14551

December 27, 1993

UNITED STATES OF AMERICA
NUCLEAR REGULATORY COMMISSION

'93 DEC 28 P1:53

BEFORE THE ATOMIC SAFETY AND LICENSING BOARD

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'S INTERROGATORIES AND REQUEST
FOR PRODUCTION OF DOCUMENTS AND REQUEST FOR ADMISSIONS

Pursuant to 10 C.F.R. §§ 2.740b, 2.741, and 2.742 of the Commission's regulations, the NRC staff (Staff) hereby requires that Oncology Services Corporation (Licensee) responds to the following interrogatories, and produces for inspection and copying, documents requested below.

Each interrogatory shall be answered separately and fully, in writing, and under oath or affirmation and shall include all pertinent information available to the Licensee, its representatives, or counsel, based upon the personal knowledge of the person answering. The production of the documents requested herein shall take place at the Office of General Counsel, U.S. Nuclear Regulatory Commission, 11555 Rockville Pike, Room 15-B-18, Rockville, Maryland, unless other arrangements are made, by agreement, in this regard.

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INSTRUCTIONS

1. To the extent that the Licensee does not have specific, complete, and accurate information with which to answer any interrogatory, the Licensee should so state, and the interrogatory should be answered to the extent information is available, identifying each person who is believed to have accurate information with respect thereto.

2. Each interrogatory shall be deemed to be continuing, and the Licensee is required seasonably to supplement answers with additional facts, documents, information, and names of witnesses which become known, in accordance with 10 C.F.R. § 2.740(e)(1) and (2).[1]

3. The words "and" and "or" shall be construed either conjunctively or disjunctively so as to bring within the scope of these discovery requests any information that might otherwise be construed to be outside their scope.

4. Wherever appropriate, the singular form of a word shall be interpreted in the plural, and vice versa, so as to bring within the scope of these discovery requests any information that might otherwise be construed to be outside their scope.

5. Please produce a copy of each document requested in the form and condition in which it exists on the date of service of this request, including all comments, notes, remarks, and other material that may have been added to the document after its initial preparation.

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[1]Under 10 C.F.R. § 2.740(e), parties are required, under certain circumstances, to supplement responses to discovery requests.

6. If the Licensee objects to or claims a privilege (*e.g.*, attorney-client, work product, or other) with respect to any interrogatory or document request, in whole or in part, or seeks to withhold documents or information because of the alleged proprietary or other nature of the data, please set forth all reasons and the underlying factual basis for the objection or claim of privilege in sufficient detail to permit the Atomic Safety and Licensing Board to determine the validity of the objection or claim of privilege. This description by the Licensee should include with respect to any document:

a. author, addressor, addressee, and recipients of indicated and "blind" copies together with their job titles;

b. date of preparation;

c. subject matter;

d. purpose for which the document was prepared;

e. all persons to whom distributed, shown, or explained;

f. present custodian;

g. all persons believed to have a copy of the document; and

h. the nature of the privilege or objection asserted.

7. For any document or part of a document that was at one time, but is no longer, in the Licensee's possession, custody, or control, or which is no longer in existence, or which cannot be located or produced, identify the document, state where and how it passed out of existence or why it can no longer be located or produced and the reasons therefore, and identify each person having knowledge concerning such

disposition or loss and the contents of the document, and identify each document evidencing its prior existence and/or any fact concerning its nonexistence or loss.

DEFINITIONS AND GUIDELINES TO BE USED IN RESPONDING TO THIS DISCOVERY REQUEST

1. "Communication" shall mean correspondence, contact, discussion, or any other kind of written or oral exchange between two or more persons or entities including, but not limited to, all telephone conversations, face-to-face meetings or conversations, visits, conferences, and internal and external discussions, and exchange of a document or documents.

2. "Computer file" means all computer files of whatever type without regard to the manner in which the file is stored.

3. "Concerns", "Concerning", or another derivative thereof, includes referring to, responding to, relating to, pertaining to, in connection with, comprising, memorializing, commenting on, regarding, discussing, showing, describing, reflecting, analyzing, supporting, contradicting, and constituting.

4. "Document" or "writing" as used herein shall mean any written matter, whether produced, reproduced or stored on paper, cards, tapes, disks, belts, charts, film, computer storage devices or any other medium and shall include, without limitation, matter in the form of books, reports, studies, statements, speeches, notebooks, agreements, appointment calendars, working papers, manuals, memoranda, notes, procedures, orders, instructions, directions, training materials, records, correspondence, diaries, plans, diagrams, drawings, periodicals, lists, telephone logs, minutes,

photographs, and any published materials and shall also include, without limitation, originals, copies (with or without notes or changes thereon) and drafts.

5. "Identify" when used in reference to a natural person means to set forth the following:

a. his/her name;

b. his/her last known residential address;

c. his/her last known business address;

d. his/her last employer;

e. his/her title or position;

f. his/her area of responsibility;

g. his/her business, professional, or other relationship with the Licensee; and

h. If any of the above information is changed subsequent to the time period referenced in a particular interrogatory, set forth in the answer, and label appropriately, current information as well as the information applicable to the time period referenced in the interrogatory.

6. "Identify" when used in reference to a document shall mean to set forth the following:

a. its title;

b. its subject matter;

c. its date;

d. its author;

e. its addressee;

f. its file designation or other identifying designation; and

g. its present location and present custodian.

7. "Identify" with respect to a contact or communication shall set forth the following:

a. the date of the communication;

b. the place of the making and place of receipt of the communication;

c. the type and means of communication;

d. the substance of the communication;

e. each person making a communication, and his location at the time the communication was made;

f. each person to whom the communication was made, and his location at the time the communication was made;

g. all other persons present during, participating in, or receiving the communication and the location of each such person at the time;

h. each document concerning such communication; and

i. each document upon which the communication is based or which is referred to in the communication.

8. "Identify" when used with respect to a computer file shall set forth the following:

a. the full file name including extension;

b. the number of bytes in the file;

c. the date and time of file creation;

d. a statement of the purpose for which the file can be used;

e. the computer equipment necessary or convenient to use the file;

9. "License" means in the context of this discovery request NRC Byproduct Material License No. 37-28540-01.

10. "Licensee" means in the context of this discovery request Oncology Services Corporation.

11. "Personnel" means in the context of this discovery request those individuals working at the specified facility, whether or not directly employed by the Licensee.

12. The Staff requests that documents produced in compliance with this request be accompanied with a specific indication as to the particular paragraphs of the Staff's discovery request under which the documents are being produced.

INTERROGATORIES AND REQUESTS FOR PRODUCTION OF DOCUMENTS

A. General Interrogatories

INTERROGATORY 1

Identify any person the Licensee intends to call as a witness in this proceeding.

INTERROGATORY 2

With respect to any person listed in response to Interrogatory A1 above, state the details of that person's education, employment history and asserted area of expertise, or, in the alternative, a copy of such person's *curriculum vitae* may be provided.

INTERROGATORY 3

Identify any persons[2] who have knowledge of the facts concerning:

a. the incident which occurred at the Indiana Regional Cancer Center (IRCC) on November 16, 1992 in which a 3.7 curie iridium-192 source was left inside

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[2] Pursuant to 10 C.F.R. § 2.740(e)(1)(i), a party is under a duty to supplement its response to any question directly addressed to the identity and location of person having knowledge of discoverable matters.

a patient receiving High Dose Rate (HDR) Brachytherapy treatment using an Omnitron 2000 HDR Afterloader (hereinafter referred to as the "November 16, 1992 incident");

b. the training provided to the personnel at the IRCC, Mahoning Valley Cancer Center, Lehighton, Pa (Lehighton facility), and the Exton Cancer Center, Exton, Pa (Exton facility) prior to December 8, 1992,

c. the activities Dr. David Cunningham relative to his duties as Radiation Safety Officer (RSO) for the Licensee, during the period from August 3, 1991 until December 18, 1992.

d. any other fact touching upon the matters in controversy herein, including, but not limited to all persons from whom the Licensee has obtained or attempted to obtain written or oral statements, whether or not the Licensee intends to call that person as a witness in this proceeding.

INTERROGATORY 4

Identify all documents the Licensee intends to rely on in this proceeding.

INTERROGATORY 5

Provide copies of the documents you have listed in response to Interrogatory A4 above.

INTERROGATORY 6

As to each document listed in response to Interrogatory A4 above, state whether or not the Licensee intends to seek to move each such document into the record as evidence in this proceeding.

INTERROGATORY 7

As to each document listed in response to Interrogatory A4 above, state what fact or opinion the Licensee intends to establish if the document is admitted into evidence.

INTERROGATORY 8

Identify all documents, computer programs or computer files that created, processed, retrieved, modified, updated, or stored any information concerning:

a. the November 16, 1992 incident;

b. the training provided to the personnel at the IRCC, Lehighton facility, and the Exton facility prior to December 8, 1992,

c. the activities Dr. David Cunningham relative to his duties as RSO for the Licensee, during the period from August 3, 1991 until December 18, 1992.

d. any other fact(s) touching upon the matters in controversy herein, whether or not the Licensee intends to rely upon such facts in this proceeding.

B. Interrogatories Relative to the Violation of 10 C.F.R. 19.12 Training Requirements of the IRCC Personnel

INTERROGATORY 1

Prior to November 16, 1992, did the radiation therapy technologists at the IRCC:

a. know how to use a survey meter;

b. know when to use a survey meter; or

c. know how to interpret the readings of a survey meter to determine the presence of a radioactive source?

If the answer to either a, b, or c, above is in the affirmative, how does the Licensee intend to establish this fact(s)?

INTERROGATORY 2

Describe the training provided to the personnel at the IRCC by the Licensee, its agents, contractors, or assignees, prior to November 16, 1992, including:

a. a list of subjects covered;

b. the approximate length of time devoted to each subject; and

c. the dates when this training was provided.

INTERROGATORY 3

If the training discussed in response to Interrogatory B2, above, was provided by an employee of the Licensee, identify the employee who provided the training. Provide

a job description for this employee and all supporting documentation, including, but not limited to, the employee's employment contract.

INTERROGATORY 4

If the training discussed in response to Interrogatory B2, above, was provided by a non-employee of the Licensee, identify:

a. the person or persons who provided the training; and

b. the relationship between the person or persons identified and the Licensee.

Provide all supporting documentation, including, but not limited to, any contract between the Licensee and the person identified above. Explain how the Licensee ensured that such training was in fact provided and provide all documentation supporting this explanation.

INTERROGATORY 5

Identify those IRCC personnel who received the training discussed in response to Interrogatory B2, above.

INTERROGATORY 6

Did the training discussed in response to Interrogatory B2, above, include:

a. the correct use of a survey meter;

b. when to use a survey meter; and

c. how to interpret the readings of a survey meter to determine the presence of a radioactive source?

Provide all documentation the Licensee intends to rely upon in this regard.

INTERROGATORY 7

Describe the use of the survey meter by radiation therapy technicians Sharon Rickett and Rudy Balko at the IRCC in 1991, when the wall mounted room radiation monitor (PrimeAlert) was undergoing replacement. Explain:

a. for what purpose the survey meter was used;

b. how many times each radiation therapy technologist used the survey meter; and

c. on what date(s) was the survey meter used.

INTERROGATORY 8

Describe the use of the survey meter by radiation therapy technicians Sharon Rickett and Rudy Balko at the IRCC in 1992, when a source was delivered at the IRCC. Explain:

a. for what purpose the survey meter was used;

b. how many times each radiation therapy technologist used the survey meter; and

c. on what date(s) was the survey meter used.

INTERROGATORY 9

Describe the training provided, if any, to the IRCC personnel by the physicist, Greg Hay, prior to November 16, 1992. Include:

a. a list of subjects covered;

b. the approximate length of time devoted to each subject; and

c. the dates of when this training was provided.

Provide all supporting documentation.

INTERROGATORY 10

Did the physicist provide the training discussed in response to Interrogatory B9, above pursuant to his job responsibilities or employment contract? If yes, how did the Licensee ensure that such training was provided? Provide all supporting documentation, including, but not limited to, the physicist's job description and employment contract.

INTERROGATORY 11

Identify those IRCC personnel who attended the training discussed in response to Interrogatory B9, above.

INTERROGATORY 12

Did the training discussed in response to Interrogatory B9, above include:

a. the correct use of a survey meter;

b. when to use a survey meter; and

c. how to interpret the readings of a survey meter to determine the presence of a radioactive source?

Provide all supporting documentation.

INTERROGATORY 13

Describe the training provided to the IRCC personnel by Omnitron prior to November 16, 1993. Did this training include:

a. the correct use of a survey meter;

b. when to use a survey meter; and

c. how to interpret the readings of a survey meter to determine the presence of a radioactive source?

Provide all supporting documentation.

INTERROGATORY 14

Did the Licensee rely on any previous formal education received by its personnel at the IRCC for radiation safety training, including:

a. the correct use of a survey meter;

b. when to use a survey meter; and

c. how to interpret the readings of a survey meter to determine the presence of a radioactive source?

If the answer to either a, b, or c above is yes, identify those IRCC personnel who received the previous formal education relied upon by the Licensee for radiation safety training. For each person identified, identify the institution from which the training was received.

C. Interrogatories Relative to the violation of 10 C.F.R. 20.201(b) survey requirement

INTERROGATORY 1

Explain how each of the following facts, if true, demonstrates that the IRCC personnel's, including Dr. James E. Bauer's, actions were reasonable under the circumstances to evaluate the extent of radiation hazards that may be present, pursuant to 10 C.F.R 20.201(b) on November 16, 1992. Provide the names of all individuals who can testify that these facts are true and provide all supporting documentation, to the extent that this information has not already been provided in response to another interrogatory. If information has been provided in response to another interrogatory, reference the responsive interrogatory or interrogatories.

a. The NRC approved Omnitron training, operating manual and/or emergency procedures.

b. All treating personnel at IRCC including the Medical Director/Authorized User, the physicist and both technologists received training from Omnitron using the Omnitron emergency procedures and Omnitron operating manual.

c. Dr. Bauer, as well as all Omnitron-trained Authorized Users, were trained pursuant to Omnitron's course that the source wire could not break.

d. The treating personnel at IRCC followed the emergency procedures in the Omnitron manual.

e. The physician/authorized user systematically reviewed the redundant Omnitron internal safety check alerts.

f. The Omnitron 2000 High Dose Rate (HDR) afterloader was defective.

g. Reliance by IRCC personnel on specific features of the Omnitron was reasonable on November 16, 1992.

h. The Licensee was not informed by Omnitron and the Licensee did not know otherwise of the possibility of deterioration despite Omnitron's knowledge of deterioration of the source wire due to a chemical reaction resulting from its packaging.

i. The treating personnel relied on the internal safety devices of the Omnitron 2000 which due to multiple machine failures incorrectly indicated source retraction.

j. The Omnitron 2000 design, manufacturing and/or warning defects was a cause of the November 16, 1992 incident in which the source wire broke.

k. The November 16, 1992 incident at IRCC occurred because of an unanticipated failure of the Omnitron 2000 retraction mechanism and a reliance by the authorized user on Omnitron procedures which did not anticipate or cover this emergency.

l. Prior to November 16, 1992, the emergency scenario that the Omnitron source wire breaks was neither expected nor reasonably anticipated by the Licensee in general and the IRCC treating personnel in particular.

INTERROGATORY 2

What other facts, other than the ones listed above, does the Licensee intend to rely upon to demonstrate that the IRCC personnel complied with 10 C.F.R. § 20.201(b)?

INTERROGATORY 3

Describe the Omnitron emergency procedures contained in the Omnitron manual which the IRCC personnel allegedly followed on November 16, 1992. Provide a copy of the manual and emergency procedures.

INTERROGATORY 4

Describe all the difficulties the IRCC personnel encountered with the HDR treatment on November 16, 1992. Describe any and all indications the IRCC personnel received from the Omnitron 2000 unit regarding these difficulties, including whether these indications provided any information regarding the presence of radiation. Identify the IRCC personnel who were aware of these indications. Did any of the personnel identified, above, inform the IRCC Medical Director/Authorized User of these indications? If yes, describe what the Medical Director/Authorized User was told.

INTERROGATORY 5

Describe all indications regarding the difficulty of the HDR treatment on November 16, 1992 received by the IRCC personnel, other than the ones from the Omnitron 2000 unit. Did any of the above-described indications provide any information regarding the presence of radiation? Did any of the personnel identified above inform the IRCC Medical Director/Authorized User of these indications? If yes, describe what the Medical Director/Authorized User was told.

INTERROGATORY 6

Describe the internal safety alerts allegedly checked by the IRCC Authorized User on November 16, 1992. Did any of theses alerts measure actual radiation levels?

INTERROGATORY 7

Describe how the Omnitron 2000 was defective.

INTERROGATORY 8

Identify where in the Omnitron Manuals and Sales Literature the fact that the source wire could not break was emphasized. Provide copies of the referenced documents.

INTERROGATORY 9

Identify the IRCC personnel who saw the room radiation monitor (PrimeAlert) flash red during the November 16, 1992 incident. When did the above-identified personnel first notice the room radiation monitor flashing red.

INTERROGATORY 10

Identify the IRCC personnel, present at the IRCC on November 16, 1992, who were aware of the fact that the room radiation monitor (PrimeAlert) flashed red during the November 16, 1992 incident. Explain:

a. when did the above-identified personnel first become aware of the fact that the room radiation monitor had flashed red;

b. how the above-identified personnel became aware of the fact that the room radiation monitor had flashed red; and

c. if the above-identified personnel were informed by another individual at the IRCC, identify that individual(s).

INTERROGATORY 11

On November 16, 1992, did any of the IRCC personnel unplug, disable, reset, disengage, or otherwise adjust the room radiation monitor? If yes:

a. identify who unplugged, disabled, reset, disengaged, or otherwise adjusted the room radiation monitor on November 16, 1992;

b. describe his or her actions regarding the room radiation monitor; and

c. the reasons for the above-described action.

INTERROGATORY 12

During the November 16, 1992 incident at the IRCC, did any of the IRCC personnel present believe that the room radiation monitor was not functioning? If yes, identify the individual(s) who believed that the monitor was not functioning.

INTERROGATORY 13

During the November 16, 1992 incident at the IRCC, did any of the IRCC personnel present believe that the room radiation monitor had signaled a false alarm? If yes, identify the individual(s) who believed that the monitor had signaled a false alarm.

INTERROGATORY 14

Describe any and all occurrences, prior to November 16, 1993 in which the room radiation monitor at the IRCC malfunctioned. Provide the dates and description of each malfunction. Did any of these occurrences involve the room radiation monitor flashing red, indicating the presence of radiation, where no radiation was present? As a result of these malfunctions, describe what steps were taken to ensure that the malfunction would not reoccur, including whether any communication or training was provided to the IRCC personnel regarding each malfunction. Provide all supporting documentation.

INTERROGATORY 15

When was the most recent check on the room radiation monitor performed prior to the November 16, 1992 incident? What was the result of that check? Identify the individual who performed the check.

INTERROGATORY 16

Does License Condition 17 require that in the event of a failure of the room radiation monitor, no personnel will enter the room without portable survey meter or audible dosimeter?

INTERROGATORY 17

Explain how the Licensee intends to establish that License Condition 17 was not violated by the IRCC's personnel, including Dr. Bauer's, failure to enter the treatment room without either a portable survey meter or an audible dosimeter on November 16, 1992 when difficulty with the treatment was encountered.

INTERROGATORY 18

Assuming that fulfillment of any applicable survey requirements of 10 C.F.R. Part 35, Subpart G satisfies the survey requirement of 10 C.F.R. § 20.201(b), explain how the IRCC personnel satisfied any of the applicable survey requirements of 10 C.F.R. Part 35, Subpart G.

D. Interrogatories Relative to 10 C.F.R. § 19.12 Training Violations at the Licensee's Exton and Lehighton Facilities

INTERROGATORY 1

Identify all personnel who worked at the Exton facility from the time the Exton facility was added to the License until December 8, 1992. Provide titles and a description of duties and responsibilities as they related to the treatment of humans using High Dose Rate brachytherapy). Describe their employment arrangement, employee, contractor, etc., for each person identified. Provide all supporting documentation.

INTERROGATORY 2

Identify all personnel who worked at the Lehighton facility from the time the Lehighton facility was added to the License until December 8, 1992. Provide titles and a description of duties and responsibilities as they relate to the treatment of humans using HDR. Describe their employment arrangement, employee, contractor, etc., for each person identified. Provide all supporting documentation.

INTERROGATORY 3

Prior to December 8, 1992, identify:

a. the individual(s) in charge of HDR treatment at the Exton facility;

b. the individual(s) in charge of HDR treatment at the Lehighton facility.

For each individual identified in a and b, above, provide the individual's title, and a description of his or her duties and responsibilities.

INTERROGATORY 4

Was the individual(s) in charge of HDR treatment at the Exton facility, identified in response to interrogatory D3, above, always at the HDR afterloader console during the delivery of treatment? Provide any supporting documentation.

INTERROGATORY 5

Was the individual(s) in charge of HDR treatment at the Lehighton facility, identified in response to Interrogatory D3, above, always at the HDR afterloader console during the delivery of treatment? Provide any supporting documentation.

INTERROGATORY 6

Identify the personnel at the Exton and Lehighton facilities who, prior to December 8, 1992, performed unsupervised HDR treatments.

INTERROGATORY 7

Identify the personnel at the Exton and Lehighton facilities who, prior to December 8, 1992, performed supervised HDR treatments. Identify the personnel at each facility who supervised these above-identified individuals. Describe each supervisor's responsibilities relative the his or her duties as a supervisor of HDR treatments. Describe the supervision provided at each facilities, including whether the supervisor was present at the HDR unit console during patient treatment.

INTERROGATORY 8

Prior to December 8, 1992, were any of the personnel at the Exton and Lehighton facilities, including, but not limited to, the authorized user and physicists, trained in:

a. the License;

b. the License Conditions; and

c. NRC regulations

by the Licensee, its employees, or agents?

INTERROGATORY 9

If the training discussed in response to Interrogatory D8, above, was provided by an employee of the Licensee, identify the employee who provided the training. Provide a job description for this employee and all supporting documentation, including, but not limited to, the employee's employment contract.

INTERROGATORY 10

If the training discussed in response to Interrogatory D8, above, was provided by a non-employee of the Licensee, identify the person or persons who provided the training and relationship between the person or persons identified above and the Licensee. Provide all supporting documentation, including, but not limited to, any contract between the Licensee and the person identified above. Explain how the Licensee ensured that such training was in fact provided. Provide all supporting documentation.

INTERROGATORY 11

Did the Licensee rely on any previous formal education received by its personnel at the Exton and Lehighton facilities for radiation safety training? If yes, identify those Exton and Lehighton personnel who received the previous formal education relied upon by the Licensee for radiation safety training. For each person identified, identify the institution from which the training was received.

INTERROGATORY 12

State any other fact(s), not previously provided in response to Interrogatories D1-D11, the Licensee intends to rely upon to demonstrate that 10 C.F.R. § 19.12 was not violated at the Exton and Lehighton facilities?

E. Interrogatories Relative to Corporate Management Breakdown

INTERROGATORY 1

Explain how each of the following facts, if true, demonstrates the absence of a significant corporate management breakdown in the control of licensed activities prior to January 20, 1993. Provide the names of all individuals who can testify that these facts are true and provide all supporting documentation, to the extent that this information has not already been provided in response to another interrogatory. If information has been provided in response to another interrogatory, reference the responsive interrogatory or interrogatories.

a. The physicist and/or Medical Director/Authorized User were at the console during HDR procedures at Exton and Lehighton.

b. The technologists at the Exton and Lehighton centers were never in charge of an HDR administration.

c. The technologists at the Exton and Lehighton centers did not perform unsupervised HDR administrations.

d. The NRC Region I performed a complete safety inspection on September 4, 1991, including review of the Licensee's entire HDR/Radiation Safety program and found no deficiencies with regard to the Licensee's corporate oversight, HDR operation or treatment procedures at that time.

e. Ongoing individualized, apprentice type training occurs at all the Licensee's facilities by the Medical Directors/Authorized User, Physicist and others.

f. No HDR treatments were performed by IRCC personnel prior to the completion of the proper training under the pertinent regulations and license conditions.

g. Medical Directors/Authorized Users received refresher training consistent with any applicable regulations and license conditions by Dr. Cunningham, the then RSO, at semi-annual meetings which address HDR and regulatory compliance.

h. On November 16, 1992, the treating personnel at IRCC followed the emergency procedures in the Omnitron manual.

i. During the training period, no HDR procedures were performed in Lehighton without direct supervision from the Harrisburg HDR team headed by Dr. Ying.

j. The technologists at the Mahoning (Lehighton) Center were trained in the correct use and operation of portable survey meters, wall-mounted radiation survey meters, door interlocks and patient audio-visual communications systems by the Licensee.

k. The Mahoning (Lehighton) Center radiation training covered a review of emergency procedures.

l. Dr. Cunningham was in continuing contact by FAX and by phone with the Lehighton Center during the six to nine months prior to the December inspection.

m. The Lehighton and Exton employees received the Omnitron Training.

n. The Atlantic City training session included personnel from the Lehighton and Exton centers.

o. The physicist at Exton received additional calibration training on the HDR unit in Harrisburg.

p. A copy of the License with all documents incorporated by reference in License Condition 17 was physically present at each of the facilities listed on the License.

q. The Licensee had a Quality Management program submitted to the NRC and in effect prior to the required deadline in January 1992.

r. The Licensee voluntarily suspended HDR treatments at the centers under the License upon learning of the November 16, 1993 incident.

s. The purpose of the Licensee's voluntary suspension of HDR activities was to enable it to understand how the Omnitron 2000 machine malfunctioned and how the IRCC personnel reacted.

t. The NRC approved an amendment sought by the Licensee on April 2, 1993, changing its Radiation Safety Officer from David E. Cunningham, Ph.D., to Bernard Rogers, M.D.

INTERROGATORY 2

State any other fact(s), other than the ones listed above, the Licensee intends to rely upon in order to demonstrate that there was an absence of a significant corporate management breakdown in the control of licensed activities prior to January 20, 1993.

INTERROGATORY 3

Describe the corporate training provided by the Licensee in Atlantic City in August, 1992. When, specifically, was this training provided? Provide a list of subjects covered and the approximate length of time devoted to each subject. Did this training include:

a. the correct use and operation of portable survey meters;

b. the correct use and operation of wall-mounted radiation survey meters;

c. the correct use and operation of door interlocks;

d. the correct use and operation of patient audio-visual communications systems;

d. training in the License;

f. training in the License Conditions; and

g. training in the NRC regulations?

If the answer to e, f, or g, above is yes, identify the specific license conditions and NRC regulations covered by this training. Provide all supporting documentation.

INTERROGATORY 4

Identify the personnel from the facilities listed on the License who attended the corporate training in Atlantic City in August, 1992. Provide all supporting documentation.

INTERROGATORY 5

Was the Atlantic City training mandatory for any personnel working at the facilities listed on the License? If yes, identify for whom was this training mandatory.

INTERROGATORY 6

Was the Atlantic City training provided free of charge to all personnel who were either required to or wished to attend?

INTERROGATORY 7

Describe the in-service training provided by Dr. Cunningham, including:

a. a list of subjects covered;

b. the approximate length of time devoted to each subject; and

c. the date of this training.

Identify the personnel from each of the facilities listed on the License who attended this training. How often was this training provided at each of the facilities listed on the License?

INTERROGATORY 8

Did the training described in response to Interrogatory E7, above, include:

a. the correct use and operation of portable survey meters;

b. the correct use and operation of wall-mounted radiation survey meters;

c. the correct use and operation of door interlocks;

d. the correct use and operation of patient audio-visual communications systems;

e. training in the License;

f. training in the License Conditions; and

g. training in the NRC regulations?

If the answer to e, f, or g, above is yes, identify the specific license conditions and NRC regulations covered by this training. Provide all supporting documentation.

INTERROGATORY 9

Describe the refresher training provided by Dr. Cunningham at semi-annual meetings to medical directors/authorized users. Include:

a. a list of subjects covered;

b. the approximate length of time devoted to each subject; and

c. the dates of when this training was provided.

INTERROGATORY 10

Identify the personnel from each of the facilities listed on the license who attended the refresher training described above in response to Interrogatory E9.

INTERROGATORY 11

Did the training described in response to Interrogatory E9, above, include:

a. the correct use and operation of portable survey meters;

b. the correct use and operation of wall-mounted radiation survey meters;

c. the correct use and operation of door interlocks;

d. the correct use and operation of patient audio-visual communications systems;

e. training in the License;

f. training in the License Conditions; and

g. training in the NRC regulations?

If the answer to e, f, or g, above is yes, identify the specific license conditions and NRC regulations covered by this training. Provide all supporting documentation.

INTERROGATORY 12

Describe any other radiation safety training provided by the Licensee, its employees, agents, contractors or assignees provided to the personnel at the Exton and Lehighton facilities prior to December 8, 1992. Identify the personnel from each of the facilities who attended this training. How often was this training provided?

INTERROGATORY 13

Did the training discussed in response to Interrogatory E12, above, include training in:

a. the License;

b. the License Conditions;

c. the NRC regulations;

d. the correct use and operation of portable survey meters;

e. the correct use and operation of wall-mounted radiation survey meters;

f. the correct use and operation of door interlocks;

g. the correct use and operation of patient audio-visual communications systems?

If the answer to a, b, or c, above is yes, identify the specific license conditions and NRC regulations covered by this training. Provide all supporting documentation.

INTERROGATORY 14

If the training discussed in response to Interrogatory E12, above, was provided by an employee of the Licensee, identify the employee who provided the training. Provide a job description for this employee and all supporting documentation, including, but not limited to, the employee's employment contract.

INTERROGATORY 15

If the training discussed in response to Interrogatory E12, above, was provided by a non-employee of the Licensee, identify the person or persons who provided the training and the relationship between the person or persons identified and the Licensee. Provide all supporting documentation, including, but not limited to, any contracts between the Licensee and the person identified above. Explain how the Licensee ensured that such training was in fact provided.

INTERROGATORY 16

For how long were the personnel at the Exton and Lehighton facilities initially trained prior to being allowed to perform supervised HDR treatments? Describe the training provided to the personnel prior to being allowed to perform supervised HDR treatments. Did this training include training in the License, License Conditions, NRC regulations? Provide all supporting documentation.

INTERROGATORY 17

For how long were the personnel at the Exton and Lehighton facilities trained prior to being allowed to perform unsupervised HDR treatments? Describe the training provided to the personnel prior to being allowed to perform unsupervised HDR patient treatments. Did this training include training in the License, License Conditions, NRC regulations? Provide all supporting documentation.

INTERROGATORY 18

How many times did Dr. Cunningham visit the Lehighton facility within the six to nine month period prior to the December 8, 1992 inspection? Describe the purpose of such visits. If training was involved, describe:

a. the exact nature of the training;

b. the subjects covered; and

c. the approximate amount of time spent on each subject.

Identify the personnel at the Lehighton facility who received any such training.

INTERROGATORY 19

During any of the above described visits, in response to Interrogatory E18, did Dr. Cunningham perform any formal audits of the Licensee's radiation safety program or compliance program? If yes, provide all documentation of these audits, including any final results

INTERROGATORY 20

Describe Dr. Cunningham's FAX and telephone contacts with the Lehighton facility during the six to nine months prior to December 8, 1992. Describe:

a. the purpose of each contacts;

b. the subject of each contact;

c. the frequency of such contacts;

d. the dates of each contact; and

e. to whom at the Lehighton facility were these contacts directed.

If training was involved, describe the exact nature of the training, including subjects covered and the approximate amount of time spent on each subject. Identify the personnel at the Lehighton facility who received any such training.

INTERROGATORY 21

For your response to Interrogatory E20, provide all supporting documentation, including, but not limited to, copies of any written contacts, including faxes, with the Lehighton facility and any telephone logs documenting these contacts.

INTERROGATORY 22

Provide the date(s) of Dr. William Ying's visits, if any, prior to December 8, 1992, to the Lehighton facility to provide training. Identify the personnel who received

any such training. Provide a list of the subjects covered and the approximate amount of time spent on each subject. Provide any supporting documentation.

INTERROGATORY 23

Prior to December 8, 1992, were copies of the documents incorporated into the License by reference available at the Exton facility? If yes, where at the Exton facility, prior to December 8, 1992 were these documents kept? Did the Exton personnel know where these documents were located. If yes, identify each person who knew where these documents were located.

INTERROGATORY 24

Describe the training provided by Dr. Ying to Paula Salinitro, the Exton physicist, on six days in November 1991 and February 1992, including a list of subjects covered and the approximate amount of time spent on each subject. Provide any supporting documentation.

INTERROGATORY 25

Prior to December 8, 1992, had Dr. David J. Moylan, Medical Director of the Lehighton facility and authorized user under the License, read the terms and conditions of the License?

INTERROGATORY 26

Prior to December 8, 1992, was Dr. David J. Moylan aware that Dr. Cunningham was the RSO named on the License?

INTERROGATORY 27

Did Dr. David J. Moylan indicate during the December 8, 1992 inspection to an NRC inspector 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? If no, describe any conversation which took place on December 8, 1992 between Dr. Moylan and NRC inspectors.

INTERROGATORY 28

Provide copies of the emergency procedures for the use of HDR unit at the Exton and Lehighton facilities in effect prior to December 8, 1992.

INTERROGATORY 29

Does License Condition 17 require that emergency training include a simulation emergency (dry run) of the source not retracting at the end of treatment?

INTERROGATORY 30

Did the emergency training provided to the radiation therapy technologists, prior to December 8, 1992, at either the Exton and Lehighton facilities include a simulation emergency ("dry run") of the source not retracting at the end of treatment? If yes:

a. describe how the simulation emergency was performed at each of the facilities;

b. identify the personnel at each facility who performed the simulation emergency; and

c. provide the date(s) of each simulation emergency performed at each facility.

INTERROGATORY 31

Describe where the emergency procedures were located, prior to December 8, 1992, at the Exton facility. Did the personnel at the Exton facility know of the location of the emergency procedures?

INTERROGATORY 32

Prior to December 8, 1992, where was the key to activate the HDR unit at both the Exton and Lehighton facilities stored while not in use? Where was the key stored on December 8, 1992 at both facilities?

INTERROGATORY 33

Prior to December 8, 1992, where was the key to activate the linear accelerator at both the Exton and Lehighton facilities stored while not in use? Where was the key stored on December 8, 1992 at both facilities?

INTERROGATORY 34

Prior to December 8, 1992, were any of the personnel at the Exton facility confused about the term "Quality Management"? If yes, identify the personnel who were confused. Explain how this confusion explains the conclusion in the Order that the

personnel at the Exton facility were not aware of the specifics of the Licensee's Quality Management Program.

INTERROGATORY 35

Prior to December 8, 1992, identify the personnel at the Exton facility who were aware of the specifics of the Licensee's Quality Management program. For each person identified, describe the specific requirements of the Quality Management program of which he or she was aware. Describe any training provided to the Exton personnel regarding the Licensee's Quality Management program.

INTERROGATORY 36

Describe the proper procedures and policies of the Licensee's Quality Management program in which the personnel at the Exton facility were trained or instructed, prior to December 8, 1992. Identify each person trained. How do the described procedures and policies differ from the specifics of the Licensee's Quality Management program?

INTERROGATORY 37

Describe, including in what form, *i.e.*, telephone conversation, letter, etc., the communication made by Dr. Bernard Rogers to the Licensee's facilities at both Exton and Lehighton on either December 1 or 2, 1992 regarding the November 16, 1992 incident at the IRCC.

INTERROGATORY 38

Identify the individuals at each facility notified by Dr. Rogers of the November 16, 1992 incident on either December 1 or 2, 1992. State what was communicated to those individuals regarding the November 16, 1992 incident, and whether those individuals were instructed to inform any other personnel at the facilities. Provide any supporting documentation, including, but not limited to, copies of any written communications made by Dr. Rogers regarding the November 16, 1992 incident made prior to December 8, 1992 or telephone logs documenting any telephone communications regarding the IRCC incident made prior to December 8, 1992.

INTERROGATORY 39

After November 16, 1992, when were HDR treatments suspended at each of the Licensee's facilities. Provide the dates for each referenced facility.

F. Interrogatories Relative to the December 18, 1992 Letter from Dr. Cunningham

INTERROGATORY 1

Regarding Dr. Cunningham's December 18, 1992 letter in which Dr. Cunningham wrote "It is not possible for Corporate Administration to supervise your radiation safety program on a routine basis," (hereinafter referred to as "December 18, 1992 letter") describe which RSO tasks Dr. Cunningham attempted to delegate in the December 18, 1992 letter. How do these tasks differ from RSO responsibilities?

INTERROGATORY 2

What was the purpose of the December 18, 1992 letter?

INTERROGATORY 3

Explain how the fact that the December 18, 1992 letter was written at a time when licensed activities were suspended at the Licensee's facilities demonstrates that the letter was an attempted delegation of tasks and not responsibilities.

INTERROGATORY 4

Explain why the proper interpretation of the December 18, 1992 letter requires an understanding that the letter was written when HDR procedures were suspended at the Licensee's facilities, except the Harrisburg and Pittsburgh centers.

INTERROGATORY 5

Explain why the proper interpretation of the December 18, 1992 letter requires an understanding that each of the Licensee's facilities listed on the Licensee was staffed from the outset with personnel who, if licensed, could operate independently of a corporate RSO and, which, if licensed, were qualified to act as direct RSOs for a particular center.

INTERROGATORY 6

Identify the personnel at each of the Licensee's facilities listed on the License who, if licensed, could operate independently of a corporate RSO. Identify the personnel at each of the Licensee's facilities listed on the licensed who were qualified to act as an RSO for the particular center where he or she worked. For each person identified, provide documentation of his or her qualifications to act as an RSO and to operate independently of a corporate RSO.

INTERROGATORY 7

State any other fact(s), not previously provided in response to Interrogatories F1-F6, the Licensee intends to rely upon to explain the December 18, 1992 letter.

G. Interrogatories Relative to the Sanction Imposed

INTERROGATORY 1

Provide a detailed description of the conduct of HDR at the Licensee's facilities not cited in the Order. Explain how the Licensee's conduct in the administration of HDR at its other facilities, not cited in the Order, indicates that the License should not be suspended, assuming that the facts in the Order are true.

INTERROGATORY 2

Identify and describe the good cause and exculpatory grounds which the Licensee believes excuses the Licensee's failure to comply with the literal terms of the License. Explain how the Licensee's failure to comply with the literal terms of the License did not result in an increased risk to its personnel as well as to the general public. Explain how the above discussed good cause, the absence of increased risk or other exculpatory grounds mitigates or excuses the Licensee's failure to comply with the literal terms of the License.

INTERROGATORY 3

Explain how "patient need" indicates that the sanction imposed in the Order is not supported by the facts as set forth in the Order?

INTERROGATORY 4

Provide any other fact(s), not previously provided in response to Interrogatories G1-G3, does the Licensee intend to rely upon to demonstrate that the sanction imposed in the Order was not supported by the facts as set forth in the Order?

REQUEST FOR ADMISSIONS[3]

1. The room radiation monitor (PrimeAlert) had alarmed, indicating the presence of radiation, during the treatment of the patient on November 16, 1992 at the IRCC.

2. During the November 16, 1992 incident at the IRCC, Dr. Bauer was aware that the room radiation monitor had flashed red, indicating the presence of radiation.

3. Dr. Bauer and the radiation therapy technologists at the IRCC knew and understood, on November 16, 1992, the significance of the fact the alarm ("red flash") on the room radiation monitor, *i.e.*, that is radiation present in the area.

4. A working hand held portable survey meter was available at the IRCC during the November 16, 1992 incident.

5. On November 16, 1992 at the IRCC, neither the authorized user/medical director nor the radiation therapy technologists upon entering the treatment room at the IRCC used either an audible dosimeter or a portable survey meter.

6. On November 16, 1992 at the IRCC, neither the authorized user/medical director nor the radiation therapy technologist, or any other IRCC personnel, surveyed the patient with a portable survey meter after terminating treatment.

Respectfully submitted,

Marian L. Zobler
Counsel for NRC Staff

Dated at Rockville, Maryland
this 27th day of December, 1993

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[3] This request for admissions may be supplemented or enlarged upon completion of discovery.

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	)	EA No. 93-006
License No. 37-28540-01)	)	

CERTIFICATE OF SERVICE

I hereby certify that copies of "NRC STAFF'S INTERROGATORIES AND REQUEST FOR PRODUCTION OF DOCUMENTS AND REQUEST FOR ADMISSIONS" in the above-captioned proceeding have been served on the following by deposit in the United States mail, first class, or as indicated by an asterisk through deposit in the Nuclear Regulatory Commission's internal mail system this 27th day of December, 1993:

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

Dr. Charles N. Kelber*
Administrative Judge
Atomic Safety and Licensing Board
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