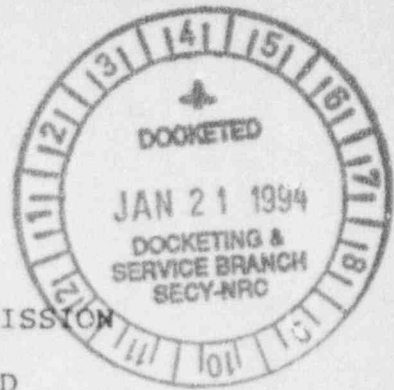


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UNITED STATES OF AMERICA NUCLEAR REGULATORY COMMISSION  
BEFORE THE ATOMIC SAFETY AND LICENSING BOARD

IN THE MATTER OF: )  
 ) Docket No. 030-31765-*EA*  
Oncology Services Corporation )  
(Byproduct Material License ) EA No. 93-606  
No. 37-28540-01) )

RESPONSE OF ONCOLOGY SERVICES CORPORATION ("OSC")  
TO NRC STAFF OBJECTIONS TO DISCOVERY REQUESTS  
AND NRC MOTION FOR A PROTECTIVE ORDER

INTRODUCTION

Pursuant to the Atomic Safety and Licensing Board's (the "Board") January 10, 1994 Order (Postponing Discovery Responses Pending Pre-hearing Conference), OSC hereby makes the following response to the NRC Staff (the "Staff") Objections to Discovery Requests and Motion for a Protective Order dated January 14, 1994 ("Staff Objections and Motion").

BACKGROUND

In response to Staff motions on March 26, 1993, June 23, 1993, and on September 21, 1993, the Board granted Orders staying OSC's discovery in the above-captioned matter. By Memorandum and Order (Establishing Administrative Directives And Scheduling Pre-Hearing Conference) dated December 17, 1993, the Board found that the last Staff stay had expired (because the Staff failed to move for an additional delay) and as a consequence held that discovery could proceed. That December 17, 1993 Board Memorandum and Order additionally set January 26, 1994 as the date for a

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pre-hearing conference at which, among other matters, the Board will consider discovery issues.

On December 26, 1993, the Staff served NRC Staff's Interrogatories and Request for Production of Documents and Admissions ("Staff Discovery Requests") on OSC. On January 3, 1994, OSC served the Staff with "Licensee's First Set of Interrogatories, First Request for Production and First Request for Admissions Directed to NRC Staff ("OSC Discovery Requests"). Because OSC cannot respond to the Staff's discovery until the Staff produces materials related to the Incident Investigation Team ("IIT") investigation, OSC moved the Board for a Protective Order ("OSC Motion for Protective Order") on January 4, 1994 to stay any and all responses by OSC to the Staff's Discovery Requests pending, among other events, Staff production of the IIT materials.<sup>1</sup>

After the Staff responded, the Board entered an Order (Postponing Discovery Responses Pending Pre-Hearing Conference) suspending the deadlines for the parties to make their responses to the discovery requests against them pending the January 26, 1994 pre-hearing conference. This Order additionally required the Staff to file any objections to or motion for protective order regarding OSC's discovery requests by January 14, 1994.

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<sup>1</sup> OSC's motion requested protection from responding to Staff Discovery Requests until such time as (i) a discovery management order and timetable can be developed at the pre-hearing conference on January 26, 1994; (ii) the Staff makes available certain witness transcripts and other materials it is presently withholding; and (iii) OSC has a reasonable time to review them. See OSC Motion for Protective Order at 5.

Subsequently, in response to Staff's motion dated January 12, 1994, the Board issued a Memorandum and Order (granting Staff's Motion for Extension of Time to File Specific Discovery Objections) wherein the Board permitted the Staff to file only a partial response to OSC's Discovery Requests on January 14, 1994, and granted the Staff an "extension of time to file specific objections to the production of individual documents ...". January 14, 1994 Memorandum and Order at 3. Although the Board did not set a time certain for the Staff's specific objections, the Board did note that a subsequent Board Order would do so based on a "precise estimate of time" provided by the Staff at the January 26, 1994 pre-hearing conference. Id.

Finally, on January 14, 1994, the Staff filed its "Objections to Discovery Requests and Motion for a Protective Order" ("Staff Objections and Motion") to which OSC hereby responds.

#### GENERAL STATEMENT

In its January 14, 1994 Objections and Motion, the Staff makes numerous objections to OSC's Discovery Requests as well as a motion for a Protective Order effectively staying discovery of the IIT materials.

OSC opposes the Staff Objections and Motion generally and asserts that the Staff's objection and motion is improper because

- 1) it is in effect a motion for delay which Staff has failed to properly and timely pursue under the Board's Memorandum and Order of September 21, 1993;
- 2) it is in effect a motion for delay which de facto denies OSC any consideration of the factors necessary to protect OSC's Due Process rights in regard to such;
- 3) by seeking to refuse OSC's discovery requests regarding concededly proper discovery, while at the same time seeking discovery responses from OSC regarding data contained in the materials it withholds, the NRC is attempting to create a catch-22 abusive of the discovery process and fatal to any fairness to OSC thereunder; and
- 4) the Staff objections to OSC discovery requests are without merit because those discovery requests directly relate and are necessary to a "complete record" for a proper determination regarding this proceeding in which OSC challenges the January 20, 1993 Staff Order Suspending [OSC's] License (Effective Immediately) (the "Suspension Order").

In this pleading OSC first responds to the Staff's motion for a protective order. Next, following a general discussion of NRC discovery standards, OSC addresses the Staff's specific objections to OSC's Discovery Requests. For the convenience of the Board, OSC has reproduced both the discovery request objected to and the Staff objection immediately before each response by OSC.

#### I. OSC RESPONSE TO THE STAFF MOTION FOR A PROTECTIVE ORDER

OSC objects to the Staff Motion for a Protective Order regarding certain of the IIT materials and other as yet unidentified materials. OSC submits fundamental fairness demands that the Staff motion for a protective order be denied as a

fatally late, de facto motion for stay which would, contrary to both the Constitution and Board Order, ignore the Due Process considerations to which OSC is entitled. See Georgia Power Company, (Vogtle Electric Generating Plant Units 1 & 2), 1993 WL 373970 (N.R.C.) at \*1 & n.4. (the question of when to require (or protect) the disclosure of documents alleged to be relevant for enforcement purposes is analogous to a stay).

In its motion the Staff "seeks to protect certain documents . . . obtained by the NRC Incident Investigation Team (IIT) which are responsive to the Licensee's Discovery Requests." Staff Objections and Motion at 21. The Staff declares that such protection is necessary because "premature release of the IIT documents could harm a potential criminal investigation" and so seeks protection of the documents at least until the Department of Justice ("DOJ") makes a decision whether to prosecute. Id.

However, the Board, correctly comprehending the analogy stated in Georgia Power Company, treated previous Staff efforts to "protect" the IIT materials for what such "protection" amounts to: a stay of the proceedings because such "protection" precludes the licensee from what may be the most crucial discovery it is entitled to. Thus by Memorandum and Order (Granting In Part NRC Staff Motion to Delay Proceeding; Requiring Submission of Staff Status Reports) dated September 21, 1993, the Board not only granted the Staff's last stay request but also specifically ordered that any "Staff request for an additional delay of any aspect of this proceeding beyond Monday, December 6, 1993, must be filed on or before Tuesday, November 16, 1993".<sup>2</sup> Order dated

<sup>2</sup> In its motion, the Board further declared that the Staff must describe in detail " . . . the specific reasons why the Board's failure to grant the additional period of delay

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September 21, 1993, at 22. (former emphasis added; later emphasis in original).

This Order correctly anticipated the concern Staff now states, that a potentially detrimental release of investigative materials may well affect the DOJ criminal-referral process following completion of the OI inquiry. See, Order dated September 21, 1993 at 18 n.5 citing LBP-93-10, 37 NRC at 459 and n.2. Indeed, the Board even went so far as to tell the Staff that "such an eventuality could cause the Staff to request an additional delay pending the outcome of any DOJ referrals." Order dated September 21, 1993 at 18 n.5. (emphasis provided). But Staff ignored the explicit cautions and express warnings of the Order and now seeks to backdoor its way to the same result by way of its "Motion for Protective Order."

It is worthwhile noting that the risk of premature disclosure of the IIT materials was the basis for all the Staff delays. See NRC Staff Motion For Additional Delay Of Proceeding dated September 1, 1993 at Fortuna affidavit at ¶ 8; NRC Staff Motion For Additional Delay Of Proceeding dated June 3, 1993 at 7; NRC Staff Motion For Temporary Delay Of Proceeding dated February 23, 1993. And no development instigating new investigation has been alleged to have occurred since the Staff allowed the Board's deadline to pass.

In addition to disregard of Board Order, the Staff's present Motion for Protective Order demonstrates disregard of OSC's Due Process rights under the Constitution. At least with

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sought will prejudice any ongoing federal or state investigation or criminal prosecution." Order dated September 21, 1993, at 22 (emphasis added).

the prior stays, OSC received consideration of the constitutional Due Process implications of the Staff withholding of these key documents. Under Staff's present motion, OSC gets no such consideration.

Moreover, OSC will suffer great prejudice and injury if it is subjected to the brunt of Staff civil discovery regarding information that is the subject matter of the very materials the Staff is now attempting to have this Board protect.

The Staff position requiring OSC to respond to various interrogatories, requests for admissions and production while at the same time "protecting" the Staff from production of the very materials which have delayed this proceeding for nearly a year now is plainly wrong. See Pennsylvania Power & Light Company & Allegheny Electric Cooperative, Inc., (Susquehanna Steam Electric Station, Units 1 & 2), 19880 WL 19266 (N.R.C.) at \* 13 ("[a] party may not insist upon his right to ask questions of other parties, while at the same time disclaiming any obligation to respond to questions from those other parties.").

The prejudice worked upon OSC by such a scenario is far worse than any stay.

In its motion for a protective order, OSC makes clear that without the crucial IIT materials it cannot respond to Staff's discovery requests because inter alia, its review of such materials is necessary, particularly in light of OI's proposed referral to DOJ, for the fullest and most complete responses to Staff's discovery requests. These materials are also necessary for OSC to address the Staff's asserted bases for the Suspension Order and/or the lack thereof.

Moreover, the NRC has not identified the "targets" of any potential DOJ referral regarding statements made in connection with the investigation of the November 12, 1992 IRCC incident; that circumstance creates a situation where any response to NRC discovery requests in this "noncriminal proceeding, if not deferred, might undermine the [as of yet undisclosed] party's Fifth Amendment privilege against self-incrimination, expand rights of criminal discovery beyond the limits of Federal Rule of Criminal Procedure 16(b), expose the basis of the defense to the prosecution in advance of the prosecution, or otherwise prejudice" the potential, yet as of now undisclosed, "targets" case. SEC v. Dresser Industries, Inc., 628 F.2d 1368, 1376 (D.C. Cir. en banc.) cert denied, 449 U.S. 993 (1980).

Therefore, although OSC objects to the Staff's motion, should the Board be inclined to provide the Staff with any relief in this regard, it should be in the form of a stay of discovery in this proceeding as it relates to the areas of protection sought by both the Staff and OSC pending the outcome of any potential DOJ referral and/or prosecution.

Under those conditions, OSC will not oppose any reasonable Staff delay in producing the IIT materials so long as OSC is granted in full the protection it seeks in OSC's Motion For A Protective Order, i.e., that all discovery by Staff against OSC be stayed until any referrals to DOJ are made and a decision by DOJ is made on the referrals. This, OSC submits, is a fair compromise that will accommodate the interests of both parties.



## II. OSC RESPONSE TO STAFF OBJECTIONS

### STANDARDS FOR DISCOVERY

Discovery under the NRC Rules of Practice, as under the Federal Rules of Civil procedure, "is intended to insure that the parties to the proceeding will have access to all relevant unprivileged information prior to the hearing and that the objectives of the discovery process include the more expeditious conduct of the hearing itself, the encouragement of settlement between the parties, and greater fairness in adjudication." Boston Edison Company, (Pilgrim Nuclear Generating station, Unit 2), 1975 WL 12215 (N.R.C.) at \*2 (emphasis added). This is so because "[a] litigant may not make serious allegations against another party and then refuse to reveal whether those allegations have any basis." Pennsylvania Power & Light Company and Allegheny Electric Cooperatives, Inc., (Susquehanna Steam Electric Station, Units 1 and 2, 1980 WL 19266 \*14 (N.R.C.).

To accomplish those ends the NRC discovery rules are interpreted broadly and liberally "so that parties may obtain the fullest possible knowledge of the issues and facts before the trial," and that the inquiries are limited only by the requirement they be "reasonable relevant to a sensible investigation." Boston Edison Company, at \*2.

10 C.F.R. §2.740 delineates the general scope of discovery stating:

Parties may obtain discovery regarding any matter, not privileged, which is relevant to the subject matter involved in the proceeding, whether it relates to the claim or defense of any other party.

Id. (emphasis added). That same section continues to warn parties that:

It is not ground for objection that the information sought will be inadmissible at the hearing if the information appears reasonably calculated to lead to the discovery of admissible evidence.

Id. (emphasis added).

OSC realizes that its discovery against the Staff is in some respects different than that against another party. For instance 10 C.F.R. §§ 2.720(h)(2)(ii) & 2.744 incorporate a requirement that interrogatories and in some instances document requests put to the Staff be "necessary to a proper decision in the proceeding." Id. However, "necessary" is not interpreted as strictly as the Staff would sometimes like.

To begin with, in Cleveland Electric Illuminating Company, (Perry Nuclear Power Plant, Units 1 & 2), 1982 WL 31663 (N.R.C.) an Atomic Safety and Licensing Board found that it is the Board, not the Staff that defines "necessary" as that term is used in the regulations. Id. at \*2. Cleveland Electric Illuminating Company additionally rejected any Staff notion that 10 C.F.R. § 2.720(h)(2)(ii) precluded Staff answers to interrogatories for information that the party "'suspects' or believes may be helpful to it." Id. The Board was clear in declaring that "[t]o erect that requirement would make a mockery of the discovery process." Id.

Thus, even given the differences for discovery against the Staff, Cleveland Electric Illuminating Company requires that the Staff must answer interrogatories focused on a subject in which Staff responses are "'necessary' to a complete record." Id.

(emphasis provided). See, 5 U.S.C. § 556(d). See also, In re Radiation Technology Inc., 10 N.R.C. 553, 1979 NRC Lexis 24 \* 7 n.8.

#### PRELIMINARY STATEMENT ON THE STAFF'S DISCOVERY OBJECTIONS

The design of OSC's discovery requests is obvious; generally they dissect the Staff's Suspension Order and seek out information related to the Staff's bases for the Suspension Order including information which would negate, clarify, explain, or put into context any of the many broad, often nonregulatory, bases the Staff purports to rely on in the Suspension Order. Thus, in addition to attempting to establish that the Suspension Order is without basis, OSC seeks to discover facts and information which will (1) disprove the specific facts alleged by the Staff or (2) prove that in the context of certain additional information, facts alleged by the Staff, even if true, do not support the license suspension.

As a general matter, the Staff's objections to OSC's discovery requests seem to repeat the objections Staff raised to the issues OSC proposed as central in this proceeding; as a consequence, a short answer to those objections is that the Board has previously determined that "most of the issues specified by OSC [to which these discovery requests pertain] appear to have a foundation in OSC's February 8, 1993 answer to the Staff's January 20, 1993 Suspension Order."<sup>3</sup> Memorandum and Order, dated November

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<sup>3</sup> Contrary to Staff assertions, adjudicatory bodies of the NRC have, "stress[ed...] that there is nothing wrong with raising a great many issues [and that...] courts have recognized that parties are entitled to discover all matters not privileged

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17, 1993 at 5. In that same Memorandum and Order the Board made it clear that it is not only the Staff's order but also the licensee's answer which together evidence "the parties explication of the matters in issue in the proceeding." Id. at 5.

Thus insofar as OSC's current discovery requests reasonably relate to the issues raised in the Suspension Order, OSC's Answer, and other pleadings, they are relevant to and necessary for a "complete record" to ensure a proper determination in this proceeding under the NRC discovery standards set forth above.

Further, because the Staff makes general allegations against OSC which appear to span the spectrum of OSC's licensed activities; i.e., "significant corporate management breakdown in the control of licensed activities" or "the corporate RSO contributed in large part to this problem by not maintaining an adequate physical presence at the satellite facilities; [and] failing to implement appropriate training programs..."; OSC must be permitted to develop relevant and necessary information through discovery that tends to disprove whether, given a true examination of the factual spectrum of OSC's conduct, there is any basis for such the contentions upon which Staff rely in the Order.

OSC is aware via the Suspension Order of what facts, if true, the Staff believes evidence a "significant corporate management breakdown in the control of licensed activities," or that "the corporate RSO...[did] not maintain[] an adequate

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that tend to support or negate the allegations in the pleadings, or which are reasonably calculated to reveal such matters." Pennsylvania Power and Light Company, at \*9.

physical presence at the satellite facilities; [or] fail[ed] to implement appropriate training programs..."; however, that is only one side of the story.

Fundamental fairness in the pursuit of developing a full and complete record demands that OSC be permitted to discover facts that not only negate the specific factual assertions the Staff makes in the Suspension Order but also support OSC's position that no such "significant corporate management breakdown in the control of licensed activities", nor failure of the RSO to maintain adequate physical presence or properly train OSC personnel ever occurred regardless of the specific Staff factual allegations. The same applies to the other Staff general allegations such as the "reasonableness" of the IRCC staff's actions on November 12, 1992.

#### OSC RESPONSES TO SPECIFIC STAFF OBJECTIONS

##### I. LICENSEE'S GENERAL DISCOVERY REQUESTS

##### A. Licensee's Interrogatories

##### INTERROGATORY 7

In connection with any device review conducted by the NRC of the Omnitron 2000 afterloader, please identify:

a. all review(s) and/or study(ies) done by the NRC of the Omnitron 2000 HDR afterloader, including but not limited to, reviews and studies of the safety of the source, the performance of the afterloader, its endurance, and its compliance with applicable standards;

b. the persons responsible for such reviews and/or studies; and

c. all documents relating to the reviews and studies, including, but not limited to, any reports (regardless of whether they are draft, interim or final) regarding the reviews and/or studies.

#### OBJECTION

The Staff objects to this interrogatory because the information requested in this interrogatory is not relevant, is not reasonably calculated to lead to the discovery of admissible evidence and is not necessary for a proper decision on any possible issue in this proceeding. The Suspension Order was based, in part, on a significant corporate management breakdown in the control of licensed activities. Among the facts cited in the Suspension Order was the failure of the IRCC personnel to perform a survey, which under the circumstances, was necessary to evaluate the extent of radiation hazards that may have been present during the incident at the IRCC, involving the treatment of a patient using an Omnitron 2000 HDR afterloader. Suspension Order at 3. Any information which may have been gathered by the NRC regarding the performance of the Omnitron 2000 NOR afterloader is not relevant, cannot reasonably lead to the discovery of admissible evidence and is not necessary for a proper decision, because the Suspension Order was not based on the performance of the Omnitron 2000 HDR afterloader at the IRCC.

#### OSC RESPONSE TO STAFF OBJECTIONS

OSC's interrogatory relating to any device review conducted by the NRC of the Omnitron 2000 afterloader is clearly relevant and/or reasonably calculated to lead to relevant evidence and is certainly necessary to a "complete record" for a proper decision regarding the general issues raised by the Staff's Suspension Order and OFC's Answer thereto. Those issues include for example, OSC's reliance on the features of the Omnitron 2000, the reasonableness of surveys performed in light of IRCC's understanding concerning the Omnitron 2000, adequacy of corporate management of licensed activities as well as sufficiency of training regarding the Omnitron 2000 and the necessity of the license suspension in the interest of the public health.

The relevance of such material to any consideration of the November 12, 1992 incident is demonstrated by the fact that an entire section of the IIT report was devoted to the characteristics, functioning, and packaging of the Omnitron 2000 afterloader involved in the November 12, 1992 IRCC incident.

OSC interrogatory requests clearly relate to and are necessary in determining whether any surveys IRCC staff made at the pertinent time were, as stated in the Suspension Order, "reasonable under the circumstances" to evaluate the extent of the radiation hazards may have been present. This request also is clearly relevant and necessary as it seeks information relating to whether or not the possibility of the source wire breaking was reasonably within the anticipation of Omnitron, the NRC, or OSC and its staff; OSC submits the likelihood of such an occurrence is directly related to what training scenarios were required and the manner of that training.

Thus OSC's discovery requests go directly to negating the Staff assertions that, among others, less than reasonable actions were taken by the IRCC staff on the day in question and that there was a "significant corporate management breakdown in the control of licensed activities."

Therefore OSC's discovery requests regarding the functioning, testing and analysis of the Omnitron 2000 are relevant (or are reasonably calculated to lead to relevant evidence) and necessary to develop a "full record" for a proper decision.

Simply put, the Staff errs, as matters of evidence and fairness in trying to limit the issues OSC may raise and the discovery OSC may conduct in this regard, since the Suspension

Order does not state the entire universe of issues relevant to determining the existence of, for instance, a "significant corporate management breakdown...." or any other conclusion by Staff. Issues relating to the Omnitron 2000 are issues that are relevant in this regard.

#### INTERROGATORY 8

Please identify any documents generated by the NRC or in its possession or control that report on analyze, compare, or otherwise relate to the design of, operation of, defects in, endurance of and/or any training proffered or provided with respect to the following HDR afterloaders:

- a. the Sauerwein GammaMed III; or
- b. the Omnitron 2000.

#### OBJECTION

*The Staff objects, in part, to this interrogatory. The Staff objects to responding to all parts of Interrogatory 8(a). The Suspension Order did not rely upon, as a basis, any use of the Sauerwein GammaMed III HDR afterloader by the Licensee. Any information provided in response to Interrogatory 8(a), therefore, would be irrelevant, could not reasonably lead to the discovery of admissible evidence and is not necessary for a proper decision on any issue which could possibly be admitted in this proceeding. In addition, the Staff objects to responding to Interrogatory 8(b), except as it relates to information regarding any training proffered or provided with respect to the Omnitron 2000 HDR afterloader, for the same reasons as discussed above in the Objection to Interrogatory 8(a).*

#### OSC RESPONSE TO STAFF OBJECTIONS

OSC's discovery requests in 8(a) above seeking information related to the Sauerwein GammaMed III are directly relevant and necessary to develop a "complete record" for a proper decision because the "dry run" provision that the Staff asserts



OSC failed to comply with in relation to training for the Omnitron 2000 was drafted and incorporated into OSC's license when OSC was using only the Sauerwein GammaMed III, not the Omnitron 2000. In fact OSC did not even own an Omnitron 2000 when the "dry run" language relating to the Sauerwein GammaMed III was written. When the Staff gave approval to OSC to put the Omnitron 2000 into service the Staff did not require an update of the license provisions relating to the GammaMed III "dry run" training. Thus, there may be differences in the NRC's understanding of these two machines which explain the Staff's failure to require a license amendment concerning "dry run" training, when the Omnitron 2000, a machine represented to have an unbreakable source wire, replaced the GammaMed III.

Once again the Staff's objection that nothing is relevant that doesn't directly contradict the Staff assertions in the Suspension Order is entirely without merit. As stated above, OSC cannot be precluded from its attempt to discover facts which although not in direct contradiction of the findings and conclusions in the Suspension Order, nonetheless demonstrate the absence of any purported "significant corporate management breakdown," "threat[ening] public health and safety." The Suspension Order simply does not state the entire universe of issues relevant to determining the existence of a "significant corporate management breakdown...." or any other conclusion by the Staff.

As for OSC's response to the Staff objection lodged against Interrogatory 8(b), see OSC's response to the Staff objections to Interrogatory I. (A) 7 above.

#### INTERROGATORY 9

With respect to all research projects initiated by the NRC or under NRC direction or control regarding high dose rate brachytherapy, please identify:

- a. the nature, title and coding (if any) of the research project;
- b. the dates of its initiation and completion;
- c. the persons responsible for the research project;
- d. any contracts for the research project;
- e. any documents setting forth or describing the research; and
- f. any reports (regardless of whether they are draft, interim or final) regarding the research.

#### OBJECTION

*The Staff objects to this interrogatory because the Suspension Order was not based on the performance of high dose rate brachytherapy at any of the Licensee's facilities. The Suspension Order was based on a significant corporate management breakdown in the control of licensed activities, as evidenced by the facts cited in the Suspension Order. Any studies performed regarding high dose rate brachytherapy, as a general matter, is not relevant to this proceeding, could not reasonably lead to the discovery of admissible evidence and is not necessary for a proper decision on any issue which could possibly be admitted in this proceeding.*

#### OSC RESPONSE TO STAFF OBJECTIONS

As stated previously, the relevance and importance of the information sought by the above discovery requests is first evidenced by the fact that the IIT report placed great importance on the extent of regulatory guidance and/or regulatory requirements that existed prior to the IRCC incident. The existence and extent of such regulatory control necessarily

constitutes the foreground against which the purported corporate breakdown in the management of licensed activities must be measured.

Additionally the absence of or confusion about the regulatory requirements concerning HDR and what satisfied any survey requirement (i.e. the IIT report statements that the NRC itself believed that the room monitor ('Prim Alert') satisfied any requirement) as well as the NRC's awareness and understanding of the same is directly relevant to the reasonableness of the actions of the IRCC Staff during the November 1992 incident.

The NRC's position that OSC's discovery requests regarding NRC understanding of High Dose Rate Brachytherapy ("HDR") are not relevant to the issues in this proceeding is entirely without merit because HDR is the licensed activity in which Staff contends OSC had a significant corporate management breakdown. Under these circumstances, NRC understanding of the "licensed activity" is of crucial significance to OSC in understanding Staff's claim against it.

Moreover, if it is the Staff's position that OSC had "a significant corporate management breakdown in the control of licensed activities" but that the Suspension Order was not, as the Staff now admits "based on the performance of high dose rate brachytherapy at any of [OSC's] facilities", the Board should treat this admission as grounds and support for a summary disposition of the issues and facts in OSC's favor that the Staff formerly asserted as bases for the Suspension Order in connection with the November 12, 1992 incident during the administration of high dose rate brachytherapy at IRCC.

B. Licensee's Requests for Production

REQUEST 3

all documents and other evidence identified in your answers to the preceding nine interrogatories.

*OBJECTION*

*The Staff also objects Request for Production 3, to the extent that it relates to Interrogatories 7, 8, and 9 above, for the same reasons discussed in the objections to Interrogatories 7, 8, and 9.*

OSC RESPONSE TO STAFF OBJECTIONS

OSC asserts that the Staff objections to this request for the production of documents are without merit for the same reasons that the Staff objections to the discovery requests that this request for production relates to.

II. LICENSEE'S DISCOVERY REQUESTS WITH RESPECT TO SECTION II OF THE ORDER SUSPENDING LICENSE (EFFECTIVE IMMEDIATELY)

A. Licensee's Interrogatories

INTERROGATORY 2

Please state the present understanding or position of the NRC with respect to the cause of the source wire break during the November 16, 1993 incident at IRCC; identify the NRC personnel responsible for the development of that understanding or position and any documents relating thereto.

*OBJECTION*

*The Staff objects to this interrogatory because the cause of the source wire break during the November 16, 1992 incident at the IRCC was not a basis for the Suspension Order, nor could this issue be raised as a defense to the Suspension Order. The case of the breakage of the source wire was not a basis for the Suspension Order. The Licensee was cited for its inadequate*

response after the wire apparently broke, i.e., its failure to perform a survey in conformance with License Condition 17 and 10 C.F.R § 20.201(b). Suspension Order at 3. Information provided in response to this interrogatory, therefore, is not relevant, could not reasonably lead to the discovery of admissible evidence and is not necessary for a proper decision in this proceeding.

#### OSC RESPONSE TO STAFF OBJECTIONS

For the same reasons identified in OSC's response to the Staff objections to the interrogatory at I. (A) 7, the Staff objections are without merit because the interrogatory above is relevant to and necessary to build a "complete record" for a proper determination of this matter. Therefore the interrogatory should be answered.

#### B. Licensee's Requests for Production

##### REQUEST 1

All documents and other evidence identified in response to the immediately preceding 6 interrogatories.

##### OBJECTION

The Staff objects to this Request for Production, as it relates to Interrogatory 2 for the same reasons as discussed in the Staffs objection to Interrogatory 2.

#### OSC RESPONSE TO STAFF OBJECTIONS

OSC asserts that the Staff objections to the above request for production of documents is relevant to and necessary to build a "complete record" for a proper decision in this proceeding for the same reasons stated in Interrogatory I. (A) 7.

III. LICENSEE'S DISCOVERY REQUESTS WITH RESPECT TO SECTION III OF THE ORDER SUSPENDING LICENSE EFFECTIVE IMMEDIATELY)

A. Licensees Interrogatories

INTERROGATORY 1

The Order states, "Dr. Cunningham, who is the RSO named on the License, had not visited the Lehighton facility in the past 6-9 months." In connection with that statement, please identify:

b. any NRC action taken against a medical use licensee prior to November 16, 1992, in part or in whole, on the basis that the RSO had not visited one of its facilities in a six to nine month period;

c. any NRC action taken against a medical use licensee (other than OSC) subsequent to November 16, 1992, in part or in whole, on the basis that the RSO had not visited one of its facilities in a six to nine month period;

d. documents regarding any final agency determinations, decisions or orders in any of the actions identified in response to the immediately preceding two subparts;

OBJECTION

*The Staff objects to interrogatory 1(b)-(d) because the staff has prosecutorial discretion to bring an enforcement action against licensees under the enforcement policy without justifying the action on a comparative basis. Hurley Medical Center, ALJ-87-2, 25 NRC 219 (1987). Thus, any information regarding enforcement action taken against other licensees has no relevance, cannot reasonably lead to the discovery of admissible evidence and is not necessary for a proper decision. The staff further objects to Interrogatory 1(b)-(d) on the grounds that, although the Staff has files related to certain NRC enforcement actions which have been taken in the past, in order to compile a list of all NRC actions based in whole or in part on the fact that the RSO had not visited one of its facilities in a six to nine month period, would require the Staff to perform research and compile data not readily known to it. To perform such research and compilation would entail an oppressive amount of research, involving the compiling and reviewing of an excessive amount of data. The Staff is not required to perform such research in order to respond to a discovery request. See Pilgrim, LBP-75-30, 1 NRC at 584. In addition, information regarding escalated NRC enforcement actions is publicly available.*

## OSC RESPONSE TO STAFF OBJECTIONS

OSC asserts that the discovery regarding any prior enforcement or other agency action is relevant to and necessary to build a "complete record" for a proper decision in this matter because as has been previously briefed before the Board, the "enforcement policy" to which the Staff refers is not a regulation or statute. Since this is an enforcement action, Due Process requires that a licensee have adequate advance notice of the conduct of the pre-existing standard under which the conduct at issue is proscribed. This interrogatory goes to the existence of the pre-existing standards, and the Staff's knowledge of, and reliance on those pre-existing standards in issuing its Suspension Order.

Therefore, OSC's discovery requests regarding any such related NRC enforcement action are plainly relevant to this proceeding as the issue of the Staff's attempted discriminatory, arbitrary and unconstitutional enforcement of nonregulatory requirements has been hotly contested throughout this proceeding. In addition, such discovery requests go to a negation of, for example, any "significant corporate management breakdown," any insufficiency of training, or unreasonable actions.

The Staff citation of Hurley Medical Center, 1987 WL 109367 (N.R.C.), as support for its objection is misleading, because it is totally inapplicable to the issues before the Board. In Hurley Medical Center, the Board was adjudicating a civil penalty action where all the violations involved were "regulatory requirements." Id. The Board, presented with stipulated violations, rejected the staff's as well as the licensee's argument that the licensee's record of violations compared to the

record of other facilities had any bearing on the severity of the civil penalty to impose, Id. at \*13, and held only that in the context of that case "the record in its entirety provides no reliable basis to add a comparative-record theory to the case against Hurley." Id.

Thus, Staff citation of Hurley Medical Center is misleading because it does not address the issue in this case, the discovery of other enforcement actions to determine if the Staff is consistently interpreting and applying the requirements upon which it now relies in the Suspension Order at issue.

Safety Light Corporation (Bloomsburg Site Decommissioning and License Renewal Denials), 1992 WL 395735 (N.R.C.) at \*1; and 1992 WL 311319 (N.R.C.) provides that authority. In that decision, the Atomic Safety and Licensing Board held that in response to discovery requests against the Staff, "the identity of other materials licensees (and documents relating to such licensees) the staff had determined were in violation of [a particular regulatory requirement] was relevant and discoverable. Id. at \*1 (emphasis added). Also found relevant and discoverable were the "bases for the staff's conclusions on noncompliance as well as the corresponding staff enforcement actions [regarding the other materials licensees]." Id. at \*1. The Board noted that "with access to this information, the licensee could determine the outcome of cases that stood as precedent, thereby providing insight into the pertinent issue of whether the staff was properly interpreting and applying its regulations in denying the licensee's renewal applications." Id. at \*2. The Board admonished the staff for its relevance objection stating that "[t]o call precedent irrelevant is to fly in the face of precedent itself." Id. at \*1.



Thus the facts and circumstances surrounding final enforcement actions are clearly relevant to and necessary to build a "complete record" for a decision because those facts provide crucial information on the consistency of Staff interpretation, knowledge, and reliance on the purported regulatory bases for the Suspension Order.

The Staff next argues that although it has files related to certain enforcement actions taken in the past, to comply with OSC's request would "require the Staff to perform research and compile data not readily known to it", and that this would amount to an "oppressive" task for the Staff. "This assertion [as to oppressiveness], without a great deal more explanation, is insufficient [however] to meet the staff's burden" as the proponent of an objection. Safety Light Corporation, 1992 WL 311319, \* 3 (N.R.C.).

More importantly, taken at their word the Staff here concedes that it based a Suspension Order, in substantial part, on alleged conduct as to which it is ignorant of any enforcement precedent. That concession proves OSC's case as to the unconstitutionally arbitrary and otherwise unlawful bases for the order.

If, the Staff wishes to argue there are enforcement actions responsive to this request which have been taken in the past, then Safety Light Corporation establishes the relevance of the information. Once information is relevant Boston Edison Company (Pilgrim nuclear Generating Station, Unit 2), 1975 WL 12215 (N.R.C.), states that "the fact that to answer interrogatories might be burdensome or expensive is not a valid objection if the information is relevant and material...." Id. at

\*4. Therefore, Staff should be required to respond to this interrogatory and its related request for production.

INTERROGATORY 3

The May 21, 1993 Order Modifying the January 20, 1993, Order Suspending License states:

Upon further review of the January 20, 1993 Order and Inspection Report No. 030-31765/92-001 (December 23, 1992), the Staff has determined that the Order erroneously identified the Leighton center as not having a copy of the documents incorporated into the License, when in fact it was the Exton Center that did not have a copy of the documents incorporated into the License.

In connection with the foregoing modification of the license, please identify:

- a. the cause of the "erroneous identification" in the order;
- b. the person or persons responsible for the "erroneous identification";
- c. the person or persons responsible for identification and/or correction of the error; and
- d. any transcriptions, summaries, records, notes or other documents relating to the error, its identification, correction and modification of the Order.

OBJECTION

*The Staff objects to this interrogatory because the cause or source of the error in the Suspension Order can have no possible relevance, cannot reasonably lead to the discovery of admissible evidence, and is not necessary for a proper decision on any possible issue in this proceeding.*

## OSC RESPONSE TO STAFF OBJECTIONS

These discovery requests by OSC relate to the Staff's erroneous identification of the Lehighton center instead of the Exton center as the center where certain license documents were allegedly not found and Staff's correction thereof. The NRC's discovery of the error provided the basis for the Staff change in the Suspension Order. As a result, discovery of the erroneous information including how the mistake was made is necessary to build a "complete record" because "the authorities are clear that interrogatories seeking specification of the facts upon which a claim or contention is based are wholly proper...." Boston Edison Company, 1975 WL 12215 (N.R.C.) at \*3.

Realizing that the Staff is susceptible to such an error, OSC discovery as to the facts relating to how the error was made, how it was identified and who the responsible person was is relevant and necessary as these facts may show that and how the present Staff allegations are similarly erroneous. OSC has the indubitable right to probe that purported reliability and accuracy. Simply put, the identification of this error casts doubt on the reliability and accuracy of the Suspension Order in general and as a consequence, makes it a fair object for discovery.

## INTERROGATORY 6

The Order states, "Additionally, although the physicists at the Exton and Lehighton facilities are key personnel who bear responsibility for avoiding or preventing the recurrence of an event such as the November 16 event described in Section II above, the inspectors determined that these individuals did not learn of the event via an appropriate corporate radiation safety communication, but instead learned about the event through the

coverage in the news media." In connection with that statement, please identify:

b. any NRC action taken against a medical use licensee prior to November 16, 1992, in part or in whole, on the basis that the licensee had failed to make "an appropriate corporate radiation safety communication;"

c. any NRC action taken against a medical use licensee (other than OSC) subsequent to November 16, 1992, in part or in whole, on the basis that the licensee had failed to make "an appropriate corporate radiation safety communication;" and

d. documents regarding any final agency determinations, decisions or orders in any of the actions identified in response to the immediately preceding two subparts.

#### OBJECTION

The Staff objects to Interrogatory 6(b)-(d) because any information regarding enforcement action taken against other licensees is not relevant, cannot reasonably lead to the discovery of admissible evidence and is not necessary to a proper decision. In addition, in order to compile a list of all NRC actions based in whole or in part on the basis that the licensee had failed to make "an appropriate corporate radiation safety communication," would require the Staff to perform research and compile data not readily known to it. To perform such research and compilation would entail an oppressive amount of research, involving the compiling and reviewing of an excessive amount of data. The Staff is not required to perform such research in order to respond to a discovery request. See *Pilgrim*, LBP-75-30, 1 NRC at 584. In addition, information regarding escalated NRC enforcement actions is publicly available. See Staff Objection to Interrogatory 1(b)-(d).

#### OSC RESPONSE TO STAFF OBJECTIONS

OSC asserts that for the same reasons as set forth in response to the Staff objections to Interrogatory III. (A) 1(b)-(d) above the information sought by the above discovery requests is relevant to and necessary to build a "complete record" for a proper determination of the issues raised by the Staff and the

issues raised in OSC's defense and that therefore the Staff objections are without merit.

B. Licensee's Requests for Production

REQUEST 1

All documents and other evidence identified in response to the immediately preceding 6 interrogatories.

OBJECTION

*The Staff objects to this Request for Production, as it relates to Interrogatories 1, 3, and 6 for the same reasons as discussed in the Staffs objections to Interrogatories 1, 3, and 6.*

OSC RESPONSE TO STAFF OBJECTIONS

OSC asserts that for the same reasons as set forth in response to the Staff objections to Interrogatories III (A) 1, 3 and 6 the documents sought by the above discovery requests are relevant to and necessary to build a "complete record" for a proper determination of the issues raised by the Staff and the issues raised in OSC's defense and that therefore the Staff objections are without merit.

IV. LICENSEE'S DISCOVERY REQUESTS WITH RESPECT TO SECTION IV OF THE ORDER SUSPENDING LICENSE (EFFECTIVE IMMEDIATELY)

A. Licensee's Interrogatories

INTERROGATORY 1

The Order states that "Dr. Cunningham sought to delegate to the Medical Director/Authorized User at each of the satellite facilities the radiation safety officer responsibilities that are assigned to Dr. Cunningham under the terms and conditions of the License. Dr. Cunningham also stated in the letter that it is

appropriate for the Medical Director/Authorized User to further delegate the radiation safety responsibilities of the Medical Director/Authorized User to 'the technical support including the physicists and chief technologist.'" In connection with that statement, please identify:

b. any NRC action against a medical use licensee prior to November 16, 1992, in part or in whole, on the basis that the RSO of the licensee had sought to make or have others make an improper delegation of responsibilities assigned to the RSO under the license;

c. any NRC action taken against a medical use licensee (other than OSC) subsequent to November 16, 1992, in part or in whole, on the basis that the RSO of the licensee had sought to make or have others make an improper delegation of responsibilities assigned to the RSO under the license; and

d. documents regarding any final agency determinations, decisions or orders in any of the actions identified in response to the immediately preceding two subparts.

#### OBJECTION

The Staff objects to Interrogatory 6(b)-(d) because any information regarding enforcement action taken against other licensees has no relevance, cannot reasonably lead to the discovery of admissible evidence and is not necessary to a proper decision. In addition, in order to compile a list of all NRC actions based in whole or in part on the basis that the RSO of the licensee had sought to make or have other make an improper delegation of responsibilities assigned to the RSO under the license would require the Staff to perform research and compile data not readily known to it. To perform such research and compilation would entail an oppressive amount of research, involving the compiling and reviewing of an excessive amount of data. The Staff is not required to perform such research in order to respond to a discovery request. See *Pilgrim*, LBP-75-30, 1 NRC at 584. In addition, information regarding escalated NRC enforcement actions is publicly available. See Staff Objection to Interrogatory 1(b)-(d).

OSC RESPONSE TO STAFF OBJECTIONS

OSC asserts that for the same reasons as set forth in response to the Staff objections to Interrogatory III (A) 1(b)-(d) above the information sought by the above discovery requests is relevant to and necessary to build a "complete record" for a proper determination of the issues raised by the Staff and the issues raised in OSC's defense and that therefore the Staff objections are without merit.

B. Licensee's Requests for Production

REQUEST 2

all other documents and other evidence referred to the response to the immediately preceding interrogatory.

*OBJECTION*

*The Staff objects to this request, as it relates to Interrogatory 1(b)-(d) for the same reasons discussed in the Staffs objections to Interrogatory 1(b)-(d).*

OSC RESPONSE TO STAFF OBJECTIONS

OSC asserts that for the same reasons as set forth in response to the Staff objections to Interrogatory III (A) 1(b)-(d) above the documents sought by the above discovery request are relevant to and necessary to build a "complete record" for a proper determination of the issues raised by the Staff and the issues raised in OSC's defense and that therefore the Staff objections are without merit.

V. LICENSEE'S DISCOVERY REQUESTS WITH RESPECT TO SECTION V OF THE ORDER SUSPENDING LICENSE (EFFECTIVE IMMEDIATELY)

A. Licensee's Interrogatories

INTERROGATORY 1

The Order states, "The facts above demonstrate a significant corporate management breakdown in the control of licensed activities wherein key Licensee employees at several satellite facilities do not know the requirements of the NRC License, do not have access to the pertinent License documents, and have not been adequately trained in either the pertinent regulatory requirements or the procedures and instrumentation to be employed to protect themselves and others from radiation exposure." In connection with that statement, please identify:

b. any NRC action taken against a medical use licensee prior to November 16, 1992 in part or in whole on the basis that the licensee had "a significant corporate management breakdown in the control of licensed activities;"

c. any NRC action taken against a medical use licensee (other than OSC) subsequent to November 16, 1992 in part or in whole on the basis that the licensee has "a significant corporate management breakdown in the control of licensed activities;"

d. documents regarding any final agency determinations, decisions or orders in any of the actions identified in response to the immediately preceding two subparts.

OBJECTION

The Staff objects to Interrogatory 1(b)-(d) because any information regarding enforcement action taken against other licensees has no relevance, cannot reasonably lead to the discovery of admissible evidence and is not necessary to a proper decision. In addition, in order to compile a list of all NRC actions based in whole or in part on the basis that the licensee has "a significant corporate management breakdown in the control of licensed activities" would require the Staff to perform research and compile data not readily known to it. To perform such research and compilation would entail an oppressive amount of research, involving the compiling and reviewing of an excessive amount of data. The Staff is not required to perform such research in order to respond to a discovery request. See Pilgrim, LBP-75-30, 1 NRC at 584. In addition, information regarding



*escalated NRC enforcement actions is publicly available. See Staff Objection to Interrogatory 1(b)-(d).*

#### OSC RESPONSE TO STAFF OBJECTIONS

OSC asserts that for the same reasons as set forth in response to the Staff objections to Interrogatory III (A) 1(b)-(d) above the information sought by the above discovery requests is relevant to and necessary to build a "complete record" for a proper determination of the issues raised by the Staff and the issues raised in OSC's defense and that therefore the Staff objections are without merit.

#### INTERROGATORY 2

The Order states, "In addition, the corporate RSO contributed in large part to this problem by not maintaining an adequate physical presence at the satellite facilities; failing to implement appropriate training programs for Licensee employees, which the RSO is required to do under 10 CFR 35.21; and failing to establish and implement a periodic corporate audit program to identify and promptly correct violations to ensure compliance with NRC regulatory requirements." In connection with that statement, please identify:

b. any NRC action taken against a medical use licensee prior to November 16, 1992 in whole or in part on the basis that the RSO of the licensee had failed to "maintain an adequate physical presence;"

c. any NRC action taken against a medical use licensee (other than OSC) subsequent to November 16, 1992 in whole or in part on the basis that the RSO of the licensee had failed to "maintain an adequate physical presence;"

d. documents regarding any final agency determinations, decisions or orders in any of the actions identified in response to the immediately preceding two subparts;

f. any NRC action taken against a medical use licensee prior to November 16, 1992 in whole or in part on the basis that

the RSO of the licensee had failed "to establish and implement a periodic corporate audit program";

g. any NRC action taken against a medical use licensee (other than OSC) subsequent to November 16, 1992 in whole or in part on the basis that the RSO of the licensee had failed "to establish and implement a periodic corporate audit program;"

h. documents regarding any final agency determinations, decisions or orders in any of the actions identified in response to the immediately preceding two subparts;

#### *OBJECTION*

*The Staff objects to interrogatories 2(b)-(d), (f)-(h) because any information regarding enforcement action taken against other licensees has no relevance, cannot reasonably lead to the discovery of admissible evidence and is not necessary for a proper decision. In addition, in order to compile a list of all NRC actions based in whole or in part on the basis that the RSO of the licensee had failed to "maintain an adequate physical presence" and to compile a list of all NRC actions based in whole or in part on the basis that the RSO of the licensee had failed "to establish and implement a periodic corporate audit program" would require the Staff to perform research and compile data not readily known to it. To perform such research and compilation would entail an oppressive amount of research, involving the compiling and reviewing of an excessive amount of data. The Staff is not required to perform such research in order to respond to a discovery request. See Pilgrim, LBP-75-30, 1 NRC at 584. In addition, information regarding escalated NRC enforcement actions is publicly available. See Staff Objection to Interrogatory 1(b)-(d).*

#### OSC RESPONSE TO STAFF OBJECTIONS

OSC asserts that for the same reasons as set forth in response to the Staff objections to Interrogatory III (A) 1(b)-(d) above the information sought by the above discovery requests is relevant to and necessary to build a "complete record" for a proper determination of the issues raised by the Staff and the issues raised in OSC's defense and that therefore the Staff objections are without merit.

## VI. LICENSEE'S REQUESTS FOR ADMISSION

### REQUEST 9

The inspector stated a belief that the requirements covered by Subpart G of 10 CFR 35 were either not applicable or covered by other sections of the field notes.

### OBJECTION

*The Staff objects to this request for admission because the Suspension Order did not cite the Licensee for a violation of 10 C.F.R. Part 35, Subpart G. This admission, even if true, therefore, is not relevant, cannot reasonably lead to the discovery of admissible evidence, and is not necessary for a proper decision in this proceeding.*

### OSC RESPONSE TO STAFF OBJECTIONS

As stated previously in OSC response to the Staff objections to Interrogatory I. (A) 9(a)-(f), the relevance and importance of the information sought by the above admission is first demonstrated by the fact that the IIT report placed great importance on the extent of regulatory guidance that existed prior to the IRCC incident including the applicability of 10 C.F.R. Subpart G and whether the PrimAlert radiation monitor satisfied any specific survey requirement contained therein.

Additionally any regulatory confusion concerning the requirements concerning HDR and what satisfied any survey requirement as well is directly relevant to the reasonableness of the actions of the IRCC staff during the November 1992 incident.

The extent of NRC regulatory requirements and/or guidance as well as regulatory clarity in this area is also directly relevant to the effectiveness of the corporate management

by OSC of licensed activities as it may demonstrate that OSC fully complied with the requirements that the NRC, through certain NRC inspectors who inspected OSC, indicated were sufficient under the then existing regulatory framework.

Thus the NRC objection to OSC's requests for admission relating to the applicability of 10 C.F.R. Subpart G is without merit as that request for admission relates directly to the licensed activity in which, according to Staff, OSC had a significant corporate management breakdown.

Furthermore, there is no requirement in 10 C.F.R. § 2.742 that requires that requests for admission directed to the Staff meet any additional standard such as "necessary for a proper decision in this proceeding." That "necessity" standard applies only to interrogatories and certain requests for production. See 10 C.F.R. §§ 2.744 & 2.720(h)(2)(ii) therefore, objection by Staff on that basis is entirely improper.

#### REQUEST 10

The inspector noted that operational and emergency procedures were covered by license conditions in lieu of 10 CFR 35.410.

#### OBJECTION

*The Staff objects to this request for admission because the Suspension Order did not cite the Licensee for a violation of 10 C.F.R. Part 35, Subpart G. This admission, even if true, therefore, is not relevant, cannot reasonably lead to admissible evidence, and is not necessary for a proper decision in this proceeding.*

OSC RESPONSE TO STAFF OBJECTIONS

For the same reasons as stated in OSC's response to the Staff objections to the request for admission in VI. (9), the Staff objections to the above request for admission are without merit and the request should be responded to.

REQUESTS 11 AND 12

REQUEST 11

The inspector believed the requirement in 10 CFR 35.404 to survey the patient after removing the source was met by the area radiation monitor in the treatment room.

REQUEST 12

The inspector stated that this belief was based on the Licensee's commitment to comply with the guidance in FC 86-4, which provides for a room monitor to verify the location of a source.

OBJECTION

*The Staff objects to Requests for Admission 11 and 12 because the Suspension Order did not cite the Licensee for a violation of 10 C.F.R. §35.404, thus, any information regarding compliance with 10 C.F.R. §35.404, is not relevant, cannot reasonably lead to the discovery of admissible evidence, and is not necessary for a proper decision in this proceeding.*

OSC RESPONSE TO STAFF OBJECTIONS

For the same reasons as stated in OSC's response to the Staff objections to the request for admission in VI. (9), the Staff objections to the above request for admission are without merit and the request should be responded to.

REQUESTS 13-26

REQUEST 13

As of November 16, 1992, the guidance provided by the NRC's Office of Nuclear Materials Safety and Safeguards for medical use programs was contained in Regulatory Guide 10.8, "Guide for the Preparation of Applications for Medical Use Programs," Revision 2, August 1987.

REQUEST 14

Regulatory Guide 10.8 provides guidance only for low dose rate brachytherapy.

REQUEST 15

As of November 16, 1992, the licensing for brachytherapy remote afterloaders by the NRC's Office of Nuclear Materials Safety and Safeguards was contained in Policy and Guidance Directive FC 86-4, "Information Required for Licensing Remote Afterloading Devices, issued on February 20, 1986.

REQUEST 16

As of November 16, 1992, the licensing guidance in FC 86-4 was outdated.

REQUEST 17

As of November 16, 1992, the licensing guidance in FC 86-4 was not well integrated with NRC medical regulations or other licensing guides.

REQUEST 18

As of November 16, 1992, no regulations expressly recognized HDR brachytherapy.

REQUEST 19

NRC Inspection Manual Chapter (MC) 2800 establishes the inspection program for medical licenses, including license priority and inspection frequency.

REQUEST 20

There is no mention of FC 86-4 in MC-2800.

REQUEST 21

MC-2800 does not otherwise discuss NOR brachytherapy.

REQUEST 22

Inspection Procedure (IP) -87100 provides inspection direction for material inspections involving nuclear medicine and medical teletherapy.

REQUEST 23

There is no mention of FC 86-4 in IP-81700.

REQUEST 24

IP-81700 does not otherwise discuss HDR brachytherapy.

REQUEST 25

The field notes used by inspectors for brachytherapy are included in Appendix B to IP-87100.

REQUEST 26

The section on brachytherapy in the field notes follows the requirements in 10 CFR Part 35, Subpart G.

OBJECTION

*The Staff objects to Requests for Admissions 13-26. The Suspension Order was based, in part, on a significant corporate management breakdown in the control of licensed activities and not on a violation of any regulation specifically related to the performance of High Dose Rate Brachytherapy. Staff guidance relative to brachytherapy in general and the applicability of such guidance to High Dose Rate brachytherapy, is therefore, irrelevant, cannot reasonably lead to the discovery of admissible evidence and is not necessary for a proper decision.*

OSC RESPONSE TO STAFF OBJECTIONS

For the same reasons as stated in OSC's response to the Staff objections to the request for admission in VI. (9), the

Staff objections to the above request for admission are without merit and the request should be responded to.

REQUEST 27

All factors to date point to failure at IRCC of the source wire on November 16, 1992 as having been caused by environmentally induced degradation of properties on nickel-titanium wire in the vicinity of the iridium source.

OBJECTION

*The Staff objects to this request. The cause of the source wire break during the November 16, 1992 incident at the IRCC was not a basis of the Suspension Order. See Objection to Interrogatory 2. Therefore, even if true, this request is not relevant, is not reasonably calculated to lead to the discovery of admissible evidence and is not necessary for a proper decision in this proceeding.*

OSC RESPONSE TO STAFF OBJECTIONS

For the same reasons identified in OSC's response to the Staff objections to the interrogatory at I. (A) 7, the Staff objections are without merit, the request for admission above is relevant to the issues in this proceeding and the request should be answered. For the reasons set forth in OSC's response to the Staff objections to the request for admission in VI. (9) the Staff's reference to a "necessary for a proper proceeding" is improper and should not be considered.



REQUESTS 28-32

REQUEST 28

Before the November 16, 1992 incident, Omnitron performed no engineering calculations on the source wires, especially in the areas of the cavity.

REQUEST 29

Before the November 16, 1992 incident, Omnitron performed a bend fatigue test on two wires, but did not validate the test results by engineering calculations or proper evaluation of the results. The bend fatigue test consisted of smooth, full radii. During treatment, a patient, or equipment, could cause a sharp bend in the source, and Omnitron performed no tests to simulate this condition.

REQUEST 30

Before the November 16, 1992 incident, Omnitron failed to determine whether the operating environment of the equipment could affect the integrity of the source wire.

REQUEST 31

Before the November 16, 1992 incident, Omnitron failed to perform tests to determine if the catheters would interfere with the integrity of the wire.

REQUEST 32

Before the November 16, 1992 incident, Omnitron was aware that there was a degradation of the teflon lining in their shipping contain, but performed no test to ensure that the degradation of the teflon wire would not affect the integrity of the source wire.

OBJECTION

*The Staff objects to requests 28-32. The cause of the source wire break during the November 16, 1992 incident at the IRCC was not a basis of the Suspension Order. See Objection to Interrogatory 2. Therefore, even if true, this request is not relevant, cannot reasonably lead to the discovery of admissible evidence and is not necessary for a proper decision in this proceeding.*

## OSC RESPONSE TO STAFF OBJECTIONS

For the same reasons identified in OSC's response to the Staff objections to the interrogatory at I. (A) 7, the Staff objections are without merit, the request for admission above is relevant to the issues in this proceeding and the request should be answered. For the reasons set forth in OSC's response to the Staff objections to the request for admission in VI. (9) the Staff's reference to a "necessary for a proper proceeding" is improper and should not be considered.

### REQUESTS 33-40

#### REQUEST 33

The park switch sensor for the source wire of the Omnitron 2000 does not detect the end of the source but rather detects the end of the source wire opposite the source end.

#### REQUEST 34

For that reason, Omnitron 's statement in its instruction manual that when the source wire is retracted in safe position, the inactive tail of the source wire reaches a park switch sensor indicating the center of the source is located at the center of the lead safe is not true.

#### REQUEST 35

For that same reason, the statement in the Omnitron instruction manual that "applicator wire lengths are checked each time the wires are retracted into the machine to ensure the entire wire has been retrieved with no break" is also not true.

#### REQUEST 36

For that same reason, the statement in the Omnitron instruction manual that the "fail-safe retract system ensures that applicator wire has been fully retracted" is not true.

REQUEST 37

On November 17, 1992, the IRCC Physicist reran the treatment sequence from the 'November 16, 1993 session; during that simulation, although the source had already been detached from the wire, no errors were detected by the Omnitron 2000 afterloader system.

REQUEST 38

The Omnitron 2000's system for reporting any source wire length errors are effective only if the source wire is being retracted by the stepping motor.

REQUEST 39

When the emergency do retract motor is activated, all optical detection mechanisms disengage, the source wire length information is lost, and the Omnitron 2000 does not report any source wire length errors.

REQUEST 40

Prior to November 16, 1993, no OSC personnel were aware of the foregoing defects in the Omnitron 2000.

OBJECTION

The Staff objects to requests 33-40. Possible issues regarding the violation of 10 C.F.R. § 20.201(b), requiring a survey to be made which would be reasonable under the circumstances, as explained by the Licensee in previous pleadings, relate to the question of whether the IRCC staff believed that the source wire could not break and whether the IRCC's reliance on the alerts on the Omnitron 2000 to evaluate the extent of the radiation hazard present was reasonable under the circumstances. Assuming it were true that there were defects in the Omnitron 2000 afterloader's alert system, the cause of such defects has no relevance, cannot reasonably lead to the discovery of admissible evidence, and is not necessary to a proper decision on any possible issue in this proceeding. Similarly, the knowledge of the OSC personnel regarding the cause of these defects has no relevance, cannot reasonably lead to the discovery of admissible evidence, and is not necessary to a proper decision on any issue which could be admitted in this proceeding.

OSC RESPONSE TO STAFF OBJECTIONS

For the same reasons identified in OSC's response to the Staff objections to the interrogatory at I. (A) 7, the Staff objections are without merit, the request for admission above is relevant to the issues in this proceeding and the request should be answered. For the reasons set forth in OSC's response to the Staff objections to the request for admission in VI. (9) the Staff's reference to a "necessary for a proper proceeding" is improper and should not be considered.

REQUEST 41

In the November 16, 1992 incident at IRCC, the emergency do retract motor returned the source wire back into the afterloader.

OBJECTION

*The Staff objects to this request. The Suspension Order was based, in part, on the incident at the IRCC in which the IRCC personnel failed, in violation of 10 C.F.R. (20.201(b) and license condition 17, to perform a survey. Whether the emergency do retract motor returned the source wire back into the afterloader is not relevant, cannot reasonably lead to the discovery of admissible evidence, and is not necessary for a proper decision.*

OSC RESPONSE TO STAFF OBJECTIONS

For the same reasons identified in OSC's response to the Staff objections to the interrogatory at I. (A) 7, the Staff objections are without merit, the request for admission above is relevant to the issues in this proceeding and the request should be answered. For the reasons set forth in OSC's response to the Staff objections to the request for admission in VI. (9) the

Staff's reference to a "necessary for a proper proceeding" is improper and should not be considered.

REQUEST 49

OSC's RSO gave draft procedures entitled, "Oncology Services Corporation, Department of Physics, HDR Treatment Manual," to the Greater Pittsburgh Cancer Center (GPCC) before November 16, 1992.

OBJECTION

*The Staff objects to this request since the Suspension Order did not cite the Licensee for not providing draft procedures entitled "Oncology Services Corporation, Department of Physics, HDR Treatment Manual," to the Greater Pittsburgh Cancer Center (GPCC) before November 16, 1992. Therefore, even if true, this request is not relevant, cannot lead to the discover; of relevant information, and is not necessary for a proper decision in this matter.*

OSC RESPONSE TO STAFF OBJECTIONS

For the same reasons identified in OSC's response to the Staff objections to the interrogatory at I. (A) 7, the Staff objections are without merit. The request for admission above is relevant to the issues in this proceeding and the request should be answered. For the reasons set forth in OSC's response to the Staff objections to the request for admission in VI. (9) the Staff's reference to a "necessary for a proper proceeding" is improper and should not be considered.

Finally, a Staff objection contending that whether the RSO supplied OSC personnel with an HDR treatment manual is not relevant to corporate management of licensed activities or the sufficiency of training strains belief in the credibility of any of the Staff's objections.

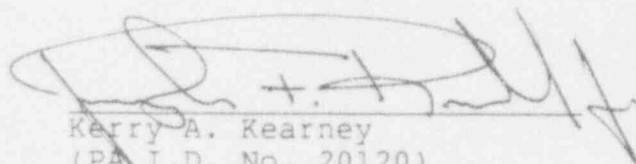
### CONCLUSION

For all the reasons set forth in this pleading OSC respectfully requests that the Board deny the Staff's Motion For A Protective Order. However, should the Board grant the stay Staff seeks, OSC requests that in fairness any order granting such a stay should also stay all NRC discovery against OSC pending the outcome of any referral to and decision by DOJ regarding potential criminal prosecution in this matter.

As to the Staff Objections, for all the reasons set forth in this pleading as well as OSC's other pleadings dealing with the relevance of the central issues raised by OSC, OSC respectfully requests that the Board dismiss or strike the Staff's Objections and order the Staff to produce responses to OSC's Discovery Requests to the extent Staff has failed to identify the

information and materials involved in those responses were not identified as pertaining to information for which the Staff sought protection pending any potential DOJ referral and/or prosecution.

Respectfully submitted,



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