14752

March 4, 1994

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

RESPONSE OF ONCOLOGY SERVICES CORPORATION TO NRC STAFF'S FIRST SET OF INTERROGATORIES AND REQUEST FOR PRODUCTION OF DOCUMENTS AND REQUEST FOR ADMISSIONS

Oncology Services Corporation files this Response of Oncology Services Corporation to NRC Staff's First Set of Interrogatories and Request for Production of Documents and Request for Admissions and incorporates by reference into each response the following general objections.

GENERAL OBJECTIONS

These general objections are hereby incorporated into each of the following discovery requests. Despite the fact that (1) the Honorable Donald Lee, U.S. District Court Judge for the Western District of Pennsylvania, in case No. 93-0939, Oncology Services Corporation v. NRC, et al., has ruled that the NRC must turn over to OSC the NRC transcripts and that; (2) no stay has been issued in that case, the NRC Staff has failed and refused to comply with the

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federal court order. Without access to such documentation it is not possible for OSC to provide more complete answers.[1] The licensee therefore objects to all discovery related in any way to alleged statements and/or the representations made by personnel to either the IIT Team or OI that form any basis for the suspension order.

Further, the NRC Staff has refused to provide critical and relevant answers posed by the license regarding specifics of the "criminal referrals." Therefore, the license objects generally to the entire set of discovery based on said basis. Until answers are provided more complete answers cannot be provided.

Moreover, the licensee objects to any request to the extent it seeks to obtain privileged information, work product material or irrelevant information/responses.

INTERROGATORY 1

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

RESPONSE:

Unknown at this time.

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[1] N.B. - Further, it should be noted that to the best of OSC's knowledge none of the OI transcripts have been reviewed by the deponents for accuracy. Further, OSC believes certain IIT transcripts likewise have not been yet reviewed for accuracy.

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.

RESPONSE:

See response to interrogatory 1.

INTERROGATORY 3

Identify any persons 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 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; and

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.

RESPONSE:

See NRC transcripts.

INTERROGATORY 4

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

RESPONSE:

Unknown at this time. Notwithstanding the foregoing, OSC may rely on 000001-001893, AM002501-AM002821, AM002960-AM003466, E000001-E001309, H000001-H003815, I000001-I000695, J0001, M000001-M001308, O000001-O011250 and X000001-X000015, as well as any other documents produced by the Licensee to the NRC, including the IIT Team and OI.

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.

RESPONSE:

Unknown at this time.

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.

RESPONSE:

Unknown at this time.

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.

RESPONSE:

Unknown at this time. Notwithstanding the foregoing, see documents identified in response to interrogatory 4A.

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)?

RESPONSE:

See NRC transcripts of IRCC personnel. It is unknown at this time how the Licensee will put in its evidence.

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.

RESPONSE:

The Licensee objects to this interrogatory because it is vague and ambiguous with respect to the word "training," and is therefore unanswerable.

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.

RESPONSE:

See response to interrogatory 2.

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.

RESPONSE:

See response to interrogatory 2.

INTERROGATORY 5

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

RESPONSE:

See response to interrogatory 2.

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.

RESPONSE:

See response to interrogatory 2.

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.

RESPONSE:

See NRC transcripts.

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.

RESPONSE:

See response to interrogatory 7.

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.

RESPONSE:

See response to interrogatory 7.

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.

RESPONSE:

See response to interrogatory 7.

INTERROGATORY 11

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

RESPONSE:

See response to interrogatory 7.

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.

RESPONSE:

See response to interrogatory 7.

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.

RESPONSE:

See NRC transcripts of IRCC personnel.

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 related upon by the Licensee for radiation safety training. For each person identified, identify the institution from which the training was received.

RESPONSE:

The Licensee hired qualified personnel who the Licensee understood to be well-educated. See NRC transcripts of IRCC

personnel for description of education and training and resumes previously produced to the NRC.

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.

RESPONSE:

See NRC transcripts, IIT Report, FDA findings and NRC-Omnitron report. Based on the above, the conduct by IRCC personnel was at all times reasonable. See also documents identified in response to interrogatory 4A.

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.

RESPONSE:

See Omnitron manual and emergency procedures that were previously produced to the NRC.

INTERROGATORY 6

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

RESPONSE:

See NRC transcripts of IRCC personnel. See Omnitron manual.

INTERROGATORY 7

Describe how the Omnitron 2000 was defective.

RESPONSE:

See FDA, NRC and IIT reports.

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.

RESPONSE:

See Omnitron materials previously produced to the NRC.

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.

RESPONSE:

See NRC transcripts of IRCC personnel.

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.

RESPONSE:

See NRC transcripts of IRCC personnel and Greg Hay.

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?

RESPONSE:

Objection. Interrogatory 16 seeks a legal interpretation. License Condition 17 speaks for itself.

D. Interrogatories Relative to 10 C.F.R. Section 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.

RESPONSE:

See NRC transcripts of Exton personnel. Further, see documents identified in response to interrogatory 4A.

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.

RESPONSE:

See NRC transcripts of Mahoning Valley personnel. Further, see documents identified in response to interrogatory 4A.

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.

RESPONSE:

The license objects to interrogatory 3 as vague, unclear and therefore unanswerable. The licensee does not understand the term "in charge of HDR treatment."

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.

RESPONSE:

See response to interrogatory 3.

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.

RESPONSE:

See response to interrogatory 3.

INTERROGATORY 6

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

RESPONSE:

See response to interrogatory 3. Further, the licensee objects to the term "unsupervised" as unclear and undefined. Therefore, interrogatory 6 is unanswerable.

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 to his or her duties as a supervisor of HDR treatments. Describe the supervision provided at each facility, including whether the supervisor was present at the HDR unit console during patient treatment.

RESPONSE:

See response to interrogatory 3 and interrogatory 6.

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?

RESPONSE:

See NRC transcripts of Exton and Mahoning Valley personnel.

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.

RESPONSE:

See NRC transcripts of Exton and Mahoning Valley personnel.

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.

RESPONSE:

See NRC transcripts of Exton and Mahoning Valley personnel.

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.

RESPONSE:

OSC objects to interrogatory 11 because the term "rely" is so vague that the interrogatory is unanswerable. Personnel at Exton and Lehighton were well-educated and knowledgeable. See NRC transcripts.

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. Section 19.12 was not violated at the Exton and Lehighton facilities?

RESPONSE:

Unknown at this time.

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.

RESPONSE:

The licensee objects to interrogatory 1 because it is vague, unclear and fails to define the term "significant corporate management breakdown." Therefore it is unanswerable.

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.

RESPONSE:

See response to interrogatory E1.

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;

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.

RESPONSE:

See NRC transcripts. See documents identified in response to interrogatory 4A.

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.

RESPONSE:

See NRC transcripts. See documents identified in response to interrogatory 4A.

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.

RESPONSE:

Interrogatory 5 is legally irrelevant and therefore objectionable.

INTERROGATORY 6

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

RESPONSE:

The Licensee paid for the Atlantic City conference.

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?

RESPONSE:

The licensee objects to interrogatory 7 as vague, unclear and unanswerable in so far as it refers to an "in-service training."

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.

RESPONSE:

See response to interrogatory E7. Further, see NRC transcripts.

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.

RESPONSE:

See NRC transcripts and documentation identified in response to interrogatory 4A.

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.

RESPONSE:

See NRC transcripts and documentation identified in response to interrogatory 4A.

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.

RESPONSE:

See response to interrogatories 9 and 10.

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?

RESPONSE:

OSC objects to interrogatory 12 as vague, unclear and therefore unanswerable. In further response, see NRC transcripts and documentation provided in response to interrogatory 4A.

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.

RESPONSE:

See response to interrogatory 12.

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.

RESPONSE:

See response to interrogatory 12.

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.

RESPONSE:

See response to interrogatory 12.

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.

RESPONSE:

OSC objects to interrogatory 16 as vague and unclear based on the term "supervised HDR treatments," and therefore it is unanswerable.

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.

RESPONSE:

OSC objects to interrogatory 17 as vague and unclear based on the term "unsupervised HDR treatment," and therefore it is unanswerable.

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.

RESPONSE:

Interrogatory 18 is legally irrelevant. There is no regulatory requirement for Dr. Cunningham to visit the Lehighton facility.

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.

RESPONSE:

Interrogatory 19 is legally irrelevant. There is no regulatory requirement for a formal audit during the six to nine month period prior to December 8, 1992.

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 contact;

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.

RESPONSE:

Unknown at this time.

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.

RESPONSE:

See phone records previously produced to the NRC by the licensee.

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.

RESPONSE:

See NRC transcripts of Mahoning Valley personnel and of Dr. Ying. Further, see documentation previously produced to the NRC by the licensee identified in response to interrogatory 4A.

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.

RESPONSE:

See NRC transcripts and documents produced identified in response to interrogatory 4A.

INTERROGATORY 24

Describe the training provided by Dr. Ying to Paula Salanitro, 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.

RESPONSE:

See NRC transcripts of Dr. Ying and Paula Salanitro.

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.

RESPONSE:

The licensee has previously produced these documents to the NRC. See documentation described in interrogatory 4A.

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?

RESPONSE:

The Licensee objects to interrogatory 29 because it seeks a legal analysis. License Condition 17 speaks for itself.

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.

RESPONSE:

See NRC transcripts of Exton and Mahoning Valley personnel.

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?

RESPONSE:

See NRC transcripts of Exton personnel.

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?

RESPONSE:

See NRC transcripts of Exton and Lehighton personnel.

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?

RESPONSE:

See NRC transcripts of Exton and Lehighton personnel.

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.

RESPONSE:

Personnel were confused by the term "Quality Management". See NRC transcripts. Relevant personnel were aware of the 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.

RESPONSE:

See NRC transcripts of Exton personnel.

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?

RESPONSE:

See NRC transcripts of Exton personnel.

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.

RESPONSE:

See NRC transcript of Dr. Bernard Rogers.

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.

RESPONSE:

See NRC transcript of Dr. Bernard Rogers.

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.

RESPONSE:

See documentation identified in response to interrogatory 4A.

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?

RESPONSE:

Objection. Interrogatory 1 seeks a legal interpretation. The December 18, 1992 letter speaks for itself. Further, see Cunningham's NRC transcripts.

INTERROGATORY 2

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

RESPONSE:

See Cunningham's NRC transcripts.

INTERROGATORY 3

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

RESPONSE:

None of the conduct is subject to a regulation requirement solely obligating the radiation safety officer.

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.

RESPONSE:

Based on the timing, there was clearly not even a transfer of tasks.

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.

RESPONSE:

See responses to interrogatories 3 and 4.

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 license 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.

RESPONSE:

The medical director at each facility is a licensed board certified radiation oncologist. See resumes previously produced to the NRC.

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.

RESPONSE:

Unknown at this time.

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.

RESPONSE:

See NRC transcripts. The conduct meets every regulatory requirement.

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.

RESPONSE:

Where literal enforcement does not equal the regulatory basis and objectives, it is arbitrary and capricious and does not impact on public safety.

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?

RESPONSE:

There was no ongoing risk. Public health and safety was not at risk but patients were denied critical care because of the suspension 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?

RESPONSE:

Unknown at this time.

REQUEST FOR ADMISSIONS

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.

RESPONSE: Denied. The room radiation monitor did not have an audible alarm that could have alarmed. The room radiation monitor flashed, however, it was not understood by IRCC personnel in this instance to indicate the presence of radiation.

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

RESPONSE: Admitted.

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.

RESPONSE: Objection. This request can neither be admitted nor denied due to the total lack of specificity.

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.

RESPONSE: Objection. Request 6 is legally irrelevant. The patient was not surveyed with a portable survey meter and no such requirement existed.

Respectfully submitted,

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Dated: March 4, 1994

'94 MAR -7 P5:20

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 copies of the Response of Oncology Services Corporation to NRC Staff's First Set of Interrogatories and Request for Production of Documents and Request for Admissions in the above-captioned proceeding have been served on the following via U.S. Mail this 4th day of March 1994:

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 & Licensing Board
U.S. Nuclear Regulatory Commission
Washington, D.C. 20555

Marian L. Zobler
Michael H. Finkelstein
U.S. Nuclear Regulatory Commission
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Dr. Peter S. Lam
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Commission
Washington, D.C. 20555

VERIFICATION

The foregoing Response of Oncology Services Corporation To NRC Staff's First Set Of Interrogatories And Request For Production Of Documents And Request For Admissions is true and correct to the best of my knowledge, information or belief.