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RELATED CORRESPONDENCE DOCKETED USNRC

June 10, 1994

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UNITED STATES OF AMERICA
NUCLEAR REGULATORY COMMISSION

OFFICE OF SECRETARY DOCKETING & SERVICE BRANCH

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)	)	

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 and every response the following general objections.

GENERAL OBJECTIONS

The Licensee objects to any request to the extent it seeks to obtain privileged information, work product material or irrelevant information/responses. Further, the Licensee is continuing its review of this matter and reserves the right to supplement and/or revise any and all responses contained herein prior to the hearing.

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INTERROGATORY 1

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

RESPONSE:

At present, Licensee may call any or all of the following as witnesses:

James Bauer, M.D.
Rudy Balko
Sharon Rickett
Greg Hay
Dave Cunningham, Ph.D.
William Ying, Ph.D.
Paula Salanitro
David Moylan, M.D.
Robbie Ackerson
Richard Yelovich, M.D.
Mark Batog
Lorraine Copenhagen
Richard Croley
Karen Wagner
Amirul Hoque, Ph.D.
Mitch Jarosz
Dr. Mohamed Shanbaky
James Lieberman, Esquire
Donna Green
Ann Wright
Abne Hasan, M.D.
Bernard Rogers, M.D.
Connie Shope
Connie Hawkins
GammaMed personnel
Robert H. Davis, Ph.D.
Abdurrahman Unal, M.D.
Roger P. Tokars, M.D.
John Glenn, Ph.D.
Carl Paperiello, Ph.D.
Daniel Flynn, M.D.
Judith Joustra
Pamela Henderson
Pat Santiago
Jerry Derdel, M.D.
Susan Shankman, Ph.D.

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:

To the best of the Licensee's knowledge, the NRC has in its possession resumes for many of the individuals named in Interrogatory A1. To the extent that the NRC lacks such resumes and the Licensee has possession of such, arrangements will be made with the Staff for copying.

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:

The following individuals have knowledge of facts pertaining to one or more of the subparts contained in this Interrogatory:

James Bauer, M.D.
Rudy Balko
Sharon Rickett
Greg Hay
Dave Cunningham, Ph.D.
William Ying, Ph.D.
Paula Salanitro
David Moylan, M.D.
Robbie Ackerson
Richard Yelovich, M.D.
Mark Batog
Lorraine Copenhagen
IIT Team
Nitan Niak
Connie Hawkins
Connie Shope
Robert H. Davis, Ph.D.
Richard Croley
Karen Wagner
Amirul Hoque, Ph.D.
Mitch Jarosz
Douglas Colkitt, M.D.
Jerry Derdel, M.D.
Ann Wright
Donna Green
Abne Hasan, M.D.
Omnitron Personnel
GammaMed Personnel

INTERROGATORY 4

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

RESPONSE:

At this time, the Licensee may rely on any of the following documents:

10 CFR 19, 20 and 35
IIT Report
NRC Inspection Report 030-31765-92-001

License No. 37-28540-01 (including tie down conditions)
Omnitron Operating Instructions/Manual
Omnitron Emergency Procedures
Omnitron Training Certificates
Laurel Mountain Physics Contract
10 CFR 19, 20 and 35
IIT Report
Colgan Autopsy dated December 21, 1992 by Sidney Goldblatt, M.D.
Omnitron 2000 Training Session Course Materials (E-0929-E-1039)
Omnitron 2000 Training Session Course Materials (Treatment Plan) (I-0348-I-0385)
Omnitron 2000 Training Session Course Materials (I-0386-I-0442)
Omnitron 2000 Training Session Course Outline (E-1194-E-1205)
Omnitron Treatment Planning (Prepublication copy) (E-0059-E-0080)
Omnitron - The New Generation of High Dose Rate Remote Afterloaders (I-000311)
Oncology Services Corporation, Department of Physics, HDR Treatment Manual (I-0444)
Oncology Services Corporation, Department of Physics, Quality Management of Brachytherapy Procedures, High Dose Rate Technique
Oncology Services Corporation, Department of Physics, Quarterly In-Service Training Log (I-000453)
Oncology Services Corporation, Department of Physics, Annually In-Service Training Log (I-000454)
Oncology Services Corporation, Department of Physics, Treatment Quality Assurance Check List (Omnitron 2000)
Oncology Services Corporation, Department of Physics, Physics Consult
Oncology Services Corporation, Department of Physics, HDR Daily Quality Assurance
Oncology Services Corporation, HDR Prescription Form
Omnitron Rectal Applicator - Shielded Information Sheet
Oncology Services Corporation, Department of Physics, Omnitron 2000 HDR Afterloader, Emergency Procedures
Manual Check Procedure for Computer Treatment Planning, Omnitron 2000 HDR Afterloading System, David E. Cunningham, Ph.D., William F. Ying, Ph.D., Physics Department, Oncology Services, Inc., June, 1992 (I-0481)
Omnitron, The Complete Company: Sources, Service and Education
Laurel Mountain Physics Contract
NRC Report No. 40, Protection Against Radiation from Brachytherapy Sources
Oncology Services Radiation Oncology Quality Assurance System, Policy and Procedure Manual for Community Cancer Centers - 1991

Oncology Services Corporation, Hershey Physician's Conference, 7/3/92-7/5/92
Oncology Services Corporation, Orlando Physician's Conference, 2/14/92-2/16/92
Hershey Agenda 9/14/90-9/16/90
Oncology Associates Physician Conference #3, Winter Symposium, Mt. Laurel, Poconos, PA, February 15-18, 1991
Refresher Course No. 506 - High Dose Rate Brachytherapy, Astro, October 19, 1990
Memorandum to all Technical Radiation Oncology Staff from Karen E. Wagner, 1/13/93
USNRC Information Notice 92-84
Mahoning Valley Cancer Center Summary of November 25, 1991 Meeting (M-0889-M-0891)
Mahoning Valley Cancer Center Radiation Safety Inservice - January 28, 1993 (M-0892-M-0894)
Schuylkill Cancer Center - Advances in Radiation Therapy Seminar Itinerary - December 3-5, 1992 (M-0895-M-0897)
Greater Harrisburg Training Safety Review Course (M-0898-M-0900)
Oncology Services Corporation, Department of Physics (MVCC) Training Session Test Sheet (M-0901-M-0903)
Oncology Services Corporation, Department of Physics, Safety Review Course - February 6, 1993 (including HDR Quality Assurance) (M-1296-M-1297)
Mahoning Valley Cancer Center - Notice of Regulations and Licenses - 1/21/91 (M-1302-M-1307)
Emergency Procedures, GammaMed (M-1308)
Letter to NRC re: Copy of Quality Management Program (I-0138-I-0141)
Draft Quality Management of Brachytherapy HDR Techniques (I-0283-0285)
HDR Emergency Procedures (E-0081)
Oncology Associates Physician Conference 7/4/91-7/7/91 (E-0091-E-0092)
Memo to Medical Directors and Physicists re: survey meter policy and room locking (E-0179)
Letter to NRC re: Quality Management Program (E-0296-E-0299)
Role of Brachytherapy Nurse (E-0876-E-0881)
Continuing Education In-Service Program for Radiation Therapy (E-0893-E-0898)
Radiographic Exposure Guidebook (E-0899-E-0910)
HDR Technical Presentation by Bernard Rogers, M.D. - 2/92 (E-0911-E-0928)
Omnitron Training Course Materials and Indication of Attendees - 2/12/91 (E-0929-E-1039)
Policy Manual - Quality Assurance Program (E-1083-E-1163)
System Description of Omnitron HDR (E-0349-E-0365)
Protection Against Radiation from Brachytherapy Sources (E-0366-E-0465)

Minutes of Harrisburg Cancer Center, Radiation Safety Meeting, 12/8/92, forwarded by Amirul Hoque, Ph.D. to David E. Cunningham, Ph.D.
Minutes of Oncology Services, Inc., a physics department meeting, 9/3/91
Minutes of Harrisburg Cancer Center Radiation Safety Committee Meeting, Monday, 2/4/91
ALARA Program, Harrisburg Cancer Center, 2/4/91
NRC Safety Inspection Report, Mahoning Valley Cancer Center, 7/8/91 Memorandum
Memorandum dated 12/20/91 re: Nuclear Regulatory License regarding training
Miscellaneous service related communications with Omnitron International, Inc.
Memoranda re: HDR training review
Omnitron training provided at Oncology Services, Inc. centers
Minutes of 12/21/92 meeting of Harrisburg Cancer Center Radiation Safety Meeting
Omnitron High Dose Rate Afterloader Emergency Procedures
Acceptance Testing and HDR Equipment Evaluation, David E. Cunningham, Ph.D., William X. Ying, Ph.D.
Radiation Orientation Vouchers
Atlantic Symposium, Outline, The Role of the Nurse in Brachytherapy
Credit Documentation Sign-in record, HDR Course
Course Description: High Dose Rate Afterloading Brachytherapy
Memo regarding HDR policies dated 12/1/92
Minutes of Harrisburg Cancer Center Radiation Safety Committee Meeting, Friday, June 28, 1991
State of Illinois, Department of Nuclear Safety, Radioactive Material Licenses, policy manual, patient care evaluations, quality assurance programs for radiation oncology, Oncology Services Corporation
Oncology Services Corporation, Department of Physics, Safety Review Course, 2/6/93
Minutes of Harrisburg Cancer Center, Radiation Safety Meeting, 12/8/92, forwarded by Amirul Hoque, Ph.D. to David E. Cunningham, Ph.D.
Minutes of Oncology Services, Inc., a physics department meeting, 9/3/91
Minutes of Harrisburg Cancer Center Radiation Safety Committee Meeting, Monday, 2/4/91
ALARA Program, Harrisburg Cancer Center, 2/4/91
NRC Safety Inspection Report, Mahoning Valley Cancer Center, 7/8/91 Memorandum
Memorandum dated 12/20/91 re: Nuclear Regulatory License regarding training
Miscellaneous service related communications with Omnitron International, Inc.
Memoranda re: HDR training review
Omnitron training provided at Oncology Services, Inc. centers

Minutes of 12/21/92 meeting of Harrisburg Cancer Center Radiation Safety Meeting

Course Description: High Dose Rate Afterloading Brachytherapy

Memo regarding HDR policies dated 12/1/92

Minutes of Harrisburg Cancer Center Radiation Safety Committee Meeting, Friday, June 28, 1991

Instruction Manual, Omnitron High Dose Rate Remote Afterloader, P-000568 to P-000589

The following documents are within P-000674 to P-0010015:

a. Greater Pittsburgh GPCC HDR Treatment Records;
b. Memo to Medical Directors/Physicists from David E. Cunningham, Ph.D., dated 12/1/92 re: HDR policies;
c. Oncology Services Corporation, Department of Physics, Quality Assurance Forms;
d. HDR Safety Check Lists; and
e. Omnitron 2000 Computer Screen Printouts re: Source Calibration Activity
f. Omnitron 2000 Training, P-000001 to P-000112;
g. Oncology Services Corporation, Department of Physics, HDR Treatment Manual, P-000113 to P-000567;

Oncology Services Corporation, Department of Physics, Quality Management of Brachytherapy Procedures, High Dose Rate Technique, 7/31/91

Acceptance testing and HDR Equipment Evaluation Documents, H-501 to H-4096

The following documents are from H-4097 to H-30297:

a. Omnitron Technical Service Bulletin No. 4;
b. Omnitron Treatment Planning Manual; and
c. Omnitron 2000 Training Session Course Materials

H-000652 to H-000843 (Training records, radiation safety)

a. Agenda, Memo from Ed Russell re: Agenda for Physicians' Conference scheduled for 2/12-14/93, Orlando, Florida;

Omnitron training provided at Oncology Services, Inc., Centers, List of Participants

Omnitron International, Inc. Certificates of Successful Completion of Omnitron High Dose Rate Treatment Planning System Training Course

Minutes of 12/18/92 Radiation Safety Meeting

Emergency Procedures, Omnitron High Dose Rate Afterloader

Minutes of 12/8/92 Harrisburg Cancer Center Radiation Safety Meeting

Memorandum from David E. Cunningham, Ph.D. re: HDR Policies dated 12/1/92

Course Description: High Dose Rate Afterloading Brachytherapy

Memoranda dated 2/3/93 form Amirul Hoque re: HDR Brachytherapy Seminar given by Dr. Cunningham at Atlantic City in 1992

Review of HDR Brachytherapy by David E. Cunningham, Ph.D. at the Oncology Services Corporation Conference in Atlantic City, 8/14-16/92

Memorandum re: Dr. David Cunningham's Speech of 8/15/92

Memorandum from David E. Cunningham, Ph.D. to all centers, 6/6/91 re: protection against radiation notice

Memorandum re: Nuclear Regulatory License regarding Training Dated 12/20/91
U.S. Nuclear Regulatory Commission, Notice to Employees
Minutes of Harrisburg Cancer Center, Radiation Safety Committee, Friday, June 28, 1991
Minutes of Oncology Services, Inc., Physics Department Meeting, 9/3/91
Minutes of Harrisburg Cancer Center, Radiation Safety Committee Meeting, Monday, 2/4/91
ALARA Program, Harrisburg Cancer Center, 2/4/91
NRC Information Notice No. 91-02: Brachytherapy Source Management
NRC Memorandum re: reporting mishaps involving LLW, Forms prepared for disposal (generic letter 91-02)
NRC Regulatory Guide
Manual Check Procedures for Computer Treatment Planning, Omnitron 2000 HDR Afterloading System, David E. Cunningham, Ph.D., William X. Ying, Ph.D., Physics Department, Oncology Services, Inc., 6/19/92
Videotape - "Radiation Safety In Hospitals"
2/28/91 Sign-in Sheet for IRCC Personnel - videotape "Radiation Safety in Hospitals"
The Oncology Services National System of Patient Care Evaluations/a Radiation Oncology Quality Assurance/Policy Manual, Procedure Manual, Primer on Quality Assurance in Cancer Care, the PCE QA Audit Folder, 1/91, H-000844 to H-000985
Harrisburg Cancer Center HDR Applicator Lists, H-002144 to H-002170
Omnitron Applicator Descriptions From Oncology Services Corporation, Department of Physics, HDR Treatment Manual
Documents H-002176 to H-002313, Acceptance testing and HDR equipment evaluation, David E. Cunningham, Ph.D., William X. Ying, Ph.D.
The following documents at P-001016 to P-001412:

a. Miscellaneous Omnitron 2000 Physics Test Sequence Execution Reports;
b. Harrisburg Miscellaneous Materials Pertaining to Application for Material License-Harrisburg Cancer Center/Oncology Services, Inc.;
c. Miscellaneous calibration reports, 2/22/92 Letter from Mitchell Jarosz to Sherry Siegel re: HDR training certificates and information;
d. Victoreen Instruction Manual;
e. Prima Pak II Instruction Manual;
f. Oncology Services Corporation, Department of Physics, Omnitron 2000 HDR Afterloader, Emergency Procedures;
g. NRC Information Notice 91-71, Training and Supervision of Individuals Supervised by an Authorized User, 11/12/91;
h. Procedure for HDR Planning - Jefferson Radiation Oncology Center, Mitch Jarosz, Revision 0, 8-19-92.

College Course curriculum for education of Rudy Balko, Sharon Rickett and Robbie Ackerson
Outline of Presentation to SUMC Residents, 8/26/92
Oncology Services Corporation, Policy and Procedure Manual for Community Cancer Centers, 1991
Excaliber Contract
Citadel Contract
Materials - Proceedings of the Winter Symposium of the Oncology Services National System of Community Cancer Care, Oncology Associates Physician Conference III, 2/15-18/93
Syllabus - Radiation Therapy of Prostatic Cancer, Prostate Refresher Course, Annual Meeting, American Society for Therapeutic Radiology and Oncology, 10/15-19/90
Outline - Topographic Anatomy - ASTRO, Refresher Course No. 205, October 16, 1990
Instructional Manual, Omnitron High Dose Rate Remote Afterloader
Miscellaneous Notes re: HDR Training
NRC Bulletin 92-03: Release of Patients after Brachytherapy, December 8, 1992
Omnitron International, Inc. - HDR Training Certificates
Mahoning Valley HDR Patient Record Sheets
Exton HDR Patient Record Sheets
Any and all documents produced to the Licensee by the NRC
Any and all official NRC documents, including drafts

as well as any and all other documents identified in response to interrogatories contained herein.

INTERROGATORY 5

Provide all documents listed in response to Interrogatory A4.

RESPONSE:

To the best of the Licensee's knowledge, the staff has copies of all of the listed documents with the exception of the Colgan Autopsy Report undated by Sidney Goldblatt, M.D., the "Radiation Safety In-Service 2/28/91 Videotape "Radiation Safety in Hospitals" sign in sheet for IRCC personnel, the videotape "Radiation Safety in Hospitals". The documents, to the extent the Licensee has them in its possession, shall be made available for inspection and copying in State College, PA. Moreover, certain documents listed above are currently not in the possession of the Licensee and therefore cannot be provided.

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:

See 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:

Yes. Through the testimony of the technologists at the IRCC, Greg Hay and James E. Bauer.

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:

Instruction in all aspects of radiation safety and use of ancillary equipment was provided both formally and informally on a regular basis prior to November 16, 1992, including viewing on 2/28/91 the videotape "Radiation Safety in Hospitals." Because of the continuous nature it is impossible to calculate time devoted to each subject matter. See 2/28/91 IRCC sign-in sheet for said videotape. Further, such general instruction was provided on a regular basis. IRCC personnel were instructed on December 9 and 10, 1991 and again in February, 1992 regarding all Omnitron related matters, including safety and emergency conditions. Instruction was also provided to the authorized user at bi-annual medical meetings.

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:

For the most part, instruction was provided by Rudy Balko, Sharon Rickett and David Cunningham. No employment contracts exist. Rickett and Balko are radiation therapy technologists. Cunningham was the RSO and Director of Physics.

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:

The following individuals all provided services and were contractors or contractor representatives: Greg Hay, Donna Green and James Bauer, M.D. With respect to Licensee comfort, the Licensee engaged highly skilled and competent personnel. See all documents listed in response to Interrogatory 4A which contain the work "Omnitron". See also Laurel Mountain Physics Contract.

INTERROGATORY 5

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

RESPONSE:

The relevant personnel are Balko, Rickett, Ackerson and Bauer.

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:

Yes. These facts will be established through personal testimony. Further, see response to Interrogatory A2.

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:

The hand held meter was used in lieu of the PrimeAlert a number of times. The exact dates are unknown.

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:

The survey meter was used at least once by each technician to measure the source activity on or about February/March 1992. Exact dates of use are unknown at this time.

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 B2.

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:

The services provided by Greg Hay were provided in accordance with his general physics responsibilities. The Licensee hired qualified and competent personnel such as Mr. Hay. See, Laurel Mountain Physics contract, previously produced.

INTERROGATORY 11

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

RESPONSE:

See response to Interrogatory A5. See 2/28/91 IRCC sign-in sheet for videotape.

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:

Yes. See response to Interrogatory A5 and Interrogatory B11.

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:

Omnitron provided instructions regarding HDR, equipment, treatment, safety and emergency procedures. See all documents listed in response to Interrogatory A4 that contain the word "Omnitron".

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.

RESPONSE:

The Licensee hired qualified personnel who the Licensee understood to be well-educated in radiation safety. The Licensee further supplemented the radiation safety knowledge through formal

and informal instruction. See resumes of Balko, Rickett and Ackerson.

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:

Each of the facts set forth in Interrogatory C-1 relates to the NRC-approved Omnitron training session outline and its supporting operating manual, as well as oral representations made by Omnitron personnel. The fact that the NRC approved the Omnitron training session outline renders each of the facts contained in Interrogatory C-1 demonstrative of the reasonableness of the action of the IRCC personnel, including Dr. James E. Bauer. Further, these facts are key to the mind set of the IRCC personnel, including Dr. Bauer.

INTERROGATORY 2

What other facts, other than the ones listed above and the ones pertaining to the actions of Dr. James E. Bauer does the Licensee intend to rely upon to demonstrate that the IRCC personnel complied with 10 CFR 20.201(b)?

RESPONSE:

Any and all facts and circumstances surrounding the November 16, 1992 incident. The Licensee intends to refute any claims of noncompliance with 10 CFR § 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.

RESPONSE:

The IRCC personnel followed emergency procedures on November 16, 1992. They determined under those procedures that no emergency

existed. The requested documents are specifically identified as such in response to Interrogatory A4.

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.

RESPONSE:

The Omnitron unit gave no indication of the improper presence of radiation or an emergency. The difficulty involved the loading of a catheter which the unit indicated. The Authorized User was told this. Bauer, Rickett, Balko and Ackerson were aware of the catheter issue.

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.

RESPONSE:

No other indications communicated difficulty with the HDR treatment.

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:

Based on the internal safety alerts of the Omnitron, it was determined that the source had retracted and that everything was "safe".

INTERROGATORY 7

Describe how the Omnitron 2000 was defective.

RESPONSE:

The wire became embrittled due to a chemical reaction during the shipping process and when the wire retracted, the Omnitron failed to sense that the entire length of the wire was not back in the safe.

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:

Omnitron representatives consistently and repeatedly informed the Licensee and its personnel that the wire could not break. The Licensee believes this fact was written in documentation that was provided to the IIT Team and a copy was not maintained by the Licensee.

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.

RESPONSE:

Rudy Balko and Robbie Ackerson saw it flash when they were in the room.

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 of another individual at the IRCC, identify that individual(s).

RESPONSE:

See response to Interrogatory C9. Dr. Bauer was told by Balko that it had flashed after Bauer was in the room. Ackerson and Rickett were aware that it had flashed.

INTERROGATORY 11

On November 16, 1992, did any of the IRCC personnel unplug, 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.

RESPONSE:

Balko adjusted the plug to the PrimeAlert when it blinked. He believed the plug was loose. After it was adjusted, it quit blinking.

INTERROGATORY 12

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.

RESPONSE:

No.

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.

RESPONSE:

No.

INTERROGATORY 14

Describe any and all occurrences, prior to November 16, 1992 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 c 'unication or training was provided to the IRCC personnel regardin, each malfunction. Provide all supporting documentation.

RESPONSE:

On one or two occasions, the PrimeAlert continuously flashed where no radiation existed. The PrimeAlert was replaced.

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:

Licensee believes that Greg Hay checked the room radiation monitor on the morni g of November 16, 1992 and the PrimeAlert flashed red when the check source was placed close to it.

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:

License Condition 17, in part, states that "in the event of failure of the room monitor, no personnel will enter the room without a 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.

RESPONSE:

There was no reason to believe an emergency condition existed that would necessitate such response.

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.

RESPONSE:

There is no greater requirement under 10 CFR Part 35, Subpart G or 10 CFR § 20.201(b) than the survey performed.

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.

RESPONSF:

Personnel involved with HDR:

Richard M. Yelovich - Medical Director/Authorized User
Paula R. Salanitro - Physicist
Mark A. Batog - RTT/Dosimetrist

See generally Transcript of Investigative Interview of Dr. Richard M. Yelovich at 5, 6, 11, 12, 16-18, 22, 25; See generally Transcript of Investigative Interview of Mark A. Batog at 5, 12, 13, 29; See generally Transcript of Investigative Interview of Paula R. Salanitro at 11, 13, 16, 18, 19, 23, 24. Documentation available in State College, PA.

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:

Personnel involved with HDR:

David J. Moylan - Medical Director/Authorized User
Karen Wagner - Physicist

See generally Transcript of David J. Moylan at 10; Transcript of Karen Wagner at 9-11. Documentation available for copying in State College, PA.

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:

(a) Richard M. Yelovich, M.D. - Medical Director

(b) David J. Moylan, III, M.D. - Medical Director

See Transcript of Investigative Interview of Richard M. Yelovich at 6, 11, 12, 16, 17, 18, 22, 25. See Transcript of Investigative Interview of David J. Moylan, III, at 12, 20, 24.

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 Transcript of Investigative Interview of Dr. Richard M. Yelovich at 16, 17; See Transcript of Investigative Interview of Mark A. Batog at 15-17; See Transcript of Investigative Interview of Paula R. Salanitro at 19, 20.

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 Transcript of Investigative Interview of David J. Moylan, III, at 20-24.

INTERROGATORY 6

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

RESPONSE:

No personnel at the Exton facility, prior to December 8, 1992, performed unsupervised HDR treatments.

No personnel at the Lehighton facility, 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 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 Interrogatories DE, D4, D5, D6.

Karen Wagner was involved in HDR related matters with Dr. Moylan and/or Dr. Hasan. Paula Salanitro was involved with HDR related matters with Dr. Yelovich.

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:

Yes.

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:

David Cunningham, Ph.D. - Radiation Safety Office/Director of Physics
Karen Wagner - Physicist
Paula Salanitro - Physicist
Richard Yelovich, M.D. - Medical Director
William Ying, Ph.D. - Physicist
Bernard Rogers, M.D. - Director

To the extent they exist, see Citadel and Excaliber contracts produced and listed in response to Interrogatory A4.

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:

Review and understanding of the referenced matters was provided by the relevant authorized users, physicists, Ann Wright, Donna Green and GammaMed personnel. The Licensee employed with and/or contracted with qualified personnel. See all documents listed in response to Interrogatory A4 that the word "Omnitron" or "GammaMed".

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:

Licensee hired qualified personnel who the Licensee understood to be well-educated and, through previous formal education, to be familiar with fundamental principles of radiation safety. See resumes.

See Transcript of Investigative Interview of Dr. Richard M. Yelovich at 6, 7; See Transcript of Investigative Interview of Mark A. Batog at 5-6; See Transcript of Investigative Interview of Paula R. Salanitro at 11, 12; See Transcript of Investigative Interview of Karen Wagner at 11; See Transcript of Investigative Interview of Dr. Hasan at 14.

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 above facts clearly would not exist if corporate management was not providing adequate oversight. Dr. Cunningham, Dr. Yelovich, Dr. Moylan, Dr. Bauer, Dr. Derdel, Rudy Balko, Sharon Rickett, Dr. Rogers, Dr. Tokars, Dr. Unal, Mitch Jarosz, Jenny Johansen, Gilbert Lawrence, Greg Hay, Dr. Ying, Paula Salanitro,

Mark Batog, Karen Wagner, Amirul Hoque. See response to Interrogatory A4.

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:

Any and all other circumstances existing 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;

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:

Yes. The Atlantic City Conference covered each of the above. It was held in August, 1992. See Amirul Hoque, Ph.D. statement, which has previously been provided to the NRC. See also photocopies of slides provided to the NRC; Statement of Robert Davis, Ph.D. See also Atlantic City Agenda and sign-in sheets.

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:

The NRC is in possession of a Bally Hotel and Casino generated list of attendees to the Atlantic City Conference, as well as "Atlantic City - Sign-In Sheets" previously produced.

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:

Attendance at the Atlantic City sessions was strongly encouraged by the Licensee.

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 all aspects of the Atlantic City conference, including travel and hotel.

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 does not know what or which "in-service training" the NRC is referring to. If the NRC would be more specific as to the timing and type of "in-service training" it is referring to the Licensee will answer fully within 5 business days.

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 7.

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:

Dr. Cunningham reviewed operations relating to HDR usage and physics at meetings.

Oncology Associates Physician Conference #3, Winter Symposium, Mt. Laurel, Poconos, PA, February 15-18, 1991

Oncology Associates Physician Conference 7/4/91 - 7/7/91 (E-0091-E-0092)

Materials - Proceedings of the Winter Symposium of the Oncology Services National Systems of Community Cancer Care, Oncology Associates Physician Conference III, 2/15-18/93

Agenda for Physician Conference, February 12-14, 1993

Hershey Agenda 9/14/90-9/16/90

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:

Dr. Bauer
Dr. Cunningham
Dr. Lawrence
Dr. Yelovich
Dr. Unal
Dr. Rogers
Dr. Moylan
Dr. Tokars

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:

Dr. Cunningham generally reviewed the above at relevant conferences. See response to Interrogatory E9.

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:

See response to Interrogatory E3. Further, Dr. Ying, Dr. Cunningham, Karen Wagner and Paula Salanitro regularly provide formal and informal instruction to the Exton and Lehighton personnel, including but not limited to, Dr. Yelovich, Dr. Moylan, Paula Salanitro and Karen Wagner and Mark Batog. Further, Ann Wright, Omnitron personnel and GammaMed personnel provided instruction.

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:

Yes. See response to Interrogatories E3 and E12.

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 E12.

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 E12.

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:

Personnel were trained in at least day long Omnitron sessions as well as multiple practice and review sessions. See response to Interrogatory 12.

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:

No unsupervised HDR treatments were done.

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:

It is unknown how many times Dr. Cunningham visited. However, Dr. Ying, at the request of Dr. Cunningham, visited the Lehighton facility on multiple occasions in the six to nine month period prior to the December 8, 1992 inspection. Dr. Ying was there to teach and assist in all aspects of HDR matters, including radiation safety. All personnel involved with HDR, previously listed.

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:

See response to Interrogatory E18.

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:

Dr. Cunningham's contacts averaged at least weekly and as necessary, related to HDR procedures. His contacts were with Karen Wagner, David Moylan, M.D. and ancillary personnel.

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:

To the extent they exist, Harrisburg Cancer Center Bell Telephone Records previously were produced to the NRC by the Licensee. No telephone logs or fax sheets were maintained.

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 response to Interrogatory E18. See also Mahoning Valley HDR Patient Record Sheets (previously produced).

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:

Yes. The documents were kept in the physicist's office. Dr. Yelovich and Paula Salanitro.

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:

Instruction for these 6 days included all aspects of HDR related matters, including safety and emergency conditions.

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?

RESPONSE:

Dr. Moylan was generally aware of the license terms and conditions.

INTERROGATORY 26

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

RESPONSE:

Yes.

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.

RESPONSE:

No. Dr. Moylan recalls a general conversation about whether he knew about the Indiana incident.

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:

"Emergency Procedures" have been previously produced.

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:

License Condition 17, in part, requires a review of the situation where the source does not retract.

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:

Yes. See generally testimony of Copenhagen at 21. Emergency procedures were reviewed by Dr. Ying and Paula Salanitro and Karen Wagner. See Omnitron certificates listed in response to Interrogatory A4.

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:

The emergency procedures were posted on the console cart, where relevant personnel knew they were located.

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 Transcript of Karen Wagner at 22. The key at Exton was kept in a cabinet in the treatment room.

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:

The key to the linear accelerator at Exton was kept in a cabinet in the treatment room when not in use. The key to the accelerator at Lehighton was kept in a container when not in use.

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:

Exton Personnel were confused by the NRC's term "Quality Management". Relevant personnel were aware of the Quality Management Program and the NRC inspectors confused the personnel.

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:

Dr. Yelovich
Paula Salanitro
Mark Batog

All of the above were generally knowledgeable and had been taught by Dr. Ying, Dr. Cunningham, Omnitron and/or Paula Salanitro.

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 response to Interrogatory 35. See 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.

RESPONSE:

See NRC transcript of Dr. Bernard Rogers at 46.
See NRC transcript of Dr. Richard Yelovich at 8.
See NRC transcript of Dr. David J. Moylan, III, M.D. at 63.

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 transcript pages referenced in the response to Interrogatory E37.

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:

In the early part of December 1992 at Indiana, Life Care, Exton and Mahoning Valley.

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:

The cited language does not evidence any attempt on the part of Dr. Cunningham to delegate RSO tasks or responsibilities. As such, there is no need to address the difference between such tasks and RSO responsibilities.

INTERROGATORY 2

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

RESPONSE:

The December 18, 1993 letter speaks for itself. Further discernment of the purpose of the letter should be obtained by the NRC from Dr. Cunningham.

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:

See response to Interrogatory F1.

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:

See response to Interrogatory F1.

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 response to Interrogatory F1.

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.

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 Transcript of Investigative Interview of Gilbert Lawrence at 25-30; Abdurrahman Unal at 32; Mitch Jarosz at 13-20; Roger Tokars at 2-17. The conduct indicates that a high quality program existed which would indicate that a suspension was wholly inappropriate.

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:

The fullest response can be made by illustration. For example, the emergency procedures at Exton were posted on the cart so that the purpose of the regulation was achieved without increased public safety risk. Therefore, any enforcement against OSC on this type of basis is lacking purpose, rationale or intellect.

REQUEST FOR ADMISSIONS

1. 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.

ANSWER:

Denied as stated. Dr. Bauer was first aware when he was already in the treatment room that the light had previously flashed, however, it was not flashing during his said presence.

2. 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.

ANSWER:

Denied as stated. Dr. Bauer and the radiation therapy technologists knew that a genuine alarm of the room radiation monitor meant that there was radiation present in the area.

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

ANSWER:

Admitted.

Respectfully submitted,

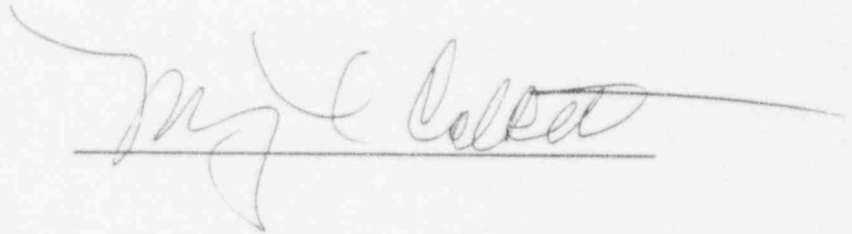
Marcy L. Colkitt
Pa. I.D. No. 53447
P.O. Box 607
Indiana, PA 15701-0607
(412) 463-3570

Joseph W. Klein
Reed Smith Shaw & McClay
435 Sixth Avenue
Pittsburgh, PA 15219

Dated: June 10, 1994

VERIFICATION

The undersigned officer of Oncology Services Corporation verifies that 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 Dated June 10, 1994 is true and correct to the best of the Licensee's knowledge, information or belief.



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OFFICE OF SECRETARY
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UNITED STATES OF AMERICA
NUCLEAR REGULATORY COMMISSION

BEFORE THE ATOMIC SAFETY AND LICENSING BOARD

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

CERTIFICATE OF SERVICE

I hereby certify that copies of the June 10, 1994 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, postage prepaid, this 10th day of June, 1994:

G. Paul Bollwerk, III, Chairman
Administrative Judge
Atomic Safety & Licensing Board
U.S. Nuclear Regulatory Commission
Washington, DC 20555

Dr. Charles N. Kelber
Administrative Judge
Atomic Safety & Licensing Board
U.S. Nuclear Regulatory Commission
Washington, DC 20555

Marian L. Zobler
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Dr. Peter S. Lam
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U.S. Nuclear Regulatory
Commission
Washington, DC 20555
ATTN: Docketing & Service
Section

Office of Commission
Appellate Adjudication (1)
U.S. Nuclear Regulatory
Commission
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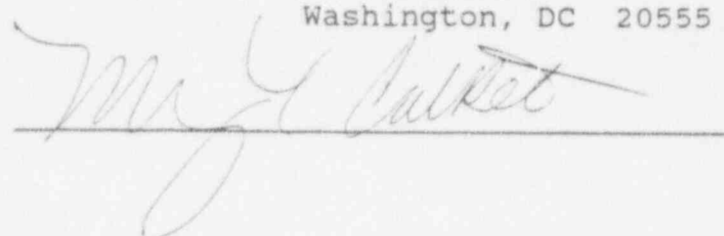

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