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January 14, 1994

UNITED STATES OF AMERICA
NUCLEAR REGULATORY COMMISSION

EXEMPTED
USNRC

BEFORE THE ATOMIC SAFETY AND LICENSING BOARD P5 19

In the Matter of)	
)	
ONCOLOGY SERVICES CORPORATION)	Docket No. 030-31765-EA
)	
(Byproduct Material)	EA No. 93-006
License No. 37-28540-01))	
)	

NRC STAFF OBJECTIONS TO DISCOVERY
REQUESTS AND MOTION FOR A PROTECTIVE ORDER

INTRODUCTION

Pursuant to 10 C.F.R. §§ 2.740(c), 2.720(h)(2)(ii), and 2.742(b) of the Commission's regulations, the Staff of the Nuclear Regulatory Commission (Staff) files its objections to certain discovery requests contained in "Licensee's First Set of Interrogatories, First Request for Production and First Request for Admissions Directed to NRC Staff." The Staff also moves the Board for a protective order, protecting certain documents from production.

BACKGROUND

On December 17, 1993, the Atomic Safety and Licensing Board (Board) designated in the above-captioned proceeding issued a "Memorandum and Order (Establishing Administrative Directives and Scheduling Prehearing Conference)" (Board Order). In its Order, the Board scheduled a prehearing conference for January 26, 1994. Board Order at 4. The Board stated that at the prehearing conference it would consider,

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inter alia, the appropriate issues for litigation and discovery. *Id.* at 4. In addition, the Board provided that in the interim, it expected the parties to move forward expeditiously with discovery and to be prepared to provide the Board with a status report on all discovery activities. *Id.* at 5 n.2.

On December 27, 1993, the Staff served "NRC Staff's Interrogatories and Request for Production of Documents and Request for Admissions" on the Licensee. The Licensee filed, on January 3, 1994, "Licensee's First Set of Interrogatories, First Request for Production and First Request for Admissions Directed to NRC Staff" (Licensee's Discovery Requests). On January 4, 1994, the Licensee filed the "Oncology Services Corporation Motion for a Protective Order" (Motion). The Staff responded on January 7, 1994, indicating that while it objected to the Licensee's Motion, it did not object to the staying of responses to discovery requests until after the January 26, 1994 prehearing conference. "NRC Staff Response to Oncology Services Corporation Motion for a Protective Order." at 6-7.

On January 10, 1994, the Board issued an "Order (Postponing Discovery Responses Pending Prehearing Conference)." In its Order, the Board suspended the deadlines for both parties to respond to the pending discovery requests until further order of the Board. Order at 2. The Board further ordered that any Staff objections or requests

for a protective order relative to the Licensee's January 3, 1994 discovery requests, be filed by January 14, 1994.¹

DISCUSSION

I. STAFF OBJECTIONS TO THE LICENSEE'S DISCOVERY REQUESTS

The Staff hereby objects to the Licensee's interrogatories, admissions, and associated requests for documents which are listed below. Section 2.740 of the Commission's regulations provides that parties may obtain discovery on any matter, not privileged, which is relevant to the subject matter involved in the proceeding. 10 C.F.R. § 2.740(b)(1). *See also Pennsylvania Power and Light Co. and Allegheny Elec. Cooperative* (Susquehanna Steam Elec. Station, Units 1 and 2), ALAB-613, 12 NRC 317, 322 (1980). In addition a request for information must be reasonably calculated to lead to the discovery of admissible evidence. *See* 10 C.F.R. § 2.740(b)(1). Further, section 2.720(h)(2)(ii) provides that written interrogatories directed to the Staff must be necessary to a proper decision in the proceeding. The Staff, therefore, objects to certain of the Licensee's discovery requests, discussed below, which seek irrelevant

¹ On January 12, 1994, the Staff filed "NRC Staff Motion for Extension of Time in Which to File Specific Objections to the Production of Certain Documents." The motion was granted on January 14, 1994. "Memorandum and Order (Granting Staff Motion for Extension of Time to File Specific Discovery Objections)." To the extent that the Licensee's requests for production of documents are associated with the interrogatories to which the Staff is objecting herein, objections to the production of documents on the same grounds are also being made.

information, are not reasonably calculated to lead to the discovery of admissible evidence, and are not necessary for a proper decision in this proceeding.

In addition, a party is not required, in response to a discovery request, to engage in an excessive amount of research or compilation of data, especially if the raw data is available to the party requesting discovery. *See Boston Edison Co. (Pilgrim Nuclear Generating Station, Unit 2)*, LBP-75-30, 1 NRC 579, 584 (1975). The Staff, therefore, objects to certain of the Licensee's discovery requests which would require the staff to engage in an excessive amount of research and compilation of data, much of which is publicly available to the Licensee.

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 HDR 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.

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 Ili; 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 Ili 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).

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.

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.

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 cause 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.

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 Staff's objection to Interrogatory 2.

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

A. Licensee's Interrogatories

INTERROGATORY 1

The Order states, "Dr. Cunningham, who is the RSO named on the License, had not visited the Leighton 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.

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 Lehighton 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.

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)*.

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 Staff's objections to Interrogatories 1, 3, and 6.

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 others 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)*.

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 Staff's objections to Interrogatory 1(b)-(d).

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)*.

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)*.

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.

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.

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.

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 HDR 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.

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.

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.

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 dc 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.

REQUEST 41

In the November 16, 1992 incident at IRCC, the emergency dc 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 dc 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.

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 discovery of relevant information, and is not necessary for a proper decision in this matter.

II. NRC STAFF MOTION FOR PROTECTIVE ORDER

DISCUSSION

Pursuant to 10 C.F.R. § 2.740(c), the Staff hereby moves the Board for a protective order, postponing certain responses to the Licensee's request for the production of documents. Good cause exists for issuance of a protective order since the premature release of certain documents could cause harm to a potential criminal proceeding.

The Staff requests a protective order deferring, in part, its response to certain of the Licensee's Discovery Requests. The Staff seeks to protect certain documents, listed below, obtained by the NRC Incident Investigation Team (IIT) which are responsive to some of the Licensee's Discovery Requests. The Staff, specifically, requests a postponement in responding to the following Licensee's Discovery Requests:

Section I, Request for the Production of Documents 1, and Request for the Production of Documents 3, as it relates to Interrogatory 1.

Section II, Request for the Production of Documents 1, as it relates to Interrogatories 4, 5, and 6.

Because, as will be discussed below, the premature release of the IIT documents could harm a potential criminal investigation, the Staff requests that the Board issue an order deferring the Staff's response, in part, to the above listed Licensee's Discovery Requests until such time that the Department of Justice (DOJ) decides whether to initiate

a criminal prosecution relative to certain matters referred to it by the NRC Office of Investigations.²

The specific IIT documents which the Staff wishes to be covered by this protective order are:

1. Transcript: Entrance Meeting, 12/3/92
2. Transcript: Interview of Robbie Ackerson, Staff Technologist, OSC (IRCC), December 4, 1992.
3. Transcript: Interview of Rudy Balko, Staff Therapist, IRCC December 4, 1992.
4. Transcripts: Volume I - Interview of Gregory Hay, Consulting Physicist, December 4, 1992. Volume II - Interview of Gregory Hay, Consulting Physicist, (cont. December 5, 1992).
5. Transcript: Interview of Patricia Korywchak, R.N. Indiana Regional Cancer Center, December 4, 1992.
6. Transcript: Interview of Sharon Rickett, Registered Radiation Therapy Technician, December 4, 1992.
7. Transcript: Interview of James Bauer, M.D., IRCC, December 5, 1992.
8. Rudy Balko - Responses to Questions (L. Ostrom), December 8, 1992.
9. Written Questions to Resolve, for Rudy Balko.
10. Transcript: Interview of Bernard Rogers, M.D., Director of Brachytherapy, OSC, 12/9/92.
11. Transcript: Interview of Jerome Dardell, M.D., Radiation Oncologist, Vice President and Medical Director, OSC, at State College, Pennsylvania, 12/9/92.
12. Transcript: Interview of Douglas Colkitt, M.D., President and CEO, OSC, State College, Pennsylvania, 12/9/92.
13. Letter to L. Ostrum, NRC Consultant, from A. Wright, dated 12/17/92
14. Reports of Robert J. Gastrof, Contractor.

² The Staff wishes to apprise the Board and the Licensee that, as a result of the Staff's further review of documents which may be responsive to specific interrogatories and requests for production, it may be necessary to object to the production of other specific documents and information in OI's possession because of the potential for a criminal proceeding. The Staff will make such objections, if appropriate, at the time it responds to the Licensee's discovery requests.

15. Transcript: Interview of David E. Cunningham, Director, Radiation Safety, OSC, 12/17/92.
16. Region I Inspection of Incident at IRCC/OSC Draft Report.
17. Response to questions for G. Hay, Consulting Physicist, IRCC; received 12/22/92.
18. Written responses to questions asked by the IIT to IRCC staff.
19. Transcript: Interview of David Cunningham, Ph.D., Director of Physics and Bioengineering, OSC, Harrisburg, Pennsylvania, January 5, 1993.

The OI investigation into the matters relative to the November 1992 incident at the Indiana Regional Cancer Center (IRCC) and deliberate incomplete and/or inaccurate statements made by the Licensee's personnel to members of the NRC Staff, as well as other license issues potentially affecting the public health and safety, is almost complete. Affidavit of Barry R. Letts in Support of NRC Staff's Motion for a Protective Order (Letts Affidavit) at ¶ 3, attached hereto as Attachment A. A preliminary decision has been made to refer certain matters to DOJ. *Id.* at ¶ 4.

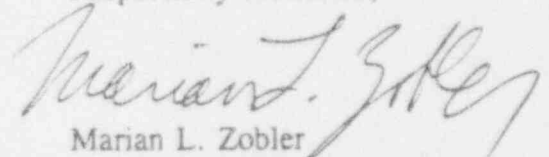
The issues to be referred to DOJ involve deliberate inaccurate and incomplete statements made by the Licensee's personnel in connection with the November 1992 incident at the IRCC. It is estimated that initial consultations with DOJ will be made within one week from the date of Mr. Letts's affidavit. *Id.* at ¶ 6. Until the referrals to DOJ are made and until DOJ decides whether to pursue a criminal prosecution, it is necessary to withhold certain IIT documents. *Id.* at ¶ 5. Since the IIT documents contain statement transcripts and other information regarding the same individuals who are likely to be called as witnesses in any grand jury proceeding related to the referred matters, it is necessary to withhold such information in order to protect the grand jury process. *Id.*

Thus, the premature release of these documents could harm a potential criminal proceeding. If DOJ declines to prosecute or if DOJ indicates that release of these documents would no longer harm its criminal proceeding, OI will inform counsel for NRC Staff who will, in turn, notify the Board and provide for the release of the documents within a reasonable time. *See id.* at ¶ 6.

CONCLUSION

As discussed above, good cause exists for granting this protective order. The Staff's motion should, therefore, be granted. A proposed protective order is attached hereto as Attachment B.

Respectfully submitted,



Marian L. Zobler
Counsel for NRC Staff

Dated at Rockville, Maryland
this 14th day of January, 1994