binding requirement, its statement that a suspension order may be used "[t]o remove a threat to the public health and safety, common defense and security, or the environment" violates OSC's due process rights because it is too vague to provide OSC with notice of the standards to which it must conform and because it impermissibly permits arbitrary and discriminatory enforcement.

In response, the staff declares that the Commission is not limited to issuing enforcement orders based only upon a violation of its regulations. Instead, it asserts that AEA section 161 places orders -- such as the staff's January 1993 enforcement order -- that are issued to protect the public health and safety on an equal footing with agency rules designed to afford the same standard of protection. Further, citing the Supreme Court's decision in SEC v. Chenery Corp., 332 U.S. 194 (1947), the staff states that in carrying out its statutorily imposed responsibility to protect the public health and safety, the agency is not limited to promulgating rules, which usually have only prospective application. Rather, it can in appropriate circumstances take action by issuing an order that delineates a standard of conduct and applies that standard to the party that is the subject of the order. Finally, the

staff asserts that the AEA provisions referred to by OSC (which also are cited in the January 1993 order) provide the Commission with broad authority to act by issuing rules or orders, among other things permitting it to suspend a license for any conditions that would warrant refusing to grant an original license application or as otherwise may be necessary to protect public health and safety or to minimize danger to life or property. See Staff Summary Disposition Response/Motion to Dismiss at 10-13.

3. The Board's Determination. OSC undoubtedly is correct that section VI.C(2)(a) of appendix C is not a legally binding requirement. Yet, this circumstance alone will not sustain its overall position. Section 2.202(a)(1) of 10 C.F.R. states that in issuing an enforcement order such as that at issue here, the staff must "[a]llege the violations with which the licensee or other person subject to the Commission's jurisdiction is charged, or the potentially hazardous conditions or other facts deemed to be sufficient ground for the action proposed." This language suggests that the Commission contemplated that orders need not be based upon a violation of a specific regulatory requirement, such as a rule, license condition, or technical specification.

Yet, it also is true that as a creature of the Congress, the agency can only wield that enforcement authority it has been given by legislative enactment. See

5 U.S.C. § 558(b). AEA section 186a, 42 U.S.C. § 2236(a), permits revocation and, by necessary implication, suspension of a license for, among other things, "any failure to observe any of the terms and provisions of this Act." Moreover, there apparently are statutory "terms and provisions" that could provide authorization for the staff's allegations of wrongdoing here. Under sections 161b and 161i(3), *id.* §§ 2201(b), 2201(i)(3), the agency is empowered to issue orders "to protect health or minimize danger to life or property." Previous judicial interpretation makes it clear that the Commission's authority under these provisions is wide-ranging, perhaps uniquely so. See Siegel v. AEC, 400 F.2d 778, 783 (D.C. Cir. 1968).

Given the broad sweep of this legislative charge, we cannot say on the present record that the agency would be unable to impose specific requirements regarding either "corporate management" or the visitation, audit, and communications components of the staff's overall management deficiency finding that are implicated in the five OSC issues.⁴ Further, a valid agency order mandating such

⁴ A further indication of the agency's broad authority to impose requirements is found in AEA section 182a, 42 U.S.C. § 2232(a), regarding license applications. It states that the Commission has the authority to require an applicant to provide information that, by rule, the Commission finds is necessary to determine that the applicant has the technical, financial, and other

(continued...)

requirements for a particular licensee is on an equal footing with a valid regulation affecting licensees generally.⁵ See AEA § 161b, 42 U.S.C. § 2201(b). See also Wrangler Laboratories (General License Authority of 10 C.F.R. § 40.22), ALAB-951, 33 NRC 505, 518 & n.39 (1991). What may be less clear, and is the crux of OSC's concern

⁴(...continued)
qualifications appropriate for a license. In turn, AEA section 186a, id. § 2236(a), permits suspension for any conditions revealed by an inspection or other means that would warrant refusal to grant an original license application. The Commission's broad authority under section 182 to define regulatory requirements likewise has received judicial recognition. See Union of Concerned Scientists v. NRC, 880 F.2d 552, 558 (D.C. Cir. 1989) (determination of what constitutes "adequate protection" of the public health and safety for reactor facilities under section 182 is a matter congressionally committed to the Commission's sound discretion).

⁵ OSC refers to the Administrative Procedure Act (APA) provision on license revocations and suspensions, 5 U.S.C. § 558(c), as providing a basis for its assertions regarding the need for the agency to allege a violation of a specific agency regulatory requirement, such as a rule, as the basis for a suspension order. See OSC Reply to Staff Summary Disposition Response/Motion to Strike at 11-12. We find this provision inapplicable.

Section 558(c) permits an agency, in cases where the "public health, interest, or safety requires," to take action without observing the requirements for affording prior notice and a "compliance" opportunity that otherwise are mandated prior to imposing a suspension. This "immediate effectiveness" authority does not, however, address the question of what violations must be alleged to provide an appropriate basis in support of the order. Rather, this depends principally upon the provisions of the agency's organic statute, such as the AEA. See 5 U.S.C. § 558(b). See also U.S. Dep't of Justice, Attorney General's Manual on the Administrative Procedure Act 88-89, 91 (1947), reprinted in Administrative Conference of the U.S., Federal Administrative Procedure Sourcebook 154-55, 157 (2d ed. 1992).

here, is the extent to which such orders can have retroactive application, i.e., whether the agency for the first time in an order can declare that certain conduct, or a failure to act, on the part of a licensee was improper so as to warrant sanctions.

The Supreme Court's pronouncements in this area, particularly its decisions in Chenery, 332 U.S. at 203, and NLRB v. Bell Aerospace Co., 416 U.S. 267, 294 (1974), establish that the choice of whether to use a general rule or an individual order to establish a standard is one within "the informed discretion" of the agency.⁶ This principle recognizes that in the face of a broad congressional mandate such as that given to the NRC, an agency simply cannot be expected to anticipate and promulgate a rule relative to

⁶ OSC maintains that the Chenery decision is inapposite here because 1) that case was decided prior to the effective date of the APA's suspension provision, 5 U.S.C. § 558(c), which OSC asserts directly addresses the instant situation, and 2) the Court's ruling did not address a situation such as this one in which an agency took summary enforcement action based upon conduct that was not previously identified as subject to any regulatory requirement or guideline. See OSC Reply to Staff Summary Disposition Response/Motion to Strike at 10 n.4. Even putting aside our doubts about the applicability of section 558(c) to the instant case, see supra note 5, we are not aware of any authority suggesting that the vitality of the Chenery decision is impacted by the fact that it was decided before the APA became effective. See Bell Aerospace, 416 U.S. at 292 n.23 (although Chenery did not involve APA rulemaking, it is analogous). Further, the tenants of that decision have been viewed as applicable in enforcement cases such as this proceeding. See National Distillers & Chem. Corp. v. Dep't of Energy, 498 F. Supp. 707, 720 (D. Del. 1980), aff'd, 662 F.2d 754 (Temp. Emer. Ct. App. 1981).

each activity that a regulated entity undertakes. Therefore, to permit administrative agencies to deal effectively with the varied, complex regulatory problems they face, those agencies must retain the power to address those problems on a case-by-case basis by issuing orders. See Chenery, 416 U.S. at 203. In the words of the Court, to do otherwise "is to exalt form over necessity." Id. at 202.

There may be instances, however, when an agency's determination to proceed by order rather than rulemaking would amount to an abuse of discretion. See Bell Aerospace, 416 U.S. at 294. OSC's general "due process" concern about the agency's failure to give it explicit prior notice of the standards set forth in an order generally is not sufficient to establish such an abuse, given the Supreme Court's recognition of the discretion afforded agencies to utilize individual orders to establish binding standards. See Beazer East, Inc. v. EPA, Region III, 963 F.2d 603, 609 (3d Cir. 1992). Instead, the critical factor appears to be whether the challenged agency order "fill[s] interstices in the law" or whether it creates a new standard, either because the order overrules past precedents relied upon by the party subject to the ruling or because it is an issue of first impression. See United Food & Commercial Workers International Union, Local No. 150-A v. NLRB, 1 F.3d 24, 34

(D.C. Cir. 1993). Only in the latter instance is a concern about retroactive application warranted.⁷

OSC has made no showing that the staff's expressed concern about a "corporate management breakdown" or the propriety of OSC's actions relative to the specific audit, communication, and visitation matters referenced in the five OSC issues are inconsistent with some prior administrative precedent. Nor can we say that this is an instance involving a question of first impression relative to the agency's regulatory program. Previously, the staff's combination of individual instances of licensee conduct have been found to support an overall finding of "corporate management breakdown" sufficient to warrant an enforcement action. See Tulsa Gamma Ray, Inc. (Materials License No. 35-17178-01), LBP-91-40, 34 NRC 297, 317-18 (1991). See also 10 C.F.R. Part 2, app. C, § VII.A (particularly serious violations, such as "serious breakdowns in management controls" may warrant escalation of enforcement sanctions). In fact, whether the staff's management deficiency

⁷ In United Food & Commercial Workers, 1 F.3d at 35, the United States Court of Appeals for the District of Columbia Circuit noted that any exceptions to the rule regarding the general validity of the retroactive application of individual agency orders may not withstand scrutiny under the Supreme Court's recent holding in Harper v. Virginia Dep't of Taxation, 125 L. Ed. 2d 74 (1993), abolishing exceptions to the retroactive application of judicial rulings in civil cases. Like the District of Columbia Circuit, we need not reach that question here given our finding below that the staff's order does not run afoul of existing exception standards.

allegation will stand depends on its ability to fill a number of "interstices," among which are questions about the extent of an RSO's responsibility to stay abreast of matters at a corporate licensee's various facilities; the need for and timing of information bulletins by a corporate licensee to alert other potential material users under its license about possibly hazardous conditions; and the need for a periodic audit program by a corporate licensee when it has authorized material users at a number of facilities.

Accordingly, we must deny OSC's request for summary disposition on its Legal Issues n, s, t, v, and x. This is not to say, however, that the validity of the staff's general charge of a "corporate management breakdown" or its specific concerns regarding the audit, communications, and visitations matters referred to in these OSC issues are now established. Because of its apparent reliance on the agency's general statutory mandate to "protect the public health and safety" instead of a specific, previously-issued regulation, order, regulatory guide, or license condition as the basis for these matters, the staff must be prepared to establish with specificity the health and safety consequences of the licensee action or inaction about which it complains. Ultimately, the staff must show how the standard to which it would hold the licensee (and presumably others similarly situated) regarding those matters is a

reasonable component of agency's general statutory mandate to protect the public health and safety.

B. Staff Motion to Dismiss OSC Summary Disposition Issues

Having thus rejected OSC's summary disposition motion regarding its Legal Issues n, s, t, v, and x, we next consider whether to grant the staff's motion to dismiss these same issues. As the staff correctly observes, if after all factual allegations in these issues are presumed to be true and all reasonable inferences are made in favor of OSC, there is no set of facts that would entitle OSC to relief on these issues, dismissal is appropriate.⁸ See Staff Summary Disposition Response/Motion to Dismiss at 26 (citing Hishon v. King & Spalding, 467 U.S. 69, 73 (1984)). See also Staff Motion to Dismiss at 8.

Applying this standard here, we note that OSC Legal Issues n, s, and x only ask whether there are any rules or license conditions that govern certain OSC activities. Because we have concluded that a negative staff response to these questions would not adversely impact the staff's prosecution of this action, these issues can be dismissed.

⁸ Notwithstanding any OSC suggestion to the contrary, see Response of Licensee [OSC] to NRC Staff's Motion to Dismiss Certain Issues Proposed by [OSC] (Sept. 16, 1993) at 2-4, and consistent with the analogous agency rules regarding contentions filed by intervenors, see 10 C.F.R. § 2.714(d)(2)(ii), we find it within our authority to entertain the staff's motions seeking dismissal of some OSC issues. See 10 C.F.R. § 2.718.

Legal Issues t and v present a somewhat different question, however. Both are worded more broadly. Legal Issue t inquires whether the staff's purported concern about the timing of a corporate safety communication regarding the November 1992 IRCC incident constitutes an appropriate "basis" for the order. As we outlined above, this is still an open question. So too, Legal Issue v asks whether any "regulatory requirement" mandated a corporate safety communication when licensed activities at other facilities were voluntarily suspended, a specification that can still be explored in the context of the statutory provisions discussed above. Therefore, given their wording, we will permit these issues to stand.⁹

C. Staff Motion to Dismiss Other OSC Issues

As noted previously, the staff also seeks dismissal of seven other OSC issues. Within the framework we used for differentiating among issues in our July 15 order, we consider these matters.

1. Unreferenced Factual Occurrences. The first category of OSC issues identified in our July 15 order are those relating to factual circumstances that are not referenced in the staff's January 20 suspension order. See July 15, 1993 Order at 5-6. Although the staff designated a

⁹ We note, however, that the reference in Legal Issue t to the immediate effectiveness of the January 1993 order is superfluous, given OSC's failure to challenge that condition at the appropriate time. See LBP-93-6, 37 NRC at 211 n.9.

number of these in its initial motion to dismiss, in response to our November 17 memorandum and order it has indicated that only two -- Factual Issues bk and bl -- are now subject to dismissal. See Staff Response to November 17, 1993 Order at 7. These issues were set forth by OSC as follows:

OSC Factual Issue bk. Whether on April 2, 1993, the NRC approved an amendment sought by OSC changing its Radiation Safety Officer from David E. Cunningham Ph.D., to Bernard Rogers, M.D.?

OSC Factual Issue bl. Whether substantial patient need exists for HDR treatment at the facilities of OSC?

Prehearing Report at 28.

The staff asserts that both these issues are irrelevant because they fail to disprove or challenge any of the bases for the January 1993 enforcement order. See Staff Motion to Dismiss at 20, 32. OSC responds that both these issues are relevant to the overarching question of whether there was a significant corporate management breakdown threatening the public health and safety so as to "justify a continuing license suspension." OSC Response to November/September Staff Filings at 6.

Both of these issues involve matters that are irrelevant to this proceeding. With its Factual Issue bk, OSC raises the question of whether a licensee's postsuspension efforts (and the staff's response to those efforts) can be considered as factors that can mitigate or nullify the bases for a suspension order. In the context of

this proceeding, OSC apparently wants to present evidence showing that, regardless of the situation at the time the suspension order was imposed, subsequent events demonstrate that it now is exercising effective corporate management control so that the suspension order should not be upheld. See Response of Licensee [OSC] to NRC Staff's Motion to Dismiss Certain Issues Proposed by [OSC] (Sept. 16, 1993) at 13 [hereinafter OSC Response to Staff Motion to Dismiss].

Under the January 1993 suspension order, the issue to be considered is whether the order "should be sustained." 58 Fed. Reg. at 6827. If we were writing on a clean slate, we might well find that our inquiry into whether the order is to be "sustained" should encompass postsuspension activities proffered as corrective actions that support modifying or remitting the suspension. We do not do so, however. As defined by the Commission, 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." Boston Edison Company (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). Likewise, in 10 C.F.R. § 2.202(b), the Commission has directed that an answer to an enforcement order is to specify "the reasons why the order should not have been issued." Moreover, while the Commission's enforcement policy explicitly notes that licensee "corrective actions"

are a factor to be considered in imposing the other two types of enforcement actions, a notice of violation or a civil penalty, see 10 C.F.R. Part 2, app. C, §§ VI.A, VI.B.2(b), it makes no such representation concerning orders, including a suspension order such as that involved here.¹⁰

What this tells us is that the Commission intended to define the scope of the proceeding to limit the Board to a determination of the sufficiency of the legal and factual predicates outlined in the order as of the time the order was issued.¹¹ The extent to which subsequent circumstances

¹⁰ Section VI.C.2 of appendix C does state that "[o]rdinarily, a licensed activity is not suspended (nor is a suspension prolonged) for failure to comply with requirements where such failure is not willful and adequate corrective action has been taken." So too, the January 1993 suspension order states that it is being entered "pending . . . the institution of appropriate corrective actions on the part of the licensee." 58 Fed. Reg. at 6827. These statements, along with the provision of the order providing for the staff to relax or rescind any of its provisions upon a good cause showing by OSC, see id., are an explicit recognition of the staff's authority to consider and act upon corrective actions put forth by OSC. Nonetheless, given the Commission's explicit statements about the scope of the proceeding detailed above, in the absence of a statement in the order providing some detail about what are the "appropriate corrective actions," we do not consider these declarations sufficient to authorize us to delve into whether the staff has abused its discretion in failing to modify or rescind the January 1993 order in light of OSC's postsuspension corrective actions.

¹¹ The fact that the suspension order here was made immediately effective and continues to be effective does not affect this authority. The immediate effectiveness

(continued...)

warrant agency action to modify or withdraw a suspension order generally is a matter that is within the discretion of the staff and is not subject to consideration in an agency adjudication.¹² Cf. San Luis Obispo Mothers for Peace v. NRC, 751 F.2d 1287, 1314 (D.C. Cir. 1984), vacated in part and rehearing en banc granted on other grounds, 760 F.2d 1320 (1985), aff'd en banc, 789 F.2d 26, cert. denied, 479 U.S. 923 (1986). Accordingly, because it seeks to present a postsuspension event that is not relevant to establishing whether the staff suspension order should be sustained, OSC Factual Issue bk must be dismissed.

¹¹(...continued)

provision in the Commission's regulations states that the only grounds for contesting effectiveness are that "the order is not based on adequate evidence but on mere suspicion, unfounded allegations, or error." 10 C.F.R. § 2.202(c)(1)(2)(i). Under this provision, the focus remains on the stated bases for the order, not subsequent licensee actions in response to the suspension.

¹² This question of the presiding officer's authority to consider whether the staff should act to revise or withdraw a challenged suspension order can be distinguished from instances in which the staff actually has acted 1) to modify or suspend a previously issued order during the pendency of an adjudicatory proceeding regarding that order, or 2) to enter into an agreement to take such actions to settle a proceeding. In both instances, agency rules provide that the staff's action is subject to scrutiny by the presiding officer. See 10 C.F.R. §§ 2.203, 2.717(b). It also is not apparent whether, at some point, staff inaction on modifying or lifting a suspension order in the face of licensee corrective actions effectively may become a type of action that would give the Board authority under section 2.717(b) to consider the sufficiency of those corrective actions.

Factual issue b1 must suffer the same fate, albeit for a different reason. The staff's order is based upon a judgment about whether the license suspension is necessary to protect the public health and safety in conformity with the agency's regulatory responsibilities under the AEA. See supra pp. 12-14. Whatever the patient "need" for the treatment with licensed materials, the agency cannot authorize their use until it is satisfied that the licensee will act consistent with this statutory mandate. Accordingly, OSC Factual Issue b1 is irrelevant to our consideration of whether the staff's January 1993 order should be sustained and is, therefore, dismissed.¹³

2. Applicability of 10 C.F.R. Part 35, Subpart G. In our July 15 order, we also referenced a category of OSC issues regarding the applicability of the requirements of 10 C.F.R. Part 35, Subpart G, which concerns the use of sources for brachytherapy. See July 15, 1993 Order at 6-7. In response to our November 17 memorandum and order, the staff now seeks dismissal of two of these matters -- OSC Legal Issues c and d. See Staff Response to November 17,

¹³ The issue of patient "need" may well be relevant to the question of whether to grant a request to delay a proceeding. See LBP-93-6, 37 NRC at 216-20. At present, however, that is not a matter in controversy in this case. See supra note 1.

1993 Order at 6. These issues were detailed by OSC as follows:

OSC Legal Issue c. 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")?

OSC Legal Issue d. 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?

Prehearing Report at 2.

The staff argues that these issues should be dismissed as irrelevant because the January 1993 suspension order was not based upon any violation of 10 C.F.R. Part 35. See Staff Motion to Dismiss at 20-21. OSC contends that these issues are relevant because its compliance with Part 35 would satisfy any survey requirement under 10 C.F.R. Part 20, including section 20.201 that is cited in the order. It also maintains that, even if Part 35 is not applicable, the staff's own uncertainty about whether the requirements of Part 35 are germane to HDR use is evidence that NRC never communicated with licensees properly about the applicable requirements and is relevant to demonstrating that the November 1992 IRCC incident was rooted in a "regulatory failure" rather than an OSC management

breakdown. See OSC Response to Staff Motion to Dismiss at 15-16.

As worded, these issues are a poor delineation of the matters OSC evidentially wants to contest, at least as outlined in its response. The question of alternative compliance is already raised much more clearly in OSC Legal Issues e and f, which the staff does not contend are subject to definitive resolution at this time. See Staff Response to November 17, 1993 Order at 8. By the same token, OSC Legal Issues a, ac, and ad, which are not among the twelve issues specified by the staff, are much more to the point regarding any "regulatory failure" concern that OSC may wish to pursue.

OSC is responsible for spelling out the matters it wishes to litigate with sufficient specificity. Given the staff's acknowledgement that 10 C.F.R. Part 35 was not a basis for the January 1992 order, these two issues require too much "reading between the lines" to link them to the particular concerns OSC now contends it wants to present. We thus dismiss these two issues.

3. Omnitron 2000 HDR Remote Afterloader Issues. The third category of issues we identified were those relating to the Omnitron 2000 HDR remote afterloader that was in use at OSC's IRCC facility during the November 1992 incident. See July 15, 1993 Order at 7. Among these are issues

regarding defects or deficiencies in that device, or in the training, instructions, and emergency procedures provided by the manufacturer regarding that device, and questions about OSC employee compliance with and reliance upon Omnitron training and procedures.

The staff indicated in its November 17 filing that three of these issues now are subject to dismissal. See Staff Response to November 17, 1993 Order at 7. They provide as follows:

OSC Factual Issue z. Whether the Omnitron 2000 HDR unit was defective?

OSC Factual Issue ab. Whether despite Omnitron's knowledge of deterioration of the source wire due to a chemical reaction resulting from its packaging, Omnitron failed to notify OSC of the defect and OSC was not otherwise informed of the possibility of deterioration?

OSC Factual Issue ad. Whether any of the Omnitron 2000 design, manufacturing and/or warning defects was a cause of the November 16, 1992 incident?

See Prehearing Report at 11-12.

The staff's position regarding all three of these issues is the same: Under the factual circumstances described in the suspension order relative to the November 1992 IRCC incident, OSC had a regulatory obligation pursuant to Condition 17 of its license and 10 C.F.R. § 20.201(b) to perform a survey of the patient that would not be excused by any alleged defects in the Omnitron 2000. See Staff Motion to Dismiss at 22. OSC asserts that under

the terms of the January 1993 order, a central question is whether its actions relating to taking a survey were, in the words of the January 1993 order, "reasonable under the circumstances to evaluate the extent of radiation hazards that may be present." 58 Fed. Reg. at 6825. Further, according to OSC, any assessment of the reasonableness of its action can only be made after determining whether the Omnitron 2000 was defective, whether that defect was the cause of the November 1992 IRCC incident, and whether the machine's manufacturer knew of and failed to inform OSC about that defect. See OSC Response to Staff Motion to Dismiss at 14-15.

We agree with OSC that as to the issue of its personnel's compliance with section 20.201(b), a central question is whether its actions relating to a survey were "reasonable under the circumstances." We disagree, however, that its proposed concerns regarding defects in the Omnitron 2000 as embodied in Factual Issues z, ab, and ad have any relevance in answering that question.

In this context, the relevant "circumstances" are those that existed at the time of the incident. Undoubtedly, an important aspect of those circumstances is what pertinent OSC management and operating personnel knew about the Omnitron afterloader and any possible defects or problems, as garnered from such things as their operational experience

or any information they were privy to as a result of training or instruction manuals. Consequently, a relevant area for litigation is the state of knowledge of OSC personnel about Omnitron afterloader defects and problems at the time of the incident.¹⁴

This is not, however, what these three "defect" issues seek to explore. As we understand it, OSC contends that at the time of the incident it did not know of any defect in the operation of the afterloader or its safety systems that could cause the metal drive wire to break and leave the iridium-192 source lodged in a patient without alerting the operator. See OSC Summary Disposition Motion at 3-4. If this indeed was the state of knowledge of OSC personnel at that time, then inquiry into whether the Omnitron machine actually was defective so as to be a cause of the November 1992 IRCC incident or whether the manufacturer should have told OSC about problems with the machine based upon some alleged duty to discover and disclose defects will not shed any light on the central question of what OSC personnel knew at the time of the incident. Indeed, for purposes of this action, even if it is assumed that the

¹⁴ Other OSC issues raise questions about such matters. See, e.g., Prehearing Report at 10 (OSC Factual Issue n (Omnitron training regarding source wire breakage)); id. at 11 (OSC Factual Issue u (use of emergency procedures in the Omnitron manual)); id. at 12 (OSC Factual Issue ag (user reliance on Omnitron procedures)).

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 a survey were "reasonable under the circumstances."

Accordingly, we dismiss OSC Legal Issues z, ab, and ad as not relevant to this proceeding.

III. CONCLUSION

Based upon our review of the parties' filings, we conclude that in this instance the staff's reliance on matters that apparently do not constitute a violation of any specific pre-existing rule, order, license condition, or technical specification as a basis for its January 1993 suspension order did not constitute an abuse of discretion so as to warrant summary disposition in favor of licensee OSC relative to those matters. We will, however, grant the staff's request that OSC Legal Issues n, s, and x asserting such staff reliance was improper be dismissed from this proceeding.

In addition, we conclude that OSC Factual Issues bk and bl should be dismissed, the former for seeking consideration of irrelevant postsuspension activities and the latter for attempting to introduce the extraneous factor of "patient need." We also dismiss OSC Legal Issues c and d

for failing to delineate the matters OSC apparently wishes to litigate under those issues.'

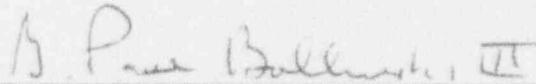
Finally, we find that the allegations about whether the Omnitron 2000 afterloader involved in the November 1992 IRCC incident was defective and a cause of the incident are irrelevant to the matters at issues here -- in particular, the focal question of whether the actions of OSC personnel regarding taking a survey during the November 1992 IRCC incident were "reasonable under the circumstances." We thus dismiss OSC Factual Issues z, ab, and ad as well.

For the foregoing reasons, it is this nineteenth day of January 1994, ORDERED, that

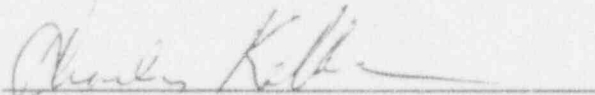
1. OSC's August 16, 1993 motion for summary disposition is denied.
2. The staff's August 16, 1993 motion to dismiss is granted as to OSC Legal Issues c and d and OSC Factual Issues z, ab, ad, bk, and bl.
3. The staff's September 16, 1993 motion to dismiss is

granted as to OSC Legal Issues n, s, and x and is denied as to OSC Legal Issues t and v.¹⁵

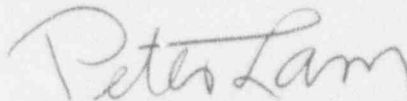
THE ATOMIC SAFETY
AND LICENSING BOARD



G. Paul Bollwerk, III, Chairman
ADMINISTRATIVE JUDGE



Charles N. Kelber
ADMINISTRATIVE JUDGE



Peter S. Lam
ADMINISTRATIVE JUDGE

Bethesda, Maryland

January 24, 1994

¹⁵ Copies of the memorandum and order are being sent this date to OSC counsel 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

ONCOLOGY SERVICES CORPORATION,
HARRISBURG, PA
(Byproduct Material License
No. 37-28540-01 - EA 93-006)

Docket No.(s) 30-31765-EA

CERTIFICATE OF SERVICE

I hereby certify that copies of the foregoing LB M&O (LBP-94-2) DTD 1/24/94 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.

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Washington, DC 20555

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Atomic Safety and Licensing Board
U.S. Nuclear Regulatory Commission
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Administrative Judge
Charles N. Kelber
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Dated at Rockville, Md. this
25 day of January 1994

Kris Carter
Office of the Secretary of the Commission

* Federal Express