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RELATED CORRESPONDENCE DOCKETED
USNRC

June 16, 1994

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UNITED STATES OF AMERICA
NUCLEAR REGULATORY COMMISSION
BEFORE THE ATOMIC SAFETY AND LICENSING BOARD

OFFICE OF SECRETARY
DOCKETING & SERVICE
BRANCH

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

OSC'S REQUEST FOR PRODUCTION OF DOCUMENTS AND
INTERROGATORIES DATED JUNE 16, 1994

OSC makes the following discovery requests and requests a timely and complete response to each. To the extent the Staff asserts that a privilege attaches to any documents requested, OSC requests that the Staff for each said document specify:

- a. The date of the document;
- b. Who the document was distributed to;
- c. The general subject matter of the document; and
- d. Where the document is presently maintained.

Document shall be defined as follows:

The use of this word is intended to refer to any material or any medium on which or by which "information" is recorded - including papers (of any kind or character), photographs, computer files, minutes and records of meetings, reports, summaries, memoranda, interoffice communication or writings by whatever name called which relate to the document(s) specifically including: (1) any material which was used in the preparation of any such document(s); (2) any and all attachments to such document(s); (3) any and all

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documents referred to in the requested "Document;" and (4) any and all subsequent additions, deletions, substitutions, amendments or modifications to the original of such "Document(s)."

INTERROGATORIES AND DOCUMENT REQUESTS

INTERROGATORY 1

Describe how OSC violated 10 CFR Section 20.201(b) on November 16, 1992.

INTERROGATORY 2

Describe specifically how OSC violated 10 CFR Section 19.12 as described in the Suspension Order. For each such alleged violation identify the name of the individual who was not properly instructed and what said individual should have been instructed in that he was not so instructed in. Identify and produce any documents and/or testimony on which you rely.

INTERROGATORY 3

Describe in specificity how OSC violated License Condition 17 which was the basis for the Suspension Order. For each such alleged violation identify the name of the individual who was not properly instructed and what said individual should have been instructed in. Identify and produce any documents on which you rely.

INTERROGATORY 4

Describe both the legal and factual basis for the NRC's belief that Dr. Cunningham sought to delegate his RSO responsibilities via the December 12, 1992 letter.

INTERROGATORY 5

Is it the NRC's legal opinion that where ambiguities exist or there is a lack of clarity in the NRC regulations that such ambiguities or lack of clarity should be construed against the Licensee or in favor of the Licensee? Cite any supporting case law.

INTERROGATORY 6

Is a PrimeAlert a survey instrument? Is a PrimeAlert a survey instrument within the meaning of 10 CFR Section 20.201(b)? Define the term "survey instrument."

INTERROGATORY 7

As of November 16, 1992, was there an NRC Regulation that required that a patient be surveyed with a radiation survey detection instrument following removal of the iridium source?

INTERROGATORY 8

Define the term "reasonable" as it is used in 10 CFR Section 20.201.

INTERROGATORY 9

Is it the NRC's position that under 10 CFR Section 20.201 the use of and reliance on the PrimeAlert was unreasonable under the circumstances on November 16, 1992 at IRCC to evaluate the extent of the radiation hazard that may have been present? If the answer is yes, provide the basis for the NRC's position.

INTERROGATORY 10

Was there a regulation or license condition in effect on November 16, 1992 that specifically required HDR patients to be surveyed with a portable survey meter in the absence of a known emergency?

INTERROGATORY 11

Is it the NRC's position that the IRCC personnel knew an emergency situation existed on November 16, 1992? If the answer is in the affirmative (i.e. yes), identify and produce any and all statements, documents/regulations and/or specific license conditions which support the NRC's position.

INTERROGATORY 12

Does License Condition 17 require entry into the treatment room with a portable survey meter or an audible dosimeter where there is not a PrimeAlert failure or malfunction? If the answer is in the affirmative, identify and produce any and all statements, documents/regulations and/or specific license conditions which support the NRC's position.

INTERROGATORY 13

Is it the NRC's position that the only proper form of training or instruction of Licensee employees pursuant to the pertinent regulations and license conditions is classroom instruction? If the answer is in the affirmative, identify and produce any and all statements, documents/regulations and/or specific license conditions which support the NRC's position.

INTERROGATORY 14

Is training of an individual by a person or entity other than the Licensee or its agents cognizable in determining whether an individual has received instructions sufficient to satisfy any applicable regulations and/or license conditions? If the answer is anything other than an unqualified yes, explain the basis for your response and produce any documents upon which you rely.

INTERROGATORY 15

Is it the NRC's position that where an individual has received instructions through his or her formal schooling that it is improper for a licensee to rely, in part or in whole, on such training? If the answer is in the affirmative, identify and produce any and all statements, documents/regulations and/or specific license conditions which support the NRC's position.

INTERROGATORY 16

Is it a violation of the 10 CFR Section 19.12 personnel training requirement, if the IRCC radiation therapy technologists had been trained in the use of a survey meter, knew when to use it and how to generally interpret its readings to determine the presence of radiation? If the answer is in the affirmative, identify and produce any and all statements, documents/regulations and/or specific license conditions which support the NRC's position.

INTERROGATORY 17

Are individuals who do not administer HDR treatments to patients nonetheless considered "individuals working in or frequenting any portion of a restricted area" within the terms of 10 CFR Section 19.12? If the answer is in the affirmative, identify and produce any and all statements, documents/regulations and/or specific license conditions which support the NRC's position.

INTERROGATORY 18

Are individuals who do not administer HDR treatments to patients at OSC nonetheless required by 10 CFR Section 19.12 to be

trained in and know the specific terms of the regulations and license conditions themselves? If the answer is in the affirmative, identify and produce any and all statements, documents/regulations and/or specific license conditions which support the NRC's position.

INTERROGATORY 19

Which specific personnel at the CSC facilities, including Exton, Lehighton and IRCC, does the NRC require to be trained in the specific terms of the regulations and license conditions themselves? Please identify personnel by job title.

INTERROGATORY 20

Is it a violation of any regulation or license condition when staff who do not administer HDR therapy are not familiar with the specifics of a licensee's quality management program but that nevertheless were instructed and/or trained in the proper procedures and policies of the quality management program pertinent to their duties? If the answer is in the affirmative, identify and produce any and all statements, documents/regulations and/or specific license conditions which support the NRC's position.

INTERROGATORY 21

Does License Condition 17 require the Licensee to conduct a dry run of the failure of the Omnitron 2000 HDR Afterloader Source to retract?

INTERROGATORY 22

Does License Condition 17 require that the Licensee conduct a dry run where the Omnitron 2000 HDR Afterloader source breaks off? If the answer is in the affirmative, identify and produce any and all statements, documents/regulations and/or specific license conditions which support the NRC's position.

INTERROGATORY 23

Under applicable regulations or licensing conditions should a corporate radiation safety communication have to been issued prior to any immediate disclosure by the NRC of an event? If the answer is in the affirmative, identify and produce any and all statements, documents/regulations and/or specific license conditions which support the NRC's position.

INTERROGATORY 24

Does the failure to issue an appropriate corporate radiation safety communication prior to immediate disclosure of an event constitute a basis to support an effective immediately

suspension order? If the answer is in the affirmative, identify and produce any and all statements, documents/regulations and/or specific license conditions which support the NRC's position.

INTERROGATORY 25

Define the term "radiation safety communications".

INTERROGATORY 26

Who does the Staff believe OSC should have communicated the Indiana Incident to at or after the incident was determined to have happened? Is it necessary for OSC to notify the physicist of such an event where the authorized user has been so notified? If so, explain why.

INTERROGATORY 27

Under the OSC license can a physicist administer an HDR treatment without an authorized user providing an oral or written directive?

INTERROGATORY 28

Is it appropriate where a failure of the Licensee to comply with the literal terms of the regulations or license conditions can be mitigated or excused when the Licensee demonstrates good cause, the absence of any increased risk of harm from such conduct or any other exculpatory ground?

INTERROGATORY 29

Assuming that OSC voluntarily suspended licensed HDR operations at Exton and Lehighton, was there any specific regulatory requirement that OSC inform the physicist at Exton and Lehighton of the November 1992 IRCC Incident via "corporate radiation safety communication" designed to prevent "the reoccurrence of an event such as the November 16, 1992 event" during the period of voluntary suspension and prior to the time that OSC and Dr. Cunningham, RSO, had an understanding of what had occurred on November 16, 1992?

INTERROGATORY 30

On what date did the NRC have a complete and full understanding of what had occurred at the IRCC on November 16, 1992, including how and why the source had broken loose? Who at the NRC had such a complete understanding?

INTERROGATORY 31

Assuming OSC was required to make an appropriate corporate radiation safety communication through the physicists at Lehigh and Exton, in order to prevent the reoccurrence of an event such as the November 16 event did communication by Dr. Bernard Rogers to the authorized users under the facts and circumstances of this case satisfy that requirement? If not, why not?

INTERROGATORY 32

Is it the NRC's position that Dr. Rogers lied when he stated that he contacted all of the Medical Directors? If the answer is in the affirmative, please provide a complete explanation for the NRC's position and any and all documents and/or statements that support said position.

INTERROGATORY 33

Do 10 CFR Parts 20, 30 and/or 35 or any License Conditions require OSC to establish and implement a periodic corporate audit program? If the answer is in the affirmative, identify and produce any and all statements, documents/regulations and/or specific license conditions which support the NRC's position.

INTERROGATORY 34

Define the term "corporate audit program." What is the frequency the NRC attaches to the term "periodic?"

INTERROGATORY 35

Taken in the context in which it was written -- at a time when all license activities were voluntarily suspended -- how did Dr. Cunningham's letter of December 12, 1992 to the various Medical Directors/Authorized Users constitute an attempt to improperly delegate radiation responsibility in violation of 10 CFR Section 35.21?

INTERROGATORY 36

Is an attempted delegation of RSO responsibility a violation of 10 CFR Section 35.21 where it was not completed? If the answer is in the affirmative, identify and produce any and all statements, documents/regulations and/or specific license conditions which support the NRC's position.

INTERROGATORY 37

Is it the Staff's position that unauthenticated or hearsay evidence is admissible in support of the order suspending the OSC license? If the answer is in the affirmative, identify and produce

any and all case law, statements, documents/regulations and/or specific license conditions which support the NRC's position.

INTERROGATORY 38

Is it the NRC's position that statements by agents, employees or other representatives of the NRC constitute admissions against the NRC? If the answer is in the affirmative, identify and produce any and all statements, documents/regulations and/or specific license conditions which support the NRC's position.

INTERROGATORY 39

Where the NRC clarifies existing regulations, does the Staff agree said clarification provides evidence of ambiguities of that regulation? If the answer is anything other than an unqualified affirmative response, provide a full basis for your answer and cite any cases on which you rely for your position.

INTERROGATORY 40

Is it the Staff's position that statements by former employees and/or agents of OSC constitute admissions against OSC? If the answer is in the affirmative, identify and produce any and all case law, statements, documents/regulations and/or specific license conditions which support the NRC's position.

INTERROGATORY 41

Did the NRC find any problems with the manner in which the wire breakage accident at the Greater Pittsburgh Cancer Center was handled? If so, please describe in detail the problems the NRC found and whether the NRC considered the actions and the conduct of the personnel at the Greater Pittsburgh Cancer Center when it suspended the entire license of Oncology Services Corporation. If not, why not?

INTERROGATORY 42

Define the term "Radiation Safety Instruction" and set forth specifically what basic instruction in radiation safety should include. Also, please cite to and produce any applicable regulations or license condition that details what basic radiation safety should include.

INTERROGATORY 43

Did the NRC determine that the BFI truck driver failed to perform a survey of the garbage obtained from the Scenery Hill Nursing Home and in fact that said truck driver lied when he indicated on a form that he had performed such a survey?

INTERROGATORY 44

Prior to the November 16, 1992 incident, did the NRC have any reason to believe that Dr. David Cunningham was not a qualified and competent RSO?

INTERROGATORY 45

Prior to November 16, 1992, had the NRC ever determined that OSC had a breakdown in corporate management with respect to licensed activities.

INTERROGATORY 46

Did NRC Region I perform a complete safety inspection on September 4, 1991, including review of the entire OSC HDR Radiation Safety Program? In that inspection did the NRC find any deficiencies with regard to OSC's corporate oversight, HDR operation or treatment procedures?

INTERROGATORY 47

Is it the NRC's position that the September 4, 1991 inspection resulted in a favorable review because of the personal and/or sexual relationship between Dr. Cunningham and the inspector?

INTERROGATORY 48

Describe in detail the personal relationship and/or sexual relationship found to exist by the NRC between Dr. Cunningham and the NRC inspector who performed the September 4, 1991 inspection.

INTERROGATORY 49

Define the term "dry run" as it is used in the OSC License.

INTERROGATORY 50

Is it the NRC's position that the Omnitron training provided to OSC personnel did not include a dry run involving the failure of the source to retract to the afterloader? If the answer is in the affirmative, identify and produce any and all statements, documents/regulations and/or specific license conditions which support the NRC's position.

INTERROGATORY 51

Describe in detail how OSC's alleged lack of corporate control of licensed activities at IRCC contributed to the occurrence of the incident that occurred on November 16, 1992?

INTERROGATORY 52

Was there at IRCC any significant lack of knowledge by key licensee employees of the requirements of the NRC license, access to pertinent license documents, adequacy of their training and knowledge of regulatory requirements, procedures and/or instructions to protect themselves and others from radiation exposure which contributed to the incident that occurred on November 16, 1992.

INTERROGATORY 53

Is it the NRC's position that the conduct of an individual OSC agent can support an inference of lack of corporate oversight where circumstances show, among other things, that such agent was properly trained and that, as Dr. Paperiello has admitted, he had only 30 seconds to act? If the answer is in the affirmative, identify and produce any and all statements, documents/regulations and/or specific license conditions which support the NRC's position.

INTERROGATORY 54

Describe in detail what instructions the NRC believes should be provided to an individual regarding the use of a handheld survey meter. Provide any documentation the NRC relies on to answer this request.

INTERROGATORY 55

Did the treating personnel at IRCC follow the emergency procedures in the Omnitron Manual on November 16, 1992? If the answer is no, state in detail how those emergency procedures were not followed.

INTERROGATORY 56

Did the PrimeAlert fail or malfunction during the November 16, 1992 incident at IRCC? If so, explain how?

INTERROGATORY 57

Did Dr. Bauer or any other personnel of OSC know of any failure or malfunction of the PrimeAlert during the November 16, 1992 incident.

INTERROGATORY 58

Was the reliance by IRCC personnel on specific safety features of the Omnitron reasonable in November 1992?

INTERROGATORY 59

Is it the NRC's position that OSC should have known on November 16, 1992 that a source wire could break due to a chemical reaction resulting from the packaging where Omnitron had failed to notify OSC of said matter and OSC was not otherwise informed of the possibility of such deterioration? If the answer is in the affirmative, identify and produce any and all statements, documents/regulations and/or specific license conditions which support the NRC's position.

INTERROGATORY 60

Did William Ying, Ph.D., an authorized user under the license, visit the Mahoning Center in Lehigh on approximately ten (10) occasions between November 1991 and March 1992 to, in part, train personnel in radiation safety training?

INTERROGATORY 61

Between November 1991 and March 1992, were any HDR procedures performed in Lehigh without direct supervision by Dr. Ying?

INTERROGATORY 62

Was a technologist at Lehigh trained in the correct use and operation of a portable survey meter, wall-mounted radiation survey meter, interlock and patient audio visual communication systems by OSC?

INTERROGATORY 63

Did the Lehigh radiation training program cover a review of HDR emergency procedures?

INTERROGATORY 64

Is it the NRC's position that Dr. Cunningham was not in continuous contact by fax or telephone with the Lehigh facility during the six to nine months prior to the December 1992 inspection? If the answer is in the affirmative, please cite any and all facts upon which the NRC will rely to establish its position.

INTERROGATORY 65

Was the physicist and/or medical director and/or the authorized user at the console during actual HDR procedures at Exton? If the answer is other than an affirmative, provide all supporting details and identify and produce supporting documentation.

INTERROGATORY 66

Was the physicist and/or medical director and/or the authorized user at the console during HDR procedures at Lehighton? If the answer is other than an affirmative, provide all supporting details and identify and produce supporting documentation.

INTERROGATORY 67

Is there a requirement in the regulations or the OSC license that the physicist and/or medical director and/or authorized user be present at the console during HDR procedures? If the answer is in the affirmative, please specify said regulation and produce any and all documents which support that position.

INTERROGATORY 68

Were Exton employees, including the Exton physicist, trained by Dr. Ying in HDR during sessions that occurred between November 1991 and February 1992?

INTERROGATORY 69

Which Lehighton and Exton employees received the Omnitron training? Identify any individuals from Exton or Lehighton the NRC contends should have received Omnitron training but that did not and specify the basis for the NRC's position that such training should have been provided.

INTERROGATORY 70

Did the physicist at Exton receive additional calibration training on the HDR unit by traveling to Harrisburg?

INTERROGATORY 71

Were the technologists at Exton ever in charge of an HDR administration? If the answer is yes, please specify in detail the NRC's position, the basis for this conclusion and provide any documents supporting that position.

INTERROGATORY 72

Were the technologists at Lehighton ever in charge of an HDR administration? If the answer is yes, please specify in detail the NRC's position, the basis for this conclusion and provide any documents supporting that position.

INTERROGATORY 73

Did the technologists at Exton or Lehighton ever perform unsupervised HDR administrations? If the NRC's position is in the affirmative, please provide in detail the basis for that response and provide any documents which support it.

INTERROGATORY 74

Were the technologists at Exton and Lehighton trained in and familiar with the required procedures and actions necessary to comply with the relevant license conditions and regulations? If the answer is other than a complete affirmative response, identify specifically who was not familiar with what.

INTERROGATORY 75

Was a copy of the license with all documents incorporated by reference in License Condition 17 physically present at each of the Centers covered by the license? If the answer is anything other than a full affirmative, specify in detail at which Centers it was not available and who will testify to that fact.

INTERROGATORY 76

Has the NRC determined that the emergency scenario that the Omnitron source wire would break, was either expected or reasonably anticipated by OSC in general and the IRCC treating personnel in particular?

INTERROGATORY 77

Did the Omnitron training include the scenario of a dry run of the source not retracting at the end of the treatment at all facilities listed on the OSC license, including Exton, Lehighton and IRCC? If not, specify in detail where that did not occur and who will testify to that fact.

INTERROGATORY 78

Did OSC have a quality management plan submitted to the NRC and in effect prior to the required deadline in January 1992? If the answer is anything other than an affirmative response, please provide the details for the NRC's position and produce and/or identify any supporting documents.

INTERROGATORY 79

Identify by name the alleged Exton staff members who purportedly were not aware of the specifics of the OSC quality management program. Specify specifically what those individuals said that made the NRC inspectors believe that those individuals were not familiar with the quality management program.

INTERROGATORY 80

Did OSC voluntarily suspend HDR treatments at the Centers under this license upon learning of the IRCC event?

INTERROGATORY 81

Was this voluntary suspension by OSC reasonable? Is there some further action OSC should have taken at that time? If so, please identify in specificity what the action should have entailed.

INTERROGATORY 82

Was it possible for OSC to issue a corporate radiation safety communication designed to prevent the reoccurrence of an event such as the November 16, 1992 event prior to the time OSC had a full understanding of how the Omnitron 2000 had malfunctioned and how the IRCC personnel had reacted to that malfunction? If the answer is in the affirmative, provide the basis for the NRC's position and provide any and all supporting documentation.

INTERROGATORY 83

Did Bernard Rogers, M.D., the OSC Director of Brachytherapy, notify each Medical Director under the license of the IRCC incident on or about December 2, 1992? If the answer is anything other than an affirmative, please provide in detail the basis for the NRC's position and any supporting documentation.

INTERROGATORY 84

Define the term "frequenting any portion of a restricted area" as it is defined in 10 CFR Section 19.12.

INTERROGATORY 85

Was it possible on the day of the Exton inspection for both the linear accelerator and the HDR machine to be activated simultaneously? If so, how? Were both machines activated simultaneously during the inspection? Has the NRC determined that both machines were activated simultaneously at Exton?

INTERROGATORY 86

Was it possible on the day of the Lehighton inspection for both the linear accelerator and the HDR machine to be activated simultaneously? If so, how? Were both machines activated simultaneously during the inspection? Has the NRC determined that both machines were activated simultaneously at Lehighton?

INTERROGATORY 87

For each of the following job descriptions specify which sections of the Quality Management Program each individual should have been aware of: Authorized User, Physicist, Radiation Therapy Technologist involved in providing actual HDR treatments, Radiation Therapy Technologists not involved in providing actual HDR treatments, X-ray Technologists, Secretary, Van Driver, Cleaning Personnel.

INTERROGATORY 88

Has the NRC determined itself or through any other agency and/or other governmental agency or entity that a problem of any type existed with PrimeAlert monitors? If so, identify any problems that the NRC is aware of and produce any and all documents in its possession relating to the investigation of PrimeAlert equipment.

INTERROGATORY 89

Define the term "breakdown of corporate oversight."

INTERROGATORY 90

Is it the NRC's position that 10 CFR Section 35.4 applies to the use of iridium-92 wire? If so, provide any and all documents which support that basis.

INTERROGATORY 91

For each and every one of the above 90 interrogatories, identify the NRC personnel who will testify as to the NRC's position on each.

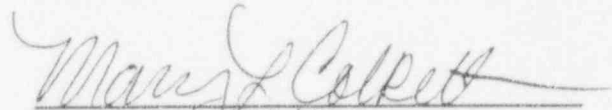
DOCUMENT REQUEST 1

Produce the final Office of Investigation Report of the OSC investigation as well as any drafts or documents relating thereto, including any notes, statements or other records obtained by OI or made by OI during that investigation.

DOCUMENT REQUEST 2

Produce any and all documents relied on, referred to or otherwise reviewed and/or used to answer any and all discovery requests contained herein.

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 16, 1994

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UNITED STATES OF AMERICA
NUCLEAR REGULATORY COMMISSION

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BEFORE THE ATOMIC SAFETY AND LICENSING BOARD

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In the Matter of)
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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 OSC'S Request For Production Of Documents And Interrogatories Dated June 16, 1994 in the above-captioned proceeding have been served on the following via U.S. Mail, postage prepaid, this 16th day of June, 1994:

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

Dr. Peter S. Lam
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

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

Marian L. Zabler
Michael H. Finkelstein
U.S. Nuclear Regulatory Commission
Office of General Counsel
Washington, DC 20555
(via telecopy)

Office of the Secretary (2)
U.S. Nuclear Regulatory
Commission
Washington, DC 20555
ATTN: Docketing & Service
Section

Atomic Safety & Licensing Board
Panel (1)
U.S. Nuclear Regulatory Commission
Washington, DC 20555

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

