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February 18, 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	)	EA No. 93-006
License No. 37-28540-01)	)	

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

INTRODUCTION

Pursuant to 10 C.F.R. §§ 2.740, 2.740b, and 2.744, and the Atomic Safety and Licensing Board's (Board) Order (Prehearing Conference Order), dated February 1, 1994, the staff of the Nuclear Regulatory Commission (Staff) hereby files its response to "Licensee's First Set of Interrogatories, First Request for Production of Documents, and First Request for Admissions Directed to the NRC Staff".[1]

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[1] The Board's Order provided that the Staff should file its answers to those interrogatories and requests for admissions in the Licensee's January 3, 1994 discovery request, as modified during the prehearing conference, to which it does not have a pending objection by February 14, 1994. On February 14, 1994, Counsel for the Staff requested and received from the Licensee's Counsel an extension of time in which to file the Staff Responses until February 18, 1994. In addition, as noted in the prehearing conference, soon after the service of the Staff's response, Counsel for the Staff will arrange with Counsel for the Licensee an appropriate time and place for producing those documents subject to the Licensee's request, which are not otherwise protected.

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GENERAL OBJECTIONS

The following general objections are made to Oncology Services Corporation's (Licensee) discovery requests. The Staff objects to the production of documents to the extent that they call for the disclosure of privileged attorney client materials. Those documents so privileged are specified below. The Staff objects to the interrogatories and document requests to the extent that they require identification of the home addresses and telephone numbers of Staff employees or contractors who are protected from such disclosure by the Privacy Act, 5 U.S.C. § 552, and 10 C.F.R. § 2.790(a)(6) of the Commission's regulations. The disclosure of such information is irrelevant and unnecessary for a proper decision in this proceeding given the Staff's identification of those persons' b siness addresses and telephone numbers.

In response to the Licensee's requests, the Staff has identified certain documents which are the subject of a protective order granted by the Board in its February 1, 1994 Order. Those documents have been designated with an asterisk and will not be produced until the appropriate time.

STAFF RESPONSE TO LICENSEE'S DISCOVERY REQUESTS

I. GENERAL DISCOVERY REQUESTS

A. Interrogatories

INTERROGATORY 1

Please identify all persons interviewed, questioned, deposed or from whom statements were in any other fashion taken in connection with any proceeding involving the Order.

RESPONSE

The following individuals were either interviewed or questioned regarding the bases for the Order Suspending License.

Oncology Services Corporation, Corporate Headquarters

Douglas Colkitt, M.D.	President, Oncology Services Corporation
David Cunningham, Ph.D.	Former Radiation Safety Officer
Bernard Rogers, M.D.	Radiation Oncologist

Indiana Regional Cancer Center, Indiana, Pennsylvania

James E. Bauer, M.D.	Medical Director
Gregory Hay	Physicist
Sharon Rickett	Chief Radiation Therapy Technician
Rudy Balko	Radiation Therapy Technician
Robbie Ackerson	X-Ray Technician

Mahoning Valley Cancer Center, Lehighton, Pennsylvania

David J. Moylan, III, M.D.	Medical Director
Abne Hasan, M.D.,	Staff Physician
Karen E. Wagner	Physicist (Consulting)
Richard Croley	Chief Radiation Therapy Technologist
Barbara Perkins	Radiation Therapy Technologist

Exton Cancer Center, Exton, Pennsylvania

Richard Yelovich, M.D.	Medical Director
Paula Salinitro	Medical Physicist
Mark Batoj	Dosimetrist
Lorraine Copenhagen	Chief Radiation Therapy Technologist
Susan Gosney	Radiation Therapy Technologist

INTERROGATORY 2

Please identify all persons whose testimony or statements you intend to introduce at any proceeding involving the Order.

RESPONSE

At this time, the Staff intends to introduce at any proceeding involving the Order the testimony of the following individuals. If this list is modified, the Staff will so notify the Licensee.

Staff of the Nuclear Regulatory Commission

Dr. Carl Paperiello	Director, Division of Industrial and Medical Nuclear Safety, Office of Nuclear Materials Safety and Safeguards (NMSS), U.S. Nuclear Regulatory Commission, Washington, D.C. 20555 (301) 504-2659
Dr. John Glenn	Chief, Medical, Academic, and Commercial Use Safety Branch, NMSS, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555 (301) 504-3418
Dr. Mohamed Shanbaky	Chief, Research & Development Section, Division of Radiation Safety and Safeguards (DRSS), Region I, U.S. Nuclear Regulatory Commission, 475 Allendale Road, King of Prussia, Pennsylvania (610) 337-5209
Joseph Delmedico	Senior Enforcement Specialist, Office of Enforcement, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555 (301) 504-2739

Penny Nessen	Health Physicist, Medical Inspection Section, DRSS, Region I, U.S. Nuclear Regulatory Commission, 475 Allendale Road, King of Prussia, Pennsylvania (610) 337-5169
James Dwyer	Senior Health Physicist, Medical Inspection Section, DRSS, Region I, U.S. Nuclear Regulatory Commission, 475 Allendale Road, King of Prussia, Pennsylvania (610) 337-5309
Judith Joustra	Chief, Effluent and Radiological Protection Section, DRSS, Region I, U.S. Nuclear Regulatory Commission, 475 Allendale Road, King of Prussia, Pennsylvania (610) 337-5205
Pamela Henderson	Senior Health Physicist, Medical Licensing Section, DRSS, Region I, U.S. Nuclear Regulatory Commission, 475 Allendale Road, King of Prussia, Pennsylvania (610) 337-6952
Ihor Czerwinskyj	Health Physicist, Medical Inspection Section, DRSS, Region I, U.S. Nuclear Regulatory Commission, 475 Allendale Road, King of Prussia, Pennsylvania (610) 337-5311

INTERROGATORY 3

Please identify all documents or other items of tangible evidence you intend to introduce at any proceeding involving the Order.

RESPONSE

At this time, the Staff intends to introduce the following documents in this proceeding. If this list is modified, the Staff will timely notify the Licensee.

NRC Byproduct Materials License 37-28540-01 (hereinafter License), including all the documents incorporated by reference into the license.

Regulatory Guide 10.8, Revision 2

Inspection Report No. 030-31765/92-001

Supplement to Part 35 Reporting Requirements, dated January 6, 1993, provided by the Licensee to the NRC

Supplement to Part 20 and 30 Reporting Requirements, dated January 6, 1993, provided by the Licensee to the NRC

December 18, 1992 letter of Dr. David Cunningham to Medical Directors

"Loss of an Iridium-192 Source and Therapy Misadministration at Indiana Regional Cancer Center Indiana, Pennsylvania, on November 16, 1992," NUREG-1480 (hereinafter, IIT Report)

Draft Inspection Report of Indiana Regional Cancer Center, dated December 2-3, 1992*

INTERROGATORY 4

Please identify any regulatory requirements, licensing guidance documents, inspection guidance documents, or other guidance documents addressing brachytherapy generally that were effective on November 16, 1992.

RESPONSE

Various parts of Title 10, Code of Federal Regulations may apply to brachytherapy. All sections of 10 C.F.R. Parts 19 and 20 would apply depending on the situations encountered in the use of byproduct material. 10 C.F.R. Part 30 is generally applicable to all byproduct material. 10 C.F.R. Part 35 applies to brachytherapy, except for Subparts D, E, F, H, and I. 10 C.F.R. Part 71 applies to transportation, and Subparts A, B and C would be most applicable to brachytherapy. 10 C.F.R. Parts 170 and 171 describe fees assessed to NRC licensees including licensees authorizing the use of byproduct material for brachytherapy.

NRC Regulatory Guide 10.8 is generally applicable to licensing of medical uses of byproduct material. Those sections specific to unsealed byproduct material including radioactive drugs would not be relevant to brachytherapy. Division 8 - Occupational Health of the Regulatory Guide Series is generally applicable. Division 8 Guides most likely to apply are: 8.1-8.4, 8.6, 8.7, 8.10, 8.13, 8.18, 8.23, 8.28, and 8.29. Regulatory Guide 8.33, "Quality Management Program," has sections specific to brachytherapy and high dose rate remote brachytherapy. Policy and Guidance Directive 86-4, "Information Required for Licensing Remote Afterloading Devices," provides specific licensing guidance for those devices. Inspection policy for medical facilities is contained in Manual Chapter 2800, and guidance on inspecting medical facilities is contained in Manual Chapter 87100 of the Inspection Manual.

INTERROGATORY 5

Please identify any regulatory requirements, licensing guidance documents, inspection guidance documents, or other guidance documents specifically addressing HDR brachytherapy that were effective on November 16, 1992.

RESPONSE

Specific regulation for HDR is limited to the definition of a written directive in 10 C.F.R. § 35.2. Regulatory Guide 8.33, "Quality Management Program," has sections specific to HDR brachytherapy. Policy and Guidance Directive 86-4, "Information Required for Licensing Remote Afterloading Devices," provides specific licensing guidance for HDR.

INTERROGATORY 6

With respect to the September 4, 1991 NRC inspection of OSC at the Harrisburg Cancer Center, please identify:

a. the Chief of the Region I Medical Licensing Section who was a member of the inspection team;

b. the senior inspector who was a member of the inspection team;

c. the qualifications of the two inspectors; and

d. any field notes, inspection reports, transcriptions, summaries, records, notes or other documents relating to the inspection.

RESPONSE

a. Jenny Johansen Chief, Medical Inspection Section A, Nuclear Materials Safety Branch, DRSS, Region I, U.S. Nuclear Regulatory Commission, 475 Allendale Road, King of Prussia, Pennsylvania (610) 337-5304

b. Judith Joustra

c. The qualifications of the two inspectors are attached hereto as Attachment 1.

d. Nuclear Medicine Inspection Field Notes for Inspection Report No. 91-001, dated September 4, 1991.

Letter to David Cunningham, Harrisburg Cancer Center from Jenny Johanson, NRC, re: Routine Inspection No. 91-001, dated September 26, 1991.

Notice of Violation, Harrisburg Cancer Center, Harrisburg Pennsylvania, Docket No. 030-31765.

Letter to NRC, Region I from David E. Cunningham, Radiation Saf ty Officer, Oncology Services Corporation, re: Routine Inspection No. 91-001, dated October 15, 1991.

Letter to David E. Cunningham, Radiation Safety Officer, Oncology Services Corporation, from Jenny M. Johansen, NRC, re: Inspection No. 030-31765/91-001, dated January 13, 1992.

INTERROGATORY 8

Please identify any documents generated by the NRC or in its possession or control that report on, analyze, compare, or otherwise relate to any training proffered or provided with respect to the following HDR afterloaders:[2]

b. the Omnitron 2000.

RESPONSE

The following documents relate to the training provided by the manufacturer of the Omnitron 2000 HDR afterloader:

IIT Report

Listing of training afforded by Omnitron for Personnel at the Nine OSC Centers with HDR Remote Afterloaders, with dates of training.

Letter to L. Ostrum, NRC consultant, from A. Wright, Omnitron, dated December 17, 1992, containing training given by Omnitron to IRCC

Omnitron Course Material, including emergency procedures in the event of a source wire retract failure

Letter from Anne Write, Omnitron, to NRC, dated December 22, 1992, re: training

Omnitron training policy

Omnitron Training Manual

B. Requests for Production

Please produce:

1. all transcriptions, summaries or other notes of persons interviewed, questioned, deposed or from whom statements were in any other fashion taken in connection with this license suspension proceeding;

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[2] Interrogatory I.A.8.b was objected to by the Staff.

2. a copy of what the NRC purports to be the complete license at issue in this proceeding; and

3. all documents and other evidence identified in your answers to the preceding nine interrogatories.

RESPONSE

The Staff will make available the documents requested in request numbers 2 and 3 to the extent that a privileged has not been asserted.

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

A. Interrogatories

INTERROGATORY 1

The Order states, "During that time period, the patient incurred a radiation dose estimated at greater than one million rads to the wall of the bowel." In connection with that statement, please identify:

a. who made the identified estimation of radiation dose;
b. the basis or bases for that estimation; and
c. any documents or other records relating to that estimation.

RESPONSE

a. David E. Cunningham, RSO

James E. Bauer, M.D.

b. The dose estimation was based on a 3.6 Ci source and including the effects of tissue absorption and scatter, at 1 cm, the dose was 1.6×10^6 cGy. A distance of 1 cm from the location of the source in the patient would include the wall of the bowel.

c. Supplement to Part 35 Reporting Requirements, dated January 6, 1993

Supplement to Part 20 and 30 Reporting Requirements, dated January 6, 1993

Addendum of Narrative Report of December 10, 1992, attached to Supplement to Part 20 and 30 Reporting Requirements, dated December 23, 1992.

IIT Report, Section 7.2.4, at 7-6.

INTERROGATORY 3

The Order states, "Further, failure of the radiation monitor requires termination of treatment until the monitor is repaired and no personnel will be permitted to enter the room without a portable survey meter or audible dosimeter." In connection with that statement, please identify:

a. what the NRC contends constitutes a "failure of the radiation monitor;"
b. what the NRC contends constitutes "repair" of the radiation monitor;
c. any persons, documents or other evidence that support the NRC's understanding either of what constitutes a "failure of the radiation monitor" or what constitutes "repair" of the radiation monitor.

RESPONSE

a. A radiation monitor has failed if it is incapable of performing its intended function. As used in the Order and placed in the right context the "failure of radiation monitor" issue was raised by Licensee personnel as a possible reason as to why they did not equate the alarming radiation monitor with the presence of radiation in the area. Rudy Balko, the technologist, stated that the Prime-Alert would keep flashing when the accelerator machine was shut off. The technologist also informed the IIT that on one separate occasion when the Prime-Alert was "flashing" after the accelerator was shut off, he checked the area with a survey meter to make sure that there was no radiation and

verified that there was no radiation even though the area radiation monitor was "flashing."

b. Repair means restoring the radiation monitor to where it is capable of performing its intended function. In the context of the Suspension Order, based on what Rudy Balko told the IIT, repair of the Prime-Alert would require that it would only alarm where there was the presence of radiation.

c. Transcript of Interview of Rudy Balko to the IIT, December 4, 1992.*

The NRC definition of "fail" is consistent with the dictionary definition: "to be lacking or insufficient, to fall short." *See* Webster's Ninth New Collegiate Dictionary. 10 C.F.R. 35.51(c) requires an operational check of survey meters each day of use.

INTERROGATORY 4

The Order states, "In addition, 10 C.F.R. 20.201(b) requires that the Licensee make such surveys as (1) may be necessary to comply with the regulations in 10 C.F.R. Part 20 and (2) are reasonable under the circumstances to evaluate the extent of radiation hazards that may be present." In connection with that statement, please identify:

a. whether you contend that on November 16, 1992 the Licensee failed at IRCC to make a survey that was necessary to comply with the regulations in 10 C.F.R. Part 20;

b. the basis or bases for making that contention;

c. whether you contend that on November 16, 1992 the Licensee failed to make a survey and that failure was not "reasonable under the circumstances to evaluate the extent of radiation hazards that may be present;" and

d. the basis or bases for making that contention.

RESPONSE

a. The Staff contends that on November 16, 1992, the Licensee failed at the IRCC to make a survey that was necessary to comply with the regulations in 10 C.F.R. Part 20.

b. Section 20.201(a) of Title 10 of the Code of Federal Regulations defines survey as an evaluation of the radiation hazards incident to the production, use, release, disposal, or presence of radioactive materials or other sources of radiation under a specific set of conditions. Section 20.201(b)(1) provides that, each licensee shall make or cause to be made such surveys that may be necessary for the licensee to comply with the regulations in this part. When appropriate, such evaluation includes a physical survey of the location of materials and equipment, and measurements of levels of radiation or concentrations of radioactive materials present.

On November 16, 1992, both the Authorized User, Dr. James E. Bauer, and the Technologist, Rudy Balko, responsible for the treatment of the affected patient failed to perform any survey which would comply with the above-stated requirements. In that, when the area radiation monitor Prime-Alert alarmed with a flashing red light indicating the presence of radiation in the area, the assumption was made by Licensee personnel that it was "acting up." Also, the Licensee's physicist stated that the technologist informed him on December 1, 1992, that they did not survey the patient with a survey meter because they believed that the Prime-Alert was malfunctioning as before and did not remember that they should survey the patient. As a result of the failure to properly evaluate the radiation hazards and properly respond to the Prime-Alert alarm, the Licensee failed to comply with numerous requirements in Part 20, such as Section 20.105(b).

c. The Staff contends that on November 16, 1992, the Licensee failed at the IRCC to make a survey that was reasonable under the circumstances to evaluate the extent of radiation hazard that may be present.

d. Under the circumstances in which the Prime-Alert indicated the presence of radiation and the Omnitron 2000 indicated that the source wire was "parked" in a safe position, it would have been reasonable for the Licensee to evaluate the extent of the radiation hazard that may have been present with other method(s), such as utilizing a portable survey meter, to evaluate the presence of radiation in the area.

INTERROGATORY 5

The Order states, "In direct violation of these requirements, and even though a calibrated, operational survey meter was available in the immediate vicinity, neither the physician nor the technologists utilized an audible dosimeter or survey meter upon entering the room, when they apparently believed that the area radiation monitor had malfunctioned and signaled a false alarm." In connection with that statement, please identify:

a. your basis or bases for stating that as the physician and technologists entered the room, they "apparently believed the area radiation monitor had malfunctioned and signaled a false alarm;"

b. any persons providing information to the NRC relating to the statement (regardless of whether such information supports or contradicts the statement);

c. as to each person, the substance of that information; and

d. any transcriptions, summaries, records, notes or other documents relating to the interview, testimony or statements of those persons.

RESPONSE

a. Dr. Bauer, the physician; and Rudy Balko, Sharon Rickett, and Robbie Ackerson, stated to the Incident Investigation Team (IIT) that they either saw or were aware that the Prime-Alert area monitor was in an alarmed condition. Rudy Balko and Sharon Rickett

both stated to the IIT that the Prime-Alert had alarmed multiple times without the presence of radiation in the treatment room, and, they, therefore, assumed that the Prime-Alert had malfunctioned during the November 16, 1992 incident. Rudy Balko stated that sometime during the incident, he had unplugged and replugged the Prime-Alert.

b. Dr. Bauer

Rudy Balko

Sharon Rickett

Robbie Ackerson

Gregory Hay

c. See response to a, above.

d. Transcript of Interview of Dr. Bauer to the Incident Investigation Team (IIT), December 15, 1992*

Transcript of Interview of Rudy Balko to the IIT, December 4, 1992*

Transcript of Interview of Sharon Rickett to the IIT, December 4, 1992*

Transcript of Interview of Robbie Ackerson to the IIT, December 4, 1992*

Transcript of Interview of Greg Hay to the IIT, December 4-5, 1992*

Region I Draft inspection report*

Transcript of IIT entrance interview, dated December 3, 1992*

INTERROGATORY 6

The Order states, "In violation of 10 C.F.R. 19.12, the radiation therapy technologists had not been trained in the use of a survey meter and did not know when to use a survey meter or how to interpret the readings of a survey meter to determine the presence of a radioactive source in the patient or in the area." In connection with that statement, please identify:

a. any persons providing information to the NRC relating to the portion of the statement (regardless of whether such information is corroborative or contradictory) that the radiation therapy technologists had not been trained in the use of a survey meter;

b. any persons providing information to the NRC relating to the portion of the statement (regardless of whether such information is corroborative or contradictory) that the radiation therapy technologists did not know when to use a survey meter;

c. any persons providing information to the NRC relating to the portion of the statement (regardless of whether such information is corroborative or contradictory) that the radiation therapy technologists did not know how to interpret the reading of a survey meter to determine the presence of a radioactive source in the patient or in the area;

d. as to each person identified in response to the immediately preceding subsections a, b and c, the substance of that information;

e. any transcriptions, summaries, records, notes or other documents relating to the interview, testimony or statements of those persons.

RESPONSE

a. Gregory Hay

Dr. Bauer

Rudy Balko

Sharon Rickett

Robbie Ackerson

David Cunningham

b. Same as a.

c. Same as a.

d. Sharon Rickett indicated that no one showed her how to use the surve r, or what it reads, and what a reading on the meter would mean.

Rudy Balko stated he used the survey meter once. In response to questions he confused which scales were more sensitive.

e. Transcript of Interview of Dr. Bauer to the Incident Investigation Team (IIT), December 15, 1992*

Transcript of Interview of Rudy Balko to the IIT, December 4, 1992*

Transcript of Interview of Sharon Rickett to the IIT, December 4, 1992*

Transcript of Interview of Greg Hay to the IIT, December 4-5, 1992*

Transcript of Interview of David E. Cunningham to the IIT, December 17, 1992*

Region I Draft inspection report*

Transcript of IIT entrance interview, dated December 3, 1992*

B. Requests for Production

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

RESPONSE

The Staff will make available documents requested in the above request, to the extent that a privilege has not been asserted or that the documents are not subject to the protective order granted by the Board.

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

A. Interrogatories

INTERROGATORY 1

The Order states, "Dr. Cunningham, who is the RSO named on the License, had not visited the Lehighton facility in the past 6-9 months." In connection with that statement, please identify:

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

b. any NRC action taken against a medical use licensee prior to November 16, 1992, in part or in whole, on the basis that the RSO had not visited one of its facilities in a six to nine month period upon which the Staff relied when issuing the Order;[3]

d. documents regarding any final agency determinations, decisions or orders in any of the actions identified in response to the immediately preceding two subparts;[4]

e. any inquiries made by the NRC with respect to any communications of Dr. Cunningham with the Lehighton facility other than by personal visits during the 6-9 months in question;

f. the substance of those inquiries and the information resulting from responses to those inquiries;

g. any inquiries made by the NRC with respect to any personal visits to the Lehighton facility or other communications with that facility by Dr. William Ying;

h. the substance of those inquiries and the information resulting from responses to those inquiries;

i. any persons providing information with respect to personal visits or other communications of Drs. David Cunningham or William Ying to and with the Lehighton facility; and

j. any transcriptions, summaries, records, notes or other documents relating to the interview, testimony or statements of those persons.

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[3] This interrogatory was modified pursuant to an agreement between the parties at the January 26, 1994 prehearing conference. See Transcript of Prehearing Conference at 64-66. In addition, based on the agreement at the prehearing conference, the Staff believes that it is no longer necessary to answer Interrogatory 1(c).

[4] Since it is the Staff's belief that it is no longer necessary to respond to Interrogatory 1(c), the Staff will respond to Interrogatory 1(d) only to the extent that documents are identifed in relation to the Staff's answer to 1(b).

RESPONSE

a. There is no specific regulatory requirement applicable to this case that delineates the frequency at which the radiation safety officer must conduct visits to each facility listed as a place of use on an NRC license. Several references in 10 C.F.R. Part 35 require periodic actions and documentation by the RSO and immediate notification of the RSO. Section 35.31(b) requires the signature of the RSO for minor changes in radiation safety procedures; section 35.59(d) requires the signature of the RSO for leak test records of sealed sources; section 35.59(g) requires the signature of the RSO on the records of quarterly inventories of brachytherapy sources; section 35.59(i) requires the signature of the RSO on records of surveys performed to measure ambient dose rates around all areas where brachytherapy sources are stored; section 35.415(b) requires immediate notification of the RSO if a patient dies or has a medical emergency.

In the Application for Material License, dated June 1, 1990, Item 10.2, which is incorporated into the License through License Condition 17, the Licensee committed to establish and implement the model ALARA (as low as reasonably achievable) program published in Regulatory Guide 10.8, Revision 2, Appendix G. Appendix G requires that the RSO be in close contact with all users and workers.

Section 35.21(a) requires that the licensee ensure, through the radiation safety officer, that radiation safety activities are being performed in accordance with approved procedures and regulatory requirements in the daily operation of the licensee's byproduct material program. Section 35.21(b) requires that the radiation safety officer establish and

implement various procedures and take various actions described therein. Read together as a whole, the regulations and license condition require that the radiation safety officer establish and maintain a presence at each facility where licensed activities are conducted that is sufficient to ensure that the requirements of the license and Parts 19, 20, 30, and 35 are met in the daily operation of the licensee's facilities.

b. The staff did not refer to, or rely on, any *specific* case or cases when issuing the Order.

d. See response to b, above.

e. In connection with the statement from the Suspension Order that "Dr. Cunningham who is the RSO named on the License, had not visited the Lehighton facility in the past 6-9 months," during the December 8, 1992 inspection at the Lehighton facility, James Dwyer and Pamela Henderson made inquiries with respect to communication of Dr. Cunningham with the Lehighton facility other than by personal visit during the 6-9 month period.

f. In connection with the above statement, during the December 8, 1992 inspection, Ms. Henderson and Mr. Dwyer asked David Moylan, M.D., Abne Hasan, M.D., and Ms. Karen Wagner about their communications with Dr. Cunningham. Ms. Henderson and Mr. Dwyer understood from these inquiries that Dr. Moylan, Dr. Hasan and Ms. Wagner regularly communicated with Dr. Cunningham regarding patient treatment plans, and that Ms. Wagner communicated with Dr. Cunningham regarding the licensed program. These latter communications included a report by Ms. Wagner of a recordable

event, modifications of license procedures and forms by Ms. Wagner, and a request for license documentation by Ms. Wagner.

g. In connection with the above statement, during the December 8, 1992 inspection at the Lehighton facility, Ms. Henderson and Mr. Dwyer made inquiries with respect to personal visits to the Lehighton facility and communications with that facility by Dr. William Ying.

h. Mr. Dwyer and Ms. Henderson asked Dr. Moylan, Dr. Hasan, and Ms. Wagner about personal visits to the Lehighton facility and communications with that facility by Dr. Ying. The inspectors understood from those inquiries that Dr. Ying had visited the Lehighton facility on occasion to change the HDR source, to fill in for Ms. Wagner during HDR therapies performed in her absence, and to provide initial training in the use of the HDR afterloader to Ms. Wagner.

i. David Moylan, M.D., Abne Hasan, M.D., and Karen Wagner provided information with respect to personal visits or other communications of Drs. David Cunningham and William Ying to and with the Lehighton facility.

j. December 23, 1992 Letter from Mr. Richard W. Cooper, II, Director, Division of Radiation Safety and Safeguards, Region I to Douglas R. Colkitt, M.D., President, Oncology Services Corporation enclosing NRC Region I Inspection Report No. 030-31765/92-001.

Inspection Report No. 030-31765/92-001.

INTERROGATORY 2

The Order states, "Dr. David J. Moylan, Medical Director of the Lehighton facility and an authorized user named on the License, indicated that he had not read the terms and conditions of the License and was not aware that Dr. Cunningham was the RSO named on the License." In connection with that statement, please identify:

a. any persons reporting Dr. Moylan made such "indications";

b. any transcriptions, summaries, records, notes or other documents relating to the statement by those persons; and

c. any other evidence supporting that statement quoted above.

RESPONSE

a. In connection with the statement quoted in interrogatory 2, above, James P. Dwyer and Pamela Henderson reported that Dr. Moylan made such "indications."

b. December 23, 1992 Letter from Mr. Richard W. Cooper, II, Director, Division of Radiation Safety and Safeguards, Region I to Douglas R. Colkitt, M.D., President, Oncology Services Corporation enclosing NRC Region I Inspection Report No. 030-31765/92-001.

Inspection Report No. 030-31765/92-001.

The following document is privileged pursuant to the attorney client privilege in that it contains statements made by the Staff at the request of Staff counsel for the purpose of assisting in a legal proceeding. This privilege has not been waived.

Memorandum to: Mohamed M. Shanbaky, Ph.D., Chief, Medical Inspection section, from Jim Dwyer, Senior Health Physicist, Medical Inspection Section, Re: Review of the Oncology Services Corporation February 8, 1993 Response to the January 20, 1993 Order, dated February 12, 1993.

c. The following document is privileged pursuant to the attorney client privilege in that it contains statements made by the Staff at the request of Staff counsel for the purpose of assisting in a legal proceeding. This privilege has not been waived.

Transcript of License Inspection Discussion, dated October 5, 1993.

INTERROGATORY 4

Please identify any other errors the Staff has identified in the Order and any transcriptions, summaries, records or other documents relating to those errors.

RESPONSE

The Staff has not identified any other errors in the Order.

INTERROGATORY 5

The Order states, "At the Exton facility, emergency procedures were not posted at the console of the HDR afterloader as required by the License." In connection with that statement, please identify:

a. what the NRC contends constitutes being "at the console of the HDR afterloader;"

b. any persons, documents or other evidence that support the NRC's understanding of what constitutes being "at the console of the HDR afterloader."

RESPONSE

a. Taken in the context of the Suspension Order and the License, the term "being at the console of the afterloader" means that the emergency procedures should be conspicuously posted near the control console for easy access by operation personnel. During the inspection, the inspectors looked for the emergency procedures near the console, including the adjacent walls and counter top. The inspectors could not locate the procedures. A technologist asked the inspectors what they were looking for. The inspector explained that she was looking for the emergency procedures. The procedures could not be located. After the inspectors left the console area and were in the lunch room, Mrs. Salinitro entered the lunch room with a piece of paper and asked the inspectors a question in effect of if this was what the inspectors were looking for. The inspector said that it was an emergency procedure but that it needed to be filled out and posted. The procedures did not contain site specific information.

b. Application for Material License, dated June 1, 1990, incorporated into the License through License Condition 17.

INTERROGATORY 6

The Order states, "Additionally, although the physicists at the Exton and Lehighton facilities are key personnel who bear responsibility for avoiding or preventing the recurrence of an event such as the November 16 event described in Section II above, the inspectors determined that these individuals did not learn of the event via an appropriate corporate radiation safety communication, but instead learned about the event through the coverage in the news media." In connection with that statement, please identify:

a. any regulatory requirement defining or otherwise addressing "an appropriate corporate radiation safety communication;"

b. any NRC action taken against a medical use licensee prior to November 16, 1992, in part or in whole, on the basis that the licensee had failed to make "an appropriate corporate radiation safety communication upon which the Staff relied when issuing the Order;"[5]

d. documents regarding any final agency determinations, decisions or orders in any of the actions identified in response to the immediately preceding two subparts.[6]

RESPONSE

a. There is no specific regulatory requirement applicable to this case that defines an appropriate corporate radiation safety communication for the November 16, 1992 event at the Indiana Regional Cancer Center. Section 35.21(a) of Title 10 of the Code of Federal Regulations requires that the licensee ensure, through the radiation safety officer,

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[5] This interrogatory was modified pursuant to an agreement between the parties at the January 26, 1994 prehearing conference. See Transcript of Prehearing Conference at 64-66. In addition, based on the agreement at the prehearing conference, the Staff believes that it is no longer necessary to answer Interrogatory 6(c).

[6] Since it is the Staff's belief that it is no longer necessary to respond to Interrogatory 6(c), the Staff will respond to Interrogatory 6(d) only to the extent that documents are identified in relation to the Staff's answer to 6(b).

that radiation safety activities are being performed in accordance with approved procedures and regulatory requirements in the daily operation of the licensee's byproduct material program. Section 35.21(b) requires that the radiation safety officer establish and implement various procedures, including procedures for using byproduct material safely, taking emergency action if control of byproduct material is lost, and training personnel who work in or frequent areas where byproduct material is used or stored. Section 19.12 requires that individuals working in or frequenting any portion of a restricted area be instructed in, among other things, precautions or procedures to minimize exposure. Section 19.12 further requires that the extent of the instruction be commensurate with the potential radiological health protection problem. Read together as a whole, the regulations require that the licensee, through the radiation safety officer, communicate emergency radiation safety information to workers in a manner that is commensurate with the radiological health protection problem.

On October 13, 1988, when the Commission published changes to the "General Statement of Policy and Procedure for NRC Enforcement Actions" (Enforcement Policy), 10 C.F.R. Part 2, Appendix C, the Commission established its expectation that an entity with more than one facility will communicate significant issues to all licensed operations under its control. In the Statements of Consideration for this change to the Enforcement Policy, the Commission wrote:

> Another important change. . . is to consider notice arising out of activities of a licensee at other facilities it controls whether or not under different licenses. This change comes out of the lessons learned from the Tennessee Valley Authority problems but is equally applicable to other reactor and material licensees who hold more than one license or have more than one

> facility or location. If a licensee is aware of a significant issue at one of its facilities that needs corrective action, NRC expects that the licensee will consider the application of corrective action at all other licensed operations it controls.

53 Fed. Reg. 40020 (October 13, 1988).

b. The staff did not refer to, or rely on, any *specific* case or cases when issuing the Order.

d. See response to b, above.

B. Requests for Production

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

RESPONSE

The Staff will make available documents in response to this request, to the extent that a privilege has not been asserted.

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

A. Interrogatories

INTERROGATORY 1

The Order states that "Dr. Cunningham sought to delegate to the Medical Director/Authorized User at each of the satellite facilities the radiation safety officer responsibilities that are assigned to Dr. Cunningham under the terms and conditions of the License. Dr. Cunningham also stated in the letter that it is appropriate for the Medical Director/Authorized User to further delegate the radiation safety responsibilities of the Medical Director/Authorized User to 'the technical support including the physicists and chief technologist.'" In connection with that statement, please identify:

a. any regulatory requirement that was breached by the purported attempted delegation;

b. any NRC action against a medical use licensee prior to November 16, 1992, in part or in whole, on the basis that the RSO of the licensee had sought to make or have others make an improper delegation of responsibilities assigned to the RSO under the license upon which the Staff relied when issuing the Order;[7]

d. documents regarding any final agency determinations, decisions or orders in any of the actions identified in response to the immediately preceding two subparts.[8]

RESPONSE

a. License Condition 11 named Dr. Cunningham as the radiation safety officer. Section 35.21(a) requires that the licensee ensure, through the radiation safety officer, that radiation safety activities are being performed in accordance with approved procedures and regulatory requirements in the daily operation of the licensee's byproduct material program. Section 35.21(b) requires that the radiation safety officer establish and implement various procedures and take various actions described therein. Section 35.13(c) requires that a licensee apply for and receive an amendment before it changes RSO's.

b. At the time that the Order was issued, the Staff was generally aware of prior cases where escalated enforcement action was taken for failure of the radiation safety officer and/or other management officials to exercise appropriate oversight and control over

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[7] This interrogatory was modified pursuant to an agreement between the parties at the January 26, 1994 prehearing conference. See Transcript of Prehearing Conference at 64-66. In addition, based on the agreement at the prehearing conference, the Staff believes that it is no longer necessary to answer Interrogatory 1(c).

[8] Since it is the Staff's belief that it is no longer necessary to respond to Interrogatory 1(c), the Staff will respond to Interrogatory 1(d) only to the extent that documents are identified in relation to the Staff's answer to 1(b).

licensed activities; however, the Staff did not refer to, or rely on, any *specific* case or cases when issuing the Order.

d. See response to b, above.

B. Requests for Production

Please produce:

1. the document NRC contends is the December 14, 1992 letter of Dr. David Cunningham referred to in the Order; and

2. all other documents and other evidence referred to the response to the immediately preceding interrogatory.

RESPONSE

The Staff will make available, in response to request no. 1 the December 18, 1992 letter of David Cunningham referred to in the Order and, in response to request no. 2 the Staff will make the documents requested in the above two requests available, to the extent that a privilege has not been asserted.

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

A. Interrogatories

INTERROGATORY 1

The Order states, "The facts above demonstrate a significant corporate management breakdown in the control of licensed activities wherein key Licensee employees at several satellite facilities do not know the requirements of the NRC License, do not have access to the pertinent License documents, and have not been adequately trained in either the pertinent regulatory requirements or the prc ' ures and instrumentation to be employed to protect themselves and others from radiation exposure." In connection with that statement, please identify:

a. any regulatory requirement defining "a significant corporate management breakdown in the control of licensed activities;"

b. any NRC action taken against a medical use licensee prior to November 16, 1992 in part or in whole on the basis that the licensee had "a significant corporate management breakdown in the control of licensed activities upon which the Staff relied when issuing the Order;"[9]

d. documents regarding any final agency determinations, decisions or orders in any of the actions identified in response to the immediately preceding two subparts.[10]

e. the "key Licensee employees at several satellite who facilities do not know the requirements of the NRC License,"

f. as to each key Licensee employee identified in the immediately preceding subsection of this interrogatory, the requirement of the NRC License as to which that employee was without knowledge;

g. the "key Licensee employees at several satellite facilities who did not have access to the pertinent License documents;"

h. the "key Licensee employees who had not been adequately trained in either the pertinent regulatory requirements or the procedures and instrumentation to be employed to protect themselves and others from radiation exposure;" and

i. as to each key Licensee employee identified in the immediately preceding subsection of this interrogatory, the specific pertinent regulatory requirement(s) and the procedures and instrumentation as to which that key Licensee employee had not been trained.

RESPONSE

a. There is no specific regulatory requirement applicable to this case that defines a "significant corporate management breakdown in the control of licensed activities." Section 35.18 states that the Commission shall issue a license for the medical use of byproduct material if, among other things, the Commission finds the applicant equipped

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[9] This interrogatory was modified pursuant to an agreement between the parties at the January 26, 1994 prehearing conference. See Transcript of Prehearing Conference at 64-66. In addition, based on the agreement at the prehearing conference, the Staff believes that it is no longer necessary to answer Interrogatory 1(c).

[10] Since it is the Staff's belief that it is no longer necessary to respond to Interrogatory 1(c), the Staff will respond to Interrogatory 1(d) only to the extent that documents are identified in relation to the Staff's answer to 1(b).

and committed to observe the safety standards established by the Commission in Title 10, Chapter I for the protection of the public health and safety. Section 35.21(a) requires that the licensee ensure, through the radiation safety officer, that radiation safety activities are being performed in accordance with approved procedures and regulatory requirements in the daily operation of the licensee's byproduct material program. Section 35.21(b) requires that the radiation safety officer establish and implement various procedures described therein. Read together as a whole, the statute and regulations require that the licensee, through the radiation safety officer, establish and maintain control over licensed activities sufficient to ensure that the requirements of the license and 10 C.F.R. Parts 19, 20, 30, and 35 and the NRC license are met in the daily operation of the licensee's facilities.

b. At the time that the Order was issued, the Staff was generally aware of prior cases where escalated enforcement action was taken for lack of management control over licensed activities; however, the Staff did not refer to, or rely on, any *specific* case or cases when issuing the Order.

d. See response to b, above.

e. The key Licensee employees at several satellite facilities who do not know the requirements of the NRC License are:

Mahoning Valley Cancer Center

David Moylan, M.D.

Exton Cancer Center

Paula Salinitro

Dr. Yelovich

Mark Batoj

Lorraine Copenhagen

f. Dr. Moylan stated he was not aware that Dr. Cunningham was the RSO listed on the license and that he had not read the license.

The technologists, Mark Batoj and Lorraine Copenhagen, stated that they had not received training from OSC on specific license conditions, the contents of the application, or regulations. The above-mentioned staff, including Mrs. Salinitro were not aware that Dr. Cunningham was RSO. In addition, Mark Batoj stated that their training did not include an emergency procedure, "dry run," which was required by the License, and he did not know that it was a requirement of the License to keep the activation key to the linear accelerator console and the activation key for the HDR unit console on the same key ring. In addition, Mark Batoj and Lorraine Copenhagen were unaware of the Licensee's quality management program, not familiar with 10 C.F.R. § 35.32, Quality Management Program, and were unaware of whether or not they were implementing the Licensee's program.

g. During the December 8, 1992 inspection, the Inspectors who inspected the Exton Cancer Center determined that the documents incorporated into the License were not

available at the Exton Cancer Center. The following individuals, therefore, did not have access to the pertinent license documents:

Paula Salinitro

Dr. Yelovich

Mark Batoj

Lorraine Copenhagen

h. See answer to e, f, g, above.

In addition, the technologists, at the Indiana Regional Cancer Center, Rudy Balko and Sharon Rickett, did not know how to adequately use a survey meter to determine the presence of a radioactive source.

i. See answer to h above.

INTERROGATORY 2

The Order states, "In addition, the corporate RSO contributed in large part to this problem by not maintaining an adequate physical presence at the satellite facilities; failing to implement appropriate training programs for Licensee employees, which the RSO is required to do under 10 CFR 35.21; and failing to establish and implement a periodic corporate audit program to identify and promptly correct violations to ensure compliance with NRC regulatory requirements." In connection with that statement, please identify:

a. any regulatory requirement as of November 16, 1992, requiring maintenance of an "adequate physical presence" at any facility;"

b. any NRC action taken against a medical use licensee prior to November 16, 1992 in whole or in part on the basis that the RSO of the licensee had failed to "maintain an adequate physical presence upon which the Staff relied when issuing the Order;"[11]

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[11] This interrogatory was modified pursuant to an agreement between the parties at the January 26, 1994 prehearing conference. See Transcript of Prehearing Conference at 64-66. In addition, based on the agreement at the prehearing conference, the Staff believes that it is no longer necessary to answer Interrogatory 2(c).

d. documents regarding any final agency determinations, decisions or orders in any of the actions identified in response to the immediately preceding two subparts,[12]

e. any regulatory requirement as of November 16, 1992, requiring establishment and implementation of a "periodic corporate audit program";

f. any NRC action taken against a medical use licensee prior to November 16, 1992 in whole or in part on the basis that the RSO of the licensee had failed "to establish and implement a periodic corporate audit program" upon which the Staff relied when issuing the Order;"[13]

h. documents regarding any final agency determinations, decisions or orders in any of the actions identified in response to the immediately preceding two subparts;[14]

i. the "appropriate training programs" for Licensee employees, which the RSO was required to implement under 10 CFR 35.21 but failed to do so;

j. any persons providing information with respect to the conduct of Dr. David Cunningham as RSO;

k. any transcriptions, summaries, notes or other documents relating to the interview, testimony or statements of those persons.

l. any other evidence relating to the statement from the Order quoted at the beginning of this interrogatory; and

m. the witnesses and other evidence you intend to use to prove the statement from the Order.

RESPONSE

a. There is no specific regulatory requirement applicable to this case that defines an "adequate physical presence." Several references in 10 C.F.R. Part 35 require periodic

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[12] Since it is the Staff's belief that it is no longer necessary to respond to Interrogatory 2(c), the Staff will respond to Interrogatory 2(d) only to the extent that documents are identified in relation to the Staff's answer to 2(b).

[13] This interrogatory was modified pursuant to an agreement between the parties at the January 26, 1994 prehearing conference. See Transcript of Prehearing Conference at 64-66. In addition, based on the agreement at the prehearing conference, the Staff believes that it is no longer necessary to answer Interrogatory 2(g).

[14] Since it is the Staff's belief that it is no longer necessary to respond to Interrogatory 2(g), the Staff will respond to Interrogatory 2(h) only to the extent that documents are identified in relation to the Staff's answer to 2(f).

actions and documentation by the RSO and immediate notification of the RSO. Section 35.31(b) requires the signature of the RSO for minor changes in radiation safety procedures; section 35.59(d) requires the signature of the RSO for leak test records of sealed sources; section 35.59(g) requires the signature of the RSO on the records of quarterly inventories of brachytherapy sources; section 35.59(i) requires the signature of the RSO on records of surveys performed to measure ambient dose rates around all areas where brachytherapy sources are stored; section 35.415(b) requires immediate notification of the RSO if a patient dies or has a medical emergency.

In the Application for Material License, dated June 1, 1990, Item 10.2, which is incorporated into the License through License Condition 17, the Licensee committed to establish and implement the model ALARA (as low as reasonably achievable) program published in Regulatory Guide 10.8, Revision 2, Appendix G. Appendix G requires that the RSO be in close contact with all users and workers. Section 35.21(a) requires that the licensee ensure, through the radiation safety officer, that radiation safety activities are being performed in accordance with approved procedures and regulatory requirements in the daily operation of the licensee's byproduct material program. Section 35.21(b) requires that the radiation safety officer establish and implement various procedures and take various actions described therein. Read together as a whole, the regulations and license condition require that the radiation safety officer establish and maintain a presence at each facility where licensed activities are conducted that is sufficient to ensure that the requirements of the license and 10 C.F.R. Parts 19, 20, 30, and 35 are met in the daily operation of the licensee's facilities.

b. At the time that the Order was issued, the Staff was generally aware of prior cases where escalated enforcement action was taken for failure of the RSO and/or other management officials to exercise appropriate oversight and control over licensed activities; however, the Staff did not refer to, or rely on, any *specific* case or cases when issuing the Order.

d. See response to b, above.

e. In the Application for Material License, dated June 1, 1990, Item 10.2, which is incorporated into the License through License Condition 17, the Licensee committed to establish and implement the model ALARA program published in Regulatory Guide 10.8, Revision 2, Appendix G. Appendix G requires a formal annual review of the radiation safety program. Section 35.21(a) requires that the licensee ensure, through the radiation safety officer, that radiation safety activities are being performed in accordance with approved procedures and regulatory requirements in the daily operation of the licensee's byproduct material program. Section 35.21(b) requires that the radiation safety officer brief management once each year on the byproduct material program. Read together as a whole, the statute, regulations, and license condition require that the radiation safety officer obtain, on a continued basis, knowledge of the compliance status of the daily operation of the licensee's byproduct material program that is sufficient to ensure that the requirements of the license and 10 C.F.R. Parts 19, 20 and 35 are met and perform a formal annual review of the radiation safety program. The process of obtaining this knowledge and performing this review is generally referred to as auditing the program.

f. At the time that the Order was issued, the Staff was generally aware of prior cases where escalated enforcement action was taken for failure of the RSO and/or other management officials to exercise appropriate oversight and control over licensed activities, including, in whole or in part, failure to perform audits; however, the Staff did not refer to, or rely on, any *specific* case or cases when issuing the Order.

h. See response to f, above.

i. Pursuant to 10 C.F.R. 35.21(b)(2)(x), the radiation safety officer is required to establish and implement written policy and procedures for training personnel who work in or frequent areas where byproduct material is used or stored. This training must meet the requirements of 10 C.F.R. 19.12. Over and above these requirements, License Condition 17, Application dated June 1, 1990, Item 8, specifies certain training to be given to individuals, including approximately 30 minutes of instructional time for each person on emergency procedures, including a "Simulation (Dry Run) Emergency."

j. In connection with the statement, quoted above, from the Suspension Order, the following individuals provided information with respect to the conduct of Dr. David Cunningham as RSO:

Mahoning Valley Cancer Center

David J. Moylan, III, M.D.

Abne Hasan, M.D.

Karen Wagner

Richard Croley

Exton Cancer Center

Richard Yelovich, M.D.

Paula Salinitro

Mark Batoj

Lorraine Copenhagen

Susan Gosney

k. Inspection Report No. 030-31765/92-001

l. All the evidence relating to the statement in the Suspension Order, quoted in the above interrogatory has been provided in response to the following interrogatories: III.A.1, II.A.6, V.A.1

m. At this time, the Staff intends to use the following witnesses in order to prove the statement from the Suspension Order:

Dr. Carl Paperiello

Dr. Mohamed Shanbaky

Penny Nessen

James Dwyer

Judith Joustra

Pamela Henderson

Ihor Czerwinskyj

The Staff, at this time, intends to use the following documents:

Inspection Report No. 030-31765/92-001

IIT Report

Region I Draft inspection report*

VI. REQUESTS FOR ADMISSION

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

1. The NRC, Region I, performed a safety inspection of OSC on September 4, 1991, one year after its initial licensing.

The Staff can neither admit or deny this request. An inspection of OSC's Harrisburg facility was performed on September 4, 1991.

2. The two individuals conducting the inspection in 1991 were experienced and well-qualified inspectors.

Admit.

3. The 1991 inspectors found that the OSC staff had been trained.

The Staff can neither admit or deny this request. Although training records were not reviewed, within the scope of the inspection and the questions asked by the inspectors, the staff at OSC's Harrisburg facility appeared to have been trained.

4. All OSC personnel questioned during the 1991 inspection were knowledgeable about both operating and emergency procedures.

The Staff can neither admit or deny this request. Within the scope of the inspection and the questions asked by the inspectors, the staff at OSC's Harrisburg facility appeared to be knowledgeable about both operating and emergency procedures.

5. All OSC personnel questioned during the 1991 inspection were knowledgeable in the areas specified in 10 CFR 19.12.

The Staff can neither admit or deny this request. Within the scope of the inspection and the questions asked by the inspectors, the staff at OSC's Harrisburg facility appeared to be knowledgeable in the areas specified in 10 C.F.R. § 19.12.

6. During this inspection, the inspectors identified two Severity Level IV violations.

Admit.

7. The violations arose from findings that one person was wearing a badge from a wrong center and a transport form had been incompletely filled out.

The Staff can neither admit or deny this request. The RSO, Dr. Cunningham, had not been assigned a whole body dosimeter (film badge) for the licensed program. He was wearing a film badge from another licensed facility where he also worked. Also, shipping papers had not been filed out completely on approximately 40 occasions. The shipping papers did not include the transportation index or the activity of the source being transported.

8. Section 12, Brachytherapy, of the NRC inspector's field notes from the September 4, 1991 inspection was marked "HDR only."

Admit.

42. Omnitron personnel believed and led most OSC personnel to believe that a source-wire break was not possible.

Admit.

43. Initial training by Omnitron personnel was approved by the NRC.

Deny.

44. On December 9 and 10, 1991, Omnitron personnel conducted a training session for IRCC personnel, including the IRCC authorized user, the physicist and one of the Radiation Therapists.

Admit.

45. The training on December 9 and 10, 1991 by Omnitron personnel included "a demonstration of the safety features and emergency procedures to be followed."

Admit.

46. During the December 9 and 10, 1991 training sessions, Omnitron personnel did not raise the possibility of or provide any training regarding emergency procedures to be followed in the event of a source wire break.

The Staff can neither admit or deny this request, since none of the NRC Staff was present at that training session.

47. On February 27, 1992 Omnitron personnel conducted another training session regarding the Omnitron 2000 for IRCC personnel.

The Staff can neither admit or deny this request. The Staff is aware that on February 27, 1992 Omnitron personnel conducted a review of the operation and safety features of the Omnitron unit.

48. During the February 27, 1992 training session, Omnitron personnel did not raise the possibility of or provide any training regarding emergency procedures to be followed in the event of a source wire break.

The Staff can neither admit or deny this request, since none of the NRC Staff was present at that training session.

49. OSC's RSO gave draft procedures entitled, "Oncology Services Corporation, Department of Physics, HDR Treatment Manual," to the Greater Pittsburgh Cancer Center (GPCC) before November 16, 1992.

Admit.

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

Admit.

Respectfully submitted,

Marian L. Zobler
Counsel for NRC Staff

Dated at Rockville, Maryland
this 18th day of February, 1994

Response to Questions Concerning Inspection of OSC

1. Qualifications of Judith A. Joustra and Jenny M. Johansen.

Judith A. Joustra
Senior Health Physicist
Industrial Applications Section C

EDUCATION

1973 Licensed and Certified Radiologic Technologist
A.S., 1981, Mercer County Community College (Biology)
B.S., 1983, Trenton State College-Trenton,NJ (Health Physics)

PROFESSIONAL EXPERIENCE

10/92 to present, Senior Health Physicist, Industrial Applications Section, Nuclear Materials Safety Branch, USNRC Region I
High Quality Award 12/92

2/91-9/92, Senior Health Physicist, Medical Licensing Section, Nuclear Materials Safety Branch, USNRC Region I
Performance Award 12/91

11/90-2/91, Senior Health Physicist, Nuclear Materials Safety Section A, Nuclear Materials Safety Branch, USNRC Region I

4/84-11/90, Health Physicist, Nuclear Materials Safety Section B, Nuclear Materials Safety Branch, USNRC Region I
Performance Award 7/89

1/84-4/84, Public Health Representative III, New Jersey State Health Department, Trenton, NJ

6/83-1/84, Radiation Laboratory Technician, Trenton State College, Trenton, NJ

8/73-9/79, Diagnostic Radiologic Technologist, Helene Fuld Hospital, Trenton, NJ

NRC INSPECTOR CERTIFICATION

May 6,1988

NRC TRAINING 1984-1992

Medical Use of Radioisotopes
Radiological Emergency Response
Fundamentals of Licensing (Agreement State)
Fundamentals of Inspection
Transportation of Radioactive Material
Assertive Communication Skills
Health Physics Training (HPS Chapter-D.V.S.R.S.)
Beta Dosimetry
Industrial Radiography
Effective Communication for Inspectors
Hazardous Materials
Protective Measures
Teletherapy and Brachytherapy
Avoiding Prejudiced Behavior
Sexual Harassment
MORT Accident Investigation Workshop
Preventing Sexual Harassment
Interviewing Techniques
Skin Dosimetry Workshop
Site Access Training

Georgia Tech Masters Program in Health Physics (video instruction - in progress)

Jenny M. Johansen, Chief, Medical Licensing Section
Nuclear Materials Safety Branch

EDUCATION

B.A., 1965, Concordia College-Moorhead, MN (Biology)
M.S., 1969, North Dakota State University-Fargo, ND (Radiation Health Physics)

PROFESSIONAL EXPERIENCE

2/91 to present, Chief, Medical Licensing Section, USNRC Region I

2/88 to 2/91, Senior Enforcement Specialist, Office of Enforcement, USNRC
High Quality Awards, 12/89 and 12/90
Certificate of Appreciation, 3/90 and 2/91

8/86 to 2/88, Senior Health Physicist, Nuclear Materials Safety Section B, Nuclear Materials Safety Branch, USNRC Region I

11/82 to 8/86, Health Physicist, Nuclear Materials Safety Section B, Nuclear Materials Safety Branch, USNRC Region I
High Quality Awards, 4/84 and 3/86

6/80 to 11/82, Health Physicist, Materials Inspection Section, Fuel Cycle and Materials Safety Branch, USNRC Region I

1/76 to 6/80 Safety Coordinator/RSO, University of Delaware

6/74 to 1/76, RSO, University of Delaware

5/71 to 5/74, Health Physics Assistant, Radiation Safety Office, Joint Center for Radiation Therapy, and New England Deaconess Hospital, Boston, MA

1/70 to 1/71, Health Physicist/Chemist-RSO, Division of Nuclear Medicine, Peter Bent Brigham Hospital, Boston, MA

1/69 to 12/69, Research Assistant-RSO, Tissue Culture & Virology Lab, Tufts School of Medicine/VA Medical Center, Brockton, MA

NRC INSPECTOR CERTIFICATION:

January 1, 1981

I qualified under the process used in 1980. I was hired by the NRC on June 16, 1980 and after observing several inspections I was the lead inspector the 3rd week in August of 1980 at the inspection of the National Naval Medical Center's broad scope licensed program. In that same week, I assisted in the inspection of Pharmatopes which resulted in Escalated Enforcement. John Kinneman stated that I was a certified inspector as of 1/1/81.

NRC TRAINING 1980-1992

Fundamentals of Inspection
Medical Uses of Radionuclides for State Regulatory Personnel
Cobalt-60 Teletherapy Calibration
ORAU-Internal Dosimetry for Fixed Nuclear Facilities
Safety Aspects of Industrial Radiography
Transportation of Radioactive Materials
Beta Dosimetry Workshop
Technical Writing
HPS Health Physics Training/Refresher Course
MORT
NRC Materials Licensing Course for Phase II Decentralization
Pre-Supervisory Orientation
MORT A&I
PWR Technology
Avoiding Prejudiced Behavior
Supervising Human Resources
Personnel Management Practices
Appraising Performance
EEO for Managers & Supervisors
Conflict Resolution
Interviewing Skills
Preventing Sexual Harassment

2. Training received in brachytherapy or HDR brachytherapy

Judith A. Joustra - NRC Teletherapy and Brachytherapy Course, September 1989. I also viewed two video tapes in the region but don't recall the dates.

Jenny M. Johansen - NRC Medical Uses of Radionuclides for State Regulatory Personnel, March 1981. This course was given at Sloan Kettering Memorial in New York City. It was about a half hour demonstration as to how it worked. From 3/71 to 5/74, while working for the Joint Center for Radiation Therapy I performed all health physics aspects involved in and assisted with the preparation and implantation of approximately 200 brachytherapy cases per year using Radium 226 sealed sources, Iridium 192 seeds in nylon ribbon, Radon 222 seeds, and Iodine 125 seeds. I also performed calibrations of orthovoltage x-ray units and the cobalt-60 teletherapy unit.

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 93-006
(Order Suspending Byproduct Material License No. 37-28540-01)	)	ASLBP No. 93-674-03-EA

AFFIDAVIT OF JAMES DWYER

I, James Dwyer, first being duly sworn, depose and state:

1. I am currently a Senior Health Physicist, Medical Inspection Section, Division of Radiation Safety and Safeguards, Region I, U.S. Nuclear Regulatory Commission. As such, I, together with Pamela Henderson, conducted an inspection of the Mahoning Valley Cancer Center, Lehighton, Pennsylvania on December 8, 1992.

2. I have participated and assisted in the preparation of the attached NRC Staff responses to Interrogatories III.A.1.e-j, III.A.2, V.A.1.e-f, h, i, and V.A.2.j filed by Oncology Services Corporation in the above-captioned proceeding.

3. I hereby certify that the answers to the above numbered interrogatories are true and correct to the best of my information and belief.

James Dwyer
Senior Health Physicist

Subscribed and sworn to before me
this 18th of February, 1994

Notary Public

My commission expires: 3/24/96

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 93-006
(Order Suspending Byproduct Material License No. 37-28540-01)	))	ASLBP No. 93-674-03-EA

AFFIDAVIT OF JOSEPH DELMEDICO

I, Joseph Delmedico, first being duly sworn, depose and state:

1. I am a Senior Enforcement Specialist, Office of Enforcement, U.S. Nuclear Regulatory Commission. As such, I participated in the preparing the Order Suspending License issued to Oncology Services Corporation on January 20, 1993.

2. I have participated and assisted in the preparation of the attached NRC Staff responses to Interrogatories III.A.1.b-d, III.A.4, III.A.6, IV.A.1.b-d, V.A.1.b-d, V.A.2.b-d, f-h filed by Oncology Services Corporation in the above-captioned proceeding.

3. I hereby certify that the answers to the above numbered interrogatories and request for admission are true and correct to the best of my information and belief.

Joseph DelMedico
Enforcement Specialist

Subscribed and sworn to before me
this 18th of February, 1994

Elizabeth Ann Tipton
Notary Public

My commission expires: 3/1/95

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 93-006
(Order Suspending Byproduct	)	
Material License No. 37-28540-01)	)	ASLBP No. 93-674-03-EA

AFFIDAVIT OF JOHN GLENN

I, John Glenn, first being duly sworn, depose and state:

1. I am currently Chief, Medical, Academic, and Commercial Use Safety Branch, Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission.

2. I have participated and assisted in the preparation of the attached NRC Staff responses to Interrogatories I.A.4, I.A.5, II.A.3, III.A.1.a, III.A.6.a, IV.A.1.a, V.A.1.a., V.A.2.a, e, i, and Request for Admission number 43 filed by Oncology Services Corporation in the above-captioned proceeding.

3. I hereby certify that the answers to the above numbered interrogatories and request for admission are true and correct to the best of my information and belief.

John E. Glenn

John Glenn, Chief
Medical, Academic, and Commercial Use Safety Branch

Subscribed and sworn to before me
this 18th of February, 1994

Elizabeth Ann Tipton

Notary Public

My commission expires: 3/13/95

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 93-006
(Order Suspending Byproduct	)	
Material License No. 37-28540-01)	)	ASLBP No. 93-674-03-EA

AFFIDAVIT OF JUDITH JOUSTRA

I, Judith Joustra, first being duly sworn, depose and state:

1. I am currently Chief, Effluent and Radiological Protection Section, Division of Reactor Safety and Safeguards, Region I, U.S. Nuclear Regulatory Commission. Formerly, I was a Senior Health Physicist in the Licensing Section, Division of Radiation Safety and Safeguards, Region I. I, together with Ihor Czerwinskyyj, conducted an inspection of the Exton Cancer Center, Exton, Pennsylvania on December 8, 1992. I also conducted an inspection of the Harrisburg Cancer Center, Harrisburg, Pennsylvania on September 4, 1991.

2. I have participated and assisted in the preparation of the attached NRC Staff responses to Interrogatories I.A.6, III.A.5, V.A.1.e-i, V.A.2.j, k, and Requests for Admissions numbers 1-8 filed by Oncology Services Corporation in the above-captioned proceeding.

3. I hereby certify that the answers to the above numbered interrogatories and request for admission are true and correct to the best of my information and belief.

Judith A. Joustra

Judith Joustra, Chief
Effluent and Radiological Protection Section

Subscribed and sworn to before me
this 18th of February, 1994

Notary Public

My commission expires: 3/24/96

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 93-006
(Order Suspending Byproduct	)	
Material License No. 37-28540-01)	)	ASLBP No. 93-674-03-EA

AFFIDAVIT OF CARL J. PAPERIELLO

I, Carl J. Paperiello, first being duly sworn, depose and state:

1. I am currently the Director, Division of Industrial and Medical Nuclear Safety, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission. I was the leader of the Incident Investigation Team chartered to investigate the incident which occurred at the Indiana Regional Cancer Center on November 16, 1992.

2. I have participated and assisted in the preparation of the attached NRC Staff responses to Interrogatories I.A.8, II.A.1, II.A.5, II.A.6 and Request for Admission numbers 42, 44-50 filed by Oncology Services Corporation in the above-captioned proceeding.

3. I hereby certify that the answers to the above numbered interrogatories and requests for admissions are true and correct to the best of my information and belief.

Carl J. Paperiello

Carl J. Paperiello, Director
Division of Industrial and Medical Nuclear Safety

Subscribed and sworn to before me
this 22 of February, 1994

Notary Public

My commission expires: 3/1/98

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 93-006
(Order Suspending Byproduct Material License No. 37-28540-01)	))	ASLBP No. 93-674-03-EA

AFFIDAVIT OF MOHAMED SHANBAKY

I, Mohamed Shanbaky, first being duly sworn, depose and state:

1. I am currently employed as the Chief, Research & Development Section, Division of Radiation Safety and Safeguards, Region I, U.S. Nuclear Regulatory Commission. I was the assistant leader of the Incident Investigation Team chartered to investigate the incident which occurred at the Indiana Regional Cancer Center on November 16, 1992.

2. I have participated and assisted in the preparation of the attached NRC Staff responses to Interrogatories II.A.3, II.A.4, and V.A.1.h-i filed by Oncology Services Corporation in the above-captioned proceeding.

3. I hereby certify that the answers to the above numbered interrogatories are true and correct to the best of my information and belief.

Mohamed Shanbaky, Chief
Research & Development Section

Subscribed and sworn to before me
this 18th of February, 1994

Notary Public

My commission expires: 3/24/96

UNITED STATES OF AMERICA
NUCLEAR REGULATORY COMMISSION

BEFORE THE ATOMIC SAFETY AND LICENSING BOARD

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

CERTIFICATE OF SERVICE

I hereby certify that copies of "NRC STAFF RESPONSE AND OBJECTIONS TO LICENSEE'S FIRST SET OF INTERROGATORIES FIRST REQUEST FOR PRODUCTION OF DOCUMENTS, AND FIRST REQUEST FOR ADMISSIONS" in the above-captioned proceeding have been served on the following by deposit in the Nuclear Regulatory Commission's internal mail system or, as indicated by an asterisk, by deposit in the United States mail, first class this 18th day of February, 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 and Licensing Board
U.S. Nuclear Regulatory Commission
Washington, D.C. 20555

Marcy L. Colkitt*
General Counsel
Oncology Services Corp.
P.O. Box 607
Indiana, PA 15701-0607

Office of the Secretary (2)
U.S. Nuclear Regulatory Commission
Washington, D.C. 20555
Attn: Docketing and Service Section

Kerry A. Kearney, Esq.*
Joseph W. Klein, Esq.
Joseph R. Rodkey, Jr., Esq.
Counsel for Oncology Services Corp.
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Mellon Square
435 Sixth Avenue
Pittsburgh, PA 15219-1886

Dr. Peter S. Lam
Administrative Judge
Atomic Safety and Licensing Board
U.S. Nuclear Regulatory Commission
Washington, D.C. 20555

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

Atomic Safety and Licensing Board
Panel (1)
U.S. Nuclear Regulatory Commission
Washington, D.C. 20555

Office of Commission Appellate
Adjudication (1)
U.S. Nuclear Regulatory Commission
Washington, D.C. 20555

Marian L. Zobler
Counsel for NRC Staff