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UNITED STATES OF AMERICA NUCLEAR REGULATORY COMMISSION

BEFORE THE ATOMIC SAFETY AND LICENSING BOARD

In the Matter of

ONCOLOGY SERVICES CORPORATION

Byproduct Material
License No. 37-28540-01)

Docket No. 030-31765-EA

LICENSEE'S FIRST SET OF INTERROGATORIES,
FIRST REQUEST FOR PRODUCTION AND
FIRST REQUEST FOR ADMISSIONS
DIRECTED TO NRC STAFF

Pursuant to 10 C.F.R. §§ 2.720(h)(2)(ii), Licensee Oncology Services Corporation ("OSC") hereby files with the presiding officer written interrogatories to be answered by NRC personnel with knowledge of the facts designated by the Executive Director for Operations. OSC submits that the interrogatories are necessary to a proper decision in the proceeding and that answers to the interrogatories are not reasonably obtainable by OSC from any other source and, accordingly, that the NRC Staff should be required to answer the interrogatories OSC now propounds.

In addition, pursuant to 10 C.F.R. §§ 2.741(e), 2.744, 2.790 and 2.742, OSC hereby submits and serves on Staff and the Executive Director for Operations its requests for production of documents and requests for admission herein. To the extent required, any request that covers documents not available pursuant to 10 C.F.R. § 2.790 is to be deemed made pursuant to § 2.744. Furthermore, to the extent that any document request is deemed to fall under 10 C.F.R. § 2.744 such documents are hereby stated to be relevant to the facts, circumstances, regulatory requirements, and/or portions of the Order mentioned in the interrogatories contained in the Roman Numeraled sections in which each document request appears.

INSTRUCTIONS

These discovery requests shall be deemed to be continuing in nature so as to require seasonal, supplemental responses and production if further data or documents are obtained subsequent to the filing of responses hereto.

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Production of the documents and other things requested hereunder shall be timely done at the offices of Reed Smith Shaw & McClay, 435 6th Avenue, Pittsburgh, Pennsylvania 15230 or at such other location(s) as is "mutually agreeable."

DEFINITIONS

- A. The word "person" means any entity and includes, but is not limited to, any natural person, joint owner, association, company, partnership, joint venture, corporation, trust or estate.
- B. The word "document" means any written, printed, recorded or graphic matter, photographic matter or sound reproductions, however produced or reproduced, pertaining in any manner to the subject matter indicated, including all copies thereof.
- "identification" when used with respect to a person means to state the full name and present or last known residence and business or permanent address of such person, and, if a natural person, his present or last known job title, and the name and address of his present or last known employer.
- "identification" when used with respect to a document means to describe the document by date, subject matter, the name of each person who wrote, signed, initialed, dictated or otherwise participated in the preparation of same, the name and address of each addressee (if any) and the name and address of each person who has possession, custody or control of such document.
- E. The words "identify," "identity," and

 "identification" when used with respect to an act, occurrence,
 statement or conduct, including an alleged violation or breach
 (hereinafter collectively called an "act"), mean to: (1) describe
 the substance of each event constituting such act and to state the
 date when such act occurred; (2) identify each person
 participating in such act; (3) identify each person present when
 such act occurred; (4) state whether the occurrence of such act
 was recorded or described in a document; (5) state whether such
 document, or a copy thereof, now exists; and (6) identify the
 person presently having possession, custody or control of each
 such document.

- F. The word "Order" means the January 20, 1993 Order Suspending License (Effective Immediately) issued by NRC Staff as amended on May 21, 1993 by the Order Modifying the January 20, 1993 Order Suspending License.
- G. The words "regulatory requirement" shall mean a legally binding requirement such as a statute, regulation, license condition, technical specification, or order.

I. GENERAL DISCOVERY REQUESTS

A. Interrogatories:

- 1. Please identify all persons interviewed, questioned, deposed or from whom statements were in any other fashion taken in connection with any proceeding involving the Order.
- Please identify all persons whose testimony or statements you intend to introduce at any proceeding involving the Order.
- Please identify all documents or other items of tangible evidence you intend to introduce at any proceeding involving the Order.
- 4. Please identify any regulatory requirements, licensing guidances documents, inspection guidance documents, or other guidance documents addressing brachytherapy generally that were effective on November 16, 1992.
- 5. Please identify any regulatory requirements, licensing guidances documents, inspection guidance documents, or other guidance documents specifically addressing HDR brachytherapy that were effective on November 16, 1992?
- 6. With respect to the September 4, 1991 NRC inspection of OSC at the Harrisburg Cancer Center, please identify:
 - a. the Chief of the Region I Medical Licensing Section who was a member of the inspection team;
 - b. the senior inspector who was a member of the inspection team;

- c. the qualifications of the two inspectors; and
- d. any field notes, inspection reports, transcriptions, summaries, records, notes or other documents relating to the inspection.
- 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;
 - 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.
- 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.
- 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;
- f. any reports (regardless of whether they are draft, interim or final) regarding the research.

B. Requests for Production

Please produce:

- 1. All transcriptions, summaries or other notes of persons interviewed, questioned, deposed or from whom statements were in any other fashion taken in connection with this license suspension proceeding.
- 2. A copy of what the NRC purports to be the complete license at issue in this proceeding.
- 3. All documents and other evidence identified in your answers to the preceding nine interrogatories.
 - II. DISCOVERY REQUESTS WITH RESPECT TO SECTION II OF THE ORDER SUSPENDING LICENSE (EFFECTIVE IMMEDIATELY)

A. Interrogatories:

- 1. The Order states, "During that time period, the patient incurred a radiation dose estimated at greater than one million rads to the wall of the bowel." In connection with that statement, please identify:
 - a. who made the identified estimation of radiation dose;
 - b. the basis or bases for that estimation; and
 - c. any documents or other records relating to that estimation.

- 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.
- 3. The Order states, "Further, failure of the radiation monitor requires termination of treatment until the monitor is repaired and no personnel will be permitted to enter the room without a portable survey meter or audible dosimeter." In connection with that statement, please identify
 - a. what the NRC contends constitutes a "failure of the radiation monitor;"
 - b. what the NRC contends constitutes "repair" of the radiation monitor;
 - c. any persons, documents or other evidence that support the NRC's understanding either of what constitutes a "failure of the radiation monitor" or what constitutes "repair" of the radiation monitor.
- 4. The Order states, "In addition, 10 C.F.R. 20.201(b) requires that the Licensee make such surveys as (1) may be necessary to comply with the regulations in 10 C.F.R. part 20 and (2) are reasonable under the circumstances to evaluate the extent of radiation hazards that may be present." In connection with that statement please identify
 - a. whether you contend that on November 16, 1992 the Licensee failed at IRCC to make a survey that was necessary to comply with the regulations in 10 C.F.R. part 20;
 - b. the basis or bases for making that contention;
 - c. whether you contend that on November 16, 1992 the Licensee failed to make a survey and that failure was not "reasonable under the circumstances to evaluate the extent of radiation hazards that may be present;" and
 - d. the basis or bases for making that contention.

- 5. The Order states, "In direct violation of these requirements, and even though a calibrated, operational survey meter was available in the immediate vicinity, neither the physician nor the technologists utilized an audible dosimeter or survey meter upon entering the room, when they apparently believed that the area radiation monitor had malfunctioned and signaled a false alarm." In connection with that statement please identify:
 - a. your basis or bases for stating that as the physician and technologists entered the room, they "apparently believed the area radiation monitor had malfunctioned and signalled a false alarm;"
 - b. any persons providing information to the NRC relating to the statement (regardless of whether such information supports or contradicts the statement);
 - c. as to each person, the substance of that information;
 - d. any transcriptions, summaries, records, notes or other documents relating to the interview, testimony or statements of those persons.
- 6. The Order states, "In violation of 10 C.F.R. 19.12, the radiation therapy technologists had not been trained in the use of a survey meter and did not know when to use a survey meter or how to interpret the readings of a survey meter to determine the presence of a radioactive source in the patient or in the area." In connection with that statement, please identify:
 - a. any persons providing information to the NRC relating to the portion of the statement (regardless of whether such information is corroborative or contradictory) that the radiation therapy technologists had not been trained in the use of a survey meter;
 - b. any persons providing information to the NRC relating to the portion of the statement (regardless of whether such information is corroborative or contradictory) that the radiation therapy technologists did not know when to use a survey meter;
 - c. any persons providing information to the NRC relating to the portion of the statement (regardless of whether such information is corroborative or contradictory) that the radiation therapy technologists did not know how to

interpret the reading of a survey meter to determine the presence of a radioactive source in the patient or in the area;

- d. as to each person identified in response to the immediately preceding subsections a, b and c, the substance of that information;
- e. any transcriptions, summaries, records, notes or other documents relating to the interview, testimony or statements of those persons.

B. Requests for Production

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

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

A. Interrogatories:

- 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,
 - a. any regulatory requirement requiring visits by Dr. Cunningham to the Lehighton facility on a basis more frequent than 6-9 months;
 - 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.

- e. any inquiries made by the NRC with respect to any communications of Dr. Cunningham with the Lehighton facility other than by personal visits during the 6-9 months in question;
- f. the substance of those inquiries and the information resulting from responses to those inquiries;
- g. any inquiries made by the NRC with respect to any personal visits to the Lehighton facility or other communications with that facility by Dr. William Ying; and
- h. the substance of those inquiries and the information resulting from responses to those inquiries.
- i. any persons providing information with respect to personal visits or other communications of Drs. David Cunningham or William Ying to and with the Lehighton facility.
- j. any transcriptions, summaries, records, notes or other documents relating to the interview, testimony or statements of those persons.
- 2. The Order states, "Dr. David J. Moylan, Medical Director of the Lehighton facility and an authorized user named on the License, indicated that he had not read the terms and conditions of the License and was not aware that Dr. Cunningham was the RSO named on the License." In connection with that statement please identify:
 - a. any persons reporting Dr. Moylan made such
 "indications";
 - b. any transcriptions, summaries, records, notes or other documents relating to the statement by those persons;
 - c. any other evidence supporting that statement quoted above.

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.
- 4. Please identify any other errors the Staff has identified in the Order and any transcriptions, summaries, records or other documents relating to those errors.
- 5. The Order states, "At the Exton facility, emergency procedures were not posted at the console of the HDR afterloader as required by the License." In connection with that statement, please identify
 - a. what the NRC contends constitutes being "at the console of the HDR afterloader;"
 - b. any persons, documents or other evidence that support the NRC's understanding of what constitutes being "at the console of the HDR afterloader."

- 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:
 - a. any regulatory requirement defining or otherwise addressing "an appropriate corporate radiation safety communication;"
 - 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;"
 - d. documents regarding any final agency determinations, decisions or orders in any of the actions identified in response to the immediately preceding two subparts.

B. Requests for Production

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

IV. Discovery Requests With Respect to Section IV of the Order Suspending License (Effective Immediately)

A. 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:

- a. any regulatory requirement that was breached by the purported attempted delegation;
- 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;
- d. documents regarding any final agency determinations, decisions or orders in any of the actions identified in response to the immediately preceding two subparts.

B. Requests for Production

Please produce:

- 1. the document NRC contends is the December 14, 1992 letter of Dr. David Cunningham referred to in the Order; and
- 2. all other documents and other evidence referred to the response to the immediately preceding interrogatory.

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

A. Interrogatories:

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:

- a. any regulatory requirement defining "a significant corporate management breakdown in the control of licensed activities;"
- 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.
- e. the "key Licensee employees at several satellite who facilities do not know the requirements of the NRC License,"
- f. as to each key Licensee employee identified in the immediately preceding subsection of this interrogatory, the requirement of the NRC License as to which that employee was without knowledge;
- g. the "key Licensee employees at several satellite facilities who did not have access to the pertinent License documents;"
- h. the "key Licensee employees who had 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;"
- i. as to each key Licensee employee identified in the immediately preceding subsection of this interrogatory, the specific pertinent regulatory requirement(s) and the procedures and instrumentation as to which that key Licensee employee had not been trained.

- 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,
 - a. any regulatory requirement as of November 16, 1992, requiring maintenance of an 'adequate physical presence" at any facility;
 - 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 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;
 - e. any regulatory requirement as of November 16, 1992, requiring establishment and implementation of a "periodic corporate audit program";
 - 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;

- i. the "appropriate training programs" for Licensee employees, which the RSO was required to implement under 10 CFR 35.21 but failed to do so;
- j. any persons providing information with respect to conduct of Dr. David Cunningham as PSO;
- k. any transcriptions, summaries, notes or other documents relating to the interview, testimony or statements of those persons.
- 1. any other evidence relating the statement from the Order quoted at the beginning of this interrogatory; and
- m. the witnesses and other evidence you intend to use to prove the statement from the Order.

VI. REQUESTS FOR ADMISSION

Please admit or deny the truth of the following specified relevant matters of fact.

- 1. The NRC, Region I, performed a safety inspection of OSC on September 4, 1991, one year after its initial licensing.
- 2. The two individuals conducting the inspection in 1991 were experienced and well-qualified inspectors.
- 3. The 1991 inspectors found that the OSC staff had been trained.
- 4. All OSC personnel questioned during the 1991 inspection were knowledgable about both operating and emergency procedures.
- 5. All OSC personnel questioned during the 1991 inspection were knowledgeable in the areas specified in 10 CFR 19.12.
- 6. During this inspection, the inspectors identified two Severity Level IV violations.
- 7. The violations arose from findings that one person was wearing a badge from a wrong center and a transport form had been incompletely filled out.

- 8. Section 12, Brachytherapy, of the NRC inspector's field notes from the September 4, 1991 inspection was marked "HDR only."
- 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.
- 10. The inspector noted that operational and emergency procedures were covered by license conditions in lieu of 10 CFR 35.410.
- 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.
- 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.
- 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.
- 14. Regulatory Guide 10.8 provides guidance only for low dose rate brachytherapy.
- 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.
- 16. As of November 16, 1992, the licensing guidance in FC 86-4 was outdated.
- 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.
- 18. As of November 16, 1992, no regulations expressly recognized HDR brachytherapy.
- 19. NRC Inspection Manual Chapter (MC) 2800 establishes the inspection program for medical licenses, including license priority and inspection frequency.

- 20. There is no mention of FC 86-4 in MC-2800.
- 21. MC-2800 does not otherwise discuss HDR brachytherapy.
- 22. Inspection Procedure (IP) -87100 provides inspection direction for material inspections involving nuclear medicine and medical teletherapy.
 - 23. There is no mention of FC 86-4 in IP-81700.
- 24. IP-81700 does not otherwise discuss HDR brachytherapy.
- 25. The field notes used by inspectors for brachytherapy are included in Appendix B to IP-87100.
- 26. The section on brachytherapy in the field notes follows the requirements in 10 CFR Part 35, Subpart G.
- 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 nickeltitanium wire in the vicinity if the iridium source.
- 28. Before the November 16, 1992 incident, Omnitron performed no engineering calculations on the source wires, especially in the areas of the cavity.
- 29. Before the November 16, 1992 incident, Omnitron performed a bend fatigue test or 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.
- 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.
- 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.

- 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.
- 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.
- 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.
- 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.
- 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.
- 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.
- 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.
- 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.
- 40. Prior to November 16, 1993, no OSC personnel were aware of the foregoing defects in the Omnitron 2000.
- 41. In the November 16, 1992 incident at IRCC, the emergency dc retract motor returned the source wire back into the afterloader.

- 42. Omnitron personnel believed and led most OSC personnel to believe that a source-wire break was not possible.
- 43. Initial training by Omnitron personnel was approved by the NRC.
- 44. On December 9 and 10, 1991, Omnitron personnel conducted training session for IRCC personnel, including the IRCC authorized user, the physicist and one of the Radiation Therapists.
- 45. The training on December 9 and 10, 1991 by Omnitron personnel included "a demonstration of the safety features and emergency procedures to be followed."
- 46. During the December 9 and 10, 1991 training sessions, Omnitron personnel did not raise the possibility of or provide any training regarding emergency procedures to be followed in the event of a source wire break.
- 47. On February 27, 1992 Omnitron personnel conducted another training session regarding the Omnitron 2000 for IRCC personnel.
- 48. During the February 27, 1992 training session, Omnitron personnel did not raise the possibility of or provide any training regarding emergency procedures to be followed in the event of a source wire break.
- 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.

50. During the December 7, 1992 incident involving a source wire break at GPCC, the GPCC physicist performed appropriate radiological measurements and assessment, ascertained the location of the source inside the connecting catheter and responded accordingly.

Respectfully submitted,

Marcy L. Colkitt, Esquire (PA I.D. No. 53447) General Counsel and Executive Vice President

Oncology Services Corp. P.O. Box 607 Indiana, PA 15701-0607 412/463-3570

OF COUNSEL

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DATED: January 3, 1994

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UNITED STATES OF AMERICA NUCLEAR REGULATORY COMMISSION

BEFORE THE ATOMIC SAFETY AND LICENSING BOARD

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

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that a true and correct copy of the within was furnished to the following this 3rd day of January, 1994:

G. Paul Bollwerk, III, Chairman Dr. Peter S. Lam Administrative Judge Administrative Judge Administrative Judge Atomic Safety & Licensing Board Panel

Fourth Floor, West Tower
4350 East West Highway
Bethesda, MD 20814

Board Panel

Fourth Floor, West Tower
4350 East West Highway
Bethesda, MD 20914

Dr. Charles N. Kelber Administrative Judge Atomic Safety & Licensing Board Panel Fourth Floor, West Tower 4350 East West Highway Bethesda, MD 20814

Marian L. Zobler Michael H. Finkelstein U.S. Nuclear Regulatory Commission Commission Office of General Counsel Washington, D.C. 20555 Washington, D.C. 20555

Atomic Safety & Licensing

Adjudicatory File (2) U.S. Nuclear Regulatory Commission Washington, D.C. 20555

> Office of the Secretary (2) U.S. Nuclear Regulatory ATTN: Docketing & Service Section

Atomic Safety & Licensing Board Panel (1) U.S. Nuclear Regulatory Commission Washington, D.C. 20555 Office of Commission Appellate Adjudication (1) U.S. Nuclear Regulatory Commission Washington, D.C. 20555

James M. Taylor
Executive Director for Operations
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MAIL STOP 17621
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Joseph D. Rodkey, Jr